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Ph.D. Thesis

An implantable measurement system for control of advanced arm prostheses: Electrode development, signal analysis, control algorithms and sensory feedback

Conducted for the purpose of receiving the academic title
'Doktor der technischen Wissenschaften'

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Abstract

Loss of an upper extremity is a traumatic and irreversible event in the life of an affected person. Often amputees are provided with state of the art prostheses to compensate for the functional deficits caused by the loss and cosmetic replacement of the lost arm. Surveys report though, that half of amputees receiving a prosthesis reject it. This is clear indication that current prosthetic arms need further improvement to better meet the needs of their users. To adequately replace a lost arm a prosthesis should be perceived by its user as a part of his or her body and not as an external robotic tool. One aspect, hindering the integration of state of the art prosthesis into the amputee's body image, is the lack of sensory information transferred from the prosthesis to the user. Another aspect is that prostheses are not intuitively controlled and only one joint can be moved at a time.

The work presented here addresses both of these aspects in order to improve future prostheses and their control. To focus on improvement of prostheses according to users' needs, their satisfaction and their suggestions for improvement of current prostheses were collected by means of a survey. This survey also covered the topic of sensory feedback by asking participants about the most relevant information they would like to feel with their prosthesis and how they would like them to be transmitted. Results showed that 80% of the 108 participants were satisfied with their prosthesis but, at the same time, 79% were not absolutely satisfied. Most often asked for improvements include appearance and durability of the cosmetic glove, more dexterity and enhanced grasping capabilities of the prosthetic hand, a more comfortable socket that reduces sweating of the stump and reduced weight of the prosthesis. In general, respondents asked for prosthesis with more degrees of freedom while at the same time demanding a more intuitive and reliable control. Sensory feedback was of importance for 88% of respondents, whereas grip force, proprioceptive information about position and movement as well as first and last contact to a grasped object were sensory information requested most often. Vibration, pressure and electrical stimulation were suggested as suitable means for transmission of these information from the prosthesis to the amputee.

To address the need for improved control of prostheses identified in the survey, a fully implantable system to measure electromyogram (EMG) was developed conjointly in an international project team. By measuring multiple EMG signals of muscles that are controlled intuitively, the system aims at controlling simultaneous movement of multiple joints of advanced arm prostheses. Moreover, issues connected to the use of surface EMG as control signal should be overcome by application of implanted electrodes. The present work reports on the development of implanted electrodes, *in vitro* and *in vivo* evaluation of the whole system in rats, sheep and primates, analysis of signals measured during these animal trials and evaluation of algorithms for prosthesis control, all of which are a significant contribution to the overall system.

Electrode development underwent multiple iterative steps. A first electrode design based on a polyimide carrier was successively improved, but mechanical *in vivo* stability was finally achieved by development of a new silicone electrode. During 56 implantations of these electrodes in rats and sheep only one contact of one silicone electrode broke. The implantation procedure developed for these electrodes provided a low invasive way to securely position electrodes at target muscles in rat and sheep experiments.

EMG signals measured with the implanted electrodes yielded a considerable increase in signal quality by reduction of artifacts and noise compared to EMG signals measured at the skin surface. High amplitudes of the EMG signal combined with reduced pick-up of external noise resulted in a signal to noise ratio of 39 dB. Analysis of EMG signals measured during reaching movements in primate experiments demonstrated clear distinctness of arm movements into different directions. Signal features and classifiers evaluated during these investigations were able to reliably discriminate between subsets of movements and demonstrated that even few basic features and simple classifiers yield good classification accuracies on these signals. The first EMG signals measured with the whole measurement system when implanted in sheep demonstrated the function of all involved components.

Based on the demonstrated reliability and safe usage of the implantable measurement system, demonstrated in animal trials, further development will focus on achieving an evaluation in humans. Additional steps will include integration of control algorithms into the implant electronics as well as incorporation of sensory feedback from the prosthesis to its user.

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Finally I would like to thank my parents, their love and faith in me were the foundation for developing the confidence to approach this work and the endurance to actually complete it.

Contents

Acronyms

Notation	Description
ADC	Analog-Digital Converter.
ADLs	Activities of Daily Life.
CAD	Computer-Aided Design.
CMOS	Complementary Metal Oxide Semiconductor.
CMRR	Common-Mode Rejection Ratio.
CNS	Central Nervous System.
DMC	Dynamic Mode Control.
DOF	Degrees Of Freedom.
DPZ	German Primate Center.
EEG	Electroencephalogram.
EIMS	Electrode Impedance Measurement System.
EMG	Electromyogram.
ENG	Electroneurogram.
FES	Functional Electrical Stimulation.
FFT	Fast Fourier Transform.
GNB	Gaussian Naive Bayes classifier.
IBMT	Fraunhofer Institute for Biomedical Engineering.
IMES	Implantable Myoelectric Sensors.
KNB	Kernel Naive Bayes classifier.
LCR meter	inductance (L), capacitance (C) and resistance (R) mesurement device.
LDA	Linear Discriminant Analysis classifier.
LDO	Low-DropOut regulator.
LIFE	Longitudinal Intra-Fascicular Electrodes.
LNB	Linear Naive Bayes classifier.

Notation	**Description**
MAV	Mean Absolute Value.
MAVS	Mean Absolute Value Slope.
MDF	Median Frequency.
MF	Mean Frequency.
MicroFlex	MicroFlex Interconnection.
MICS	Medical Implant Communication Service.
MU	Motor Unit.
MUAP	Motor Unit Action Potential.
MyoPlant	Project for development of a implantable EMG measurement system.
PCA	Principal Component Analysis.
PCB	Printed Circuit Board.
PNS	Peripheral Nervous System.
PSD	Power Spectral Density.
PTFE	Polytetrafluoroethylene.
QDA	Quadratic Discriminant Analysis classifier.
QNB	Quadratic Naive Bayes classifier.
RC circuit	Resistor-Capacitor circuit.
RF	Radio Frequency.
RMS	Root Mean Square.
RSS	Residual Sum of Squares.
SNR	Signal-to-Noise Ratio.
SSC	Slope Sign Changes.
TENS	Transcutaneous Electrical Nerve Stimulation.
tfLIFE	thin-film Longitudinal Intra-Fascicular Electrodes.
TMR	Targeted Muscle Reinnervation.
TUHH	Hamburg University of Technology.
WA	Willison Amplitude.
WFL	Wave Form Length.

Chapter 1

Introduction

1.1 Upper extremity prosthetics

1.1.1 Loss of the upper extremity

The amputation of a hand or an arm is a traumatic and irreversible event for an amputee. This event changes the life of the amputees in regard to their perception by others, their capability to live an independent live, their ability to carry out certain activities and it might also have influence on their occupational life. The psychological reaction to an upper limb amputation were subdivided into three phases by Beasley [Beasley, 1981], disbelief, realization and adaptation, that are similar to a grieving reaction. Other studies found that there was a 30% higher prevalence of depressive symptomatology for upper limb amputees compared to a nonclinical sample [Desmond, 2007]. Provision of amputees with prostheses that meet their demands may overcome some of the problems caused by amputation, since satisfaction with, and use of, a prosthesis is positively associated with increased social integration and an absence of emotional problems [Ham and Cotton, 1991].

Prevalence. Determining the number of amputees and prosthesis users is difficult, since in most countries there is no central register for amputations. Especially in the United States of America, with their 314 million inhabitants, it is difficult to obtain reliable information, since even health insurance is not mandatory. Studies estimate the number of new upper limb amputations [Atkins and Meier, 1989] and new amputees that are potential users of myoelectric prostheses [Parker et al., 2006] to be 12,000 and 10,000 per year, respectively. More reliable data is available from Denmark and the United Kingdom which have official registers. In Denmark, with 5.6 million inhabitants, about 50 amputations of the upper extremity are performed each year [Ebskov and Ebskov, 1995]. In the United Kingdom, with around 64 million inhabitants, in average 272 upper limb amputees were newly referred to prosthetics service centers each year from 1997 to 2005 [NASDAB, 2005]. Though, these sources do not report absolute numbers of upper limb amputees or prosthesis users. In Germany, having nearly 81 million inhabitants, the Federal Statistical Office evaluates data of the pension office. For the year 2009 a number of 20,996 upper limb amputees was reported [Destatis, 2012b]. Details of this data are presented in table 1.1.

Reasons for amputation. Amputations of the upper extremity are carried out for a variety of reasons. There are congenital limb deficiencies, which are already existing at birth, but the majority of amputations is acquired. Acquired amputations of the upper extremity are mostly

Table 1.1: Upper extremity amputees in Germany in the year 2009, subdivided into number of lost limbs and sex [Destatis, 2012b].

amputation		men	women	all
one arm		11,011	4,693	15,704
both arms		1,590	636	2,226
one arm one leg		1,084	444	1,528
three to four limbs		1,004	534	1,538
overall	individuals	14,689	6,307	20,996
	fraction	70%	30%	100%

caused by trauma. Other reasons for amputation, that cause only a small fraction of acquired amputations, include cancer and vascular diseases [Täger and Nast-Kolb, 2000, Dijkstra et al., 2002]. The distribution of reasons for amputation largely varies between studies, of which some are summarized in table 1.3.

Amputation level. Amputations of the upper extremity are classified into different amputation levels introduced in figure 1.1. Transradial amputation is commonly reported to be the most frequent amputation level. The incidence of the different amputation levels found in several surveys is presented in table 1.3 on page 15. The segment of the residual limb between the most distal joint and the end of the limb is denoted as stump. The shorter a stump is, the lower is the rehabilitation success, since for amputees with shorter stumps it is more challenging to customize sockets that provide a secure fit and adequate transmission of mechanical loads. In a shorter stump there is generally a smaller volume of muscles which makes it harder to measure an adequate number of control signals. Besides stump length, it is essential to maintain the big joints, shoulder and elbow, even if this results in a short stump, since it is better to maintain a physiologically controlled joint rather than trying to replace its function by an artificial prosthesis [Baumgartner, 2007].

In general there are muscles remaining in the stump that, prior to amputation, moved parts of the arm that were lost. For wrist exarticulations and transhumeral amputations there are muscles in the forearm stump which moved fingers and wrist, for elbow exarticulations and transhumeral amputations there are biceps and triceps which flexed and extended the elbow. Besides generating the control signals for control of powered prostheses (see section 1.1.3) these remaining muscles are also used to cover the bone of the stump by suturing them to each other

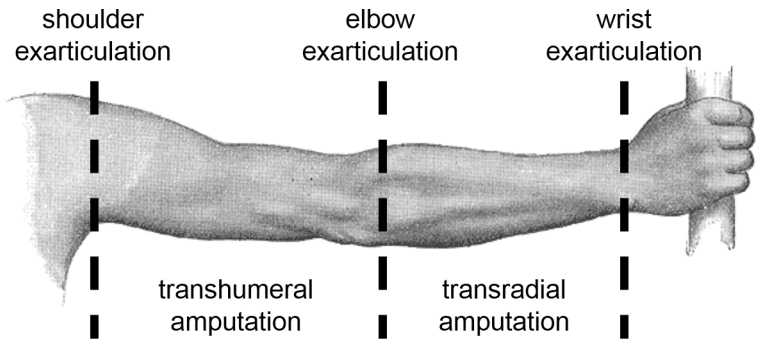


Figure 1.1: Different levels of upper extremity amputation (adapted from [Gray and Lewis, 2000]).

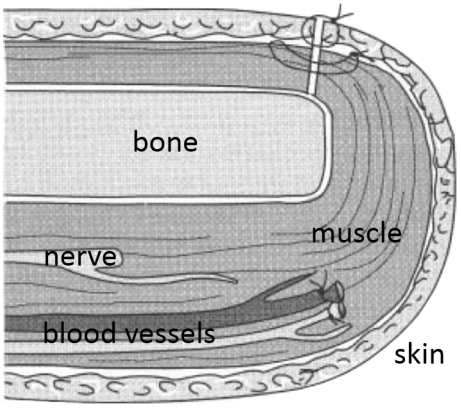


Figure 1.2: Schematic section through an amputation stump (adapted from [Kampas, 2001]).

or attaching them at the bone, like shown in figure 1.2. Covering the bone with soft tissue is essential to achieving a pain free stump with good blood perfusion and load bearing capacity, which is a basis for later prosthesis use [Kampas, 2001, Baumgartner et al., 2008].

1.1.2 Prostheses for the upper extremity

After amputation, amputees can be provided with different kinds of prostheses. The choice is based on factors related to the amputation, as stump length and muscles remaining in the stump, as well as the demands of the amputee in regard to appearance and function of the prosthesis. The three most relevant types of upper extremity prosthesis are

- cosmetic prostheses,
- body-powered prostheses and
- myoelectric prostheses.

They are shown in figure 1.3 and described in more detail in the following based on [Baumgartner, 2007, Baumgartner et al., 2008, Milde and Näder, 2011]. These are

Cosmetic prostheses. The main purpose of cosmetic prostheses is visual replacement of the lost body part. The prosthetic hand mimics the natural one in a relaxed position and its appearance can be adapted in size, skin color and even up to a degree in which the skin texture and hair are reproduced. Many amputees use cosmetic prostheses in addition to an active prosthesis, one for achieving adequate visual and the other for functional replacement, respectively. The benefits of cosmetic prostheses are their natural appearance, their wearing comfort and their low weight, which makes them the most common prosthesis type for very short stumps. To deal with their limited functionality they can be equipped with different passive adapters like hooks, rings and steering aids. There are also passive adapters dedicated to certain activities like playing different instruments, throwing and catching balls, cycling, kayaking, swimming and many more (TRS Inc., Boulder, USA). These adapters can also be applied for other prostheses types described in the following but have the highest impact on increasing the functionality of cosmetic ones.

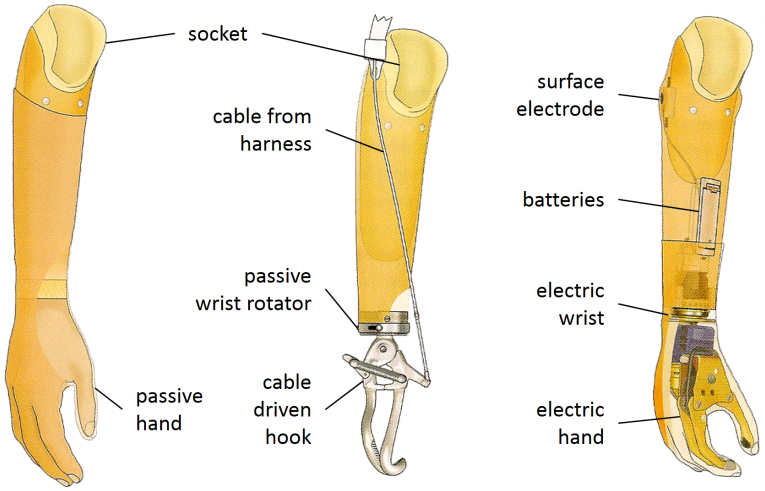


Figure 1.3: Three different prosthesis types (from left to right): cosmetic, body-powered and myoelectric upper limb prostheses for transradial amputees (adapted form [Milde and Näder, 2011]).

Body-powered prostheses. Body-powered prostheses are active prostheses that are actuated by movements of the shoulder girdle. These movements are picked up by a harness and transferred to the movable parts of the prostheses via cables. In forearm prostheses these cables actuate the opening of the hand, which closes passively otherwise. For upper arm prostheses these cables also control the flexion and arresting of the elbow. Body-powered prostheses are reliable, have a low susceptance to failure and provide a certain degree of sensory feedback about the joint angles [Simpson, 1974]. Drawbacks associated with this prosthesis type are that the harness is often perceived as annoying by their users and they require unphysiological movements for their control. Besides this principle of control is only capable of actuating two degrees of freedom and prostheses are not able to achieve a cosmetic adequate replacement of the hand.

Myoelectric prostheses. Myoelectric prostheses use electric potentials resulting from contractions of muscles in the stump as control signals. This process is described in detail in section 1.1.3. According to these control signals the prosthesis activates electric motors, powered by batteries, to move different joints. Depending on amputation level, state of the art prostheses allow opening and closing of the hand, sometimes hands even provide different grip types, rotation of the wrist as well as flexion and extension of the elbow. Myoelectric prostheses integrate all functional components in the socket or the prosthesis itself and do not need a harness. They allow for active movements in both directions of each degree of freedom and do not need a persistent action of the user to maintain a constant position. Despite their benefits, myoelectric prostheses are susceptible to control failures, more expensive compared to cosmetic and body-powered prostheses, require regular maintenance and have a higher weight. Besides, the working principle of myoelectric control does not provide the user with any sensory feedback. Despite their current limitations myoelectric prostheses have the potential to provide most adequate functional replacement for a lost upper limb.

1.1.3 Control of myoelectric prostheses

In the following the control of myoelectric prostheses is introduced in more detail, since the present work focuses on their improvement. Description of physiologic control of movements and analysis of involved signals provides the basis for introduction of state of the art prosthesis control. This description includes

- physiologic control of movements,
- measurement of the myoelectric signal,
- control of one degree of freedom,
- control of multiple degrees of freedom and
- control strategies to integrate the control of a prosthesis into the physiologic control of the user.

Physiologic control of voluntary movements

Description of control of voluntary movements starts with a overview of the sensorimotor loop and then closer investigates the different electrical signals generated during this process for their applicability to control hand prostheses. These signals comprise

- Electroencephalogram (EEG),
- Electroneurogram (ENG) and
- Electromyogram (EMG).

Sensorimotor loop. The process described in the following is visualized in figure 1.4. Voluntary movements of the upper extremity are initialized in the Central Nervous System (CNS). Impulses are generated in the motor cortex where they generate localized electrical activity that can be measured as EEG. From here the impulses are forwarded to the spinal cord which initiates the activation of muscles needed to execute the planned movement. These impulses are transferred to the Peripheral Nervous System (PNS) where peripheral motor nerves lead the impulses to target muscles. These action potentials traveling along the peripheral nerves can be measured as ENG. At the end of the peripheral motor nerves the action potentials are transferred to the muscle over the motor end plate. This results in contraction of the target muscle which thereby generates electric potentials that can be measured as Electromyogram (EMG).

The evoked movement of the upper limb and the interaction with its surrounding generate sensory information that are detected by different sensors. Muscle spindles provide information about the length and tension of the muscle, sensors around the joints provide information about joint angles and exteroceptive sensors in the skin provide information about the interaction of the body with its surrounding. All this information are send along peripheral sensory nerves towards the CNS. When they enter the CNS at the spinal cord they are evaluated to eventually generate reflexive movements by actuation of muscles. After being forwarded further to the brain these sensory information about the actual movement is compared to the planned movement. If there is a discrepancy between planned and actual movement the brain sends corrective impulses. This closed loop of movement control is called the sensorimotor loop. The tree signals that could be used as control input for prosthesis control are introduced in more detail in the following.

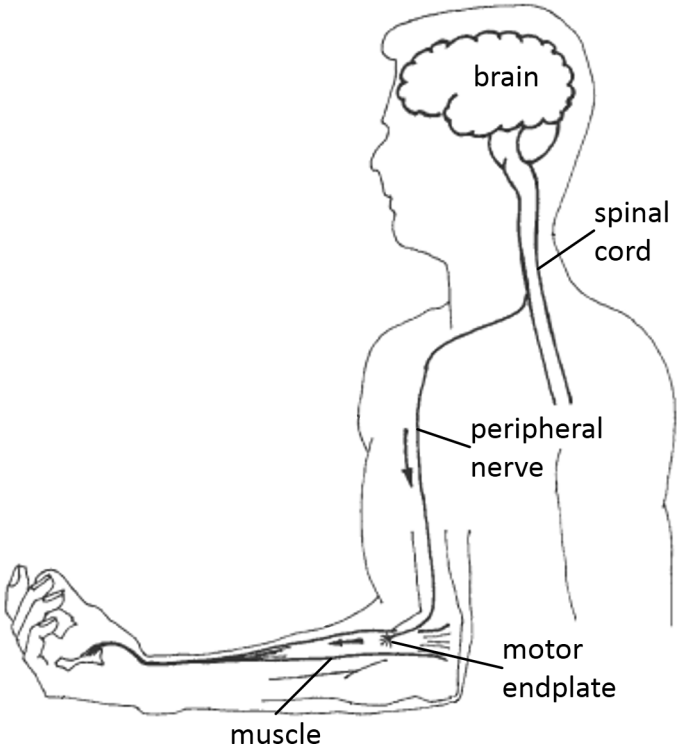


Figure 1.4: Generation of voluntary movements (adapted from [Kampas, 2001]). Intentional movements are initiated in the brain. Impulses are forwarded to the spinal cord which then activates the muscles, required to perform the intended movement, by sending action potentials along peripheral nerves.

Electroencephalogram (EEG). Voluntary movements are planned in the motor cortex. The activity of the neurons involved in this process generates electric potentials that can be measured in two ways. The first is to place surface electrodes on the skin of the head and the other is to implant electrodes into the head which both yield signals in the µV range (EEG). The measurement of the EEG requires only the activity of the brain and generates control signals even if patients suffer from a high spinal cord injury. On the other hand, measurement of EEG is challenging and needs for a high number of electrodes securely positioned on the scalp or implanted in the head. During the former caps are needed to position the electrodes which would probably cause acceptance issues with amputees due to its visibility to their surroundings. The latter demands for an operation in one of the most delicate regions of the human body introducing the risk of severe complications.

Electroneurogram (ENG). After amputation of a limb nerves remain in the stump that lead information from the CNS to the lost part of the limb. These ENG signals have amplitudes of several µV when measured at outside the nerve and contain control signals for the lost muscles and would allow for an almost physiological control if they could be measured and interpreted [Di Pino et al., 2009]. Even there are several approaches to establish interfaces to peripheral nerves [Navarro et al., 2005, Ortiz-Catalan et al., 2012], those which proved long term stability were electrodes placed on or around the nerve and thereby provide only low selectivity. This is a problem, since a lot of information, control signals originating from the CNS as well as sensory information sent towards the CNS, is transferred through a small cross section of the nerve. Interfaces that penetrate the nerve to achieve higher resolution also introduce the risk of

nerve damage and still have to prove long-term stability when implanted [Lago et al., 2007].

Electromyogram (EMG). The smallest functional units of muscles are motor units. Each Motor Unit (MU) consists of one motor neuron with its cell body in the spinal cord and its axon leading to the muscle, the motor end plates at the end of the axon and all muscle fibers innervated by this one motor neuron.

Activation of the muscle is initiated by transfer of the action potential from the nerve to the muscle in the motor end plate. It leads to a depolarization of the cell membrane of a muscle fiber from the resting potential of $-80\,\mathrm{mV}$ to a maximum membrane potential of $30\,\mathrm{mV}$. This impulse is followed by a repolarization leading back to the resting potential of $-80\,\mathrm{mV}$. The depolarization is propagating from the motor end plate in both directions of the muscle with a speed between $2\,\mathrm{m\,s^{-1}}$ and $6\,\mathrm{m\,s^{-1}}$. During contraction of a muscle all muscle fibers in one MU are activated synchronously. The resulting Motor Unit Action Potential (MUAP) is a summation of all action potentials of all muscle fibers of one MU. A continuous contraction is archived by subsequent activations of MUs resulting in trains of MUAPs. During stronger contractions several MUs are activated in a muscle. The resulting summation of the single membrane potentials is the EMG. If this signal is measured with electrodes directly on or in the muscle it is referred to as intramuscular EMG. The surface EMG signal is measured with surface electrodes on the skin after it has been affected by filtering effects of tissues through which it has traveled.

Compared to EEG and ENG which have amplitudes in the of uV range, the muscle producing a stronger EMG signal of several mV. The EMG signal also provides a higher selectivity since it only contains the activation of one muscle while the ENG contains motor information for many muscles and sensory information from numerous sensors. Another benefit of the use of EMG as control signal is the possibility for non-invasive measurement which does not need for implantation of electrodes and other components.

But the non-invasive measurement of the surface EMG is also responsible for the most disadvantages of this approach. The measured EMG signal is mainly originating from larger muscles since they contain more muscle fibers and thus generate higher signal amplitudes. The filtering effect of the tissue between muscle and electrode causes high damping of EMG signals originating from deeper muscles. Furthermore there is a significant amount of cross talk between different muscles. These effects contribute to the limited number of control signals that can be measured, even if there are several muscles remaining in the stump. The placement of electrodes on the skin also suffers from changes of the skin impedance over time or due to sweating, which is a common problem in prostheses sockets. Also electrode movement and lift-offs caused by relative movement between socket and stump lead to artifacts in the signal that might be misinterpreted by the control unit resulting in unintended movement of the prosthesis. Measurement of the EMG with implanted electrodes might overcome these limitations but introduces the need of implantation of electrodes (see section 1.2.2).

Measurement of the myoelectric signal

State of the art electric prostheses use the EMG signals measured with surface electrodes on the skin of the stump as control signal. This approach was initially suggested by Reiter as early as 1948 [Reiter, 1948]. Surface electrodes applied for prosthesis control generally incorporate a first stage of signal processing which preprocesses the recorded EMG signal and the resulting output is sent to the prosthesis control. This signal processing is illustrated in figure 1.5 and contains the following steps [Kampas, 2001]:

- An *instrumentation amplifier* provides a fixed amplification of the differential EMG signal. The amplifier has a band-pass characteristic which only amplifies the signal components between 20 - 500 Hz.
- A *notch filter* filters the regional power line frequency of 50 Hz or 60 Hz.
- An *adjustable amplifier* allows adaptation of the EMG signal level generated by the amputee to the level necessary for prosthesis control.
- A *full-wave rectifier* inverts the negative signal components.
- A *low-pass filter* with a time constant which is high compared to the frequency content of the EMG signal yields an average over a short time span.

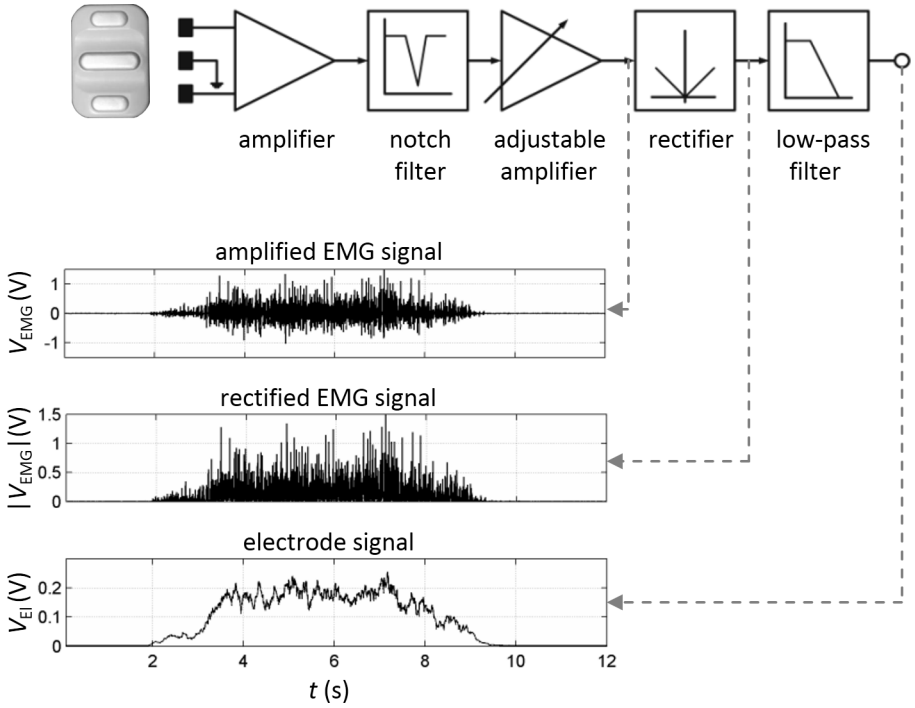


Figure 1.5: Signal processing integrated into a surface electrode (13E200, Otto Bock): Block diagram of signal processing and resulting signals (adapted from [Reitinger, 2007]). The surface EMG is measured between the outer contacts of the electrode, amplified by a fixed gain amplifier with high input impedance, notch-filtered and then amplified to the desired amplitude by an adjustable amplifier. The resulting EMG signal V_{EMG} is then rectified $|V_{\mathrm{EMG}}|$ and low-pass filtered to obtain the electrode signal V_{El} used for prosthesis control.

Control of one degree of freedom

Prosthesis control systems commercially available today provide the amputee with direct control of one degree of freedom at a time. Two surface electrodes are used to obtain two separate control inputs if there are enough muscles on the stump that the amputee can contract voluntarily and generate an EMG signal strong enough to be measured with surface electrodes. For intuitiveness of generation of control inputs it is preferred to use a combination of agonist and antagonist. For

a fore arm amputation for example the wrist and finger flexors are used to close the prosthetic hand and contraction of muscles that extended fingers and wrist before amputation is used to open the hand. The relation between amplitude of the control signal and actuation of the prosthesis cam follow one of the two approaches introduced in the following.

Digital control. In digital control the drive of the hand is activated as soon as the EMG activity of one channel raises above a certain threshold. The respective movement of the hand is maintained until the EMG falls below this threshold or the maximum grip strength is reached. An extension of this principle, which is also one option available in Otto Bock hand prostheses, defines three thresholds for the electrode signal resulting in three speeds of movement, like presented on table 1.2.

Table 1.2: Thresholds for the electrode signal in a basic control scheme.

control signal (V)	state
$0.00 \leq x \leq 0.55$	OFF
$0.55 < x \leq 1.00$	ON
$1.00 < x \leq 1.50$	LOW
$1.50 < x$	HIGH

Proportional control. Proportional control drives the motors of the prosthesis proportional to the amplitude of the EMG signal [Bottomley, 1965]. Thereby the drive of the motors actuating the hand is linearly related to the amplitude of the myoelectric signal. Inconvenience is caused by the non-linear relationship between strength of muscle contraction and the amplitude of the resulting EMG which makes it challenging to control slow motions and small grip forces [Perry and Bekey, 1981].

To overcome the shortcomings of basic proportional control approach it was refined in Dynamic Mode Control (DMC) [Robinson, 1995]. DMC takes into account the nonlinear relationship between strength of muscle contraction and resulting EMG amplitude by defining two independent relationships between EMG amplitude and power supply to the motors, one for speed of movement and one for application of grip force. Which of these two modes is active is defined by monitoring the grip force in the prosthetic hand. The speed of prosthesis movement is controlled according to the one relationship until a set grip force threshold is met. As long as this threshold is exceeded the grip force is controlled according to the second relationship [Kaitán, 1997]. This results in control of the prosthesis, which is perceived as linear to control effort by the user and provides control adequate for fine movements and low grip forces as well as for fast movements and high grip forces.

Control of multiple degrees of freedom

For amputation levels higher than wrist exarticulation, prostheses usually integrate more degrees of freedom than just opening and closing the hand. There are approaches of controlling multiple degrees of freedom simultaneously by using a high number of electrodes and classification algorithms but due to their limited performance in real life application none of them has been implemented in a commercially available product yet [Hudgins et al., 1993, Zardoshti-Kermani et al., 1995, Parker et al., 2006, Tkach et al., 2010]. Hence it is necessary to switch between control of different degrees of freedom. This can be achieved by co-contraction of both measured

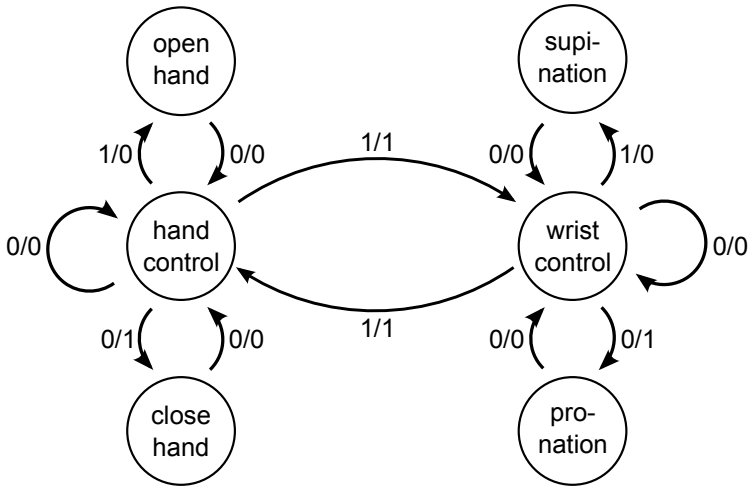


Figure 1.6: State transition diagram of sequential control algorithm: Each state describes a control state and arrows represent transitions between states. These transitions are initiated by the activity of the two channels of EMG as indicated by the corresponding numbers (0/0: no channel, 1/0: extensor channel, 0/1: flexor channel and 1/1 both channels active).

muscles. While contracting either of the measured muscles moves one degree of freedom in one or the other direction, a co-contraction of both muscles switches to the next degree of freedom. The operation of this control strategy is illustrated in the in the state transition diagram in figure 1.6 for a two degree of freedom prosthesis. The first degree of freedom is provided by a hand prosthesis (open and close) and the second degree of freedom by a wrist rotator (supination and pronation).

This sequential control scheme becomes inappropriate as soon as prostheses provide more than two degrees of freedom, since it necessitates much switching between degrees of freedom. In addition, it is not capable of realizing the simultaneous control of different degrees of freedom. For example drinking from a glass with a state of the art prosthesis incorporating elbow, wrist and a one degree of freedom hand becomes cumbersome. The user is standing in front of a table on which the glass is positioned. Grasping the glass requires opening of the hand, switching to wrist control, adapting the orientation of the hand by rotating the wrist and switching to hand control again for closing the hand to grasp the glass. To bring the glass to the mouth the control has to be switched to the elbow and the elbow has to be flexed. This results in tilting of the glass which has to be compensated by repeatedly switching to wrist control and rotate the wrist accordingly. At the end of movement, when the glass is reaching the lips, the elbow flexion should be performed simultaneous to wrist rotation for tilting the glass but simultaneous movements are not realizable applying the sequential control scheme.

To overcome the limitations of sequential control, more control signals become necessary. Whether the number of control signals is sufficient to control each degree of freedom by two control signals directly, or pattern recognition techniques are applied to try to derive the user intention (see section 1.2).

Control strategies

So far, only the forward control of the prosthesis by the user was considered. In the following, three different concepts for integration of prostheses into the physiologic control of movements are described, including

- open-loop control,
- closed-loop control and
- sensory feedback.

Open-loop control. In open-loop control (figure 1.7) a sensor measures a control input generated by the user and forwards it to the prosthesis control (coupling). The prosthesis control tries to correctly interpret the user intention and actuates the prosthesis accordingly. To evaluate if the prosthesis is moving as intended the user has to visually observe the resulting movements of the prosthesis and thereby close the control loop. In addition the user is not provided with information about the interaction between the prostheses and the outside world. Non-visual effects like grip force applied to non-deformable objects or temperature of an object touched cannot be accessed and visual effects like slipping of a grasped object need the continuous attention of the user [Lundborg and Rosén, 2001].

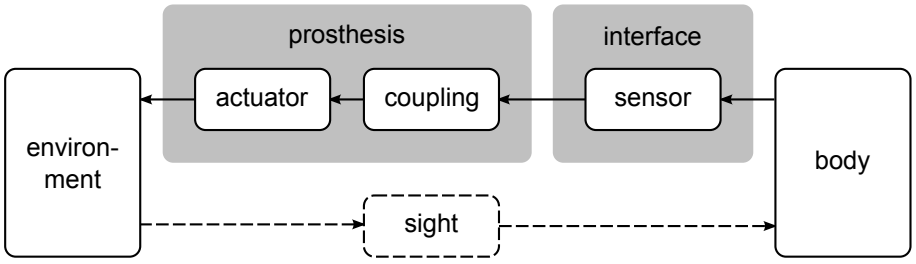


Figure 1.7: Open-loop control: Control signals are measured by a sensor and transfered to the prosthesis. Here they are interpreted by a control unit and the actuators are driven to achieve the according movement. The only possibility for the user to close the control loop is to observe the movement of the prosthesis.

Closed-loop control. In closed-loop control (figure 1.8) the open-loop control is complemented by sensors that measure properties like the grip force or contact between prosthesis and objects. This information is then forwarded to the prosthesis control to be integrated into actuation of the prosthesis.

Closed-loop control is mainly applied to prevent slipping of grasped objects. This becomes especially important since the side of amputation becomes the non-dominant side for most amputees and they tend to use their prosthesis for holding objects if both hands are needed for a task [Kaitán, 1997]. This slip prevention mechanism reduces the attention the amputee has to spend on holding an object in the prosthetic hand and therefore allows to concentrate on the manipulation of the object or anything else he or she wants to carry out while holding the object. The principle of slip detection is based on the measurement of the contact force at the points of contact between a prosthetic hand and a grasped object. This force contains two components, a tangential force resulting from the weight of the object held and a normal component resulting from the grip force. If the object starts sliding out of the hand, the tangential component

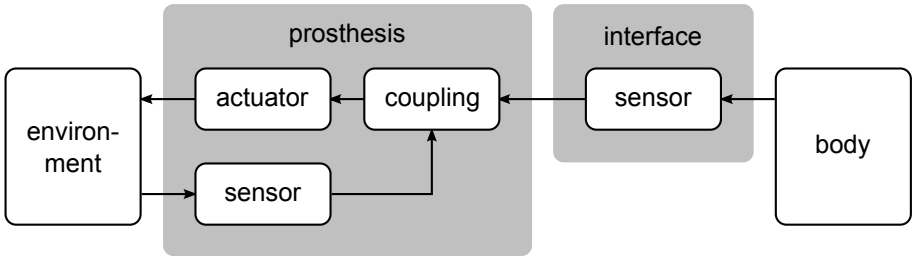


Figure 1.8: Closed-loop control: Sensors measure parameters related to the movement of the prosthesis and feed it to the control unit which is integrating these measures into the actuation of the prosthesis.

decreases in relation to the normal component. The control unit then automatically increases the grip force until the slipping is stopped [Puchhammer, 1999].

A more complex closed-loop control is suggested in the hierarchical control algorithm [Baits et al., 1968, Kyberd et al., 1993, Light et al., 2002, Kyberd et al., 2007a]. It divides control of the hand between a higher level, intentionally controlled by the user, and a lower level, which is automatically actuated by prosthesis control. At the higher level the user only gives simple commands to open or close the hand or whether an object should be held or squeezed. The sensors in the prosthesis, which measure grip force and contact regions between prosthesis and object, provide prosthesis control with the information to autonomously perform the rest of the control task of the lower level, like choice of grip type and application of appropriate grip force.

Even though no evidence was found in literature, prosthesis users reported to be uncomfortable when experiencing their hand automatically performing activities that where not intended. One example given was handing over a piece of paper to another person who wants to pull it out of the fingers of the prosthetic hand. If automatic slip prevention interprets this as slipping the hand increases the grip force and prevents handing over the sheet. In personal conversation orthopedic technicians also reported that a considerable number of prosthesis users use prosthetic hands with integrated slip control but deactivate this function.

Sensory feedback. A more physiological approach to integrate a prosthesis into the sensorimotor control loop of the human is provision of the measured sensory information directly to the user. Several studies investigated the provision of sensory feedback. Sensory information most often measured by the prosthesis and subsequently transferred to the user was grip force [Almström et al., 1981, Pylatiuk et al., 2006] but also information about the contact between prosthesis and grasped objects [Dario, 1991] as well as proprioceptive information about the position of the prosthesis were used [Mann and Reimers, 1970, Bark et al., 2008].

Sensory information was transferred to the stump of the amputee. This might achieve an intuitive sensory substitution, since it was reported that the distal region of the stump takes over parts of the sensory functions of the amputated limb [Merzenich et al., 1984, Katz, 1992]. Principles applied include electric stimulation through surface electrodes [Prior et al., 1976, Weiss et al., 2007, Walter-Walsh et al., 2009], vibration transmitted by vibration motors [Mann and Reimers, 1970, Shannon, 1976, Pylatiuk et al., 2006] or pressure applied to the skin of the stump [Meek et al., 1989]. Other researchers used electric stimulation of sensory nerves to transfer information to the amputee [Anani et al., 1977, Dhillon and Horch, 2005, Rossini et al., 2010, Horch et al., 2011]. Studies reported that it was possible to elicit different sensation which were referred to different parts of the lost limb.

Provision of sensory feedback by the prosthesis not only allows the user to control his or

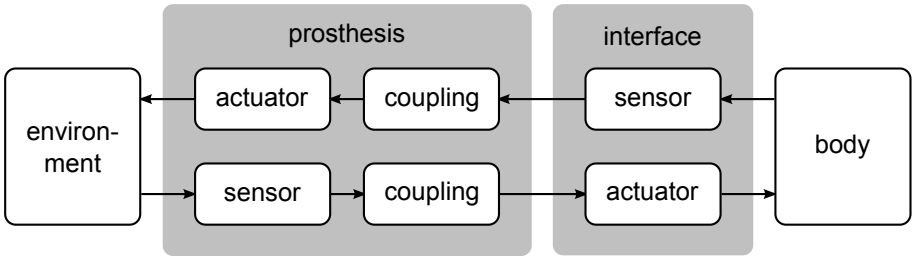


Figure 1.9: Sensory feedback: Sensory information are measured by the prosthesis but not fed to the control unit but transmitted to the prosthesis user to close the physiologic sensorimotor loop.

her prosthesis with less visual attention but might also allow for the integration into physiologic control, including spinal reflexes. Providing amputees with sensory information referred to the lost limb also has the potential to reduce phantom pain and might result in a integration of the prosthesis into the body image of the amputee [Hill, 1999, Weiss et al., 2007]. Furthermore, it was found that users who experience sensory feedback use their prosthesis for longer and are more satisfied with them [Silcox et al., 1993].

1.1.4 Satisfaction with current prostheses

Several surveys were conducted to evaluate the satisfaction of users with their prostheses and ask them about suggestions for further improvements. In general, surveys of prosthesis users suffer from two limitations. On the one hand the number of prosthesis users is small compared to the whole population and on the other hand in most countries there is no central register of prosthesis users which makes it difficult to get in contact with them. Due to this limitation of possible participants, only few of these surveys either focus on users of myoelectric prostheses only [Pylatiuk et al., 2007] or differentiate their results according to prosthesis type used by the respondents [Atkins et al., 1996]. The results of five surveys that achieved a relevant number of respondents, including users of myoelectric prostheses, and derived findings on user satisfaction and suggested improvements are presented in table 1.3.

The most *important Activities of Daily Life* (ADLs) found in the studies indicate during which activities the function of their prosthesis is of particular importance to users. A high importance of prostheses is reported during activities that use the grasping of the prosthesis like eating with cutlery and drinking from a glass and also the manipulation of objects for example when performing handicrafts or opening of doors. Activities for self-care including personal hygiene, dressing and undressing as well as tying shoe laces were also found to have high importance to prosthesis users. They also want to achieve independence in daily live by being able to operate electronic devices like computers and being able to drive a car. The need for not being perceived as handicapped by others becomes clear by the requirements of natural appearance and the ability to use a natural body language.

Satisfaction with different aspects of the prosthesis was found to be high for the terminal device, denoting the hand or gripper, putting the prosthesis on and taking it off again (donning and doffing), the comfort of the socket when the prosthesis is worn, the strength of the grip and the low maintenance. Low satisfaction of prosthesis users was present for perspiration in the socket, limited durability and fast staining of the cosmetic glove. Regarding prosthesis control respondents were dissatisfied with control of precise movements, adaptation of the hand to the shape of objects and the lack of sensory feedback received from the prosthesis.

The *suggested improvements*, explicitly surveyed by the authors or introduced by respondents

themselves, span a wide range of aspects. Suggestions related to the prosthesis in general ask for reduced weight and cost as well as implementation of faster but quiet movements. Single prosthesis components mentioned were the socket, mainly wishing for less sweating inside it, and the cosmetic glove, which should be less sensitive to dirt, more durable and have a more life-like appearance. A large number of suggestions could be assigned to enhanced movability of the hand. These suggestions included independent movement of fingers, explicitly extension of the index finger, movement of the thumb to the side and into opposition to single fingers. Also a higher dexterity, better handling of small objects as well as the availability of more grip types were mentioned. Prosthesis users also wished for more movability of the wrist including rotation as well as flexion and extension. These requirements asking for more independent degrees of freedom are in conflict with the wishes of respondents regarding the control of their prosthesis. They would like a more intuitive control which is more reliable and less prone to failures while allowing for more precise control of movements and applied grip forces. Approach to overcome this difficult situation are presented in section 1.2.

Findings about sensory feedback of the presented surveys are of limited extent, since none of them focused on this topic and only one [Pylatiuk et al., 2007] contained one question explicitly asking about the importance of three possible information, that could be provided. Even though, it was found that prosthesis users are not satisfied with the amount of sensory information provided by their current prosthesis and receiving more sensory feedback is of interest to them. This would also satisfy the demand of paying less visual attention to the prosthesis during use. Kinds of sensory information identified as important were grip force and temperature while tactile information was less important.

Table 1.3: Results of upper extremity prosthesis user surveys on satisfaction with and suggested improvements of prostheses.

topic	Atkins 1996	Davidson 2002	Biddis 2007	Kyberd 2007	Pylatiuk 2007
participants	438	70	242	113	54
prostheses type	only electric prostheses reported here	no differentiation	20% cosmetic 35% body-powered 45% myoelectric	60% cosmetic 27% myoelectric 13% others	only myoelectric
amputation level	53% transradial	16% hand and wrist 31% transradial 23% transhumeral 10% shoulder	16% wrist 54% transradial 21% transhumeral 7% shoulder	58% below elbow 38% above elbow	80% transradial 15% transhumeral
reason for amputation	congenital: 95% of children trauma: 77% of adults	70% trauma 27% congenital 3% vascular disease	congenital: 91% of children 41% of adults	-	44% congenital 56% trauma
important ADLs	use computer open door tie shoes eat with cutlery drink from glass cut meat	68% drive a car	gripping steadying manipulating appearance body language	-	eat with cutlery personal hygiene handicrafts dress open doors use electronic devices
satisfaction	dissatisfaction with frequent repairs: 34% cosmetic glove 26% batteries	*highest:* terminal device comfort of the socket *lowest:* sweating in the socket comfort of the arm	*lowest:* perspiration in socket staining of glove	*highest:* maintenance donning and doffing strength *lowest:* sensory feedback precision control adaptation to objects	-
suggested improvements	bend fingers thumb to side less visual attention thumb opposition grasp small objects wrist rotation	adaptation of socket to higher ambient temperatures	weight, glove material, cost, sensory feedback, dexterity, heat, control failures, life like, comfort of harness, reliability, size, independent fingers, wrist movement, fit	quiet operation more grip shapes control of grip force reliable operation intuitive control	100% extend index finger 90% individual fingers 89% quiet operation 78% reduce weight 76% faster movement 70% wrist flexion 57% cosmetics
findings on sensory feedback	less visual attention	-	4^{th} design priority 'Overall, greater sensory feedback was of interest to all prosthesis users [...]'	low satisfaction with sensory feedback provided by current prostheses	sensory information: 91% grip force 61% temperature tactile information is less important

1.2 Implantable systems for prosthesis control

There are generally two different approaches for improving the control of current myoelectric prostheses for the upper extremity:

1. *Advanced signal processing:* Development of improved signal processing, pattern recognition and control algorithms that compensate for the shortcomings related to measurement of muscle activity with surface electrodes.

2. *Improved signal acquisition:* Improvement of the measurement of the EMG by use of implanted electrodes.

1.2.1 Advanced signal processing and related challenges

Extensive research focused on development of new signal processing approaches like pattern recognition and classification. Progress of these approaches seem to have reached a steady state, since several different approaches have been found to reach similar levels of accuracy [Hargrove et al., 2007]. Though, none of these approaches reached acceptable performance when applied to prosthesis control in everyday life. Several major challenges, which have to be solved before these approaches could become clinically relevant, have been identified [Scheme and Englehart, 2011]:

- *Electrode shift:* Every time a user puts a prosthesis on, electrodes contained in the shaft will be placed in slightly different positions in relation to the muscles contained in the stump. These shifts in electrode position decrease the reliability of the prosthesis control to a degree that they are no longer suited for clinical application [Hargrove et al., 2006,Hargrove et al., 2008].

- *Variation in force:* Pattern recognition approaches classify the muscle activity to one of different movement classes but do not differentiate between speed or force of these movements, which results in a digital control. Anyway, if muscles are contracted in the same pattern but with different strength the classification performance is considerably decreased [Scheme and Englehart, 2011].

- *Variation in limb position:* Movement of a prosthesis leads to variation in the mechanical loading transfered from the prosthesis to the stump. If this leads to compression of muscles in the stump the characteristic of their EMG is altered. Pressure on the muscles may also mechanically stimulate the muscle [Scheme et al., 2010].

- *Transient changes in EMG:* Other influences on the recording of the EMG are external interference, changes in skin impedance, electrode movement and liftoff as well as muscle fatigue. Most kinds of external interference can be compensated by filtering, but the other influences are intrinsic to measurement of EMG with surface electrodes inside a prosthesis socket.

1.2.2 Improved signal acquisition

Some of these issues connected to advanced signal processing approaches can be overcome by use of implanted electrodes to measure intramuscular EMG. But as soon as a large number of implanted electrodes is used, it is questionable if these signal processing approaches are needed at all [Hargrove et al., 2007]. As an example, a long stump of a transradial amputee includes

Table 1.4: Comparison of recent implantable EMG measurement systems intended for prosthesis control.

name	IMES	Ripple	TU Munich	Newcastle Uni
publications	[Weir 2009] [Baker 2010]	[McDonnall 2012] [McDonnall 2012b]	[Weber 2008]	[Baker 2013]
topology	electrodes with contained electronics	central implant with electrode leads	central implant with electrode leads	central implant with electrode leads
packaging	ceramic tube with metal caps	epoxy and silicone	epoxy and silicone	silicone
power supply	inductive	inductive	inductively chargeable battery	inductive
data transmission	RF transceiver	modulated on inductive link	RF transceiver	RF transceiver
resolution	8 bit, 24 Hz - 1 kHz	12 bit, 2 kHz	10 bit	12 bit, 5 kHz
channels	up to 32 bipolar	4 bipolar	3 monopolar	16 bipolar
connection of electrodes	integrated	direct	direct	direct
electrodes	intramuscular	epimysial, intramuscular	epimysial	-
status	implantation in a primate for two years, implantation in cats for nine months	implantation in dogs for one week	*ex vivo* recording of surface EMG	-
comments	two RF bands with low and high bandwidth	additional ground electrode	combination of commercially available products, 3 DOF accelerometer	electronics for energy supply and telemetry separately capsuled, external antenna

all muscles that actuated flexion and extension of the four fingers before amputation. Simple measurement and comparison of their EMG amplitude, which is related to the force they were transmitting to the fingers, should allow an intuitive and separate control of the fingers.

Most of the studies that demonstrated prosthesis control using implanted electrodes were short-term experiments applying percutaneous wires for establishing contact to these electrodes [Caldwell and Reswick, 1975, Basmajian and De Luca, 1985, Dhillon et al., 2004, Dhillon, 2005, Dhillon and Horch, 2005, Micera et al., 2010, Rossini et al., 2010, Micera et al., 2011, Horch et al., 2011]. However percutaneous cables are not suitable for connecting implanted electrodes over longer periods of time since they are subject to breakage, introduce a risk of infection and occurrence of granuloma [Marsolais and Kobetic, 1986, Knutson et al., 2002]. To overcome the drawbacks of percutaneous wires, implantable measurement systems were developed which allowed a wireless transmission of measured signals through the skin. Some recent EMG measurement systems that were developed for application in prosthesis control are introduced in table 1.4.

The first implantable EMG measurement system developed for the control of myoelectric prostheses was implanted as early as 1966 [Hirsch et al., 1966]. This system already included the fundamental components also found in recent systems. Energy was inductively transfered to the implant where a rectifier produced the direct current to power the measurement electronics. The measured EMG was then transferred via a Radio Frequency (RF) link to the external prosthesis control unit. Electrode and electronics were integrated into one unit which was encapsulated in two layers of epoxy and subcutaneously implanted in one amputee for 10 days. After this period of time shrinkage of the epoxy capsule led to damage of the implant electronics. Two

years later this system was revised with a focus on a more durable encapsulation [Herberts et al., 1968]. The electronic components were separately capsuled in a hermetic metal housing before the whole implant was encapsulated in an adapted epoxy. This system was implanted below the skin of the fore arms of two healthy subjects and two transradial amputees for up to fifteen months. Limitations of these early systems were the amount of energy required by the implanted electronics and limited capacity of batteries of the external prosthesis which had to provide the energy for the inductive power supply.

Over 30 years later this approach of implanted telemetry electrodes with integrated electronics, responsible for energy supply, measurement of EMG and data transmission, was followed again during development of Implantable Myoelectric Sensors (IMES) [Weir et al., 2003]. This system applied state of the art components that allowed a first stage of signal processing on the implant [Weir et al., 2005] and hermetic encapsulation of all components in a ceramic tube. In contrast to the previous systems which were placed subcutaneously, IMES electrodes are designed for intramuscular placement. This allows for measurement of deeper muscles in the stump and thereby increases the number of accessible control signals. Due to this location of implantation, energy supply maintains a crucial challenge in the IMES system. Electrodes have only small coil diameters and are not in exact alignment whether amongst each other nor with the external magnetic field. In addition, electrodes are moving independently when muscles are contracted. This results in a low efficiency of the conductive energy supply. Therefore large magnetic fields have to be generated around the entire arm which may cause interference and make it hard to power the devices by the limited battery of the prosthesis over longer periods of time [McDonnall et al., 2012a, McDonnall et al., 2012b]. Besides, the entire area in which electrodes are implanted has to be surrounded by a coil and external ferromagnetic objects near the magnetic field lead to detuning of the inductive link which 'propagates through all aspects of the IMES system operation' [Weir et al., 2009].

An approach to overcome these problems in energy supply is division of the implant into different components: a central implant which is housing all electronics and several electrodes connected to it via cables. This approach, applied by the three other systems also presented in table 1.4, has the advantage that electronics and electrodes can be positioned independently. Electrodes can be placed on muscles most important for generation of control signals even if they are deep within the arm or laying far apart. The central implant, however, can be placed underneath the skin in a region where it does not move due to muscle contractions and an external coil could easily be placed directly above. This results in a small distance between and more reliable coaxial alignment of primary and secondary coil. In addition, the secondary coil can be larger to enclose a larger area of the magnetic field. The drawback of this approach is, that cables have to be run between each electrode and the central implant. In all of the systems presented in table 1.4 electrodes are directly directly connected to the central implant without connectors in the cables. This makes it necessary to explant and replace the entire system in case of a defect in any of its components. Since the body covers all implanted components with a layer of connective tissue [Schmit and Mortimer, 1997] the explantation might become more complicated and traumatic than the initial implantation.

1.3 Aims of the present work

By analyzing the current state of the art in upper-extremity prostheses, three areas in which further research could achieve substantial improvement of future prostheses were identified:

1. A detailed understanding how satisfied prosthesis users are with different aspects of state of the art myoelectric prostheses and how they want them to be improved, provide an important basis for development of future prostheses. Especially the needs of prosthesis users towards sensory feedback were not systematically evaluated yet.

2. An implantable EMG measurement system should be developed and evaluated for its potential to fundamentally improve prosthesis control.

3. Intramuscular EMG signals measured with the implantable measurement system and algorithms for their classification should be investigated for their applicability for prosthesis control.

Starting from the current state of the art of upper extremity prostheses, the present work investigates these different aspects in the three parts introduced in more detail below.

Evaluation of prosthesis users' needs. A survey is developed and carried out to evaluate the satisfaction of users of myoelectric upper-extremity prostheses with their current prosthesis and their suggested improvements for future prostheses. Another important aspect surveyed is the need of prosthesis users towards sensory feedback, including the information they want to perceive and how they should be transferred by the prosthesis. Furthermore, phantom sensations and the movability of the phantom arm are investigated, to determine if they could provide a means to achieve intuitive control of future prostheses.

Development and evaluation of the implantable EMG measurement system. Based on the findings of the survey, an implantable EMG measurement system is developed in cooperation with Otto Bock Healthcare Products, Hamburg University of Technology (TUHH) and Fraunhofer Institute for Biomedical Engineering (IBMT), to achieve improvement of control of advances arm prostheses. The present work focuses on evaluation and improvement of a first electrode design based on polyimide and subsequently the development of a new implantable silicone electrode and a low invasive procedure for its implantation. The implantation procedure and the mechanical stability of these electrodes as well as the function and stability of the entire implantable measurement system are then evaluated in animal trials in rats, sheep and primates. During these experiments also the process of electrode encapsulation by connective tissue and the resulting collagen capsule formed around electrodes are investigated.

Evaluation of the measured muscle activity. EMG signals measured with the implantable system during reaching movements in primate experiments are analyzed in detail. In a first step signal properties are determined to compare them to those of EMG measured at the skin surface. Finally, directions of arm movement are identified by analysis of these signals. In this process different signal features and classification algorithms are evaluated for their applicability in prosthesis control.

Chapter 2

Materials and methods

As a basis for the presented work, the needs of prosthesis users towards future prostheses were evaluated by conducting a survey introduced in section 2.1. To address some of the users' demands resulting from this survey, an implantable EMG measurement system was evaluated and further developed, like described in section 2.2. This evaluation included animal trials which are outlined in section 2.3. Impedance measurements described in section 2.4 were carried out to characterize different electrodes and monitor the process of electrode encapsulation over time after implantation. The EMG signals measured with the implanted electrodes were analyzed and classified according to the methodology presented in section 2.5.

2.1 User survey

A user survey was designed to gain insight into three major topics:

- satisfaction of users with current electrical prostheses and suggestions for their improvement,
- demands towards sensory feedback from the prosthesis to its user and
- occurrence of phantom and pain phenomena comprising pain in the residual limb, phantom pain, non-painful phantom sensation and movability of the phantom limb.

For statistical analysis of responses also personal data of participants was surveyed, including information about their amputation and prosthesis use. To survey these topics a questionnaire was developed which was then answered by amputees that were using a myoelectric prosthesis.

2.1.1 Structure of the survey

The survey was composed of 42 questions and is presented in the Appendix starting at page 163. It was structured into the following four parts that are described in more detail below.

1. satisfaction with current myoelectric prostheses and suggestions for their improvement
2. users' needs towards sensory feedback
3. phantom pain, phantom sensations and movability of the phantom arm
4. personal data of participants

The *first part* of the questionnaire covered satisfaction with the current prosthesis and suggestions for improvements of current prostheses. In the opening question participants were asked for their spontaneous satisfaction with their electrical prosthesis. In the following question the satisfaction with the prosthesis was surveyed in more detail by asking participants about their satisfaction with different features of their prosthesis and the performance of their prosthesis during different Activities of Daily Life (ADLs). To identify which ADLs were most important to prosthesis users participants were asked to give the three activities that were of most importance to them. In the following their attitudes towards control and embodiment were surveyed. At the end of the first part participants were given a free text field to give their ideas about how their current prosthesis could be improved.

The *second part* of the survey focused on sensory feedback. At first, prosthesis users were asked which sensory information they already employ to gain information about their current electrical prosthesis during use and how they apply this information during prosthesis control. In the following participants were asked of what importance different kinds of sensory information were to them and which were the three most important kinds of information. Subsequently the importance of sensory information during different ADLs was surveyed, also asking for the three ADLs in which receiving sensory information would be most important. Thereafter it was investigated how the transmission of sensory information could be realized. Amputees were asked about the sensitivity of their residual limb to pressure, temperature and vibration, followed by a question about their acceptance of different feedback modalities. The closing question was asking participants to rate the overall importance of sensory feedback to them.

In the *third part* of the survey participants were asked to describe the phantom and pain phenomena they experienced. At first participants were asked how often they felt phantom sensations, phantom pain and pain in the residual limb, followed by the development of their frequency over time. Subsequently they were asked about the intensity and its development over time of both pain phenomena. In the following respondents could describe the pain they felt in a free text. Experiences with the treatment of pain and the extent of restrictions by pain closes the questions about pain. Participants who feel phantom sensations were asked about the parts of their phantom arm they could feel and were asked to describe their sensations in a free text. Participants who were able to move their phantom arm were asked about which parts of the arm they could move and if the phantom movability changed over time.

The *fourth part* at the end of the survey collected personal data of the participants. This comprised year of birth, sex, side and level of amputation(s) and weather the absence was congenital or caused by an amputation. Patients who underwent amputation were asked about the year of and the reason for amputation, which was their dominant hand before amputation and what was their occupation prior to amputation. In the following all participants were asked about their present occupation and if they were supported by others during daily live. The activity of the participants was surveyed by asking which physical activities were carried out for how long. The closing questions of this part surveyed which types of prosthesis a participant owned, for how many years they were owned and how long they were used per day.

After thanking the participants for taking part in the survey they were asked in a final question if they preferred a mailed or an on-line survey and had the opportunity to give any comment on the survey.

2.1.2 Questions

Question were worded especially for easy comprehension and accounted for the fact that respondents might have no insight into the technology behind their prosthesis and had no experiences with sensory feedback systems. The survey followed a partly standardized approach. Closed

questions were used whenever possible to allow quantitative analysis, while open questions were analyzed qualitatively, to investigate highly individual aspects like feelings and sensation and allow the introduction of new aspects by the participants.

Closed questions were predominantly used to reduce time for completion for participants and facilitate statistical evaluation of the questionnaire by making answers to central topics comparable amongst respondents. Besides *yes* or *no* and multiple choice questions, attitude of respondents towards different statements was surveyed by Likert items [Likert, 1932]. Response scales were only labeled at their end points to support the perception of equidistant intervals between levels and to allow interpretation of resulting data as interval scaled. End points span a one dimensional response space between *not at all* at the left and *absolutely* at the right side of the scale. This space was subdivided into four response categories to avoid a middle category, which could be misperceived as *neither agree nor disagree* and be used as escape category [Porst, 2009]. It was assumed that respondents do not have very differentiated opinions towards many of the topics. Therefore no six or more level scales were used. Associated questions were grouped to matrices with identical response scales.

Open ended questions were used when closed questions could not account for the variety of individual conditions and attitudes. They were also used to give the respondents the opportunity to introduce new ideas and topics beyond the constraints of closed questions. At the end of some matrix questions blank items were given that had the same response scales as items above and could be defined by participants (e.g. Appendix on page 166, question A3). These items allowed them to introduce new aspects to a given question and report their attitude in accordance with the items above. Free text questions provided the space for participants to freely describe their sensations or ideas on how their prosthesis could be improved.

2.1.3 Pretesting the survey

Validation of the survey was carried out under two constraints. On the one hand, the population of upper extremity amputees wearing an electrical prosthesis makes up only a small part of the European society, what made contacting this population difficult. On the other hand, Otto Bock had no contact information of prosthesis users for reasons of data protection described in chapter 2.1.4. Under these constraints of a small population and limited accessibility it was not possible to conduct a field test without considerably reducing the number of potential participants in the survey.

Therefore pretesting was based on qualitative laboratory techniques. The first tests were carried out with single questions which were evaluated by subject matter experts [Ramirez, 2002], comprising biomedical engineers experienced in prosthesis development and orthopedic technicians. From these revised questions a draft of the survey was established and evaluated in an expert review, like proposed in [Prüfer and Rexroth, 1996] and methodologically revised by a social scientist experienced in surveys. After expert reviews three different laboratory techniques were applied to pretest the survey with a small group of only three amputees who were attending other research related test procedures at Otto Bock. In *Concurrent Think Aloud* method [Sudman et al., 1996, van den Haak and de Jong, 2003] subjects were instructed to verbalize their thoughts while they answered the survey questions. This was used to learn about the cognitive processes and recall strategies subjects used to answer questions and to identify misinterpretation of questions. After answering of particular questions *Follow-Up-Probing* [Hess and Singer, 1995] was used to evaluate the comprehension of certain crucial aspects of these questions. After completion of the survey the respondents were asked some *Debriefing Questions* [Hess and Singer, 1995] about the overall survey.

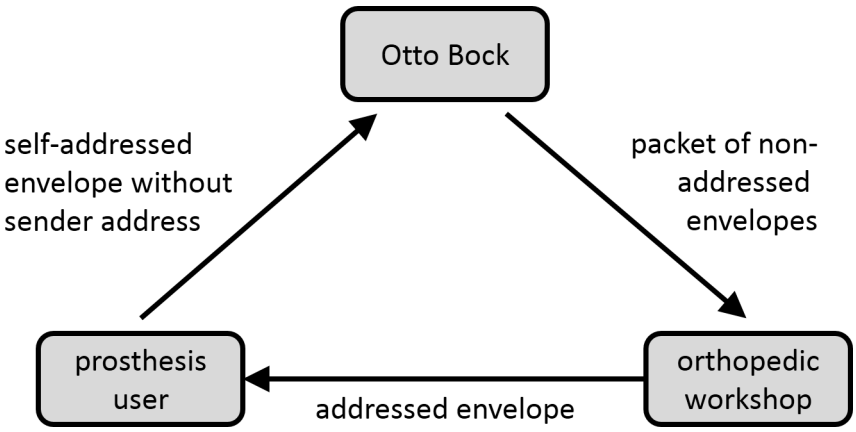


Figure 2.1: Distribution of the mailed survey: To ensure anonymity of participants, survey documents were sent to orthopedic workshops, which forwarded them to their customers. Returned surveys did not contain name or address of participants.

2.1.4 Distribution of the survey

Two different ways were applied to distribute the survey. The first was distribution as a mailed survey. Distribution of this survey assured that all respondents met the inclusion criterion of using an electrical upper limb prosthesis. The second instrument was an open on-line survey which reproduced the questionnaire as closely as possible. It was made available after the mailed survey ended in order to further increase the number of respondents.

Mailed questionnaire. Mailing a questionnaire to a population meeting certain inclusion criteria requires personal information of these individuals. The acquisition and processing of personal data is regulated by the Austrian Data Protection Law [DSG, 2000]. All data concerning the health status of a person is classified as *sensitive data* which is subject to extended protection (§4/2). This also includes information about amputation and whether a electrical prosthesis is used or not. This information is only available to juristic persons who need it for provision of health care services (§9/12). Otto Bock is producing standardized components which orthopedic technicians then use for building individual prostheses especially fitted for each amputee. Therefore orthopedic workshops are providing the actual health care service to the amputees and are allowed to have contact information of amputees, while Otto Bock is only providing components to the orthopedic workshops and is therefore not allowed to have this information. The transmission of this data is generally not allowed. One exception is, if it is not possible to directly relate the data to a individual (§9/2) which is generally not possible for contact information. Another viable execution is to approve the transmission of the data, for a specific use to a specific person, by each individual (§9/6, §47/1). Attaining this approval includes an effort for the orthopedic technician to contact amputees and for the amputees to opt in and would therefore reduce the number of participants considerably [Dijkstra et al., 2002].

To contact the amputees in compliance with the Austrian Data Protection Law a procedure for indirect contact was applied which is illustrated in figure 2.1. For the mailed survey 400 unaddressed envelopes containing a covering letter, the questionnaire and a stamped self-addressed envelope were sent to 17 orthopedic technicians throughout Germany. The orthopedic technicians then forwarded the survey documents to their patients that were using electric upper limb prostheses. Amputees then had the opportunity to opt in by filling out the questionnaire and sending it back or opt out by doing nothing. If they used the self-addressed envelope to send

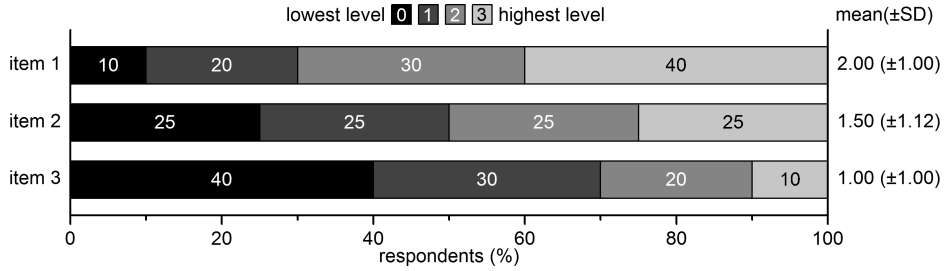


Figure 2.2: Example diagram used for presentation of the survey results: *"Wording of the question asked?"*

it back neither the envelope nor the questionnaire contained any information that would have allowed identification of the respondent. Therefore collection and processing of data obtained in this way was conform to the Austrian Data Protection Law (§9/2).

On-line survey. An on-line survey was established by reproducing the questionnaire as close as possible. There was no provider of on-line surveys which originally supported all kind of questions used in the questionnaire. Therefore the survey was hosted on the on-line platform onlineFragebogen (www.soscisurvey.de), since many question types were already available as standard questions and others, especially the blank Likert items, could be realized by integration of HTML and PHP code. The link to this questionnaire was mailed to orthopedic technicians in Austria and Norway who forwarded it to patients fulfilling the inclusion criteria.

2.1.5 Statistical evaluation

All questionnaires that met the inclusion criterion, that respondents used a myoelectric prosthesis, were included into statistical analysis that was carried out using SPSS 20 (SPSS: An IBM Company). Since not all questions were answered by all respondents, pairwise deletion was applied for each statistical test. Only non-parametric tests were applied because normal distribution was not given for most variables. Differences in independent samples were compared applying the Mann-Whitney-U-Test and the Kruskal-Wallis-H-Test for two and more variables, respectively. Two dependent samples were compared applying Wilcoxon-Tests and more dependent samples were compared with Freidman-Test. Correlation between variables was quantified with Spearman's rank correlation coefficient. The level of significance was chosen to be $\alpha = 0.05$ for all quantitative analyses. Answers to open questions were evaluated applying qualitative statistics according to [Mayring, 2007].

Responses to attitude questions are presented in stacked bar diagrams showing percentage of ratings for each level structured like the example graph in figure 2.2. The question that was asked is repeated in the caption while the corresponding response scale presented to the participants, with corresponding values for each level, is shown in the legend above each figure. For each item ratings of all respondents were averaged and are shown on the right side of each graph. These mean values were used for ranking of items from highest to lowest.

2.2 Implantable measurement system for prosthesis control

Improving control of upper extremity prosthesis was the central aim of the MyoPlant project. To address some of the needs, identified in the user survey, like reliability of control and simultaneous

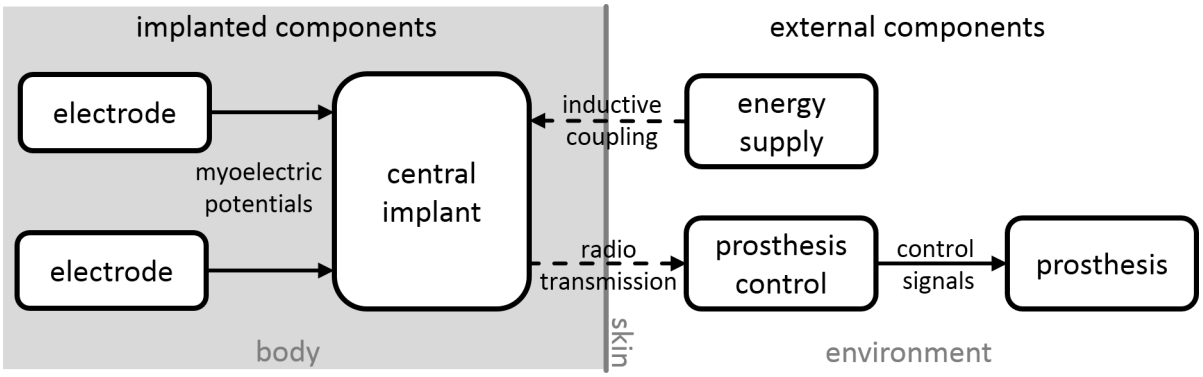


Figure 2.3: Schematic presentation of the components of the implant electronics. The basis for the implanted components (left) is a central implant (see figure 2.4) to which up to four electrodes are connected. The central implant is inductively powered and transmits measured EMG signals over a radio link.

control of more Degree Of Freedoms (DOFs), an implantable EMG measurement system was developed.

The fundamental components of the system and their interactions are shown in figure 2.3. Up to four electrodes were implanted on target muscles and passed the measured myoelectric potentials to a central implant. The central implant was inductively powered by an extracorporeal energy supply. It amplified and digitized the myoelectric potentials received from the electrodes. Digitized data was then sent from the implant to the external prosthesis control by radio transmission. The prosthesis control interpreted these signals and sent control signals to the prosthesis to move it according to user intention. All these components are introduced in more detail in the following. The implant electronics was developed by the Hamburg University of Technology (TUHH), while energy supply and data transmission were developed by the Fraunhofer Institute for Biomedical Engineering (IBMT).

2.2.1 Implant electronics

The block diagram of the implant electronics is shown in figure 2.4. It was built around a custom designed microchip (MyoC1) [Abu-Saleh et al., 2011], a microcontroller (MSP430, Texas Instruments) and a RF transceiver (ZL70101, Zarlink). All components were connected to a four layer Printed Circuit Board (PCB).

The MyoC1 was manufactured in a 130 nm Complementary Metal Oxide Semiconductor (CMOS) process, had an overall size of 1.525 mm x 1.525 mm and was directly bonded to the PCB. The potential differences present at the contacts of the electrodes entered the implant at the inputs of differential pre-amplifiers, one dedicated for each channel. These pre-amplifiers had input impedances that were much larger compared to those of the electrode-tissue interfaces in order to obtain a large voltage drop on the input of the amplifier [Abu-Saleh et al., 2012]. After amplification the signals passed through a anti-aliasing filter. This filter was realized as a 5^{th} order Bessel low-pass filter whose cut-off frequency was set according to the sampling rate of the Analog-Digital Converter (ADC) [Abu-Saleh et al., 2011]. A multiplexer was subsequently forwarding the different channels to the post-amplifier. This amplifier had a variable gain which was the same for all channels. It could be set to result in an overall gain of x50, x120, x600 or x1200. After amplification the analog signal was passed from the analog to the digital part of the microchip. Here it was digitized by an ADC which had a resolution of up to 10 bit. This ADC was realized as a Successive Approximation Converter (SAR) which had the advantages of low power

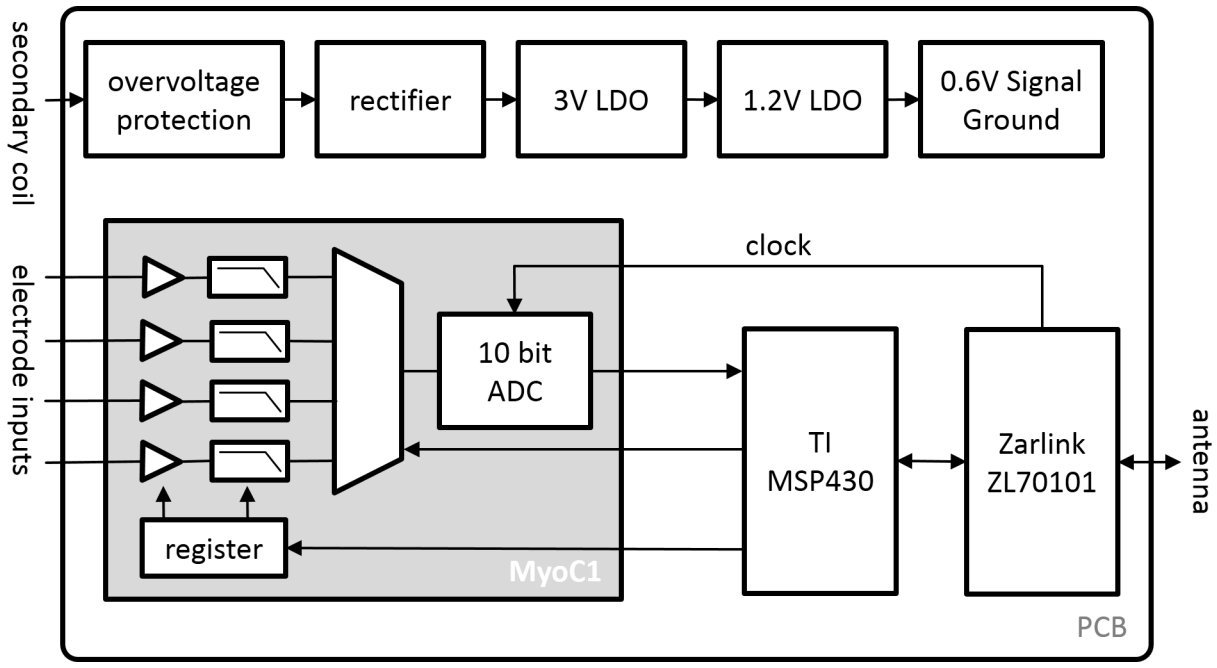


Figure 2.4: Central implant: Schematic presentation of system components of the power supply (top) and signal measurement and transmission (bottom) (adapted from [Abu-Saleh et al., 2010]).

consumption and a low footprint on the die [Abu-Saleh et al., 2012]. The temporal resolution was up to 14.29 kHz. The digitized data was then forwarded over a parallel interface to the micro controller which compiled data packages and forwarded them to the RF transceiver [Abu-Saleh et al., 2010]. The resulting specification of the implant electronics can be found in table 2.1. The parameters of the MyoC1 could be set over the wireless link by changing a configuration register which defined active channels, bandwidth, amplifier gain and resolution of the ADC.

Table 2.1: Properties of the MyoC1 microchip [Abu-Saleh et al., 2010,Abu-Saleh et al., 2011,Abu-Saleh et al., 2012].

property	value
channels	4
bandwidth	6-800 Hz or 6-1500 Hz
input range	±0.5-12 mV
resolution	8 or 10 bit
data rate per channel	1.6-3 kS/s
amplification	x50, x120, x600, x1200
input referred noise	$\leq 2.5\,\mu V_{RMS}$
Crosstalk	−50 dB
Common-Mode Rejection Ratio (CMRR)	≥ 69 dB
power consumption (per channel)	0.5 mW
power consumption (overall)	5.3 mW

2.2.2 Energy supply

Energy was transmitted to the implant by inductive coupling between an extracorporeal primary coil, which was realized as a four-layer PCB coil, and a coaxially aligned secondary coil that was hand wound around the PCB of the central implant [Cardona et al., 2011a]. On the primary side a class D amplifier generated a magnetic field with a frequency of 125 kHz which generated an alternating current in the secondary coil by magnetic coupling. The resulting voltage was passed through an overvoltage protection and then rectified. A first Low-DropOut regulator (LDO) was used to generate a voltage of 3 V for the digital part of the MyoC1 and the following LDO generated the core voltage of 1.2 V for the MyoC1. These voltages had a fluctuation below 1 mV to avoid changes in the amplifier gain [Abu-Saleh et al., 2012]. The reference voltage of 0.6 V was generated by an operational amplifier [Abu-Saleh et al., 2010]. The inductive coupling was optimized for a distance of 3 cm between primary and secondary coil and achieved an efficiency of 64% [Cardona et al., 2011b].

2.2.3 Data transmission

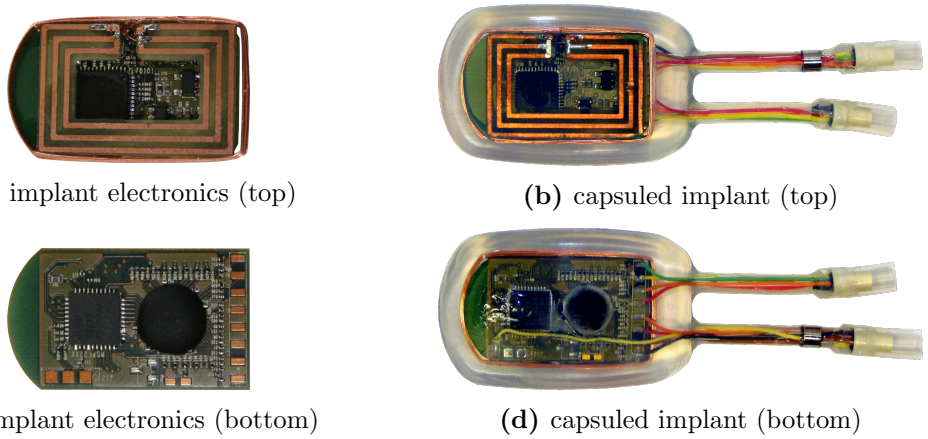
Bidirectional wireless data transmission from the RF chip on the implant to an external base station (BSM100, Rev. E, Zarlink) used the Medical Implant Communication Service (MICS) band (402-405 MHz) which is defined by the Federal Communications Commission (FCC) and the European Telecommunications Standards Institute (ETSI). For this communication the binary Frequency Shift Keying (2FSK) modulation was applied which was able to achieve a net data rate of 134 kbit s^{-1} and provides an effective data rate of 114.3 kbit s^{-1}. The measured latency of this connection was 23±7 ms [Abu-Saleh et al., 2010]. The data rate allowed for transmission of 10 channels of EMG with a resolution of 10 bit [Cardona et al., 2011b].

2.2.4 Packaging

All components of the measurement system but the electrodes are housed in a central implant which is shown in figure 2.5. For encapsulation the circuit board populated with all components was cleaned and subsequently coated with a silicone primer (MED-160, Nusil). Afterwards it was placed in a molding form and injection molded into a 2 mm thick silicone (MED-4244, Nusil) encapsulation. Electrodes were connected to the central implant by two multi-polar connectors (NCP-06, Omnetics Connector Corporation), shown in figure 2.6, each contacting two electrodes. For intraoperative sealing a silicone tube was attached around the implant side of the connector (see figure 2.5b). When the electrode side of the connector was plugged into the implant side, it was also inserted into this silicone tube. After proper contact was verified, the entire connection was sealed by injecting silicone adhesive (Silastic Medical Adhesive Silicone, Type A, Dow Corning) into the tube. A ground electrode was realized by a metal ring around the cables running between PCB and connectors. Prior to implantation all components were sterilized in an ethylene oxide process at 38 °C.

2.2.5 Electrodes

Two types of electrodes were applied in this study to establish electrical contact to the muscle tissue. Both designs were flexible and thin to meet the requirements for subepimysial implantation (described below). The first design was based on polyimide and was provided by Fraunhofer IBMT. The second design was based on silicone and was developed by the author during the present work. Both types of electrodes are presented in the following.



(a) implant electronics (top)

(b) capsuled implant (top)

(c) implant electronics (bottom)

(d) capsuled implant (bottom)

Figure 2.5: Implant electronics (left) and capsuled implant (right) from both sides [Abu-Saleh et al., 2010]. The energy coil, wound around the PCB, and the RF antenna, placed on top of the PCB, are located at the top side of the implant, which is oriented towards the skin, when implanted.

Polyimide electrodes

The technology of using polyimide for implantable electrodes originates from thin-film Longitudinal Intra-Fascicular Electrodes (tfLIFE) [Yoshida et al., 2000b]. tfLIFEs are one subtype of Longitudinal Intra-Fascicular Electrodes (LIFE) which is based on polyimide thin-film technology. LIFEs are multi-site electrodes that were developed for intrafascicular implantation into peripheral nerves. They were initially developed to reduce stimulus intensity and increase selectivity in Functional Electrical Stimulation (FES) [Navarro et al., 2005]. When applied for recording of neural activity they yielded higher amplitudes of compound action potentials compared to electrodes outside of the nerve [Yoshida et al., 2000a]. Rossini et al. [Rossini et al., 2010] implanted four tfLIFE electrodes in the nerve stumps of an amputee and were able to reliably record ENG for 4 weeks and preformed sensory stimulation which efficiency decayed after 10 days. Farina et al. [Farina et al., 2007] demonstrated that tfLIFEs are also applicable for detection of MUAPs when acutely implanted into a muscle.

For the present study this concept was adapted to measure the EMG of skeletal muscles in longterm applications. Placement was changed from penetration of the nerve tissue to placement on the superficial fibers of the muscle of interest. The surface area of the contacts was increased to achieve lower impedance and the physical dimensions of the carrier were also increased to improve the mechanical stability of electrodes when in contact with the mechanically active muscle tissue.

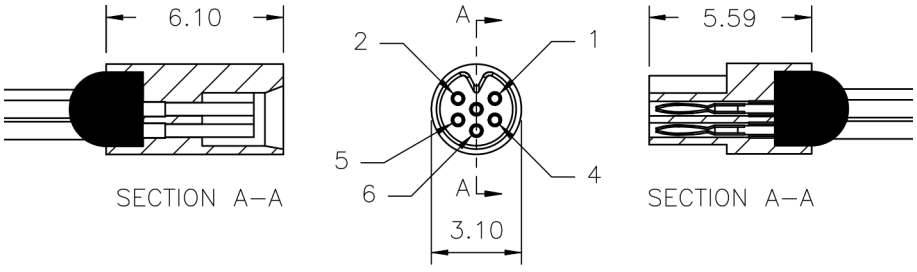
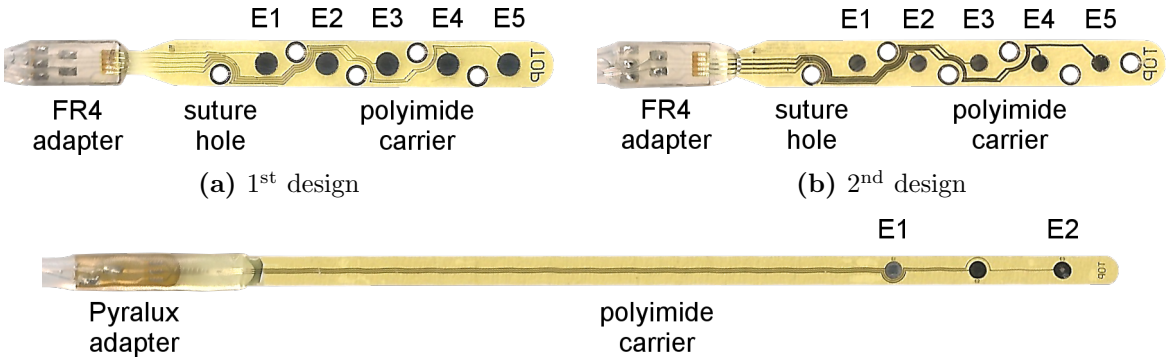


Figure 2.6: Schematic presentation of the female (left) and male (right) sides of the NCP-06 connector (all measures in mm).



(a) 1st design **(b)** 2nd design

(c) 3rd design

Figure 2.7: Polyimide electrodes: three different designs that evolved from each other (x2 magnification).

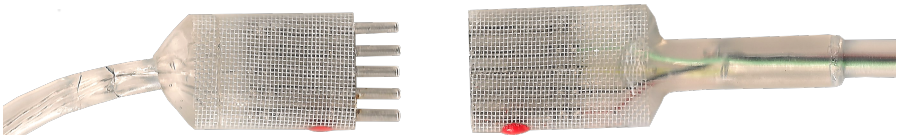
Pyralin (PI 2611, HD Microsystems) was the polyimide used for the electrode carrier. This choice was based on several beneficial properties of this material. It was proven to be nontoxic [Akin et al., 1994, Stieglitz et al., 2000] and demonstrated biostability for periods of up to 12 months of implantation as material of neural sieve [Navarro et al., 1998] and cuff [Rodriguez et al., 2000] electrodes. Compared to silicone it has a similar insulation resistance at lower density and a higher flexibility. An additional major advantage of the material is that it can be processed with standard cleanroom equipment for microelectronics [Stieglitz et al., 2000]. Microstructuring of polyimide by photolithography allows production of thin foils with feature sizes of down to 2 µm to 3 µm. In the polyimide foil, electrode contacts and tracks made of platinum or gold can be integrated [Ruff et al., 2010]. Moreover, to decrease electrode impedance due to small contact surfaces, the electrochemical properties of the electrodes can be optimized by coating with materials such as microporous platinum [Poppendieck et al., 2008].

Three designs of electrodes with polyimide carrier combined with platinum contacts and tracks, used during the investigations, are presented in figure 2.7. The specifications of these different designs can be found in table 2.2.

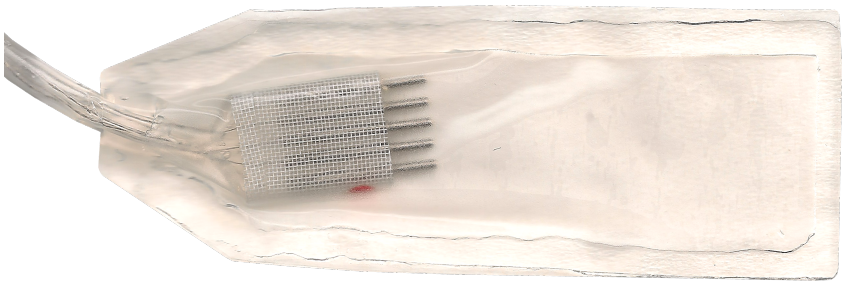
1st polyimide design. Polyimide electrodes of the first design, shown in figure 2.7a, were the initial adaptation of the tfLIFE electrodes and provided by Fraunhofer IBMT. They were based

Table 2.2: Comparison of parameters between the three different polyimide electrode designs.

component	property	1st design	2nd design	3rd design
electrode carrier	thickness	20 µm	30 µm	50 µm
	width	3-5 mm	3 mm	2 mm
	length	30 mm	30 mm	60 mm
electrode contacts	no. contacts	5	5	2 (+1)
	contact area	1-5 mm^2	2 mm^2	2 mm^2
	contact surface	smooth	smooth/ microporous	microporous
adapter	material	ceramic (FR4)	ceramic (FR4)	polyimide (Pyralux)



(a) Male (left) and female (right) parts of the Craggs connector



(b) Craggs connector with silicone bag used for intraoperative sealing

Figure 2.8: Craggs connector developed for acute connection of measurement equipment to the implanted electrodes (x2 magnification).

on a 20 µm thick polyimide carrier which was, depending on size of the contacts, 3 mm or 5 mm wide and 60 mm long. At the side, where it was attached to the cable, it had a tail with a width of only 1.5 mm. It was carrying five platinum contacts (E1-E5) which had a smooth surface with an area of 1 mm^2, 2 mm^2 or 5 mm^2. The center to center distance between neighboring contacts was 4 mm. Five suture holes were provided for fixation along both long edges of the electrode. These holes were metalized at their edges with a 300 µm wide platinum track. The tip was carrying the writing *TOP* which could be read by the surgeon, if the electrode was placed with its contact surfaces towards the muscle. This was necessary, since it was hard to judge the orientation otherwise. The connection between cables and polyimide carrier was realized using a ceramic (FR-4) adapter plate. It was 6 mm long, 2.5 mm wide, 0.3 mm thick and carried 100 µm wide copper-gold tracks. The polyimide carrier was connected to one end of the ceramics by MicroFlex Interconnection (MicroFlex) bonds [Stieglitz et al., 2000] and stainless steel cables (AS631, Cooner Wire Company) were laser welded onto the other end. The cables had a length of 20 mm and were placed in a silicone tube (Silastic Rx-50, d_i =1.02 mm, d_o =2.16 mm, Dow Corning). This tube ended 0.5 mm past the end of the ceramic carrier, at which the polyimide carrier was attached, and was sealed with silicone there.

For connection of electrodes to measurement equipment, five-polar Craggs connectors (figure 2.8a) [Donaldson, 1985] were attached at the end of the cables. On the one side they consisted of five 10 mm long stainless steel bolts with an outer diameter of 0.6 mm, on the other side of five 7 mm long stainless steel pipes. The five contacts on both sides were molded into silicone. When plugged-in the entire connector was 22 mm long, 7.7 mm wide and had a thickness of 1.9 mm. Like shown in figure 2.8b, connectors at the side of the electrode were surrounded by bags of thin silicone foil. These bags were cut open at their ends to allow access to the connector during implantation. The remaining length of the bag allowed for intraoperative sealing with silicone adhesive (Silastic Medical Adhesive Silicone, Type A, Dow Corning) for two subsequent measurements to allow storing the connectors implanted in the animal between measurements.

2nd polyimide design. The second design of the polyimide electrode introduced some changes compared to its predecessor. The thickness of the polyimide carrier was increased from 20 µm to

30 µm. An additional suture hole was provided at its tip to achieve better fixation over the whole length of the electrode. The electrodes still had five contact surfaces but they had an uniform surface area of 2 mm^2. The second design also introduced coating with microporous platinum [Poppendieck et al., 2008] as an optional treatment of the contact surfaces. This was applied to reduce the impedance of the electrical interface between electrode and surrounding tissue by increasing the effective surface area of contacts. To unify the access resistance introduced by the tracks on the polyimide carrier, their width was adapted according to their length. The width of short tracks was decreased while the width of long tracks was increased to achieve a resistance of 150 Ω for all contacts.

The length of the electrode cables was increased to 300 mm. A thinner silicone tube (Silastic Rx-50, d_i =0.64 mm, d_o =1.19 mm, Dow Corning) was used which extended further past the ceramic carrier, covering the narrow tail at the beginning of the polyimide carrier over 2.5 mm, to increase the mechanical stability in that region. It got gradually thinner to achieve a gradual transition from the stiff ceramic plate to the highly flexible polyimide carrier.

Figure 2.6 shows the new type of multipolar connector (NCP-06, Omnetics Connector Corporation) that was attached to the end of the cables. This connector was sealed with a removable silicone capsule to keep it clean when being subcutaneously tunneled during implantations. This capsule consisted of a silicone tube (Silastic Rx-50, d_i =1.98 mm, d_o =3.18 mm, Dow Corning) which was sealed with silicone at both ends. Additionally this capsule was color coded with colored silicone to allow correct assignment of connectors to the corresponding electrodes after tunneling of cables.

3rd polyimide design. The third design of the polyimide electrodes, shown in figure 2.7c, introduced further changes to the previous designs to increase mechanical durability of electrodes once implanted. The main idea was to transfer the transition between cable and polyimide carrier, in which the largest changes in mechanical properties occurred, to a mechanically less demanding region of the muscle. To achieve this the polyimide carrier was extended to a length of 60 mm. By this it could span the distance between the contacts positioned at the belly of the muscle, where the highest signal amplitudes could be measured, and the tendon of the muscle, where the least mechanical stress was expected. To improve the mechanical durability of the polyimide carrier its thickness was further increased to 50 µm and the width of the platinum tracks was broadened to 250 µm, which also reduced their resistance to compensate for their increased length.

To further improve the mechanical properties of the transition between cable and polyimide carrier the stiff ceramic plate was replaced with a more flexible polyimide plate (Pyralux, DuPond). This plate was 100 µm thick, 7 mm long and had the same width of 2 mm as the polyimide carrier. The edge towards the polyimide carrier was formed as a semicircle to prevent introduction of high strains at the edges of the polyimide carrier by the edges of the adapter plate when the electrode is twisted around its long axis. Conductive tracks on the Pyralux plate were copper-gold. Their cross section was 150 µm wide and had a height of 35 µm. Compared to the second design the tube extended even further beyond the adapter plate to mechanically shield the polyimide carrier over a region of 5 mm.

There were two versions of the polyimide electrodes of the third design, which solely differed in the fixation technique. The first version, shown in figure 2.7c, had no suture holes to avoid damage of the electrodes due to tension in the polyimide carrier. The only fixation was a suture around the Pyralux plate to prevent electrode movement due to stains in the cable. The rest of the positioning should be provided by the surrounding tissue. The second version of the electrode integrated only one suture hole at its tip. This was integrated to prevent retraction

and folding of the electrode carrier.

The number of contacts was reduced in the third design. The electrode had two contacts for bipolar measurements which had a inter contact distance of 10 mm and one contact between them which was initially provided as ground but not used in the actual system. All contacts had a surface area of 2 mm^2 and were coated with microporous platinum. The reduced number of tracks used to connect the contacts allowed for reduction of the width of the carrier to 2 mm.

The electrode cables of the bipolar electrodes were consisting of two wires only and their length was reduced to 250 mm. The connector stayed the same as in the second design but two electrodes were connected to each connector. The sealing of the connectors for subcutaneous tunneling of the electrode cables was adapted by using a thinner silicone tube (Silastic Rx-50, d_i =0.76 mm, d_o =1.65 mm, Dow Corning).

Implantation procedure for polyimide electrodes. The term *subepimysial* denotes the location of electrodes after implantation, which is just underneath (*sub*) the fascia (*epimysium*) of the muscle. When implanted that way the contacts of the electrodes lay directly on the superficial fibers of the muscle which are generating the EMG signal to be measured. The surgical procedure of subepimysial implantation of electrodes was initially developed by Dr. Thomas Meiners (Werner Wicker Klinik, Bad Wildungen, Germany) and Dr. Alexander Gail (German Primate Center, Göttingen, Germany). A surgical incision was made in the skin directly overlaying the part of the muscle into which the electrode should be implanted. The skin was retracted to expose the belly of the muscle in a region slightly longer than the electrode.

At one end of the desired electrode position an incision was made in the epimysium. This incision was at least as wide as the width of the electrode and ran perpendicular to the muscle fiber orientation. At the other end of the desired electrode position, one electrode length along the fiber direction, a second incision was made having the same size and orientation. Subsequently a tunnel was formed from the distal incision to the proximal one by blunt separation of the epimysium and the muscle with a pair of tweezers. Once the tweezers came out at the proximal incision the electrode was grabbed with the tweezers and drawn into the tunnel between muscle and epimysium by pulling back the tweezers. After correct placement, the electrode was fixed in position by suturing it to the epimysium and the underlying muscle. Where these sutures were placed and how many were made depended on the different designs of the polyimide electrode described above and is described in the following for each electrode implanted.

This procedure results in an electrode that lies on the superficial fibers of the muscle parallel to the fiber direction. This orientation provides the best measurement of the activity of the motor units in the surrounding of the electrode contacts [Basmajian and De Luca, 1985, De Luca, 2006]. Placing the electrode in the tunnel below the epimysium is providing primary stability by preventing allocation and lift-offs of the electrode. Besides, the epimysium itself provides electrical insulation which damps external signals and thereby, for example reduces the crosstalk originating from other muscles.

Silicone electrode

Based on the experience gained during implantation of polyimide electrodes (section 3.2.2), the author developed an alternative electrode concept to provide a more durable electrical interface to the muscle. Even though these electrodes are results of the presented work which were published in [Lewis et al., 2013a] (see Pub.4 on page 110), they are introduced as materials, since they were applied to achieve further results of this work.

A schematic representation of the developed silicone electrode is shown in figure 2.9. Based on the good *in vivo* long term stability of epimysial electrodes used for FES [Kilgore et al., 2003] and

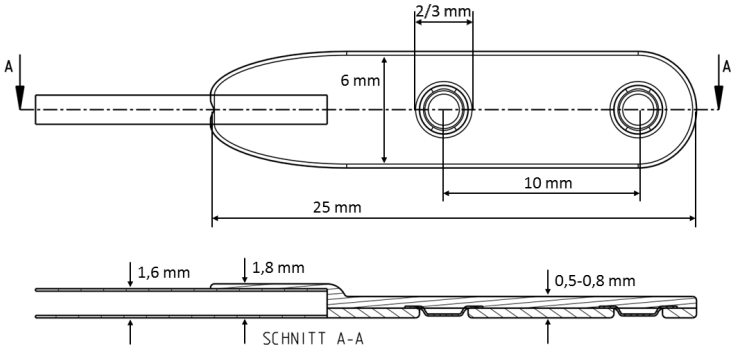
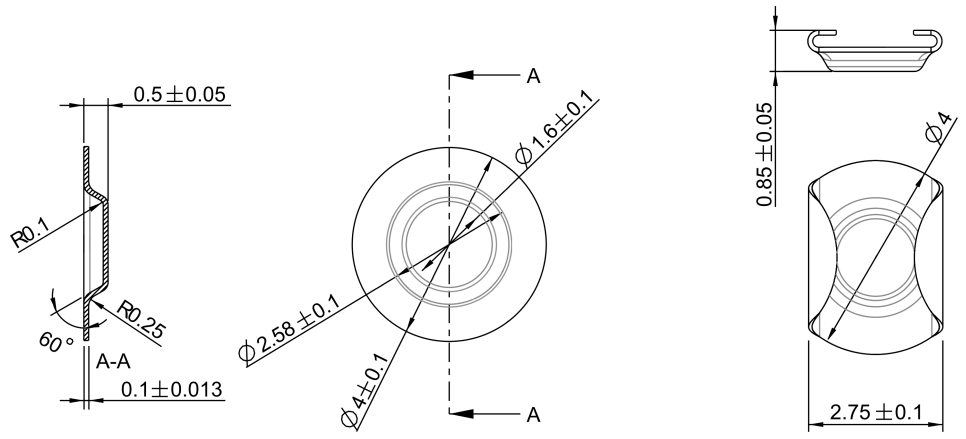


Figure 2.9: Schematic drawing of the developed silicone electrode for subepimysial implantation. A silicone carrier reinforced with PTFE mesh provides the mechanical basis for positioning two metal contacts on the muscle.

EMG recording [Muñoz et al., 2002], silicone was used as carrier material. Besides silicone was chosen for its known biocompatibility and mechanical durability [Donaldson, 1991, Donaldson and Aylett, 1995, Donaldson, 1995, Donaldson, 1997]. To increase the mechanical stiffness of the silicone carrier it was built from Polytetrafluoroethylene (PTFE) reinforced silicone sheets. This provided a better mechanical shielding of the leads and welding points in the electrode. The PTFE mesh also allowed fixation of electrodes at the muscle with sutures, if desired by the surgeon. Platinum-iridium contacts were also used because of their biocompatibility and mechanical durability [Kilgore et al., 2003]. Besides, platinum-iridium was reported to have advantageous impedance properties compared to stainless steel contacts [Ragheb and Geddes, 1991]. Coiled cables were used to connect to the electrodes. This allowed for a stretchability of the cables which was especially important when cables were rooted over joints. The coiled structure also reduced local stress in the leads due to bending of the cable.

Production process. In a first step the single stranded, PTFE isolated cables (MP35N, Heraeus) were coiled, leaving straight ends to run inside the silicone carrier and being welded to the contact discs. The coiled cable was then tubed in a silicone tube (Silastic Rx 50, $d_i = 0.76\,\text{mm}$, $d_o = 1.65\,\text{mm}$, Dow Corning).



(a) disc before bending **(b)** bend disc

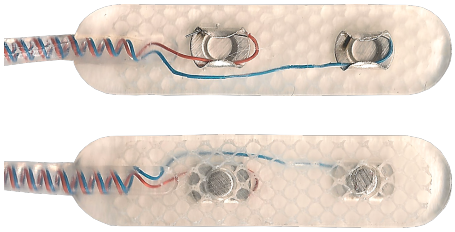
Figure 2.10: Schematic drawing of platinum-iridium contact discs used for electrode production.

The contact discs (see figure 2.10) were made from initially flat platinum-iridium discs with a diameter of 4 mm and a thickness of 0.1 mm. From these discs a central dome was deep-drawn which had a height of 0.5 mm and a flat surface with a diameter of 1.6 mm at its top. In a subsequent step, two opposing flaps were bent from the rim of the discs. These flaps had two distinct functions. Since the applied silicone components did not adhere to the platinum-iridium discs, on the one hand they should provide a better form fit of the contacts discs in the silicone carrier. On the other hand, they provided mechanical shielding of the welding point at which the cables were laser welded to the contact discs. To achieve this the cable follows a course like shown in figure 2.11a (top). It is run below one flap and laser welded to the disc where it sticks out at the other side. Then the free end of the cable is bent to form a 180° turn underneath the contact disc and run below the second flap in the opposite direction. By this, there was no tension or bending transmitted from the cable which can act on the welding point. The cable with the attached contact discs was used for both of the two silicone electrode designs introduced in the following.

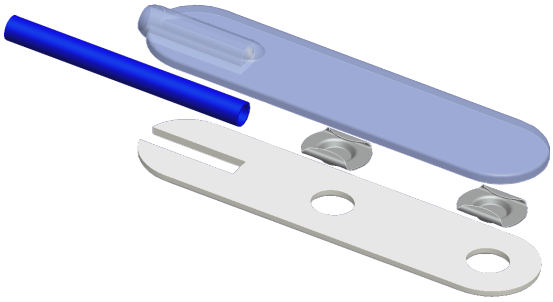
1st silicone design. The first design of silicone electrodes was based on a PTFE reinforced silicone sheet which had a thickness of 0.5 mm and was cut to be slightly smaller than the final electrode. A space for the cable and holes for the contact discs with a diameter of 2 mm and a center to center distance of 10 mm were cut using a biopsy punch (figure 2.11b). Contact discs which were already welded to the tubed cables were placed in these holes and were attached with silicone (MED-1132, Nusil). Then the entire assembly was placed in an injection molding form shown in figure 2.11c. This form was placed in a vacuum chamber where the applied vacuum was drawing the silicone (MED-4011, Part A + Part B (1:10), Nusil) into the form. By this a 0.6 mm layer of silicone was molded onto the back of the silicone sheet and filled the edges around it. The resulting electrode is shown in figure 2.11a.

2nd silicone design. The aim of the second design (see figure 2.12a) was to reduce the thickness of the electrode carrier. To achieve this the carrier was built from two layers of PTFE reinforced silicone sheets (NA 501-1, Nagor) having a thickness of only 0.175 mm. Two rectangular patches slightly larger than the dimension of the resulting electrode were cut. One of them was used as the base layer for the assembly of all components. Like for the first design, two holes with a diameter of 2 mm each were cut from this sheet with a biopsy punch. These holes were used for positioning the contact discs which were fixed in position by silicone (MED-1132, Nusil). The silicone tube of the cable and the wires themselves were positioned in the same way. When all components were properly positioned, the whole upper side of the assembly was covered with a layer of silicone (MED-1132, Nusil) and the second reinforced silicone sheet was stuck on top of it. After curing of the silicone the electrode was cut to its final shape. Fibers of the PTFE mesh that were sticking out of the cutting edge were covered with silicone by dip coating in a mixture of silicone (MED-1137, Nusil) and Heptane. After dip coating the electrode surfaces were cut free using the same biopsy punch applied for initial cutting of the holes. This process resulted in a thinner electrode (type A) which had a thickness between 0.5 mm in the region between the contacts and 1 mm at the contact discs. The Fraunhofer IBMT reproduced silicone electrodes with this design (type B, figure 2.12b) but chose thicker silicone sheets, resulting in a thickness of 0.9 mm to 1.1 mm, and stainless steel disks with a surface area of 7.1 mm^2 as contacts.

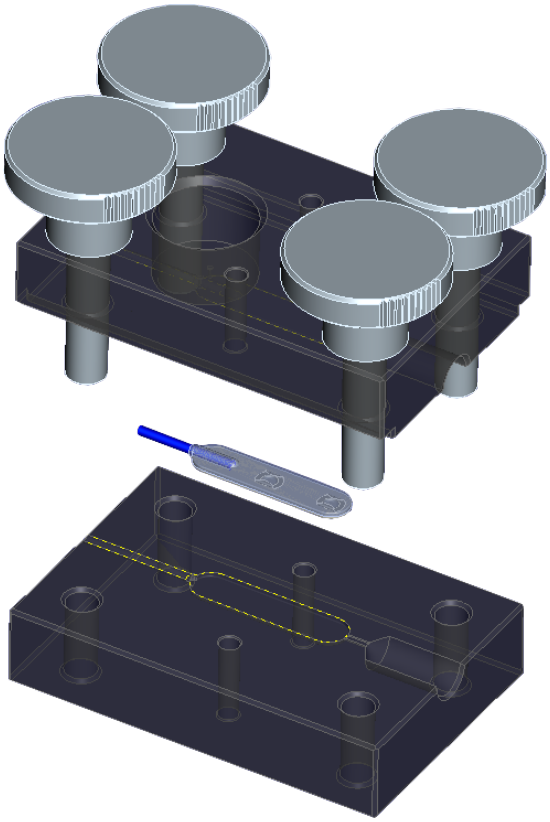
For the implantation electrode cables were sealed with silicone adhesive injected into their ends at a length of approximately 5 mm. For trials with measurements during implantation and explantation only, one such seal was made at the end of the silicone tube, letting the two stripped wires stick out. After these ends were used for measurements during implantation the



(a) silicone electrode of the first design, back (top) and front (bottom) of the electrode (x2 magnification)



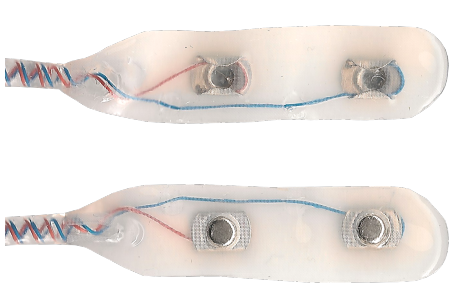
(b) arrangement of the components (cables not shown)



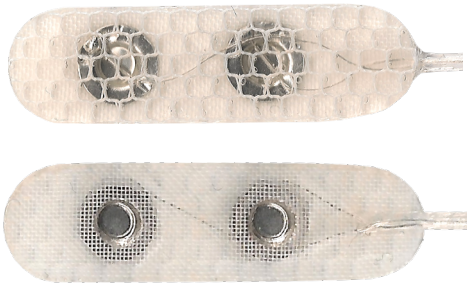
(c) molding tool with finished electrode

Figure 2.11: Silicone electrode of the first design.

cable was cut in the region of the silicone seal and stored in the animal. For measurements during explantation the entire silicone filling was cut off and the coiled cables were drawn out of the tube and stripped to access the electrodes again. For implantations during which more subsequent measurements were carried out, several of these silicone seals separated by regions without silicone filling were placed one after another.

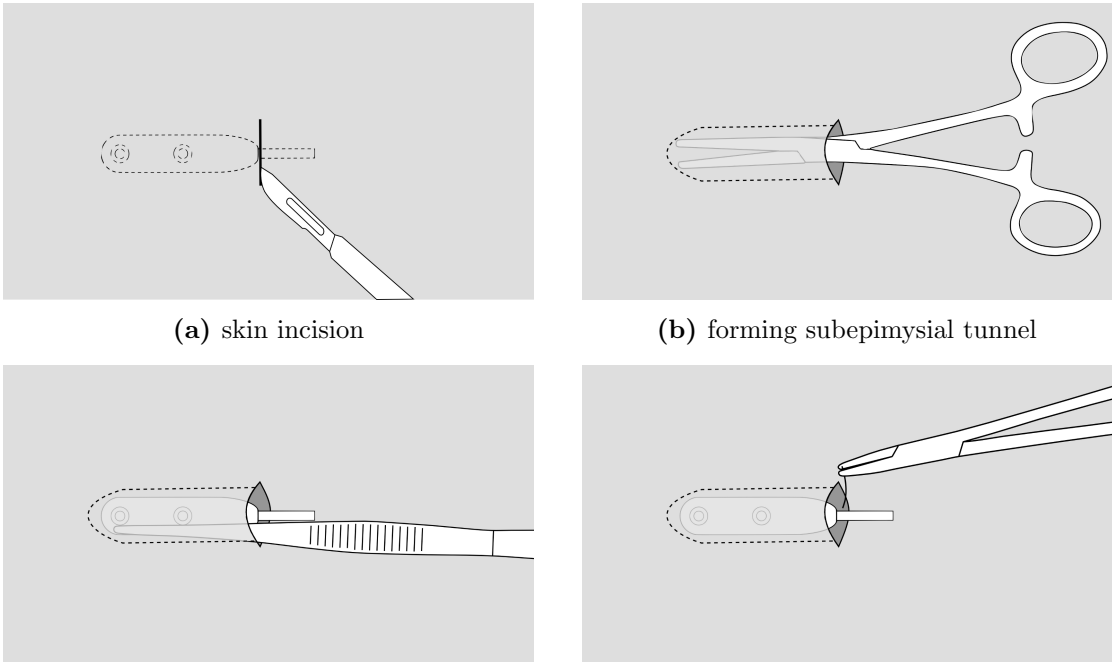


(a) type A



(b) type B

Figure 2.12: Second design of the silicone electrodes. Pictures of the back (top) and the front (bottom) of type A (a) and type B (b) electrode (x2 magnification).



(a) skin incision

(b) forming subepimysial tunnel

(c) insertion of electrode

(d) closing epimysium and fixation of electrode

Figure 2.13: Implantation procedure for subepimysial placement and fixation of the developed silicone electrode.

Implantation procedure for silicone electrodes. The implantation procedure was developed by the author and was published in [Lewis et al., 2013a] (see Pub.4 on page 110). It is an adaptation of the procedure for implantation of polyimide electrodes and was meant to achieve a reliable positioning of silicone electrodes while introducing as little trauma as possible. Just like the polyimide electrodes, also the silicone electrodes were designed for *subepimysial* implantation. During implantation the epimysium was separated from the underlying muscle and electrodes were placed underneath it on top of the superficial muscle fibers. The steps of the implantation procedure are shown in figure 2.13. An incision was made at the intended position of the electrode where the cable leads into the carrier (figure 2.13a). This incision was only slightly wider than the electrode and was extended past the epimysium down to the superficial muscle fibers. An arterial clamp was used to form a pocket by blunt separation of epimysium and muscle (figure 2.13b). It started at the incision and continued in the direction of the muscle fibers until it had the size of the electrode. The electrode was then inserted into the pocket with a pair of forceps (figure 2.13c). For primary fixation of the electrode and closing of the incision made in the epimysium, only one suture was made around the cable where it passed into the electrode using an absorbable filament (figure 2.13d). Another suture was used to close the incision in the skin.

2.3 Animal models

Animal trials were carried out to investigate different aspects of the implantable EMG measurement system and establish a basis for later prosthesis control based on the EMG signals measured with the developed system. The different aspects investigated and related methods for their investigation are presented in table 2.3 and the time line of the different animal trials

Table 2.3: Animal trials: Investigated aspects of the implanted EMG measurement system and methods applied for their investigation.

	aspect to be investigated	methods applied
system	functionality and durability of the entire implantable system	implantation of the whole system, performing EMG measurements with the system
	connectors and sealing	implantation
electrodes	implantation procedure	implantation of electrodes following the developed implantation procedure
	contact size and surface structure	*in vivo* impedance measurements of implanted electrodes to verify the findings from *in vitro* measurements
	distance between contacts for bipolar measurements	bipolar measurement of EMG with different distances between contacts
	mechanical stability of electrodes and leads	implantation of electrodes on the mechanically active muscle and rooting of cables across joints
	encapsulation of implanted electrodes	impedance measurements at several instances over time after implantation
signals	compare monopolar with bipolar recordings	analysis of EMG measured in both configurations
	characterization of intramuscular EMG measured with the electrodes	measurement of EMG during voluntary contractions
	establish a basis for prosthesis control	measurement and analysis of EMG originating from voluntary contractions during repeatable, goal directed arm movements

undertaken to achieve these goals is presented in figure 2.14. The figure also includes the development of the different electrode designs, since they were determining the process. Initially the animal experiments aimed at investigation of as many of these aspects as possible in a single animal model. Therefore rhesus macaques were used despite the complexity of the model and the high ethical demands. Since it was not possible to achieve long term stability of polyimide electrodes during the first three experiments in monkeys, rats and sheep were introduced as additional animal models which allowed higher numbers of implantations and faster generation of inputs for further development of electrodes. After electrodes were thoroughly tested for their mechanical stability, the whole measurement system was implanted in sheep to perform EMG measurements that demonstrate the functionality of the whole system.

2.3.1 Primate model

The measurement of EMG of voluntary contractions during repeatable goal directed arm movements posed the highest demands on the animal model and led to the choice of primates. The animal trials were carried out at the German Primate Center (DPZ) at the Leibniz Institute for Primate Research in Göttingen, Germany. Animal care and all experimental procedures of primate experiments were conducted in accordance with German laws governing animal care and

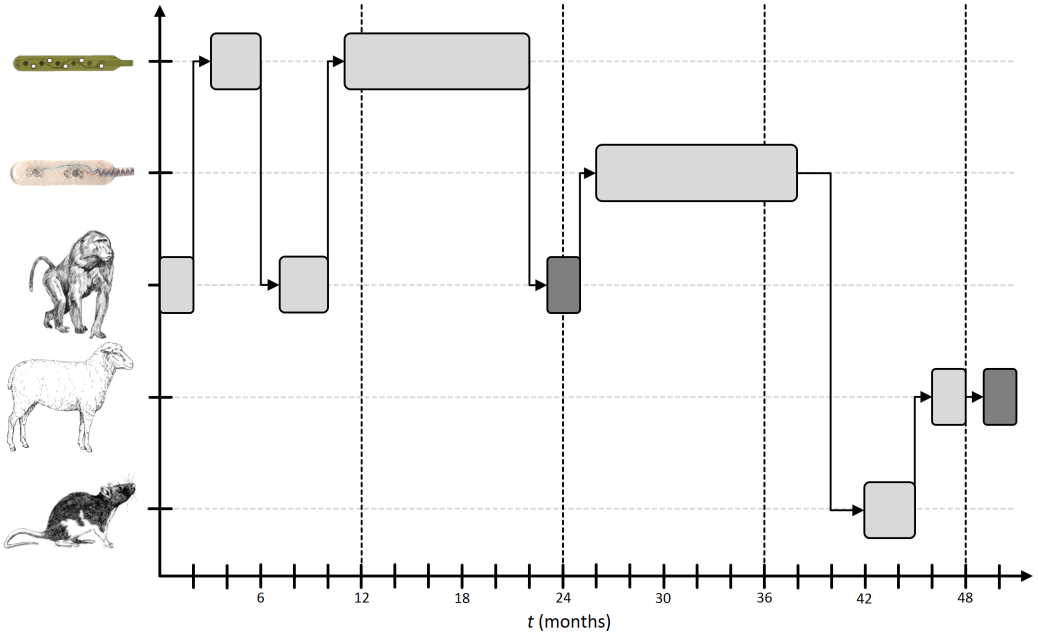


Figure 2.14: Overview over animal trials: The three different animal models (lower three rows) are presented in their chronological order and with connection to electrode development (upper two rows). Animal trials during which which only electrodes were implanted are represented by light gray bars while the dark gray bars denote implantations of the whole measurement system in the third primate and second sheep experiment.

were approved by LAVES (Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit, Oldenburg, reference number: 33.11.42502-064/07).

Reaching task. To be able to measure EMG during repeatable voluntary contractions of muscles, all rhesus macaques underwent behavioral training to perform goal directed reaching movements with their arms. During these experiments, a monkey sat in a primate chair, and a touch screen was placed at a distance of 30 cm frontoparallel to the animal. On this screen the monkey was previously trained to conduct visually instructed reaches in 8 different directions (see figure 2.15). Each trial was initialized by a fixation stimulus (figure 2.15, no. 0) in the center of the touch screen. The monkey had to touch this square and hold it for 500 ms. Then, this stimulus was replaced by a randomly chosen one of 8 possible peripheral target stimuli (figure 2.15, no. 1-8) at 9 cm eccentricity. If the animal hit the target and held it for one second it was rewarded by a few drops of diluted juice [Gail et al., 2009]. While reaching for these circles, the monkey performed repeatable goal directed movements with its arm, thus generating reproducible voluntary contractions of the muscles under investigation. Synchronization between reaching movements and recorded EMG data was realized by a digital trigger sent from the computer controlling the reaching task to the EMG measurement system.

1st primate experiment

Objectives. The first primate experiment aimed at investigating different aspects of the first polyimide electrode design. The feasibility of the implantation procedure for polyimide electrodes was investigated by evaluating the first surgery and any outcomes of the experiments that were related to the way electrodes were implanted. The encapsulation of the electrode over

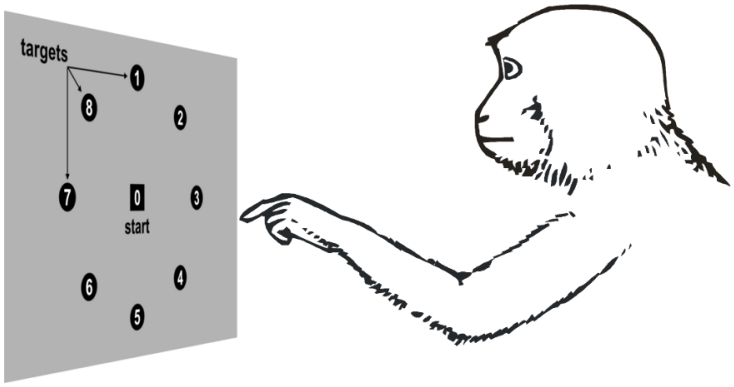


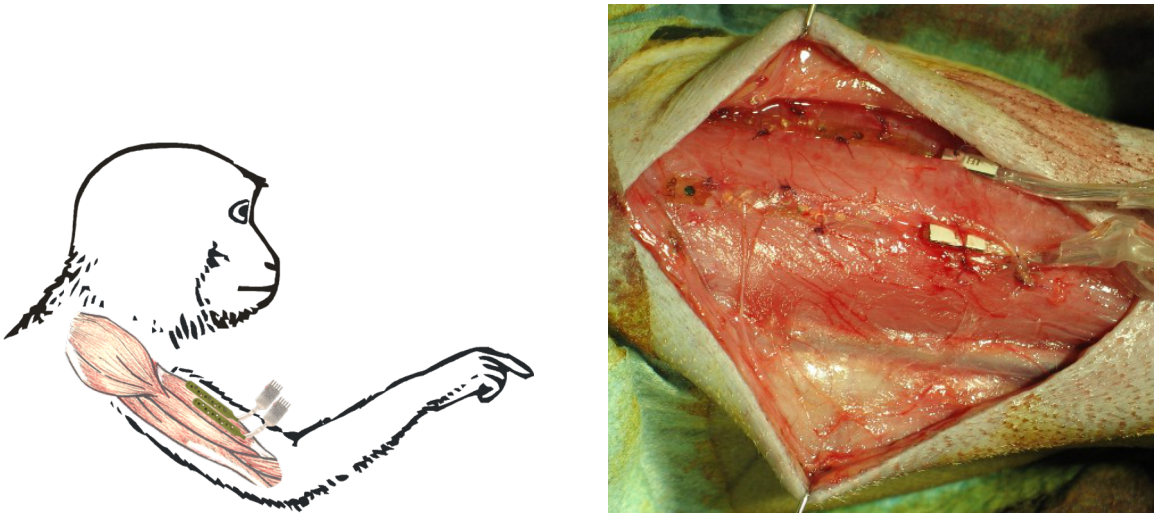
Figure 2.15: Experimental setup of the reaching task: The monkey was sitting in front of a touchscreen that was presenting only one of the nine cues (no. 0–8) at a time. Each trial started with fixation of the center cue (no. 0) and subsequent arm movements were performed in the direction of one of the outer cues (no. 1-8).

time after implantation was monitored by impedance measurements that were carried out during implantation and an intermediate experiment. These impedance values were also used for layout of the input amplifiers of the MyoC1. To perform first measurements of muscle activity, contractions were stimulated during surgery and it was planned to measure EMG of voluntary contractions in an awake monkey to characterize the intramuscular EMG recorded with the implanted electrodes.

Surgical procedure and intraoperative measurements. The experimental animal was a male rhesus macaque with an age of 6 years and a weight of 6 kg. Two electrodes of the first design (figure 2.7a) with smooth contact surfaces and a surface area of 1 mm^2 were subepimysially implanted at the *biceps brachii* of the dominant side of the rhesus macaque (figure 2.16). Both electrodes were placed on the belly of the muscle, one at the medial (*electrode 1*) and one at the lateral (*electrode 2*) side. The tips of both electrodes were pointing towards the shoulder and the cables were leading in the direction of the elbow. *Electrode 1* laid right below the epimysium but its tip sticked out of the tunnel up to the contact E4. In figure 2.16b all structures of the electrode can be seen through the epimysium. For fixation all but the suture hole closest to the cable were used and one suture was made around the ceramic adapter with a non-absorbable filament. During forming the tunnel for *electrode 2*, the epimysium was damaged over the whole length of the electrode. Therefore the electrode was sutured directly on the superficial muscle fibers of the muscle exposed by this defect in the epimysium. All suture holes were used and an additional suture was made around the ceramic adapter. After fixation the carrier was waving between the second and third sutures as well as between the first suture and the ceramic carrier.

For intraoperative impedance measurements the silicone bags around the Cragg connectors (figure 2.8b) were cut open at their end to allow connection of the measurement equipment. Impedance measurements were carried out to check whether the electrodes, cables and connectors were intact. They were also the first measurement for monitoring the impedance over time. After these measurements were completed the silicone bags were sealed again. For this, approximately the distal 5 mm of the bag were separated from the connector using a pair of tweezers. The outer compartment was then filled with silicone adhesive (Silastic Medical Adhesive Silicone, Type A, Dow Corning) to seal the bag. Finally the connectors were stored subcutaneously and the incision was closed.

Four weeks after implantation the monkey underwent a second surgery. During this surgery



(a) schematic of electrode positions in the rhesus macaque

(b) two electrodes implanted on the *biceps brachii* during implantation surgery (*electrode 1* bottom, *electrode 2* top)

Figure 2.16: First primate experiment: Electrode positions (a) and implantation site (b) of polyimide electrodes of the first design.

the Craggs connectors which were stored underneath the skin of the upper arm were exposed. The incision was closed again leaving the short cables between electrodes and connectors leading through the skin to provide access to the connectors during and after surgery. A strain-relief was realized by suturing around the cables where they passed through the skin. The sealed silicone bags around the connectors were cut open at their ends again, leaving enough space for sealing them for a last time after the measurements.

Impedance measurements were repeated to quantify the influence of the encapsulation tissue formed in the first four weeks after implantation on the electrode impedance. Subsequently EMG measurements were carried out during stimulated contractions to ensure that the implanted electrodes were capable of measuring the resulting potentials. Transcutaneous Electrical Nerve Stimulation (TENS) was applied at the axilla of the monkey to stimulate the *brachial plexus* and evoke contractions of the arm muscles including the *biceps brachii*. Stimulation and parallel monitoring of EMG response was carried out using a NeuroScreen Plus (Jaeger Toennies). Stimulation pulses had a constant current of 5 mA for a duration of 200 µs and were applied with a frequency of 1 Hz. Reference and ground were connected via Ag/AgCl surface electrodes at the shoulder and chest, respectively. Resulting potentials were recorded with the EMG measurement system described in section 2.5.

After these measurements the monkey was dressed in a tailored long-sleeve shirt, made from tear-proof fabric, to mechanically protect the connectors and prevent the monkey from noticing them. Then the monkey was allowed to recover from narcosis in his cage.

Postoperative measurements. After recovery from narcosis it was planned to connect the EMG measurement system to the connectors again and measure the EMG during the reaching task described above. These measurements could not be carried out in the first primate experiment due to destruction of electrodes by the primate, described in more detail in section 3.2.1.

2nd primate experiment

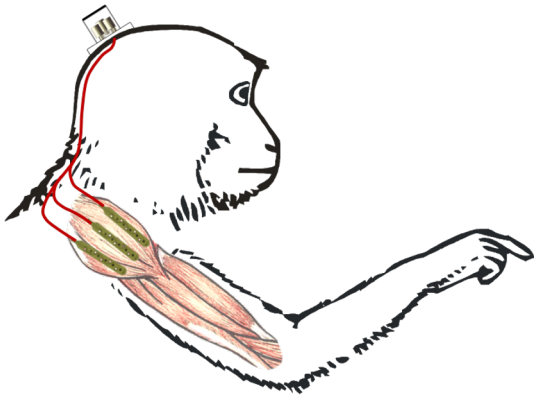
Objectives. The second implantation aimed at monitoring the encapsulation of the electrode over a longer period of time after implantation and with a higher temporal resolution. This aimed at a better estimation of when the process of encapsulation is completed and the electrical parameters of the interface between muscle and electrode can be expected to be stable over time. In addition the influence of different contact surface structures on the electrode impedance was investigated *in vivo*.

Besides investigation of the electrodes the intramuscular EMG measured with the electrodes was analyzed in more detail. For this the EMG measured during repeatable voluntary contractions during the reaching task. The first investigated aspect of the EMG measurement was whether it should be recorded in monopolar configuration, between a monopolar electrode on each target muscle and one reference electrode common to all channels, or bipolar configuration, between two contacts of one bipolar electrode on each target muscle. These measurements were also used for determination of an adequate distance between two contacts for bipolar recording of EMG. The intramuscular EMG was measured during repeatable movements of the monkeys' arm was used to create a basis for establishing a prosthesis control. Analysis of the measured data is described in section 2.5.

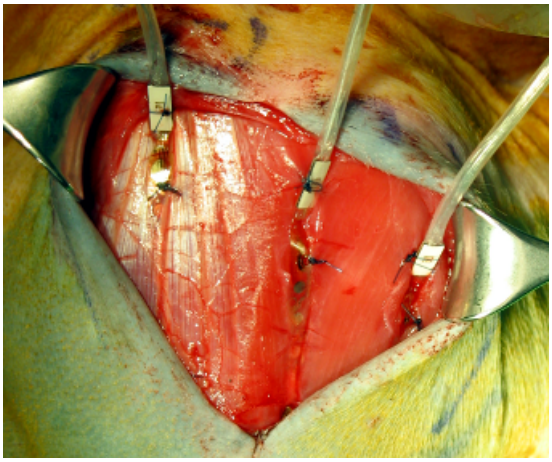
Surgical procedure and intraoperative measurements. In the second primate experiment the surgical procedure was adapted according to the experiences made in the first experiment. This affected the target muscle but in particular the access to the electrodes after implantation.

The experimental animal was the same male rhesus macaque with an age of 6 years and a weight of 6 kg, that was already used in the first primate experiment. Considering the trauma in the region of the *biceps brachii* resulting from the first implantation, during second implantation electrodes were placed at the right *musculus deltoideus* of the monkey (figure 2.17a). Three polyimide electrodes of the second design (figure 2.7b) were implanted subepimysially on the anterior (*electrode 1*), lateral (*electrode 2*), and posterior (*electrode 3*) compartments of *pars acromialis* of the muscle. All electrodes had contacts with a surface area of 2 mm^2. Contacts of *electrode 2* and *electrode 3* had smooth surfaces while those of *electrode 1* had a microporous surface structure. They were oriented along the muscle fibers and had a distance of approximately 2 cm between them. Separation of the fascia from the superficial muscle fibers of the *musculus deltoideus* was more challenging than expected. Figure 2.17b shows that *electrode 3* (left) laid below the superficial muscle fibers in the muscle. *Electrode 2* (middle) was positioned on the superficial muscle fibers but was not covered by the fascia over its whole length, since the fascia was damaged in the process of forming the tunnel. After tunneling, all electrodes were fixed in position by a first suture at the tip, followed by one at the suture hole closest to the ceramic adapter plate and finally one around the adapter plate with a non-absorbable filament. Figure 2.17b also shows that *electrode 2* was not laying flat on the muscle but a wave formed between the middle suture and the ceramic carrier.

To avoid transcutaneous cables, which led to premature termination of the previous experiment (see section 3.2), connectors at the end of the electrode cables were stored in a connector housing (figure 2.18) at the back of the head of the monkey. For this cables were subcutaneously rooted from the shoulder to the back of the monkey and from there along the neck to the back of the monkey's head. The outer housing was attached to the skull by seven bone screws and the connectors were glued to a detachable inner part which positioned them in the housing. Bone cement (Palacos, Hereus) was used to seal the bottom of the housing from body fluids. This housing was opened during each trial to connect the measurement equipment and sealed with a



(a) schematic of electrode positions in the rhesus macaque



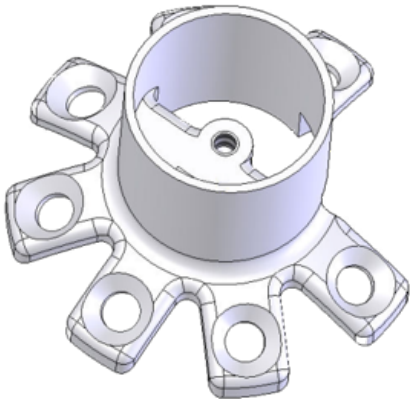
(b) three electrodes implanted at the lateral *musculus deltoideus* during implantation surgery (from left to right: *electrode 3*, *electrode 2* and *electrode 1*)

Figure 2.17: Second primate experiment: Electrode positions (a) and implantation site (b) of polyimide electrodes of the second design.

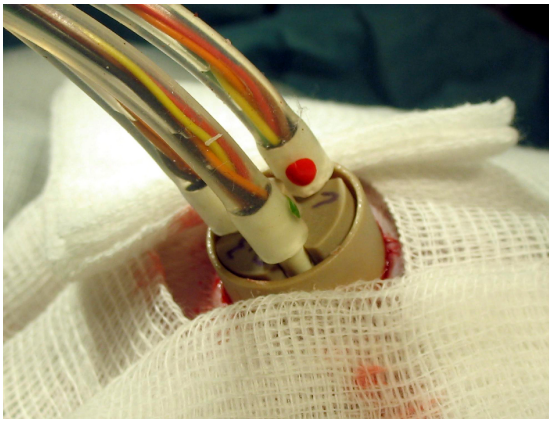
lid for the rest of the time. This resulted in an implant that induces less irritation in the tissue around the electrodes and was less palpable for the rhesus macaque.

At the end of implantation surgery impedance measurements were carried out to ensure the functionality of all electrodes, cables and connectors, especially after the process of tunneling the cables.

Postoperative measurements. To monitor the process of electrode encapsulation, impedance measurements were repeated two, four and eight weeks postoperatively. Impedance was mea-

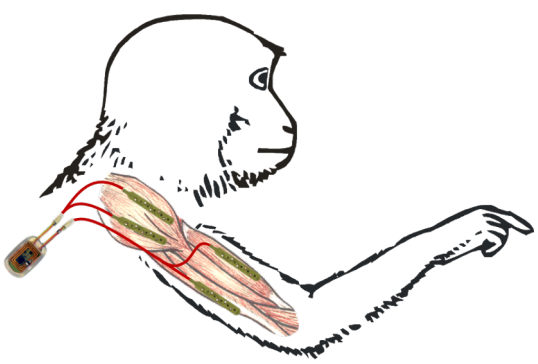


(a) CAD model of the connector housing (lid not shown)

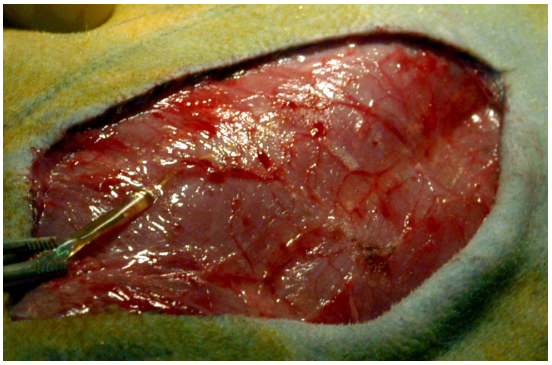


(b) housing with connected cables during implantation surgery

Figure 2.18: Connector housing which was attached to the skull of the monkey during the second primate experiment to store the three NPC-06 connectors that allowed direct access to the three implanted electrodes.



(a) schematic of electrode positions in the rhesus macaque



(b) one electrode implanted on the *triceps brachii* during implantation surgery

Figure 2.19: Third primate experiment: Electrode positions (a) and implantation site (b) of polyimide electrodes of the third design.

sured between all possible combinations of the five contacts of each electrode. Reaching experiments were also performed two, four and eight weeks after implantation. EMG measurements during reaching movements were carried out according to the description in section 2.5.

3rd primate experiment

Objectives. The third monkey experiment was undertaken to demonstrate the functionality of the whole implantable EMG measurement system. Therefore the whole system containing the central implant and four electrodes was implanted. In addition the third experiment aimed at obtaining simultaneous EMG from more than one muscle involved in the reaching movements of the arm.

Surgical procedure and intraoperative measurements. During the third experiment, the complete EMG measurement system was implanted in a second rhesus macaque. It was a male monkey with an age of 8 years and a weight of 8 kg. A total of four polyimide electrodes of the third design (figure 2.7c, but with an additional suture hole for fixation at the tip) were subepimysially implanted on different muscles of the monkey (figure 2.19a).

Electrode 1 and *electrode 2* were implanted at the posterior and lateral compartments of *pars acromialis* of the *musculus deltoideus*, respectively. *Electrode 3* was implanted on the lateral *biceps brachii* and *electrode 4* on the lateral *triceps brachii* of the dominant side of the monkey. After electrodes were inserted in these tunnels they were fixed in position by the one suture hole at their tips. Then a suture was made around the Pyralux adapter plate to position the transition between electrode and cable at the other side. For the electrode on the *triceps brachii* it was possible to place this transition on an mechanically less active region at the tendon of the muscle. On the *biceps brachii* the proximal transition to the tendon was covered by other muscles and was nether easily accessible nor a region where the electrode would have been exposed to less mechanical stress. Therefore the end of the electrode was fixated in the region of the *sulcus deltoideopectoralis*, a groove between *musculus pectoralis major* and *musculus deltoideus*. The electrodes implanted on the *musculus deltoideus* were so long that they spanned the whole muscle and were fixed close to the *acromion*.

The central implant was implanted at the back of the monkey. An incision was made below the shoulder blades and a suitable position was found between the shoulder blades. At this

location muscle tissue was present in which a pocket was formed to position the central implant. It was fixed in position by closing the pocket with two sutures around the two cables of the implant. This muscle tissue also provided mechanically shielding from external forces. Additionally the monkey could not easily reach that location and would be less aware of the implanted foreign body. For reaching tasks this position also provided a good possibility to position the primary coil for energy transmission in the primate chair without constricting the movement of the animal. The coil could be installed close to the implant and there was little relative movement expected between primary and secondary coil. The electrode cables were rooted to the back of the monkey and impedance measurements were carried out to ensure the electrical integrity of electrodes, leads and connectors. Then the connectors were connected to the central implant and sealed with silicone adhesive afterwards. Excessive cable was stored in a subcutaneous pocket near the central implant.

Postoperative measurements. After the monkey recovered from surgery it was regularly attempted to perform EMG measurements during reaching tasks over the whole time of implantation. While the system was implanted no direct connection to the electrodes was available, which is why no impedance measurements were carried out. During explantation the impedance of all four electrodes was measured again to check their functionality.

2.3.2 Rat model

The rat model was established to achieve a larger number of electrode implantations in a less complex animal model. This should speed up the demonstration of mechanical stability of the silicone electrodes or speed up their development by providing more information about possible improvements in less time. Rat experiments were carried out in cooperation with the Christian Doppler Labor for Bionic Reconstruction (Vienna General Hospital) at the Institute of Biomedical Research (Medical University of Vienna). Animal care and all experimental procedures of rat experiments were conducted in accordance with Austrian laws governing animal care and were approved by the BMWF (Bundesministerium für Wissenschaft und Forschung, reference number: BMWF-66.009/0309-II/3b/2010).

Objectives. A rat model was established for the first *in vivo* evaluation of silicone electrodes to investigate three fundamental aspects of these electrodes. The surgical procedure which was adapted to the silicone electrodes was evaluated during its first application in these experiments. It was investigated if the procedure could be carried out like planned, it was able to achieve a secure long term fixation of electrodes and how much trauma was introduced by the surgery. The mechanically stability of silicone electrodes and their coiled cables were investigated for the first time during implantation in a living organism. Electrical function was measured by impedance measurements during implantation and explantation. And finally the rat model allowed for explantation of the tissue surrounding the electrodes what made it possible to closer investigate the effects of implanted electrodes on the surrounding tissue by histological analysis.

Implantation. 24 male Sprague Dawley rats having a weight of approximately 400 g were used for the experiments. Both types of the second design o silicone electrodes, type A and type B (figure 2.12), were implanted in all rats, either of them on one *gluteus superficialis* following the surgical procedure of subepimysial implantation presented in figure 2.13. The first incision was made in the proximal region of the muscle. After the incision was extended down to the superficial muscle fibers the tunnel between epimysium and superficial muscle fibers was formed

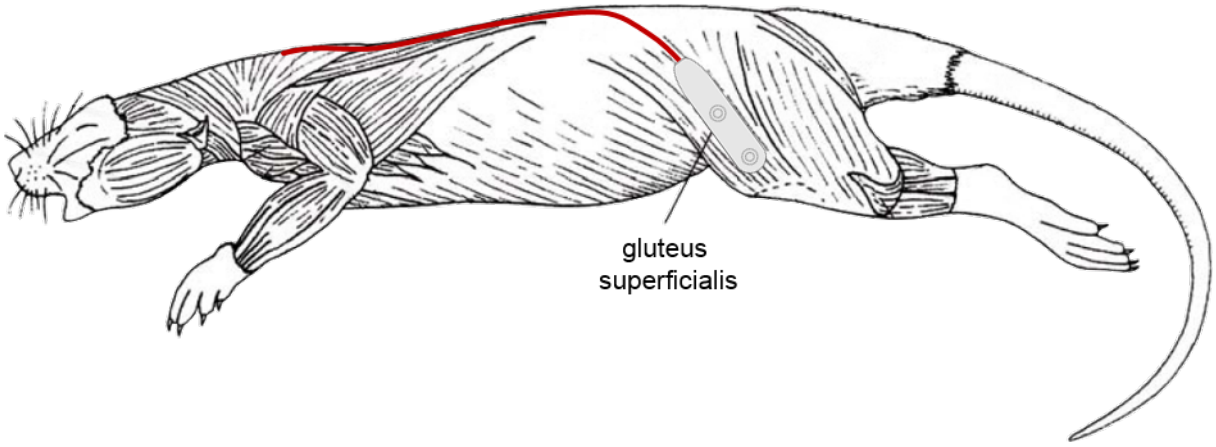


Figure 2.20: Rat experiment: Silicone electrode of the second design implanted on the *gluteus superficialis* muscle and rooting of cables (adapted from [Campbell, 2007]). One silicone electrode of type A and type B was implanted in every rat, each on one side.

along the fiber direction. This resulted in a orientation of the electrode in which the tip of the electrode pointed to the knee and the electrode cables led into the direction of the lower spine. Electrode cables were 130 mm long and were rooted from the electrodes over the hip joint along the spine and ended in the soft tissue at the neck of the animals. Electrodes stayed implanted for eight weeks and twelve weeks in half of the animals, respectively. Proper contact between electrodes and muscle tissue was confirmed by impedance measurements before the cables was tunneled towards the neck of the animal and again at the end of surgery before all incisions were closed.

Explantation. Surgeries for explantation of electrodes were carried out eight or twelve weeks after implantation for half of the animals, respectively. An incision was made at the neck of the animal to expose the ends of the electrode cables. The parts of the cables that were sealed with silicone were cut off and the isolation was stripped from the wires to carry out impedance measurements. Afterwards rats were sacrificed. Then the incision at the neck was extended towards the tail until the entire region in which the cables were running was exposed. The cables were then excised from the connective tissue surrounding them starting from their ends towards the electrodes. The electrode was then extracted from the tissue pocket and the resulting cavity was filled with a silicone dummy having the same geometry as the electrode but contained none of its metal components. This ensured that the geometry of the surrounding tissue was preserved for later investigations and allowed preparation of histologic slices without damaging the microtome with those metal components. Since the electrodes were not damaged in the process of tissue preparation it was possible to visually examine them after explantation. Then the dummies were explanted with all surrounding tissue including the whole *gluteus superficialis*.

Histology. The histological investigation of the tissue surrounding the electrodes was performed at the Christian Doppler Labor for Bionic Reconstruction. The tissue samples were fixated in Bouin solution and afterwards embedded in paraffin. These blocks were then cut in 3 µm thick slices which were oriented perpendicular to the long axis of the electrode. Of these slices a region in the middle of the electrode carrier was analyzed. The tissue was stained in Masson's trichrome stain which was applied for distinguishing the connective tissue from other

cells surrounding the implant. Connective tissue was stained in green while muscle tissue, erythrocytes and cytoplasm appeared in red and cell nuclei became dark brown dots. This stain was used to differentiate the collagen capsule from the other tissue and measure its dimensions. These measurements included the thickness of the capsule at the side of the muscle and the side of the epimysium. By comparison of the tissue samples it was investigated if two electrode designs evoked a different immune repose resulting in differing thickness of the connective tissue capsule. The comparison between the two periods of implantation provided more insight into the process on encapsulation and its transition towards a chronic state.

Visual inspection of explanted electrodes. After electrodes were explanted they were rinsed with physiologic saline and dried for later analysis. A stereo microscope was used to investigate all components of the electrodes. For documentation photos were taken with a digital camera which was attached to one ocular of the microscope. During visual inspection the electrodes were searched for mechanical failures and signs of corrosion of their metal components as well as any remains of body tissue or fluids.

2.3.3 Sheep model

Two experiments were carried out in sheep. The first investigated the mechanical stability of silicone electrodes and cables under higher mechanical stress in a larger animal. The second experiment was carried out to demonstrate the function of the whole implantable measurement system when using mechanically stable electrodes.

Like the rat experiments also sheep experiments were carried out in cooperation with the Christian Doppler Labor for Bionic Reconstruction (Vienna General Hospital). Implantation surgery was carried out at the Institute of Biomedical Research (Medical University of Vienna). Afterwards sheep were transfered to the Lehr- und Forschungsgut Kremesberg (VetMedUni, Vienna) where the intermediate measurements were carried out. Animal care and all experimental procedures of sheep experiments were conducted in accordance with Austrian laws governing animal care and were approved together with the rat experiments by the BMWF (Bundesministerium für Wissenschaft und Forschung, reference number: BMWF-66.009/0309-II/3b/2010).

1st sheep experiment

Objectives. The first sheep experiment aimed at demonstrating the mechanical stability of developed silicone electrodes and cables under higher mechanical stress. Besides, it allowed for evaluation of the developed surgical procedure for their implantation under different physiological conditions in another animal model. The first experiment was also used to identify relevant muscles and a good location for the central implant to prepare for the implantation of the whole measurement system in the second sheep experiment. A follow up measurement should also allow for measurement of EMG when electrode cables were directly accessed.

Implantation. Four electrodes were implanted at one forelimb of two merino sheep. Target muscles were chosen due to their function for the movement of the forelimb, since EMG should be measured during reflexive retraction of the forelimb. For the movement of the whole limb the *musculus brachiocephalicus* was chosen, which is moving the limb forward and the *musculus latissimus dorsi* responsible for moving the limb backward. The second movement was knee flexion and extension which was performed by the *musculus brachialis* and *musculus triceps brachii*, respectively.

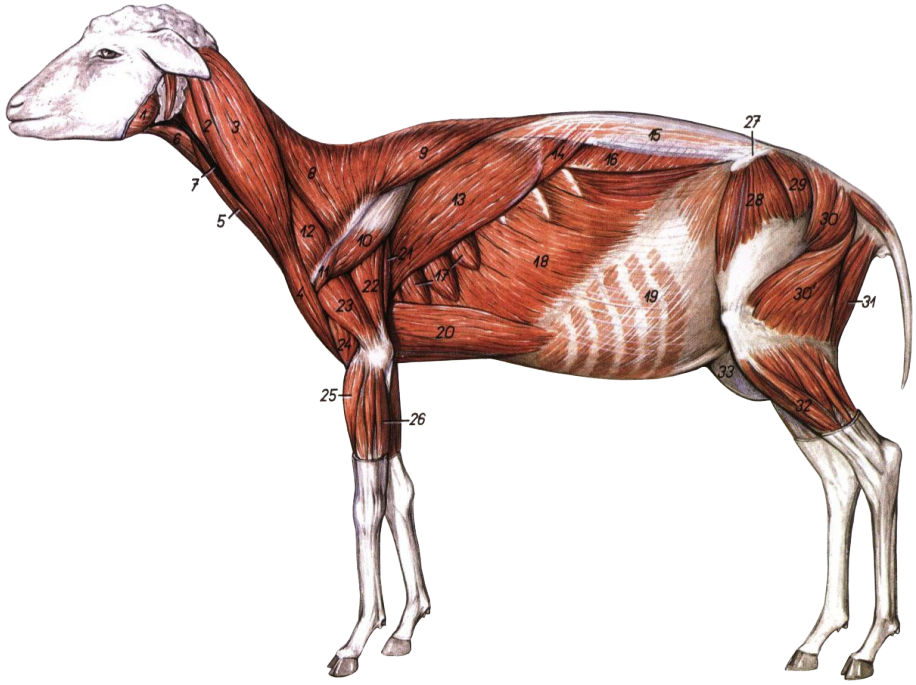


Figure 2.21: Muscles of the sheep shown from the side. Implantation sites of electrodes on *musculus brachiocephalicus* (4), *musculus latissimus dorsi* (13), *musculus triceps brachii* (22), *musculus brachialis* (24). (modified from [Popesko, 2011]).

All electrodes were implanted according to the procedure presented in figure 2.13. The only difference was that an absorbable filament was used. Subcutaneous rooting of cables was performed with a custom designed tunneling tool. It consisted of a 350 mm long stainless steel rod with two exchangeable tips. The first was a cone having a diameter of 8 mm and a rounded tip. It was applied to form the subcutaneous tunnel by blunt separation. The tip was inserted between skin and underlying tissue at the incision where the cables should end and was pushed towards the implanted electrodes. The second tip was a gripper of the same outer diameter, which was attached to the rod while it sticked out at the electrode side of the formed tunnel. Electrode cables were clamped into this tip and inserted into the subcutaneous tunnel by retracting the tool again. At the back of the sheep the cables were bound together with a non-absorbable filament and stored subcutaneously caudal to the shoulder blade.

Postoperative measurements. Twelve weeks after implantation, sheep were anesthetized and the ends of the electrode cables were retrieved during surgery. The first sealed compartment of the silicone tube around the cables were removed and the measurement equipment was connected. Impedance measurements were carried out for each electrode. All electrodes were then connected to the EMG measurement system and it was tried to elicit reproducible contractions of the measured muscles by provoking reflexive retraction of the forelimb.

2nd sheep experiment

Objectives. After investigation of the mechanical stability of silicone electrodes and identification of appropriate locations for their implantation in the first sheep experiment, the second experiment in sheep was carried out to demonstrate the function of the whole measurement system (see page 25). Electrodes that were mechanically improved compared to those used in

the third primate experiment should allow for first measurement of muscle activity with the whole system during walking of sheep.

Implantation. Analog to the first sheep experiment four silicone electrodes were implanted on *musculus brachiocephalicus*, *musculus latissimus dorsi*, *musculus brachialis* and *musculus triceps brachii* of one for limb of two sheep. Proper contact of these electrodes to the muscle was ensured by intraoperative impedance measurements. Electrode cables were then rooted towards the back of the sheep with the tunneling tool. There they were connected to the central implant which was placed caudal of the shoulder blade.

Postoperative measurements. Three weeks after implantation, first EMG measurements with the whole implanted measurement system were carried out. A custom made saddle was used to position electronics and battery for energy supply as well as the base station for data transmission on the back of the sheep. The saddle also allowed for adaptable placement of primary coil and antenna directly above the central implant. Recordings were then carried out to measure the EMG signals of several successive steps during unconstrained movement in a fenced area of approximately two times two meters.

2.4 Impedance measurement and analysis

Impedance measurements were carried out using a custom designed impedance measurement system (section 2.4.1). Impedance was measured *in vitro* (section 2.4.2) for comparison of electrodes with different properties, such as contact size, material and surface structure, and *in vivo* (section 2.4.3) for quantifying the influence of those properties when electrodes were implanted, monitoring of electrode functionality over time of implantation and the process of encapsulation by connective tissue.

2.4.1 Electrode impedance measurement system

A custom designed Electrode Impedance Measurement System (EIMS) [Glindemann, 2009] was used to measure impedance under different conditions. This system was portable to allow impedance measurement during animal trials in different laboratories and during surgery in different operating theaters.

To measure the impedance of the electrode-tissue interface as well as the impedance of the tissue between the contacts, measurements were carried out in a two-electrode setup. An inverting amplifier (figure 2.22) was used as constant current source that generated the current I_Z which was applied between two contacts of one electrode:

$$I_\mathrm{Z} = I_{\mathrm{R_{current}}} = \frac{V_\mathrm{in}}{R_\mathrm{current}}. \tag{2.1}$$

The current I_Z was proportional to the input voltage V_in which was constructed from a linear combination of sinusoids with equal amplitude at 21 measurement frequencies between 1 Hz and 10 kHz (1 Hz, 2 Hz, 4 Hz, 6 Hz, 8 Hz, 10 Hz, 20 Hz, 40 Hz, 55 Hz, 80 Hz, 110 Hz, 200 Hz, 400 Hz, 600 Hz, 800 Hz, 1 kHz, 2 kHz, 4 kHz, 6 kHz, 8 kHz, 10 kHz). This signal was then scaled to cause a measurement current $I_\mathrm{Z} = 1\,\mu\mathrm{A_{RMS}}$ and generated by a data acquisition card (NI USB-6259, National Instruments). The digital-analog conversion had a data rate of 100 kHz and

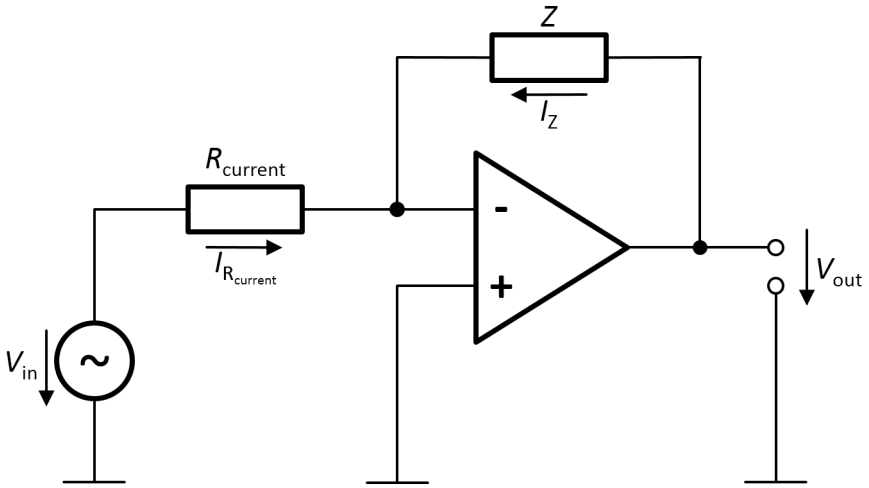


Figure 2.22: Amplifier circuit applied for impedance measurement.

a resolution of 16 bit for ±10 V. The voltage V_{out} generated by the current I_Z between the two electrode contacts is

$$V_{out} = -V_{in}\frac{Z}{R_{current}} \tag{2.2}$$

and was measured with the same data acquisition card in parallel at a sampling rate of 100 kHz and a resolution of 16 bit for a range of either ±0.5 V or ±10 V, depending on the amplitude of the measured signal. The impedance could thus be calculated as

$$Z = \frac{-V_{out}R_{current}}{V_{in}}. \tag{2.3}$$

Both current waveforms, V_{in} and V_{out}, were then windowed using a rectangular window and decomposed in the frequencies induced by Fast Fourier Transform (FFT). One full wavelength of the lowest frequency investigated passed between beginning of measurements and starting point of FFT. The magnitude of the impedance was calculated from the Fourier coefficients, $F_{V_{in}}$ and $F_{V_{out}}$, for each frequency f [Searle and Kirkup, 1999]:

$$|Z(f)| = \frac{|F_{V_{out}}(f)|\ R_{current}}{|F_{V_{in}}(f)|}. \tag{2.4}$$

The phase shift was calculated by measuring the delay between zero crossings of applied and resulting voltage for each frequency. This approach allowed measuring the impedance at the 21 frequencies in about 3 s.

All impedances were averaged over three subsequent measurements. Comparison between single measurements allowed judgment of the consistency of the results and determination of loose contacts of damaged electrodes. Impedance values reported in the following were averaged over these three measurements at each frequency measured. Impedances of electrodes having more than two contacts were calculated by averaging over all single measurements of all possible combinations of contacts.

Validation of the impedance measurement system

The impedance measurement with EIMS was validated in two different measurements. In a first series of measurements the impedances of different resistances (from 1 Ω to 1 MΩ), covering

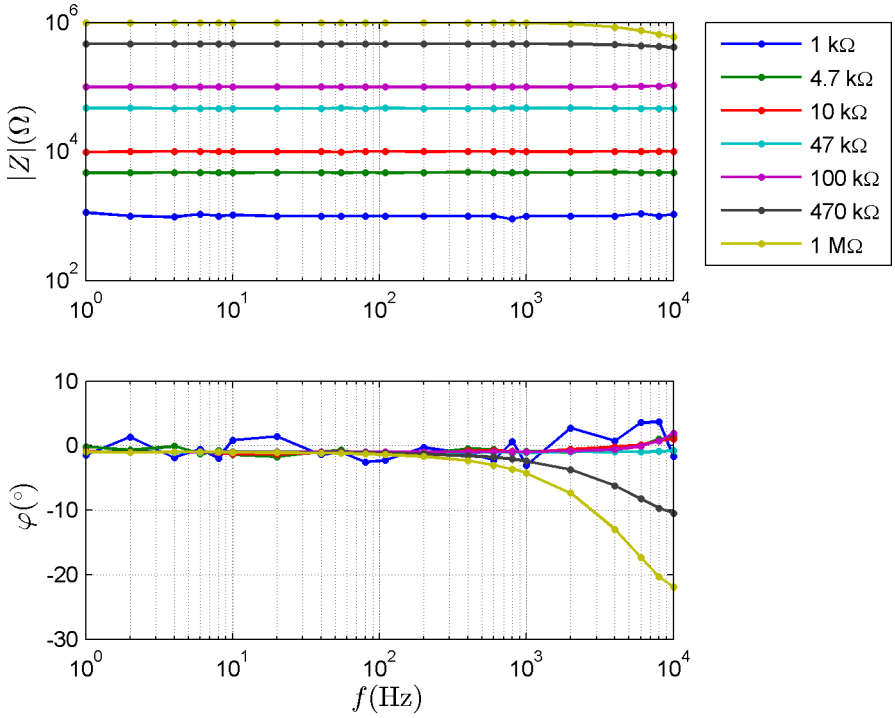


Figure 2.23: Impedances resulting from measurement of different resistors having resistances between 1 kΩ and 1 MΩ, carried out with EIMS.

the expected measurement range of the system, were measured and the resulting errors were determined. In a second measurement the same impedance was measured with EIMS and with a commercial inductance (L), capacitance (C) and resistance (R) mesurement device (LCR meter) and the results of both measurements were compared.

Results of the measurements of different resistances are presented in figure 2.23. In the frequency range from 1 Hz to 1 kHz the system was able to measure the impedances from 2.2 kΩ to 1 MΩ with an measurement error of $<\pm 5\%$ in magnitude and $<\pm 4°$ in phase. For higher frequencies up to 10 kHz this accuracy was only achieved for impedances up to 100 kΩ. For higher resistances there was a considerable drop in magnitude and phase that increased with frequency (see figure 2.23). At 10 kHz the error in magnitude was -12.6% for 470 kΩ and -41.3% for 1 MΩ while the error in phase was $-10.6°$ and $-22.8°$, respectively. For impedances below 2.2 kΩ the standard deviation of magnitude and phase increased considerably. For an impedance of 1 kΩ the error in magnitude grew to $<\pm 20\%$ and that in phase to $<\pm 10°$.

The comparison between EIMS and an LCR meter (4284A, Hewlett Packard) by measurement of the same impedance was limited by two characteristics of the LCR meter. On the one hand its frequency range from 20 Hz to 1 MHz did not cover the low frequencies measured with EIMS which reached down to 1 Hz. On the other hand it required a minimum measurement current of 50 µA which was considerably higher than the 1 µA used by EIMS. In *in vitro* measurements of electrodes this would have caused different current densities at the electrode-electrolyte interface which could have influenced the impedance measured [Schwan, 1968, Geddes et al., 1971, Ragheb and Geddes, 1990, Ragheb and Geddes, 1991]. Besides, the various transient effects [Mirtaheri et al., 2005] causing changes in the electrode-electrolyte impedance over time were the reason for not carrying out the validation by *in vitro* measurements of electrodes in electrolyte but using an Resistor-Capacitor circuit (RC circuit) with an impedance characteristic similar to electrodes investigated in the following.

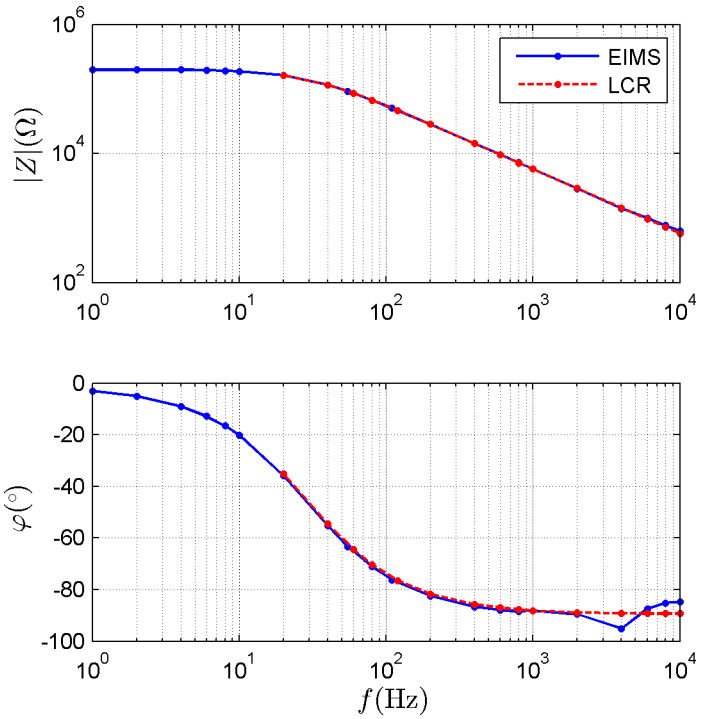


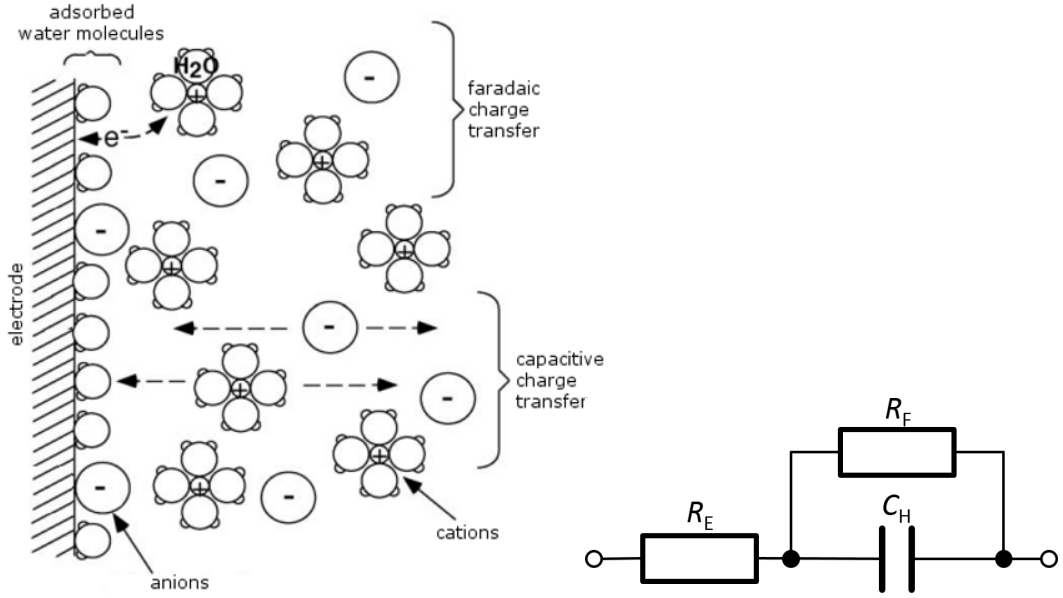
Figure 2.24: Impedance of a circuit consisting of a resistance of 200 kΩ parallel to a capacitance of 22 nF measured with EIMS and an LCR meter (HP 4284A).

Results of the comparison between the impedance of the RC circuit, consisting of a parallel connection of a resistance of 200 kΩ and a capacitance of 22 nF, measured with EIMS and the LCR meter are presented in figure 2.24. The difference in magnitude between the measurements of both systems was $<\pm 1\%$ over the whole frequency range. Also the difference in measured phase shift was only $<\pm$ 1° for frequencies from 20 Hz to 2 kHz but increased to ±6° in the frequency range between 4 kHz and 10 kHz. This increase in measurement error was caused by the low magnitudes that fell below 1.4 kΩ for these frequencies. This effect was already described in the previous measurements of resistances if the magnitude decreased below 2.2 kΩ.

In conclusion, the accuracy of the system was found to be $<\pm 5\%$ in amplitude and phase for impedances between 2.2 kΩ and 1 MΩ in a frequency range between 1 Hz and 1 kHz. For frequencies between 1 kHz and 10 kHz this accuracy is only achieved for impedances up to 100 kΩ which is sufficient since the magnitude of electrode impedance investigated decreases with increasing frequencies. Impedances below 2.2 kΩ have higher standard deviation and should be interpreted carefully.

Equivalent circuits. For further analysis of measured electrode impedances, the impedance of a simple equivalent circuit was fitted to the measured electrode impedance by variation of the circuit element properties. The resulting values of the circuit element properties allowed for a closer investigation of different components of the electrode impedance and thereby further analysis and interpretation of the underlying mechanisms.

A simple equivalent circuit that allows for differentiation between three processes contributing to the charge transfer 2.25a resulting in the measured impedance was proposed by Randles [Randles, 1947] and is shown in figure 2.25b. It consists of a resistance R_E in series with a parallel connection of another resistance R_F and a capacitance C_H. This equivalent circuit is



(a) processes involved in charge transfer (adapted from [Merrill et al., 2005])

(b) Randles equivalent circuit $R_\mathrm{E} - R_\mathrm{F}||C_\mathrm{H}$

Figure 2.25: Schematic of the charge transfer between electrode and electrolyte (a) and the Randles equivalent circuit representing the involved processes (b). R_E represents the resistance of the electrolyte, R_F comprises all chemical reactions caused by transfer of electrons between electrode and electrolyte while C_H sums up all capacitive processes caused by adsorption and redistribution of ions (see page 52).

able to approximate the impedance of an electrode over the whole frequency range under investigation with only one set of circuit element properties [Grimnes and Martinsen, 2008]. Besides, it maintains a simplicity that allows for interpretation of parameters and their changes. R_E can be interpreted as excess resistance caused by the bulk resistance of the electrolyte between the two measurement electrodes, while C_H represents the Helmholtz capacitance, introduced by the double layer formed at the electrode surface and redistribution of ions in the electrolyte, while R_F represents the Faraday resistance, caused by charge transfer via different chemical reactions caused by transfer of electrons between electrode and electrolyte [Stieglitz et al., 2000]. The impedance of the Randles equivalent circuit can be described as follows [Grimnes and Martinsen, 2008]

$$Z_\mathrm{R} = R_\mathrm{E} + \frac{R_\mathrm{F}}{1 + j\omega R_\mathrm{F} C_\mathrm{H}}. \tag{2.5}$$

For fitting the equivalent circuits' impedances to those of the electrodes measured, measured impedances were converted into their real and imaginary parts first. Then they were imported to the impedance analysis software ZView (Scribner Associates, Inc.) which used LEVM (J. R. Macdonald, www.jrossmacdonald.com) to perform complex nonlinear-least-squares (CNLS) data fitting [Barsoukov and Macdonald, 2005]. The fitting process [Moré, 1977] aimed at finding the parameters P that minimize the Residual Sum of Squares (RSS)

$$RSS(P) = \sum_{\mathrm{i}=1}^{\mathrm{m}} w_\mathrm{i}[Z_\mathrm{i}^\mathrm{meas} - Z_\mathrm{i}^\mathrm{calc}(P)]^2. \tag{2.6}$$

Table 2.4: Results of fitting the impedances of an RC circuit consisting of a parallel connection of a resistor and a capacitance, measured with two different measurement systems.

	resistance	capacitance	χ^2	RSS
RC circuit	200 kΩ	27 nF		
EIMS	200.6 kΩ	27.4 nF	0.018	0.729
LCR meter	199.8 kΩ	27.7 nF	0.001	0.017

The sum is taken over the total number m of data points i. w_i is the weight associated with the i^{th} point, $Z_\mathrm{i}^{\mathrm{meas}}$ is the measured value of the i^{th} data point to be fitted, and $Z_\mathrm{i}^{\mathrm{calc}}(P)$ is the corresponding value calculated by the fitting function involving the set of parameters P. The weighting factor w_i was calculated by normalizing the weight of each value to its magnitude measured

$$w_\mathrm{i} = \frac{1}{Z_\mathrm{i}^{\mathrm{meas}}}. \tag{2.7}$$

The goodness of fit was quantified by the RSS, which is proportional to the average percentage error between the experimental data and the simulated values and is particularly useful when comparing the quality of fit of two different models to a single set of impedance data.

For validation of the impedance measurement and fitting, the impedance of the RC circuit, built from a resistance of 200 kΩ in parallel to a capacitance of 22 nF, measured with EIMS and an LCR meter was fitted to a model of the same topology. The resulting circuit element properties are given in table 2.4. Fitting of the impedance measured with EIMS resulted in a resistance of 200.6 kΩ and a capacitance of 27.4 nF, corresponding to relative errors of 0.3% and 1.5%, respectively. The fit achieved a RSS of 0.729. Fitting the impedance measured with the LCR meter resulted in a resistance of 199.8 kΩ and a capacitance of 27.7 nF which is according to relative errors of 0.1% and 2.6%, respectively. Even though determination of circuit element properties achieved similar accuracy, the latter RSS is 0.017 which indicates a considerable better fit compared to that achieved for the EIMS measurement. This is probably caused by the inaccuracies in phase above 2 kHz present in the EIMS measurements (see figure 2.24).

2.4.2 *In vitro* measurements

In vitro measurements of electrode impedance were carried out in the process of electrode development. They allowed quantification of the influence of different surface areas of the electrode contacts on the impedance and were used to analyze the effect of microporous coating on the impedance. For the measurements electrodes were placed in 0.9% NaCl solution at room temperature (22 °C).

2.4.3 *In vivo* measurements

During implantation surgeries, impedance measurements were carried out to determine if the electrodes were intact and had proper electrical contact to the muscle tissue. In trials were it was possible to directly contact the implanted electrodes, repeated impedance measurements were carried out to monitor the process of encapsulation of electrodes over time, by measuring the influence of the encapsulation tissue on the impedance. These repeated measurements also provided information if electrodes were still intact or in which period of time issues occurred. During explantation surgeries, impedances were measured to gain last information about their

in situ condition before they were removed from the tissue. For further details on when *in vivo* measurements were carried out during the different experiments see section 2.3.

2.5 Measurement and analysis of muscle activity

EMG measurement. EMG signals were recorded in monopolar and bipolar configuration. Monopolar measurements were carried out between one of the contacts of an electrode implanted on a target muscle and a subcutaneous hookwire electrode (PHW-50mm, smg medical monitoring) which was used as common reference. These bipolar hookwire electrodes consisted of two PTFE insulated stainless steel wires (AISI T302, d =0.08 mm) threaded through a hypodermic needle. The tips of the two cables were bent at 180° from the needle and contact surfaces were formed by stripping 2 mm at their ends. The distance between both contacts was 3 mm and they were shorted to form the reference electrode. Bipolar measurements were carried out between two contacts on the same electrode.

In experiments in which direct access to electrodes was available, measurements were carried out using a biosignal acquisition device (g.USBamp, g.tec medical engineering). It had 16 channels each with an input range of ±250 mV and an input impedance $>10^{10}\,\Omega$. There was a separate ADC for each channel with a resolution of 24 bit. EMG signals were sampled at 4.8 kHz and band-pass filtered with a pass band from 2 Hz to 2 kHz. Since the measured EMG signals should be investigated over their whole frequency spectrum, no notch filter was applied. The amplifier was directly connected to the measurement computer via USB. The computer was running g.Recorder (V2.09a, g.tec medical engineering GmbH) a measurement software which stored all recorded data in HDF5 file format. In trials in which the whole system was implanted the measurement electronics described in chapter 2.2.1 was used to perform bipolar EMG measurements.

EMG analysis. Analysis of measured EMG signals had different aims. At first, it was investigated how the intramuscular EMG was best measured with epimysially implanted electrodes (section 2.5.1). For this monopolar and bipolar measurements were compared. Then the optimal distance between contacts for bipolar measurements was determined. Afterwards the measured EMG signal itself was analyzed. The signal to noise ratio was calculated and the frequencies relevant for analysis were determined (section 2.5.2). In the following it was tried to discriminate between the different movement directions by means of the measured EMG (section 2.5.3). To obtain a first impression about the differences in the EMG recorded during arm movements in different directions the Root Mean Square (RMS) averaged over all movements in each direction was compared. Afterwards it was tried to classify the measured EMG according to the underlying movement direction. As a basis several features were calculated from the EMG signal to establish a feature space representation of the trials. Afterwards a Principal Component Analysis (PCA) was used to gain first insight into the relevance of features for discriminating between the movement directions. Then different classifiers were trained to automatically classify the measured EMG as originating from one of the movement directions. All signal processing was performed in MATLAB (2012b, The MathWorks).

2.5.1 Identification of the optimal measurement configuration

The first EMG measurements were carried out to determine which type of measurement, whether monopolar measurements between one contact on each muscle and a common reference electrode, or bipolar measurements between two contacts on each muscle, should be used in the developed

implantable EMG measurement system. The Power Spectral Density (PSD) of the recorded EMG signals was calculated by FFT using Welch's method [Welch, 1967]. It was used to compare the signals measured in monopolar and bipolar configuration by quantifying the power of the signal over the whole frequency range as well as comparing the amount of noise contained in both recordings. The redundancy contained in channels of the same electrode were investigated by analyzing their cross correlation. In the following the optimal contact distance for bipolar recordings was determined. Again, the PSD was used to compare the spectral power of the signals measured with different distances between contacts.

2.5.2 Determination of relevant frequencies

In the following the PSD was calculated to determine the Signal-to-Noise Ratio (SNR). This was calculated from the difference between measurements carried out during contraction (signal) and relaxation (noise) of the muscle under investigation. The measurements used for this investigation were carried out during the second experiment in rhesus macaques (see page 42). For establishment of a data vector of sufficient length the active periods during reaching movements were appended one after another. For this, one reaching movement in each direction was used. The measurements during relaxation were carried out while an animal trainer held the arm of the monkey and determined when the muscle under investigation was relaxed. The SNR was calculated by dividing the PSD of the signal by that of the noise at each frequency. This allowed identification of the frequency range of the EMG signal containing relevant information. The lower end of the frequency range was set, where the influence of low frequency artifacts reached a minimum while its upper end was set to a frequency at which the SNR dropped below a value of 10. The maximum SNR was calculated and the frequency at which it occurred was identified.

2.5.3 Differentiation of movement directions

In a first approach, the measured EMG resulting from arm movements into different directions was analyzed in time domain. For this the raw EMG was rectified and filtered by application of a moving average over 15% of movement duration, which was defined in section 2.3.1 as time between release of the center cue until the monkey touched the outer target. The RMS of these signals was calculated and time was scaled to 100% of movement duration. Then the average was calculated over all trials in one direction. The resulting waveforms for the different movement directions were compared.

In a second approach a classification of measured EMG according to the movement direction of the arm was realized. For this several features which were commonly used for EMG analysis were calculated (see below). Those features were investigated for their ability to discriminate between the different movement directions in PCA. Afterwards these features were used as input for different classifiers. In a first step classifiers were applied to the whole feature set and the classification results between the different classifiers were compared. In the following feature selection algorithms were applied for each classifier separately. The selected feature sets were compared as well as the resulting classification performance.

Features

Classification of movement direction was based on seven features in time and frequency domain [Hudgins et al., 1993,Zardoshti-Kermani et al., 1995,Zecca et al., 2002,Tkach et al., 2010]. These features were calculated on windows of 64 ms length. The first five features were *time domain features* which were calculated from the time series of the EMG signal.

Mean Absolute Value (MAV) is an estimate for the mean absolute value of the signal over a window with N samples having measured signal amplitudes of x_{n}.

$$MAV = \frac{1}{N}\sum_{\mathrm{n}=1}^{\mathrm{N}} |x_{\mathrm{n}}| \tag{2.8}$$

Mean Absolute Value Slope (MAVS) is the difference in MAV between two adjacent windows w.

$$MAVS = MAV_{\mathrm{w}} - MAV_{\mathrm{w}-1} \tag{2.9}$$

Wave Form Length (WFL) provides information about the complexity of the waveform. It is defined as the cumulative length of waveform over the window.

$$WFL = \sum_{\mathrm{n}=2}^{\mathrm{N}} |x_{\mathrm{n}} - x_{\mathrm{n}-1}| \tag{2.10}$$

Willison Amplitude (WA) is an indicator for firing of motor unit action potentials by counting the number of times that the change in amplitude exceeds a certain threshold [Willison, 1963]. A threshold between 50 and 100 mV was reported in literature [Zardoshti-Kermani et al., 1995]. In this study a threshold of 50 mV was applied.

$$WA = \sum_{\mathrm{n}=1}^{\mathrm{N}} f(|x_{\mathrm{n}} - x_{\mathrm{n}-1}|) \tag{2.11}$$

$$f(x) = \begin{cases} 1 & \text{if } x > \text{threshold} \\ 0 & \text{otherwise} \end{cases}$$

Slope Sign Changes (SSC) is related to the frequency of the signal by counting the number of times the slope of the signal changes sign within a window.

$$SSC = \sum_{\mathrm{n}=2}^{\mathrm{N}-1} f(x_{\mathrm{n}-1}, x_{\mathrm{n}}, x_{\mathrm{n}+1}) \tag{2.12}$$

$$f(x_{\mathrm{n}-1}, x_{\mathrm{n}}, x_{\mathrm{n}+1}) = \begin{cases} 1 & \text{if } \{x_{\mathrm{n}-1} < x_{\mathrm{n}} \text{ and } x_{\mathrm{n}} > x_{\mathrm{n}+1}\} \text{ or } \{x_{\mathrm{n}-1} > x_{\mathrm{n}} \text{ and } x_{\mathrm{n}} < x_{\mathrm{n}+1}\} \\ 0 & \text{otherwise} \end{cases}$$

Besides *time domain features* also two *frequency domain features* were used. Their calculation was based on the PSD calculated as described above.

Mean Frequency (MF) is the average frequency and denotes the center of the distribution of power spectral density *P(f)* across frequencies *f*.

$$MF = \frac{\int_0^\infty f P(f)\, df}{\int_0^\infty P(f)\, df} \tag{2.13}$$

Median Frequency (MDF) is the frequency at which the power spectrum is divided into two parts with equal power.

$$\int_0^{\mathrm{MDF}} P(f)\, df = \int_{\mathrm{MDF}}^\infty P(f)\, df = \frac{1}{2}\int_0^\infty P(f)\, df \tag{2.14}$$

Principal component analysis

A PCA was performed to estimate the importance of the investigated features for description of the variance contained in the EMG signals measured during the arm movements into different directions. Besides, PCA was used to identify features that were strongly correlated. The PCA was also used to get a first impression of the separability of different movement directions in the space spanned by the principal components. Results of the PCA were presented in a two-dimensional biplot [Greenacre, 2010]. This representation displayed the loadings of the different features on the first two principal components as vectors as well as the projection of the single trials into the space spanned by the first two principal components as one point for each trial. The vectors of the different features allowed judging of their influence on the principal components and to recognize dependencies between them. The smaller the angle between the vectors the more they were connected [Greenacre, 2010]. The projection of the single trials allowed to judge, if there are clusters appearing in the principal component space, that indicate a good separability of movement directions.

Movement classification

Different classifiers were trained and applied to classify the EMG signals recorded during the reaching movements according to the movement direction which evoked them. All classifiers were applied according to their implementation in MATLAB.

Linear Discriminant Analysis (LDA) denotes a statistical method to find linear decision boundaries that allow to assign an EMG sample according to its feature vector to one of the eight classes representing the different movement directions. The idea proposed by Fisher [Fisher, 1936] was to maximize a function that will give a large separation between the projected class means while also giving a small variance within each class, thereby minimizing the class overlap [Bishop, 2009]. For this the LDA assumes that the data of each feature is normally distributed which makes is possible to use Gaussian densities for their analysis. The second assumption is that the covariance in each class is identical. The function that assigns a feature vector x to one of K $(k = 1, ..., K)$ classes C_{K} is called *discriminant*. The simplest representation of a linear discriminant function for the case of two classes $K = 2$ is

$$y(x) = w^{\mathrm{T}}x + \omega_0 \tag{2.15}$$

where w is the weighting vector and ω_0 describes the bias. A feature vector x is assigned to class C_1 if $y(x) > 0$ and to class C_2 if$y(x) < 0$. The corresponding decision boundary is defined by the relation $y(x) = 0$, which corresponds to a $(D-1)$-dimensional hyperplane (see figure 2.26) within the D-dimensional input space [Bishop, 2009].

For more than two classes $K > 2$ the discriminant can include K linear functions of the form

$$y(x)_{\mathrm{k}} = w_{\mathrm{k}}^{\mathrm{T}}x + \omega_{\mathrm{k0}}. \tag{2.16}$$

Then the feature vector x is assigned to class C_{k} if $y_{\mathrm{k}}(x) > y_{\mathrm{j}}(x)$ for all $j \neq k$. The decision boundary between the classes C_{k} and C_{j} is given by $y_{\mathrm{k}}(x) = y_{\mathrm{j}}(x)$ and

$$(w_{\mathrm{k}} - w_{\mathrm{j}})^{\mathrm{T}}x + (\omega_{\mathrm{k0}} - \omega_{\mathrm{j0}}) = 0 \tag{2.17}$$

defines the corresponding (D-1)-dimensional hyperplane [Bishop, 2009].

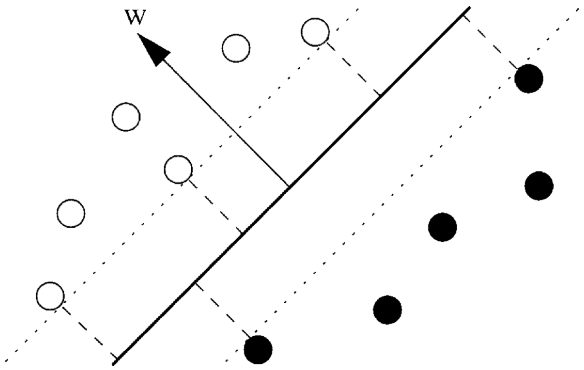


Figure 2.26: Linear classifier and margins: A linear classifier is defined by a hyperplane's normal vector w and an offset ω_0, i.e., the decision boundary is $y(x) = w^{\mathrm{T}}x + \omega_0 = 0$ (thick line). Each of the two halfspaces defined by this hyperplane corresponds to one class. The margin of a linear classifier is the minimal distance of any training point to the hyperplane (distance between dotted and thick lines) [Müller et al., 2001].

Application of the Bayes' theorem [Bayes, 1763]

$$p(Y|X) = \frac{p(X|Y)p(Y)}{p(X)} \tag{2.18}$$

to a classification of a vector x into $K > 2$ classes leads to

$$p(C_{\mathrm{k}}|x) = \frac{p(x|C_{\mathrm{k}})p(C_{\mathrm{k}})}{\sum_{\mathrm{j}} p(x|C_{\mathrm{j}})p(C_{\mathrm{j}})}. \tag{2.19}$$

for $k \neq j$. For the assumption that all classes share the same covariance matrix Σ this leads to a linear discriminant function [Hastie et al., 2009]

$$\delta_{\mathrm{k}}(x) = x^{\mathrm{T}}\Sigma^{-1}\mu_{\mathrm{k}} - \frac{1}{2}\mu_{\mathrm{k}}^{\mathrm{T}}\Sigma^{-1}\mu_{\mathrm{k}} + log(\pi_{\mathrm{k}}) \tag{2.20}$$

where μ_{k} denotes the mean and π_{k} the prior probability of of class C_{k}.

Quadratic Discriminant Analysis (QDA) makes the same assumption about the normal distribution of features but does not assume the covariance of all classes to be the same. It allows that every class C_{k} has its own covariance Σ_{k}. In this case, some cancellations which were applied to the linear case no longer occur and the discriminant becomes a quadratic function of x [Hastie et al., 2009]

$$\delta_{\mathrm{k}}(x) = -\frac{1}{2}log|\Sigma_{\mathrm{k}}| - \frac{1}{2}(x-\mu_{\mathrm{k}})^{\mathrm{T}}\Sigma_{\mathrm{k}}^{-1}(x-\mu_{\mathrm{k}}) + log(\pi_{\mathrm{k}}) \tag{2.21}$$

Therefore the resulting decision boundaries are described by quadratic equations [Bishop, 2009].

If there are D input features in discriminant analysis, a general distribution would correspond to a table of 2^{D} numbers for each class. To avoid this exponential growth in relation to the number of features, naive Bayes classifiers were investigated. They also apply Bayes theorem

[Bayes, 1763] but combine it with the (naive) assumption that all features are conditionally independent.

$$p(x|C_{\mathrm{k}}) = \prod_{\mathrm{i}=1}^{\mathrm{D}} p(x_{\mathrm{i}}|C_{\mathrm{k}}) \tag{2.22}$$

Which leads to only D independent parameters for each class [Bishop, 2009].

Even if the assumption of conditionally independent features is often not true, it greatly simplifies the training, by estimating one-dimensional densities for each feature individually and naive Bayes classifiers have been found to work well on many data sets. It turns out that the naive-Bayes classifier can be very robust to violations of its independence assumption, and it has been reported to perform well for many real-world data sets [Theodoridis and Koutroumbas, 2009].

Linear Naive Bayes (LNB) and Quadratic Naive Bayes (QNB) classifiers use the the same approach as LDA and QDA classifiers, respectively, but account for the assumed independence of variables by use of a diagonal covariance matrix. Therefore they are a specific examples of a Naive Bayes classifiers.

Gaussian Naive Bayes (GNB) assumes normal distribution of features to calculate mean and standard deviation of each class. This results in

$$p(x|C_{\mathrm{k}}) = \prod_{\mathrm{i}=1}^{\mathrm{D}} \mu_{\mathrm{k_i}}^{\mathrm{x_i}} (1 - \mu_{\mathrm{k_i}})^{(1-x_{\mathrm{i}})}. \tag{2.23}$$

Kernel Naive Bayes (KNB) is a generalization of the GNB classifier which only assumes a continuous distribution of features and allows separate estimation of the class-conditional marginal densities $p(x|C_{\mathrm{k}})$ by kernel density estimates [Hastie et al., 2009]. The use of a Gaussian kernel yielded [Murakami and Mizuguchi, 2010]

$$p(x|C_{\mathrm{k}}) = \frac{1}{nh} \sum_{\mathrm{j}=1}^{\mathrm{n}} \frac{1}{\sqrt{2\pi}} e^{-\frac{(x-\mu)^2}{2h^2}}. \tag{2.24}$$

The classifier automatically selected the bandwidth h for each class and feature individually. Compared to the previous classifiers this approach needs more computing time and memory.

Dimensionality reduction. After all classifiers were applied to all features, subsets of features were compiled. Separate feature sets were established for each classifier in combination with each set of movements applying a forward sequential selection algorithm. This algorithm selected a set of features that was best suited to correctly classify the direction of movement. To do so, it sequentially selected features which most improve classification performance until no significant further improvement in classification accuracy could be achieved by inclusion of additional features. Misclassification rate was chosen as criteria for classification accuracy and calculated applying a leave-one-out cross validation. For further investigation of misclassifications, confusion matrices were established by computing the redistribution errors during each classification.

Chapter 3

Results

Presentation of the results starts with the findings from the user survey in section 3.1. In the following the results from evaluation of the implantable EMG measurement system are presented in section 3.2, and outcomes from EMG analysis and classification of movement direction are presented in section 3.3.

3.1 User survey

Presentation of the findings resulting from evaluation of the user survey starts with the response rate and a description of the participants. In the following, section 3.1.1 reports on the satisfaction of prosthesis users with their current prosthesis and their suggestions for improvement of future prostheses, which both were published in [Lewis et al., 2013c] (see Pub.1 on page 74). The use of sensory information for control of current prostheses and user needs towards sensory feedback in future prostheses are presented in sections 3.1.2 and 3.1.3, respectively. These findings were published in [Lewis et al., 2012a] (see Pub.2 on page 76). Findings on phantom and pain phenomena are presented in section 3.1.4 and section 3.1.5 summarizes all findings of the survey.

Response to the survey. Of the 400 questionnaires (see page 24) sent out, 105 were returned of which 101 met the inclusion criterion of being filled out by a user of a myoelectric prosthesis. This corresponds to a response rate of 25%. The on-line survey (see page 25) was visited 120 times, which cannot be interpreted as a response rate, since the distribution of links to the survey could not be quantified. Thirty-two (27%) visitors proceeded from the welcome page to the first page containing questions. Nine surveys (8%) were completed of which seven surveys (6%) fulfilled the inclusion criteria. Every fourth respondent to the mailed survey would have preferred an on-line survey.

Sample description. Respondents had an age between 6 and 79 years with a mean of 43 ($\pm$17) years. More than three quarter of the respondents (77%) were male and 23% were female. 31% of the respondents had a congenital absence of the upper limb. Amputations of the remaining (69%) were carried out from the first year of living till an age of 65 years with a mean of 30 ($\pm$16) years. Average time since (first) amputation was 19 ($\pm$15) years. The vast majority of amputations (91%) were carried out due to trauma. Unilateral amputations made up the most (93%) amputations, only 7% of respondents underwent bilateral amputation. Due to amputation 55% of respondents lost their dominant hand. Most respondents were amputated

Table 3.1: Average time of prosthesis use during the week and the weekend for different types of prostheses.

	daily use (h)	
Prosthesis type	during the week	at the weekend
Electric	10.1	8.6
Mechanic	2.9	1.2
Cosmetic	2.8	4.2

at the forearm (60%) and the upper arm (14%). Joint exarticulations were less frequent and performed at the wrist (13%), at the shoulder (7%) and at the elbow joint (5%).

In addition to their electrical prosthesis, 10% of respondents used a mechanical and 19% a cosmetic prosthesis. Only 3% of participants had all three types of prostheses. Average times of prosthesis use for different types of prostheses during the week and the weekends are presented in table 3.1. During the week electrical prostheses were worn significantly longer than mechanical ($p = 0.033$) and cosmetic ($p = 0.003$) prostheses. During the weekend they were also worn longer ($p = 0.005$) compared to mechanic prostheses. Electrical prostheses were worn longer ($p < 0.001$) during the week compared to the weekend while cosmetic prostheses were worn longer ($p = 0.046$) during the weekend.

3.1.1 Satisfaction with current prosthesis

When asked for their overall satisfaction with their electrical prosthesis only 5% of respondents stated that they were *not satisfied at all* (figure 3.1). 15% of respondents were rather not satisfied and the majority of 59% were rather satisfied with their prosthesis. 21% of respondents were even *absolutely satisfied* with their current electrical prosthesis. Average satisfaction on a scale from 0: *not satisfied at all* to 3: *absolutely satisfied* was 1.96 (±0.75) corresponding to rather satisfied.

More detailed information about the satisfaction with different features of the prosthesis is presented in figure 3.2. The highest average satisfaction was found for *donning and doffing* of the prosthesis, which denotes the process of putting the prosthesis on and taking it off again, followed by *opening and closing the hand*. Average satisfaction for the most features, naming *movement of elbow*, *control of movements*, *functional rage*, *reliability*, *optical appearance* and *movement of wrist*, was in the range between 2.0 and 1.9. Less satisfaction was only present for *wearing comfort* and the *weight* which was the feature respondents are least satisfied with. Average satisfaction with different features of the prosthesis was 1.98 (±0.59) and lightly correlates with the time an electric prosthesis was worn during the week ($r = 0.214$, $p = 0.04$) and at the weekend ($r = 0.291$, $p = 0.004$).

Table 3.2 summarizes the wishes and ideas of respondents when asked how their prosthesis

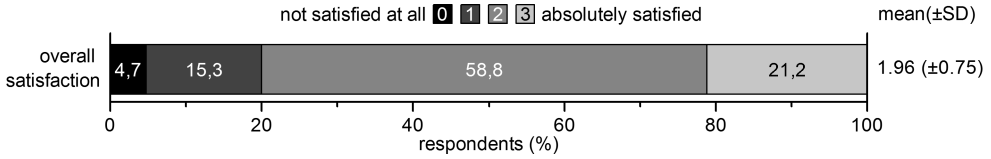


Figure 3.1: Overall satisfaction with the prostheses: *"How satisfied are you with your prosthesis overall?"*

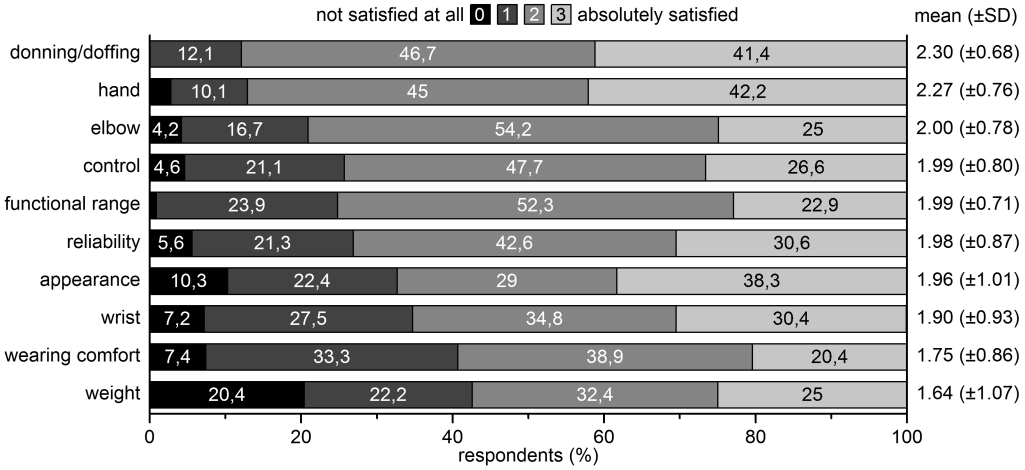


Figure 3.2: Satisfaction with different features of prostheses: *"How satisfied are you with the following features of your prosthesis?"*

could be improved. Suggested improvements were categorized into five superordinate categories addressing certain *components* of the prosthesis ($n = 150$), aspects of the overall *design* ($n = 70$), performance during different *activities* ($n = 36$), aspects of prosthesis *control* ($n = 26$) and *sensory feedback* ($n = 9$). When evaluating the particular suggestions, respondents most often asked for improvements of the cosmetic glove ($n = 51$) making it less sensitive to dirt, easier to clean, more durable and giving it a more natural look. Second most often addressed were the fingers of the prosthetic hand ($n = 37$), mainly wishing for independent movement of single fingers, closely followed by the socket ($n = 36$), demanding less sweating and a thinner design. Improvements of the wrist were suggested 22 times, asking for enhanced movability. A reduction of the weight was mentioned by 19 respondents and 10 respondents asked for improvements of the hand, especially for a relaxed position of the hand while it is not actively used.

Satisfaction of respondents with the prosthesis during different activities is presented in figure 3.3. The highest average satisfaction with prosthesis performance was present for *driving a car* and *contact with others*. During these activities over 40% of respondents were absolutely satisfied with their prosthesis. Average satisfaction between 2 and 1.5 was present for most other activities. Only for *eating with cutlery* respondents were rather not satisfied than satisfied on average. Satisfaction with the prosthesis averaged over all investigated activities was 1.77 (± 0.67). This was significantly lower than the overall satisfaction ($p = 0.004$) and the average satisfaction with different features of the prosthesis ($p < 0.001$). Just like the average satisfaction with different features of the prosthesis the satisfaction with the prosthesis during different activities correlated lightly with the time an electric prosthesis was worn at the weekend ($r = 0.293$, $p = 0.004$) but there was no significant correlation to the prosthesis use during the week.

When asked to give the three activities in which prosthesis use was most important to them, 27% of respondents name *manual work*, 23% *eating with cutlery* and 21% *grasping of objects*. For certain activities prosthesis users did not use their prosthesis at all. The activity during which prostheses were used least was *personal hygiene*, 48% of respondents did this without using their prosthesis. 39% of respondents did not *drink from a glass* with their prosthesis and 37% did not use their electric prosthesis for *doing sports*. 28% did not *drive a car* with the help of their prosthesis and 22% *prepared meals* without utilizing their prosthesis. On the other hand, 98% of respondents actively used the hand for *grasping* and *holding objects*.

Participants were asked four questions about their perception of their electrical prosthesis

Table 3.2: Suggested improvements of electrical prostheses given to a free text question: *"Please state your wishes and ideas how your prosthesis could be improved?"*

category	sub category	times given	details
components	overall	150	
	cosmetic glove	51	less sensitive to dirt/better to clean, more natural appearance, durability
	hand & fingers	47	separate movabilty of fingers, relaxed position
	socket	36	reduce sweating, thinner material
	wrist	22	movability
design	overall	70	
	weight	19	lighter
	sound	7	less operational sounds
	susceptibility to failure	6	less often, less expensive repairs
	battery indicator	5	indication of remaining operational time
activities	overall	36	
	grasping	12	reliability of grasp, grasping of small objects
	eating with cutlery	6	
control	overall	26	improved motion control, immunity to interferences
sensory feedback	overall	9	grip force

and its control. As shown in figure 3.4 there was a clear tendency towards rather agreeing (checking of one of the two right boxes) than not agreeing with all of the statements. The first two questions asked for the perception of the prosthesis as a part of one's body and as a tool. 67% of respondents rather agreed with perceiving their prosthesis as a part of their body while the highest degree of agreement (76%) was present for perception of the prosthesis as a tool. When comparing the difference between the agreements with these two statements, 40% of respondents had a stronger degree of agreement with perception of the prosthesis as a tool, one third of respondents gave an equal degree of agreement and only 27% had stronger agreement with perceiving their prosthesis as a part of their body. This supports the hypothesis, that prosthesis users in general perceive their prosthesis as a tool rather than as a part of their body. Also high agreement of 72% was present for the statement that prosthesis users currently control their prosthesis without thinking about it. This statement had also the highest fraction of respondents that *totally agree* with it. Nonetheless, 57% of respondents agreed with the statement that they had to learn the control of the prosthesis at the beginning.

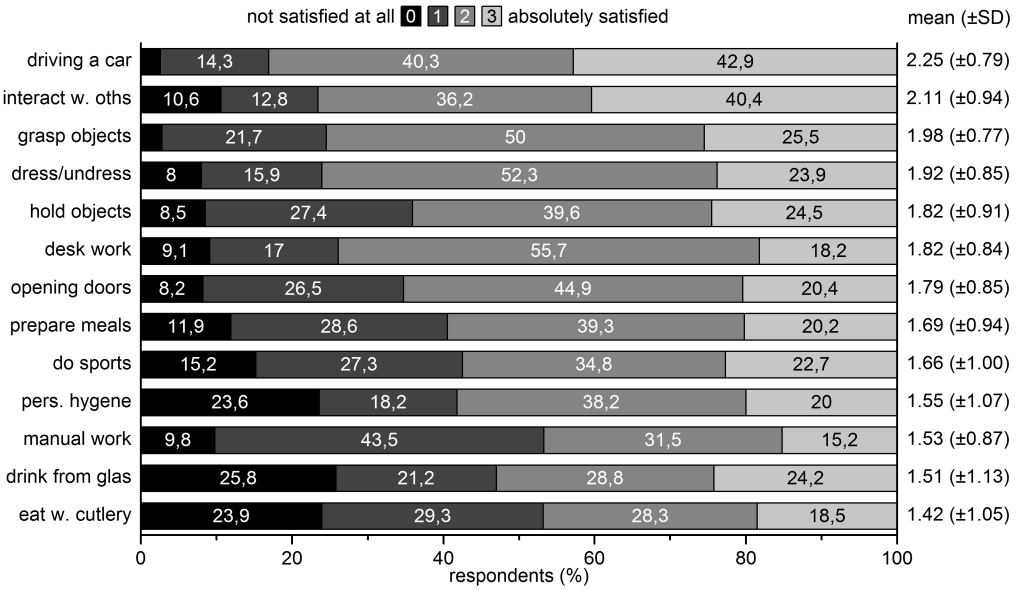


Figure 3.3: Satisfaction with the prosthesis during different ADLs: *"How satisfied are you with your prosthesis when carrying out the following activities?"*

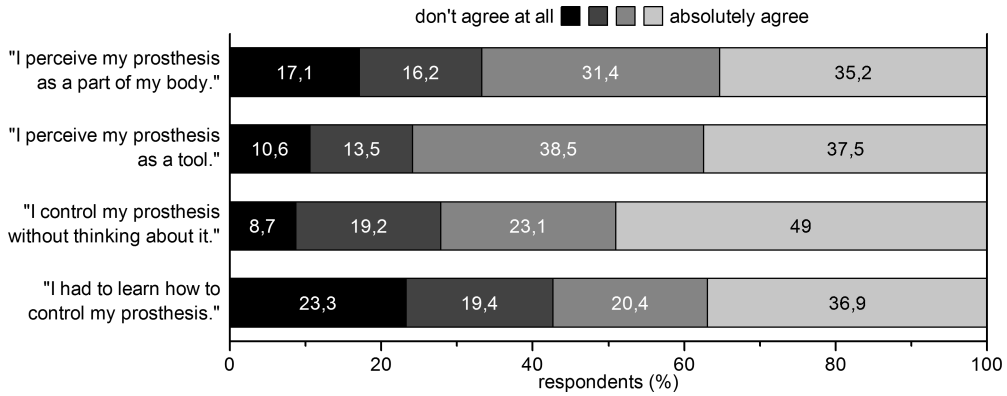


Figure 3.4: Attitude of respondents towards their electrical prosthesis and its control: *"To which degree do you agree with the following statements?"*

Table 3.3: Use of different perceptions respondents applied for control of current electrical prostheses: *"How do you perceive your prosthesis during use?"* (second column), *"In which situations do you use the perceptions given before to control your prosthesis?"* (third to sixth column).

	Use of	Application in prosthesis control			
Perception	perception	Grasp	Hold	Proprioception	Sum
Visual observation	77%	15	2	18	35
Listening	67%	7	1	14	22
Sensations at the stump	75%	1	12	1	14

3.1.2 Current use of sensory information

To investigate the status quo, respondents were asked two questions about their use of perceptions during control of their current prosthesis. The first question asked which perceptions were used to gain information about their current electric prosthesis during operation. Most respondents (41%) used two perceptions in parallel. Three or only one perceptions were used by 27% and 26% of respondents, respectively. Only 6% of respondents selected none of the perceptions presented in the question. As shown in table 3.3 over three-quarter of the respondents were visually observing their prosthesis, two-thirds were using the sounds emitted by their prosthesis and 57% used sensations at the residual limb to gain information about their prosthesis during use.

In the second question participants were asked to describe how they use these perceptions for prosthesis control in a free text. The utilization of the different perceptions for distinct actions is presented in table 3.3. Corresponding to the results of the previous question, visual observation of the prosthesis was the most frequently mentioned source of information about the prosthesis. It was mainly applied for coordination of grasping and to gain information about position and movement of the prosthesis. Second frequently used was the sound of the prosthesis. It was utilized to hear if the prosthesis was moving, how fast it was moving and which joint moved. During grasping the sound was used to gain information about the grip force. Sensations at the residual limb were mentioned less frequently and were mainly applied during holding objects. Respondents felt the weight of an object held and when it started to slip.

3.1.3 Sensory feedback

When asked about the overall importance of receiving sensory feedback from their prosthesis, 45% of respondents rated sensory feedback as *absolutely important*, 43% attached medium importance to sensory feedback by choosing one of the two middle categories and only 12% stated it was *not important at all*.

When asked to rate the importance of different kinds of sensory information *grip force* had the highest mean importance and was absolutely important for two-third of the respondents. Proprioceptive information about *movement* and *position* of the prosthesis had second and third highest mean importance, respectively. Perception of the *first contact* during grasping and the *end of contact* when releasing an object followed. Figure 3.5 shows that considerable lower mean importance was attached to information about objects touched.

After rating the level of importance, respondents were asked to name the three kinds of sensory information that were most important to them in a free text. 98% of the various statements could be categorized into the three categories *grasp and hold*, *touch* and *proprioception*. In sum-

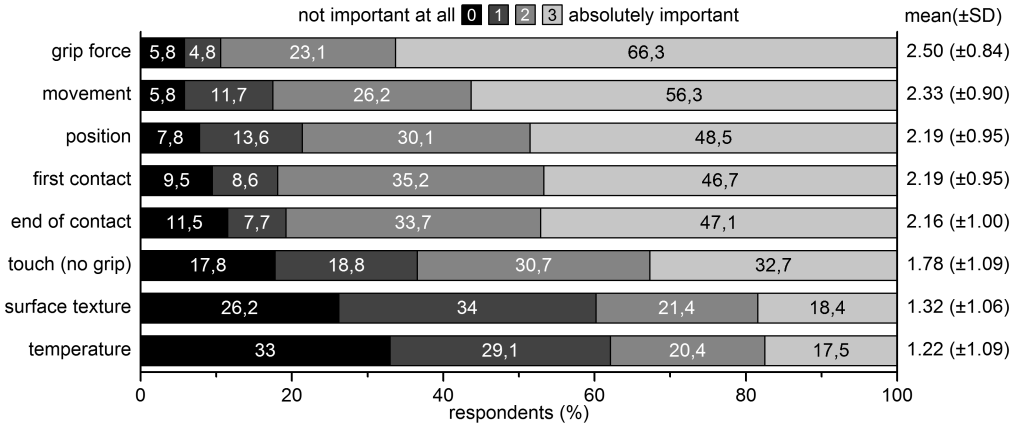


Figure 3.5: Importance of sensory information: *"How important would being able to feel the following sensations with your prosthesis be to you?"*

mary over the three priority levels, sensory information about grasp was named most often and information about touch and proprioception were named considerably less often, as shown in table 3.4. More than half of the respondents rated information about grasping and holding of objects as most important. Proprioceptive information and information about touched objects were second and third often named as highest priority. For the second priority information about grasp and hold were named less frequently while touch and proprioception were given more often. For the third priority all three categories achieve approximately one third of nominations.

Figure 3.6 shows how important sensory feedback is to users of electrical prostheses during different activities. The two activities which had the highest mean importance were *grasping objects* and *holding objects*. Also the next activities, *manual work* and *eating with cutlery* were closely related to grasping and holding objects.

Sensitivity at the residual limb The self-assessed sensitivity at the residual limb to pressure, vibration and temperature stimuli is presented in figure 3.7. Highest sensitivity was reported for pressure, closely followed by vibration. Sensitivity to temperature changes was lowest. Important to note is the fact that nearly every fifth respondent reported not to feel any temperature difference at his or her residual limb at all. Respondents with congenital absence of a limb were significantly ($p = 0.02$) more sensitive to temperature at their residual limb (2.31 $\pm$1.06) compared to respondent who underwent amputation (1.86 $\pm$1.15). On average women reported significantly ($p < 0.04$) higher sensitivity to pressure (♀:2.58 $\pm$0.58, ♂:2.15 $\pm$0.99), temperature (♀: 2.54 $\pm$0.83, ♂: 1.83 $\pm$1.18) and vibration (♀:2.67 $\pm$0.57, ♂:2.10 $\pm$1.05) at their residual limb.

Table 3.4: Categories of sensory information most important to respondents: *Please name the three sensations most important to you.*.

Category of sensory information	Sum of nominations	1st priority	2nd priority	3rd priority
Grasp and hold	108	59%	46%	35%
Touch	60	17%	29%	32%
Proprioception	57	22%	23%	31%

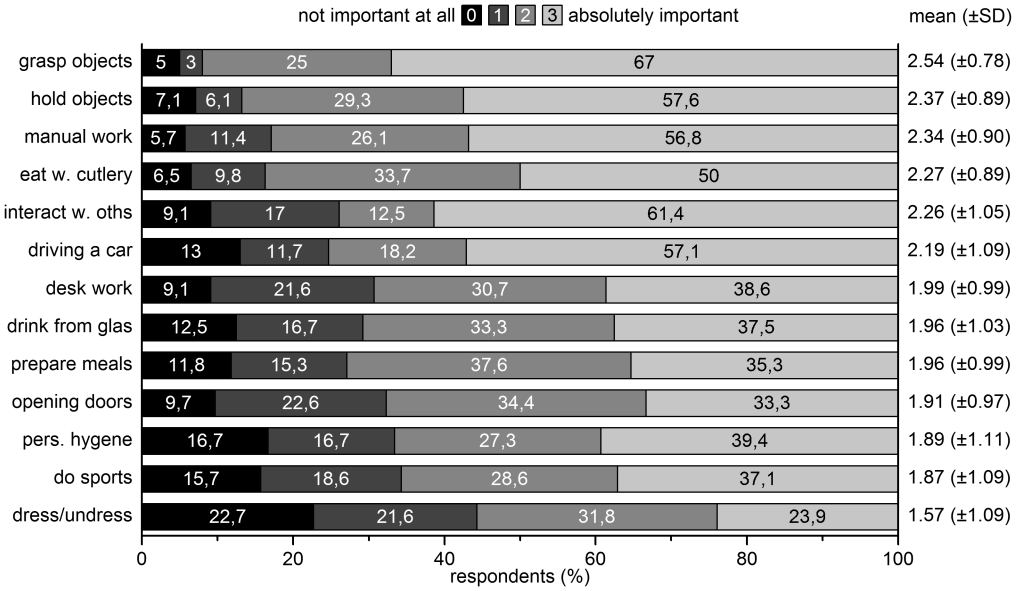


Figure 3.6: Importance of sensory feedback during different ADLs: *"How important would it be to you to percive sensations from your prosthesis during the following activities?"*

When asked for their preference in regard to different feedback modalities, information transmitted by surfaces that are changing their temperature had the highest mean acceptance followed by vibration, electric stimulation and pressure, see figure 3.8. Considerably lower acceptance was achieved by visual and acoustic representation of sensory information. Noteworthy is that the vibrational feedback was least often rejected and the majority of respondents explicitly rejected acoustic and visual feedback.

When asked to summarize the overall importance of sensory feedback to them on a scale from 0 (*not important at all*) to 3 (*absolutely important*) respondents gave an average rating of 2.06 (±1.05), corresponding to rather important. Sensory feedback had a significantly ($p = 0.01$) higher relevance to prosthesis users with a congenital absence of the upper limb (2.41 ±0.88) compared to those who underwent amputation (1.89 ±1.09). Respondents whose residual limb ended at the forearm attached a significant ($p = 0.01$) higher overall importance to sensory feedback (2.22 ±0.99), compared to participants whose residual limb ended at the upper arm (1.50 ±1.16).

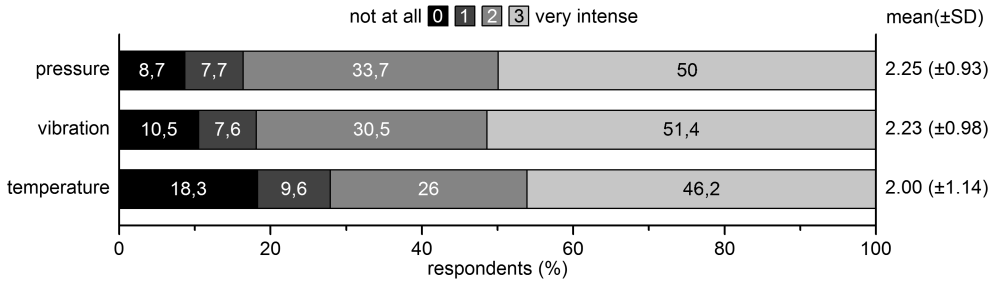


Figure 3.7: Sensibility at the residual limb: *"How intense do you feel the following sensations with your residual limb?"*

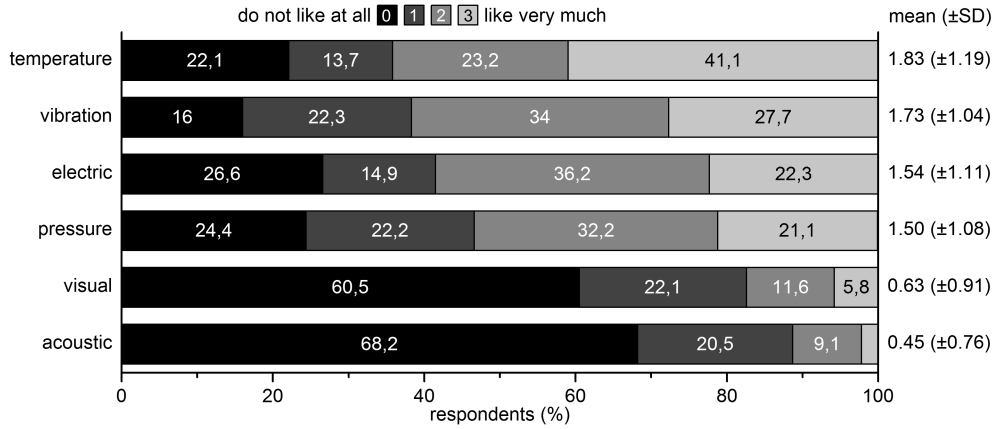


Figure 3.8: Acceptance of different feedback modalities: *"How would you like to have the sensations transfered by your prosthesis?"*

3.1.4 Phantom and pain phenomena

Phantom pain. Prevalence of phantom pain was 51%. The frequency with which affected respondents experienced phantom pain is shown in figure 3.9. 69% of respondents experienced painful sensations in their phantom limb *seldom* or *sometimes* and only 31% of respondents *often* or *always*. For those respondents who experienced phantom pain, frequency of phantom pain was reported to stay constant over time for 78% and decrease for 22% of respondents. No one reported an increasing frequency of phantom pain. The intensity of phantom pain is presented in figure 3.10. 92% of respondents chose one of the middle categories and only 8% of respondents described the intensity of the pain as *worst pain imaginable*. Of those respondents who reported to experience phantom pain 78% reported the intensity to stay constant and 22% reported it to decrease over time. No reports about increasing intensity of phantom pain were given. When asked to state triggers for phantom pain, 14 respondents related it to changes in weather, 5 to relaxation and 3 to the use of the prosthesis. Phantom pain of 7 respondents was not correlated to any circumstances and 6 respondents felt continuous phantom pain.

Pain in the residual limb. Pain in the residual limb was reported by 59% of respondents. 80% of affected respondents experienced it only *seldom* or *sometimes* and just 20% felt pain *often* or *always*. Of those respondents who experienced pain in the residual limb, 67% reported it to occur with constant frequency, 17% reported a decrease and 16% an increase of frequency. When asked for the intensity of pain in the residual limb 17% of respondents who experience stump pain described its intensity as *no pain*. 81% of respondents who experienced pain in

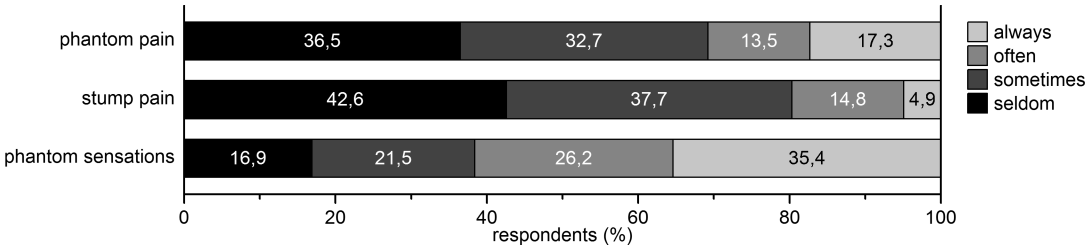


Figure 3.9: Frequency of phantom and pain phenomena are experienced by affected respondents: *"How often did you feel the following sensations during the last six months?"*

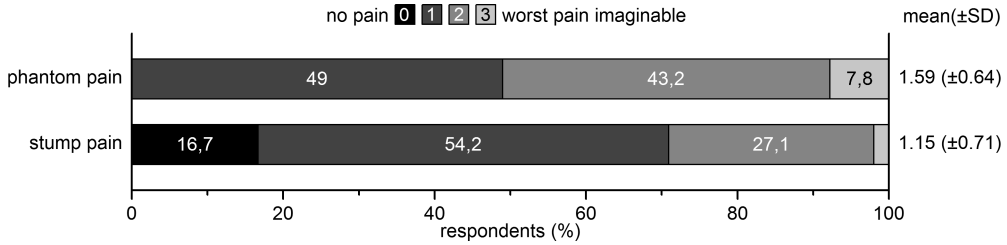


Figure 3.10: Intensity of phantom pain and pain in the residual limb experienced by affected respondents: *"If you have residual limb or phantom pain, how intense is it?"*

the residual limb chose one of the two middle categories and only 2% of affected respondents reported the intensity to be the *worst pain imaginable* (figure 3.10). Of those respondents who report to experience pain in the residual limb 65% reported it to have a constant intensity over time. 21% reported it to decrease and 14% to increase over time. When asked for triggers for stump pain, 26 respondents stated the use of the prosthesis (intensity and duration), 14 the weather (7 high or low temperatures, 6 changes in weather and wind), 4 sweating in the socket and 4 reported it not to be correlated to other circumstances.

Restriction by pain. Respondents were asked about the degree of restriction that was caused by phantom pain and pain in the residual limb during professional work, recreational activities and prosthesis use (figure 3.11). 43% of respondents, whether affected by pain or not, reported to experience *no restriction* in all three fields. The highest average restriction experienced by respondents who were affected by at least one kind of pain was present during professional work. 48% of respondents experienced *no restriction* by pain, 44% chose one of the middle categories and 8% experienced *absolute restriction* during professional work. During recreational activities, 45% of respondents were not restricted, 53% chose one of the middle categories and only 2% were experiencing an *absolute restriction* during recreational activities. Respondents with pain experienced the least average restriction during use of their prosthesis. 53% of respondents were not restricted by pain when using their prosthesis. 40% chose one of the middle categories and 7% were *absolutely restricted* in using their prosthesis.

Treatment of pain. To evaluate how participants treat their pain they were asked what methods they applied for relive of pain. Of those participants who had phantom pain and/or pain in the residual limb 51% had taken attempts for treatment. The different treatments of stump and phantom pain and the resulting effect experienced by the amputees are presented

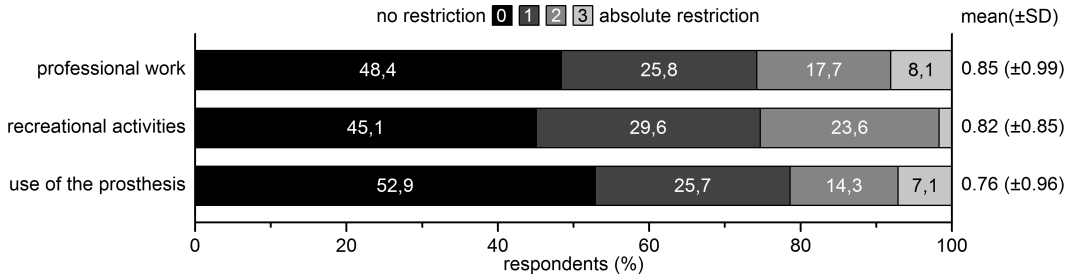


Figure 3.11: Degree of restriction caused by phantom and stump pain for respondents experiencing one or both of pain phenomena in different situations: *"How strongly does residual limb or phantom pain restrict you during the following activities?"*

Table 3.5: Treatment of pain: *"What methods have you used to relieve residual limb or phantom pain?"*

	tried by	effect on pain		
Treatment	(% resp. with pain)	became worse	no change	got better
Drugs	36%	-	27%	73%
Alcohol	22%	13%	63%	25%
Electric stimulation	18%	8%	54%	39%
Acupuncture	14%	10%	40%	50%
Surgery of the stump	13%	11%	33%	56%
Injections into the stump	3%	-	50%	50%

in table 3.5. Most respondents (36%) used drugs to treat their pain, which was also reported to be the most effective treatment. Second most often (22%) respondents reported to have tried to ease the pain by consumption of alcohol but this had the least positive effect. Electric stimulation, acupuncture and surgery at the stump had similar effects on the pain and were tried by 18%, 14% and 13%, respectively. Least respondents (3%) had experiences with injections into the stump.

Overall twenty respondents used the free items to introduce additional treatments they used to relief their pain phenomena. The single statements were categorized as follows. Six times they named physical treatment like massage, touch and tight wrapping. Application of salves, exposing the stump to temperature (hot, cold or changing) and physical activities were stated four times each. Three respondents took their prosthesis off or cushioned parts of the socket. Another three moved their phantom limb or scratched their prosthesis. Ease of pain by mental training, distraction or use of cannabis was reported one time each.

Phantom sensation and movability. The highest prevalence amongst phantom and pain phenomena was present for phantom sensations which were experienced by 64% of respondents. As shown in figure 3.9, 38% of respondents felt parts of their phantom limb *seldom* or *sometimes* and 62% *often* or *always*. The occurrence of phantom sensations and phantom movability in different parts of the phantom arm is presented in figure 3.12. Over half of respondents (52%) felt the fingers and the hand of their phantom limb. The other joints of their phantom arm were felt by around one third of respondents, 33% felt their wrist, 37% felt their elbow and 33% felt their shoulder. Segments of the phantom limb that do not include joints were felt by fewer respondents. 29% of respondents felt their upper arm and only 21% felt their forearm. Closer investigation of respondents with phantom sensations showed that frequency of occurrence of phantom sensations was constant for 84% of respondents with phantom sensations, for 13% it was decreasing and increasing for 3% only.

45 respondents used the free text field to describe their phantom sensations. 21 were able to move their phantom while seven felt their phantom in a fixed position. 38 did not describe any painful sensation. Non painful feelings were most often described as tingling ($N = 11$). Only seven respondents had painful sensations described as stabbing, burning or pressure.

Most respondents who could feel a joint of their phantom arm were also able to move it. Only at the shoulder the movability is considerably lower than the sensation. Phantom movability had an overall tendency to decrease over time. For the largest part of respondents who could move a part of their phantom arm (78%) phantom movability stayed constant over time, for 18% it was decreasing and only 4% reported increasing movability of their phantom limb.

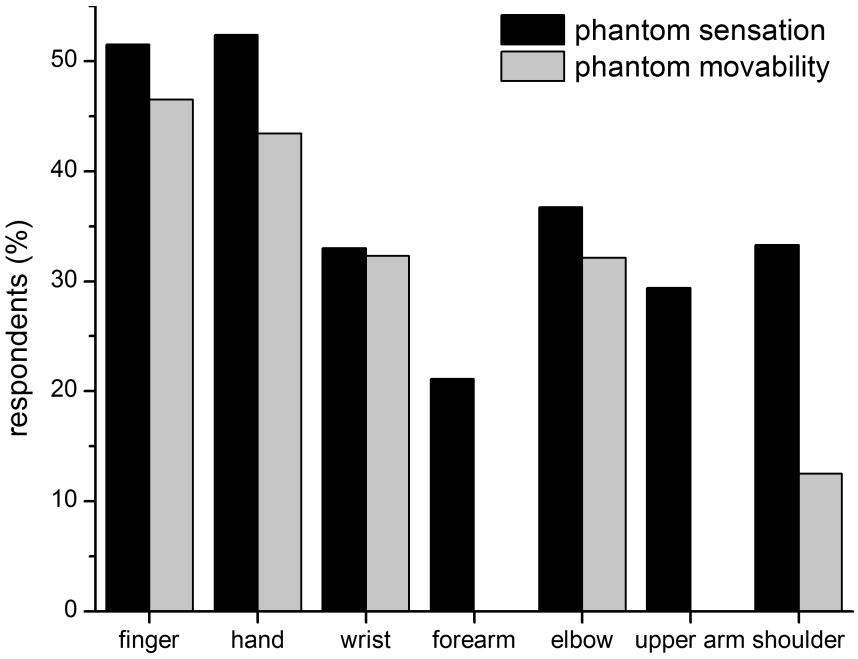


Figure 3.12: Phantom sensation and phantom movability of different parts of the phantom limb: *"Which parts of your phantom arm can you feel / are you able to move?"*

Correlations between phantom and pain phenomena. Investigation of the relation between phantom sensation and phantom pain showed that most respondents (49%) report to experience both, 15% had phantom sensations only and just 2% felt phantom pain but no phantom sensation. 34% of respondents stated not to experience any phantom phenomena. Correlation was present in occurrence ($p < 0.001$, $r = 0.670$) and frequency ($p < 0.001$, $r = 0.675$) of phantom pain and phantom sensations. Relation between phantom and stump pain showed that most respondents (41%) were affected by both kinds of pain, 19% felt stump pain and 10% phantom pain only. 31% of respondents reported not to be affected by any of these pain phenomena. For phantom and stump pain the occurrence ($p < 0.001$, $r = 0.435$), frequency ($p < 0.001$, $r = 0.468$) and intensity ($p < 0.001$, $r = 0.569$) were correlated.

3.1.5 Summary

The mailed and on-line surveys achieved 108 responses of prosthesis users. These provided a broad basis for statistical evaluation regarding the following subjects.

Satisfaction. 80% of respondents were rather or absolutely satisfied with their current electrical prosthesis. Lowest satisfaction with single features was found for wearing comfort and weight and suggested improvements mentioned most often were improvement of cosmetic glove, prosthetic hand, socket, prosthesis control including sensory feedback and reduction of weight. Prostheses were rather perceived as tool rather than as part of one's body.

Sensory feedback. Prosthesis users already applied sensory information, including observation, sounds of the motors and sensations at the stump, during control of current prostheses. Though, 88% found receiving dedicated sensory feedback from their prosthesis to be important. Information of highest importance to respondents was grip force, followed by proprioceptive

information about movement and position of the prosthesis as well as grasp related information about beginning and end of contact to a grasped object. According to sensitivity at the stump and acceptance of respondents vibration was the modality best suited for transmission of these information. Also electric stimulation and pressure were found to be appropriate while visual and acoustic information was clearly rejected by the majority of respondents.

Phantom phenomena. 51% of respondents were affected by phantom pain and its frequency had a slight tendency to decrease on average. Stump pain was experienced by 51% but maintained a constant frequency over time. Both kinds of pain were experienced only seldom or sometimes by over 70% of affected respondents and caused only light restriction in professional live and recreational activities in over 75% of them. 64% of all respondents could feel their phantom arm and most of them could also move those parts of the phantom limb which they could feel.

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SATISFACTION OF PROSTHESIS USERS WITH ELECTRICAL HAND PROSTHESES AND THEIR SUGGESTED IMPROVEMENTS

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Abstract: *To obtain input for future development of myoelectric upper extremity prostheses that meet users' needs better, the presented survey asked them about their satisfaction with and suggested improvements of their current prosthesis. Analysis of 108 responses has shown that 80% of respondents were satisfied with their current prosthesis. Highest satisfaction for a single feature of the prosthesis was present for donning & doffing and the prosthetic hand itself, while satisfaction was lowest with wearing comfort and weight of the prosthesis. Improvements that were most often suggested referred to the cosmetic glove, hand & fingers and the socket. Satisfaction with the prosthesis during different activities was highest for driving a car, interaction with others and grasping of objects and lowest for manual work, drinking from a glass and eating with cutlery.*

Keywords: *Survey, upper extremity, amputee, myoelectric prostheses, satisfaction, improvements*

Introduction

By evaluating the satisfaction of prosthesis users with current prostheses and collecting their suggestions for future prostheses, user surveys provide an important input for development of prostheses.
Previous surveys evaluated satisfaction of users with their prosthesis [1],[2] and with their ability to perform different activities with their prosthesis [1],[3]. Also the design priorities and suggestions for developments of future prostheses were investigated [2]-[5]. The presented survey aimed at repeating these measurements for current myoelectric prostheses while establishing a detailed picture of satisfaction with different features of the prosthesis and prosthesis performance during different activities of daily living (ADLs).
Results of this survey related to sensory feedback were already presented [6] and are not part of this article.

Methods

The part of the survey presented in the following asked participants about their satisfaction with and improvement of current prosthesis. Inclusion criterion was use of myoelectric upper limb prosthesis.
All 108 questionnaires that met the inclusion criterion were included into statistical analysis. Responses are presented in stacked bar diagrams showing percentage of respondents who have chosen each level. The question wording is given in the caption and the legend shows response scales, from 0 (not satisfied at all) to 3 (absolutely satisfied), that were presented to the participants with the corresponding numeric value for each level. If applicable, these numeric values were averaged over all responses for each item and shown on the right side of each graph. These mean values were used for ranking of items.

Results

Respondents had a mean age of 43 (±17) years and more than three quarter of them (77%) were male. Only 31% of the respondents had a congenital absence of the upper limb. The vast majority of amputations (91%) were carried out due to trauma and only 7% of respondents underwent bilateral amputation. Most respondents were amputated at the forearm (60%) and the upper arm (14%). Joint exarticulations were less frequent and performed at the wrist (13%), at the shoulder (7%) and at the elbow joint (5%).
Overall satisfaction: When asked to give their overall satisfaction with their prosthesis the majority of 59% is rather satisfied and 21% of respondents are absolutely satisfied with their current myoelectric prosthesis. Average satisfaction is 1.96 (±0.75) corresponding to an individual score of rather satisfied.
Satisfaction with prosthesis' features: More detailed information about the satisfaction with different features of the prosthesis is presented in Figure 1. The highest average satisfaction is found for donning and doffing of the prosthesis, followed by the opening and closing of the hand. Average satisfaction for the most features is in the range between 2.0 and 1.9. Less satisfaction is only present for wearing comfort and the weight which is the feature with least satisfaction. Average satisfaction with different features of the prosthesis is 1.98 (±0.59).

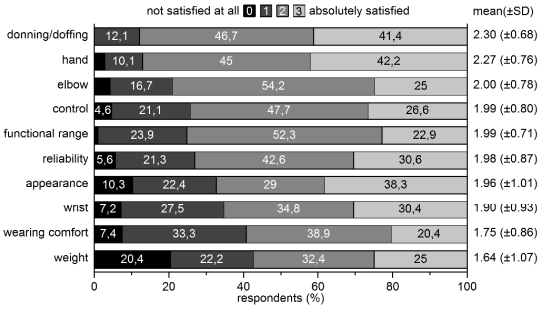

Figure 1: Satisfaction with different features of myoelectric prostheses. "*How satisfied are you with the following features of your prosthesis?*"

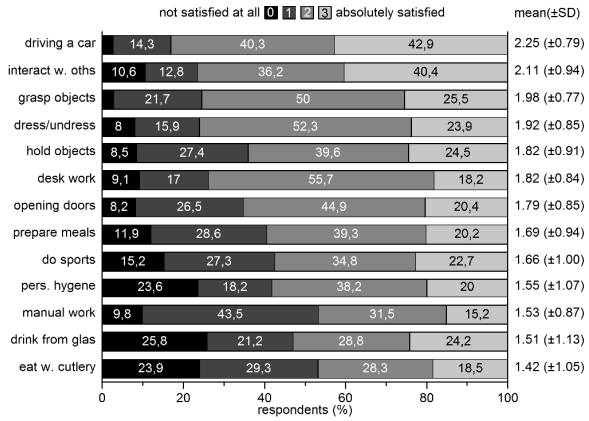

Figure 2: Satisfaction with myoelectric prostheses during different ADLs. "*How satisfied are you with your prosthesis when carrying out the following activities?*"

Satisfaction during activities: Satisfaction of respondents with the prosthesis during different activities is presented in Figure 2. The highest average satisfaction with prosthesis performance is present for driving a car and contact with others. During these activities over 40% of respondents are totally satisfied with their prosthesis. Average satisfaction between 1.98 and 1.51 is present for most of other activities. Only for eating with cutlery respondents are rather not satisfied than satisfied in average. Satisfaction with the prosthesis averaged over all investigated activities is 1.77 (±0.67). This is significantly lower than the overall satisfaction ($p<0.01$) and the average satisfaction with different features of the prosthesis ($p<0.001$).

When asked to give the three activities in which prosthesis use is most important to them, 27% of respondents name manual work, 23% eating with cutlery and 21% grasping of objects. Evaluation of activities for which prosthesis are not used showed that 48% of respondents do not use their prosthesis for personal hygiene, 39% do not drink from a glass and 37% do not use their myoelectric prosthesis for doing sports. 28% do not drive a car with the help of their prosthesis and 22% prepare meals without utilizing their prosthesis. On the other hand, 98% of respondents actively use the prosthetic hand for grasping and holding objects.

Suggested improvements: Table 2 summarizes the wishes and ideas of respondents when asked how their prosthesis could be improved. When evaluating the particular suggestions respondents most often asked for improvements of the cosmetic glove (n=51) making it less sensitive to dirt, easier to clean, more durable and giving it a more natural look. Second most often addressed were the prosthetic hand and its fingers (n=47) mainly wishing for independent movement of single fingers and a relaxed position of the hand when not in use. The socket was addressed 36 times, demanding less sweating and a slim design. Improvements of the wrist were suggested 22 times asking for enhanced movability. A reduction of the weight is mentioned by 19 respondents, 12 respondents demand a more reliable grasping and 9 ask for provision of sensory feedback by their prosthesis.

Table 1: Suggested improvements.

Category	Times Suggested	Often Mentioned
Cosmetic glove	51	Less sensitive to dirt, better to clean, more natural look, durability
Hand & Fingers	47	Ability to move separate fingers, relaxed position of the hand
Socket	36	Reduce sweating, slim design
Control	26	Improved control of movement, less prone to interference
Wrist	22	Rotation, flexion, extension, ulnar/radial deviation
Weight	19	lighter
Grasping	12	Reliability, gasping small objects
Sensory Feedback	9	Information about grip force and position.

Discussion

This study reveals that 80% of respondents are rather or absolutely satisfied with their current myoelectric prosthesis in general while satisfaction with the prosthesis during different ADLs is significantly lower.

Improvements respondents suggested most often were related to the cosmetic glove. This might be addressed by providing interchangeable gloves suited for different activities, e.g. durable ones for manual work and more natural looking ones for social interaction. Another approach for improvement would be accepting the convenient process of donning and doffing to become more difficult which might give room for development of sockets that lead to more wearing comfort and less sweating.

Acknowledgement

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User demands for sensory feedback in upper extremity prostheses

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Abstract—**This paper presents the results of 108 responses to a survey asking users of electrical upper limb prostheses about sensory feedback. The survey aimed to identify whether sensory feedback was of interest to users, which kinds of information were important and what feedback modality would be suited for transfer of information. Moreover the situations in which sensory feedback would be most useful should be identified. To answer these questions we designed a survey which was sent by mail and was also available online. 88% of respondents placed different degree of importance on obtaining sensory feedback from their prosthesis. Grip force was most important followed by proprioceptive information. First contact during grasping and end of contact during release of an object was also of interest to respondents. Vibration, pressure and electrical stimulation were identified as appropriate means for transmission of sensory information from the prosthesis to the amputee, based on their acceptance and sensitivity at the residual limb. These findings allow conclusions for further development on what information has to be measured by feedback prostheses and how this information can be transmitted to the amputee. Investigation of perceptions respondents apply to control their current electrical prosthesis reveals that observation, listening and sensations at the residual limb are used and applied to gain certain information about the prosthesis. This could be the basis for a training of prosthesis users aiming at prosthesis control with less visual attention.**

Keywords-upper extremity prostheses; sensory feedback; porsthesis control; user survey;

I. INTRODUCTION

User surveys provide essential input for research and development in prosthetics by identification of satisfaction of amputees with different aspects of their prostheses and requirements towards improved prostheses. Previous surveys focused on prosthesis satisfaction and resulting use or abandonment [1]-[4]. Besides this some surveys [5]-[7] also asked respondents about their ideas how their current prosthesis could be improved and their whishes towards enhanced prostheses.

Even though none of the previous user surveys focused on the amputees' need for sensory information, several hints were found that sensory feedback could enhance prosthesis control. Atkins [5] reports that users want to control their prostheses with less visual attention. Biddis [6] describes that users of electrical prostheses are not satisfied with the feedback their prostheses provide during control and Pylatiuk [3] observed that most prosthesis users whish for information about grip force and temperature.

In the present study a user survey is designed to investigate the need for sensory feedback in more detail to deduct requirements for research in and development of future feedback prosthesis that meet amputees' needs.

II. MATERIALS AND METHODS

A survey was designed that was composed of 42 questions structured into the four parts satisfaction with current prosthesis, demands for sensory feedback, phantom phenomena and general data on participants, including information about their amputation and prosthesis use. Inclusion criterion was the use of an electric upper limb prosthesis. In this paper we report only on the results related to sensory feedback.

At first prosthesis users were asked which sensory information they employ to gain information about their current electrical prosthesis during use and how they apply this information during prosthesis control. In the following participants were asked of what importance different kinds of sensory information are to them and which are the three most important kinds of information. Subsequently the importance of sensory information during different activities of daily living (ADLs) is surveyed also asking for the three ADLs in which receiving sensory information would be most important. Thereafter it is investigated how the transmission of sensory information could be realized. Amputees were asked about the sensitivity of their residual limb to pressure, temperature and vibration, followed by a question about their acceptance of different feedback modalities. The closing question is asking participants to rate the overall importance of sensory feedback to them.

The attitude of respondents towards different statements was measured with four-level, unipolar interval scales. Scales were only labeled at their end points to support the perception of equidistance intervals between levels and allow interpretation of resulting data as interval scaled. Associated questions were grouped to matrices with identical response scales. Open ended questions were used when closed questions could not account for the variety of individual conditions and attitudes. They were also used to allow the respondents to introduce new ideas and topics without the constraints of

closed questions. The question wording is designed for easy comprehension and accounts for the fact that respondents might have no insight into the technology behind their prosthesis and had no experiences with sensory feedback systems.

A. Pretest

Because of constrains of the small group and limited accessibility of prosthesis users pretesting of the survey was based on qualitative laboratory techniques. Single questions were evaluated by subject matter experts, according to [8]. The complete questionnaire was then evaluated in an expert review like proposed in [9] and revised by a social scientist experienced in surveys. Finally the questionnaire was filled out by three prosthesis users applying Concurrent Think Aloud, Follow-Up-Probing and some debriefing questions like described in [10,11].

B. Distribution

For the mailed survey 400 stamped but unaddressed envelopes containing a covering letter, the questionnaire and a stamped self-addressed envelope were sent to 17 orthopedic technicians in Germany. The orthopedic technicians then forwarded the survey to patients that were using electric upper limb prosthesis. An online survey was established that was consistent with the questionnaire. The link to this questionnaire was mailed to orthopedic technicians in Austria and Norway who forwarded it to patients fulfilling the inclusion criteria.

C. Statistical Analysis

All questionnaires that met the inclusion criteria were included into statistical analysis that was carried out using SPSS [IBM]. Since not all questions were answered by all respondents pairwise deletion was applied for each statistical test. Only non-parametric tests were applied because normal distribution was not given for most variables. Differences in independent samples were compared applying the Mann-Whitney-U-Test and the Kruskal-Wallis-H-Test for two and more variables, respectively. Two dependent samples were compared applying Wilcoxon-Tests and more dependent samples were compared with Freidman-Test. Answers to open questions were evaluated according to [13]. Responses to attitude questions are presented in stacked bar diagrams showing percentage of ratings for each level. The legend above each graph shows response scales that were presented to the participants with the corresponding value of each level. For each item ratings of all respondents are averaged and shown on the right side of each graph. These mean values are used for ranking of items.

III. RESULTS

A. Sample Description

Of the 400 questionnaires sent out 105 were returned of which 101 met the inclusion criterion. This corresponds to a response rate of 25%. The online survey was visited 120 times and 32 visitors proceeded from the welcome page to the first page containing questions. Nine surveys were completed of which seven surveys fulfilled the inclusion criterion.

Respondents had an age between 6 and 79 years with a mean of 43 (±17) years. More than three quarter of the respondents (77%) were male and only 23% were female. Only 31% of the respondents had a congenital absence of the upper limb. Amputations of the others (69%) were carried out from the first year of living till an age of 65 years with a mean of 30 (±16) years. Average time since (first) amputation was 19 (±15) years.

The vast majority of amputations (91%) were carried out due to trauma. Unilateral amputations made up the most (93%) amputations, only 7% of respondents underwent bilateral amputation. During amputation 55% of respondents lost their dominant hand. Most respondents were amputated at the forearm (60%) and the upper arm (14%). Joint exarticulations were less frequent and performed at the wrist (13%), at the shoulder (7%) and at the elbow joint (5%).

B. Current Use of Sensory Information

To investigate the status quo, respondents were asked two questions about their use of perceptions during control their current prosthesis. The first question was asking which perceptions they use to gain information about their current electric prosthesis during operation. As shown in Tab. 1 (*Use of perception*) over three-quarter of the respondents were visually observing their prosthesis, two-thirds were using the sounds emitted by their prosthesis and 57% used sensations at the residual limb to gain information about their prosthesis during use. Most respondents (41%) used two perceptions in parallel. Three and only one perceptions were used by 27% and 26% of respondents, respectively. Only 6% of respondents selected none of the perceptions presented in the question.

In the second question participants were asked to describe their use of these perceptions in a free text. The utilization of the different perceptions for distinct actions is presented in Tab. 1 (*Application in control*). Corresponding to the results of the previous question observation of the prosthesis is the most frequently mentioned source for information about the prosthesis. It is mainly applied for coordination of grasping and gaining information about position and movement of the prosthesis. Second frequently used is the sound of the prosthesis. It is utilized to hear if the prosthesis is moving, how fast it is moving and which joint is moving. During grasping the sound is used to gain information about the grip force. Sensations at the residual limb are mentioned less frequently and are mainly applied during holding objects. Respondents feel the weight of an object held and if it starts to slip.

TABLE I. USE OF DIFFERENT PERCEPTIONS FOR CONTROL OF CURRENT ELECTRICAL PROSTHESES

Perception	**Use of percep-tion**	**Application in control**			
		Grasp	***Hold***	***Proprio-ception***	***Sum***
Visual observation	77%	15	2	18	35
Listening	67%	7	1	14	22
Sensations at residual limb	57%	1	12	1	14

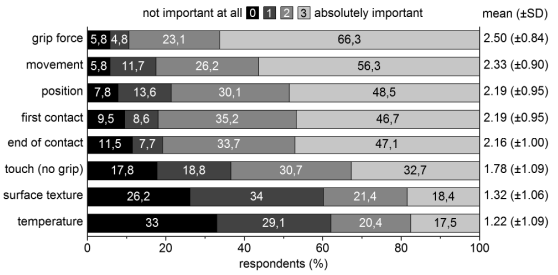

Figure 1. Importance of sensory information: "How important would being able to feel the following sensations with your prosthesis be to you?"

C. Sensory Feedback

When asked for the overall importance of receiving sensory feedback from their prosthesis 45% of respondents rate sensory feedback as *absolutely important*, 43% attached medium importance to sensory feedback by choosing one of the two middle categories and only 12% stated it was *not important at all*.

When asked to rate the importance of different kinds of sensory information grip force has the highest mean importance and is *absolutely important* for two third of the respondents. Proprioceptive information about movement and position of the prosthesis has second and third highest mean importance, respectively. Perception of the first contact during grasping and the end of contact when releasing an object follow. Fig. 1 shows that considerable lower mean importance is attached to information about objects touched.

After rating the level of importance respondents were asked to name the three kinds of sensory information that are most important to them in a free text. 98% of the various statements could be categorized into the three categories *grasp and hold*, *touch* and *proprioception*. Summarized over the three priority levels sensory information about grasp is named most often and information about touch and proprioception were named considerably less, as shown in Tab. 2. More than half of the respondents rated information about grasping and holding of objects as most important. Proprioceptive information and information about touched objects were second and third often named as highest priority. For the second priority information about grasp and hold are named less frequently while touch and proprioception are given more often. For the third priority all three categories achieve approximately one third of nominations.

TABLE II. CATEGORIES OF SENSORY INFORMATION MOST IMPORTANT TO RESPONDENTS

Category of sensory information	Sum of nominations	1st priority	2nd priority	3rd priority
Grasp and hold	108	59%	46%	35%
Touch	60	17%	29%	32%
Proprioception	57	22%	23%	31%

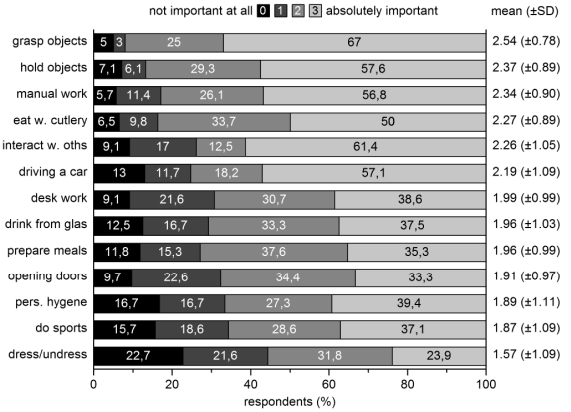

Figure 2. Importance of sensory feedback during ADLs: "How important would it be to you to percive sensations from your prosthesis during the following activities?"

Fig. 2 shows how important sensory feedback is to users of electrical prostheses during different activities. The two activities having the highest mean importance are *grasping objects* and *holding objects*. Also the next activities, *manual work* and *eating with cutlery* are closely related to grasping and holding objects.

D. Sensitivity at the Residual Limb

The self assessed sensitivity at the residual limb to pressure, vibration and temperature stimuli is presented in Fig. 3. Highest sensitivity was reported for pressure closely followed by vibration. Sensitivity to temperature changes is lowest. Important to note is the fact that nearly every fifth respondent reports not to feel any temperature difference at his or her residual limb at all. Respondents with congenital absence of a limb were significantly ($p=0.02$) more sensitive to temperature at their residual limb (2.31 ±1.06) compared to respondent who underwent amputation (1.86 ±1.15). In average women report significantly ($p<0.04$) higher sensitivity to pressure (f:2.58 ±0.58, m:2.15 ±0.99), temperature (f:2.54 ±0.83, m:1.83 ±1.18) and vibration (f:2.67 ±0.57, m:2.10 ±1.05) at their residual limb.

When asked for their preference in regard to different feedback modalities, information transmitted by surfaces that are changing their temperature have the highest mean acceptance followed by vibration, electric stimulation and pressure, see Fig. 4. Considerably lower acceptance is achieved by visual and acoustic representation of sensory information. Noteworthy is that the smallest fraction of rejections is present in vibrational feedback and the majority of respondents explicitly rejects acoustic and visual feedback.

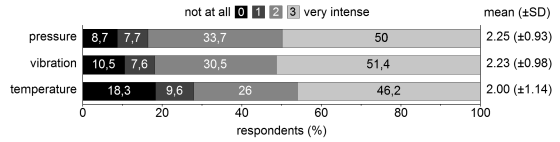

Figure 3. Sensitivity at the residual limb: "How intense do you feel the following sensations with your residual limb?"

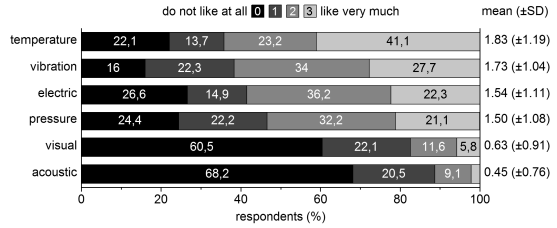

Figure 4. Acceptance of different feedback modalities: "How would you like to have the sensations transfered by your prosthesis?"

When asked to summarize the overall importance of sensory feedback to them on a scale from 0 (*not important at all*) to 3 (*absolutely important*) respondents gave an average rating of 2.06 (±1.05). Sensory feedback had a significantly (p=0.01) higher relevance to prosthesis users with a congenital absence of the upper limb (2.41 ±0.88) compared to those who underwent amputation (1.89 ±1.09). Respondents whose residual limb ended at the forearm attach a significant (p=0.01) higher overall importance to sensory feedback (2.22 ±0.99) than participants whose residual limb ended at the upper arm (1.50 ±1.16).

IV. DISCUSSION

The investigation of the use of perceptions during control of current electric prosthesis led to the same three perceptions also found by Silcox [3]. Closer investigation in this study provided new insight into how often these perceptions were used and what information they provide. Raising the awareness of sounds emitted by the prosthesis and sensations at the residual limb as sources for information, combined with practicing their application in prosthesis control might achieve better control requiring less visual attention for prosthesis users with their current prosthesis.

The high importance of obtaining sensory feedback is in accordance to Atkins [5] who ranked it third most important improvement and Biddis [6] who found it to be the fourth highest design priority for electric prosthesis users. The percentage of respondents who attach importance to information about grip force (94%) and temperature of an object touched (67%) is in good agreement to Pylatiuk [3] who found that these information were wanted by 91% and 61% of respondents, respectively. Differences may be caused by the different response scales. Some of the respondents answering *not important* to a yes or no question may give a low degree of importance on a four level scale. The ranking of the importance of sensory information provides a basis for choosing the kinds of information that need to be measured by the prosthesis.

Temperature was the most favored modality for transmission of sensory information. Taking into account the low sensitivity to temperature changes at the residual limb, the slow change rate and high energy consumption of pettier elements, thermal actuation is not a viable way to transmit sensory information. Modalities well suited for provision of sensory information are vibrations, electric stimulation and pressure. All of these three modalities have already been used for feedback systems in prostheses. Vibrational feedback is especially interesting for application because application in consumer electronics like cell phones and game controllers led to development of miniaturized, energy efficient and low cost actuators.

With 108 responses from electric prosthesis users the presented survey provides a broad basis for statistical analysis. It should be taken into account that the sample might be biased in two ways. Orthopedic technicians chose to which surveys they forwarded the survey. Some of them reported to chose more active and open-minded users, others selected patients who attend their workshops more often. Furthermore self-selection of respondents might lead to participants that are over-average interested in the topic. Due to these influences it is difficult to assess how well the findings describe the population as whole.

Further analysis of the data collected in the survey will focus on different aspects like users' satisfaction with their current prostheses, their suggestions on improvements of their current prostheses as well as phantom sensations and phantom pain.

ACKNOWLEDGMENT

The authors thank all participating orthopedic technicians for the distribution of the survey, all respondent for the time they took to thoroughly fill out the questionnaire and Claudia Hildenbrand for valuable advice and support during survey design.

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3.2 Implantable measurement system for prosthesis control

Some of the users' needs, especially those related to improved control of electrical upper limb prostheses, were addressed by development of the implantable EMG measurement system. In the following, results from evaluation of the system are presented. General outcomes of the animal trials, are described in section 3.2.1. Findings from evaluation of polyimide and silicone electrodes are presented in section 3.2.2 and section 3.2.3, respectively. Finally, the outcomes related to the implantable EMG measurement system are summed up in section 3.2.4.

3.2.1 Process of the *in vivo* evaluation

1st primate experiment. Implantation of the first polyimide electrode of the first design (see page 30) in the first primate experiments (see page 39) went as planned. Though, during forming of the subepimysial tunnel for the second electrode the epimysium ruptured over the whole length of the tunnel. During subsequent fixation of the electrode on the muscle without the epimysium for keeping it in place, the surgeon realized that there should be an additional suture hole at the tip of the polyimide carrier. After fixation of electrodes the elbow was flexed to quantify the electrode movements in relation to the surrounding tissue during arm movements. This movement was estimated to be in the range of 2 mm to 3 mm. Intra-operative opening and sealing of the silicone bags around the Craggs connectors (see figure 2.8 on page 31) was possible but storing them under the skin was difficult, since they were quite large for the thin arm of the monkey.

During the second surgery Craggs connectors were easily discovered and found to be covered with a thin layer of connective tissue. The leads were led through the skin, the incision was closed and impedance as well as EMG measurements during stimulated contractions of the biceps were carried out. After the surgery the monkey was dressed in the long-sleeve shirt made for protection of the connectors and put into his cage for recovery. Nonetheless, during the wake up period the primate explanted parts of the electrodes by pulling at the connectors sticking out of his arm. Strain reliefs sutured around the holes in the skin through which cables were led prevented larger damages to the skin and closed resulting wounds. Since there was no medical indication for a second operation all parts of the electrodes that were not explanted by the monkey were left in place to prevent introduction of additional trauma. After explantation it was not possible anymore to carry out any of the initially planned measurements.

2nd primate experiment. During implantation of polyimide electrodes of the second design (see page 31) in the second primate experiment (see page 42) it was possible to form the subepimysial tunnel for the first electrode as planned. During forming the tunnel for the second electrode the epimysium ruptured again. Precaution to not damage the epimysium during forming the third tunnel resulted in penetration of the superficial muscle fibers, resulting in a rather intramuscular than subepimysial position of the electrode. By intraoperative impedance measurements a break of one electrode was identified after tunneling, which turned out to be caused by a cut in the cable resulting from the process of tunneling. This electrode was subsequently replaced. Fixation of the connector housing at the monkeys head went well but the sealing of the base, where the cables entered the housing, was difficult. During sealing the base of the housing was not entirely dry. This resulted in body fluid entering the housing every now and then over the ten weeks of implantation.

Approximately eight weeks after implantation signs of inflammation became visible in regions where the cables ran closely below the skin. These inflammation probably originated from the

connector housing and propagated along the cables. Medication with antibiotics was an effective treatment to cure these inflammations.

After the EMG measurements indicated connection problems also for the last polyimide electrode of the second design ten weeks after implantation, all electrodes were explanted. Since a fragment of one electrode started to penetrate the skin of the monkey, the explantation surgery was performed the next day. Due to this short time frame no further impedance measurements were carried out during explantation.

After electrodes have been exposed during explantation surgery, it could be seen that the polyimide carrier of all electrodes was broken close to the ceramic adapter plate. Further examination showed that the carriers themselves were broken into fragments. Without introducing additional trauma only about half of the polyimide carrier of one electrode could be explanted for further examination. For explantation of the electrode cables, the connectors were removed from the connector housing at the head and cables were retracted by pulling at their electrode ends. All explanted components were then sent to the Fraunhofer IBMT for further investigation.

Findings about polyimide electrodes, the process of their encapsulation and analysis of muscle activity measured during the second primate experiment were in [Lewis et al., 2010] (see Pub.3 on page107), [Lewis et al., 2011], [Lewis et al., 2012b] (see Pub.5 on page 123) and [Lewis et al., 2013b] (see Pub.6 on page 127).

3rd primate experiment. The elongation of the polyimide carrier in the third design of the polyimide electrodes (see page 32) for the third primate experiment (see page 44) made it necessary to form longer tunnels between fascia and superficial muscle fibers. This made the tunneling procedure even more challenging. When connecting the electrodes to the central implant at the monkey's back, it turned out that the cables were too long. Excessive cables were subcutaneously stored in loops at the back of the monkey.

During surgery after implantation was completed, the primate was temporarily placed in a sitting position in which contact to the central implant was successfully established. If the primate was laying on the operation table the telemetry was disturbed by its metal components and no measurements of voluntary EMG during the wake up period could be carried out. Over the whole period of implantation it was repeatedly tried to establish a reliable connection to the implanted system. Nonetheless, it was not possible to measure EMG during the reaching task.

Since the implanted system did not function as planed, the entire system was explanted nine weeks after implantation. During explantation of electrodes it was observed that they were not fixated at their tips anymore and retracted in the subepimysial tunnels. Polyimide carriers were still intact but folded in a zig-zag pattern. Explanted electrodes were sent to the Fraunhofer IBMT and the central implant to the TUHH for further analysis.

Rat experiment. Implantation of silicone electrodes (see page 35) during rats experiments (see page 45) was easier compared to implantation of polyimide electrodes in primates, manly for two reasons. The first was related to forming the subepimysial tunnel. It was easier to separate the epimysium from the superficial muscle fibers and the epimysium was mechanically more durable compared to the primates. This resulted in no rupture of the epimysium in any of the 48 implantations. The second reason was application of the adapted implantation procedure (see page 36). Just like planned, one small incision was sufficient for accessing the muscle and forming the subcutaneous tunnel. The stiffer electrodes were easily inserted into the tunnel through this incision and only one suture around the cable was sufficient to fix the electrode in place and close the subepimysial tunnel. Subcutaneous tunneling of cables over the relatively short distance between *gluteus superficialis* and the neck of the rats was easily performed with

an arterial clamp.

Over the eight to twelve weeks of implantation, irritations were observed in the neck of seven of the 24 rats, which sometimes developed to defects in the skin. In four rats a local red region at the neck indicated an ongoing inflammation which lasted up to one week and in three rats these inflammations developed to open wounds which healed over two weeks. Both kinds of observed complications were successfully treated with salves. Even though the cables were ending further toward the tail of the rats, it was expected that they introduced mechanical loads during head movements that damaged the skin over time.

During explantation surgery, carried out eight or twelve weeks after implantation, all electrodes and cables were covered by a layer of connective tissue that provided secure positioning. No signs of tissue damage or inflammation were visible. All electrodes and cables were mechanically intact and electrodes were still positioned at the *gluteus superficialis*. One electrode was turned 90° around its long axis and visual inspection indicated that a thicker capsule of connective tissue was formed around it. Electrodes were explanted and underwent closer visual inspection in the following.

1st sheep experiment. During implantation in the first sheep experiment (see page 47) the implantation procedure for silicone electrodes (see page 36) could not be followed entirely. Since surgeons were not familiar with the anatomy of sheep, larger incisions had to be made to be able to identify target muscles. Nonetheless, electrodes were placed and fixed as planned. The tunneling tool worked very well and made subcutaneous tunneling of the cables over the large distance between electrodes and the back of the sheep easy. Forming the subcutaneous tunnel during insertion of the tool as well as insertion of cables in this tunnel during retraction of the tool worked as planned. A few days after implantation a swelling in the region were the ends of the cables were stored was observed in one sheep. This decayed over several days without any intervention.

During surgery after twelve weeks, it was possible to measure the impedance of all implanted electrodes. Subsequent measurements of EMG during reflexive movements did not yield any reproducible contractions. The first sheep was randomly contracting the muscles of the forelimb as soon as it was extended. This might have been caused by a too weak narcosis. The second sheep did not show proper retraction reflexes and only very short and weak contractions were elicited. Therefore results of these measurements are not reported in the following.

Findings about developed silicone electrodes, their implantation procedure and their encapsulation, gained in the rat experiment, were published in [Lewis et al., 2013a] (see Pub.4 on page 110).

2nd sheep experiment. During second implantation in sheep (see page 48) surgeons were more familiar with the sheep anatomy resulting in smaller incisions for electrode implantation. All electrodes were positioned on target muscles and good contact was approved by impedance measurements. Cables were easily tunneled with the surgeon tool and the central implant was placed in subcutaneous pocket at the back of the sheep. Intraoperative plugging and sealing of connectors between electrodes and central implant was performed successfully. No complications after implantation were observed in any of the two sheep.

For measurements three weeks after implantation, all external components were mounted on the custom made saddle. In this setup it was not possible to establish a connection to the implant. During the following attempts the primary coil was manually positioned directly above the central implant. This allowed for sufficiently supplying the central implant with energy, establishment of a stable data connection and measurement of EMG signals. Investigation of

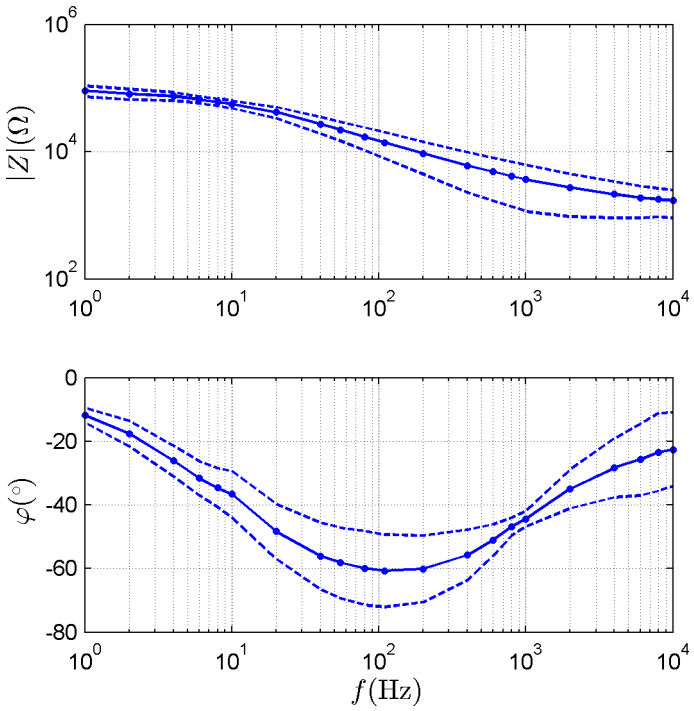


Figure 3.13: *In vitro* impedance of a polyimide electrode of the first design (see page 30) with smooth contacts having a surface area of 1 mm^2. Mean value averaged over all ten bipolar combinations of the five electrode contacts. Dashed lines denote the standard deviation.

the influence of relative movement between primary and secondary coil showed that the primary could be lifted off the skin for about 10 mm but even small relative movement in the plane of the coils interrupted the connection to the implant immediately. Since movements of the forelimb of the head of the sheep led to relative movements between central implant and the primary coil when mounted to the saddle, the primary coil had to be manually positioned and held in place for all measurements. This did not allow for planned measurements during unconstrained walking of sheep. Though, all EMG signals reported in section 3.3.7 originate from less dynamic movements sheep performed in a corner they were standing in as soon as someone entered their stable.

3.2.2 Polyimide electrodes

The polyimide electrodes analyzed in the following were provided by the Fraunhofer IBMT and were already introduced in chapter 2.2.5. Their evaluation and redesign were part of the present work and published in [Lewis et al., 2010] (see Pub.3 on page107). Differences between the three different types of electrodes are shown in figure 2.7 summarized in table 2.2 on page 30.

In vitro evaluation

The in vitro impedance of a polyimide electrode of the first design (see page 30) is shown in the Bode diagram in figure 3.13. The magnitude of the impedance at 1 Hz was 90.7 kΩ and steadily decreased to 1.7 kΩ at 10 kHz. Also the corresponding standard deviation between measurements of all possible combinations of contacts decreased steadily from 17.8 kΩ at 1 Hz to 797 Ω at 10 kHz. The electrode introduced a phase shift of −12° at 1 Hz which increased with

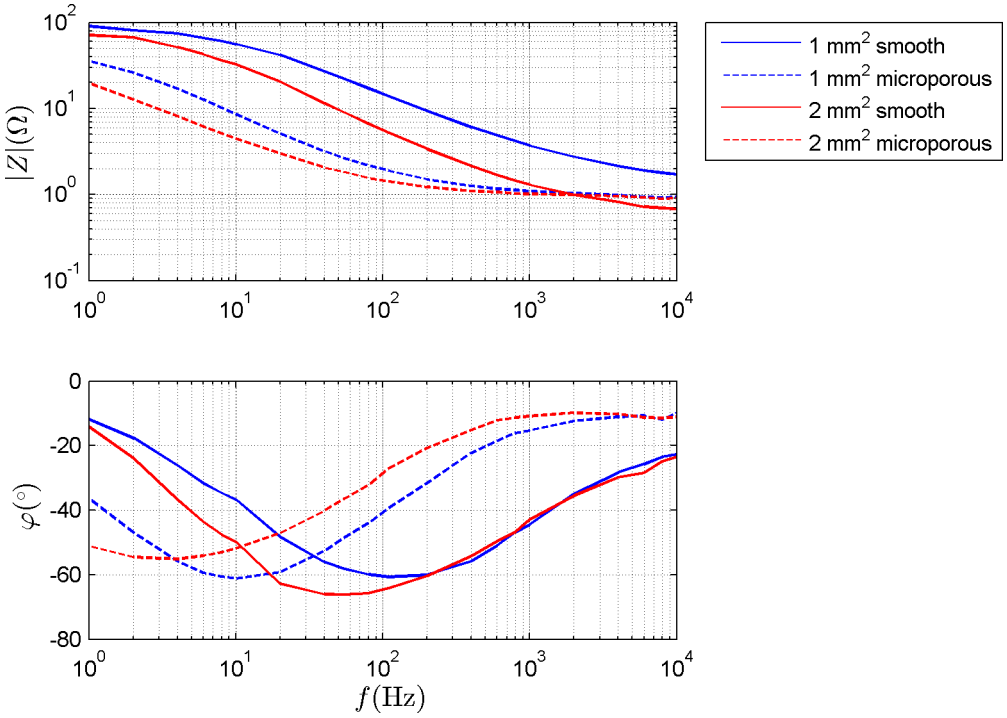


Figure 3.14: *In vitro* impedance of polyimide electrodes of the first design (see page 30) with contacts of 1 mm^2 (blue) and 2 mm^2 (red) surface area and a smooth (solid) and microporous (dashed) surface structure.

increasing frequency to a maximum of −61° at 100 Hz. For higher frequencies the phase shift decreased again to −22° at 10 kHz. The smallest standard deviation of 2° was present at 1 Hz and 1 kHz and the largest of 12° at 80 Hz and 8 kHz. A characteristic that applies to all polyimide electrode designs investigated in the following is the decrease in magnitude of impedance with increasing frequency. Subsequently electrodes with differently sized surface areas and different surface structure were measured to quantify the effects of these modifications. Results of these measurements are presented in figure 3.14.

Surface area. Doubling the surface area of electrode contacts, and thereby increasing the contact area between electrode and electrolyte, led to a reduction of the magnitude of the impedance. For electrode contacts having a smooth surface this reduction had a larger influence on the magnitude at high frequencies. At low frequencies up to 2 Hz the magnitude of the impedance was reduced by 20%. This reduction increased to 50% at 20 Hz towards a maximum reduction of 66% at 600 Hz. For microporous electrode contacts, increasing the surface area had a smaller effect on the magnitude of the impedance. In contrast to smooth electrode contacts the influence was more pronounced for lower frequencies. Below 10 Hz the magnitude of the impedance was reduced by about 50%. This effect became weaker with increasing frequencies and fell below 10% for frequencies above 500 Hz.

The effect of increased surface area on the phase shift varied between smooth and microporous electrode contacts. Phase shift was increased for smooth electrode contacts for frequencies up to 200 Hz. This increase was highest in the frequency range from 4 Hz to 40 Hz where the phase shift was 10° to 15° larger. For frequencies above 200 Hz the phase shift stayed nearly constant. For electrodes with microporous contact surfaces, doubling the surface area led to a decrease of the phase shift for frequencies from 4 Hz to 5 kHz. A decrease of over 10° was present in the

Table 3.6: Circuit element properties of an $R_E - R_F||C_H$ circuit (see page 52) when fitted to the *in vitro* impedance of polyimide electrode contacts with different surface areas and surface structures.

surface		excess resistance		Faraday resistance		Helmholtz capacity		quality of fit
structure	area	R_E	error	R_F	error	C_H	error	RSS
smooth	1 mm²	2.1 kΩ	9.2%	69.4 kΩ	8.3%	97.5 nF	8.4%	7.80
	2 mm²	0.8 kΩ	8.6%	58.3 kΩ	9.2%	292.1 nF	7.2%	6.76
micro-	1 mm²	1.1 kΩ	5.1%	34.1 kΩ	10.7%	1.7 µF	6.5%	7.06
porous	2 mm²	1.1 kΩ	5.3%	20.5 kΩ	13.7%	3.8 µF	8.1%	12.55

frequency range from 10 Hz to 200 Hz.

The circuit element properties resulting from fitting the impedance of the $R_E - R_F||C_H$ equivalent circuit to the impedance of the 1 mm² and 2 mm² electrodes are given in table 3.6. For smooth contact surfaces, both resistances were reduced by increasing the surface area. The excess resistance R_E of the electrolyte was reduced from 2.1 kΩ to 0.8 kΩ and the Faraday resistance R_F was reduced from 69.4 kΩ to 58.3 kΩ. At the same time the Helmholtz capacity C_H was nearly tripled from 97.5 nF to 292.1 nF. For the microporous contact surfaces the excess resistance stayed unchanged while the Faraday resistance decreased from 34.1 kΩ to 20.5 kΩ and the Helmholtz capacity was increased from 1.7 µF to 3.8 µF.

Surface structure. Microporous coating of electrode surfaces of polyimide electrodes of the second design (see page 31) led to a reduction of magnitude of impedance for both surface areas over nearly the whole frequency range (also seeS Pub.3 on page107). This effect was more dominant for low frequencies and had a higher influence on contacts with smaller surface area. For electrodes with a contact area of 1 mm² the amplitude of the impedance decreased by over 50% in a frequency range from 1 Hz to 6 kHz. The maximum reduction of 88% was present at 40 Hz. The impedance of 2 mm² electrode contacts was reduced by at least 50% for frequencies up to 400 Hz. In the frequency range from 400 Hz to 2 kHz the magnitude was reduced by less than 50% and even slightly increased for frequencies above 2 kHz. The maximum reduction of 86% was observed at 40 Hz.

The phase shift introduced by electrodes with microporously coated contacts was increased for low frequencies and reduced for high frequencies when compared to electrodes with smooth contacts. For contacts with a surface area of 1 mm² the phase shift was increased up to a frequency of 30 Hz with a maximum of 30° at 4 Hz. At higher frequencies the phase shift was reduced by up to 34° at 400 Hz. For the larger contact surfaces of 2 mm², microporous coating had a larger effect on the phase shift. It was increased for frequencies up to 10 Hz with a maximum of 37° at 1 Hz. Reduction at higher frequencies was largest at 200 Hz where the phase shift was reduced by 40°.

The circuit element properties of the $R_E - R_F||C_H$ equivalent circuit presented in table 3.6 show that the microporous coating had an inconsistent effect on the excess resistance of the two sizes of electrode contacts. For electrodes with 1 mm² contacts the excess resistance was reduced from 2.1 kΩ to 1.1 kΩ while it was increased from 0.8 kΩ to 1.1 kΩ for 2 mm² contacts. In contrast to smooth electrode contacts the impedance of microporous contacts stayed constant for both contact sizes. Microporous coating considerably reduced the Faraday resistance, by one half for the 1 mm² and even two-thirds for the 2 mm² contacts. Coating had the largest effect

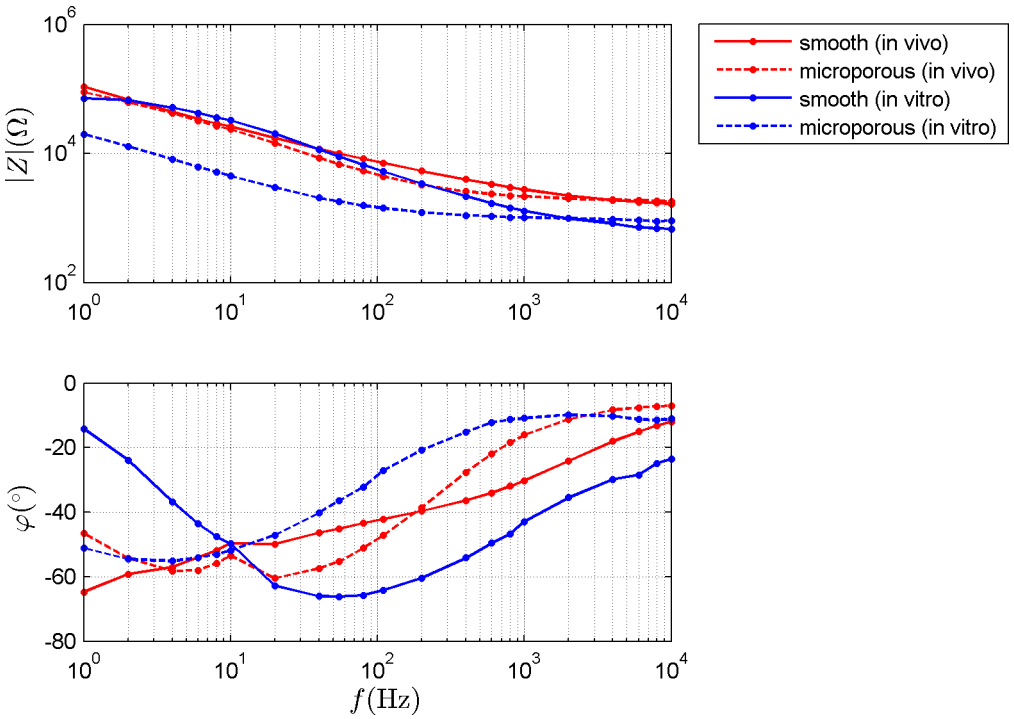


Figure 3.15: *In vivo* impedance of polyimide electrodes of the first design (see page 30, A =2 mm^2) with smooth (solid) and microporous (dashed) contact surfaces measured *in vitro* (blue) and directly after implantation (red).

on the Helmholtz capacity. The capacity was seventeen times as high after coating for 1 mm^2 contacts and twelve times as high for 2 mm^2 electrodes.

Summary of *in vitro* evaluation of polyimide electrodes. Microporous coating had the largest effect on reducing the electrode impedance. Its influence was more dominant at lower frequencies which resulted in electrodes reaching constant impedance values at lower frequencies. The largest effect of microporous coating on the equivalent circuit was the increase of Helmholtz capacity. Increasing the surface area had lower effect on impedance reduction. For smooth contact surfaces it was more dominant at higher frequencies but had only small effect on the impedance of mircoporous contacts.

In vivo evaluation

For evaluation of their *in vivo* impedance three polyimide electrodes of the second design (see page 31) with 2 mm^2 contacts were implanted during the second primate experiment (see page 42) and impedance was measured over the first eight weeks after implantation.

Surface structure. Of the three implanted electrodes (see figure 2.17b on page 43), *electrode 2* and *electrode 3* had smooth contact surfaces while the contacts of *electrode 1* had a microporous surface structure. Figure 3.15 shows the average impedance of the two electrodes with smooth contact surfaces and that of the one with microporous contact surface structure. In addition the *in vitro* impedances of the same electrode types are shown for comparison.

Magnitude of *in vivo* impedance of smooth electrodes steadily decreased with frequency and ranged form 108.5 kΩ at 1 Hz to 1.7 kΩ at 10 kHz. Microporous coating decreased the magnitude

Table 3.7: Circuit element properties of an $R_E - R_F||C_H$ circuit (see page 52) when fitted to the impedance of polyimide electrode contacts with smooth and microporous surface structures *in vitro* and directly after implantation.

surface		excess resistance		Faraday resistance		Helmholtz capacity		quality of fit
structure	condition	R_E	error	R_F	error	C_H	error	RSS
smooth	*in vitro*	0.8 kΩ	8.6%	58.3 kΩ	9.2%	292.1 nF	7.2%	6.76
	in vivo	2.4 kΩ	12.5%	84.2 kΩ	20.1%	423.3 nF	8.4%	29.93
micro-	*in vitro*	1.1 kΩ	5.3%	20.5 kΩ	13.7%	3.8 µF	8.1%	12.55
porous	*in vivo*	2.1 kΩ	6.2%	68.1 kΩ	12.0%	576.9 nF	7.1%	8.42

of the *in vivo* impedance for frequencies up to 3 kHz. The achieved reduction was 18% at 1 Hz. It decreased with increasing frequencies up to 4% at 4 Hz. The reduction became larger for higher frequencies until it reached its maximum of 39% at 200 Hz. The reduction became smaller for increasing frequencies and impedance was even increased for frequencies above 4 kHz with a maximum of 9% at 10 kHz. The *in vivo* magnitude of electrodes with both, smooth and microporous contact surfaces, is similar to the *in vitro* impedance of smooth surfaces up to 100 Hz. For higher frequencies it reached a constant level of around 1.7 kΩ which was 1 kΩ higher when compared to the *in vitro* impedance. The effect of microporous coating of contact surfaces was not as pronounced as *in vitro*.

The phase shift introduced by smooth electrodes *in vivo* ranged from −65° at 1 Hz to −12° at 10 kHz. Microporous coating lead to a decrease in phase shift for frequencies below 4 Hz and frequencies above 200 Hz. Maximum decrease in phase shift for low frequencies was 18° at 1 Hz and 14° at 1 kHz for high frequencies. For frequencies between 4 Hz and 200 Hz the phase shift was increased by microporous coating by a maximum of 11° at 40 Hz. The phase shift introduced by electrodes of both kinds was similar to that of microporous electrodes *in vitro* for frequencies up to 10 Hz. Above 10 Hz the *in vivo* phase shift of both electrode types laid well between *in vitro* phase shift of smooth and microporous electrodes.

The circuit element properties of the $R_E - R_F||C_H$ equivalent circuit with impedances corresponding to electrodes with smooth and microporous contact surfaces are presented in table 3.7. For both contact surface structures excess resistance and the Faraday resistance increased while the Helmholtz capacity was reduced after implantation. This effect was more dominant for the electrode with microporous contact surfaces. This led to smaller differences in the circuit element properties of electrodes with smooth and microporous surfaces *in vivo* when compared to those corresponding to their *in vitro* impedance.

A comparison of the *in vivo* impedance of electrodes with smooth and microporous contact surface structures over time after implantation was not possible due to issues described in the following for the single electrodes.

Impedance over time after implantation. Development of the impedance of smooth electrodes over time after implantation was measured during the second primate experiment (see page 42) and is exemplified by the impedance of *electrode 2* (see figure 2.17b on page 43) shown in figure 3.16 and was published in [Lewis et al., 2010] (see Pub.3 on page107). As already described above and shown in figure 3.15, impedance of the smooth electrode just after implantation was similar compared to the impedance measured *in vitro*, but had a higher magnitude at high frequencies. The phase shift decreased nearly logarithmic to frequency.

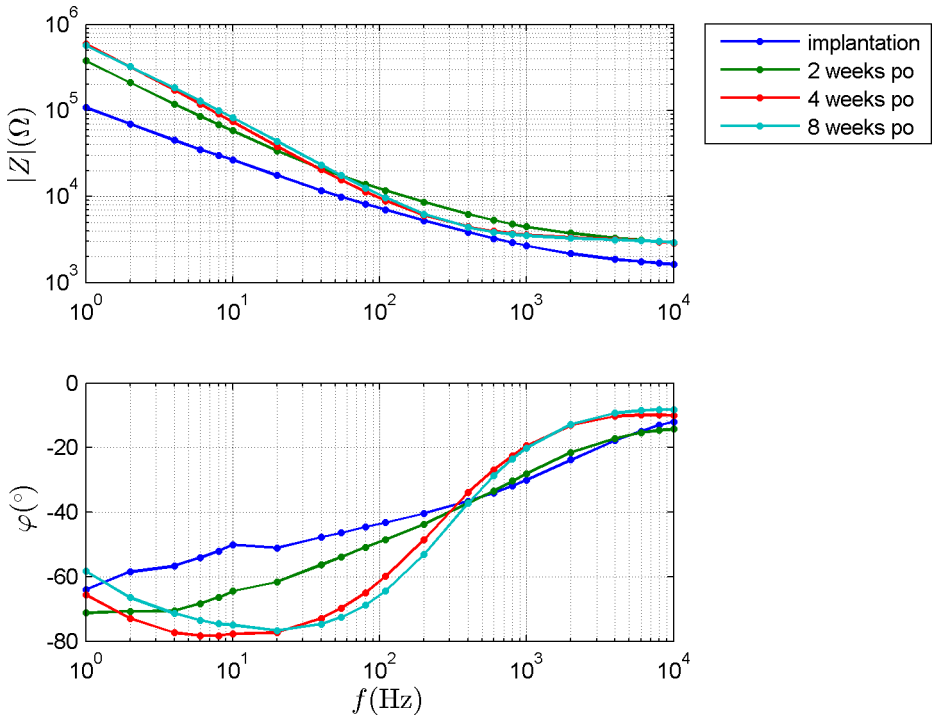


Figure 3.16: *In vivo* impedance of *electrode 2* (second design polyimide electrode (see page 31) with smooth 2 mm^2 contacts) over time after implantation in the second primate experiment (see page 42).

Two weeks after implantation, impedance increased over the whole frequency range while the graph maintained a similar course. The highest increase of 248% was present at 1 Hz. The extend of the increase diminished to a minimum of 43% at 500 Hz and in the following grew with increasing frequencies to 79% at 6 kHz. The introduced phase shift was increased for frequencies below 400 Hz and above 5 kHz by a maximum of 14° at 8 Hz. Largest decrease in phase shift between 400 Hz and 5 kHz was only 2° at 2 kHz.

Four weeks after implantation, impedance was further increased by up to 56% at 1 Hz for frequencies below 35 Hz and reduced by up to 30% at 200 Hz for higher frequencies. The course of the magnitude also had a more pronounced bend at the transition towards nearly constant magnitudes around 1 kHz. The phase shift was further increased for frequencies up to 400 Hz by up to 16° at 40 Hz and decreased for higher frequencies by up to 8° at 1 kHz. This changed the phase shift to the characteristic course that was already observed *in vitro* (figure 3.14). At low frequencies the phase shift increased until a pronounced maximum of −79° was reached at 6 Hz and subsequent decreased until a nearly constant phase shift of −10° was reached at high frequencies.

Eight weeks after implantation, there was hardly any further change in the impedance of the electrode-tissue interface. Magnitude was slightly increased with a maximum of 15% at 30 Hz and the maximum phase shift decreased to −77° and was shifted to 20 Hz.

Equivalent circuit element properties of the $R_E - R_F||C_H$ circuit resulting from fitting its impedance to those of *electrode 2* at different times after implantation is presented in table 3.8. Over the whole time the impedance was measured, the excess resistance increased moderately from 2.3 kΩ to 3.2 kΩ. The Faraday resistance increased tenfold from 85.8 kΩ to 855.3 kΩ and the Helmholtz capacity decreased by more than half from 415.2 nF to 183.8 nF. Two weeks after implantation the excess resistance nearly doubled, the Faraday resistance increased six times

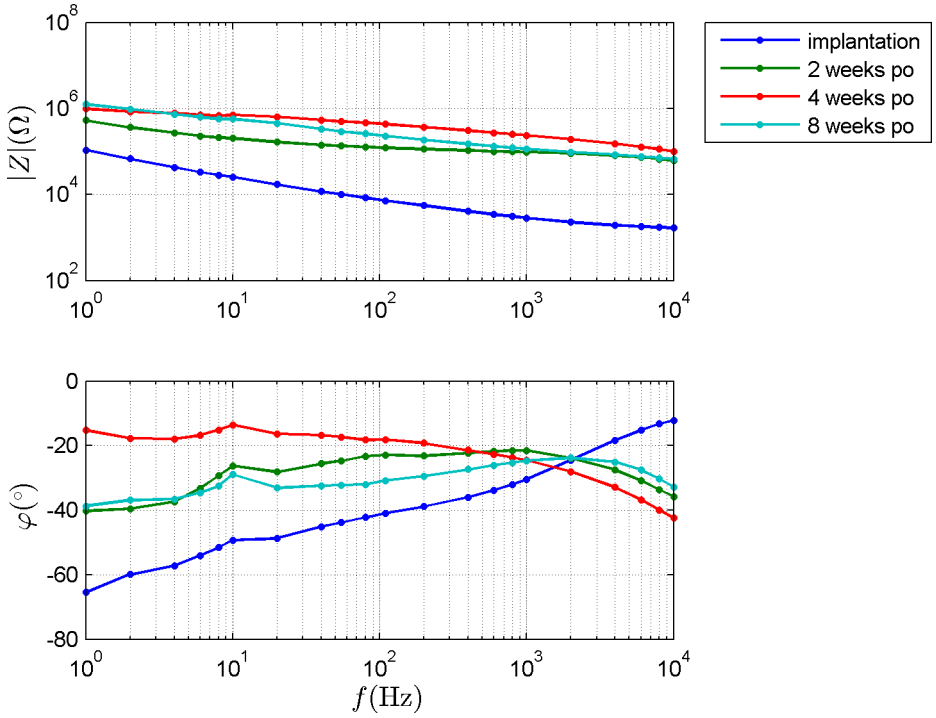


Figure 3.17: *In vivo* impedance of *electrode 3* (second design polyimide electrode (see page 31) with smooth 2 mm^2 contacts) over time after implantation in the second primate experiment (see page 42).

and the Helmholtz capacity was more than halved. Four weeks after implantation a change of tendency in the excess resistance was observed while the Faraday resistance increased and the Helmholtz capacity decreased further. Eight weeks after implantation the smallest relative changes compared to the previous measurements were observed. The excess resistance stayed nearly constant, the Faraday resistance decreased for the first time and the Helmholtz capacity decreased further.

The impedance of the *electrode 3* (see figure 2.17b on page 43), which was identically constructed as *electrode 2*, over time after implantation is presented in figure 3.17. The impedance measured directly after implantation was virtually the same as that of *electrode 2*. The largest deviations in magnitude were -5% at 6 Hz and +6% at 600 Hz. The deviation in phase shift was largest at 30 Hz where it was by 3° lower.

Two weeks after implantation there was a considerable increase in magnitude a decrease in phase shift. The magnitude was increased between 389% at 1 Hz and 4081% at 4 kHz while the phase shift was decreased by 15° to 25° in the frequency range between 1 Hz and 600 Hz and increased by up to 24° for high frequencies. A closer look at the impedances of different combinations of contacts of *electrode 3* two weeks after implantation is allowed in figure 3.18. Here it can be seen that not all electrodes were affected by the impedance changes in the same way. Contact pairs only containing the contacts E3, E4 and E5 did not have largely increased impedances while the impedance of all contact pairs containing E1 and/or E2 was considerably increased in the frequency region above 20 Hz compared to the impedance just after implantation.

Four weeks after implantation, the magnitude increased further. This increase was 88% at 1 Hz and became larger with increasing frequency until it reached its maximum of 278% at 20 Hz after which it decreased to 66% at 10 kHz. The phase shift decreased by 25° at 1 Hz. This decrease diminishes nearly logarithmic with frequency till 500 Hz. Above this phase shift

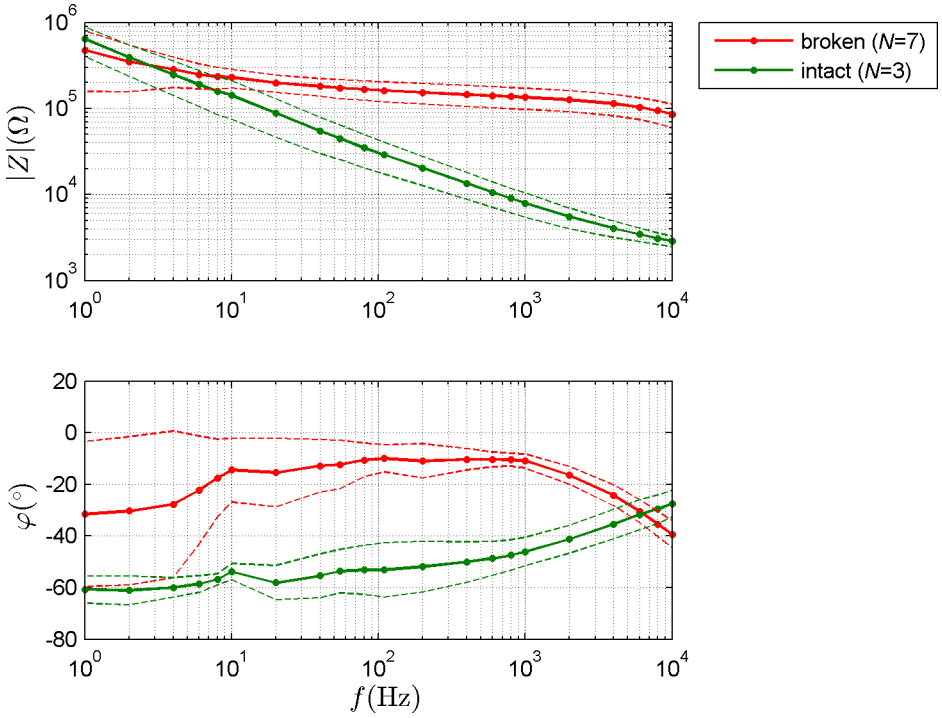


Figure 3.18: *In vivo* impedance of broken (see page 91) and intact contact pairs of *electrode 3* two weeks after implantation in the second primate experiment (see page 42). Green graphs represent the average impedances of the three combinations of contacts that only contained contacts E3, E4 and E5 and stayed intact. Red graphs represent the average impedance of the seven combinations of contacts containing E1 and/or E2 and were broken.

is increased by up to 7° at 10 kHz.

Eight weeks after implantation, the magnitude started to decrease for frequencies above 3 Hz. The maximum decrease of -52% was observed at 600 Hz. The phase shift was increased for frequencies below 1 kHz and decreased for higher frequencies.

Equivalent circuit element properties corresponding to the *in vivo* impedance of *electrode 3* over time after implantation, presented in table 3.8, show an increase in both, excess and Faraday resistance while the Helmholtz capacity was reduced. The largest changes occurred during the first two weeks after implantation. The excess resistance increased nearly forty times and the Faraday resistance five times. The Helmholtz capacity was only one third of its value during implantation. Four weeks after implantation both resistances increased further but there was a considerable decrease in Helmholtz capacity which is only a hundredth of the value it had two weeks before. Eight weeks after implantation the excess resistance started to decreased while the Faraday resistance increased further. The Helmholtz capacity increased from the low value it had four weeks before.

The impedance of *electrode 1* (see figure 2.17b on page 43) which had microporous contact surfaces is presented in figure 3.19. The differences in impedance compared to smooth electrodes are shown in figure 3.15 and were discussed before. The development of the impedance over time after implantation is similar to *electrode 3* but two weeks after implantation all combinations of contacts underwent the same increase of impedance. Therefore there were hardly any differences between two and four weeks after implantation, neither in magnitude nor in phase shift. The decrease in magnitude eight weeks after implantation was again corresponding to the changes

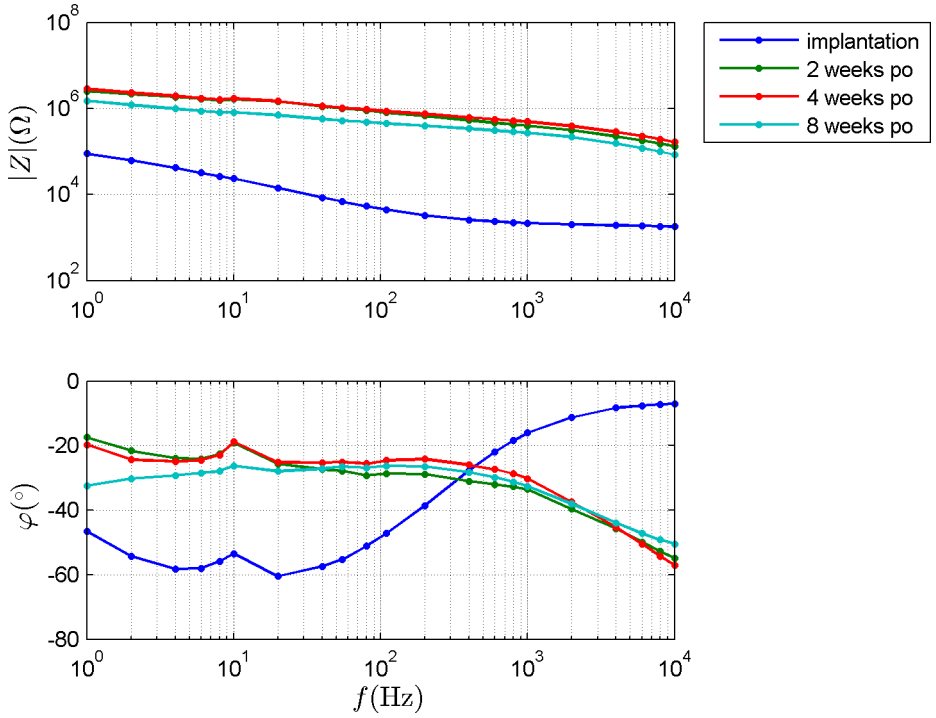


Figure 3.19: *In vivo* impedance of *electrode 1* (second design polyimide electrode (see page 31) with microporous 2 mm^2 contacts) over time after implantation in the second primate experiment (see page 42).

seen in the impedance of *electrode 3*.

The circuit element properties of the $R_E - R_F||C_H$ equivalent circuit resulting from fitting its impedance to those of *electrode 1* at different times after implantation is presented in table 3.8. The largest changes, which were even more pronounced as those observed for *electrode 3*, occurred in the first two weeks after implantation. The excess resistance multiplied by one hundred and six and the Faraday resistance by fifteen. The Helmholtz capacity was only a two thousandth of the value it had after implantation. All further changes were small compared to this development. From two to four weeks after implantation the values of all three circuit elements increased. Between week four and week eight after implantation the tendency of changes of the resistances reversed resulting in decreased excess and Faraday resistances and a further increased Helmholtz capacity.

Summary of *in vivo* evaluation of polyimide electrodes. Impedance of implanted electrodes was generally larger compared to that measured *in vitro*. Over time after implantation the impedance of the intact electrode further increased till four weeks after implantation. Afterwards only marginal changes occurred. While microporous coating of contact surfaces had the highest effect on reducing the electrode impedance *in vitro*, its influence diminished as soon as the electrodes were implanted.

Mechanical stability

Mechanical stability of the 1st design. Hardly any conclusions about the mechanical stability of polyimide electrodes of the first design (see page 30) can be drawn from their implantation during the first primate experiment. Four weeks after implantation both electrodes

Table 3.8: Circuit element properties of an $R_E - R_F||C_H$ circuit (see page 52) when fitted to the *in vivo* impedance of second design polyimide electrodes with 2 mm^2 contact surfaces over time after implantation in the second primate experiment.

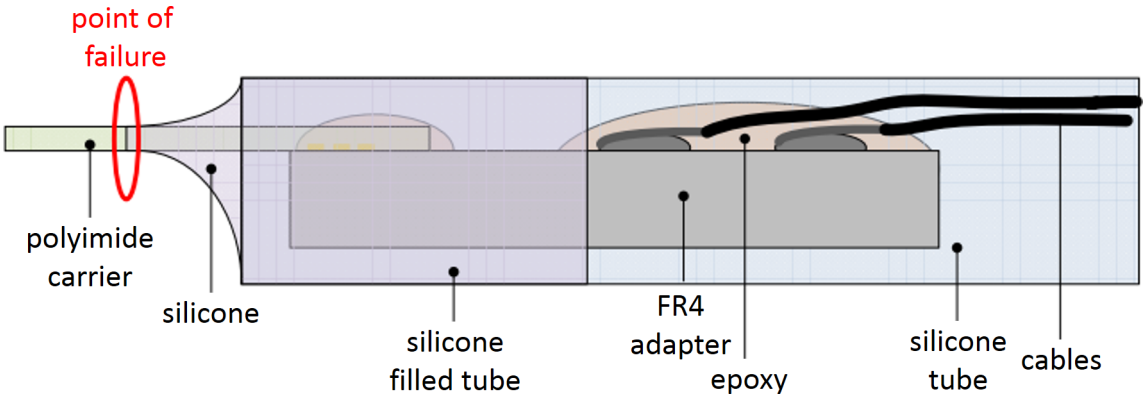
		excess resistance		Faraday resistance		Helmholtz capacity		quality of fit
electrode	time	R_E	error	R_F	error	C_H	error	RSS
electrode 1	impl.	2.1 kΩ	6.2%	86.1 kΩ	12.0%	576.9 nF	7.1%	8.42
	2 wk.	222.7 kΩ	16.3%	1.268 MΩ	12.3%	1.2 nF	22.3%	36.60
	4 wk.	366.8 kΩ	13.9%	1.319 MΩ	14.9%	2.5 nF	26.9%	46.54
	8 wk.	205.5 kΩ	14.0%	700.6 kΩ	17.2%	6.7 nF	28.5%	57.91
electrode 2	impl.	2.3 kΩ	12.2%	85.8 kΩ	19.6%	415.2 nF	13.6%	27.74
	2 wk.	4.1 kΩ	10.0%	517.1 kΩ	15.7%	233.6 nF	9.8%	20.03
	4 wk.	3.3 kΩ	3.5%	1.170 MΩ	15.1%	206.9 nF	3.2%	2.65
	8 wk.	3.2 kΩ	3.4%	855.3 kΩ	10.6%	183.8 nF	3.0%	2.19
electrode 3	impl.	2.5 kΩ	12.9%	82.8 kΩ	20.6%	432.9 nF	14.7%	32.25
	2 wk.	96.6 kΩ	8.0%	376.8 kΩ	22.0%	138.3 nF	20.0%	67.70
	4 wk.	141.5 kΩ	12.7%	490.8 kΩ	10.2%	1.6 nF	21.5%	28.72
	8 wk.	99.8 kΩ	11.0%	709.3 kΩ	14.3%	13.0 nF	17.8%	30.20

had reasonable impedance values and could be applied for the intraoperative measurement of stimulated EMG presented in section 3.3.1. This indicates that they were still intact at that time. When the primate explanted the electrodes by force, one failed in the region of the polyimide carrier where it was connected to the ceramic adapter plate and the other failed in the connection between cables and adapter plate. All parts that were not explanted by the monkey were left implanted and did not undergo further analysis.

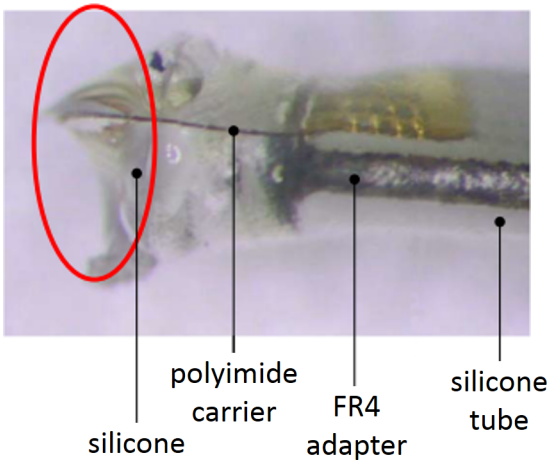
Mechanical stability of the 2nd design. Figure 3.20 shows the point of failure that was common to all electrodes of the second design (see page 31) after explantation in the second primate experiment (see page 42). It can be seen that the break did not occur directly at the transition between flexible polyimide carrier and stiff ceramics. This transition was mechanically shielded by a bit of silicone tube that extended beyond this region and was filled with silicone. The failure was located where this silicone shielding ended. Visual inspection of these fragments revealed no other failures neither in the region of the MicroFlex bonds connecting the polyimide carrier to the ceramics nor in the welding between cables and ceramics.

Electrical testing of the electrode fragments confirmed these findings. When measuring the resistance between open ends of the tracks at the point of failure and the connectors at the end of the cables all five connections had reasonably low resistances. This also supports the results of the impedance measurements. Even though the impedances increased considerably, there was still an electrical connection between the different channels of the electrodes. While a complete break in the region where the electrode was sealed would have led to a complete disconnection of the contacts, increased impedances measured could be accounted to a considerable decrease in contact surface. By the failure of the polyimide carrier the contact area to the surrounding tissue was reduced from the 2 mm^2 of the contacts surfaces to the cross section of the tracks at the point of failure.

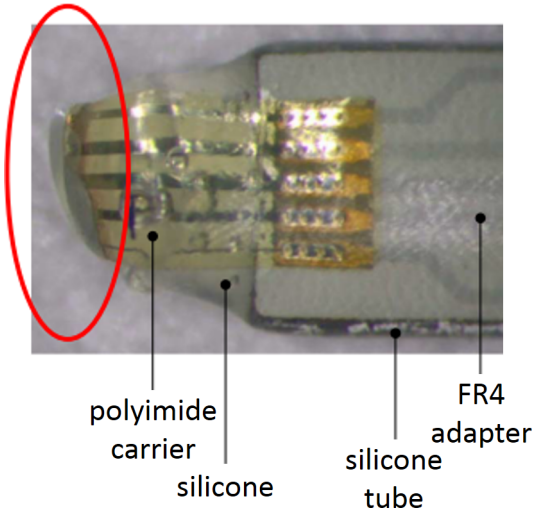
Being aware of the failure also allows further analysis of the sequence of failure of contacts



(a) schematic of the transition from polyimide carrier to cable



(b) region of failure from the side



(c) region of failure from top

Figure 3.20: Fragment of a polyimide electrode of the second design (see page 31) after ten weeks of implantation in a rhesus macaque during the second primate experiment (see page 42). Top: schematic of the components in the region of transition between cable and polyimide carrier. Bottom: Pictures of the explanted electrode (pictures provided by Fraunhofer IBMT).

observed for *electrode 3* during second implantation in the rhesus macaque (figure 3.18). Looking at the course of the platinum tracks on the polyimide carrier in figure 2.7b on page 30, it can be seen that the tracks connecting contacts E1 and E2 ran on both outer sides of the carrier at the point of failure. Electrodes E3 and E4 were connected by the tracks that were second from the sides of the carrier and contact E5 was connected by the track running in the middle. Keeping this in mind it is probable that the failure of the polyimide carrier of *electrode 3* started from both sides and continued towards the middle of the carrier. Therefore impedance between all combinations of contacts containing E1 and E2 were high already, two weeks after implantation, and all combinations of contacts that contained contacts E3, E4 and E5 only, maintained reasonably low impedances.

Mechanical stability of the 3rd design. Despite the third electrode design (see page 32) applied further adaptations to the polyimide electrodes, also the third implantation (see page

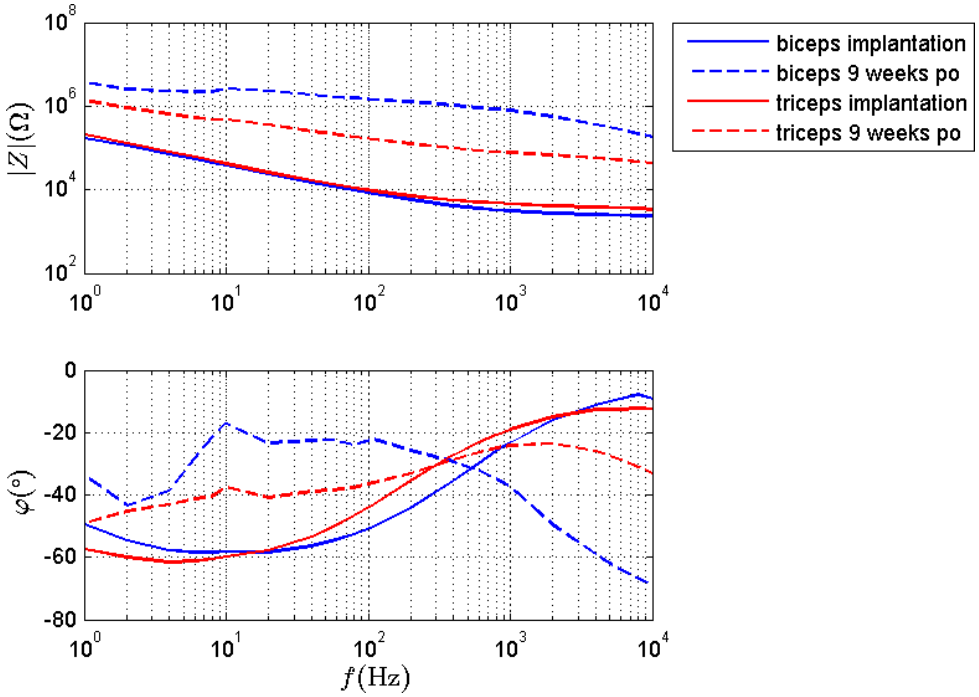
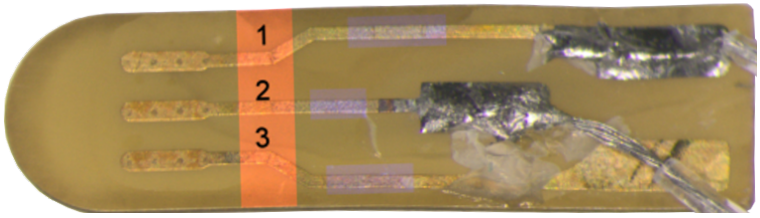


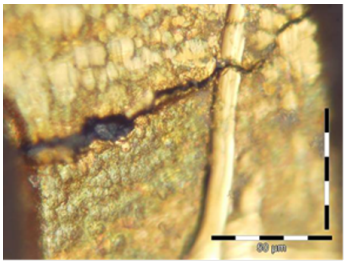
Figure 3.21: *In vivo* impedance of polyimide electrodes of the third design (see page 32): Electrodes on the *biceps brachii* (blue) and *triceps brachii* (red) were measured during implantation (solid) and explantation (dashed) after nine weeks during the third primate experiment (see page 44).

44) led to failure of all implanted electrodes. The impedance of the two electrodes on the *triceps brachii* and *triceps brachii* during implantation and explantation after nine weeks is shown in figure 3.21. The impedance of the two electrodes on the *musculus deltoideus* is not shown in the figure, since it was not possible to measure the impedance during explantation, because it exceeded the measurement range of EIMS which reached up to 1 MΩ.

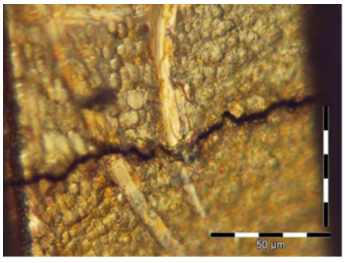
During explantation of the electrodes all of them were mechanically intact, but the polyimide carriers were folded in a zig-zag pattern. Further analysis was performed at the Fraunhofer IBMT where they were cut into three segments that were separately analyzed. The first segment included the connectors and the cables, the second the adapter plate with short pieces of cable and polyimide carrier on either side and the third segment was the remaining polyimide carrier. Electrical analysis of connectors and cables showed no increased impedance and were therefore not causing the electrode failure. The polyimide carriers showed considerable deformation caused by folding but were mechanically intact and no increase in impedance between contact surfaces and the ends of tracks at the adapter side of the carrier was measured. Analysis of the adapter plates used to connect the polyimide carriers to the cables yielded, that there was no electrical contact between the cable and polyimide carrier side. Pictures from visual inspection of the pyramid plates are shown in figure 3.22. All three tracks were broken in the region of the orange marker. Microscope images show dark gaps that span the whole width of the tracks. These failures completely interrupted the connection between cables and electrodes for the deltoid electrodes. And since these breaks were in the region that was capsuled in silicone neither tissue nor body fluid could gap these breaks.



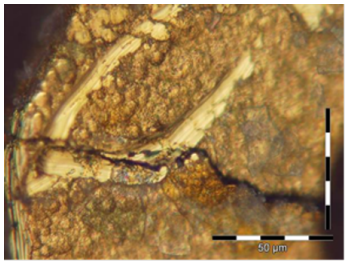
(a) Pyralux adapter



(b) broken copper-gold track (1)



(c) broken copper-gold track (2)



(d) broken copper-gold track (3)

Figure 3.22: Pyramid adapter plate of a polyimide electrode of the third design (see page 32) after nine weeks of implantation in the third primate experiment (see page 44). The upper picture shows the whole carrier with the region of the failures. Pictures in the lower row shows the magnification of the three breaks (pictures provided by Fraunhofer IBMT).

Summary of mechanical stability of polyimide electrodes

The major mechanical issue of the polyimide electrodes was the difference of mechanical properties of adjacent materials. In the second design it became obvious in the transition from polyimide carrier to the ceramic adapter plate. Increasing the thickness of the polyimide carrier and avoiding the tail at the cable side of the carrier in the third design, resulted in no breaks of the carrier when it was not firmly attached to the muscle. Anyway, the carriers of the third design retracted in the subepimysial tunnels and were folded in a zig-zag pattern. This resulted in a relocation of the contacts that were not placed at the intended position for measurement of EMG anymore. Adaptation of the material of the adapter plate to Pyralux in combination with the copper-gold tracks introduced a new weak point to the electrodes which led to breakage of all four electrodes during the *in vivo* evaluation. Since it was not possible to achieve long term stability of polyimide based electrodes during the first three iterations, the concept was no longer followed.

3.2.3 Silicone electrodes

Silicone electrodes were developed by the author in the present work, since polyimide electrodes did not achieve mechanical stability. The electrodes and their production process were already described in section 2.2.5. In the following, results from their *in vitro* and *in vivo* evaluation in rats and sheep experiments are presented.

In vitro evaluation

First impedance measurements of silicone electrodes were carried out *in vitro*. The impedance spectrum of type A electrodes (see figure 2.12a on page 36) having 3.1 mm^2 contacts made of

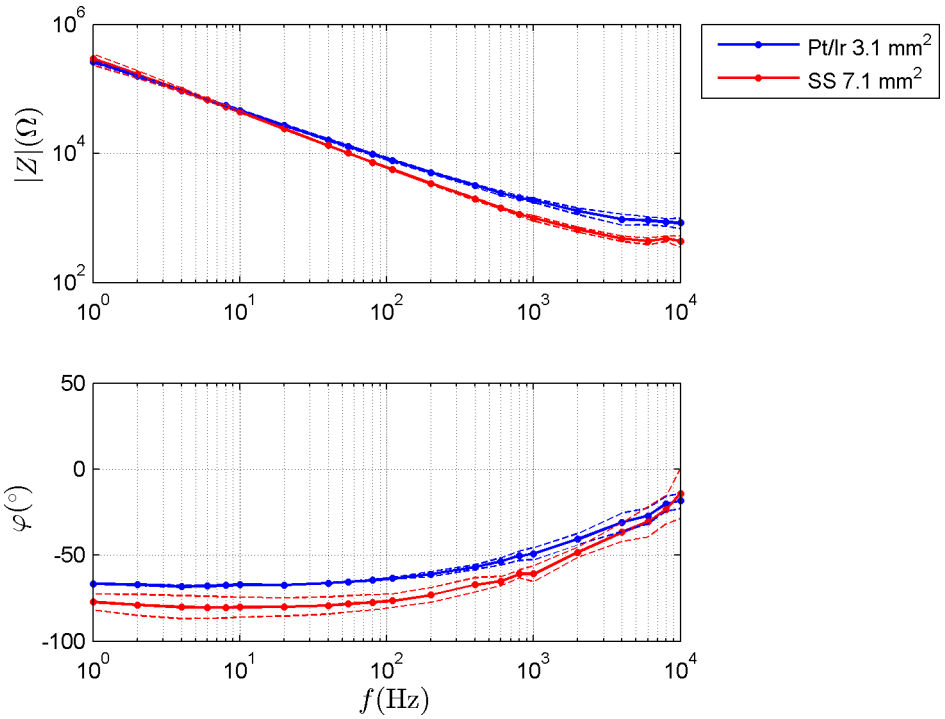


Figure 3.23: *In vitro* impedance of silicone electrodes (see figure 2.12 on page 36) with 3.1 mm^2 platinum-iridium (type A, blue) and 7.1 mm^2 stainless steel (type B, red) contact surfaces. Dashed lines indicate the standard deviation.

platinum-iridium and type B electrodes (see figure 2.12b on page 36) with stainless steel contacts of 7.1 mm^2 surface area are presented in the Bode plot in figure 3.23. The magnitude at 1 Hz was 264.6 kΩ and 293.6 kΩ for electrodes with platinum-iridium and stainless steel contacts, respectively. Both decreased with increasing frequencies up to 1 kHz where the impedance of platinum-iridium contacts was 1.3 kΩ and that of stainless steel contacts 660 Ω. Above 1 kHz both electrodes approach values that stay nearly constant for increasing frequencies. The smaller electrodes with platinum-iridium contacts reach this plateau at 840 Ω and larger stainless steel electrodes at 440 Ω.

The phase shift introduced by both electrode types had a nearly constant value at frequencies below 100 Hz. The phase shift of electrodes with platinum-iridium contacts varied in a range from −64° to −68° and that of electrodes with stainless steel contacts in the range from −76° to −80°. Above 100 Hz the phase shift introduced by both electrode types decreased. At 10 kHz the platinum-iridium contacts introduced a phase shift of −18° and the stainless steel contacts one of −14°. The standard deviation in the phase shift was higher for electrodes with stainless steel surfaces up to a frequency of 500 Hz above which they had a comparable extend.

The properties of the circuit elements of the $R_E - R_F||C_H$ equivalent circuit are presented in table 3.9. The excess resistance of electrodes with stainless steel contacts was only half as large as that of electrodes with platinum-iridium contacts. However, the Faraday resistance was lower for platinum-iridium contacts. The Helmholtz capacity of both electrodes was similar even though the platinum-iridium contacts had less than half of the contact area compared to the stainless steel contacts.

Table 3.9: Circuit element properties of an $R_E - R_F||C_H$ circuit (see page 52) when fitted to the *in vitro* impedance of silicone electrodes (see figure 2.12 on page 36) with platinum-iridium (Pt/Ir, type A) and stainless steel (SS, type B) contacts.

contact		excess resistance		Faraday resistance		Helmholtz capacity		quality of fit
material	area	R_E	error	R_F	error	C_H	error	RSS
Pt/Ir	3.1 mm^2	1.0 kΩ	13.0%	286.2 kΩ	21.8%	238.9 nF	9.8%	18.27
SS	7.1 mm^2	0.5 kΩ	9.8%	714.6 kΩ	29.1%	288.2 nF	6.0%	11.45

In vivo evaluation in rats

Electrode impedances measured directly after implantation in rats (see page 45) as well as eight and twelve weeks after implantation are presented in figures 3.24 and 3.25 for electrodes with platinum-iridium (type A) and stainless steel contacts (type B), respectively. For both electrode types the impedance spectrum just after implantation as well as eight and twelve weeks after implantation was calculated from the mean of the twelve electrodes from the eight and twelve week experimental groups.

Platinum-iridium. The impedance of the electrode with platinum-iridium contacts (see figure 2.12a on page 36) shown in figure 3.24 just after implantation had the largest magnitude of 437.5 kΩ at 1 Hz. The magnitude decreased nearly linear with increasing frequency up to 1 kHz where it reached a value of 6.0 kΩ. Above 1 kHz the decrease is slowed down and the magnitude reached its lowest value of 2.7 kΩ at 10 kHz. Eight weeks after implantation the magnitude

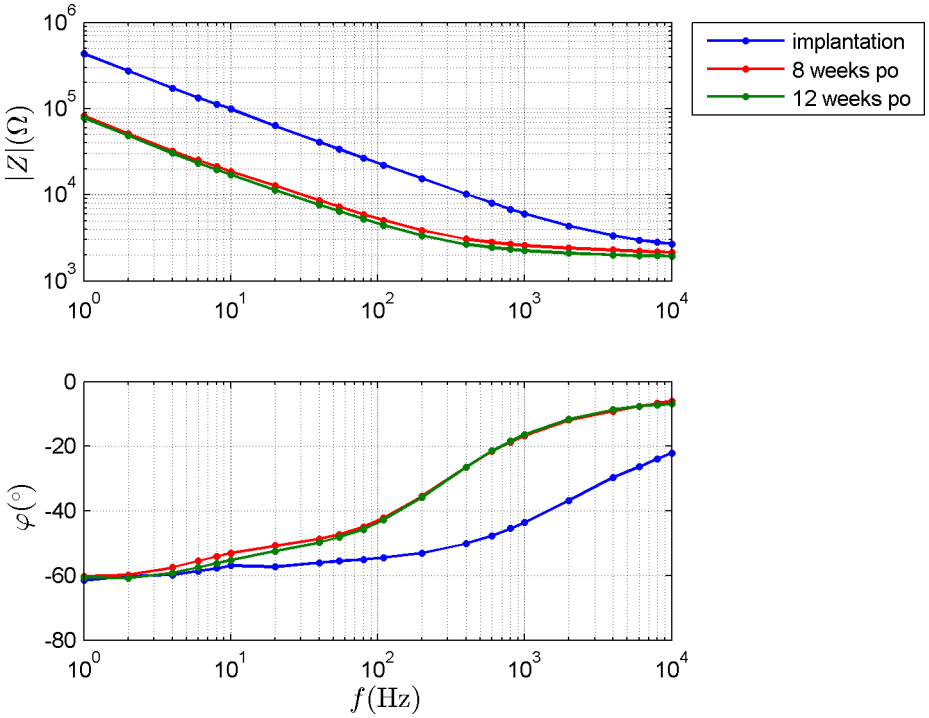


Figure 3.24: *In vivo* impedance of Pt/Ir silicone electrodes of type A (see figure 2.12a on page 36) over time of implantation in rats (see page 45).

Table 3.10: Circuit element properties of an $R_E - R_F||C_H$ circuit (see page 52) when fitted to the *in vivo* impedance of silicone electrodes that were implanted in rats for eight and twelve weeks.

contact	period	excess resistance		Faraday resistance		Helmholtz capacity		quality of fit
material	of time	R_E	error	R_F	error	C_H	error	RSS
Pt/Ir	impl.	3.7 kΩ	15.1%	325.9 kΩ	20.0%	92.9 nF	13.3%	26.15
	8 wk.	2.5 kΩ	8.2%	78.7 kΩ	16.8%	677.7 nF	10.4%	17.80
	12 wk.	2.2 kΩ	7.9%	79.2 kΩ	16.8%	755.8 nF	9.9%	16.40
SS	impl.	11.9 kΩ	13.0%	249.4 kΩ	21.0%	104.7 nF	16.1%	36.61
	8 wk.	3.6 kΩ	5.7%	108.8 kΩ	26.0%	1.7 µF	9.2%	21.04
	12 wk.	3.0 kΩ	6.2%	64.4 kΩ	20.2%	1.9 µF	9.8%	21.30

decreased over the whole frequency range. At 1 Hz the magnitude was 82.3 kHz. The frequency range in which the magnitude decreased nearly linear with frequency reached only up to 100 Hz where magnitude was 5.0 kΩ. The magnitude reached a nearly constant value for frequencies above 1 kHz resulting in a magnitude of 2.1 kΩ at 10 kHz. Twelve weeks after implantation the magnitude was slightly decreased but the course stayed very similar. At 1 Hz the magnitude was 78.6 kΩ and decreased to 2.0 kΩ at 10 kHz.

The phase shift introduced by the electrodes with platinum-iridium contacts was decreasing with increasing frequencies over the whole frequency range for all measurements. Just after implantation the phase shift ranged from −61° at 1 Hz to −22° at 10 kHz. Eight and twelve weeks after implantation the introduced phase shift was virtually identical. Similar to measurements after implantation it was −60° at 1 Hz but decreased faster with increasing frequencies. The largest difference was 2° at 1 kHz. At 10 kHz the phase shift decreased to −6° and −7° at 8 and 12 weeks after implantation, respectively.

Circuit element properties of the $R_E - R_F||C_H$ equivalent circuit, presented in table 3.10, show that the excess resistance decreased by one third and the Faraday resistance by two thirds during the first eight weeks after implantation. From eight to twelve weeks after implantation there were only minor changes in the circuit element properties. The excess resistance further decreased by 12% and the Helmholtz capacity further increases by 12% while the Faraday resistance stayed virtually the same.

Stainless steel. Impedance of silicone electrodes with stainless steel contacts (see figure 2.12b on page 36) presented in figure 3.25 just after implantation had a magnitude which decreased steadily with increasing frequency from 326.5 kΩ at 1 Hz to 6.8 kΩ at 10 kHz. Eight weeks after implantation the course of the magnitude changed. A region of steady decrease between 1 Hz and 10 Hz was followed by a transition towards a region of nearly constant magnitude values that began at 1 kHz. The magnitude of 54.6 kΩ at 1 Hz decreased to 3.0 kΩ at 10 kHz. Twelve weeks after implantation the course of the magnitude stayed similar though the impedance of 47.5 kHz at 1 Hz and that of 2.3 kΩ at 10 kHz were lower compared to the values measured four weeks before.

Just like the magnitude also the phase shift introduced by the electrodes with stainless steel surface decreased over the whole frequency rage for all measurements. Just after implantation phase shift was −64° at 1 Hz and decreased to −21° at 10 kHz. Eight weeks after implantation the phase shift increased to −73° at 1 Hz but became smaller compared to the measurements

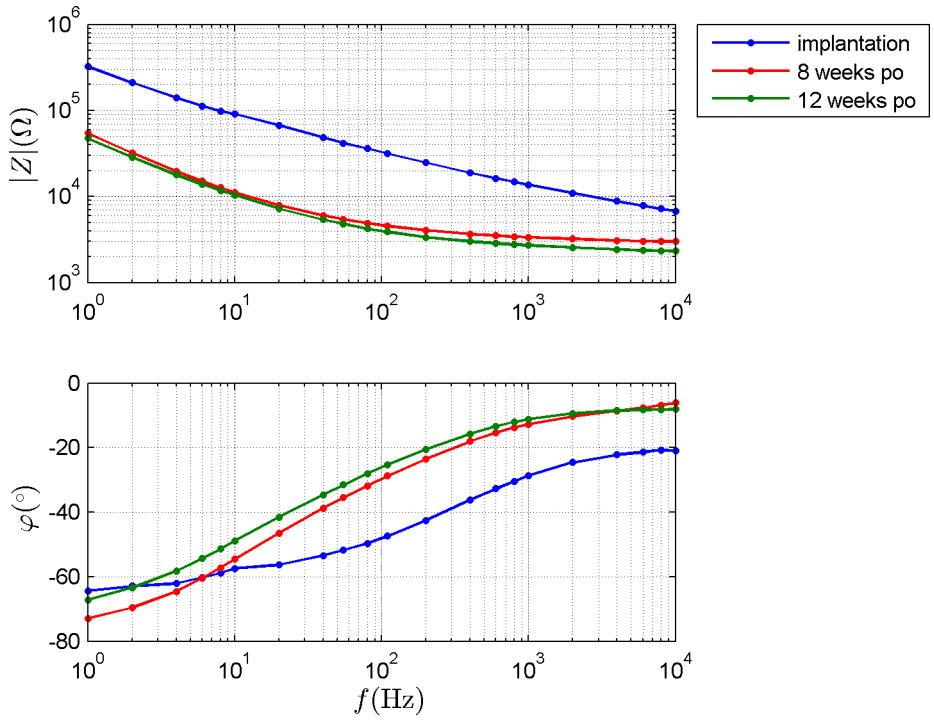


Figure 3.25: *In vivo* impedance of stainless steel silicone electrode of type B (see figure 2.12b on page 36) over time of implantation in rats (see page 45).

during implantation above 6 Hz. At 10 kHz it decreased to −6°. Over the following four weeks magnitude decreased further for frequencies up to 4 kHz. At 1 Hz it decreased to −67° while it increased to −8° at 10 kHz.

The circuit element properties presented in table 3.10 show that both resistances decreased steadily while the capacity steadily increased over time after implantation. The largest changes happened in the first eight weeks after implantation. The excess resistance decreased by over two thirds and the Faraday resistance was reduced by 56%. In the same time the Helmholtz capacity increased sixteen fold. From eight to twelve weeks after implantation the excess resistance decreased by 17% and the Farady resistance decreased by 26%. The Helmholtz capacity further increased by 12%.

For comparison of the long term properties of implanted silicone electrodes with platinum-iridium an stainless steel contacts their impedance was compared at twelve weeks after implantation (figure 3.26). When looking at the magnitude it can be seen that electrodes with stainless steel contacts had the lower impedance at low frequencies. This region ranges from 1 Hz to 200 Hz and the largest difference was 39% at 1 Hz. Above 200 Hz the stainless steel electrodes had up to 1% higher magnitudes. The standard deviation between all single measurements of all electrodes was considerably higher for stainless steel electrodes. The phase shift introduced by electrodes with stainless steel contacts was lower in the frequency rang between 4 Hz and 4 kHz. The maximum difference of 18° was observed at 80 Hz. When comparing their circuit element properties (table 3.10) it turns out that electrodes with the smaller platinum-iridium contacts had a lower excess resistance but larger ones with stainless steel contacts had the lower Faraday resistance and the higher Helmholtz capacity.

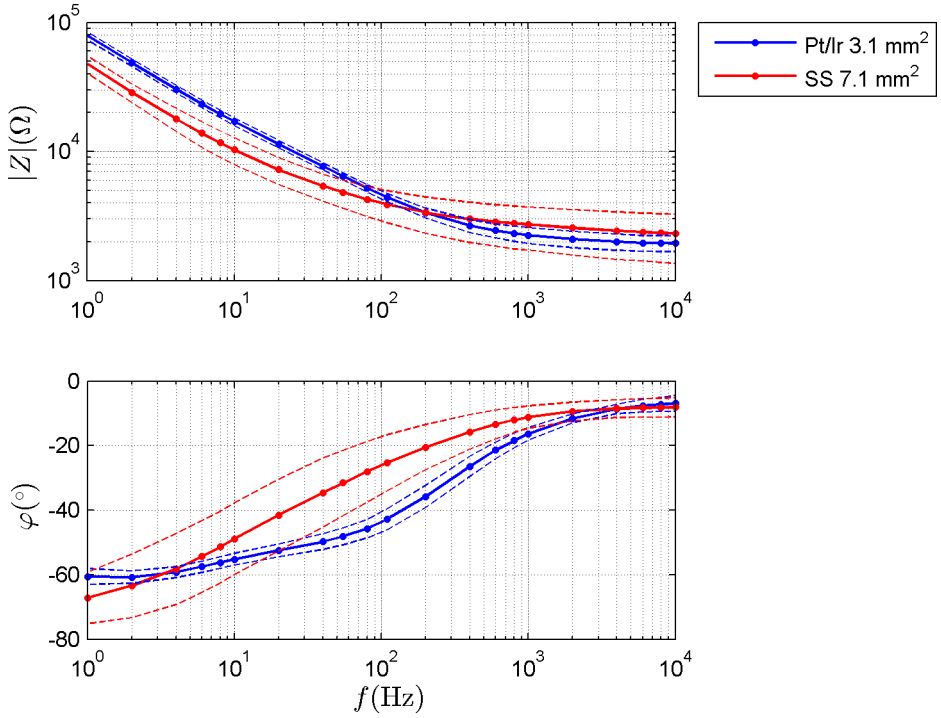
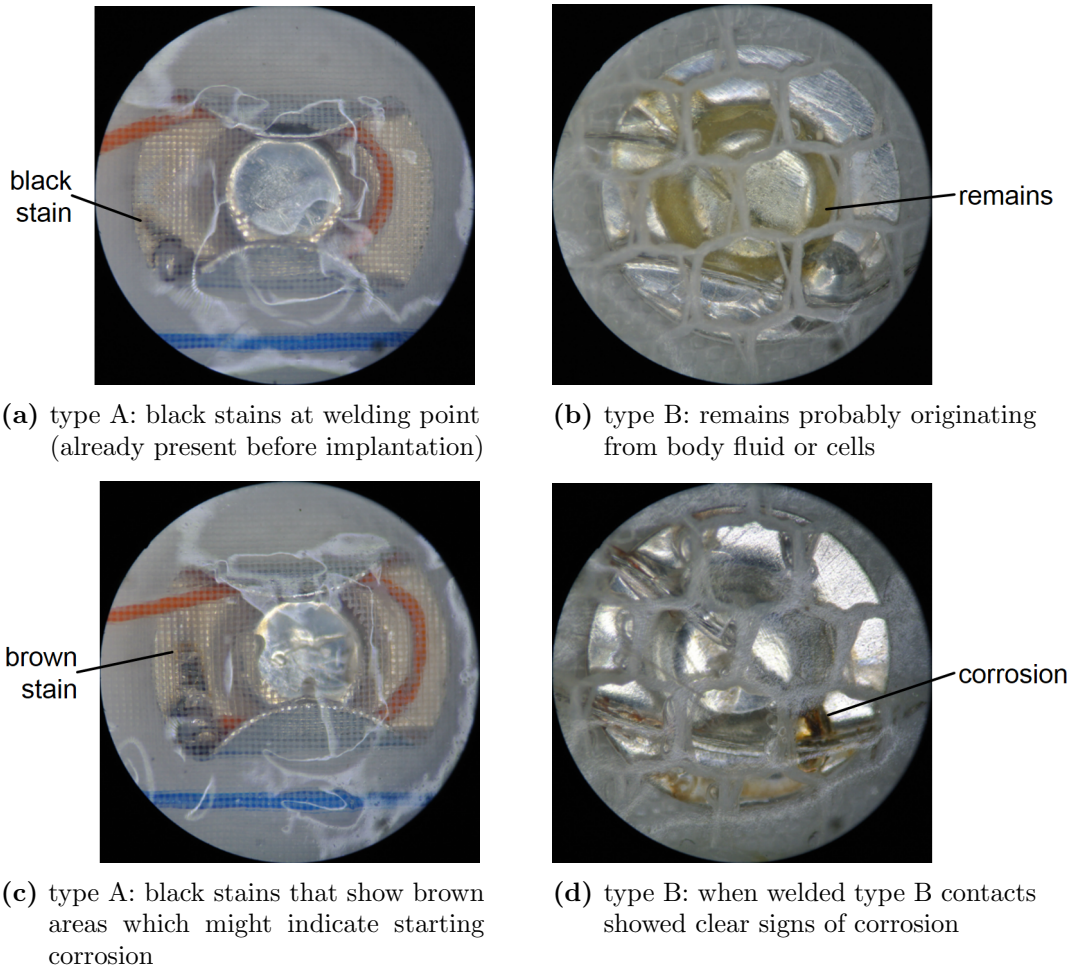


Figure 3.26: *In vivo* impedance of silicone electrodes (see figure 2.12 on page 36) with 3.1 mm² platinum-iridium (type A, blue) and 7.1 mm² stainless steel (type B, red) contacts twelve weeks after implantation in rats (see page 45). Dashed lines denote the standard deviation.

Visual inspection of explanted electrodes. After implantation of eight or twelve weeks all explanted electrodes underwent visual inspection. Examples for the different observed changes to electrode discs are shown in figure 3.27 and the number of electrodes on which different changes were observed is presented in table 3.11. An electrode was included in a category as soon as the change was observed on one of its contacts. Neither damaged cables or silicone carriers nor broken welding or soldering points were observed at any of the electrodes.

All electrodes of type A (see figure 2.12a on page 36) showed black staining of the platinum-iridium discs at the welding points (see fig 3.27a) after eight and twelve weeks of implantation. These stains were already present before implantation, but documentation of electrodes before implantation was not detailed enough to tell if the size of the stains changed over time after implantation. Brown stains on the border of the black areas (see figure 3.27c) were observed for one electrode eight weeks after implantation and for two after twelve weeks. These could have been the starting points of corrosion, but no clear corrosion of larger areas was observed.

Only one electrode of type B (see figure 2.12b on page 36) showed brown staining eight weeks after implantation, which might have been caused by beginning corrosion. All other electrodes of this type did not show any changes at that time. Twelve weeks after implantation remains, probably originating from body fluid or cells (see figure 3.27b), were found at the back of nine type B electrodes. At two further electrodes corrosion was clearly visible (see figure 3.27d). These were the only two electrodes in which cables were welded to the stainless steel contact discs and not soldered as it was done for all other electrodes of type B. Sometimes it was hard to differentiate between the remains and corrosion, but larger areas of light brown color were classified as remains and smaller stains of darker brown as corrosion.



(a) type A: black stains at welding point (already present before implantation)

(b) type B: remains probably originating from body fluid or cells

(c) type A: black stains that show brown areas which might indicate starting corrosion

(d) type B: when welded type B contacts showed clear signs of corrosion

Figure 3.27: Visual inspection of explanted silicone electrodes (see figure 2.12 on page 36): Four examples of observed changes to contacts of type A (left) and type B (right) electrodes

Tissue response to implanted silicone electrodes. A sample of tissue around the explanted electrodes is shown in figure 3.28. It shows a cross section perpendicular to the long

Table 3.11: Visual inspection of explanted electrodes: Observable changes of the two types of silicone electrodes (see figure 2.12 on page 36) eight and twelve weeks after implantation in rats (see page 45). At least one of the two contacts of an electrode showed the reported observations.

	Type A (Pt/Ir)		Type B (SS)	
observation	8 weeks	12 weeks	8 weeks	12 weeks
no visible breaks	12	12	12	12
remains of fluid or cells	0	0	0	9
corrosion	(1*)	(2*)	0	2** (8)

* brown stain next to the black welding point

** all electrodes of type B that were welded and not soldered

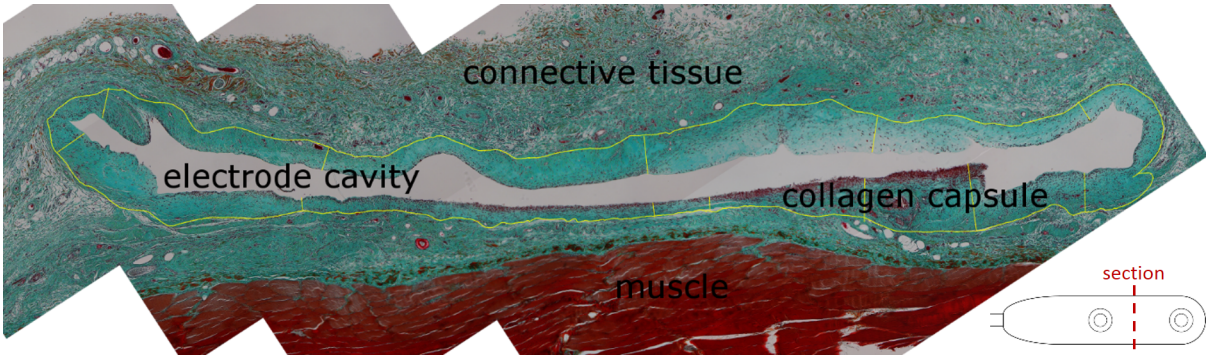


Figure 3.28: Cross section trough a capsule formed around an implanted silicone electrode: Orientation of the cross section is perpendicular to the long axis of the electrode. The cavity in the middle originates from the electrode. Green tissue around the cavity enclosed by the yellow line is collagen rich connective tissue of the capsule. Red tissue underneath the electrode shows the muscle.

axis of the electrode, originating approximately from the middle between both electrode contacts. The electrode was laying in the cavity in the middle of the image. Tissue above was in contact to the back of the electrodes and oriented towards the skin. Red tissue below the electrode cavity is muscle tissue at the contact side of the electrode. The yellow line around the electrode cavity denotes the outer border of the collagen capsule formed around the electrode. Table 3.12 summarized the average thickness of the collagen capsule found around explanted electrodes for the two different types of silicone electrodes and implantation times of 8 or 12 weeks.

Eight weeks after implantation, electrodes of type A in average had thinner capsules formed around them on the muscle side as well as on the back of the electrode. These differences were significant ($p < 0.01$) only for the capsule formed at the back of the electrode. For type A electrodes the capsule was significantly ($p = 0.04$) thinner at the back of the electrode when compared to the muscle side. For type B electrodes there was also a significant ($p = 0.02$) difference between the thickness of the capsule at both sides of the electrode but here the layer on the muscle side was thinner compared to that formed at the back of the electrode.

Twelve weeks after implantation, the average capsule thickness at the back of both electrode types stayed nearly constant. A significant ($p = 0.05$) decrease in thickness was observed at the muscle side of type A electrodes, while an increase, which did not reach significance, was observed for electrodes of type B. There was no significant difference in capsule thickness between both sides of any of the electrode types anymore. Twelve weeks after implantation the thickness of capsules formed around electrodes of type A was significantly thinner, on the muscle side ($p = 0.01$) and their back ($p = 0.01$), compared to electrodes of type B.

In vivo evaluation in sheep

For *in vivo* evaluation under higher mechanical stress, four silicone electrodes of type A with $3.1\,\mathrm{mm}^2$ platinum-iridium contacts were implanted in each of two sheep. The course of the impedance during implantation and an intra-operative measurement twelve weeks after implantation measured in the first sheep is shown in figure 3.29. Small standard deviations at both points of time indicate that all four electrodes had a very similar impedance characteristics. The magnitude decreased over the whole frequency range during the first twelve weeks after implantation. The difference between the impedance at both points in time was largest with

Table 3.12: Thickness of capsule around both types of silicone electrodes (see figure 2.12 on page 36) over time of implantation in rats (see page 45). Values are averaged over all 12 rats of each group.

time of	Type A (Pt/Ir)		Type B (SS)	
implantation	muscle	back	muscle	back
8 weeks	92.9(±31.3) µm	78.2(±26.5) µm	100.8(±36.8) µm	128.8(± 54.7) µm
12 weeks	71.7(±29.7) µm	78.2(±37.8) µm	112.0(±42.2) µm	127.5(±51.6) µm

70% at 1 Hz and steadily decreases to below 1% above 200 Hz. Also the phase shift decreased over the time of implantation. For high and low frequencies the decrease was around 6° and the largest reduction of 14° was found between 200 Hz and 800 Hz. Element properties of the equivalent circuit presented in table 3.13 indicate a small decrease on excess resistance and a reduction of the Faraday resistance by 77% over twelve weeks of implantation. During the same period of time, the Helmholtz capacity increased nearly two and a half times.

Impedances of electrodes implanted in the second sheep are presented in figure 3.30. In the second sheep standard deviations were already higher during implantation compared to the first one and further increased over time of implantation. In contrast to the first sheep impedance increased over time. The highest difference of 40% was observed at 4 Hz which steadily decreased with increasing frequencies to 1% at 10 kHz. The phase shift introduced by the electrodes was decreased for frequencies up to 1 kHz and decreased for higher frequencies. The largest decrease

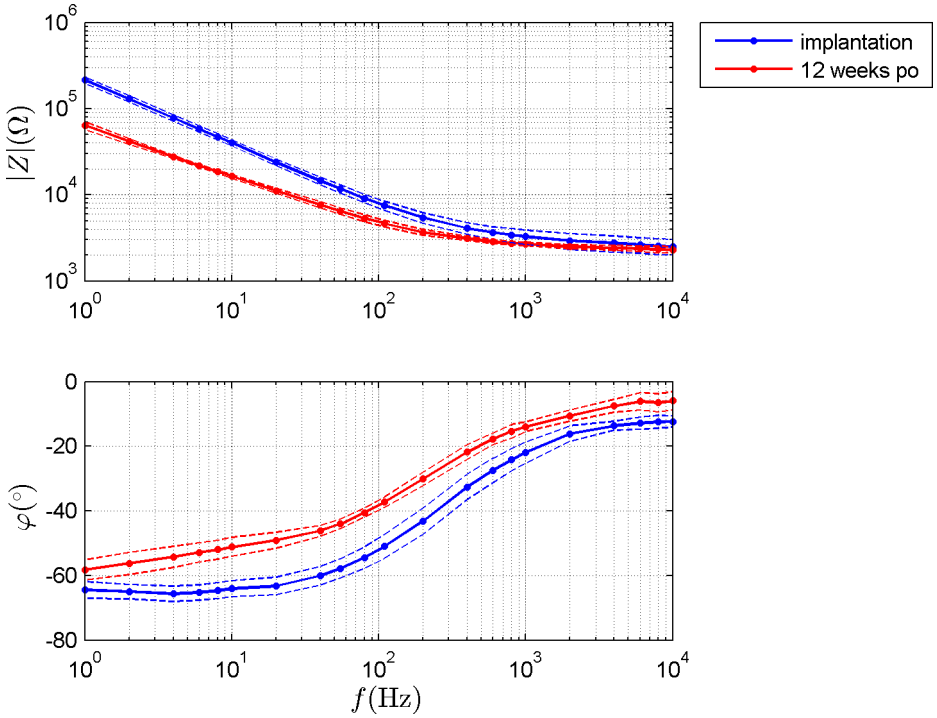


Figure 3.29: *In vivo* impedance of silicone electrodes of type A (see figure 2.12a on page 36) with platinum-iridium contacts over time of implantation in sheep 1 during the first sheep experiment (see page 47). Solid lines denote the average over all four implanted electrodes and dashed lines correspond to the standard deviation.

Table 3.13: Circuit element properties of an $R_E - R_F||C_H$ circuit (see page 52) when fitted to the *in vivo* impedance of type A silicone electrodes (see figure 2.12a on page 36) that were implanted in two sheep for twelve weeks (see page 45). For sheep 2 twelve weeks after implantation it was differentiated between the mean impedance of the intact *electrodes 1*, *2* and *3* (e1-e3) and that of the broken *electrode 4* (e4).

	point	excess resistance		Faraday resistance		Helmholtz capacity		quality of fit
animal	of time	R_E	error	R_F	error	C_H	error	RSS
sheep 1	implantation	3.0 kΩ	7.6%	266.9 kΩ	18.2%	340.7 nF	7.9%	12.26
	12 wk.	2.7 kΩ	7.3%	60.9 kΩ	15.4%	833.3 nF	10.1%	16.58
sheep 2	implantation	5.5 kΩ	9.3%	309.8 kΩ	17.0%	185.6 nF	10.0%	17.08
	12 wk. (e1-e3)	4.0 kΩ	7.0%	69.5 kΩ	18.9%	1.2 µF	11.3%	24.40
	12 wk. (e4)	25.6 kΩ	20.6%	714.2 kΩ	12.4%	3.5 nF	15.1%	28.40

of 17° was observed between 20 Hz and 50 Hz while the largest increase of 6° occurred at 6 kHz. For electrodes 1 to 3, development of the equivalent circuit element properties, presented in table 3.13, is similar to sheep 1. A small decrease in excess resistance and a larger decrease of 77% in Faraday resistance were accompanied by an increase of Helmholtz capacity. In contrast, for *electrode 4* both resistances were increased by 466% and 230% for excess and Faraday resistance, respectively. At the same time Helmholtz capacity decreased by 98%.

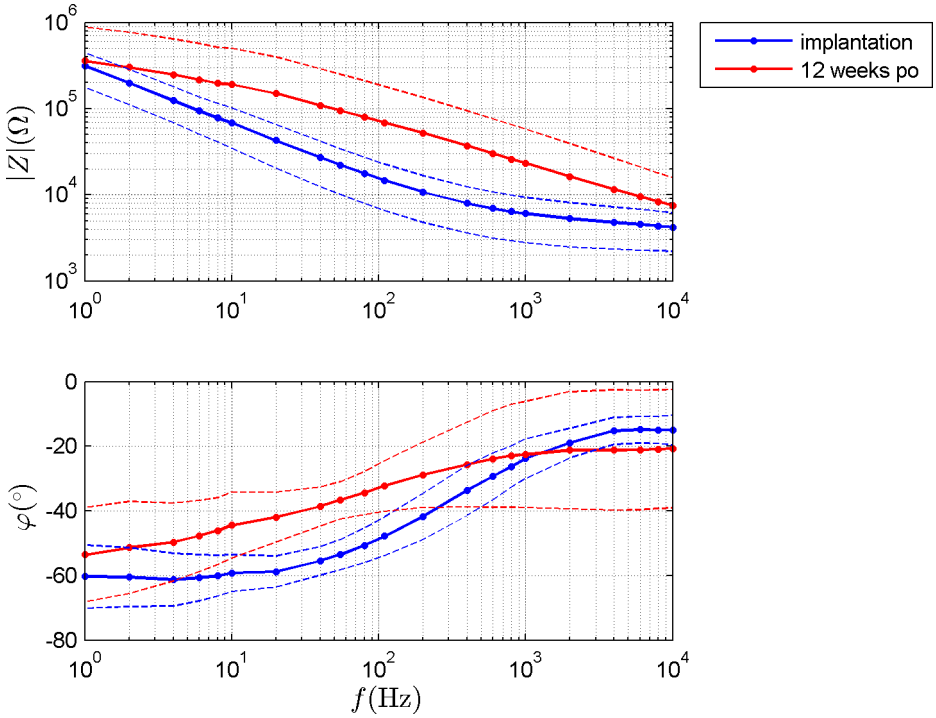


Figure 3.30: *In vivo* impedance of silicone electrodes of type A (see figure 2.12a on page 36) with platinum-iridium contacts over time of implantation in sheep 2 during the first sheep experiment (see page 47). Solid lines denote the average over all four implanted electrodes and dashed lines correspond to the standard deviation.

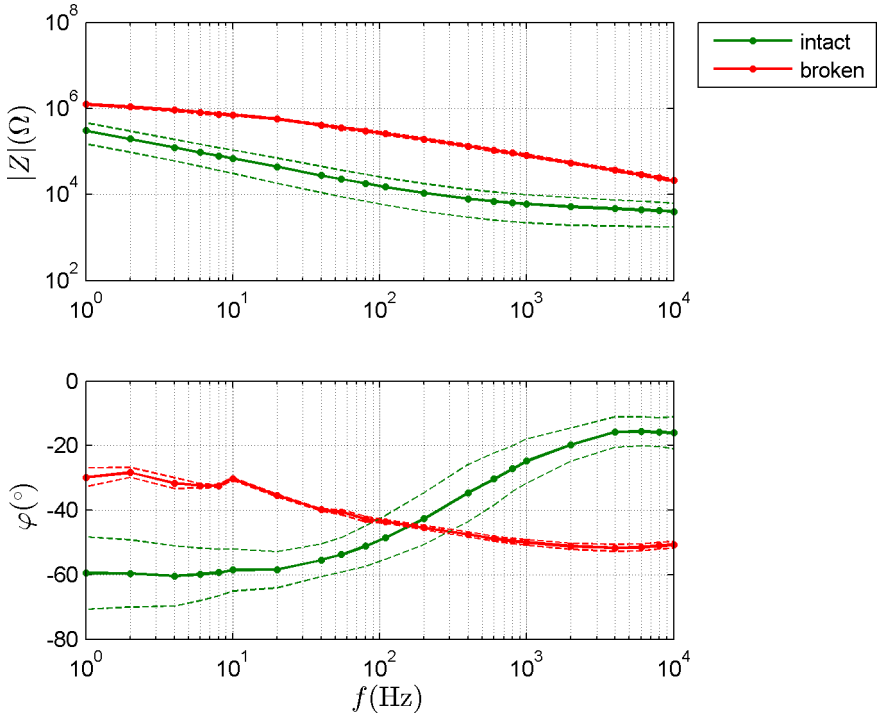


Figure 3.31: *In vivo* impedance of silicone electrodes of type A (see figure 2.12a on page 36) with platinum-iridium contacts in sheep 2 during the first sheep experiment (see page 47), twelve weeks after implantation. The solid green graph represents the average impedance of intact electrodes (*electrode 1* - *electrode 3*) and the red graph corresponds to the impedance of the broken *electrode 4*. Dashed lines denote the standard deviation.

A closer look at single electrode impedances revealed that the increase in standard deviation and magnitude were caused by *electrode 4*. Figure 3.31 shows that at 1 Hz the magnitude was up to 300% higher compared to the average of the other three electrodes. Also the course of the phase shift over frequency was changed. In contrast to the average of other electrodes it was smaller for low frequencies and decreased with frequency. This indicated the first break observed for silicone electrodes in all animal experiments carried out. Impedance measurements between each of the contacts of *electrode 4* and contacts on other electrodes separately showed that only one of the contacts caused the increased impedance.

Summary of the development and evaluation of silicone electrodes

The essential benefit of silicone electrodes, in contrast to polyimide electrodes, was their mechanical stability. No breaks were observed for the 48 electrodes implanted in rats and only one contacts of one of the eight electrodes implanted in sheep showed increased impedance.

Type A electrodes with smaller platinum-iridium contacts and type B electrodes having larger stainless steel contacts showed similar impedance characteristics *in vitro* and *in vivo* over time after implantation. As observed for polyimide electrodes, most of the changes in impedance occurred in the first eight weeks after implantation. Though, histological analysis showed that there were still considerable changes in capsule thickness between eight and twelve weeks after implantation. The thickness of the collagen capsule was significantly thinner for type A electrodes and they also showed fewer signs of corrosion and none of remaining cells or

body fluids.

The implantation procedure developed for silicone electrodes considerable reduced the trauma caused during implantation compared to implantation of polyimide electrodes. At the same time, it achieved reliable fixation of electrodes.

3.2.4 Summary

Even after two redesigns for improving their mechanical stability, polymide electrodes (see page 29) did not achieve long-term stability when implanted. The developed silicone electrodes (see page 33), however, achieved mechanical stability and seem to be suitable for long-term implantations. *In vitro* and *in vivo* evaluation of the implantable EMG measurement system demonstrated that the system was easy to implant. Especially the implantation procedure for silicone electrodes (see page 36) and the application of the developed surgeon tool for tunneling of electrode cables allowed implantation with little trauma. Also intraoperative connection of electrodes to the central implant was good and sealing of the connectors went well. Though, inductive energy supply of the implant was not sufficient as soon as the system was implanted, which did not allow for EMG measurements with the whole implanted EMG measurement system during the third primate experiment.

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Performance of implanted multi-site EMG recording electrodes: In vivo impedance measurements and spectral analysis.

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Abstract

The presented work is part of the development of a fully implantable EMG recording system for control of upper limb prosthetic devices. In the following, investigations on the usability of an implantable thin film electrode with multiple recording sites for measurement of intramuscular EMG are presented. Electrodes were implanted epimysially on the musculus deltoideus of a rhesus macaque. To our knowledge, this is the first investigation of such electrodes for muscular EMG recordings. Incorporation was monitored by periodic impedance measurements over eight weeks after implantation. Increase of impedance plateaued after four weeks indicating a completed encapsulation of the electrodes. EMG was recorded during relaxation and reproducible voluntary contractions of the muscle. Power spectral analysis confirmed that EMG signals with a frequency content of up to 1.2 kHz could be recorded. During contraction the signal at 200 Hz was four orders of magnitude higher than during relaxation.

***Keywords**: intra muscular EMG, implanted electrode, impedance, electrode encapsulation.*

Introduction

Recent developments of prosthetic limbs have resulted in increased functionality. Latest prosthetic hands offer a high number of degrees of freedom and sometimes even the movement of individual fingers. The challenge now is to provide adequate control signals for these devices.

State of the art is the use of surface EMG electrodes. Surface EMG records compound muscle activation and has a limited capacity to detect signals from deeper or smaller muscles. Moreover, differentiation of signals from different muscles (close to each other) is poor. It also frequently is influenced by movement artefacts and its sensitivity to changes in skin condition.

One approach to overcome this problem is the use of intracorporal signals. In transcarpal amputees who are still able to control the muscles in their forearm and amputees who underwent targeted muscle reinnervation [1] a high number of independent, intuitively controlled signals could be obtained by means of implanted electrodes recording intramuscular EMG.

The work presented here ultimately aims at controlling an upper extremity prosthesis by means of a new type of permanently implanted EMG electrode. Previously the first tests of the electrodes were reported [2]. Here we will report on in-vitro EMG recordings and first impedance measurements for eight weeks following implantation. We also report on a preliminary analysis of signals from the relaxed and contracted muscle.

Material and Methods

Animal model

For permanent recording of EMG three electrode arrays were implanted epimysially into the musculus deltoideus of one rhesus macaque. Suitable locations were chosen frontal, lateral and dorsal on the muscle with a distance of approximately 2 cm between electrode arrays. Electrodes were connected to a connector housing placed on the skull of the animal via subcutaneous cables. For follow-up investigations the monkey was placed in a monkey chair. The animals performed repeatable directed voluntary movements with his arm, thus generating reproducible contractions of the muscle under investigation. Animal care and all experimental procedures were conducted in accordance with German laws governing animal care.

Electrode arrays

The electrode arrays were fabricated in a micro technological process [3]. Each of the electrode arrays (Fig. 1) consisted of a 20 µm thick polyimide structure carrying five platinum recording sites with a surface area of 1 mm^2 and an inter-contact distance of 4 mm.

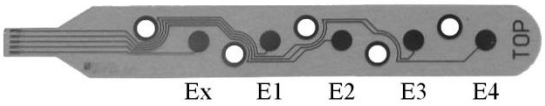

Fig. 1: Electrode array. Dark circles are the recording sites. White circles are suture holes for electrode fixation.

Two of the implanted electrodes had smooth platinum surfaces and one was coated with micro porous platinum [4].

Impedance measurement

Prior to implantation, impedance of electrodes with smooth and coated recording sites was measured in-vitro in saline (0.9% NaCl) to quantify the effect of coating on impedance reduction.

To monitor the process of electrode encapsulation, impedance measurements were carried out during implantation as well as two, four and eight weeks postoperatively. Impedance was measured between all possible combinations of recording sites of each electrode.

A custom built impedance measurement system was used [5]. The system applied a current of 1 μA_{RMS} consisting of a linear combination of frequencies from 1 Hz to 10 kHz between two recording sites. The resulting voltage was measured and decomposed into the induced frequencies by FFT, which allowed the calculation of the impedance at each frequency separately.

EMG measurements

Eight weeks after implantation EMG signals were recorded using a biosignal acquisition device (g.USBamp, g.tec). The signal was band-pass filtered with a pass band from 2 Hz to 2 kHz and sampled at 4.8 kHz. Spectral density of the recorded EMG signals was calculated in MATLAB (The MathWorks, Inc.) using Welch's method.

Results

Impedance in vitro

The reduction of impedance achieved by microporous coating of the contact surfaces is most dominant at low frequencies (Fig. 2). At 1 Hz impedance is reduced by 66.8% (330 kΩ). This reduction declines to 31.7% (1 kΩ) at 1 kHz. Coating of contact surfaces also reduces the introduced phase shift in the range of 8° to 12°.

Due to the loss of signals from the coated electrode within two weeks after implantation no further comparison between smooth and coated electrodes was possible.

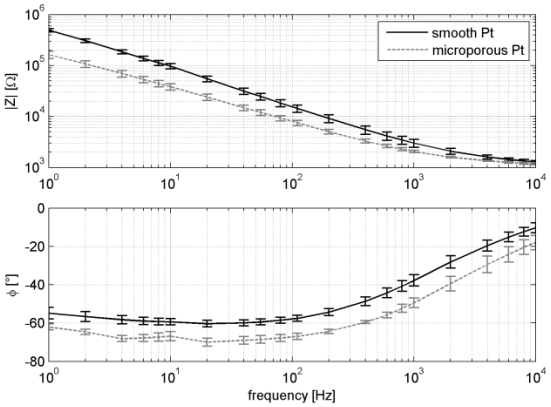

Fig. 2: Bode Plot of electrode impedance in saline of electrodes with smooth and coated surfaces.

Impedance of implanted electrodes

As shown in Fig. 3, impedance of the smooth electrode just after implantation is lower than the impedance measured in vitro, but at the same time showing a very similar course of the curve. The phase shift shows a decrease nearly logarithmic to frequency.

Two weeks after implantation impedance increases over the whole frequency range while the graph maintains a similar course. The introduced phase shift is increased for frequencies below 400 Hz.

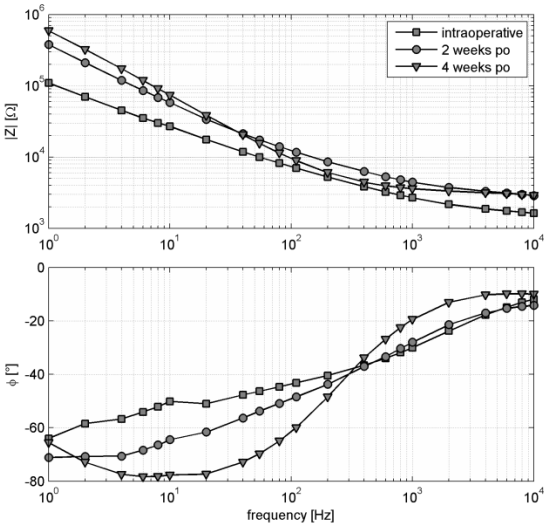

Fig. 3: Bode Plot of averaged impedance (all combinations of Ex-E4) of a smooth electrode over time after implantation.

Four weeks after implantation impedance is further increased for frequencies below 35 Hz and slightly reduced for higher frequencies. The course of the magnitude also shows a more pronounced bend at the transition towards nearly constant magnitudes around 1 kHz. The phase shift is further increased for frequencies up to 400 Hz and decreased for higher frequencies, reaching a constant value of -

10° above 4 kHz. Changes in electrode impedance plateaued four weeks after implantation.

Spectral differences between passive and activated muscle

Power spectral densities during activity and relaxation were calculated (Fig. 4) to evaluate the sensitivity to muscle activity.

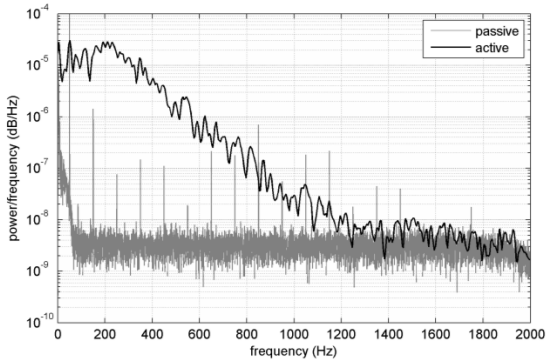

Fig. 4: Power spectral density estimate of recorded data during relaxation (passive) and movement (active) of the arm.

Power spectral density during relaxation of the muscle shows a constant frequency content from 70 Hz up to 2 kHz (onset of the low-pass filter). The spikes shown (Fig. 4) are the harmonics of the 50 Hz artefact which was intentionally not filtered. During contraction power spectral density is increased for frequencies up to 1.2 kHz with a peak at 200 Hz resulting in a clearly distinguishable power spectrum. At 200 Hz four orders of magnitude were observed between the signals (Fig. 4).

Discussion

Impedance was reduced in in-vitro and in intra-operative measurements by the microporous coating. Due to the loss of signals from the coated electrode the benefit of such electrodes in chronic conditions could not be investigated.

Impedance measurements showed considerable changes in electrode impedance over time following implantation. Magnitude of changes decreased over time and plateaued after a period of four weeks indicating a complete incorporation of the implanted electrodes.

The results confirm that the electrodes used are suitable to record intramuscular EMG for up to eight weeks. We were able to clearly distinguish activation and relaxation of the investigated muscle. We therefore conclude that the electrode is of interest for use in an implanted system for long-term permanent recording of intramuscular EMG.

Chronic long-term stability for more than 8 weeks will be investigated in follow-up experiments.

Additionally we will concentrate on further analysis of the recorded signals with an emphasis on efficient detection of muscle activity.

Conclusions

The applied electrodes were able to record intramuscular EMG for up to eight weeks after implantation. A clear discrimination between contracted and relaxed muscle could be made by offline analysis of the recorded data. Electrode impedance plateaued four weeks after implantation, indicating a complete incorporation of the electrodes at this point in time.

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IMPLANTABLE SILICONE ELECTRODE FOR MEASUREMENT OF MUSCLE ACTIVITY: RESULTS OF FIRST IN VIVO EVALUATION

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Abstract: *An implantable silicone electrode for acquisition of the electromyogram (EMG) was developed and tested on the musculus gluteus superficialis of fourteen rats for a period of eight weeks. A simple and low invasive procedure for electrode implantation was developed and achieved reliable and reproducible positioning of the electrodes. All electrodes stayed mechanically intact over implantation period. Electrode impedance decreased from implantation to explantation and no electrical failures of electrodes were observed.*

Keywords: *implantable electrode, implantation procedure, electrode impedance, encapsulation tissue*

Introduction

State of the art prosthetic hands offer an increasing number of degrees of freedom, sometimes even the movement of individual fingers. However there is still the challenge of providing an intuitive control for this functionality. One approach to overcome this problem is to use intracorporal signals [1]. In transcarpal amputees who are still able to control the muscles in their forearm, or in amputees who underwent targeted muscle reinnervation [2], a high number of independent, intuitively controlled signals could be obtained by means of implanted electrodes recording EMG directly on the muscles.
The work presented here is part of the development of a fully implantable EMG recording system for control of upper limb prosthetic devices [3], [4].

Methods

The developed implantable silicone electrode (Figure 1) is based on monopolar stimulation electrodes that have proven good long term stability [5]. A silicone carrier is built from two layers of PTFE reinforced silicone sheets (NA 501-1, Nagor) stuck together with silicone (MED 4011, NuSil). It carries two contact disks that were laser welded to single stranded, PTFE isolated cables (MP35N, Heraeus). The cables were coiled and tubed in a silicone tube (Silastic Rx 50, Dow Corning). A first design had smooth platinum-iridium (Pt/Ir 90/10) contact discs with an area of 3.1 mm^2, whereas the second design had contact surfaces of 7.1 mm^2 made from stainless steel (SS).

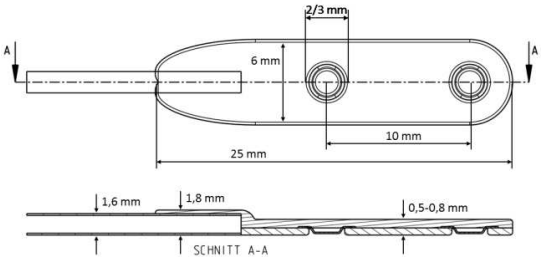

Figure 1: Schematic drawing of the developed silicone electrode for subepimysial implantation.

The steps of the implantation procedure are shown in Figure 2. An incision is made at the intended position of the transition between electrode and cable. This incision is only slightly wider than the electrode and is extended past the epimysium down to the superficial muscle fibres. An arterial clamp is used to form a pocket which starts at the incision and has the size of the electrode. The electrode is then inserted into the pocket with a pair of forceps. For fixation of the electrode only one suture is made around the cable where it passes into the electrode using a non-absorbable filament.
To test stability and biocompatibility of the electrodes as well as the implantation procedure and its ability of properly fixating the electrodes, electrodes were implanted in 14 Sprague Dawley Rats for eight weeks. Both electrode designs were implanted in each rat, one on each musculus gluteus superficialis. Cables were rooted over

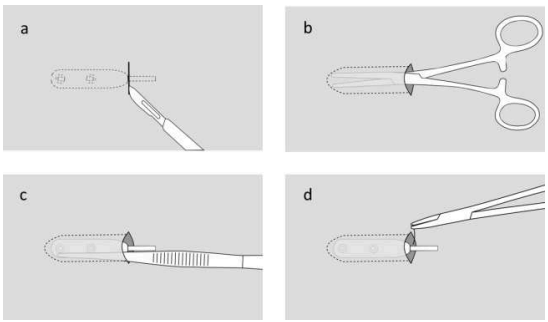

Figure 2: Implantation procedure for subepimysial placement and fixation of the developed silicone electrode.

the hip joint, to achieve mechanical loading of the leads, and then subcutaneously to the neck where they were fixed in place. After implantation and before explantation the position of the electrodes was marked on the skin and documented on pictures that were compared afterwards. Intraoperative impedance measurements were carried out with a custom built impedance measurement system [6]. The system applied a current of 1 μA_{RMS} consisting of a linear combination of 21 frequencies from 1 Hz to 10 kHz between the two contacts of each electrode. The resulting voltage was measured and decomposed into the induced frequencies by FFT, which allowed the calculation of the impedance at each frequency separately.
During explantation electrodes were excised with the connective tissue formed around them. These tissue samples are intended for later histological analysis.

Results

The handling of electrodes during implantation was good and allowed a precise placement with little tissue damage in combination with the developed implantation procedure. Eight weeks after implantation all electrodes and cables were covered by a layer of connective tissue that provided secure positioning. No signs of tissue damage or inflammation were visible. All electrodes and cables were mechanically intact and electrodes were still positioned at the gluteus superficialis. One electrode was turned 90° around its long axis and visual inspection indicated that a thicker capsule of connective tissue was formed around it. Two of the fourteen SS electrodes showed signs of corrosion in the region of the welding points which was not observed on the Pt/Ir electrodes.
Electrode impedances measured directly after implantation and just before explantation are presented in Figure 3. No electrode breaks were observed at any time. The magnitude of the impedance decreased over the whole frequency range for both contact materials over the first eight weeks after implantation. This decrease is smallest for Pt/Ir contacts at high frequencies.

Discussion

The developed silicone electrodes demonstrated good stability and the procedure for their subepimysial implantation achieved reliable positioning while causing little tissue damage. The corrosion observed at two SS electrodes is expected to be caused by modification of material properties due to excessive heating during welding. Based on their mechanical durability the developed silicone electrodes will be tested in further animal experiments, finally aiming at clinical testing in the human. Further testing will increase mechanical loads on the implanted components and allow for measurement of EMG during voluntary muscle contractions. Also the implantation procedure will be refined for further experiments.
The presented animal trial includes a second group of rats, which will be implanted for twelve weeks. Histological analysis of connective tissue samples of both groups will show if there is on-going formation of connective

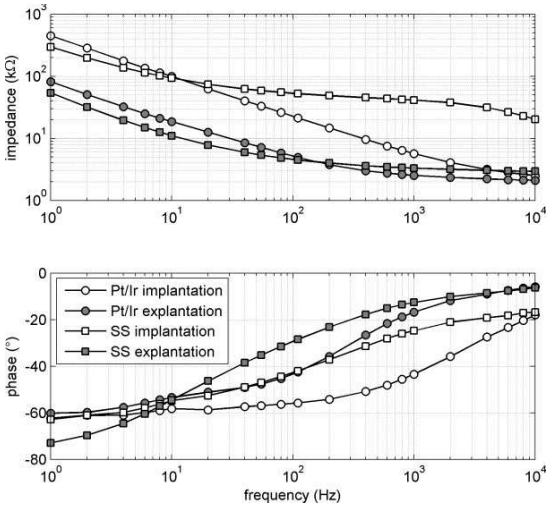

Figure 3: Bode plot of impedance measured during implantation and explantation of platinum-iridium (Pt/Ir) and stainless steel (SS) electrodes.

tissue around electrodes even after eight weeks of implantation or if incorporation can be expected to be stable as observed for other electrodes implanted at the same position [6]. Results from histologic analysis will be related to the impedance measurements.

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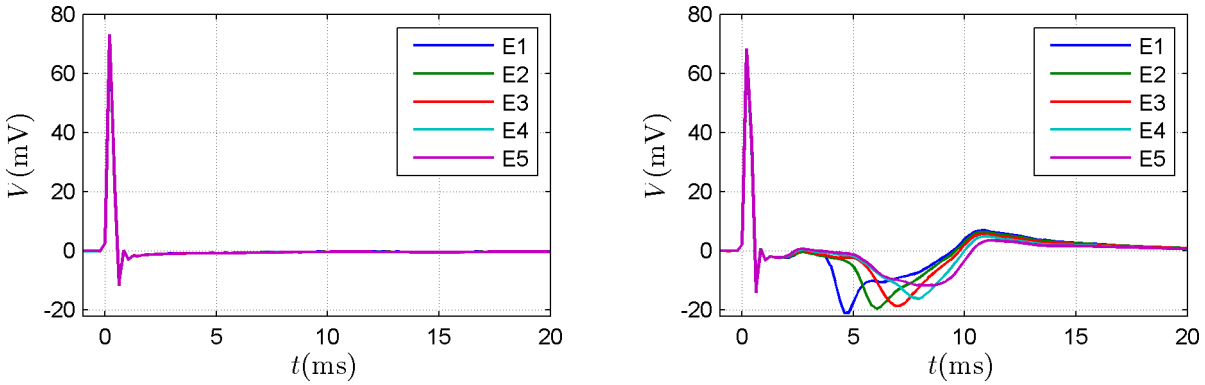
3.3 Analysis of intramuscular EMG

After investigation of the electrodes developed for the fully implantable EMG measurement system, the following chapter investigates the signals measured with these implanted electrodes. The first section (3.3.1) presents the signals resulting from stimulated muscle contractions. All following analyses are entirely based on EMG measured during voluntary contractions and investigate different measurement configurations (section 3.3.2) and the properties of the intramuscular EMG signal (section 3.3.3) [Lewis et al., 2010] (see Pub.3 on page107). In the following, these signals were analyzed according to their movement direction. First a differences in EMG signals were investigated in time domain (section 3.3.4) [Lewis et al., 2012b] (see Pub.5 on page 123). Subsequently a PCA was performed to get an insight into independence of features and separability of movement directions (section 3.3.5) and finally different approaches were evaluated for their ability to classify the measured muscle activity according to the movement direction that evoked them (section 3.3.6) [Lewis et al., 2013b] (see Pub.6 on page 127).

3.3.1 Stimulated EMG

Measurement of muscle contractions, which were evoked by Transcutaneous Electrical Nerve Stimulation (TENS), was carried out during the second surgery of the first primate experiment (see page 39). Figure 3.32 shows the results from the EMG measurements while stimulation did not evoke a contraction of the muscle (figure 3.32a) and when a contraction was evoked (figure 3.32b). When no contraction of the muscle was evoked, only the stimulation artifact was measured. It started with a positive peak which had a maximal amplitude of 73 mV and a width of 0.5 ms and was followed by a smaller negative peak which had an amplitude of −12 mV and a width of 3 ms.

When the stimulation resulted in contractions of the muscle this contraction produced an additional potential that followed the stimulation artifact (figure 3.32b). There was a delay of about 4 ms between the onset of the stimulation artifact and the first potentials resulting from the activation of the muscle. This corresponds to the propagation delay of the action potential in



(a) stimulation without contraction

(b) stimulation with elicited contraction

Figure 3.32: Stimulation artifact and subsequent muscle activity: Graphs show the average over 31 subsequent stimulations measured with the five contacts of *electrode 2* (see figure 2.17b on page 43) in monopolar configuration during the first primate experiment (see page 39). The large peak, common in all channels, is the stimulation artifact. The following m-waves, only present in (b), originate from the contraction of the muscle.

the nerve from stimulation site at the axilla to the motor end plate at and the delay introduced by transition from nerve to muscle at the motor end plate. The potentials resulting from the muscle activity took the same characteristic course for monopolar measurements with all five contacts of *electrode 2* (see figure 2.17b on page 43). The potential became negative while the muscle fibers were contracting, followed by a positive region with a smaller amplitude but longer duration during repolarization of the muscle. This activation was different for each monopolar channel but varied systematically. The maximum amplitude of the negative peak gradually decreased from −21 mV measured at contact E1 to −12 mV measured at contact E5. At the same time, the negative wave started later, which was related to the delayed propagation of the activity along the muscle, and the wave became less peaked.

3.3.2 Measurement configuration

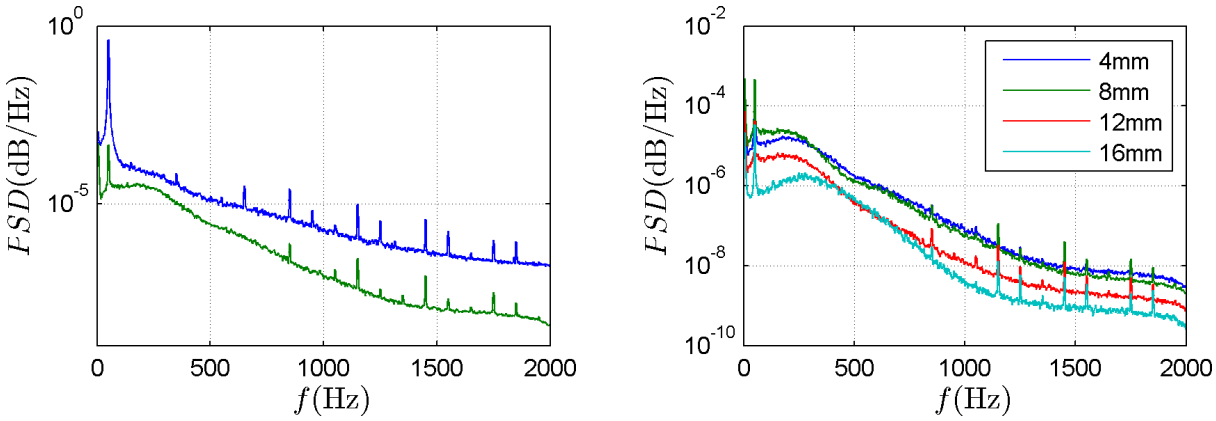
During the first measurements of EMG during voluntary contractions in the second primate experiment (see page 42), it was investigated which measurement configuration yielded the best results. This included whether the EMG should be recorded in monopolar or bipolar configuration and which contact distance should be used for bipolar measurements (see section 2.5.1).

Monopolar vs. bipolar configuration. For the investigation of the measurement configuration, two separate averages were calculated over the Power Spectral Density (PSD) of all monopolar and all bipolar measurements of one reaching task (see figure 2.15 on page 40) with 10 to 12 arm movements into each direction. A graph of these averages is shown in figure 3.33a. It can be seen that the signals measured in monopolar configuration had a higher frequency content over the whole frequency range. Taking a closer look at the differences, the PSD of the signal measured in monopolar configuration was up to 31 dB larger, but this occurred in the frequency range of the 50 Hz power line interference. In the frequency range of interest up to 1.2 kHz (see section 3.3.3) the difference in PSD was only up to 15 dB. The power line interference also spanned over a wider frequency range and dominated the signal for frequencies up to 100 Hz in monopolar measurements.

For further investigation between monopolar and bipolar configurations the cross correlation between all single channels of both configurations were calculated. The data vectors used for these calculations were established by appending one trail recorded during each arm movement direction after another. The correlation of monopolar measurements, presented in table 3.14, was in the ranged from 0.988 to 0.997. This was extremely high compared to the correlations between bipolar measurements presented in table 3.15, which ranged from 0.001 to 0.893. These differences originate from the strong power line noise contained in the monopolar measurements, which was dominating the course of the signal in time domain.

For bipolar measurements, higher correlations were present for channels that covered a similar region of the muscle. The highest correlation, for example, was observed between the channels E1-E3 and E2-E3, which both measure across the region between the contacts E2 and E3. The second highest correlation between channels E3-E4 and E3-E5 shared the region between contacts E3 and E4.

Contact distance for bipolar measurements. For the comparison of measurements with different inter-contact distances the mean PSDs of all combinations of contacts having the same inter-contact distance were calculated and plotted in figure 3.33b. Measurements with a inter-contact distance of 4 mm and 8 mm had higher powers over the whole frequency range when



(a) monopolar (blue) and bipolar (green)

(b) different inter-contact distances

Figure 3.33: Power spectral density (PSD) of EMG signals recorded with polyimide electrodes of the second design (see page 31) in monopoar (blue) and bipolar (green) configuration (a) and with different inter-contact distances in bipolar configuration (b) during contraction of the *musculus deltoideus* in the second primate experiment (see page 42).

compared to measurements with a distance of 12 mm. The measurement between contacts E1 and E5, which was the only combination of contacts with a contact distance of 16 mm, had an even lower PSD over most of the frequency range. A closer comparison between the measurements with inter-contact distances of 4 mm and 8 mm showed, that the latter had a higher frequency content for frequencies up to 300 Hz and only a slightly lower PSD at higher frequencies.

Preferred measurement configuration After evaluation of the different measurement configurations the first decision was to use a bipolar configuration with two contacts of one electrode on each target muscle. This decision was based on the strong power line interference in monopolar recordings which interfered with an important frequency range of the EMG signal. The second decision to be made, was to choose the appropriate contact distance for the bipolar recordings. The higher PSD of smaller distances suggested to choose a contact distance below 12 mm. Since important information were expected in the frequency range up to 300 Hz a contact distance of 8 mm was used for the following investigations based on the five-polar polyimide electrodes. The contact distance of the bipolar polyimide (see page 32) and silicone (see page 35)

Table 3.14: Cross correlation between the five EMG channels measured with polyimide electrodes of the second design (see page 31) in monopolar configuration between each contact and a needle electrode at the back of the monkey.

	E1	E2	E3	E4	E5
E1	1	0.997	0.987	0.994	0.996
E2	0.997	1	0.988	0.992	0.995
E3	0.987	0.988	1	0.995	0.991
E4	0.994	0.992	0.995	1	0.997
E5	0.996	0.995	0.991	0.997	1

Table 3.15: Cross correlation between ten channels measured in bipolar configuration with an polyimide electrode of the second design (see page 31) in the second primate experiment (see page 42).

	E1-E2	E1-E3	E1-E4	E1-E5	E2-E3	E2-E4	E2-E5	E3-E4	E3-E5	E4-E5
E1-E2	1	0.257	0.104	0.279	-0.206	-0.473	-0.467	-0.261	-0.102	0,174
E1-E3	0.257	1	0.715	0.437	0.893	0.489	0.216	-0.690	-0.816	-0.512
E1-E4	0.104	0.715	1	0.715	0.676	0.828	0.583	0.012	-0.325	-0.596
E1-E5	0.279	0.437	0.715	1	0.312	0.476	0.719	0.115	0.164	0.135
E2-E3	-0.206	0.893	0.676	0.312	1	0.715	0.437	-0.577	-0.778	-0.600
E2-E4	-0.473	0.489	0.828	0.476	0.715	1	0.780	0.157	-0.230	-0.626
E2-E5	-0.467	0.216	0.583	0.719	0.437	0.780	1	0.295	0.225	-0.001
E3-E4	-0.261	-0.690	0.012	0.115	-0.577	0.157	0.295	1	0.831	0.116
E3-E5	-0.102	-0.816	-0.325	0.164	-0.778	-0.230	0.225	0.831	1	0.649
E4-E5	0.174	-0.512	-0.596	0.135	-0.600	-0.626	-0.001	0.116	0.649	1

electrodes, which were designed for the later experiments, was chosen to be 10 mm to combine the good frequency characteristics of the measured signal with measuring a larger volume of the muscle, which contains several motor units.

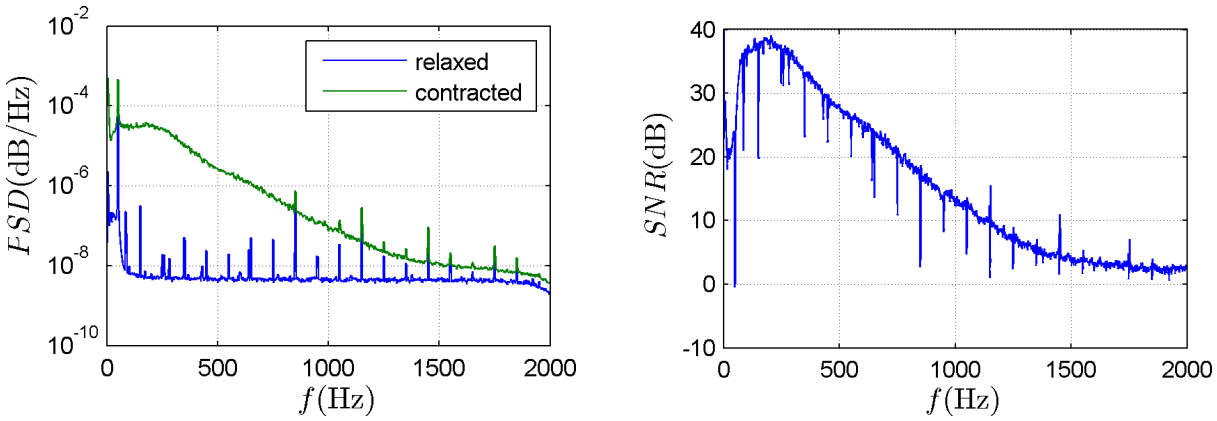
3.3.3 Properties of the EMG signal

The PSD of signals measured during relaxation and contraction of the muscle are depicted in figure 3.34 [Lewis et al., 2010] (see Pub.3 on page107). The PSD of the signal measured during relaxation of the muscle had its maximum at the power line frequency of 50 Hz which was intentionally not filtered and which caused the spikes occurring at some of its harmonics over the whole frequency range. Apart from these artifacts the PSD had a nearly constant value between 70 Hz and 2 kHz. During contraction power spectral density was considerably increased over the whole frequency range. The increase was larger for low frequencies having a peak around 200 Hz. This caused the PSD to reach a nearly constant region not until frequencies of 1.5 kHz. There was a decrease in power spectral density in both signals above 1.9 kHz which was caused by the low-pass filter used for antialiasing. The resulting SNR over the whole frequency range is presented in figure 3.34b. After the SNR reached a local minimum of 18 dB at 16 Hz it increased to a maximum difference of 39 dB which was present at a frequency of 206 Hz. Above this the SNR steadily decreased with increasing frequencies until it reached a relatively constant level of below 2.5 dB at high frequencies above 1.7 kHz.

3.3.4 Differentiation between movement directions in time domain

The EMG signals analyzed for the results presented in the following were measured during voluntary contractions of the *musculus deltoideus* during arm movements in the second primate experiment (see page 42). Eight weeks after implantation these signals were measured between contacts E2 and E4 of *electrode 2* (see figure 2.17b on page 43), which was the last electrode that was intact at that time (see section 3.2.2).

The muscle activity for each direction of arm movement in time domain was calculated according to section 2.5.3 on page 56 and is shown in figure 3.35. Time passed between release of the starting cue (figure 3.35, center: 0) till touch of one of the targets (figure 3.35, center: 1–8) ranged from 440 ms to 641 ms and was normalized to 100% movement duration for each trial.



(a) power spectral density (PSD) **(b)** signal to noise ratio (SNR)

Figure 3.34: Comparison of signals measured during relaxation and contraction of the muscle in frequency domain: (a) PSD of both signals recorded at the *musculus deltoideus*, (b) SNR between the measurements during contraction (signal) and relaxation (noise) of the muscle.

The RMS of the EMG signal averaged over all movements into one direction showed a good agreement for each direction of arm movement. Standard deviation was considerably smaller than characteristic peaks in the signal. The average reaction time from appearance of a target to initiation of arm movement varied between 20% and 40% of movement duration for different movement directions but was consistent for all trials of each movement direction. There was a clear decrease in activity of the *musculus deltoideus* from movements to the upper left (direction 8) to movements to the lower right (direction 4). For arm movements to the left (directions 6, 7, and 8) graphs show two peaks, a smaller one around 50% of movement and a higher with an amplitude of up to 1.9 mV around 80% of movement. The amplitude of the first peak decreased from direction 8 to 6. For movements in the directions 1, 2, and 3 the graph shows three distinct peaks around 40%, 60%, and 90% of movement. These peaks had amplitudes between 0.06 mV and 0.14 mV that decreased for the first and third peak from direction 1 over 2 to 3. Movement in direction 5 generated only a small activity of the deltoid muscle resulting in one peak around 90% of movement. Mean RMS for arm movement in the directions 4 was below 0.05 mV for the whole movement and thereby generated no clear activity pattern of the deltoid muscle.

3.3.5 Principal component analysis

Results from principal component analysis (PCA) are shown in the biplot in figure 3.36 and were part of the publication [Lewis et al., 2013b] (see Pub.6 on page 127). The vectors originating from the origin show that all investigated features (see page 56) contributed to the first two principal components and thereby to the description of the variance present in the signal. No strong linear dependencies were present between features, indicating that features did not describe redundant information. Projection of different arm movements into the feature space spanned by the two first principal components are denoted with the numbers of the respective movement direction. Their distribution largely overlapped but they were roughly arranged along the first principal component. Downward movements (direction 5) had the most negative values. Along the positive direction of the axis of the first principal component they were overlapping with movements to the lower-left and lower-right (directions 6, 4). Movements to the left (direction 7) were projected to negative values of the first principal component close to zero while arm

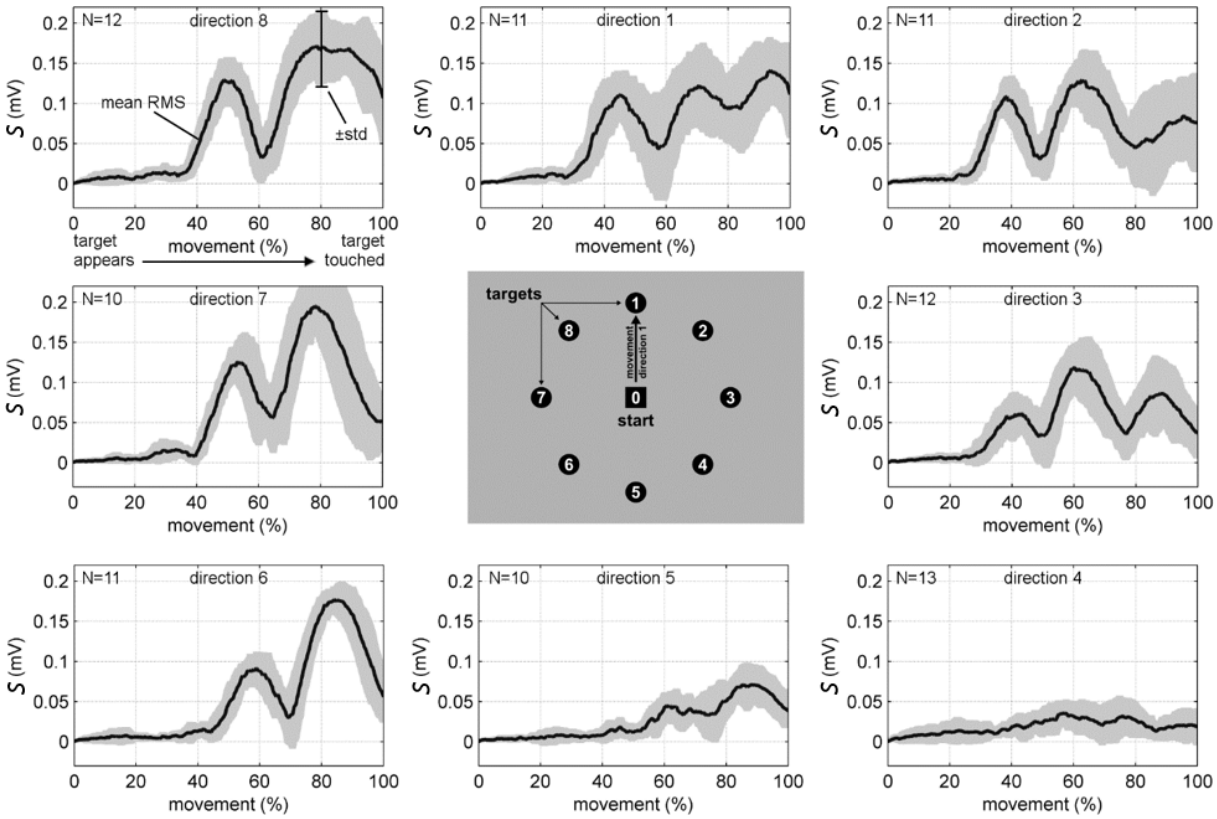


Figure 3.35: Analysis of reaching movements into different directions in time domain: Description of reaching task (center) and resulting activity of deltoid muscle for different directions of arm movement (outside). Center: All possible stimuli presented to the monkey at the touch screen of which only one was shown at a time. All trials began with the monkey touching the center (0). After a short period one of the outer targets (1–8) appeared and the recording of muscle activity shown in the outer graphs began (0%). After a certain reaction time the monkey started to move the arm toward the target and ended the measurement by touching the target (100%). The average time for one trial was about 500 ms. Outside: Graphs show the filtered RMS of the EMG signal S averaged over all movements in each movement direction (N) plotted over the time normalized to 100% of movement. Grey areas denote the standard deviation.

movements to the upper-left (direction 8) were spread around the origin. Along the positive axis of the first principal component movements to the right (direction 3) were followed by upward movements (direction 1) and finally movements to the upper- right (direction 2). The second principal component had hardly any influence on the differentiability of the movement directions. Beside these tendencies there was no apparent distinct grouping for differentiation of movement directions.

3.3.6 Classification of movement direction

Performance of classification of all investigated classifiers (see page 58) applied to discriminate between different sets of movements (see figure 2.15 on page 40) is presented in table 3.16 and were published in [Lewis et al., 2013b] (see Pub.6 on page 127). Classification accuracy was evaluated using leave-one-out cross validation for two sets of input features for each classifier.

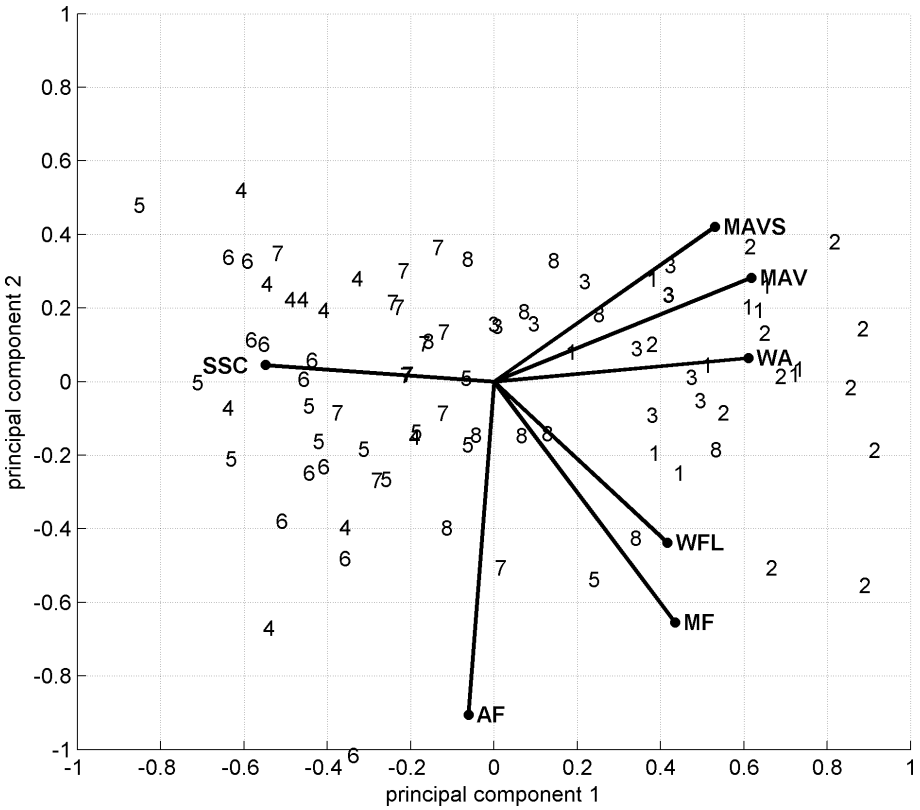


Figure 3.36: Biplot showing the results of the PCA (see page 58). Contributions of all investigated features (see page 56) to the first two principal components are shown as solid circles that are connected to the origin by black lines. The single trials of the different movement directions are projected in the space spanned by the first two principal components denoted by numbers according to their movement direction.

The first feature set comprised all investigated features (see page 56) and the features contained in the second feature set were separately chosen in forward selection (see page 60), for each combination of classifier and set of movements.

In the first set of movements, each movement direction formed a separate class. Classification accuracy for these movements ranged from the worst performance of 31.8%, achieved with a QDA classifier using all features, to the best classification performance of 59.1%, achieved by LNB classifier and a feature set containing MAV, WFL,WA and SSC.

The second set of movements was established to reduce the complexity of the classification task. It consisted of three classes that were subdivided based on the distribution of movement directions along the first principal component. Movements to the upper right (directions 1, 2, and 3) formed the first class, movements to the lower left (directions 5, 6, and 7) made up the second class and the remaining movements along the diagonal from upper left to lower right (directions 4 and 8), separating these first two classes, were comprised in a third class. Classification accuracy between 62.5% and 80.8% was achieved by a QDA classifier using all features and a KNB classifier evaluating MAV and WFL, respectively. This was considerably better when compared to the first set of movements.

The selection of movements for the third set was based on good separability. It contained the two classes comprising the movements into the upper right and lower left of the second set but excluded the movements in the directions 4 and 8. For these movements all classification

Table 3.16: Performance of investigated classifiers (see page 58) for different sets of movements (see figure 2.15 on page 40). Classification accuracy is given for classifiers using all investigated features (see page 56) or only a set of features compiled in forward selection.

	eight classes (1,2,3,4,5,6,7,8)		three classes (1-3,5-7,4+8)		two classes (1-3,5-7)	
classifier	features	class. accuracy	features	class. accuracy	features	class. accuracy
LDA	all features	48.9%	all features	72.7%	all features	98.5%
	MAV,SSC	53.4%	MAV,MAVS,WA	76.1%	MAV	100%
QDA	all features	31.8%	all features	62.5%	all features	100%
	MAV,MAVS,WFL	58.0%	MAV,SSC	77.3%	MAV,MAVS	100%
LNB	all features	50.0%	all features	70.4%	all features	95.5%
	MAV,WFL,WA,SSC	59.1%	MAV,WA	76.1%	MAV	100%
QNB	all features	45.4%	all features	68.2%	all features	100%
	MAV,WFL,SSC	51.1%	MAV	75.0%	MAV,WFL	100%
GNB	all features	43.2%	all features	68.2%	all features	100%
	MAV,WFL,WA,SSC	50.0%	WA,SSC	77.3%	MAV	100%
KNB	all features	45.4%	all features	75.0%	all features	100%
	MAV,MAVS,WA	48.9%	MAV,WFL	80.8%	MAV	100%

performance laid between 95.5% and 100%. All classifiers that operated on selected features correctly assigned all of the movements to the two classes and only the linear classifiers applying all features performed worse.

Selection of features yielded better classification accuracy than using all investigated features for all combinations of classifiers and movements, if not both approaches yielded 100% classification accuracy. The MAV was the most important feature for classification and was part of the selected feature sets of all but one classifier. Four classifiers used only the MAV and thereby achieved 100% classification accuracy for the simplest set of movements. Frequency domain features MF and MDF were not selected for any of the classifiers.

For further investigation of misclassifications, confusion matrices were established from redistribution errors, not leave-one-out cross validation as above, of classifiers that are using all features investigated. The confusion matrix in table 3.17 sums up the redistribution results from all classifiers applying all investigated features. A clear tendency for correct classification was present. Classification accuracy for single movements ranged from 53.8% to 76.7%. Movements in the directions 1, 2, 3, 5, 6, and 7 were most often classified correctly. Classification of movements in direction 4 was worst. Most incorrect classified movements were confused with movements into the first or second direction following clockwise or counter-clockwise. Movements in direction 3 were also mistaken for movements in direction 8 and movements in direction 8 with those in direction 3. The confusion matrix in table 3.18 shows classification results of the QDA classifier which yielded least redistribution errors. The QDA classifier using all investigated features correctly classifies all movements into the directions 2, 3, 6, 7, and 8. Again classification of movements in direction 4 was worst.

Table 3.17: Confusion matrix containing redistribution errors for classification of all eight movements (see figure 2.15 on page 40) using all investigated features (see page 56). Summation of classification results of all investigated classifiers (see page 58).

actual	predicted direction								redistribution
direction	1	2	3	4	5	6	7	8	accuracy (%)
1	46	9	5	0	0	0	0	0	76.7
2	15	46	5	0	0	0	0	0	69.7
3	5	0	50	0	0	0	0	11	75.8
4	0	0	0	35	1	15	9	0	58.3
5	0	0	0	9	42	10	5	0	63.6
6	0	0	0	15	3	48	0	0	72.7
7	0	0	0	2	13	3	58	2	74.4
8	2	3	9	0	0	0	11	41	62.1

Table 3.18: Confusion matrix containing redistribution errors for classification of all eight movements (see figure 2.15 on page 40) using all investigated features (see page 56). Confusion matrix of the best performing QDA classifier (see 59).

actual	predicted direction								redistribution
direction	1	2	3	4	5	6	7	8	accuracy (%)
1	9	1	0	0	0	0	0	0	90.0
2	0	11	0	0	0	0	0	0	100
3	0	0	11	0	0	0	0	0	100
4	0	0	0	8	1	1	0	0	80.0
5	0	0	0	1	10	0	0	0	90.9
6	0	0	0	0	0	11	0	0	100
7	0	0	0	0	0	0	13	0	100
8	0	0	0	0	0	0	0	11	100

3.3.7 EMG measured with the whole implantable measurement system

The first EMG signals recorded with the whole implantable measurement system, were acquired during the second sheep experiment (see page 48). Implanted components comprised four electrodes on muscles moving the forelimb and the central implant, which was inductively powered by by an external power supply. The amplifier gain was set to x600 and signals were filtered with a bandpass from 6 Hz to 800 Hz before they were digitized by the ADC with a resolution of 8 bit and a sampling frequency of 1.8 kHz. Measured signals were then sent via wireless transmission to the external base station. For off-line analysis signals were filtered with a bandpass filter having a pass-band from 60 Hz to 200 Hz.

The resulting signals of the four measured channels are presented in figure 3.37. The first three channels represent the EMG signals of *musculus brachialis*, *musculus triceps brachii* and *musculus latissimus dorsi*, while the fourth channel went into saturation, due to issues related to the realization of this one channel on the microchip, and did not measure any EMG signals. Since EMG could not be recorded during walking of sheep over longer distances for reasons described on page 82, signals represent three successive steps backwards which the sheep made to move out of a corner it was standing in. Timing of these steps is indicated in the bottom graph of figure 3.37. All channels presented signal amplitudes below ±10 mV when muscles are not actively used. During periods of activity of measured muscles, EMG signals amplitudes increased to around ±200 mV with peaks up to ±300 mV.

When taking into account the function of the measured muscles (see page 47), signals allow for an interpretation of the measured muscle activity during these three steps backwards. *Musculus triceps brachii* extends the forelimb during stance. It exhibits signal amplitudes around ±200 mV when the forelimb touches the ground and supports the weight of the sheep while the activity diminished as soon as the limb is lifted off the ground. Slightly higher EMG amplitudes are present during push off, before the forelimb is lifted around 2 s and 12.5 s. *Musculus brachialis* flexes the knee and becomes active as soon as the leg is lifted off the ground around 2.5 s, 10 s and 13 s. When looking at the EMG signals of these two muscles, it can be seen that agonist and antagonist were not co-contracting over longer periods of time. *Musculus latissimus dorsi* is moving the whole forelimb backwards and is also responsible for stabilizing the limb during stance. Main activity in this channel is present when the limb is lifted off the ground and moved backwards to initiate a new step around 2.5 s, 10 s and 13 s.

Around 7 sthe sheep was lifting the contralateral forelimb which resulted in a higher load of the instrumented forelimb leading to an increased activity of *musculus triceps brachii* for load bearing and *musculus latissimus dorsi* probably for stabilizing the limb.

3.3.8 Summary

Comparison of different electrode configurations for measurement of intramuscular EMG resulted in using bipolar measurements with an inter-contact distance between 0.8 cm and 1 cm. Intramuscular EMG measured in this setup achieved a SNR of up to 39 dB. During muscle activity, a clear increase in PSD was observed for frequencies up to 1.7 kHz.

Analysis of EMG recorded during arm movements into eight different directions in time domain showed clear differences in muscle activity between these movements. Already the PCA indicated difficulties of discriminating between these movements, when only features of short frames of EMG were investigated, since no clearly separable classes were present in the space spanned by the first two principal components. Insufficient accuracies achieved during classification of measured EMG into all eight movement directions confirmed that one channel of EMG from the *musculus deltoideus* was not sufficient for discrimination between these arm

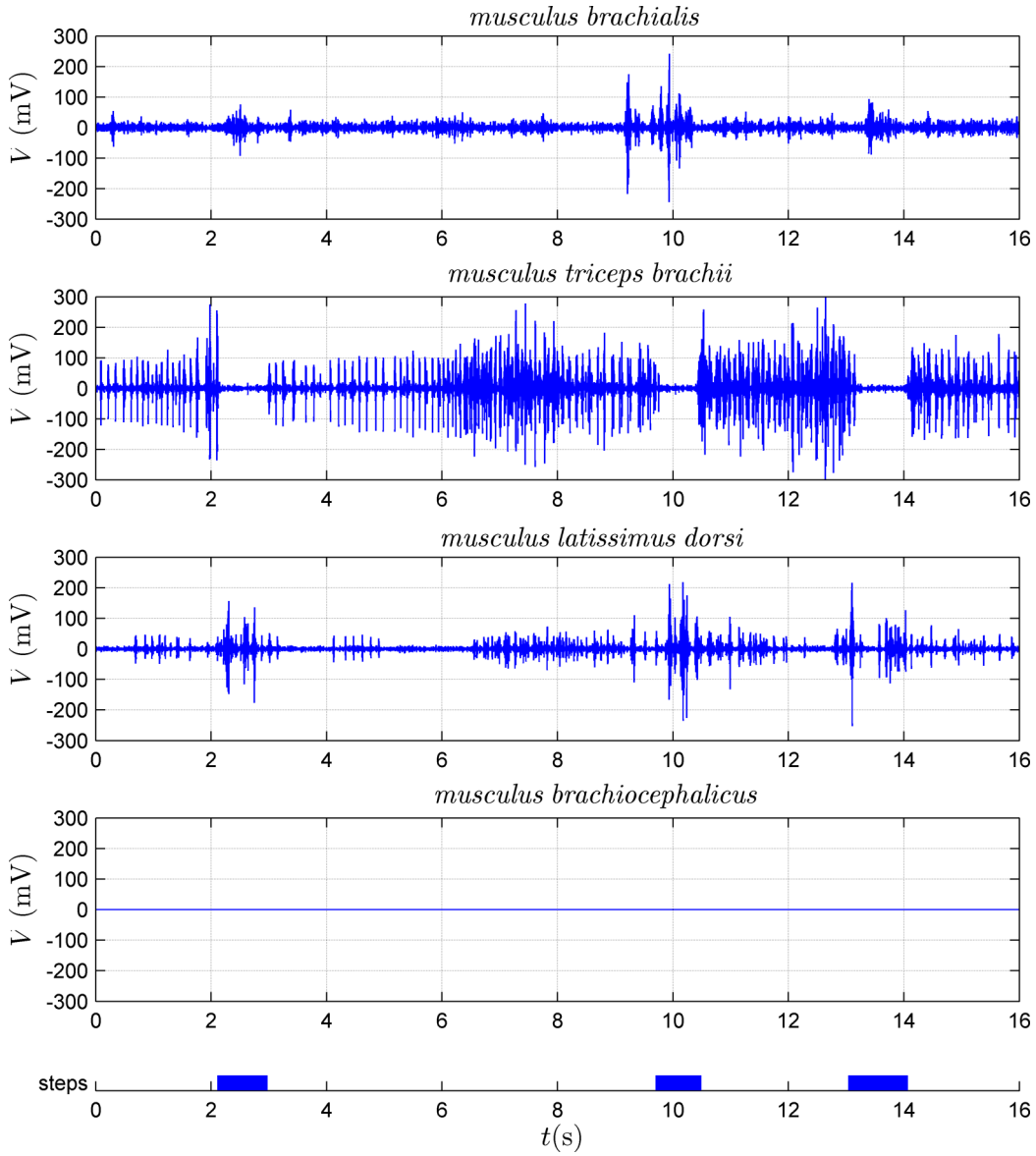


Figure 3.37: Muscle activity measured with the whole implantable EMG measurement system during the second sheep experiment (see page 48). The first three channels contain EMG signals originating from respective target muscles while the fourth channel went into saturation due to known issues of the microchip. The bottom graph indicates the duration of visually observed steps.

movements. Thoug, high classification accuracies for discrimination between movements into the upper right and lower left indicate that activity of *musculus deltoideus* was sufficient for their discrimination even with few features and simple classifiers.

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Acquisition of muscle activity with a fully implantable multi-channel measurement system

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Abstract—**This work presents intramuscular measurements of the electromyogram (EMG) during goal directed arm movements. Thin film electrode arrays were epimysially implanted on the deltoideus of a rhesus macaque and the encapsulation process was monitored by impedance measurements. Increase of impedance plateaued after four weeks indicating a complete incorporation of electrodes. EMG recorded with these electrodes yielded a signal to noise ratio of about 80 dB at 200 Hz. The EMG recorded during goal directed arm movements showed high similarity amongst movements in the same direction while presenting clear differences between different movement directions. A second implantation of the whole measurement system for nine weeks proved good handling and biotolerance.**

Keywords-intra muscular EMG; implanted electrode; electrode encapsulation; impedance; arm movement

I. INTRODUCTION

The human hand is providing a high degree of dexterity and intuitive control to the individual and therefore is the organ most important to a human for interaction with his physical surrounding. When the hand is lost, prostheses can only provide a functionally inadequate replacement. Even though latest prosthetic hands offer an increasing number of degrees of freedom, sometimes even the movement of individual fingers, there is still the challenge to provide an intuitive control for this functionality.

State of the art prosthesis control uses the electromyogram (EMG) recorded at the skin surface of the residual limb. This signal represents the compound muscle activity originating from a volume below the electrode. It has a limited capacity to detect signals from deeper or smaller muscles. Moreover, differentiation of signals from muscles located close to each other is poor. It is also frequently influenced by artifacts caused by relative movements between electrode and skin. Further drawbacks originate from sensitivity to changes in skin conductivity and pickup of external electromagnetic noise.

One approach to overcome these problems is the use of intracorporal signals. For example in transcarpal amputees who are still able to control the muscles in their forearm, which controlled the movement of the fingers prior to amputation a high number of independent, intuitively controlled signals could be obtained by means of implanted electrodes recording intramuscular EMG.

The work presented here is part of the MyoPlant project [1] which ultimately aims at controlling upper extremity prostheses by means of intramuscular EMG, recorded with a new type of permanently implanted EMG measurement system. Previously the first tests of the electrodes were reported [2], [3] and the implant electronics was presented [4], [5].

In this paper we report on the incorporation of implanted electrodes and the first EMG measurements after incorporation was completed. In these measurements we investigate the clear difference between activity and passivity followed by an analysis of EMG activity for different arm movement directions. Finally we present the results from a first implantation of the whole measurement system.

II. MATERIAL AND METHODS

The developed system was evaluated in two different rhesus macaques. In a first implantation transcutaneous connection to the electrodes (II. *A*) allowed measurement of impedance (II. *B*) and muscle activity (II. *C*). In the second implantation (II. *D*) the whole system was implanted to evaluate its usability and biotolerance.

A. Electrodes

The electrode arrays were fabricated in a micro technological process [6]. Fig. 1 shows an electrode array consisting of a 20 µm thick polyimide structure carrying five platinum recording sites with a surface area of 1 mm^2 and an inter-contact distance of 4 mm. After the first implantation, the electrode design was mechanically improved [7].

B. Impedance Measurement

A custom built impedance measurement system based on [8] was used to evaluate the electrode impedance over time after implantation and thereby monitor the process of electrode encapsulation. The system applied a current of 1 μA_{RMS} consisting of a linear combination of frequencies from 1 Hz to 10 kHz between two contacts of one electrode. Reported impedances are averages over all ten possible combinations of contacts of each electrode array.

C. EMG Measurement

EMG signals were recorded using a biosignal acquisition device (g.USBamp, g.tec). The signal was band-pass filtered with a pass band from 2 Hz to 2 kHz and sampled at 4.8 kHz. Spectral density of the recorded EMG signals was calculated in MATLAB (The MathWorks, Inc.) using Welch's method. For analysis of movement direction in time domain raw EMG was rectified and filtered by application of a moving average over 15% of movement duration.

D. Implantable EMG Measurement System

The implant (Fig. 1) is built up from a custom designed micro chip [5], a microcontroller (Atmel ATMEGA 88PA) and a RF transceiver (Zarlink ZL70101). Input signals from the electrodes are band-pass filtered (6-1500 Hz) and subsequently amplified in a two stage differential amplifier with adjustable gain. The resulting signal is then digitized with 10 bit resolution. Wireless data transmission from implant to a base station is using the MICS band between 402 and 405 MHz [4]. Energy is inductively coupled into the implant [9]. Packaging was realized by injection moulding the implant electronics into silicone.

E. Animal Experiments

In a first implantation three electrode arrays were implanted epimysially into the deltoideus of a first rhesus macaque. Suitable locations were chosen frontal, lateral and dorsal on the muscle with a distance of approximately 2 cm between electrode arrays. Electrode cables were subcutaneously routed to a connector housing on the animal's skull, and could be connected there to the measurement system. Impedance measurements were carried out during implantation as well as two, four and eight weeks after implantation to monitor the process of electrode encapsulation. EMG measurements were carried out two, four and eight weeks after implantation.

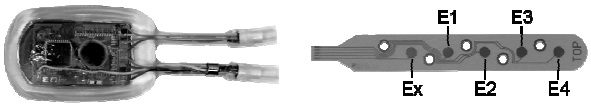

Figure 1. Components of the implantable EMG measurement system: Left: Implant electronics capsuled in silicone. Right: Electrode array. Dark circles are contacts for recording. White circles are suture holes for electrode fixation.

In a second implantation the whole system was implanted in a second rhesus macaque for nine weeks. As shown in Fig. 2 four electrodes were epimysially implanted, one at the biceps brachii, one at the triceps brachii and two frontal and lateral at the deltoideus. The implantable EMG measurement system was placed subcutaneously between the shoulder blades and electrodes were connected by subcutaneous cables.

For behavioral testing the monkey was placed in a monkey chair in front of a touch screen, on which he was previously trained to conduct visually instructed reaches [10]. At the beginning of each trial a white square (Fig. 2: 0) was presented which had to be touched by the monkey. After that the square disappeared and one of the outer circles (Fig. 2: 1-8) was presented at the screen as new target. While reaching for these circles the monkeys performed repeatable goal directed movements with their arm, thus generating reproducible voluntary contractions of the muscle under investigation. Animal care and all experimental procedures were conducted in accordance with German laws governing animal care.

III. RESULTS

All impedance and EMG data presented in the following (III. *A*-*C*) are based on recordings from the lateral deltoid muscle eight weeks after the first implantation. Reports on handling and biotolerance (III. *D*) are based on findings from the second implantation.

A. In vivo Impedance

Impedances characteristic over time is presented in Fig. 3. Just after implantation impedance shows a characteristic very similar to measurements in physiologic saline [3] but slightly lower magnitude. The phase shift shows a decrease nearly logarithmic with frequency.

Two weeks after implantation impedance increases over the whole frequency range while the graph maintains a similar shape (Fig. 3). The introduced phase shift is increased for frequencies below 400 Hz.

Four weeks after implantation impedance is further increased for frequencies below 35 Hz and slightly reduced for higher frequencies. The graph of the magnitude also shows a more pronounced bend at the transition towards nearly constant magnitudes around 1 kHz. The phase shift is further increased

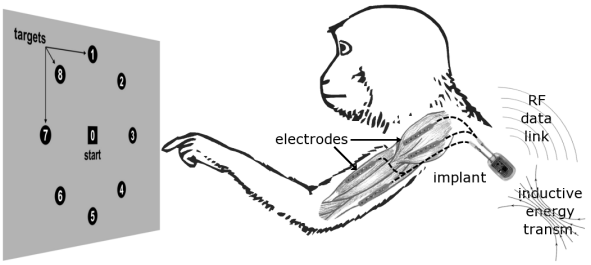

Figure 2. System validation in Monkey: Implantation sites of electrodes and implantable EMG measurement system with inductive energy transmission and RF data link.. The screen to the left shows all possible cues for the reaching task.

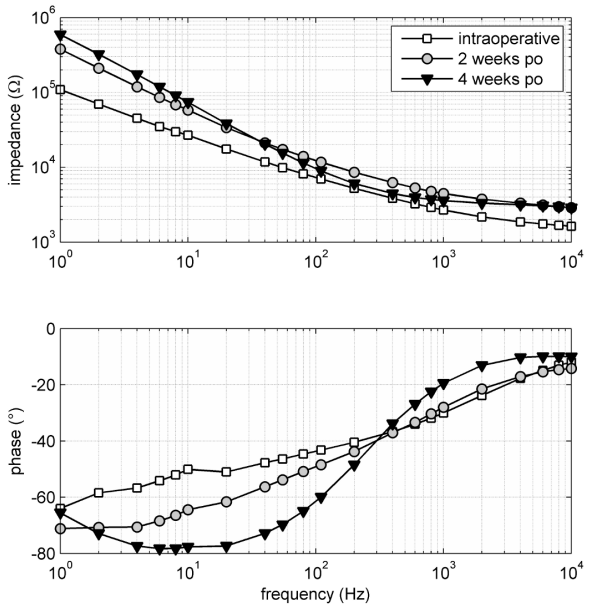

Figure 3. Bode Plot of impedance (averaged over all combinations of Ex-E4) of one electrode over frequency at three time periods after implantation.

for frequencies up to 400 Hz and decreased for higher frequencies, reaching a constant value of – 10° above 4 kHz. Changes in electrode impedance plateaued four weeks after implantation.

B. *Activity / Passivity*

Power spectral densities during relaxation and contraction of the deltoideus were calculated to evaluate the sensitivity to muscle activity. Power spectral density during relaxation of the muscle has constant frequency content from 70 Hz up to 2 kHz (onset of the low-pass filter). During contraction power spectral density is increased for frequencies up to 1.2 kHz with a peak at 200 Hz resulting in a clearly distinguishable power spectrum. At 200 Hz a difference of about 80 dB was observed between the signals.

C. *Movement Direction*

The muscle activity for each movement direction in time domain is shown in Fig. 4. The RMS of the EMG signal averaged over all movements in one direction shows a good agreement for each movement direction. Standard deviation is considerably smaller than characteristic peaks in the signal. The average reaction time from appearance of the target to initiation of arm movement varies between 20% and 40% of movement for different movement directions but is consistent for all trials of each movement direction.

There is a clear decrease in activity of the deltoid muscle from movements to the upper left (direction 8) to the lower right (direction 4). For arm movements to the left (directions 6, 7 and 8) the graph shows two peaks, a smaller one around 50% of movement and a higher with an amplitude of up to 1.9 mV around 80% of movement. Especially the amplitude of the first peak is decreasing from direction 8 to 6. For movements in the directions 1, 2 and 3 the graph shows three distinct peaks around 40%, 60% and 90% of movement. These peaks have amplitudes between 0.06 and 0.14 mV that are decreasing for the first and third peak from direction 1 over 2 to 3. Movement in direction 5 generates only a small activity of the deltoid muscle resulting in one peak around 90% of movement. Mean RMS for arm movement in the directions 4 is below 0.05 mV for the whole movement and thereby generates no clear activity pattern of the deltoid muscle.

D. *Usability and Biotolerance*

The handling of electrodes during implantation was good and allowed a precise placement with minimal tissue damage in combination with the developed implantation procedure. In the second implantation the whole EMG measurement system was implanted for nine weeks. During the explanation all components were encapsulated into connective tissue but no signs of tissue damage or inflammation were visible.

IV. DISCUSSION

Impedance measurements showed considerable changes in electrode impedance over time following implantation. Magnitude of changes decreased over time and plateaued after a period of four weeks indicating a complete incorporation of the implanted electrodes.

The results confirm that the electrodes used are suitable to record intramuscular EMG for up to eight weeks. We were able to clearly distinguish contraction and relaxation of the investigated muscle. The observed 80 dB between signals from relaxed and contracted muscle at 200 Hz are a huge improvement compared to the SNR < 10 of surface EMG [11].

The investigation of the activation of the deltoid muscle during different arm movements showed a high degree of agreement for different trials of each movement direction while revealing clear differences between different movement directions. Direction dependent investigation in time domain is only a first step in establishment of a prosthesis control based on intramuscular EMG. Since differences between movement directions in time domain become clear after the movement is completed only an offline control could be established. In prostheses control the prosthesis has to react to inputs from the amputee within 150 ms not to be experienced as too slow. To achieve this it is necessary to establish a control that interprets control inputs online and therefore allows adaptation of the prosthesis movement during execution.

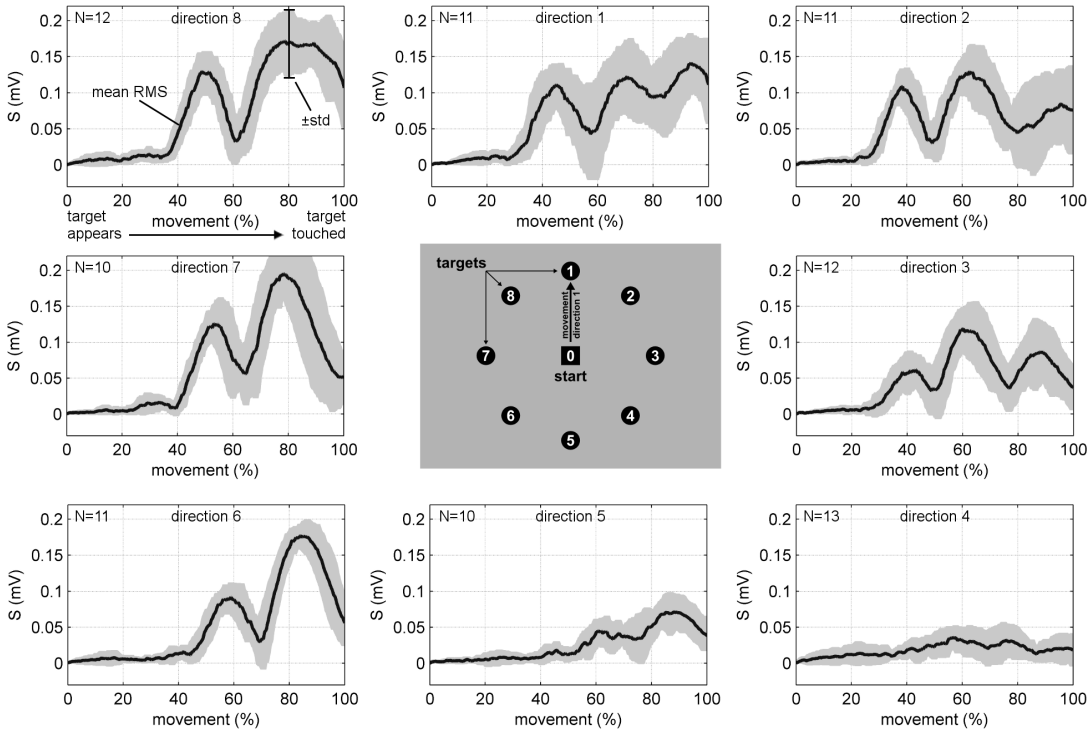

Figure 4. Description of reaching task (center) and resulting activity of deltid muscle for different directions of arm movement (outside). Center: All possible stimuli presented to the monkey at the touch screen. Only one stimuli is shown at a time. All trials begin with the monkey touching the center (0). After a short period one of the outer targets (1-8) appears and the recording of muscle activity shown in the outer graphs begins (0%). After a certain reaction time the monkey starts to move the arm towards the target and ends the measurement by touching the target (100%). The average time for one trial is 500 ms. Outside: Graphs show the filtered RMS of the EMG signal *S* averaged over all movements in each movement direction plotted over the time normalized to 100% of movement. Grey areas denote the standard deviation.

Further investigations on the predictability of movement direction will include EMG from different muscles and focus on the use of a combination of time and frequency domain features to reliably classify the muscle activity during the first 150 ms after movement onset.

The first implantation of the whole implantable system for EMG recording yielded good biocompatibility of electrodes, cables and implant. This is a key finding for further development of the system with the ultimate aim of implantation into a human amputee. Further results from measurements with the complete system will be published in future.

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Fully Implantable Multi-Channel Measurement System for Acquisition of Muscle Activity

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***Abstract*—This paper presents intramuscular electromyogram (EMG) signals obtained with a fully implantable measurement system that were recorded during goal directed arm movements. In a first implantation thin film electrodes were epimysially implanted on the deltoideus of a rhesus macaque and the encapsulation process was monitored by impedance measurements. Increase of impedance reached a constant level after four weeks indicating a complete encapsulation of electrodes. EMG recorded with these electrodes yielded a signal-to-noise ratio of about 80 dB at 200 Hz. The EMG recorded during goal-directed arm movements showed a high similarity to movements in the same direction and at the same time presented clear differences between different movement directions in time domain. Six classifiers and seven time and frequency domain features were investigated with the aim of discriminating the direction of arm movement from EMG signals. Reliable recognition of arm movements was achieved for a subset of the movements under investigation only. A second implantation of the whole measurement system for nine weeks demonstrated simple handling during surgery and good biotolerance in the animals.**

***Index Terms*—Electrode encapsulation, feature selection, impedance, implanted electrode, intramuscular electromyogram (EMG), movement classification.**

I. INTRODUCTION

THE ACTIVITY of skeletal muscles is measured in a variety of fields. In sports, it is used for motion analysis, in medicine for diagnosis of neuromuscular disorders, and there are even human–computer interfaces based on muscle activity [1]. The present paper demonstrates first results of the development of a fully implantable system for control of upper extremity prostheses.

Despite new principles for measurement of muscle activation like optical muscle activation sensors (oMAS) that measure the optical density of the muscle [2] or measurement of the oscillation frequency and decay in response to mechanical excitation [3]–[5], state of the art prosthesis control still uses the electromyogram (EMG) recorded from the skin surface of the residual limb as input [6]. Most commonly this surface electromyogram (sEMG) is recorded with electrodes that are placed on the skin above the muscles of interest. The electrical potential measured is caused by contraction of the muscle. For short time sEMG recordings Ag/AgCl electrodes, that apply hydro gels [7] to establish a uniform electrode skin contact with low impedance, are frequently used. Due to drying-out of this layer of gel, acquisition of sEMG over longer periods of time is generally performed with dry electrodes. They normally have higher polarization impedance [8], although recently developed electrodes yield comparable performance during long-term EMG measurements [9]. In the special case of controlling state of the art prostheses, bipolar metal electrodes that also incorporate some signal processing electronics are often applied [10]. More comfortable solutions for longterm monitoring might be flexible dry electrodes [11], textile electrodes that can be directly integrated into clothes [12] or capacitive electrodes that are separated from the skin by a dielectric layer and are capable of measuring sEMG through thin layers of garment [13]. The main shortcoming of measuring muscle activity from the skin surface is the limited capacity to detect signals from deeper or smaller muscles. Moreover, differentiation of signals from muscles located close to each other is poor. Signal quality is also frequently influenced by artifacts due to relative movements between electrode and skin. Further drawbacks originate from sensitivity to changes in skin conductivity and pickup of external electromagnetic noise [14].

We propose though that it is possible to overcome most of these shortcomings by measuring the intramuscular electromyogram (iEMG) instead. It is less prone to artefacts due to movement of electrodes, achieves better signal-to-noise ratio and has the ability to measure small and deep muscles [14]. On the other hand iEMG represents the activity of a small volume of muscle only and requires the application of intramuscular electrodes. For example, transcarpal amputees often are still

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Fig. 1. Components of the implantable EMG measurement system: (a) Central implant (size: 38×25×8 mm) consisting of electronics capsuled in silicone (Center for Medical Physics and Biomedical Engineering, Medical University of Vienna). (b) Polyimide thin film electrode array (size: 28×3×0.02 mm). Dark circles are contacts surfaces (E1–E5), white circles are suture holes for electrode fixation.

able to control the muscles in their forearm, which controlled the movement of the fingers prior to amputation. Thus, a large number of independent, intuitively generated control signals for control of hand prostheses could be obtained by means of implanted electrodes, recording iEMG from those partly small and deep muscles. In the past, several groups have identified suitable muscles for classification of arm movements in the chest and shoulder region [15], [16]. The focus of this paper though is not primarily to establish the most suitable implant locations, but rather to develop a new measurement system that can later be used to record data from these optimal sites.

Temporary recording of iEMG is done by needle or hook-wire electrodes that are inserted into the muscle under investigation without the need of a surgery. Unfortunately transcutaneous wires introduce a huge risk of infection and are thus not advised for daily life and use in a commercial product.

Implantation of electrodes introduces additional risks though. Insertion of electrodes causes trauma in the tissue and surgery itself introduces the risk of infection. In case of rejection or breakage of implanted electrodes a second surgery is needed for revision or explantation. In some cases, such as when a targeted muscle reinnervation [17] is performed, the electrodes could be positioned during the initial surgery. In this special group of patients a high number of control signals on a small surface area are often observed and they could benefit largely from implanted electrodes.

For permanent recordings of iEMG either intramuscular electrodes are implanted into the muscle [18], [19] or epimysial electrodes are placed at the epimysium of the muscle [20]. Both technologies have demonstrated the ability to achieve longterm stability [20]. In the paper presented here a novel electrode—based on a polyimide thin film—has been developed and was placed underneath the epimysium. Electrode impedance, which was repeatedly measured, was used to determine electrode functionality [21], [22] and to investigate the tissue response to implanted electrodes [23], [24].

A major challenge in development of any implantable electrode is the connection of the electrodes to the rest of the system. Transcutaneous cables are not suitable for chronic home-use because of discomfort for subjects and the risk of infection due to perforation of the skin. In the past, several implantable systems have been proposed. All establish a telemetry link to transmit the measured information to the outside. These implants are battery powered [25] or use inductive recharging of accumulators [26], [27]. The system presented here is especially designed for prosthesis control. Therefore, it only needs to operate when the prosthesis is worn and is thus inductively powered by the prosthesis during use of the system.

The work presented here is part of the MyoPlant project [28] that ultimately aims at controlling upper extremity prostheses by means of intramuscular EMG, recorded with a new type of permanently implanted wireless EMG measurement system. Previously, first results of measurements with the novel electrodes were reported [29], [30] and the implant electronics were presented [31], [32]. Prosthesis user's demands for provision of sensory feedback by their prosthesis were also surveyed in the scope of the MyoPlant project [33] as a basis for user-oriented development of sensory feedback systems. First results of the encapsulation of implanted electrodes and the first EMG measurements were presented previously [34]. Here, we present the difference between activity and rest of muscles, followed by an identification of reaching movements in the frontal plane based on the analysis of shoulder EMG-data. This analysis will form a basis for future prosthesis control. Finally, the results from an implantation of the whole measurement system are presented.

II. Material and Methods

A. Implantable Multi-Channel Measurement System

The developed measurement system is based on a central implant that is shown in Fig. 1(a). It is built around a custom designed micro chip [32], a microcontroller (Texas Instruments MSP430) and a RF transceiver (Zarlink ZL70101). Input signals from the electrodes are bandpass filtered (6–1500 Hz) and subsequently amplified in a two stage differential amplifier with adjustable gain. The resulting signal is then digitized with 10 bit resolution. Wireless data transmission from implant to a base station uses the MICS band between 402 and 405 MHz [31]. Energy is inductively coupled into the implant [35]. Packaging was realized by preparation of the surface by a silicone primer (MED160, Nusil) and subsequent injection moulding the implant electronics into silicone (MED4244, Nusil). Electrodes were connected by two multipolar connectors (NCP-06, Omnetics Connector Corporation) each contacting two electrodes. These connectors were intra-operatively sealed with silicone (MED2000, Nusil). The electrodes were fabricated in a micro technological process [36]. Fig. 1(b) shows an electrode consisting of a 20 μm thick polyimide structure carrying five platinum contacts (E1-E5) with a surface area of 1 mm^2 and an inter-contact distance of 4 mm. After breakage of electrodes during first implantation, the electrode design was

mechanically improved [37]. All components were sterilized in an ethylene oxide process at 38 °C.

B. Impedance Measurement

A custom built impedance measurement system based on the work of Searle [38] was used to evaluate the electrode impedance over time after implantation. This allowed us to monitor the encapsulation process of the electrodes by measuring the influence of the tissue formed around the electrodes on the impedance. The system applied a current of $1\,\mu A_{\mathrm{RMS}}$ consisting of a linear combination of sine waves of 21 frequencies between 1 Hz and 10 kHz (1 Hz, 2 Hz, 4 Hz, 6 Hz, 8 Hz, 10 Hz, 20 Hz, 40 Hz, 60 Hz, 80 Hz, 100 Hz, 200 Hz, 400 Hz, 600 Hz, 800 Hz, 1 kHz, 2 kHz, 4 kHz, 6 kHz, 8 kHz, 10 kHz) between any two contacts of a single electrode. The actual current flow and resulting voltage were measured, windowed with a rectangular window and decomposed into the excited frequencies by FFT. One full wavelength of the lowest frequency investigated passed between beginning of measurements and starting point of DFT, leading to an overall measurement time of three seconds. Magnitude of the impedance was calculated by dividing the amplitude of current by the amplitude of voltage for each frequency. The phase shift was calculated by measuring the delay between current and voltage. Impedance was measured between all ten possible pairs of the five contacts (E1–E5) of each electrode during relaxation of muscles. Reported impedances are averages of these ten measurements because they better represent steady changes of electrode encapsulation over time.

C. Animal Experiments

In a first implantation, three electrodes (without the central implant) were implanted epimysially into the right deltoideus of a first rhesus macaque (male, 6 years, 6 kg) for eight weeks. Suitable locations were chosen at the anterior, lateral, and posterior compartments of pars acromialis of the deltoid with an orientation along the muscle fibers and a distance of approximately 2 cm between electrodes. Electrode cables (AS631, Cooner Wire) in silicone tubes (AMT-1110, Aromandeo Medizin Technik) were subcutaneously routed to a connector housing on the animal‘s skull, and could be connected to the measurement system there. Impedance measurements were carried out during implantation as well as two, four, and eight weeks after implantation to monitor the encapsulation by a layer of connective tissue that is formed around electrodes. EMG measurements were carried out two, four, and eight weeks after implantation. Data analysis was performed on EMG data recorded eight weeks after implantation since the electrode-tissue interface was stable at that time.

In a second implantation the whole system, consisting of the central implant and four electrodes, was implanted in a second rhesus macaque (male, 8 years, 8 kg) for nine weeks. As shown in Fig. 2, four electrodes were epimysially implanted, one at the lateral biceps brachii, one at the lateral triceps brachii, and two at the posterior and lateral compartments of pars acromialis of the deltoideus. All electrodes were centered on the longitudinal extension of the muscles and oriented along the direction of muscle fibers. The implantable EMG measurement system was placed subcutaneously between the shoulder blades and electrodes were connected by subcutaneous cables.

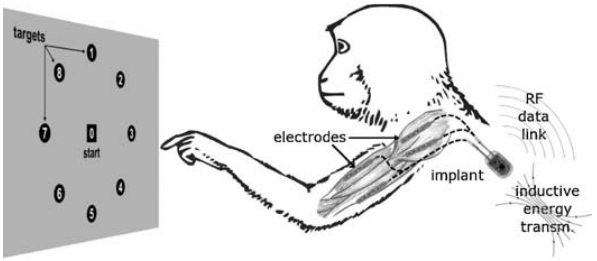

Fig. 2. Experimental setup: Implantation sites of electrodes and implantable EMG measurement system with inductive energy transmission and RF data link. The monkey is sitting in front of a touchscreen that is presenting only one of the nine cues (0–8) shown at a time as target for a single arm movement.

For all measurements, the monkey was placed in a monkey chair in front of a touch screen, on which he was previously trained to conduct visually instructed reaches [39]. At the beginning of each trial a square (Fig. 2: 0) was presented that had to be touched by the monkey. After that the square disappeared and one of the outer circles (Fig. 2: 1–8) was presented at the screen as new target. While reaching for these circles, the monkeys performed repeatable goal directed movements with their arm, thus generating reproducible voluntary contractions of the muscle under investigation. Animal experiments were carried out at the German Primate Center (Göttingen, Germany). Animal care and all experimental procedures were conducted in accordance with German laws governing animal care and were approved by LAVES (Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit, Oldenburg, reference number: 33.11.42502-064/07).

D. EMG Measurement and Analysis

EMG signals were recorded in a bipolar configuration between contacts E2 and E4 of one electrode using a biosignal acquisition device (g.USBamp, g.tec). To achieve a high bandwidth for characterization and analysis of the measured iEMG, the signal was recorded at the maximum sampling frequency of 4.8 kHz and bandpass filtered with a pass band from 2 Hz to 2 kHz to prevent DC offset and aliasing. Signal processing was performed in MATLAB (The MathWorks, Inc.). For calculation of signal-to-noise ratio (SNR) power spectral density of the recorded EMG signals was calculated using Welch’s method [40]. For analysis of muscle activation, the root mean square of the raw EMG was calculated and filtered by application of a moving average over 15% of movement duration. Then time from release of the first cue (Fig 2: 0) to touch of one of the targets (Fig. 2: 1–8) was normalized to 100% movement duration. Classification of movement direction was based on seven features in time and frequency domain [41]–[44]. These features were calculated on raw EMG in windows of 64 ms length.

Mean Absolute Value (MAV) is an estimate for the mean absolute value of the signal over a window with N samples

with measured signal amplitude of x

$$MAV = \frac{1}{N}\sum_{n=1}^{N}|x_n|.$$

Mean Absolute Value Slope (MAVS) is the difference in MAV between two adjacent windows w

$$AMVS = MAV_w - MAV_{w-1}.$$

Wave Form Length (WFL) provides information about the complexity of the waveform. It is defined as the cumulative length of waveform over the window

$$WFL = \sum_{n=2}^{N}|x_n - x_{n-1}|.$$

Willison Amplitude (WA) is an indicator for firing of motor unit action potentials by counting the number of times that the change in amplitude exceeds a certain threshold [45]. A threshold between 50 mV and 100 mV was reported in the literature [42]. In this paper, a threshold of 50 mV was applied

$$WA = \sum_{n=1}^{N} f(|x_n - x_{n=1}|).$$

$$f(x) = \left\{ \begin{array}{c} 1\ if\ x\ >\ threshold \\ 0\ otherwise \end{array} \right\}.$$

Slope Sign Changes (SSC) is related to the frequency of the signal by counting the number of times the slope of the signal changes sign within a window

$$SSC = \sum_{n=2}^{N-1} f(x_{n-1}, x_n, x_{n+1}).$$

$$f(x_{n-1}, x_n, x_{n+1}) = \left\{ \begin{array}{l} 1\ if\{x_{n-1} < x_n\ and\ x_n > x_{n+1}\}\ \ or\ \ \{x_{n-1} > x_n\ and\ x_n < x_{n+1}\} \\ 0\ otherwise \end{array} \right.$$

Mean Frequency (MF) is the average frequency and denotes the center of the distribution of power spectral density *P(f)* across frequencies *f*

$$MF = \frac{\int_0^\infty fP(f)df}{\int_0^\infty P(f)df}.$$

Median Frequency (MDF) is the frequency at which the power spectrum is divided into two parts with equal power

$$\int_0^{MDF} P(f)df = \int_{MDF}^{\infty} P(f)df = \frac{1}{2}\int_0^\infty P(f)df.$$

These features were used as a basis for classification of the EMG into different movement directions by six different classifiers. Linear discriminant analysis (LDA) and quadratic discriminant analysis (QDA), linear Naïve Bayes (NBL) and quadratic Naïve Bayes (NBQ) classifiers with diagonal covariance matrix and two Naïve Bayes classifiers based on Gaussian (NBG) and Kernel (NBK) density estimates were applied on either all or selected subsets of calculated features.

Dimensionality reduction was realized in two steps. In a first step a principal component analysis (PCA) was performed to estimate the importance of the investigated features for description of the variance contained in the signals and to investigate any linear dependencies between features. PCA was also used to get a first impression about the separability of different movement directions. In the second step subsets of features were compiled. Separate feature sets were established for each classifier in combination with each set of movements applying a forward sequential selection algorithm. This algorithm selected a set of features that was best suited to correctly classify the direction of movement. To do so, it sequentially selected features that most improve classification performance until no significant further improvement in classification accuracy could be achieved by inclusion of additional features. The fraction of correctly classified trials was chosen as criterion for classification accuracy and calculated applying a leave-one-out cross validation. For further investigation of misclassifications, confusion matrices were established by computing the redistribution errors during each classification. The aim of classification of movement directions was to evaluate the different approaches for classification and determine how many and which movements could be distinguished.

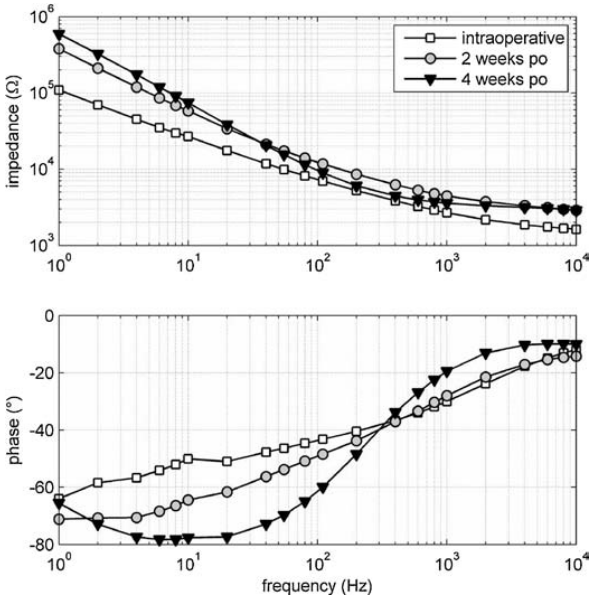

Fig. 3. Bode plot of impedance (averaged over all combinations of Ex-E4) of one electrode over frequency at three time periods after implantation.

III. Results

All impedance and EMG data presented below (Sections III. *A-D*) is based on recordings from one electrode implanted at the lateral deltoid muscle during first implantation. Contact to other electrodes was lost two weeks after implantation due to breakage of electrodes. For reasons of animal well-care a revision surgery was not performed. Signal analysis was performed on data measured eight weeks after the first implantation since electrode tissue interface was expected to be stable by that time. Reports on handling, function and biotolerance of the whole system (Section III-D) are based on findings from the second implantation.

TABLE I
PERFORMANCE OF DIFFERENT CLASSIFIERS FOR DIFFERENT SETS OF MOVEMENTS CLASSIFICATION ACCURACY IS GIVEN FOR CLASSIFIERS USING ALL INVESTIGATED FEATURES OR ONLY A FEATURE SET COMPILED IN FORWARD SELECTION

	all directions (1–8)		Three classes (1–3, 5–7, 4 and 8)		Two classes (1–3, 5–7)	
classifier	features	classification accuracy	features	classification accuracy	features	classification accuracy
LDA	MAV,SSC	53.4%	MAV,MAVS,WA	76.1%	MAV	100%
	all features	48.9%	all	72.7%	all	98.5%
QDA	MAV,MAVS,WFL	58.0%	MAV,SSC	77.3%	MAV,MAVS	100%
	all	31.8%	all	62.5%	all	100%
NBL	MAV,WFL,WA,SSC	59.1%	MAV,WA	76.1%	MAV	100%
	all	50.0%	all	70.4%	all	95.5%
NBQ	MAV,WFL,SSC	51.1%	MAV	75.0%	MAV,WFL	100%
	all	45.4%	all	68.2%	all	100%
NBG	MAV,WFL,WA,SSC	50.0%	WA,SSC	77.3%	MAV	100%
	all	43.2%	all	68.2%	all	100%
NBK	MAV,MAVS,WA	48.9%	MAV,WFL	80.8%	MAV	100%
	all	45.4%	all	75.0%	all	100%

A. In vivo Electrode Impedance

Impedance characteristics over frequency for different time spans after implantation is presented in Fig. 3. Just after implantation impedance shows a characteristic very similar to measurements in physiologic saline [30]. Impedance decreases nearly logarithmic and phase shift nearly linear with frequency. Two weeks after implantation impedance increases over the whole frequency range while the graph maintains a similar shape. Phase shift is increased for frequencies below 400 Hz. Four weeks after implantation impedance is further increased for frequencies below 35 Hz and slightly reduced for higher frequencies. The impedance also shows a more pronounced bend at the transition toward a nearly constant region around 1 kHz. The phase shift is further increased for frequencies up to 400 Hz and decreased for higher frequencies, reaching a constant value of $-10°$ above 4 kHz. Eight weeks after implantation no further changes in impedance were observed, indicating that encapsulation has reached a steady state after four weeks.

B. Signal-to-Noise Ratio of Intramuscular EMG

Power spectral densities during relaxation and contraction of the deltoideus were calculated to evaluate the sensitivity to muscle activity. Power spectral density during relaxation of the muscle has constant frequency content from 70 Hz up to 2 kHz (onset of the low-pass filter). During contraction power spectral density is increased for frequencies below 1.2 kHz with a peak at 200 Hz. At 200 Hz a difference of about 80 dB was observed between the signals.

C. Activity of Deltoideus Muscle During Arm Movements

The muscle activity for each movement direction in time domain is shown in Fig. 4. Average time passed between release of the starting cue (Fig. 2: 0) till touch of one of the targets (Fig. 2: 1–8) ranged from 440 ms to 641 ms. The root mean square (RMS) of the EMG signal averaged over all movements in one direction shows a good agreement for each movement direction. Standard deviation is considerably smaller than characteristic peaks in the signal. The average reaction time from appearance of the target to initiation of arm movement varies between 20% and 40% of movement for different movement directions but is consistent for all trials of each movement direction. There is a clear decrease in activity of the deltoid muscle from movements to the upper left (direction 8) to movements to the lower right (direction 4). For arm movements to the left (directions 6, 7, and 8) graphs show two peaks, a smaller one around 50% of movement and a higher with an amplitude of up to 1.9 mV around 80% of movement. The amplitude of the first peak especially is decreasing from direction 8 to 6. For movements in the directions 1, 2, and 3 the graph shows three distinct peaks around 40%, 60%, and 90% of movement. These peaks have amplitudes between 0.06 mV and 0.14 mV that are decreasing for the first and third peak from direction 1 over 2 to 3. Movement in direction 5 generates only a small activity of the deltoid muscle resulting in one peak around 90% of movement. Mean RMS for arm movement in the directions 4 is below 0.05 mV for the whole movement and thereby generates no clear activity pattern of the deltoid muscle.

D. Classification of Movement Direction

Results from principal component analysis are shown in the biplot [46] in Fig. 5. All investigated features contribute to the first two principal components and thereby to the description of the variance present in the signal. No strong linear dependencies are present between features indicating that features do not describe redundant information. The distributions of arm movements in different directions largely overlap but are roughly arranged along the first principal component. Downward movements (direction 5) have the most negative values. Toward the origin they are overlapping with movements to the lower-left and lower-right (directions 6, 4). Movements to the left (direction 7) are projected to negative values of the first principal component close to zero. Arm movements to the upper-left (direction 8) are spread around the origin. Along the positive axis of the first principal component movements to the right (direction 3) are followed by upward movements (direction 1) and finally movements to the upper-right (direction 2). The second principal component has hardly

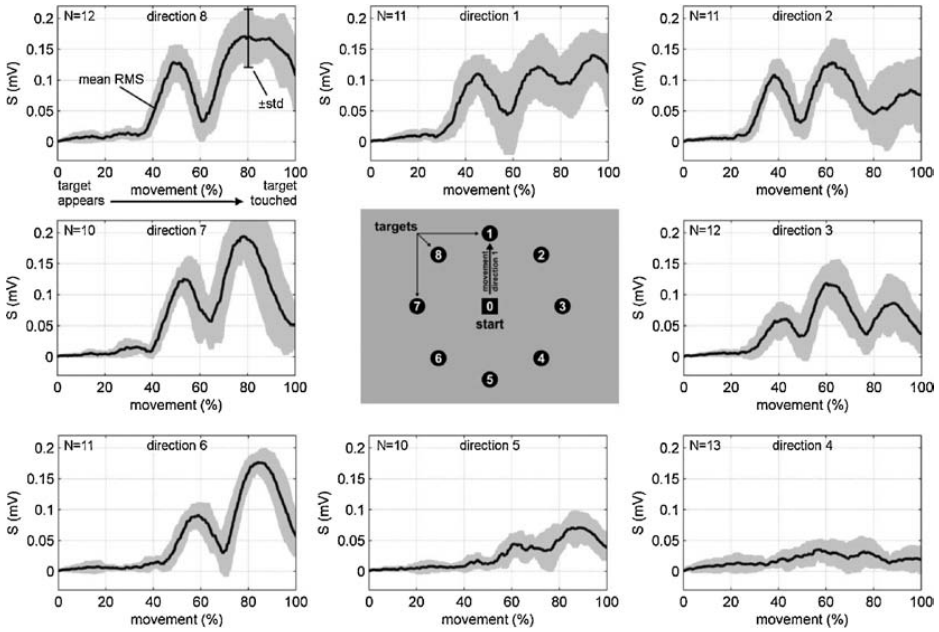

Fig. 4. Description of reaching task (center) and resulting activity of deltoid muscle for different directions of arm movement (outside). Center: All possible stimuli presented to the monkey at the touch screen. Only one stimuli is shown at a time. All trials begin with the monkey touching the center (0). After a short period one of the outer targets (1–8) appears and the recording of muscle activity shown in the outer graphs begins (0%). After a certain reaction time the monkey starts to move the arm toward the target and ends the measurement by touching the target (100%). The average time for one trial is about 500 ms. Outside: Graphs show the filtered RMS of the EMG signal *S* averaged over all movements in each movement direction (N) plotted over the time normalized to 100% of movement. Grey areas denote the standard deviation.

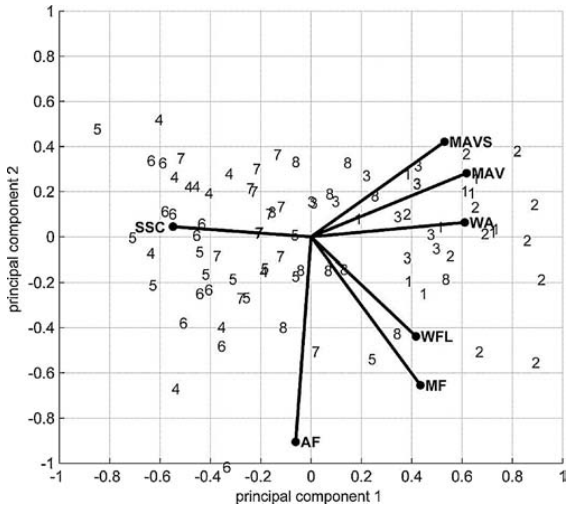

Fig. 5. Biplot showing the results of the PCA. Contributions of features to the first two principal components are shown as black bullets that are connected to the origin by black lines. The single trials of the different movement directions are projected in the space spanned by the first two principal components denoted by numbers according to their movement direction.

any influence on the differentiability of the movement directions. Beside these tendencies there is no distinct grouping for differentiation of movement directions.

Performance of classification of different sets of movements for all classifiers is shown in Table I. Classification accuracy is evaluated using leave-one-out cross validation for feature sets separately chosen in forward selection, for each combination of classifier and sets of movements. In the first set of movements, each movement directions form a separate class. Classification accuracy for these movements ranges from 31.8% to 59.1%. Best classification performance is achieved by NBL classifier and a feature set containing MAV, WFL, WA, and SSC. From the low accuracy of classification it becomes obvious that one channel of EMG from the lateral deltoid is not sufficient for reliable discrimination between arm movements in all eight directions. The second set of movements consists of three classes that are subdivided based on the distribution of movement directions along the first principal component. Movements in the directions 1, 2, and 3 form the first class, movements in directions 5, 6, and 7 make up the second class and the remaining movements (directions 4 and 8) form a third class. Classification accuracy lies between 62.5% and 80.8% and is considerably higher when compared to the first set of movements. A NBK classifier evaluating MAV and WFL features performs best on these movements. The selection of movements for the third set is based on good separability. It comprises the first two classes of the second set but excludes movements in the directions 4 and 8. For these movements all classification performance lays between 95.5% and 100%. All classifiers that operate on selected features correctly assign all of the movements to the two classes.

TABLE II
CONFUSION MATRIX CONTAINING REDISTRIBUTION ERRORS FOR CLASSIFICATION OF ALL EIGHT MOVEMENTS USING ALL INVESTIGATED FEATURES. TOP: SUMMATION OF CLASSIFICATION RESULTS OF ALL INVESTIGATED CLASSIFIERS. BOTTOM: CONFUSION MATRIX OF THE BEST PERFORMING QDA CLASSIFIER

	actual movement direction	predicted movement direction 1	2	3	4	5	6	7	8	redistribution accuracy (%)
sum of all classifiers	1	46	9	5	0	0	0	0	0	76.7
	2	15	46	5	0	0	0	0	0	69.7
	3	5	0	50	0	0	0	0	11	75.8
	4	0	0	0	35	1	15	9	0	58.3
	5	0	0	0	9	42	10	5	0	63.6
	6	0	0	0	15	3	48	0	0	72.7
	7	0	0	0	2	13	3	58	2	74.4
	8	2	3	9	0	0	0	11	41	62.1
QDA classifier	1	9	1	0	0	0	0	0	0	90.0
	2	0	11	0	0	0	0	0	0	100.0
	3	0	0	11	0	0	0	0	0	100.0
	4	0	0	0	8	1	1	0	0	80.0
	5	0	0	0	1	10	0	0	0	90.9
	6	0	0	0	0	0	11	0	0	100.0
	7	0	0	0	0	0	0	13	0	100.0
	8	0	0	0	0	0	0	0	11	100.0

Selection of features yields better classification accuracy than using all investigated features for all combinations of classifiers and movements, if not both approaches yield 100% classification accuracy. The MAV is the most important feature for classification and is part of the selected feature sets of all but one classifier. Four classifiers use only the MAV and thereby achieve 100% classification accuracy for the simplest set of movements. Frequency domain features MF and MDF were not selected for any of the classifiers.

For further investigation of misclassifications, confusion matrices were established from redistribution errors, not leave-one-out cross validation as above, of classifiers that are using all features investigated (Table II). The upper confusion matrix sums up the redistribution results from all classifiers applying all investigated features. A clear tendency for correct classification is present. Classification accuracy for single movements ranges from 53.8% to 76.7%. Movements in the directions 1, 2, 3, 5, 6, and 7 are classified correctly most often. Classification of movements in direction 4 is worst. Most incorrect classified movements are confused with movements into the first or second directions following clockwise or counterclockwise. Movements in direction 3 are also mistaken for movements in direction 8 and movements in direction 8 with those in direction 3. The lower confusion matrix shows classification results of the QDA classifier which yields least redistribution errors. The QDA classifier using all investigated features correctly classifies all movements in the directions 2, 3, 6, 7, and 8. Again classification of movements in direction 4 is worst.

E. Results From Implantation of the Whole Measurement System

The handling of electrodes and central implant during implantation and subcutaneous tunneling of wires were good and allowed for precise placement with little tissue damage in combination with the developed implantation procedure. Intraoperational sealing of connectors in silicone was easily done by the surgeon and did not extend operation time for long. Inductive energy transmission to the central implant worked well and a data link could be established to the RF transceiver for the whole period of implantation of nine weeks. However, we encountered contact problems between the electrodes and the circuit board, resulting in a loss of EMG signals. It was thus not possible to record EMG from the connected electrodes. When explanted after nine weeks, all components were encapsulated into connective tissue but no signs of tissue damage or inflammation were visible. Visual inspection of silicone packaging of implant electronics showed no signs of leakage or breakage.

IV. CONCLUSION

Implantation of the whole measurement system demonstrated biotolerance for up to nine weeks. Impedance measurements showed considerable changes in electrode impedance over time following implantation. Changes decreased over time and reached a constant level after a period of four weeks indicating a completed encapsulation of the implanted electrodes. It was possible to clearly distinguish contraction and relaxation of the investigated muscle. The observed SNR of 80 dB at 200 Hz is a considerable improvement compared to the SNR < 10 of surface EMG [6].

The investigation of the activation of the deltoid muscle during different arm movements showed a high degree of agreement for different trials of each movement direction while revealing clear differences between different movement directions. Reliable discrimination of reaching movements in the frontal plane between upward-outward movements (directions 1,2 and 3 for the right hand) and downward-inward movement (directions 5, 6 and 7 for the right hand) of the arm was made possible by the application of simple classifiers on a small number of time domain features. This indicates that EMG from the lateral deltoideus is a good indicator for discriminating these arm movements in the frontal plane. Taking into account that this was the only signal for classification, it had to be expected that it would not be possible to reliably classify all eight movement directions.

Soma et al [15] tried to discriminate reaching movements in five different directions by measuring sEMG and acceleration of eight shoulder and chest muscles. For three human subjects they used data segments of 1 to 1.5 seconds and achieved an average classification accuracy of 87.5%. The same group also investigated the importance of the eight investigated muscles for classification performance and found pectoralis major to be most important, followed by trapezius and deltoid muscles [16]. Investigations on prosthesis control [42]–[44] evaluated two channels of sEMG and focused on classification of clearly distinguishable contraction patterns that were intentionally generated by human subjects. Hudgins *et al.* [43] classified four different contraction patterns using six features calculated on 40 ms long frames of EMG achieving 91.2% of correct classifications. Tkach *et al.* [44] achieved around 90% of correct classification of five arm movements by evaluation of four features over analysis windows of 150 ms.

Selection of feature sets achieves better classification accuracy for all investigated classifiers and sets of movements.

The most important feature for classification is the MAV. Its efficient calculation in combination with application of a simple LDA classifier allows implementation in low-power hardware. This is a key concern in prosthetics since energy supply is limited and large batteries increase the weight of the prosthesis and thereby the discomfort of the user. Even though a longer time window for analysis would improve classification performance [42], [47] the short window length of 64 ms allows for previous detection of movement onset and following processing time to achieve a response of the prosthesis within about 150 ms. This is essential since prosthesis users experience this short delay as instantaneous response of the prosthesis, which is important for acceptance of prostheses by their users [48]. Further investigations will focus on reliable intramuscular measurement of further muscles that are relevant for other arm movements. As soon as these signals are integrated into the identification of arm movements it should be possible to achieve good accuracy.

The problems encountered with the whole implantable system during EMG recording have not been observed during extensive *in vitro* testing of identical implants. A single fault in the implanted system seems thus the most likely cause for the loss of EMG-signals. The implantation of the whole system yielded good intra-operative handling and biocompatibility of electrodes, cables and central implant. Combined with high signal to noise ratio and promising performance even with simple classification algorithms these findings endorse the approach of using intramuscular EMG for control of hand prosthesis. Development of the fully implanted EMG measurement system will continue with the ultimate aim of implantation into a human amputee.

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Chapter 4

Discussion

The aim of this work has been to advance the state of the art in upper extremity prosthetics according to the actual needs of prosthesis users. To ensure the relevance of the work for prosthesis users it was based on a survey asking them about their satisfaction with their current prostheses and their suggestions for improvement of future prostheses. The developed implantable EMG measurement system for prosthesis control addressed the need for improved control found in the survey. It reached mechanical stability and was able to measure multiple channels of EMG. Analysis of the measured signals indicated good suitability for prosthesis control and algorithms capable of identification of movements from these signals were identified. The following discussion of these diverse results is subdivided into the following parts:

- Section 4.1 compares findings on all aspects of the user survey to those reported by other authors to estimate their validity and then points out conclusions relevant for prostheses and their control.

- Section 4.2 discusses the developed implantable measurement system, comprising electrode development, implantation procedure and findings form animal experiments.

- Section 4.3 addresses the analysis of measured signals, including signal properties, classification of movements from these signals and the first measurements carried out with the whole implanted measurement system.

- The final conclusions, highlighting the relevance of these findings for future prostheses, are then drawn in chapter 5.

4.1 User survey

The user survey achieved detailed insights into the satisfaction of prosthesis users and their suggested improvements for future arm prostheses [Lewis et al., 2013c] (see Pub.1 on page 74). In addition it investigated the need for sensory feedback in a detail not reported before and reports aspects of phantom phenomena in relation to prosthesis use and control [Lewis et al., 2012a] (see Pub.2 on page 76). The 108 surveys answered by electric prosthesis users provided a broad basis for statistical analysis and deduction of user demands. Nonetheless, the validity of the findings is confirmed by comparison to other studies, in the following.

4.1.1 General results

Participation. Taking into account the large extend of the survey documents and the indirect contact to perspective respondents, the achieved response rate of 25% to the mailed survey is a reasonable result. The generally low participation in the on-line survey, in contrast to the high participation of amputees contacted by one highly engaged orthopedic technician in Norway, emphasizes the necessity of a direct personal contact when inviting amputees to take part in such a survey [Wright and Schwager, 2008].

To facilitate the integration of user demands into the development process of future prosthesis, it would have been handsome to establish a panel of amputees willing to participate in future surveys. Giving participants the opportunity to opt-in such a panel would have been easy, but it was not possible for Otto Bock to fulfill all requirements necessary for handling of sensitive data in accordance with privacy protection laws, to allow for establishment of such a panel.

Pretesting and possible improvements. Taking into account the constraints, of the small population of upper limb amputees and the difficulties to contact them, which did not allow for an extensive pretesting of the survey in the field, a thorough pretesting was performed by combining several applicable laboratory techniques. Though the need for improvement of at least two questions might have been identified in extensive field tests with subsequent statistical evaluation.

In question A5 (Appendix on page 167) of the survey participants were asked how much they agree with different statements. The first two statements were if they *"perceive their prosthesis as a part of their body"* and if they *"perceive their prosthesis as a tool"*. These two statements should have been brought together in one item as opposing endpoints of one bipolar scale asking whether respondents perceive their prosthesis as a part of their body or as a tool. The last two statements asked for agreement with participants are able to *"control their prosthesis without thinking about it"* and if they *"had to learn how to control their prosthesis"*. It should be investigated how intuitive prosthesis control was in the beginning and how much attention it needs after it was learned. These questions should be operationalized in two items with bipolar response scales with opposed statements at their endpoints. The first should have asked whether the control of the prosthesis was intuitive right from the beginning or it was hard to learn. The second question should have asked whether respondents have to think about controlling their prosthesis or if they do not have to pay attention, after they initially learned to control it. The way the question was posed in the survey, answers showed a tendency for agreement with all items and thereby inhibit deduction of clear statements.

The second question found to be improvable was the question about physical activity (D11, Appendix on page 178). At the end of an extensive survey participants had to engage with a new type of question and retrieve extensive information about their everyday live. During laboratory techniques applied for pretesting, respondents and experts took the time to think about the question and answered it thoroughly. However, in the field many respondents skipped this question or answered only parts of it. This made evaluation of answers impossible since both *days per week* and *minutes per day* were needed to calculate the physical activity of respondents. The question should have been shorter and easier to answer. Even though it might have not given a precise quantification of the respondents' physical activity, it would have achieved evaluable information over a larger fraction of respondents.

Representativeness of the sample. The mean age of respondents was 43 ($\pm$17) years. This is considerably lower than the mean age of above 60 years of upper extremity amputees in

Germany found by the Federal Statistics Office in 2009 [Destatis, 2012b]. On the other hand also other studies [Montoya et al., 1997, Kooijman et al., 2000, Silcox et al., 1993, Kyberd et al., 2007b] report mean ages of participants between 41 and 44 years. The only study found that matched the high age was the survey of Dijkstra [Dijkstra et al., 2002] who reported a mean age of 62 years. In the most extensive survey on upper extremity prosthesis users Atkins [Atkins et al., 1996] received responses from 2477 individuals with a mean age of 28 ($\pm$23) years. In this study users of electric prostheses had a considerably lower mean age of 25 ($\pm$20) years compared to a mean age of 32 ($\pm$21) years of users of body powered prostheses. If the population of electric prosthesis users is actually younger than that of amputees, in average, this might be a reason the lower mean age of respondents to this survey on electric prostheses compared to the mean age of amputees in Germany.

Besides, it is probable that the sample selection had an influence on including younger patients. In a first step orthopedic technicians selected prosthesis users to which they forwarded the survey. In personal communication some reported to have forwarded the survey to those of their patient that were active users of electric prosthesis and interested in technology and new developments in the field of prosthetics. The second step is the self-selection of respondents. Each prosthesis user who received a questionnaire had to decide whether he was motivated to give information that is *'accounted for in future development'* of prostheses. This might be more encouraging for younger amputees who might live to see the results of this development.

The high fraction (77%) of male respondents to the survey closely resembles the division between female (30%) and male (70%) amputees in Germany surveyed by the Federal Statistics Office in 2009 [Destatis, 2012a]. Transradial amputation made up 60% of amputations and was the most common level of limb absence amongst respondents. This lays in the range of other studies which reported transradial amputations of 31% [Davidson, 2002], 45% [Atkins et al., 1996], 54% [Biddiss et al., 2007], 68% [Shukla et al., 1982] and 80% [Pylatiuk et al., 2007]. Biddiss [Biddiss and Chau, 2007] reported an average of 80% of amputee subjects to have a transradial amputation when comparing 22 studies.

Prosthesis use. Participants of this study used their myoelectric prostheses extensively, on average 10 hours per day during the week and for 9 hours a day on the weekend. This corresponds with the findings of Kooijman [Kooijman et al., 2000], Kyberd [Kyberd et al., 2007b] and Pylatiuk [Pylatiuk et al., 2007] who found that prostheses were worn for more than 8 hours a day by 72%, 76% and more than 80% of respondents, respectively. In the survey of Kyberd 46% of respondents used their prosthesis even more than 12 hours per day. Respondents were using their prosthesis longer during the week than at the weekend. This is in accordance with other studies that found that electric prostheses are used more during work than at home [Davidson, 2002, Silcox et al., 1993] and wearing time is shorter during recreational time [Pylatiuk et al., 2007].

Analysis of the wearing time of different prosthesis types showed that electric prostheses are used for longer compared to other prosthesis types during the week. This indicates that electric prostheses are most functional in professional life for most respondents. It is also noteworthy that only cosmetic prostheses are worn longer during the weekend than during the week. This might be caused by the fact that even though they are more practical for performing tasks related to professional work, electrical prostheses do not meet all demands of prosthesis users. When accounting for suggested improvements, discussed below, this might be the higher weight and worse cosmetic appearance of electric prostheses compared to cosmetic ones. These findings are supported by those of Gaine [Gaine et al., 1997] who found that prosthesis users wear different types of prostheses depending on the task.

4.1.2 Satisfaction and suggested improvements

Prosthesis satisfaction. Three different aspects of the satisfaction of prosthesis users with their current electric prosthesis were investigated: the overall satisfaction, satisfaction with different features of the prosthesis and satisfaction with the prosthesis during different activities of daily life (ADLs). Respondents were rather satisfied with the prosthesis itself and its features but a significantly lower satisfaction was present with the prosthesis during different ADLs. This indicates that development of prostheses is good in optimizing single parameters of the prosthesis. Though, paying more attention to the performance of prostheses during important ADLs might improve the capabilities of amputees in everyday life. This supports the opinion of the author, that development of prosthesis is too much technology driven and does not sufficiently account for the complex requirements arising from actual needs of prosthesis users.

The light correlation between the satisfaction with different features of the prosthesis and the time a electric prosthesis is worn during the week and at the weekend was also observed by Davidson [Davidson, 2002]. In the present study the correlation between average satisfaction with the prosthesis and time of wearing an electrical prosthesis at the weekend is higher and more significant than during the week. Besides, the satisfaction with different features of the prosthesis is significantly correlated to the time of using an electrical prosthesis only at the weekend. This indicates that prosthesis users have to be more satisfied with their prosthesis and its application for using it for long times at the weekend, while during the week prosthesis users wear their prosthesis for long times, even though they are not very satisfied with it.

Activities of daily living. The most important activities that prosthesis users want to carry out with their prosthesis found in this study were *manual work* (27%), *eating with cutlery* (23%) and *grasping of objects* (21%).

During *manual work*, the activity most important to prosthesis users, they were third least satisfied with the performance of their prosthesis. Accounting for this in future development is difficult, since on the one hand *manual work* is a wide category containing a variety of activities and on the other hand these activities might use a wide range of the capabilities of the human hand, which points out the shortcomings of prostheses to replace its functional range.

It is also noteworthy that *eating with cutlery* has the second highest importance of ADLs and the lowest satisfaction with the prosthesis while performing the task. *Eating with cutlery* asks for high dexterity and precise control of the prosthetic hand. For example moving a full spoon from a plate to the mouth demands for fine and simultaneous control of several joints. At the same time eating with others also has a social dimension, in which prosthesis users might not want to be perceived as handicapped and failures would be perceived as embarrassing. In contrast to *manual work*, *eating with cutlery* is a well-defined application of the prosthesis, which should be accounted for in future developments. An interesting approach to reduce the control effort and allow for simultaneous movement of joints, even with current myoelectric control, is to define trajectories form arbitrary points in space to the mouth of the amputee. The user can grasp a glass using the normal control of the prosthesis and then switch to trajectory control, which coordinates the simultaneous movement of joints for moving the glass to the mouth while the speed of the movement can be controlled by the user via proportional control [Karnitz, 2010].

That *grasping of objects* was found to be the third most important activity only, might be due to the classification of the free text answers. Activities given by the respondents were only classified as *grasping objects* as long as no further reference was given. For example grasping a hammer was classified as *manual work* and not as *grasping objects*. In addition, the previous question in the survey differentiated between *grasping objects* and *holding objects*. This differentiation was partly kept by respondents when answering the free text question. *Holding objects*

was one of the top activities for another 15% of respondents. Adding the nominations of *grasping objects* and *holding objects* would make it by for the top priority with 36% of nominations. The satisfaction of respondents with their prosthesis during *grasping objects* and *holding objects* ranked third and fifth highest, respectively. Though, there are approaches having the potential to further increase the prosthesis function during these tasks. During grasping of objects self-adaptation of the hand shape can be achieved by underactuated mechanisms that increase reliability of the grasp while not posing an additional control effort on the user [Carrozza et al., 2003, Kamikawa and Maeno, 2008, Kyberd et al., 2011]. Another approach is subdividing the control of the prosthesis into a high-level and a low-level control [Carrozza et al., 2006]. The high-level control interprets the user intentions just like in standard control scheme while the low-level control maintains stability of grasp resulting in a secure holding of grasped objects without the need for user attention.

Other studies support the importance of the activities found in this study. Being able to carry out *manual work* was also found to be important by Pylatiuk [Pylatiuk et al., 2007]. In his survey he asked for the importance of *handicrafts* and found it to be the most important activity for females and second most important activity for male prosthesis users. *Eating with cutlery* was identified by several studies to be important. Pylatiuk [Pylatiuk et al., 2007] found it to be amongst the top three activities for female, male and child prosthesis users. In the survey of Atkins [Atkins et al., 1996] *use a spoon or fork* ranked amongst the top five priorities for both transradial and transhumeral amputees using electric prostheses. *Using a fork and knife* was also identified to be an important ADL to evaluate prosthesis function during an expert workshop [Peerdeman et al., 2011].

The survey showed that *driving a car* was the activity during which respondents were most satisfied with their prosthesis in average. The survey was not able to identify whether this is due to the importance of being able to drive a car for living an independent live and respondents are happy about being able to do it at all, or the prosthesis actually performs well when *driving a car*. Davidson [Davidson, 2002] found a similar fraction of 68% of respondents that drove a car and also Kyberd [Kyberd et al., 1998] emphasized a general importance of driving for prosthesis users. On the other hand nearly one third of respondents (28%) did not use their prosthesis when *driving a car*. This number includes respondents that don't drive a car at all as well as those who drive without using their prosthesis.

When analyzing the activities that respondents carry out without using their prosthesis, it turned out that only 2% do not use it for grasping and holding objects. This means that 98% of respondents use their myoelectric prosthesis actively and not only for cosmetic reasons. This finding is in stark contrast to those of Biddis [Biddiss and Chau, 2007] who reviewed studies which reported passive use of active prostheses between 16% and 38% for adult prosthesis users. The difference between active use between these studies and the present survey might be caused by sample selection. As reported above, orthopedic technicians preferred active users of prostheses when forwarding the survey documents.

The activities that most respondents carried out without using their prosthesis were *personal hygiene* (48%) followed by *drinking form a glass* (39%) and *doing sports* (37%). This may lead to the interpretation that prostheses are not necessary for *personal hygiene*. Taking into account Pylatiuk's [Pylatiuk et al., 2007] results, who asked participants for which activities prostheses should be useful and found *personal hygiene* to be the most important activity for children (83%) and the second most important for women (78%), the low utilization of prosthesis during *personal hygiene* may be caused by their limited functionality for this specific task. Besides the need for simultaneous coordination of different joints addressed above, *drinking from a glass* also needs a good awareness of the force applied to the glass for not breaking it. The provision of

the user with sensory information about the gripforce would facilitate handling of fragile objects and is discussed in more detail in section 4.1.3. Better performance of prosthesis during *doing sports* might require a variety of movements, probably including fast movements and high forces, during different sports. One approach to improve the performance during different sports is to use prosthesis specific to each activity. For example many amputee triathletes use three different prostheses for swimming, biking and running.

Improvements. The improvement that was most often mentioned by respondents was the cosmetic glove. Of importance were three aspects of the glove, namely a more natural appearance as well as better durability and less sensitivity to dirt. The cosmetic glove in general [Atkins et al., 1996,Biddiss et al., 2007,Pylatiuk et al., 2007] and the closely related aspects of appearance [Kyberd et al., 1998] and aesthetics [Pons et al., 2004] of the prosthesis were also one of the most important improvements in other studies. Providing prosthesis users with the ability to easily change their cosmetic gloves could allow wearing cosmetic gloves suited for certain activities. For example a durable glove could be worn for manual work and an aesthetically appealing one during social activities. The latter could even achieve an important improvement of prostheses respondents already own.

The suggestion that was given second most often for improvement of prostheses concerned hand and fingers, mainly wishing for separate movability of fingers and a relaxed position of the hand. Atkins [Atkins et al., 1996] also found movability of fingers and thumb to be the greatest desire of respondents. In another survey [Pylatiuk et al., 2007], 100% of respondents wished for the ability to extend the index finger and 90% for movement of individual fingers. Higher dexterity of hand and fingers poses two challenges. The mechanical challenge is to incorporate more degrees of freedom while maintaining weight, durability and robustness. The second challenge is to provide adequate control of these additional degrees of freedom. For example, flexion and extension of individual fingers would require a high number of control signals that cannot be provided by conventional means. One attempt to to provide these control signals is use of implanted systems for measurement of EMG (see table 1.4 on page 17) like the one introduced in the present work. Signal acquisition with these systems aims at measuring more independent control signals, also originating from deep and small muscles, which would be especially suited for achieving independent movement of fingers in transradial amputees. If all muscles that moved the fingers before amputation are still present in the stump of a transradial amputee, he or she could contract the muscles in the same way as before amputation. The implantable measurement system would allow separate acquisition of the activity of all muscles involved in finger movement and prosthesis control would interpret these activities to move the fingers of the prosthesis accordingly, thus providing intuitive control of multiple degrees of freedom.

Improvements of the socket were found to be third most important to participants. The vast majority of respondents asked for modifications that reduce sweating in the socket. Previous surveys also found comfort [Biddiss and Chau, 2007,Davidson, 2002,Pons et al., 2004], fit [Biddiss and Chau, 2007, Kyberd et al., 1998] and sweating [Davidson, 2002] to be problems associated with current socket designs. It is noteworthy that *donning and doffing* achieved the highest mean satisfaction while *wearing comfort* scored the second lowest. Accepting the convenient process of donning and doffing to become more difficult or take longer might give room for development of sockets that lead to more comfort when the prosthesis is actually worn. Use of an implantable system for measurement of muscle activity will also reduce the demands on the socket. Not needing for exact and stable placement of electrodes on defined positions of the stump, will allow for more freedom in socket design.

The fourth most important improvement found in the present study was control of prosthesis which was explicitly mentioned in other surveys only by Biddiss [Biddiss and Chau, 2007] as better control of fine movements and reduction of control failures. The improvement of prosthesis control is the main aim of the developed implantable EMG measurement system. Besides the provision of more intuitively generated independent control signals, more precise measurement of muscle activity will probably enable users to execute fine movements more precisely. Furthermore, a considerable reduction of control failures is expected since measured muscle activity is not influenced by changes in skin conductivity, i.e. due to sweating, or electrode artifacts due to relative movement between socket and stump anymore. Nine respondents nominated sensory feedback to be an important improvement for their prosthesis, which is discussed in detail below.

4.1.3 Sensory feedback

To the knowledge of the author the presented survey is the only one that contained a section on sensory feedback and achieved such detailed information about users' needs towards sensory feedback in future prostheses. Thereby the survey provides a valuable basis for development of feedback prostheses according to users' needs.

Current use of sensory information. Investigating the use of perceptions during control of current electric prosthesis led to three important perceptions: *visual observation*, *listening* and *sensations at the stump*. Closer analysis in this study provided new insight into how often these perceptions were used, what information they provide and how they were applied in control of current prostheses. Raising the awareness of sounds emitted by the prosthesis and sensations at the residual limb as sources of information, combined with practicing their application in prosthesis control might achieve better control requiring less visual attention for prosthesis users with their current prosthesis. If physiotherapists integrate these findings into initial training of prosthesis control, it might increase satisfaction with and reduce rejection of current prostheses.

Demands for future sensory feedback. The high importance of obtaining sensory feedback found in the present survey is supported by the findings of Atkins [Atkins et al., 1996] who ranked it third most important improvement and Biddiss [Biddiss et al., 2007] who found it to be the fourth highest design priority for electric prosthesis users. The percentage of respondents who attach importance to information about grip force (94%) and temperature of an object touched (67%) is in good agreement to Pylatiuk [Pylatiuk et al., 2007] who found that these information were wanted by 91% and 61% of respondents, respectively. The ranking of the importance of sensory information found in the present study provides a basis for choosing the kind of information that need to be measured by the prosthesis.

For transmission of sensory information from prosthesis to user, temperature was the most favored modality. Taking into account the low sensitivity of respondents to temperature changes at their residual limb as well as the slow change rate and high energy consumption of Peltier elements, thermal actuation is not a viable way to transmit sensory information. Modalities well suited for provision of sensory information are vibrations, electric stimulation and pressure which already have been applied for transmission of sensory information [Mann and Reimers, 1970, Pylatiuk et al., 2006], [Shannon, 1979, Kilgore et al., 1997, Weiss et al., 2007] and [Meek et al., 1989], respectively. Vibrational feedback is especially suitable because its application in consumer electronics, like cell phones and game controllers, led to development of miniaturized, energy efficient and low cost actuators. Visual and auditory stimuli achieved by far the least acceptance for transmission of sensory information. Both, auditory [Lundborg et al., 1999] and

optical [Engeberg and Meek, 2012] stimulation were used to transfer sensory information before but the low acceptance may be caused by the fact that other people would also notice them and additional attention would be drawn on the prosthesis.

4.1.4 Phantom phenomena

Phantom phenomena were surveyed by other studies before, but to the knowledge of the author none of the previous surveys reported phantom movability of different parts of the phantom arm in this detail and thereby investigated its applicability for intuitive prosthesis control.

Phantom sensation. The prevalence of phantom sensations in the sample population was 64%. This lays well within a wide range of prevalence between 43% [Davidson, 2002] to 86% [Shukla et al., 1982] found in other surveys [Dijkstra et al., 2002, Kooijman et al., 2000, Montoya et al., 1997]. 61% of respondents with phantom sensations experienced them *often* or *always* which is in accordance with Kooijman's [Kooijman et al., 2000] finding that 60% experience it *a few times a day* or more. The tendency that intensity of phantom sensations decreases over time was also observed by Montoya [Montoya et al., 1997].

A new aspect of phantom sensations on which no reports have been found in other studies is the fraction of amputees who can feel and move parts of their phantom arm. It was found that respondents were more aware of parts of their phantom arm that included joints compared to limb segments without joints. The fact that nearly half of participants could move their phantom hands and fingers might make it especially feasible to integrate phantom movability into the control of future prosthesis. Further research is needed to evaluate how much of this phantom movability can be measured either in the peripheral ENG or the EEG. Targeted muscle reinnervation [Kuiken et al., 2009] is one step in this direction but efferent ENG was reported to cause contractions in reinnervated muscles though the phantom does not move [Stubblefield et al., 2009]. In a system that derives phantom limb movement from peripheral ENG and uses electric stimulation of peripheral nerves to provide interpretable sensory feedback to the amputee, the prosthesis could become a physical representation of the phantom limb, which would make it intuitive to control.

Phantom pain. Phantom pain was experienced by 51% of amputees who responded to the present survey. In other surveys the prevalence is considerably lower [Gaine et al., 1997, Dijkstra et al., 2002] or higher [Davidson, 2002, Shukla et al., 1982], but there are several surveys that found similar prevalence between 50% and 51% [Montoya et al., 1997, Kooijman et al., 2000, Sherman et al., 1984]. Hill [Hill, 1999] reviewed surveys on phantom limb pain and found prevalence to range between 5% and 85% with an estimated medium of 51%.

Two reasons for overestimation of prevalence of phantom pain in some studies are assumed to be referred to sample selection [Hill, 1999]. On the one hand, for some studies investigators recruited participants in institutions where they seek treatment of pain. On the other hand, a self-selection bias might be caused by respondents that experience phantom pain being more probable to opt-into a survey that focuses on phantom pain. The present survey was distributed to prosthesis users through prosthetic workshops were amputees did not seek treatment of phantom limb pain. Since the primary focus of the survey was on *feeling prostheses* and the part on phantom pain was only secondary, it is also not expected that self-selection ratio was higher for amputees with phantom pain.

31% of respondents who experienced phantom pain experienced it *often* or *always*. The same percentage of respondents experienced phantom pain *daily at frequent intervals* in the survey

conducted by Montoya [Montoya et al., 1997]. Kooijman [Kooijman et al., 2000] found a higher fraction of 48% of amputees to experience phantom pain *a few times a day* or more. Like other studies reported before [Shukla et al., 1982, Montoya et al., 1997, Hill, 1999] in this survey it was found that average intensity of phantom pain diminishes over time tough it stays constant for some amputees [Sherman et al., 1984, Gaine et al., 1997].

Stump pain. 59% of respondents of the present study reported to experience stump pain. This is higher than all other prevalence found in literature [Gaine et al., 1997, Montoya et al., 1997, Dijkstra et al., 2002, Davidson, 2002, Kooijman et al., 2000] that range between 33% [Gaine et al., 1997] and 49% [Kooijman et al., 2000].

Even though the prevalence found in this survey is considerably higher than in others, the reported frequencies and intensities of stump pain are lower [Kooijman et al., 2000, Montoya et al., 1997]. The higher prevalence of stump pain compared to other studies might have been caused by the way participants were contacted. Stump pain is often related to the prosthesis, especially to poor fitting sockets, and therefore prosthesis users who experience stump pain might have more frequent contact to their orthopedic workshops. Since participants were recruited through orthopedic workshops this might have caused a higher prevalence of stump pain in the sample population. The higher prevalence in combination with lower frequencies and intensities of stump pain might have two other explanations. On the one hand, the first part of the survey on prosthesis satisfaction rose the awareness of the problems caused by the socket that often result in at least uncomfortable situations at the stump. On the other hand, the previous part of the survey on sensory feedback asked respondents for intense engagement in sensations at the stump. Both might have led to reporting of discomforts that would not have been reported as stump pain otherwise. This assumption is supported by the fact that 17% of respondents who reported to experience stump pain described its intensity as *no pain*.

Correlation. In the present study a strong correlation between phantom sensation and phantom pain was present, in both prevalence and frequency. This might be caused by the definition of phantom sensation and phantom pain, which are very similar and ask the amputee to decide whether a sensation is painful or not [Hill, 1999]. Phantom pain and pain in the residual limb were also found to be correlated in prevalence, frequency and intensity. These correlations were not as strong as those between phantom sensations and phantom pain but also highly significant. It was reported that amputees are not always able to differentiate between stump and phantom pain [Sherman et al., 1984, Sherman and Sherman, 1985]. Correlation between these phantom and pain phenomena were also reported by other authors. Dijkstra [Dijkstra et al., 2002] found the presence of phantom sensations and stump pain to be important risk factors for the occurrence of phantom pain. A significant association of phantom sensation and phantom pain as well as phantom pain and stump pain was also found by [Kooijman et al., 2000]. Montoya [Montoya et al., 1997] even found correlation between intensity and prevalence of phantom and stump pain.

Triggers. No previous studies that investigated triggers for phantom and stump pain in free text questions were found. Therefore it seems to be a new finding that even though both kinds of pain are related to the weather, phantom pain being mainly triggered by changes in weather while stump pain is triggered by high or low temperatures. Effects that were investigated and identified as potential triggers in other studies were the difference in temperature between the stump and the contralateral intact arm [Hill, 1999] and the presence of neuroma or other stump pathologies [Sherman, 1989, Kooijman et al., 2000, Hill, 1999].

Treatment. In the present study only half of the respondents who experienced phantom and/or stump pain attempted treatment. The contrast between the size of the problem and the seeking of treatment was also reported by others [Kooijman et al., 2000, Machin and C Williams, 1998]. In her review Hill [Hill, 1999] found even higher percentages between 54% and 85% of amputees not seeking treatment even though reporting significant levels of phantom limb pain. Effectiveness of treatment ranged between 25% for alcohol and 73% for drugs and was therefore way more effective than success rates of 1% reported by Sherman [Sherman et al., 1984, Sherman and Sherman, 1985]. The free text question collected new ideas for treatment of pain phenomena and showed that using the electrical prosthesis helped dealing with phantom limb pain in two patients. Positive effects of prosthesis use on phantom pain were also reported by other authors [Weiss et al., 1999, Flor et al., 2001, Weiss and Miltner, 2003].

4.1.5 Conclusions for the development of future prostheses

In the user survey it was possible to obtain information from a large number of users of myoelectric prostheses and derive relevant input for development of future prostheses. Features of the prosthesis needing improvement comprised appearance and durability of the cosmetic glove, more dexterity and enhanced grasping capabilities of the prosthetic hand, a more comfortable socket that reduces sweating of the stump and reduced weight of the prosthesis. First approaches to overcome most of these issues were already suggested above. Besides improvement of single features of the prosthesis, development of future prostheses should also consider design scenarios comprising different ADLs. As a basis for this it was found that prostheses are most important to users during *manual work*, *eating with cutlery* as well as *grasping* and *holding of objects*. At the same time they were least satisfied with their prosthesis during *manual work*, *drinking from a glass* and *eating with cutlery*. These activities should be considered in development of future prostheses and further input could be obtained by dedicated surveys that focus on the importance of and satisfaction with their prosthesis during different ADLs.

The presented findings on sensory feedback are, to the knowledge of the author, the most detailed ones published yet. It was found that receiving sensory feedback has a high relevance for most prosthesis users. Sensory information found to be most important to users, and therefore should be provided by future feedback prostheses, were *grip force*, proprioceptive information about *movement* and *position* of the prosthesis followed by *first contact* and *end of contact* to a grasped object. Modalities identified as appropriate for transmission of these information were *vibration*, *electric stimulation* and *pressure*. They should be considered for transfer of sensory information from feedback prostheses to their users. Until prostheses that provide their users with sensory feedback become available, the information identified to be already applied by amputees to control their current prosthesis should be integrated into initial prosthesis training by physiotherapists. Besides visual observation, these also include the sound of the motors to gain information about the movement of the prosthesis and the grip force applied as well as sensations at the stump for acquiring information about objects held. Training to use these sensations during prosthesis control may achieve a higher satisfaction with current prostheses and thereby reduce the rate of their rejection.

The most important finding on phantom phenomena, which was not reported in this detail before, is the movability of different parts of the phantom arm. The high fraction of amputees who can feel and move their phantom hand, makes using phantom movability a appropriate means for achieving intuitive control of future prostheses.

In relation to the developed implantable EMG measurements system for prosthesis control, the most important findings were that prosthesis users want improved control, including movement of more degrees of freedom, even for individual fingers, less control errors and better control

of fine movements.

4.2 Implantable measurement system for prosthesis control

The developed implantable EMG measurement system provides a means for fundamental improvement of prosthesis control, which was found to be an important concern in the user survey [Lewis et al., 2013c] (see Pub.1 on page 74). Thorough testing of developed electrodes [Lewis et al., 2010,Lewis et al., 2013a] (see Pub.3 and Pub.4 on page107) and the entire system demonstrated good *in vivo* stability and the function of all components was proven during first EMG measurements with the whole system.

4.2.1 Evaluation of the implantable EMG measurement system

Animal trials. The animal trials carried out for *in vivo* evaluation of the system were necessary before a future clinical trial in humans. The encountered challenges emphasize the necessity of these experiments to gain reliable information about the function and the durability of the system before it is implanted in humans. The optimism towards the developed system and the wish to achieve a human evaluation in in a short time frame, led to choosing a complex animal model right from the beginning of the preclinical evaluation. Though encountered challenges made it necessary to go back to less complex models in smaller animals later. Retrospectively, it would have been better to start with investigation of electrodes and leads in rats, then evaluate the mechanical stability and function of the whole system in sheep and finally investigate the measured EMG in more detail in primates. This proceeding would have considerably increased the number of trials and information gained in simpler animal models, providing the opportunity to faster overcome encountered problems, while at the same time decreasing the number of primate experiments.

The primate experiments had high aims. Regarding the physical system, these experiments should confirm the expected mechanical stability of all implanted components and the appropriate packaging of implant electronics. Besides, it aimed at proving that the inductive energy supply and wireless data transmission work *in vivo* as good as they did during *in vitro* tests. Measurement of *in vivo* impedance of implanted electrodes should provide information for layout of the input stages of the amplifiers of the central implant and monitor the process of encapsulation for determining when it can be expected to be completed. Further, EMG measurements during the reaching task should provide the basis for development of a prosthesis control, which, by the way, was the initial goal of the presented work. These ambitious aims were not reached for reasons discussed in the following.

The rhesus macaque was an attractive model for the experiments due to the similarity of its anatomy to the human. It has two arms that contain the same joints and that are moved in a manner similar to humans. This allowed implantation of electrodes on muscles that might be target muscles for implantations in transhumeral amputees, too. Though, the intended application of the final system is the implantation in the muscles of the forearm of transradial amputees or reinnervated chest muscles of amputees who underwent Targeted Muscle Reinnervation (TMR). Cables could be run over the same joints with a similar range of motion compared to the human. However the central implant could not be placed in locations that are intended for human implantation due to the smaller size of the monkeys. Anyway, it might be beneficial to place the central implant in the stump of amputees to be able to place the primary coil for energy transmission in the socket of the prosthesis. Then, electrode cables would not have to cross joints, but the prosthesis would introduce external forces acting on the implanted

components, which were not investigated in any of the animal models.

The reaching task in which the animals were trained was a good setup for measurement of EMG during reproducible voluntary contractions of arm muscles. If it would have been possible to record more than one channel of EMG from the *musculus deltoideus*, this setup would have probably been a good experiment for later classification of signals into the eight movement directions. On the other hand the contractions of the arm muscles during reaching movements were different from those expected to be generated by amputees for prosthesis control. The reaching movements were very fast and were generated from short dynamic contractions of the arm muscles. In contrast, amputees use sustained contractions of different strength and their muscles often don't change length during contraction since they are connected to the distal bone of the stump [Baumgartner et al., 2008]. It was reported that these contractions of residual muscles produce different EMG signals compared to intact muscles [O'Neill et al., 1994]. The measurement of physiologic movements for evaluation of prosthesis control algorithms is often a problem since healthy human subjects achieve higher success rates compared to amputees [Cipriani et al., 2011, Jiang et al., 2012]. Another shortcoming of the reaching task was, that only the point in time of onset and end of the reaching movement as well as the movement direction were externally measured. This did not allow for an estimation of the forces generated by the muscles. Three-dimensional motion tracking of the different segments of the arm would have allowed to measure the segment accelerations. These could then be used for estimating the joint moments by application of inverse dynamics, which in turn would have allowed estimation of the muscle forces [Winter, 1990]. For direct measurement of forces the setup has to be changed fundamentally, for example to handling of objects which are instrumented to measure the force acting on them.

In the rat experiments, the high number of implantations and the possibility to perform a biopsy of the tissue surrounding the electrodes during explantation, made the model suitable for a thorough investigation of the implantation procedure as well as the effect of the implanted electrodes on the surrounding tissue. Rat experiments also allowed for investigation of mechanical stability of a high number of electrodes with moderate effort and in short time. Even though the mechanical stress on the electrodes was not expected to be as high as in implantations in humans, it was possible to root the cables over a joint which was actively used by the rats. These limitations had to be kept in mind when interpreting the finding that not a single silicone electrode showed any electrical or mechanical failure. Anyway, this result was a good starting point to proceed with an animal model which introduced more mechanical stress.

Sheep experiments were carried out to increase the mechanical stress on the electrodes and to carry out the first EMG measurements with the whole implantable measurement system. Increasing the mechanical stress was an important test for stability of silicone electrodes, during which the first and only break of a silicone electrode was observed. Since the animal model did not include sacrificing the sheep and spontaneous explantation of electrodes was not feasible during surgery, it was not possible to determine the point of failure. If there will be another opportunity for surgery, the electrodes should be explanted. Then they should be investigated for failures and tissue around the electrodes should undergo histological analysis, just like carried out in rat experiments.

In the second sheep experiment it was possible to demonstrate the function of the whole implantable measurement system. This included the implanted components of electrodes and central implant as well as the external components of energy supply and data transmission. The success of this experiment reached an important milestone on the way to further develop the system for an implantation in humans.

Implantation procedure. The initial implantation procedure was evaluated during the three implantations of three subsequent designs of polyimide electrodes in monkeys. The placement of the electrodes in a tunnel between the epimysium and muscle resulted in a secure positioning. Electrode contacts were positioned on the superficial muscle fibers, thus, in directly contact to the EMG signal source. Though, over time a layer of connective tissue formed around the electrodes, separating the contacts from the muscle fibers. This inevitable process of encapsulation would have also occurred in other locations [Grill and Mortimer, 1994]. Even though, no comparison measurements were carried out between the applied subepimysial and epimysial implantation, in which the electrodes are implanted on the outside of the epimysium, it is expected that subepimysial implantation yields higher signal amplitudes and lower cross talk between nearby muscles, since the epimysium does not attenuate the EMG signal of the target muscle but does attenuate EMG signals originating from nearby muscles, respectively. Forming the subepimysial tunnel was sometimes challenging and ruptures of the epimysium were observed. It was noticed that there were differences between the mechanical properties of the epimysium of different species. In the rhesus macaque it was harder not to damage the epimysium during tunneling in comparison to rats and sheep. One drawback of the first implantation procedure was that the incision in the skin had to extend beyond the length of the electrode, to be able to access both ends of the tunnel at the same time for pulling the electrode into it.

The second implantation procedure, developed in the present work for implantation of silicone electrodes, reduced the invasiveness by demanding access to only one end of the subepimysial tunnel. Thereby the incision had to be only a little wider than the width of the electrode carrier. To from the epimysial tunnel from this incision was unproblematic given the more durable epimysium of rats and sheep. Due to the higher stiffness of their carrier, also the insertion of the silicone electrodes could be performed from the one accessible side of the tunnel. The stiffness also prevented folding of the carrier which made it sufficient to fix the electrodes with only one suture around the cable, which also closed the subepimysial tunnel. Only one of the implanted silicone electrodes turned about 90° along its long axis and contact surfaces of all other electrodes were still facing the muscle during explantation. In addition all electrodes were held in place by the suture at the cable side and were still pointing towards the knee of the rats with the other. This demonstrated the reliability of electrode positioning achieved by the second implantation procedure.

For precise placement along the fiber direction of the muscle, it is important to form a tunnel that is not considerably larger than the electrode. To enable the surgeon to easily access whether the tunnel has the appropriate size, it would be handsome to provide a tool which has the shape of the electrode but is a little wider in each dimension so that the electrode can easily be inserted as soon as the tool fits in. This would avoid forming of too large tunnels as a precaution and evaluation of the size of the tunnel by insertion of the electrode itself, which introduces mechanical stress to the electrode. It would also be possible to construct the tool in a way that it can be used for forming the tunnel, but acceptance among surgeons might be limited since they tend to employ the instruments they are used to.

If this second implantation procedure is also applicable for implantations in humans is depending on the ability to separate the epimysium from the superficial muscle fibers to form the tunnel from the small incision. The little trauma introduced would be an important benefit, especially in the delicate region of the stump after traumatic amputations [Baumgartner et al., 2008].

Encapsulation of electrodes. The effect of encapsulation of polyimide electrodes on the electrical properties of the electrode-tissue interface seems to be mostly completed four weeks

after implantation. This is a good measure for when when control algorithms should be trained earliest and physiotherapists can start to practice prosthesis control with amputees.

Closer investigation of the encapsulation of silicone electrodes, carried out in rat experiments, indicate that the type of electrode influences the thickness of the capsule formed and therefore the electrical properties of the electrical interface. The thinner capsule formed around smaller and more flexible silicone electrodes of type A encourage development of electrodes having these properties. Decrease in the thickness of the collagen capsule between eight and twelve weeks after implantation showed that the process is not completed, even though it has hardly any influence on the impedance any more. For a closer investigation of the state of the encapsulation, further histological analysis should also investigate the cell types contained in the capsule to determine if there are still signs for an active foreign body response and at which time it can be expected to be completed.

The changes in the difference of the impedance of electrodes after implantation for different surface areas, surface structures and contact materials are addressed below. These differences between *in vitro* and *in vivo* impedance emphasize the necessity to carry out *in vivo* elements to characterize the electrical properties of implanted electrodes.

Implantation of the whole system. The implantation of the whole system in the third primate and second sheep experiment allowed for evaluation of the whole procedure including subcutaneous tunneling of the cables, intraoperative sealing of implanted connectors and placement of the central implant. Forming the subcutaneous tunnels and tunneling of the cables was easily done. Since forming of longer tunnels might become necessary in humans, it will be beneficial to use an adapted version of the tunneling and cable insertion tool used for implantation in sheep.

Before each implantation in humans the preoperative planning should consider several aspects. The target muscles should be identified in cooperation with a physiotherapist which previously accessed the capabilities of the amputee to generate control signals and, if necessary, trained the amputee in generation of additional ones. For each target muscle the intended position of the electrode should be defined which ensures a large volume of muscle under the electrode but avoids the innervation zones since this may lead to smaller signal amplitudes and introduces an increased risk of nerve damage if electrodes are migrating over time. Then, the placement of the central implant should be considered. If it is possible to place the central implant in the region of the stump which is enclosed by the socket, this would allow to correctly position the primary coil during donning of the prosthesis. Another possibility is positioning of the central implant in the limb segment proximal to the stump or at the chest. This would reduce the demands towards stable positioning between socket and stump and therefore, in addition to not needing precise positioning of surface electrodes, allow for more freedom of socket design. Though, this would make it necessary to rum cables over joints, which introduces additional mechanical stress that could be avoided otherwise. Finally, the course of the cables between electrodes and central implant should be planned precisely. The course should avoid nerves and other sensitive structures to prevent damaging them during tunneling. When cables have to be rooted across joints the cable should run in a way that introduces the least tension in the cable during movement of joints.

The distance between each electrode and the central implant should be determined and electrode cables should be manufactured accordingly. This prevents excessive length of cables which would have to be stored subcutanelusly. Storing the excessive length of the cable near the implant could also have a negative effect on inductive energy transmission and radio link for data transmission. Especially if the excessive cable is stored in loops, it can also lead to

increased pickup of electromagnetic noise.

4.2.2 Electrodes

Impedance measurement setup. All impedance measurements applied for evaluation of electrode properties were carried out in a bipolar configuration. This technique has the drawback that each measurement sums up the impedances of the electrode-tissue interfaces of both contacts and that of the tissue between the contacts into one impedance value. The impedance of a single electrode-tissue interface could have been measured in a three-electrode setup and a four-electrode setup would have allowed measurement of the impedance introduced by the tissue only [Grimnes and Martinsen, 2008, Grill and Mortimer, 1994]. Even though initial polyimide electrodes had enough contacts to allow implementation of these measurement setups, the aim was to develop bipolar electrodes, which didn't provide enough contacts for these measurements. Besides, the aim of the impedance measurements was to compare differences in impedance between electrodes with different properties. Also, the determination when the effect of encapsulation could be expected as completed, concerning the electrical properties of the interface, was investigated by comparing difference in impedance of subsequent measurements. For these investigations no absolute values of the impedance of neither one electrode-tissue interface nor the medium between the contacts were necessary. The only question which demanded for absolute values was the layout of the input stages of amplifiers on the central implant. To ensure that most of the potential appears at the input of the amplifiers, their input impedance had to be high compared to the source impedance of the electrodes-tissue interface. Overestimation of the actual impedance of the electrodes introduced a worst case scenario, which increased the requirements but had no negative effect on the resulting system.

Equivalent circuits. Even though the impedance of the medium between the contacts could not be measured directly, the Randles equivalent circuit (figure 2.25b), used for modeling of the measured impedances, introduced the excess resistance R_{E} to separately estimate the part of the resistance introduced by the medium between the contacts [Muñoz et al., 2002, Stieglitz et al., 2000]. The other two components, Faraday resistance R_{F} and Helmholtz capacity C_{H}, still comprised the effects of the interfaces at both contacts.

The quality of fit varies over electrode types and measurement setups. In general the RSS value became lower over time after implantation, for all investigated electrodes that did not break, indicating that the model is more suitable for describing these impedances. The clearest example was *electrode 2* in the second primate experiment whose RSS decreases from a value of 28 during implantation to 2 after eight weeks of implantation. The quality of fit as well as a better description of the impedance introduced by the medium between the contacts could be addressed by application of more detailed equivalent circuits. One approach is to introduce more realizable, that is frequency independent, circuit elements representing the electrode interface to the equivalent circuit. In a previous study [Lewis, 2009] this allowed for more exact fitting of the impedance of cuff electrodes using the same contact discs as the silicone electrodes developed in the present work. Increasing the complexity of the equivalent circuit representing the medium between the electrodes is another approach. For example, Barsoukov et al. [Barsoukov and Macdonald, 2005] used a separate Randles equivalent circuit for approximating the impedance introduced by the medium. Nonetheless, in the present study the medium was modeled by a resistor only, since the impedances of physiologic saline [Grimnes and Martinsen, 2008], muscle tissue [Faes et al., 1999] and connective tissue formed around epimysially implanted silicone electrodes [Grill and Mortimer, 1992, Grill and Mortimer, 1994] were reported to be nearly constant over the investigated frequency range. Another approach, if it is not

possible to mimic the impedance behavior with physically realizable circuit elements, is to introduce non-realizable circuit elements with frequency dependent properties to the equivalent circuit [Grimnes and Martinsen, 2008]. For example the constant phase element was reported to improve the description of impedance properties of epimysially implanted electrodes [Ragheb and Geddes, 1991,Barsoukov and Macdonald, 2005]. Nonetheless, the Randles equivalent circuit allowed for a better interpretation of the measured impedances by accounting observed changes to different components of the charge transmission.

Contact size and surface structure. Impedance measurements showed that microporous coating had a larger effect on reducing *in vitro* impedance compared to doubling of the contact surface for the relevant frequencies up to 2 kHz. The decrease in impedance caused by increasing the surface area was present over the whole frequency range but did not change the characteristics of the curve. These effects were also observed by Ahuja et al. [Ahuja et al., 2008]. In contrast, microporous coating changed the course of the magnitude of the impedance in a way that it reached the minimum values at lower frequencies and a characteristic bent is present at this transition towards constant values for higher frequencies. This change in characteristics was also observed for fractally coated electrodes and described as 'decrease in cut-off frequency' [Boltz et al., 1995]. Measurements also indicate that increasing the surface area of coated electrodes yields only a minor further decrease in magnitude at low frequencies but further decreases the introduced phase shift. Both, the decrease in Faraday resistance R_{F} and the increase in Helmhotz capacity C_{H}, were lager for electrodes of the same contact area when coated compared to doubling the surface area of contacts of the same surface structure.

In vivo impedances have shown that the effect of microporous coating on the electrode-tissue impedance measured with implanted electrodes is not as pronounced as on the electrode-electrolyte interface during *in vitro* measurements. Since only polyimide electrodes were manufactured with smooth and microporous contact surfaces and only one smooth electrode stayed intact until the first impedance measurement following implantation surgery, the difference in the impedance of the two contact surface structures could not be investigated over longer periods after implantation. The observed decrease in the effect on impedance reduction of microporous coating after implantation is probably due to limiting effects at the tissue side of the electrode-tissue interface which were not present at an electrode-electrolyte interface. It might also be related to changes in the microporous coating. Differences in mechanical properties, between contact and applied coating, might caused defects when the flexible contact surfaces were bent. It is also possible that mechanical abrasion decreased the effective surface of the microporous coating by damaging its fine structures. The possibility of metal abrasion which might release metal particles into the body should be investigated in more detail before microporously coated electrodes are implanted in humans.

Contact material. Impedances of contact discs made from platinum-iridium and stainless steel were compared with silicone electrodes which also had different contact areas. This made it difficult to identify whether differences in impedance were caused by the contact material or the contact size. What could not be quantified during these measurements was how the effective surface area of the electrodes was influenced by tissue or body fluids entering the interface between metal contact and silicone carrier. This effect was already described and investigated in *in vitro* measurements [Mirtaheri et al., 2005, Lewis, 2009], during which it was possible to control the effect which was not possible during the present implantations. Just like for the comparison of the surface structures and areas, also for the different contact materials the *in vitro* and *in vivo* measurements yield different relations between the impedances. This suggests

that even though *in vitro* measurements can give a good insight into impedance characteristics, *in vivo* measurements should be carried out to determine the actual impact on the impedance of implanted electrodes.

Corrosion discovered during visual inspection of explanted silicone electrodes showed that even biocompatible materials like stainless steel can develop adverse properties. In this case exposure to excessive heat during welding might have changed the resistance to corrosion. Remains of body fluids or cells found at the back of stainless steel contact discs could be a sign of inflammation as response whether to corrosion or non-biocompatible substances which might have originated from the used solder. This should be investigated in more detailed histological analyses of explanted encapsulation tissue and again emphasizes the importance to test all components of a system in animal trials before implantation in humans.

Mechanical stability. Polyimide electrodes were continuously failing when implanted on muscles. Of the nine electrodes implanted in three subsequent primate experiments only one was still intact when the first EMG measurements were planned. The reasons for failing were investigated after each experiment and successive changes were introduced to the initial design. In most cases the problems encountered in the previous experiments were overcome by these adaptations but new issues arose during their next *in vivo* evaluation.

In the first design of the polyimide electrodes, the only issue related to the electrode itself was an improvable fixation on the muscle, which was accounted for by introducing an additional suture hole at the tip of the electrode in the second design. Apart from this, the electrode was found to be electrically intact during the impedance measurements four weeks after implantation. The mechanical failures in the first experiment arose from the way electrodes were contacted during measurements in the awake primate. This included subcutaneous storing of the short cables and connectors close to the electrodes, which had the positive effect that no strong relative movements between connectors and electrodes were expected. Besides, the cables did not cross joints, which would have introduced another source for tension in the cable transmitted to the electrode. On the other hand, the short cables which were led through the skin to access the connectors for measurements in the awake monkey, were the reason for failure of the first primate experiment. Both, the aversion of the primate against foreign objects sticking out of its body as well as its decisiveness to get rid of them, were greatly underestimated. The tear-proof long sleeve shirt, intended as a precaution, was not able to effectively prevent the primate from noticing and explanting both electrodes himself. This problem was addressed by adapting the method for connection of the electrodes in the second design.

The second design improved the connection to the electrodes for measurements according to the experiences made in the first implantation. Cables were run from the electrodes at the shoulder of the monkey along its back and neck towards the back of its head, where the connectors at their ends were stored in a connector housing. This successfully achieved toleration of the implanted electrodes and prevented their destruction by the monkey. Nonetheless, four weeks after implantation only one of the three implanted electrode was fond to be entirely intact. The failures during this experiment were likely caused by strains in the electrode carrier. These could have either been introduced by relative movements of electrode carrier in relation to the adapter plate due to changes in length of the muscle they were fixed on, or by strains in the electrode cables pulling at the ceramic adapter plate which transferred the tension to the polyimide carrier. Regardless of the source of the mechanical stress, the reason for failure at this specific location was presumably the difference in mechanical properties between flexible polyimide carrier and stiff ceramic adapter plate. The successive increase in impedance observed for *electrode 3* in the second primate experiment (figure 3.18 on page 90) gave an insight into

the process of mechanical failure. Since the impedance of the two contacts, that were connected via the outer connective tracks on both sides of the polyimide carrier, increased first, it could be concluded that the mechanical failure started at both sides of the electrode. Combined with the region of the failure which was apparent after explantation, the tail of the carrier towards the adapter plate was eliminated in the next design of the electrode.

In the third design of polyimide electrodes the transition between polyimide carrier and adapter plate was improved in two ways. The first was to avoid the tail just before the carrier and the second was to use a less stiff adapter plate to decrease the difference in mechanical properties of both adjunctive structures. The wider polyimide carrier did not have any noticeable negative effects on the stability of the electrode but the Pyralux adapter introduced a new point of failure which led to breaks of all electrodes implanted during the third primate experiment. The adapter in combination with the conductive tracks was obviously not thoroughly tested for its mechanical stability before implantation. The assumption that the mechanically delicate part of the electrode, where the carrier was connected to the adapter, should be located in a mechanically less active region of the muscle, introduced further changes to the electrode design. The polyimide carrier was extended to span the region between the belly of the muscle and the tendon attached to the muscle. This concept was based on naive assumptions and turned out not to be suitable during implantation. On the one hand, each muscle had a different length between the intended position of the contacts and the tendon where the adapter should be positioned, so that electrode length would have to be adapted to each muscle separately. On the other hand, the proximal tendon of the triceps was not accessible, since it was covered by other muscles. This led to a placement of the adapter in a passive region of other muscles which moved relative to the target muscle the contacts were placed on. The second issue with the elongation of the carrier was, that it led to a enlargement of a weak point of the polyimide electrodes. During explantation it became apparent that the carriers of all electrodes, even though they were fixed at their tips with a non-absorbable filament, retracted in the subepimysial tunnel and were folded several times along their length. Even if contact would not have been broken at the adapters, contacts would not be placed at the regions of interest anymore.

Concluding, it was not possible to achieve mechanical stability for polyimide electrodes. Even though it might be possible to develop designs of polyimide electrodes that are suitable for implantation on muscles, it was not in the scope of the presented work to run through the iterations to eventually achieve this. There are several reports on short term implantations of polyimide electrodes into nerves [Citi et al., 2006, Lago et al., 2007, Rossini et al., 2010] and even muscles [Farina et al., 2007], but, to the knowledge of the author, no reliable long term implantations of polyimide electrodes were reported yet. Successful application of polyimide for implantation of up to 4.5 months was only reported for polyimide electrode arrays which were floating in the mechanically protected region between skull and cortex [Rubehn et al., 2009]. Here they were neither connected to a tissue which changes its length nor were there mechanical forces acting on them from outside. But also for this application investigators switched to silicone based electrode arrays [Henle et al., 2011].

After these repeated failures of the polyimide electrodes, the author developed an alternative electrode design for being able to conduct the planned EMG measurements. The concept of the silicone electrodes resulted in considerably thicker and larger electrode carriers which were also less flexible. Though, they achieved mechanical stability which resulted in no observed electrode failure during 48 implantations in rats and only one failure during eight implantations in sheep, both for up to twelve weeks. Other groups also reported a good stability of implanted silicone electrodes [Muñoz et al., 2002, Flores-Martínez et al., 2010]. The most valuable experience for choosing the carrier material was made with the Free Hand System [Smith et al., 1987],

a formerly commercially available system for FES of paralyzed arms, implanted to allow the patients to perform simple arm and hand movements. Analysis of 238 electrodes of this system that were epimysially implanted on different arm muscles for 3 to 16 years yielded a survival rate of almost 99% [Kilgore et al., 2003]. These findings support the expectation that the silicone electrodes developed in the present work will be durable since their carrier is also based on a PTFE reinforced silicone sheet and the contact surfaces are made from solid metal discs.

4.2.3 Cables and connectors

The straight stainless steel cables as well as the coiled MP35N cables showed no breaks in any of the implantations. This was expected since the mechanical durability of cables from stainless steel [Lewandowski et al., 2008] as well as from MP35N [Altman et al., 1998, Fallen et al., 2001] was repeatedly reported. Straight wires could be led through smaller silicone tubes which resulted in a smaller outer diameter of the cable. Since they were multistrand they were easier bended and single strands could brake without loosing the contact to the electrode. Coiling of the singlestrand wire led to an increased diameter of the resulting cable. Though, coiling prevented the occurrence of local stress in the wire and allowed elongation of the coil in the elastic silicone tube what acted as a strain relief, if the cable crossed moved joints [Altman et al., 1998]. This also prevented strains on electrodes, connectors and the central implant.

In contrast to other implantable EMG measurement systems presented in table 1.4 on page 17 the system applied in this work integrated connectors in the cables between electrodes and central implant. This facilitates implantation of the system since electrodes and central implant can be positioned independently. Subsequently, the connectors can be tunneled towards the central implant instead of exposing the electrodes to the mechanical stress of tunneling [Letechipia et al., 1991]. When considering that systems may stay implanted over several decades, precautions have to be taken concerning the replacement of broken components. Connectors allow exchange of each component separately whether it is broken or technologically outdated [Letechipia et al., 1991]. The experiences during implantation showed that it is important do distinctly label each connector for identification after tunneling and this becomes even more important during revision surgeries years after implantation. To allow any revision it has to be ensured that connectors can be properly sealed after reconnection [Strojnik et al., 2000] which was not tried in the presented experiments.

For the developed measurement system connectors were used which were not suitable for implantation themselves. Therefore they had to be sealed in silicone. Before long term implantation in humans the long term stability as well as the possibility to seal them again after revision surgery have do be investigated. One alternative would be to switch to a commercial implantable mulitpolar connector which is integrated into the central implant like the Sygnus system (Bal Seal Engineering Inc.). This approach would have the shortcoming that all electrodes are leading into one connector and all of them would have to be explanted as soon as one fails. Besides, during implantation the electrodes would have to be tunneled instead of the connector. Another viable way would be the use of four polar in-line connectors (Medtronic). They would connect two electrodes reducing the invasiveness of revision if one electrode breaks, but still require explantation of one intact electrode. The large volume of these connectors is another draw back of their application. The favored solution for connection of electrodes to a central implant would be a small bipolar in-line connector in each cable leading to a single electrode, which is positioned near the central implant.

4.2.4 Central implant

The whole implant achieved good performance in *in vitro* tests but had issues when implanted during *in vivo* experiments. Implantation of the whole system demonstrated good intra-operative handling and biocompatibility of electrodes, cables and central implant for up to nine weeks.

The inductive coupling used for energy supply of the implant was one point of failure during the third primate experiment. The requirements established for development considered a scenario in which the system is implanted into an amputee and the primary coil can be positioned at the skin of the user, directly above the implant. During animal trials this was not possible and the primary coil was positioned in the primate chair. The relative movement of the primate in relation to the magnetic field led to interruptions in the energy supply, which made continuous measurement of EMG and synchronization of the measured signals to the behavioral task impossible. Other implantable EMG measurement systems used inductively rechargeable batteries [Seydnejad 2010, Lichter 2010]. Those batteries or high capacity capacitors would have the potential to bridge these gaps in power supply but in general they suffer from a limited lifespan, higher complexity of the implant electronics and they increase the size of the central implant. For later application in prosthesis control they will not be necessary, since the implant only has to work if the prosthesis is worn and can supply the implant with power.

Resolution and sampling frequency used for measurement of EMG was appropriate for measuring the relevant frequencies with a sufficient resolution and was in the range of other systems presented in table 1.4 on page 17. The problems encountered with the whole implantable system during EMG recording have not been observed during extensive *in vitro* testing of identical implants, carried out before. A single fault in the implanted system seems thus the most likely cause for the loss of EMG signals.

The four channels available in the implantable measurement system are expected to be sufficient for achieving simultaneous proportional control of up to two degrees of freedom. For control of hand prostheses with more degrees of freedom the system would have to be adapted. The RF data link for transmission of the measured EMG data which performed well during all experiments, as long as the central implant was supplied with energy, would be able to transmit up to ten channels with 10 bit resolution [Cardona et al., 2011b]. In addition, it is already planned to integrate data reduction algorithms in future versions of the microchip which will further reduce the bandwidth necessary for each channel.

Silicone was used as outer material of the packaging due to its known biocompatibility, elastic properties which prevent mechanical damage of the surrounding tissue and the possibility to use molding for applying the outer layer [Donaldson, 1991, Donaldson and Aylett, 1995, Donaldson, 1995, Donaldson, 1997]. For a long-term implantation in humans the housing has to be adapted to a hermetical sealing ether from ceramics or metal.

4.2.5 Conclusion of the implantable EMG measurement system

By the successful EMG measurements during the second sheep experiment, the implantable measurement system has achieved an important step towards implantation in humans. The only other implantable EMG measurement systems with a central implant which was reported to successfully work in *in vivo* experiments in dogs yet, is the Ripple system [McDonnall et al., 2012a, McDonnall et al., 2012b].

Several topics still have to be addressed before a human evaluation. The packaging of the electronic components was sufficient for the time the system was implanted in the animal trial. Nonetheless long-term stability over several decades has to be guaranteed. This will generate the need for a hermetic housing probably based on ceramics or metal. To allow independent

revision of single components, resealable connectors will have to be integrated for each electrode separately. The mechanical challenges encountered during animal trials seem to be solved. Anyway, it has to be accounted for the different situation when implanted into the stump of amputees, in which considerable mechanical loads are transferred from the socket to the stump. Another important aspect is to quantify the heating of the tissue surrounding the implant.

If these technological challenges are solved the actual potential of the system for improving prosthesis control can be evaluated in a human amputee. It will certainly overcome some limitations connected to surface electrodes like electrode lift-offs, changes in skin impedance and the pick-up of noise. Still, the impact on improvement of prosthesis control has to be demonstrated.

Further improvements of the system could comprise an independently adjustable gain for each channel, to compensate differences in encapsulation, the integration of signal analysis into the implant electronics, which would allow that only the feature values have to be transmitted to the prosthesis control and it would even be possible to integrate stimulation for provision of sensory feedback.

4.3 Analysis of intramuscular EMG

Analysis of EMG signals measured with the implanted electrodes demonstrated good signal properties [Lewis et al., 2010] (see Pub.3 on page107) and it was possible to differentiate between different movements based on these signals [Lewis et al., 2012b,Lewis et al., 2013b] (see Pub.5 and Pub.6 on page 123). Also the muscle activity measured with the whole implantable measurement system achieved good signal quality and allowed for identifying the contribution of measured muscles to the observed movement of the sheep.

4.3.1 EMG measurements

In the first measurements of intramuscular EMG during the second experiment monopolar and bipolar configurations were compared. In monopolar measurements large power line interference was present. Besides, the characteristic peak at 50 Hz the noise also extended to frequencies up to 100 Hz. A filter suitable to attenuate this noise would rather have band-stop than notch characteristic and would have also attenuated important information of the EMG signal contained in this frequency range [Basmajian and De Luca, 1985].

In bipolar measurements the power-line noise was considerably reduced. Not only its magnitude was decreased by 31 dB, also its frequency range decreased considerably. When reporting that there still was power-line noise contained in the signal, it has to be taken into account that even in the bipolar measurements, there were external cables between primate and measurement equipment which were running through a lab full of electronic equipment. When investigating the optimal contact distance for bipolar recordings, measurements with a distance of 8 mm yielded the largest PSD for frequencies up to 300 Hz. Even though, for bipolar electrodes a contact distance of 10 mm was chosen, since it was expected that the larger contact distance, even though it resulted in a lower PSD, would measure a larger volume of the muscle, including more motor units. Therefore they would more reliably detect weak contractions, during which only few motor units are recruited. It was tried to quantify the motor units measured with different contact distances with EMGLab [McGill et al., 2005] but the analysis yielded no reliable results and was therefore not reported here. This was probably due to the short duration and high dynamics of voluntary contractions recorded during the reaching task. To further use multipolar electrodes would have allowed to choose the combination of contacts, which yielded the best EMG signal for bipolar recordings. Nevertheless, the choice of switching to bipolar

electrodes was based on the lower amount of cables and smaller dimension of electrodes.

Comparison of contact size, surface structure and contact material were only investigated in impedance measurements and not compared in regard to their influence on the measured EMG, since EMG recordings during voluntary contractions were only carried out with one smooth polyimide electrode in the second primate experiment and silicone electrodes with stainless steel contacts during the second sheep experiment. Further more, electrodes were placed with a distance between each other or even on different muscles, since the intention was to measure independent signals, to allow differentiation between movement directions, and not the same signals to closely compare the measurements. Other studies have reported that stainless steel electrodes yield more noisy signals when compared to platinum-iridium ones [Grimnes and Martinsen, 2008]. The improvement of the measurement properties of coated electrodes was described by Boltz et al. [Boltz et al., 1995]. They found that coating nearly doubled the amplitude of the recorded signal and thereby allowed more exact measurement of small signals.

In the applied bipolar recording configuration it was possible to clearly distinguish contraction and relaxation of the investigated muscle. The observed SNR of 39 dB around 200 Hz is a considerable improvement compared to the SNR < 10 of surface EMG [Parker et al., 2006]. The frequency range of interest was identified between the end of the low frequency artifacts at 16 Hz and 1.7 kHz where the SNR decreased below 2.5 dB.

4.3.2 Differentiation between movement directions

Differentiation in time domain. The investigation of the activation of *musculus deltoideus* during different arm movements (figure 3.35 on page 117) showed a high degree of agreement for different trials of each movement direction while revealing clear differences between different movement directions. Since differences between movement directions in time domain became clear after the movement was completed, it was necessary to establish a signal processing that faster differentiates between movement directions.

Classification. Reliable discrimination of reaching movements in the frontal plane between upward-outward and downward-inward movements of the arm was made possible by the application of simple classifiers on a small number of time domain features. During classification of eight movement directions all classifiers achieved accuracies between 49% and 59%, only, when they used selected features. While the difference between different classifiers is only 10%, feature selection improved the classification performance by up to 26% for the QDA classifier. For classification of measured EMG into three classes the classification accuracy with selected features was increased and laid between 75% and 80%, hence the difference in accuracy between investigated classifiers decreased to 5%. At the same time, the largest benefit of feature selection decreased to 15%. For differentiation between two classes for the reduced set of movement direction all classifiers achieved a classification accuracy of 100% when forward selection was applied to determine the most important features. The feature selection still had an influence of up to 5% for the LNB classifier. This shows that the difference in performance of different classifiers decreases for increased classification accuracy as well as the influence of feature selection but selection of the appropriate features is more important for good classification than selection of the classifier. This is in accordance with other studies [Merletti and Parker, 2004, Tkach et al., 2010] that found the used features have a larger influence on classification performance than the classifiers. The feature most important for classification was the MAV. It was part of 17 of the 18 feature sets established in forward selection. In 5 combinations of task and applied classifier the MAV was also the only feature used, which means that inclusion of additional features did

not improve classification accuracy. In comparison other features were only selected four to six times.

The high classification accuracy in discrimination of two classes, indicates that EMG from the lateral *musculus deltoideus* is well suited for discriminating these arm movements in the frontal plane. Taking into account that this was the only signal for classification, it had to be expected that it would not be possible to reliably classify all eight movement directions. The classification of all movements could have been improved by inclusion of more independent EMG signals originating from more muscles involved in the generation of the investigated movements. The *biceps brachii* and *triceps brachii* are responsible for flexion and extension of the elbow. Therefore they might have provided additional information about upward-inward and downward-upward movements. Even if the elbow is not actively flexed or extended, maintaining a stable joint angle during acceleration of the arm will need activity of these muscles to compensate for the inertia of the forearm. These signals were planned to be measured parallel to the *musculus deltoideus* during the third primate experiment which was not possible due to failure of the central implant. Measurement of EMG from *pectoralis major* and *musculus trapezius* could have yielded more information about the movement of the arm in the horizontal plane, since they accelerate the arm inwards and outwards, respectively.

Gonzalez et al. [Gonzalez, 2010, Soma et al., 2011] tried to discriminate reaching movements in five different directions by measuring surface EMG and acceleration of eight shoulder and chest muscles. For three human subjects they used data segments with a length between 1 s and 1.5 s and achieved an average classification accuracy of 87.5%. The same group also investigated the importance of the eight investigated muscles for classification performance and found *pectoralis major* to be most important, followed by *musculus trapezius* and *musculus deltoideus* [Horiuchi et al., 2009].

For establishment of a prosthesis control it is a good result, that the MAV evaluated with a LDA classifier achieved good classification performance. The calculation of the feature as well as the classification with this classifier are computationally efficient and allow implementation in low-power hardware. This is a key concern in prosthetics since energy supply is limited and large batteries increase the weight of the prosthesis and thereby the discomfort of the user.

Even though a longer time window for analysis would improve classification performance [Zardoshti-Kermani et al., 1995, Smith et al., 2011] the short window length of 64 ms allows for previous detection of movement onset [Staude and Wolf, 1999] and following processing time to achieve a response of the prosthesis perceived as instantaneous by the users. When investigating the competing effects of classification accuracy and control delay other studies found optimal values between 100 ms and 125 ms [Farrell and Weir, 2007] or 150 ms and 250 ms [Smith et al., 2011].

Investigations on prosthesis control [Zardoshti-Kermani et al., 1995, Hudgins et al., 1993, Tkach et al., 2010] evaluated two channels of surface EMG and focused on classification of clearly distinguishable contraction patterns that were intentionally generated by human subjects. Hudgins et al. [Hudgins et al., 1993] classified four different contraction patterns using six features calculated on 40 ms long frames of EMG achieving 91.2% of correct classifications. Tkach et al. [Tkach et al., 2010] achieved around 90% of correct classifications of five arm movements by evaluation of four features over analysis windows of 150 ms.

Further investigations will focus on reliable intramuscular measurement of further muscles that are relevant for the investigated arm movements. As soon as these signals are integrated into the identification of arm movements it should be possible to achieve better accuracy. This will be done in further primate experiments that will also include measurement of the force produced by the arm, to establish a situation in which measured EMG is more similar to that of

sustained contractions generated by amputees to control their prostheses. Though quantification of the actual value of the implantable EMG measurement system for improvement of prosthesis control will not be possible in animal trials. For this the system will have to be implanted into a human amputee who is intentionally producing contractions of the muscles in his or her stump to control a prosthesis.

4.3.3 Conclusions of the EMG analysis

EMG signals measured with the implanted electrodes demonstrated several advantages compared to those measured with surface electrodes at the skin. One advantage was the reduced pick-up of external noise. Combined with high signal amplitudes achieved by placing electrodes directly on the superficial muscle fibers, which are the source of the EMG signal, this resulted in a high signal to noise ratio of up to 39 dB. Moreover, even during the highly dynamic arm movements of the reaching task, no movement artifacts were present.

Identification of movement direction from EMG measured during the reaching task was limited by the availability of only one channel of EMG originating from the shoulder of the monkey. Nonetheless, EMG of this one channel showed high similarity amongst movements in the same direction and at the same time presented clear differences between different movement directions in time domain. Subsequent classification demonstrated that even basic classifiers and easily computable features are sufficient to achieve good classification results. Besides, it could be demonstrated, that EMG originating from the lateral *musculus deltoideus* was enough to reliably differentiate between arm movements to the lower left and the upper right. The first EMG measurements carried out with the whole implanted measurement system demonstrated good signal quality and allowed or identification of the contribution of measured muscles to the observed movements of the sheep.

Chapter 5

Conclusions

State of the art myoelectric arm prostheses provide amputees with valuable and important, yet at the same time only rudimentary, functional replacement of the lost limb. The limitations become apparent in high rejection rates caused by amputees not using their prosthesis at all. To increase prostheses' functionality, newly developed devices provide amputees with an increasing number of degrees of freedom, thus also posing higher demands on state of the art prosthesis control. These additional control needs are often poorly met and finally result in a disappointingly cumbersome and inadequate user experience. The work presented here demonstrated suitable and practical possibilities for future improvements of arm prostheses and their control.

The user survey demonstrated high satisfaction of prosthesis users with their current prostheses but at the same time identified different aspects of these prostheses and especially provision of sensory feedback and refined prosthesis control as important improvements. Development of future prostheses should focus on these aspects to provide users with prostheses that meet their needs and thereby increase prosthesis satisfaction and use. A reduced rejection rate would also hugely benefit the overall health care system.

The implantable EMG measurement system was developed to address the need for improved control of advanced arm prosthesis. It allowed for reliable measurement of highly independent control signals, that the user could generate intuitively. In this work mechanically stable electrodes and a procedure for their implantation were developed and the function and stability of the whole measurement system was demonstrated in animal experiments. Analysis of EMG signals measured during primate experiments demonstrated the good signal properties. Identification of arm movement from measured muscle activity as well as determination of suited signal features and classification algorithms provide a good basis for development of a prosthesis control on signals measured with the implantable measurement system. First EMG measurements carried out with the whole measurement system implanted in sheep demonstrated that all of its components functioned as intended.

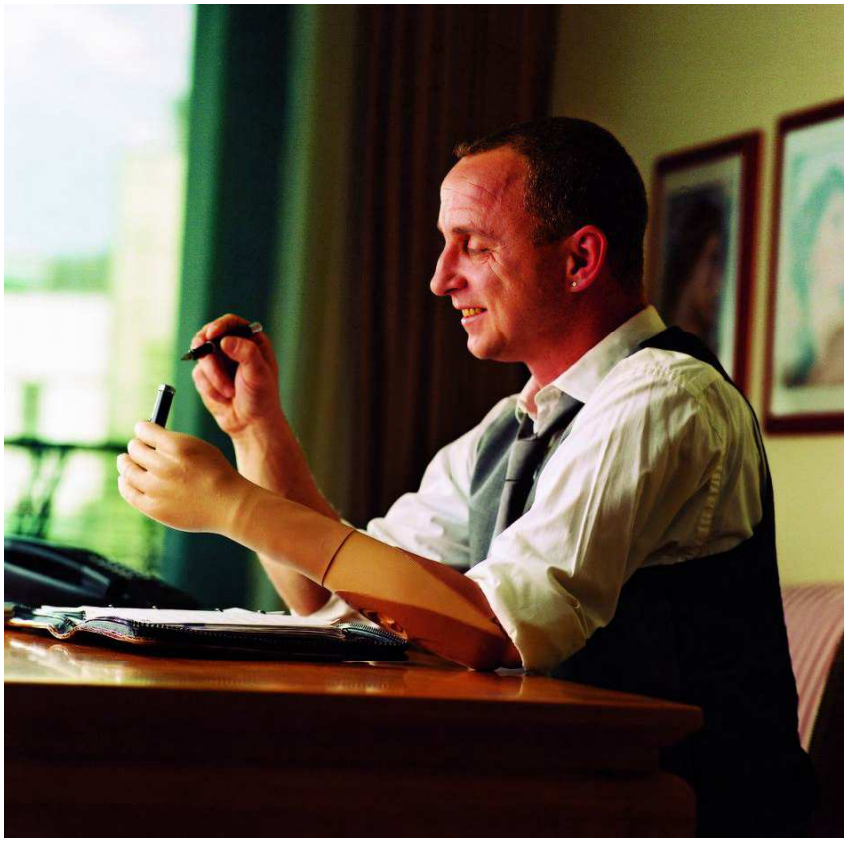
Good results achieved in animal experiments are an important milestone on the way towards the ultimate aim of an implantation of the developed system in humans, where it has the potential to fundamentally improve prosthesis control. Achieving this requires further research in two main topics. Long term stability over decades of implantation requires a hermetical housing of the electronics in the central implant. This could be realized by packaging of electronics in either a metal or a ceramic housing. Besides this, modularity of the system has to be achieved by integration of long term stable and repluggable connectors in each electrode cable to allow for separate exchange of single components of the system if they break. The first evaluation in humans will then allow for voluntary control of prostheses and thereby provide the first

possibility to quantify the actual benefit of the implantable measurement system for prosthesis control. Future development of the system will include integration of control algorithms into the implant electronics and provision of sensory feedback.

In conclusion the developed implantable EMG measurement system allows for more reliable measurement of more independent control signals, which provide the basis for intuitive and simultaneous control of multiple degrees of freedom available in advanced arm prostheses.

Appendix

Befragung von Prothesennutzern zu „Fühlenden Prothesen“



Durchgeführt im Rahmen des Verbundprojektes

MyoPlant

gefördert durch das Bundesministerium für Bildung und Forschung (BMBF),
Förderkennzeichen: 16SV3695,

Vielen Dank für Ihr Interesse an dieser Befragung!

Ziel der Befragung ist es die Wünsche und Bedürfnisse von Prothesenträgern bezüglich „Fühlender Prothesen“ kennen zu lernen, um diese bei der Entwicklung zukünftiger Prothesen zu berücksichtigen.

Die folgende Befragung ist Teil des MyoPlant-Projekts, in dem derzeit die Grundlagen für neuartige Prothesen erforscht werden. Dieses Projekt wird vom Bundesministerium für Bildung und Forschung gefördert (Förderkennzeichen: 16SV3695) und wird von den Folgenden Projektpartnern durchgeführt:

Fraunhofer IBMT · Otto Bock QUALITY FOR LIFE · TUHH Technische Universität Hamburg-Harburg · DPZ · Werner-Wicker-Klinik Bad Wildungen

Hinweise zum Ausfüllen

Der Fragebogen beinhaltet Fragen zu den vier Bereichen:

A Zufriedenheit mit Ihrer derzeitigen Prothese
B Ihre Wünsche an „Fühlende Prothesen“
C Phantomschmerzen und Phantomempfindungen
D Angaben zu Ihrer Amputation

Das Ausfüllen des Fragebogens wird ungefähr 30 Minuten in Anspruch nehmen.

Um Ihre Wünsche und Anregungen bei der Entwicklung zukünftiger Prothesen berücksichtigen zu können, ist es wichtig, dass Sie alle Fragen korrekt ausfüllen. Machen Sie die Kreuze jeweils in einem der vorgesehenen Kästchen und machen Sie, wenn nicht anders angegeben, nur ein Kreuz bei jeder Auswahl. Sollten Sie ein Kreuz versetzen wollen, malen Sie das ganze Kästchen mit dem fälschlich gesetzten Kreuz aus und setzten sie das neue in das angemessene Kästchen.

Alle Fragen beziehen sich auf Ihre elektronisch gesteuerte Prothese. Sollten Sie eine zweite kosmetische oder mechanische Prothese haben, berücksichtigen Sie diese bei Ihren Antworten nicht.

Wenn Sie den Fragebogen ausgefüllt haben, senden Sie ihn bitte im beigefügten Freiumschlag an uns zurück. Ihre Antworten sind dann absolut anonym, da weder der ausgefüllte Fragebogen noch der Freiumschlag Ihren Namen enthalten.

Falls Sie Fragen zum Fragebogen haben, beantworte ich diese gerne. Sie erreichen mich von Montag bis Mittwoch in der Zeit von 9h bis 17h und donnerstags zwischen 9h und 14h unter:

Telefon: +43 68183 496 940

Email: soeren.lewis@ottobock.com

A Zufriedenheit mit Ihrer derzeitigen Prothese

Der erste Abschnitt dieses Fragebogens enthält Fragen dazu, wie zufrieden Sie mit Ihrer derzeitigen Prothese sind.

A 1 Wie zufrieden sind Sie insgesamt mit Ihrer Prothese?

Machen Sie bitte ein Kreuz in dem Kästchen, welches Ihre Zufriedenheit mit Ihrer Prothese am besten widerspiegelt.

überhaupt nicht zufrieden ☐ ☐ ☐ ☐ voll und ganz zufrieden

A 2 Wie zufrieden sind Sie mit den folgenden Eigenschaften Ihrer Prothese?

Bei den letzten drei Eigenschaften haben Sie die Möglichkeit in der rechten Spalte „nicht zutreffend" anzukreuzen, wenn das entsprechende Gelenk nicht Teil Ihrer Prothese ist.

							nicht zutreffend
Funktionsumfang der gesamten Prothese	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	
Steuerung von Bewegungen	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	
Zuverlässigkeit	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	
Erscheinungsbild	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	
Gewicht	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	
Tragekomfort	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	
An- und Ablegen der Prothese	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	
Öffnen und Schließen der Hand	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Rotation des Handgelenks	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Beugen des Ellenbogens	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐

A 3 Wie zufrieden sind Sie mit Ihrer Prothese bei folgenden Tätigkeiten?

Sollten Sie eine aufgeführte Tätigkeiten gar nicht ausführen wählen Sie für diese bitte „wird nicht ausgeführt".

Wenn Ihnen weitere Tätigkeiten wichtig sind, tragen Sie diese bitte in die letzten Zeilen ein.

							wird nicht ausgeführt
Kleidung an- und ausziehen	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Essen zubereiten	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Mit Besteck essen	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Aus einem Glas trinken	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Körperpflege	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Büroarbeit	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Handwerkliche Arbeit	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Sport treiben	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Türen öffnen	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Gegenstände greifen	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Gegenstände tragen	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Autofahren	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Kontakt zu Menschen	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Weitere: _____	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Weitere: _____	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐
Weitere: _____	überhaupt nicht zufrieden	☐	☐	☐	☐	voll und ganz zufrieden	☐

A 4 Nennen Sie bitte die drei Tätigkeiten, die für Sie am wichtigsten sind.

Sortieren Sie die Tätigkeiten dabei nach ihrer Wichtigkeit. (1. am wichtigsten, 2. am zweitwichtigsten, ...).

1. _____
2. _____
3. _____

A 5 Wie sehr stimmen Sie mit den folgenden Aussagen überein?

„Ich nehme meine Prothese als einen Teil meines Körpers war.“	stimme über-haupt nicht zu	☐	☐	☐	☐	stimme voll und ganz zu
„Ich nehme meine Prothese als Werkzeug war.“	stimme über-haupt nicht zu	☐	☐	☐	☐	stimme voll und ganz zu
„Ich kann meine Prothese bedienen, ohne darüber nachzudenken.“	stimme über-haupt nicht zu	☐	☐	☐	☐	stimme voll und ganz zu
„Ich musste die Steuerung meiner Prothese erst erlernen.“	stimme über-haupt nicht zu	☐	☐	☐	☐	stimme voll und ganz zu

A 6 Welche Wünsche und Ideen haben Sie, wie man Ihre Prothese verbessern könnte?

Wenn Sie Ideen haben, welche Funktionen Ihre Prothese zusätzlich oder besser als zur Zeit erfüllen sollte, nutzen Sie bitte das folgende Feld, um diese knapp zu beschreiben.

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B Ihre Wünsche an „Fühlende Prothesen“

Die folgenden Fragen befassen sich mit „Fühlenden Prothesen", die im MyoPlant-Projekt gerade erforscht werden. In den Fragen haben Sie die Möglichkeit mitzuteilen, in welchen Situationen Sie es am meisten vermissen mit Ihrer Prothese fühlen zu können und welche Empfindungen Sie von Ihrer Prothese übermittelt bekommen möchten.

B 1 Wie nehmen Sie Ihre Prothese während der Nutzung wahr?

Wenn Sie Ihre Prothese auch auf andere Weise wahrnehmen, tragen Sie dies bitte in die letzten drei Zeilen ein. Mehrfachnennungen möglich

- ☐ durch Beobachten der Bewegung
- ☐ durch Geräusche bei der Bewegung der Prothese
- ☐ durch Empfindungen am Stumpf (z.B. Druck des Schaftes, Vibrationen der Motoren)
- ☐ weitere Wahrnehmung: _____
- ☐ weitere Wahrnehmung: _____
- ☐ weitere Wahrnehmung: _____

B 2 Wie nutzen Sie die in Frage B 1 genannten Wahrnehmungen bei dem Gebrauch Ihrer Prothese.

Beschreiben Sie knapp, wie Sie die Wahrnehmungen in einer bestimmten Situation nutzen.

_____

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B 3 Wie wichtig wäre es Ihnen, die folgenden Empfindungen mit Ihrer Prothese wahrzunehmen?

In den letzten drei Zeilen haben Sie die Möglichkeit weitere Empfindungen einzutragen.

Griffkraft mit der ein Gegenstand gegriffen wird	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Erster Kontakt beim Ergreifen eines Gegenstandes	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Ende des Kontakts beim Loslassen eines Gegenstandes	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Berühren eines Gegenstandes (ohne zu greifen)	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Temperatur eines berührten Gegenstandes	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Oberflächenbeschaffenheit eines berührten Gegenstandes	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Position der Prothese (Stellung der Gelenke)	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Bewegung der Prothese (Richtung, Geschwindigkeit)	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Weitere: _____	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Weitere: _____	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig
Weitere: _____	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig

B 4 Nennen Sie bitte die drei Empfindungen, welche Ihnen am wichtigsten sind.

Sortieren Sie die Empfindungen dabei nach ihrer Wichtigkeit. (1. am wichtigsten, 2. am zweitwichtigsten, ...).

1. _____

2. _____

3. _____

B 5 Wie wichtig währe es Ihnen in den folgenden Situationen Empfindungen mit Ihrer Prothese wahrnehmen zu können?

Sollten Sie eine der genannten Tätigkeiten nicht ausführen wählen Sie bitte „wird nicht ausgeführt". (Dies sind dieselben Tätigkeiten, für die Sie zuvor die Zufriedenheit mit Ihrer Prothese bewertet haben.)

							wird nicht ausgeführt
Kleidung an- und ausziehen	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Essen zubereiten	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Mit Besteck essen	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Aus einem Glas trinken	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Körperpflege	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Büroarbeit	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Handwerkliche Arbeit	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Sport treiben	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Türen öffnen	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Gegenstände greifen	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Gegenstände tragen	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Autofahren	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Kontakt zu Menschen	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Weitere: _____	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Weitere: _____	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐
Weitere: _____	überhaupt nicht wichtig	☐	☐	☐	☐	sehr wichtig	☐

B 6 Bei welchen Tätigkeiten wäre es Ihnen am wichtigsten mit Ihrer Prothese Empfindungen wahrnehmen zu können.

Sortieren Sie die Situationen dabei nach ihrer Wichtigkeit. (1. am wichtigsten, 2. am zweitwichtigsten, ...).

1. _____
2. _____
3. _____

B 7 Wie gut spüren Sie die folgenden Empfindungen an Ihrem Stumpf?

Beantworten Sie diese Frage für die überwiegende Hautfläche Ihres Stumpfes, während Sie keine Prothese tragen. Lassen Sie daher bitte einzelne besonders empfindliche oder taube Regionen aus der Bewertung heraus.

Druck auf die Haut	gar nicht	☐	☐	☐	☐	sehr intensiv
Wärme eines berührten Gegenstandes	gar nicht	☐	☐	☐	☐	sehr intensiv
Vibration	gar nicht	☐	☐	☐	☐	sehr intensiv

B 8 Wie würden Sie sich wünschen Empfindungen von Ihrer Prothese übermittelt zu bekommen?

Eine Wahrnehmung der Empfindungen wie mit einer gesunden Hand wird in naher Zukunft nicht möglich sein. Daher müssen die Informationen auf einem anderen Weg an Sie übermittelt werden.

							weiß nicht
Flächen im Schaft die ihre Temperatur verändern (kalt/warm)	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐
Vibration im Schaft (langsam/schnell oder schwach/stark)	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐
Fläche die unterschiedlich stark an den Stumpf drückt (nicht schmerzhaft)	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐
Geräusche (Variation von Tonhöhe, Lautstärke) ...	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐
Optische Signale (z.B. Lämpchen, Bildschirm)	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐
Elektrische Impulse (nicht schmerzhaft)	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐
Weitere: _____	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐
Weitere: _____	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐
Weitere: _____	überhaupt nicht gerne	☐	☐	☐	☐	sehr gerne	☐

B 9 Wie wichtig wäre es Ihnen insgesamt mit Ihrer Prothese Empfindungen wahrnehmen zu können?

überhaupt nicht wichtig ☐ ☐ ☐ ☐ sehr wichtig

C Phantomschmerzen und Phantomempfindungen

Dieser Abschnitt enthält Fragen dazu, ob Sie im Zusammenhang mit dem nicht vorhandenen Teil Ihres Armes oder dem Gebrauch Ihrer Prothese unter Schmerzen leiden und wie Sie gegebenenfalls damit umgehen. Dazu werden zunächst die folgenden vier Begriffe erläutert, welche in den Fragen auftauchen werden:

Phantomarm ist der nicht vorhandene Teil eines Armes, der als noch anwesend empfundenen wird.

Phantomempfindungen sind alle nicht schmerzhaften Empfindungen im nicht vorhandenen Teil des Armes. Beispiele für Phantomempfindungen sind die Wahrnehmung von Position oder Bewegung des nicht vorhandenen Teils des Armes sowie Empfindungen von Wärme oder Kälte.

Phantomschmerzen umfassen die genannten Phantomempfindungen, oder andere Wahrnehmungen aus dem nicht vorhandenen Teil des Armes, die so intensiv sind, dass sie als schmerzvoll empfunden werden.

Stumpfschmerzen sind schmerzvolle Empfindungen am Stumpf.

C 1 Wie häufig spürten Sie die folgenden Empfindungen innerhalb des letzten halben Jahres?

	nie	selten	gelegentlich	oft	immer
Phantomempfindungen	☐	☐	☐	☐	☐
Phantomschmerzen	☐	☐	☐	☐	☐
Stumpfschmerzen	☐	☐	☐	☐	☐

C 2 Hat sich die Häufigkeit der Empfindungen seit der Verwendung Ihrer elektrischen Prothese verändert?

	seltener geworden	gleichgeblieben	häufiger geworden
Phantomempfindungen	☐	☐	☐
Phantomschmerzen	☐	☐	☐
Stumpfschmerzen	☐	☐	☐

C 3 Wenn Sie Stumpf- oder Phantomschmerzen haben, wie stark sind diese Schmerzen?

Phantomschmerzen	keine Schmerzen	☐	☐	☐	☐	stärkster vorstellbarer Schmerz
Stumpfschmerzen	keine Schmerzen	☐	☐	☐	☐	stärkster vorstellbarer Schmerz

C 4 Hat sich die Stärke der Schmerzen seit der Verwendung Ihrer elektrischen Prothese verändert?

	abgenommen	gleichgeblieben	verstärkt
Phantomschmerzen	☐	☐	☐
Stumpfschmerzen	☐	☐	☐

C 5 Wann treten bei Ihnen Stumpf- oder Phantomschmerzen auf, bzw. wodurch werden sie begünstigt?

Bitte nennen Sie Situationen in denen bei Ihnen diese Schmerzen auftreten und Umstände unter denen Sie häufig diese Schmerzen spüren. Geben sie zu den jeweiligen Situationen bitte immer die Art des Schmerzes (Stumpf- und/oder Phantomschmerz) an.

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C 6 Welche Erfahrungen haben Sie mit Methoden zur Linderung von Stumpf- oder Phantomschmerzen gemacht?

	verschlimmert	gleichgeblieben	gelindert	keine Erfahrung
Medikamente	☐	☐	☐	☐
Elektrische Stimulation	☐	☐	☐	☐
Spritzen in den Stumpf	☐	☐	☐	☐
Operationen am Stumpf	☐	☐	☐	☐
Akupunktur	☐	☐	☐	☐
Alkoholkonsum	☐	☐	☐	☐
Weitere: _____	☐	☐	☐	☐
Weitere: _____	☐	☐	☐	☐
Weitere: _____	☐	☐	☐	☐

C 7 Wie stark werden Sie durch die Stumpf- oder Phantomschmerzen in den folgenden Bereichen eingeschränkt?

Sollten Sie in weiteren Bereichen eingeschränkt werden, tragen Sie diese bitte in die letzten drei Zeilen ein.

	keine Einschränkung					vollkommene Einschränkung
Benutzung der Prothese		☐	☐	☐	☐	
Gestaltung der Freizeit		☐	☐	☐	☐	
Ausübung des Berufs		☐	☐	☐	☐	
Weitere: _____		☐	☐	☐	☐	
Weitere: _____		☐	☐	☐	☐	
Weitere: _____		☐	☐	☐	☐	

C 8 Haben Sie Phantomempfindungen?

☐ ja **(weiter mit Frage C 9)**

☐ nein **(weiter mit Frage D 1)**

C 9 Welche Teile Ihres Phantomarms können Sie spüren?

Antworten Sie für Teile Ihres Phantomarms mit "ja" oder "nein". Für Regionen die noch Teil Ihres Körpers sind wählen Sie bitte "Teil des Körpers".

	ja	nein	Teil des Körpers
Einzelne Finger	☐	☐	☐
Ganze Hand	☐	☐	☐
Handgelenk	☐	☐	☐
Unterarm	☐	☐	☐
Ellenbogen	☐	☐	☐
Oberarm	☐	☐	☐
Schulter	☐	☐	☐

C 10 Beschreiben Sie bitte kurz Ihre Phantomempfindungen.

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C 11 Haben Sie das Gefühl Ihren Phantomarm bewegen zu können?

☐ ja **(weiter mit Frage C 12)**

☐ nein **(weiter mit Frage D 1)**

C 12 Welche Teile Ihres Phantomarms können Sie bewegen?

Antworten Sie für die Gelenke Ihres Phantomarms mit „ja“ oder „nein“. Für Gelenke, die noch Teil Ihres Körpers sind wählen Sie bitte „Teil des Körpers“.

	ja	nein	Teil des Körpers
Einzelne Finger	☐	☐	☐
Ganze Hand	☐	☐	☐
Handgelenk	☐	☐	☐
Ellenbogen	☐	☐	☐
Schulter	☐	☐	☐

C 13 Wie hat sich die Beweglichkeit Ihres Phantomarms innerhalb des letzten Jahres entwickelt?

	abgenommen	gleichgeblieben	zugenommen
Phantombewegung	☐	☐	☐

D Fragen zu Ihrer Amputation

Damit Ihre Antworten in die Entwicklung zukünftiger Prothesen einfließen können, brauchen wir abschließend noch einige Informationen zu Ihrer Person und Ihrer Amputation.

D 1 Geburtsjahr

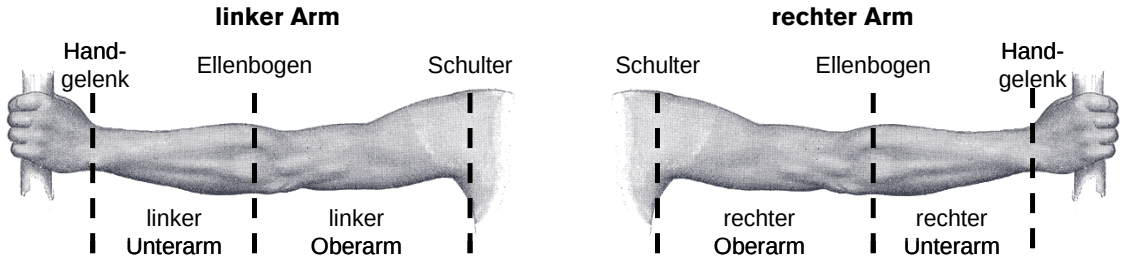
_____ Jahr

D 2 Geschlecht

☐ weiblich
☐ männlich

D 3 Bitte zeichnen Sie auf der entsprechenden Seite die Länge Ihres Stumpfes ein.

Sollten Sie beidseitig amputiert sein, tragen Sie bitte auf beide Seiten die Länge des jeweiligen Stumpfes ein.



D 4 Fehlt Ihnen ein Teil Ihres Armes seit der Geburt, oder seit einer Amputation?

☐ seit der Geburt **(weiter mit Frage D 9)**
☐ seit einer Amputation **(weiter mit Frage D 5)**

D 5 Wann wurde die (erste) Amputation durchgeführt?

_____ Jahr

D 6 Aus welchem Grund wurde die (erste) Amputation durchgeführt?

☐ Blutgefäßerkrankungen
☐ Diabetes
☐ Unfall / Verletzung
☐ Krebs
☐ Infektion
☐ Anderer Grund: _____

D 7 Welches war vor der Amputation Ihre dominante Seite?

☐ Linkshänder
☐ Rechtshänder

D 8 Waren Sie zum Zeitpunkt der Amputation erwerbstätig?

- ☐ ja, als:_____
- ☐ nein
  - ☐ Kindheit
  - ☐ Ausbildung (Schule, Studium, Weiterbildung)
  - ☐ Ruhestand
  - ☐ Kindererziehung
  - ☐ Hausarbeit
  - ☐ Arbeitslos / Arbeitsuchend
  - ☐ Sonstiges: _____

D 9 Sind Sie zurzeit erwerbstätig?

- ☐ ja, als: _____
- ☐ nein
  - ☐ Kindheit
  - ☐ Ausbildung (Schule, Studium, Weiterbildung)
  - ☐ Ruhestand
  - ☐ Kindererziehung
  - ☐ Hausarbeit
  - ☐ Arbeitsunfähigkeit auf Grund des fehlenden Armes
  - ☐ Arbeitslos / Arbeitsuchend
  - ☐ Sonstiges: _____

D 10 Werden Sie in Ihrem Alltag von anderen Menschen unterstützt?

- ☐ ja, ich werde im Alltag unterstützt von:
  - ☐ Partner
  - ☐ Eltern
  - ☐ Kindern
  - ☐ Mitbewohnern
  - ☐ Pflegekräfte
  - ☐ Sonstige Personen: _____
- ☐ nein, ich werde in meinem Alltag nicht unterstützt

D 11 Welche körperlichen Aktivitäten führen Sie regelmäßig aus?

			mache ich nicht
Zu Fuß zur Arbeit / zum Einkaufen gehen	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Mit dem Rad zur Arbeit / zum Einkaufen fahren	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Treppensteigen	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Walken / Joggen / Laufen	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Schwimmen	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Tanzen	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Fitnessstudio (Krafttraining, Sport-Kurse)	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Weitere: _____	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Weitere: _____	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐
Weitere: _____	an ___ Tagen in der Woche	ca. ___ Minuten pro Tag	☐

D 12 Was für eine Art von Prothese besitzen Sie?

Sollten Sie mehrere Prothesen besitzen, wählen Sie bitte jede dieser Prothesen, auch wenn Sie diese nicht benutze sollten.

elektrisch (Elektroden messen die Muskelaktivität am Stumpf, Motoren erzeugen die Kraft) ..... ☐

mechanisch (Seilzüge übertragen die Kraft, Zuggurt-Bandagen) ..... ☐

kosmetisch (nur ein optischer Ersatz) ..... ☐

D 13 Wie viele Jahre besitzen Sie Ihre Prothese(n) bereits?

	Zeitraum	besitze ich nicht
elektrisch	_____ Jahre	☐
mechanisch	_____ Jahre	☐
kosmetisch	_____ Jahre	☐

D 14 Wie viele Stunden am Tag nutzen Sie Ihre Prothese(n) durchschnittlich?

Sollten Sie eine ihrer Prothesen während des letzen Monats gar nicht mehr benutzt haben, wählen Sie für diese bitte „nutze ich gar nicht".

	an einem Arbeitstag	an einem arbeitsfreien Tag	nutze ich gar nicht
elektrisch	____ Stunden am Tag	____ Stunden am Tag	☐
mechanisch	____ Stunden am Tag	____ Stunden am Tag	☐
kosmetisch	____ Stunden am Tag	____ Stunden am Tag	☐

Vielen Dank!

Vielen Dank für die Zeit die Sie sich für die Beantwortung der Fragen genommen haben.

Für die Planung zukünftiger Befragungen würde es uns abschließend noch interessieren, welche Form der Befragung Sie bevorzugen?

☐ Gedruckter Fragbogen per Post

☐ Online-Fragebogen im Internet

Sollten Sie noch Anregungen zur Befragung haben, können Sie den Folgenden Platz nutzen, um diese mitzuteilen.

_____

_____

_____

_____

_____

_____

_____

_____

Bitte senden Sie den ausgefüllten Fragebogen in dem beiliegenden, frankierten Rücksendekuvert zurück. Dies gewährleistet die Anonymität Ihrer Antworten und Ihnen entstehen keine Kosten.

Mit freundlichen Grüßen,

Sören Lewis

Die Durchführung des Projekts erfolgt in Kooperation folgender Partner:

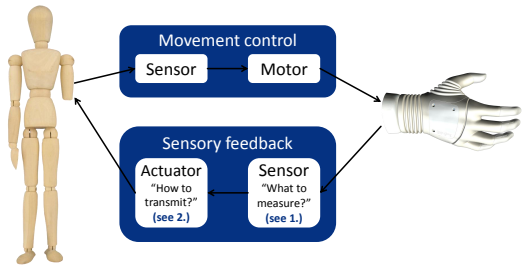
Fraunhofer IBMT · Otto Bock QUALITY FOR LIFE · TUHH Technische Universität Hamburg-Harburg · DPZ · Werner-Wicker-Klinik Bad Wildungen

Poster: IEEE International Symposium on Medical Measurement and Applications
18.-19. May 2012, Budapest, Hungary

User demands for sensory feedback in upper extremity prostheses

ottobock.

Sören Lewis, Michael Friedrich Russold and Hans Dietl, Otto Bock Healthcare Products
Eugenijus Kaniusas, Vienna University of Technology



Loosing a hand is a traumatic incident for an individual and causes, among others, two severe constrictions:

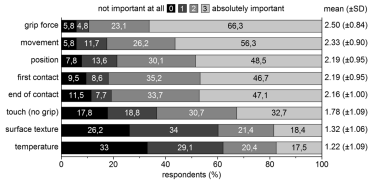
Manipulation – Amputation of a hand takes a way the most powerful tool for interaction with ones surrounding. Today's active prostheses compensate for a part of the functional loss by providing a controllable grasping tool attached to the end of the residual limb. Extensive research aims at improving control of these prostheses.

Sensation – All sensory information originating from the amputated hand are lost. This hinders tactile exploration but also changes the body image of amputees and causes changes in the brain that promote the occurrence of phantom pain.

We carried out a survey that asked amputees about their demands towards feeling prostheses, to provide a basis for a user-oriented research and development of hand prostheses that substitute the sensory information lost.

1. What users want to feel

What kind of Information



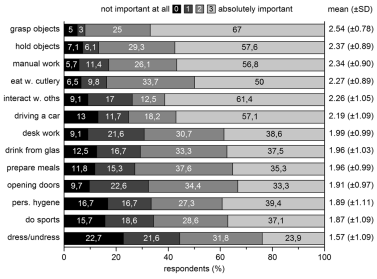
Grip force is the most important sensory information. Having this information is especially important during handling of breakable objects.

Information about movement and position of the prosthesis was of second and third highest importance to respondents, respectively. Being able to feel this information would greatly reduce the visual attention that users need to observe what their prosthesis does.

Perception of the first contact during grasping and the end of contact when releasing an object are also of high importance. This information would reduce visual attention during handling tasks.

Considerable lower mean importance is attached to information about objects that are touched but not grasped.

During which activities

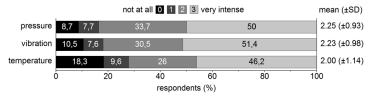


During grasping objects and holding objects sensory feedback has the highest importance to prosthesis users.

Also the next most important activities, manual work and eating with cutlery are closely related to grasping and holding objects.

2. How users want to feel

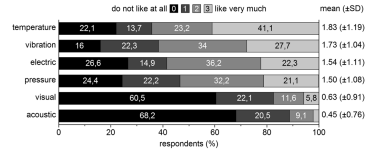
Sensitivity at residual limb



Highest sensitivity was reported for pressure on the skin of the residual limb closely followed by sensitivity to vibration. Sensitivity to temperature changes is lowest. Nearly every fifth respondent reports not to feel any temperature difference at his or her residual limb at all.

Sensitivity to different stimuli at the residual limb reported here is self assessed by respondents and not measured in physiologic tests.

Preferred modality of transmission



Amongst the modalities for transmission of sensory information surfaces at the residual limb that change their temperature have highest acceptance.

Vibrational and electric stimulation as well as pressure applied to the skin of the residual limb achieve high acceptance.

Considerably lower acceptance is achieved by visual and acoustic representation of sensory information. Noteworthy is that the smallest fraction of rejections is present in vibrational feedback and the majority of respondents explicitly rejects acoustic and visual feedback.

3. Implications for feeling prostheses

- 88% of respondents want to be able to feel with their prosthetic hand
- Information that has to be measured:
  - Grip force
  - First and last contact to an object during grasping
  - Position and movement of the whole prosthesis
- Viable modalities for transmission of sensory information are:
  - Vibrational stimulation
  - Electric stimulation
  - Pressure on the skin

Quality for life

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Poster: 3-Länder-Tagung D-A-CH
19.-21. September 2012, Graz, Austria

Satisfaction of prosthesis users with electrical hand prostheses and their suggested improvements

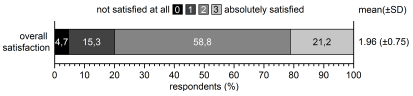
ottobock.

Sören Lewis, Michael Friedrich Russold and Hans Dietl, Otto Bock Healthcare Products
Eugenijus Kaniusas, Vienna University of Technology

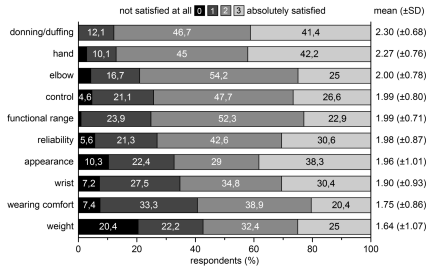
108 prosthesis users participated in a survey in which they reported about their satisfaction with their current myoelectric hand prosthesis. The satisfaction was evaluated in general, in relation to different features of the prosthesis and the use of the prosthesis during different activities. In addition, respondents gave recommendations on how their current prosthesis could be improved or what should be accounted for in development of future prostheses.

Satisfaction with current prostheses

80% of respondents are rather or absolutely satisfied with their current myoelectric prosthesis

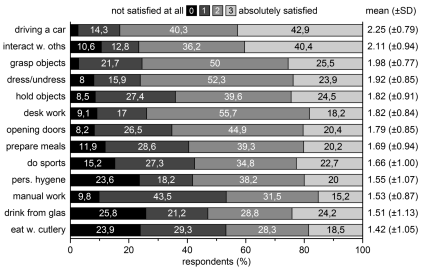


Satisfaction with different features



The highest average satisfaction is found for donning and doffing of the prosthesis, followed by the opening and closing of the hand. Average satisfaction for the most features is in the range between 2.0 and 1.9. Less satisfaction is only present for wearing comfort and the weight which is the feature respondents were least satisfied with. Average satisfaction with different features of the prosthesis is 1.98 (±0.59) which corresponds to ***rather satisfied***.

Satisfaction during different activities



The highest average satisfaction with prosthesis performance is present for driving a car and contact with others. During these activities over 40% of respondents are totally satisfied with their prosthesis. Average satisfaction between 1.98 and 1.51 is present for most of other activities. Only for eating with cutlery respondents are rather not satisfied than satisfied in average. Satisfaction with the prosthesis averaged over all investigated activities is 1.77 (±0.67) which is significantly lower than the satisfaction with features of the prosthesis ($p=0.001$) but sill corresponds to ***rather satisfied***.

Suggestions for future prostheses

Suggested improvements

Category	Times suggested	Often mentioned
Cosmetic glove	51	Less sensitive to dirt, better to clean, more natural look, durability
Hand & fingers	47	Ability to move separate fingers, relaxed position of the hand
Socket	36	Reduce sweating, slim design
Control	26	Improved control of movement, less prone to interference
Wrist	22	Rotation, flexion, extension, ulnar/radial deviation
Weight	19	lighter
Grasping	12	Reliability, gasping small objects
Sensory feedback	9	Information about grip force and position

Respondents most often asked for improvements of the cosmetic glove (n=51) making it less sensitive to dirt, easier to clean, more durable and giving it a more natural look. Second most often addressed were the prosthetic hand and its fingers (n=47) mainly wishing for independent movement of single fingers and a relaxed position of the hand when not in use. The socket was addressed 36 times, demanding less sweating and a slim design. Improvements of the wrist were suggested 22 times asking for enhanced movability. A reduction of the weight is mentioned by 19 respondents, 12 respondents demand a more reliable grasping and 9 ask for provision of sensory feedback by their prosthesis.

Implications for design of future prostheses

- Most often suggestions were related to the cosmetic glove. They might be addressed by providing interchangeable gloves suited for different activities, e.g. durable ones for manual work and more natural looking ones for social interaction.
- Accepting the convenient process of donning and doffing to become more difficult which might give room for development of sockets that lead to more wearing comfort and less sweating.
- Many suggestions were related to an increased dexterity of the hand and also on improvement of prosthesis control.
- While state of the art prostheses offer an increasing number of degrees of freedom they place high demands on prosthesis control making it even more challenging.
- In the scope of the MyoPlant project we are developing an implantable EMG measurement system that should achieve intuitive control of multi degree of freedom prostheses for the upper extremity.

Quality for life

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Own Publications

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