Innovative aids in rehabilitation and for the disabled

Kraft, Maisner, Basta, Gleich, Goll, Hussein, Wilkening, Rupp, Schmitz, Riecke, Seifert et al.
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Editorial: Innovative aids in rehabilitation and for the disabled

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The quality of rehabilitation after an accident or a serious disease is linked strongly with the state of the art of technical devices in rehabilitation engineering. Starting with the ancient Egyptians who carved artificial toes as prostheses, people added canes, wooden legs and arms as well as eyeglasses to a long list of technical aids that have been invented over the last centuries to ease the activities of daily living. Hearing aids complemented the mechanical and optical aids by electronic functionality. Mechatronics, micro systems, information and communication technology as well as new materials have been in the focus of research in the late 20th century. Their application in biomedical and rehabilitation engineering has added completely new opportunities to this field and fostered innovative approaches, devices and therapies for numerous applications in rehabilitation.

The significance of these technical solutions will grow more and more in the future. The ageing societies in all industrialized countries will lead to an increasing demand, while the growing number of so-called diseases of civilization will also increase the number of patients in need of effective rehabilitation. In addition, as a result of further development, the solutions themselves will be improved thus to be applied in more and more indications.

The German Federal Ministry of Education and Research answered this growing demand with a large funding program. From 2007 to 2011, 11 clusters all over Germany were supported to increase the technical insight and possibilities of rehabilitation. The successful work of the projects portrayed in this special issue resulted in a second call of the federal funding to be worked on during the following years.

We wish you exciting insights and a lot of pleasure while reading through these papers which were presented at the European Conference “Technically Assisted Rehabilitation 2011”.

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Bus-ID: RFID Technology eases Access to various Means of Transportation for Blind and Low Vision Persons

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Abstract
The usage of RFID technology is a promising expansion of existing orientation support for people incurring blindness and low vision. Within the “Bus-ID” concept, a person carries an RFID transponder which is detected when approaching an RFID receiver. In the first phase of the “Bus-ID” project, this concept has been designed for bus stops to provide valuable information, such as the location of the bus stop, timetable information and the position of the incoming bus. Test results have proven that the concept satisfies users’ needs.

However, the idea of the Bus-ID is not solely limited to bus stops; additional support can be provided at other public locations, for instance at bus terminals (to find the right bay) or at underground terminals (to find the right platform). Moreover, the RFID transponder could also trigger audible traffic light signals.

1 Public Barriers with regards to Mobility and documentation of the idea “Bus-ID”

At the end of 2007, the amount of people incurring blindness and low vision in Germany counted 348,442 [1]. The major part needs to rely on public transportation and moving in street traffic to achieve truly independent mobility. Without the support of guides, they need to rely on public transportation such as busses and trains or reach destinations by walking. When modified in a correct fashion, public transportation systems and audible traffic light signals can contribute substantially in order to facilitate aspects of daily life. In public areas and particularly on the way to bus stops and train stations, various kinds of obstacles and traffic prevail which are generating possible dangerous situations. In addition, most of the essential information, ranging from the location of the stop, the bus lines, traffic light signals and information signs, is solely accessible via the visual channel. People incurring blindness and low vision are usually depending on public transport personnel or other passengers in order to be certain that they are boarding the correct vehicle or moving right in subway stations.

In order to improve accessibility, tactile tiles [2] have been installed at bus stops and train stations. These paving tiles with tactile grooves can be detected both acoustically and tactually by the long cane used by blind people. On the one hand, such paving tiles have been proved as useful in practice for the barrier-free access to public transportation. On the other side, they supply only static information and none regarding schedules, terminal stations, lines and information with respect to route direction. Furthermore, usability is strongly reduced in heavy pedestrian traffic [3]. Thus, the plan of the “Bus-ID” project implies that concerned people carry an RFID transponder which is detected by an RFID receiver for instance at a bus stop. Consequently, bus stops provide valuable information, such as the location of the bus stop, timetable information and the bus number of the incoming bus. A test phase with 43 blind participants and people incurring low vision in 2008 demonstrated that the “Bus-ID” concept serves user needs. Subsequently, the aim is to provide support in other public locations like bus terminals, underground terminals (subways) and need-based audible traffic light.

2 RFID Technology for People with Blindness and Low Vision

The use of RFID technology is a promising alternative or expansion on tactile surface tiles. Radio frequency identification (RFID) enables a wireless identification (radio wave recognition) and localization of RFID transponders (“tags”) by RFID reader. Primarily, RFID technology serves to identify objects being moved passively (merchandise and goods). It is, however, also used in chip cards (for access verification, entrance tickets and as a ticket for public transportation for example). Depending on the technical configuration, especially the size of the antenna and the existence of power supply of the tags, RFID tags can recognized at distances from a few centimeters to more than 100m.
Within the Bus-ID project, the affected people carry an active tag which is user friendly concerning handling and the access to information. It is necessary to use an active tag (power supply delivered from a battery) to achieve the required range from 10 m up to 100 m. The tag is small and light in weight. Furthermore, this component achieves user needs because it is cheap and has only got one user button for additional functions. The tag is automatically detected (for instance by a reader at a bus stop) and can trigger certain signals, such as tones or verbal announcements. Hence, the Bus-ID system enables having ears and hands free and requires only simple user interaction for the additional tag button in case further information such as remaining time of the next arriving bus is requested.

3 Using RFID in order to facilitate Access to various Means of Transportation

The basic concept of Bus-ID supports a facilitated access to bus stops. However, the implementation of the technology is not solely limited to the former. Additional support in street traffic is needed with respect to locating audible crossing lights and orientation in underground terminals. The technical concepts or rather tentative draft for the applications mentioned above, are listed in the following:

Bus Stop
There are three elements: The visually impaired person, the bus with its driver and the bus stop pole which communicates current positions and supplies further information. Both, the person and the bus are equipped with active tags. The bus stop pole is equipped with readers and antennas. The user receives an audible orientation signal if he is located within the range (about 10 to 15 m) of the reader. This orientation signal helps to find the access point of the bus stop. If the user is situated in the range of 3 – 4 m to the bus stop he receives audible information such as the name of the bus stop, the operating bus lines and schedule information. In case a person using the device is already waiting at the bus stop, arriving busses with active tags are being identified by the reader. In this case, the bus gets announced to the user by the speaker.

Figure 2: Concept Bus Stop

Audible Traffic Light
Audible traffic lights are already existing systems being applied in many cities and communities. They have been proved as an effective orientation support for visual impaired people in order to find crosswalks through receiving an audible orientation signal. Without these systems, blind pedestrians would have considerable difficulties locating crosswalks and would thus depend on assistance provided by guides to move in street traffic. Unfortunately, nearby residents consider the steady alert as annoying and too noisy, which causes problems regarding implementation of the system. Consequently, the sound of some devices has been reduced and even switched off during night time. In case a crossover is rather wide with respect to the distance, has considerably high turning traffic and therefore creates a lot of noise, recognizing cars which are moving or starting to move is being aggravated. Furthermore, the time frame before perpendicular traffic is permitted to move may be too short to be able to cross the street because signals are timed regarding the needs of vehicles [4].

Besides, the RFID technology could be used correspondingly in order to increase the sound level of an orientation signal and extend the pedestrian timing if necessary. Besides, it is feasible to reactivate the system at night through a RFID tag. Therefore, it is required to install RFID reader as add-on components at each traffic light pole in order to automatically identify visual impaired people.

The concept which has been demonstrated above is a rough approach and would be an investment in safety, orientation and independence of concerned pedestrians while crossing dangerous, signalized intersections. All in all, the acceptance of audible traffic lights could be increased by applying RFID.
Underground Terminals

Underground terminals are perceived as very complex and difficult for people with visual derogations. Thus, they are in need of special support in order to find desired directions. The rule regarding output of information requires that all details (for instance direction signs) are available to people with sight and as well others with derogations. Existing navigation systems such as GPS are unfortunately unable to work properly in indoor locations because of the necessary line-of-sight to the satellites. In comparison, the RFID system supports indoor and outdoor applications and is independent with respect to atmospheric conditions.

Whilst applying RFID in underground terminals, it would be possible to detect impaired people in front of an intersection at a range of approximately 5 m. Thus, using a special (patch) antenna aligned to the path of the user could help to detect the direction. An audible orientation signal would notify the user of the underground intersection. In addition, it would be possible that further speakers report sequential direction information out of the relative corridor. However, further research should be undertaken to investigate in speaker-concepts which are matching the needs of visual impaired people because they need to align direction through audible information especially with regards to noisy and complex underground terminals.

The above mentioned concepts “Audible Traffic Light” and “Underground Terminals” are so far rough approaches and do not conform to fully developed concepts. Within further research (second phase of “Bus-ID”) these concepts should be methodically developed in close cooperation with concerned people.

4 Accuracy of Detecting RFID Tags

The first phase of “Bus-ID” was undertaken to investigate the needs of pedestrians impaired concerning sight, the functional model of the RFID assistance system for bus stop and the acceptance of this orientation aid. On the basis of the results of the tests with blind people, it was possible to determine a number of decisions about designing an assistance system [5]. The second phase will be undertaken to observe the characteristic of the RFID technics, especially the accurate ranging of active tags with low investment in infrastructure (for example number of reader and antenna, cabling), and the additional Bus-ID concepts, represented in the previous section. The aim of these duties is a pre-commercial development which provides a RFID assistance system for blind people in order to improve safety, orientation and independence in public traffic and transportation.

In the previous phase of Bus-ID, it was experienced that the quality of RFID signal depends on specific influencing variables and signal disturbances. Influencing variables are the type and size of antenna, the operating frequency and transmit time interval. Based on extensive experiments with support of statistical designs of experiments, signal disturbances were identified which are the alignment of the tag antenna, multipath signal propagation and non-line-of-sight or rather absorbance of the signal by the human body if the tag is worn close to the body. All of these influences have an effect on the range measurement and cause errors in locating people. In order to guarantee a successful aid in orientation, one of the most essential conditions that needs to be resolved is the location accuracy of 1 – 2 m. Solely with this accuracy it can be assured that the user receives audible information at the right time.

There are currently two different existing principles of RFID systems available on the market to range active tags at a distance of 10 m and more. This is on the one hand Received Signal Strength Indicator (RSSI) method and on the other hand Time of Flight (ToF) or rather Two Way Ranging (TWR).

Within an RSSI system, the distance between a tag and a reader is determined by the received signal strength of a tag. The signal output power P of the tag decreases with increasing distance r because of spherical spreading of signal power on an imaginary surface of a sphere. With help of the measured RSSI it is possible to draw a conclusion with respect to the distance. The accuracy depends on the environment and the number of readers. Mainly multipath signal propagation in an alternating environment (especially indoor) leads to increasing or attenuation RSSI values due to signal overlapping. Apart from that, the alignment of the antenna (based on antenna radiation pattern) and interruption line-of-sight (based on frequency) have a significant influence. Signal disturbances can be counteracted and minimized by an appropriate handling of the tag for instance through installing a tag on a long cane for a defined antenna and a distance to the human body.

![Figure 4: Measuring Distance with RSSI](image)

The researched active RSSI system is already available on the market as well as affordable for the users. The system operates in the licence free 433 MHz ISM band.
The above mentioned signal disturbances lead to an increase or attenuation of RSSI values due to signal overlap. Multipath signal propagation in particular leads to incalculable and unstable RSSI values. A signal attenuation of approximately 30 RSSI (compare values “Non-Line-of-Sight”) denotes a deviation of 10 m to the origin position. RSSI values could even be too low so that no reception of any signals can be obtained (compare values “Alignment of the Antenna”).

Figure 5: Signal Disturbances

The ToF method uses measured elapsed time for a transmission between a tag and a reader based on the propagation speed of a signal. The problem related to ToF is the clock offset and clock drift of the components which leads to inaccuracies. To increase accuracy and avoid the need to synchronize the clocks of the components, ranging measuring can be conducted with TWR. During the TWR measurements, a signal propagates from the tag to the reader and back. The time measured by the tag is twice the time of signal propagation through the air. The accumulated time is used to calculate the distance between the tag and the reader [6]. Also, this principle is affected by signal disturbances because of the already mentioned influences. Different to RSSI is the direct measuring of the distance so that it is not necessary to draw a conclusion with respect to the distance and environment.

Both procedures must be compared within further research in order to achieve receiving accurate and stable signals.

5 Conclusion and Prospects

Whilst the first phase of „Bus-ID“ was undertaken to investigate the needs of impaired pedestrians, the functional model and the acceptance of an RFID orientation aid, within the second phase the observation of additional aid concepts, functions and accurate ranging of active RFID tags were targeted to be achieved.

The location accuracy is one of the most essential conditions that needs to be resolved. Because of the already gained experience through working with active RFID components it is known, that the accuracy of ranging depends on specific influencing variables and signal disturbances. Hence, within further research signal disturbances should be methodically evaluated aiming to achieve minimization of such by installing measures or even through varying influencing variables. Solely with this accuracy it can be assured, that the user receives audible information at the right time to benefit from advantages represented within the above discussed concepts, which have to be tested in reality in close cooperation with concerned people. Therefore, the objective is to transform the functional model into a prototype prepared for tests in order to be afterwards released on the market.


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Clinical application of a vibrotactile balance prosthesis
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Abstract
Balance prostheses are neurofeedback systems to support the maintenance of balance. The present project was aimed at developing a vibrotactile system which reduces the body sway to prevent falls. The technical design of the balance prosthesis (Vertiguard®) is aimed at recording body sway so that a continuous monitoring of the movement profile in action is possible. When a patient is encountered, the device gives a vibrotactile signal to the hip in case certain, pre-defined limits of body sway are exceeded. In this way, a total of 102 patients with different types of balance disorders have been studied. All objective (sway measurement) and subjective (questionnaires) parameters of the balance disorder improved significantly in the test group but not in the double-blinded placebo controls. The results show very clearly that the new developed vibrotactile balance prosthesis reduce the body sway effectively which lead in turn to an increased safety during every day life conditions.

1 Introduction
Balance deficits are frequently characterized by an increase of body sway and a higher risk to fall. Different rehabilitation strategies have been applied over the last few decades to initiate central compensation of the tonus imbalance and to facilitate substitution in different types of peripheral or central vestibular dysfunction. Various exercise programs (home or supervised) have been described, including physical training, Cawthorne-Cooksey interventions, alternative strategies – such as Tai Chi -, etc. (Curthoys, 2000). However, these vestibular rehabilitation strategies mostly require a long lasting intensive training (months) and are not successful in many patients. Current studies showed that new training procedures, which use a sensory feedback, are more effective for the rehabilitation of patients with balance deficits (Basta & Ernst, 2008). One of the first applications of such a method was the training of standing tasks with visual feedback (Viirre and Sitarz, 2002), galvanic feedback (Danilov et al., 2007) or vibrotactile feedback (Kentala et al., 2003). Since patients tend to fall mostly during dynamic conditions, rehabilitation with neurofeedback training in everyday life situations should be advantageous. Earlier studies showed a high effectiveness of a free field auditory neurofeedback training to reduce the body sway in patients with different peripheral (semicircular canal or otolith) vestibular disorders. During such a neurofeedback training body sway is encoded as an auditory signal and the patient should maintain their postural control in the normal range due to the location of the sound source in two dimensions. The use of this not intuitive information for an adequate reposition of the body in space is quiet difficult for a large number of patients (elderly or patients with central vestibular disorders). This is why an intuitive tactile neurofeedback stimulus seems to be an advantage for the encoding of individual sway during the training of everyday life conditions. Thus, the present study aimed at investigating the efficacy of new developed vibrotactile balance prosthesis for vestibular rehabilitation.

2 Methods
2.1 Patients’ characteristics
The inclusion criteria to participate in the study was a pathological body sway (measured at the hip in pitch and roll direction) compared to normal age and gender related controls (inbuilt normative data of the diagnostic device Vertiguard®-D). The pathological sway should be presented in at least one condition of the Standard Balance Deficit Test (SBDT) or the Geriatric Standard Balance Deficit Test (gSBDT) (Basta et al., 2008).

The SBDT contained the following tasks (in the performed order):
- standing on two legs with eyes open/closed,
- standing on one leg with eyes open/closed,
- eight tandem steps (one foot in front of the other) with eyes open,
- standing with two legs on a foam support surface (height 10 cm; density 25 kg/m3) with eyes open/closed,
- standing on one leg on a foam support surface,
- eight tandem steps on a foam support surface,
- walking 3 m while rotating the head,
- walking 3 m while vertically pitching the head in rhythm,
- walking 3 m forward with eyes closed,
- walking up/down stairs (step height 23 cm),
- walking over four barriers (height 26 cm with an inter-barrier distance of 1 m).
The following tasks were skipped in the gSBDT (for patients aged over 59 years):
- standing on one leg with eyes closed,
- standing on one leg on a foam support surface,
- walking up/down stairs (step height 23 cm)
The tasks “stand up” and “sit down” were added as last conditions of the gSBDT.
The measurement time was 20s for all standing tasks and as long as needed for walking tasks (mostly <20s).
Out of 130 patients who suffered from dizziness or instability, 102 patients were included in this study.
The total sample contained patients with six different peripheral or central balance disorders such as:
semicircular canal function loss, otolith disorder, acoustic neuroma, microvascular compression syn-
drome, Parkinson's disease or presbyvertigo. Patients with presbyvertigo were aged over 59 years and suffered from vertigo without any detected related disease.
Fourteen patients were randomly selected for the control (placebo) group.

2.2 Vestibular rehabilitation training
The training was performed by using the Vertiguard®-training device (Vesticure GmbH, Germany). It con-
tains a battery driven main unit (120 x 76 x 32 mm, 190g) which is fixed on a belt at the centre of body
mass (hip) and one vibration stimulator on the front, back, left and right side, respectively (Fig. 1). The vi-
bration stimulators are mounted on the same belt as the main unit. They are adjustable by sliding over the
belt to the correct position in the individual patient.
The main unit determine continuously the coriolis force during body movements in pitch and roll by inbuilt
gyroscopes and compare the values with individual preset  thresholds for the stimulator activation in the
specific direction. Preset thresholds were task specific. They were determined for the individual patient
based on the maximum age and gender related normative sway in the specific
condition and direction. The thresholds were stored for each training task in
the main unit. Training tasks were selected automatically by analysing the
results of the SBTD or gSBDT. Only those six tasks, which showed to most
pathological results, were included in the training program. The patient was
able to switch between the tasks by pressing the related button on the main
unit. To prevent the selection of wrong thresholds for the performed task, the
chosen task was written together with the patient’s name in the display of the
main unit. No vibrotactile feedback was applied if the patient’s sway was
below the preset thresholds. Above the thresholds, the perceived vibration
increased with increasing sway. The patient was instructed to adjust the
preset thresholds for each training task daily (all directions together) by
pressing the sensitivity buttons on the main unit until he was able to react
adequate to the neurofeedback signal.
Vestibular rehabilitation exercises were performed daily over a two-week
period (weekends excluded). Each session contained five repetitions of the
selected tasks. The time limit for one repetition was 20s for all standing tasks
and as long as needed for walking tasks (similar to the measurement time in
the SBTD or gSBDT). The total daily training time was approximately 15-20
minutes.
Patients of the control group performed the similar protocol with a sham
device. The patients as well as the supervisor didn’t know the group
classification (double blinded study design).

Figure 1: Application of the vibrotactile neurofeedback balance prosthesis Vertiguard®. The system with a
main unit (1) and vibration stimulators (2) is fixed on a belt at the center of body mass. Only 2 of the 4 vi-
bration stimulators are visible in the picture.

2.3 Evaluation of the effects of the vestibular rehabilitation
Trunk sway of the patients was measured in pitch and roll for each exercise task (without feedback) be-
fore and after the training by means of the Vertiguard®-D system (Vesticure GmbH, Germany).
The composite score of the sensory organization test (SOT) on the Equitest® (Nicolet Biomedical, USA)
ankle-sway referenced system (platform), the dizziness handicap inventory (DHI) and the vestibular
symptom score (VSS) were obtained before the training, after the training and 3 months later.
3 Results
The results of the trunk sway and ankle sway measurements before and after the training were statistically significant different in the verum group. The trunk sway decreased in the pitch direction by 30 % (power: 1.00, effect size: 0.81) and by 31 % in roll direction (power: 0.99, effect size: 0.65). The composite score of the SOT increased significantly (increase of stability) by 10.6 % on average (power: 0.99, effect size: 0.64). The scores of the questionnaires, DHI and VSS, were significantly reduced (reduced symptoms) after the training (power: 0.99, effect size: 0.48 and power: 0.99, effect size: 0.63, respectively). The significant differences of all these parameters were also present in the follow up measures. No statistically significant differences could be observed in the placebo group. This holds true for all of the investigated outcome measures.

4 Discussion
The present results indicate that a specific vibrotactile neurofeedback rehabilitation program, which is related to the individual balance deficit, can significantly improve the postural control in stance and gait. This was shown by the significant reduction of body sway in pitch and roll direction during everyday life conditions and the significant increase of stability (SOT-composite score) in different sensorimotor stance conditions (force plate measurements). The reliability and clinical relevance of these results could be proven by a power value of approx. 1 and an effect size of more than 0.6. Moreover, the improvement was only present in patients of the feedback-training group compared to the controls. The vibrotactile neurofeedback signal seems to be a very effective stimulus for vestibular information, since it's perception during the training was very intuitive. Furthermore no important sensory inputs (e. g. auditory, visual) are impaired by the vibrotactile signal, no sensory conflict occurs and the signal processing is not influenced by simultaneous vestibular stimulation. The subjective parameters, such as DHI- and VSS-scores, were significantly reduced with a high statistical power and effect size only in the verum group. The controls showed a slightly but not significant reduction of these symptom related scores. This is somewhat surprising since the dissociation between self-perception and actual vestibular handicap was reported in previous studies (Whitney et al., 2004). However, in the present investigation we found a very strong correlation between the objective and subjective vestibular parameters in both of the study groups.

In essence, balance training with the vibrotactile neurofeedback prosthesis Vertiguard® is a highly efficient method for the reduction of body sway in different balance disorders. Since the rehabilitation program is easy to perform and not exhausting, elderly patients and those with serious long lasting balance problems could also participate. Future studies should investigate the long term follow up (12 months) to detect a possible re-training interval.

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2-Channel Magnetic Stimulator For Peripheral Muscle Stimulation Of Paretic Patients

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Abstract

Magnetic stimulation is a chance to painlessly activate neuronal cells via the induction of an electric field. It is mainly used for transcranial diagnosis (TMS) where only few magnetic pulses (up to 2.000) are applied over the cortex. Much longer stimulation times and therefore more pulses (up to 20.000 pulses) are required to be applied in rehabilitation and physiotherapy. To achieve this two magnetic stimulation devices were combined to form a 2-channel magnetic stimulation device. In combination with an ergometer it can be used for the rehabilitation of paretic patients. We developed a magnetic stimulation device with cooled stimulation coils, which is suitable for long term stimulation of both legs and could generate a 2.5-fold higher isometric force than electric stimulation for up to 30 min.

1 Introduction

Besides the very first achievements in counteracting atrophy ([1]), neuromuscular electrical stimulation has conquered several additional fields of applications. Today, it plays an indispensable role in rehabilitation, physiotherapy ([2]) and treatment of chronic pain ([3]). Especially in paretic patients with incomplete lesions or spasticity, very sophisticated methods allow the training of quite complex motion sequences for relearning. Cycling tasks represent a very natural load and are at present the most promising training tasks ([4]-[6]). However, electrical stimulation shows several crucial drawbacks. Among other issues, are at first the stimulation-related pain ([7]), but also the limited force response and electrochemical degradation effects near the electrodes ([8, 9]). In addition the limited penetration of the current into the muscle, due to the parallel paths through the surface layers, reflect badly on this very promising and potent method. Lately, magnetic stimulation has been introduced into the field of therapeutic peripheral stimulation ([10-12]) and found to be an auspicious candidate for solving those problems. However, the performance of available devices and coils was rather weak ([12]). This was a severe drawback as the training effect is correlated with the contraction intensity ([1]). To overcome these physical and technical issues of magnetic stimulation a new device with new coils was developed.

2 Construction of the 2-channel magnetic stimulator

The casing of the two-channel stimulator is a construction made of aluminium profiles. The individual components are oscillation decoupled and earthed. The couplings are flush-mounted and mounted on bounded panels. Figure 1a) shows a schematic overview of the internal control unit, which was realized using a SPS S7-200. In Figure 1b) a 3-d mechanical drawing of the inside illustrating the pumps, the cooling unit and the two stimulation devices is presented. Figure 3b shows a photograph of the realised stimulator with two cooled stimulation coils.

![Figure 1: a) schematic overview of the control system b) mechanical drawing of the inside of the device](image-url)
2.1 Magnetic stimulator

Two commercially available magnetic stimulators (PowerMAG 30, MAG&More GmbH, Geltendorf, Germany) underwent reconstruction for continuous operation at high stimulation intensities. Therefore copper wires with a cross section of 35 mm² replaced all high-current cables inside the stimulators. Furthermore, the stimulators were equipped with custom made interface electronics to communicate with the control system. Due to safety reasons, were all signals (e.g. temperature) to and from the control system galvanically isolated from the stimulation devices and the stimulation coils. Each magnetic stimulator provides a biphasic sinusoidal stimulation current (up to 5,000 A) through the stimulation coils with a frequency of 6.25 kHz. These stimulation pulses can be applied up to 30 times per second, resulting a repetition rate up to 30 Hz. The magnetic stimulators can be externally triggered through e.g. a computer system (Figure 3b).

2.2 Closed-loop cooling system

There are two independent cooling loops – one for each coil. Both are monitored with temperature and flow sensors. Because of the high breakdown voltage, transformer oil (Renolin Eltec, Fuchs Europe Schmierstoffe GmbH) is used as isolating cooling liquid. Attention was paid to the low surface tension, so that the oil can easily reach the loopholes, but also to the high viscosity, so that the flow velocity is relatively slow, especially at low temperatures. Because of the chemical resistance a tube made of nitrile butadiene rubber (THOMAFLUID®-NBR-Chemieschlauch) is used for the connections of the cooling loops.

2.3 Stimulation coils

Mechanical construction

The coils are sintered from PA12 and afterwards infiltrated for a better resistance to the fluid. Embedded in the bottom is a template for the setting of the litz wire (RUPALIT® Safety Litz wire). The litz wire is moulded with a resin and the cooling oil is directly flowing over it. Figure 2b shows a 3-d mechanical drawing of the coil. The temperatures of the surface of the coil, of the litz and of the power cable are monitored via four LM35 sensors and send to the control system.

Electromagnetic coil design

The coils for the stimulation system are especially designed for neuromuscular stimulation. For the rehabilitation of nervous lesions and in cardiovascular training the extensor muscles of the thigh play an important role ([10, 12]). The innervation of these muscles is based on widely spread axonal tree structures ([13]). Accordingly, the target volume for the induced electric field was designed to be very broad for a homogeneous activation, whereas field peaks and focal behaviour, which are more likely to activate nociceptors in the skin, were avoided. For the application in neuromuscular stimulation, two issues had to be faced. First, the low electrical conductivity of the tissue is a general problem for magnetic stimulation and can hardly be changed. Besides that, the inductive coupling factor had to be raised notably for an efficient stimulation. Due to these requirements, all commercially available coil systems are inappropriate for the neuromuscular stimulation, because they are designed for other applications. Our design of the coil leads to a notably better penetration of the targeted muscles compared to commonly used round coils (Figure 2a). This is owed to the much better inductive coupling to the tissue. Additionally, the widespread induced electric field is relatively homogeneous. The lateral indentations (Figure 2b) shift the field towards the centre of the m. rectus femoris. Averaged over the muscle, the induced energy is approximately 2.5 fold higher compared to the round coil at the same stimulation current.

Figure 2: a) calculated induced electric field (current 5000 A) of the new coil design and a round coil in the thigh at two different positions (upper row: outside of the focus of the coil; lower row: at the middle of the coil) The new design shows a much deeper penetration compared to the round coil topology. b) Mechanical drawing of the cooled stimulation coil.
3 Results

3.1 Generated force of the new coil design

Figure 3a depicts the typical recruiting curve of the thigh for the new coil design and a round coil. The stimulations were carried out on healthy subjects during stimulation of the *m. quadriceps femoris* at a repetition rate of 20 Hz. The amplitude (relative to the stimulator system's maximum output power) evoking first detectable responses is only slightly shifted to the left. The dominant change occurs in the slope of the force increase with stimulation amplitude. A more detailed study of the saturation has been impeded by the enormous force levels generated with this device and less by induced pain, which is the main obstacle for reaching the specific saturation of round coils in neuromuscular stimulation ([12]).

![Recruiting curve of the new coil design compared to a round coil.](image)

**Figure 3:** a) Recruiting of the novel coil design (red) compared to a classical round shape (black). The force of the extensor muscles of the thigh was detected isometrically at the ankle. The position of the round coil was already at the optimum point, which was checked and corrected slightly beforehand. b) Photograph of the 2-channel magnetic stimulator with two cooled coils.

3.2 Treatment time

The heating of cooled and uncooled stimulation coils is shown in Figure 4. According to EN 60601, the maximum allowed temperature of the coils and the power cables and all other parts which can get in contact with patients is limited to 41 °C. Compared to a standard round coil, the stimulation duration of the cooled coil is extended from 2 min to 35 min. Also the cool down time is much shorter than for uncooled coils (15 min vs. >70 min).

![Multi-coil heating curves.](image)

**Figure 4:** coil temperature vs. time for a commercially available round coil (green) without cooling and for two different cooled coils (black, red). The larger coil (black) shows a slower heating during stimulation than the smaller one (red). The blue curve shows the temperature of the surface of the power cables. Test conditions are 10 Hz repetition rate and 3600 A coil current.
4 Discussion

Using this new set up some draw backs have to be taken into account. First of all, magnetic stimulators, especially those with cooled coils, produce a very loud acoustic artefact. Secondly is the magnetic stimulation equipment quite large and expensive in contrast to electric stimulation devices. It also has to be said, that although magnetic stimulation is much more painless than electric stimulation, minor pain can occur. Besides these facts, we have shown two crucial aspects for the use of magnetic stimulation for the rehabilitation of paretic patients. On the one hand extended stimulation time is possible if cooled stimulation coils are used. On the other hand the generation of larger isometric forces compared to electric stimulation is possible when the stimulation coils are of special geometry.

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Wireless implantable round window actuator

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Abstract

A partially implantable hearing aid is introduced. It consists of an external device for sound reception and signal processing, an optical transmission line for the signal and energy transfer through the tympanic membrane, and an actuator directly coupled to the round window membrane. The implantable part consists of a photo diode array, which receives the incoming light, a piezoelectric disc spring actuator, and a highly flexible cable connecting them. The conception and the design of this inner part shall be discussed in detail.

1 Introduction

In the case of severe hearing loss, conventional hearing aids often fail. Implantable hearing aids can be a suitable solution [1]. However, the effort for an implantation is comparatively high. In order to tackle this problem, we are currently developing the prototype of an implantable hearing device. Contrary to other hearing implants, the actuator of this novel device will be small enough to be inserted into the round window niche. Furthermore, the optical transmission line is expected to significantly reduce the extent of the surgery as well as the duration of the operation [2].

A build-up of the implantable hearing aid is shown in Fig. 1. The external case behind the ear – containing microphone, power supply, and the processor – is connected to the tube. The light cone emitted by the infrared diode at the end of the tube falls through the tympanic membrane and is partially collected by the photovoltaic element. The energy of the light is used for the power supply of the actuator; simultaneously, the modulation of the light contains the necessary acoustical information.

2 Implantable device

In the following, we shall focus on the main results concerning the actuator, the assembly of the inner part of the hearing system, and the optical transmission line.

2.1 Actuator

We developed a slotted, piezoelectric disc actuator [3], consisting of a passive silicon layer, on which an active piezoelectric layer was deposited using a sol-gel process. Applying a voltage vertical to the piezoelectric layer evokes a length change of the active layer and thus a bending motion of each segment. The
mechanical decoupling of the actuator segments leads to an amplitude which is clearly higher than in a non-slotted membrane.

In Fig. 2, one of the first examples of a fully contacted, functioning actuator can be seen. Laser-Doppler vibrometry (LDV) measurements on this kind of actuator showed that a peak voltage of 1 V yielded a peak amplitude of around 1 µm, in fact nearly frequency independent up to a corner frequency of around 25 kHz. This is, up to 7 dB, the value which had been predicted using analytical and numerical models.

In force measurements at the same voltage we found, using a high precision balance, forces of around 30 µN per segment. The values of the forces agree even better with the theoretical predictions than the values of the amplitudes. Higher forces can be achieved by stacking single actuators and connecting their tips.

2.2 Implantable device

The implantable device consists of a photo diode array and the actuator, connected by a flexible cable. This cable is fabricated as follows: A thin layer (5-7 µm) of the precursor pyralin is polymerized. This yields a first polyimide layer, which is subsequently covered with layers of titanium and gold by physical vapor deposition. These are structured using optical lithography and dry etching. In the next step a second polyimide layer is deposited. The contacts at the end of the cable are exposed by etching.

The photo diode array is fixed to the cable with a biostable glue and contacted by ultrasonic wire bonding. The actuator was connected at the other end of the cable, as shown in Fig. 3.

2.3 Optical transmission line

The optical transmission line comprises an infrared emitter in the auditory canal in front of the tympanic membrane, a photo diode array behind that membrane, and the optical path in-between, see Fig. 4.

The total energy loss within the transmission line is the sum of the loss in the circuit, the loss due to electro-optical and opto-electrical conversion as well as geometrical loss. The latter is due to the fact that only a part of the emitted light is collected by the diode array, because the angle of beam is chosen to be quite large. Narrowing the beam would increase the efficiency, but requires a highly stable relative placement of the light cone and the photo diode array, which cannot be guaranteed during activities of the daily life. The loss due to the absorption in the eardrum can be neglected.

![Fig. 2: Exposure of the contacted, working actuator under the microscope.](image1)

![Fig. 3: Implantable device in comparison with a Q-Tip.](image2)

![Fig. 4: Setup of the optical pathway: Infrared LED (left) and photodiode array (right), consisting of one diode for signal reception surrounded by six diodes for power supply.](image3)
3 Conclusions

We have shown that a miniaturized actuator which is able to fit into the round window niche, can be assembled. This is possible based on our new development of a slotted, piezoelectric disc actuator. The connection between this actuator and the photo diode array, providing energy and signal, is realized by a ultrathin, highly flexible, encapsulated cable, which is available in multiple layouts. As a main benefit, the duration and impact of surgical procedures are expected to be considerably reduced due to the optical power supply of the implantable part of the hearing system.

References


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Virtual haptic environments for patient adaptive gait rehabilitation training

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Abstract

Over the last decade robot-assisted gait training was established as a promising approach to improve training quality and efficiency in neurological rehabilitation therapy. Special attention has been laid on cooperative training algorithms to maximize the benefit of robot assisted training. This paper presents an approach to patient adaptive gait training for end-effector based rehabilitation robots using a linear, robust control based haptics framework. From a set of fixed and moving polygonal primitives the basic training environment is synthesized by superposition. Additionally a nominal trajectory with a compliant tolerance zone and adjustable assistance along the trajectory can be applied to provide patient adaptive assistance for a training task. The framework was implemented on the robotic walking simulator \textit{HapticWalker}. To evaluate the proposed approach two types of pilot trials were conducted. The first type assessed the rendering of the basic training environment without restrictions along any trajectory. The adjustable assistance mode, provided by the haptic simulation, was tested within a second trial again with healthy subjects.

1 Introduction

Walking is an essential part of our daily activities and a reduced gait ability seriously restricts mobility and increases the risk for consequential injuries, e.g. caused by falls. Current rehabilitation methods lead to limited treatment results. Therefore an increasing need for more effective rehabilitation methods arises. According to the current state of knowledge in neurological research, a high training intensity and a task specific training are important factors for the rehabilitation outcome. A promising approach is the use of robots to assist gait training. For gait rehabilitation two basic types of robots can be distinguished:

1. end-effector based devices and
2. exoskeleton devices.

Over the last decade robot-assisted gait training was established as a promising approach to improve training quality and efficiency in neurological rehabilitation therapy. Cooperative control methods for rehabilitation robots have especially been in the focus of research. To date in the field of gait rehabilitation these patient cooperative training paradigms have only been applied to exoskeleton type rehabilitation robots [1], [2], [3]. For the end-effector based \textit{Gait Trainer GT I} a concept for performance based adaptation of training speed was proposed and simulated in [4].

2 Design and rendering of virtual haptic training environments

To enable task specific and patient adaptive gait training on end-effector based gait rehabilitation devices, the application of a haptic control framework is chosen. The approach allows for the synthesis and simulation of a variety of training environments for situations from daily life and assistive functions to help the patient to fulfill the training task. The proposed approach is implemented on the robotic walking simulator \textit{HapticWalker} depicted in Fig. 1. To enable aforementioned haptic simulation the \textit{HapticWalker} works as admittance display. The design of the underlying admittance controller is detailed in [5]. It is based on robust control design and $\mathcal{H}_\infty$ synthesis and incorporates a known upper bound for the worst case environment impedance. The presented work evaluates the stable rendering of example training environments in pilot trials with healthy subjects, as well as the rendering of a virtual tunnel to provide assistance during training.

2.1 Synthesis of training environments

The virtual training environments defining the training task are composed of a set of convex objects called primitives. The restriction on convex objects simplifies the procedure of collision detection between the probes, i.e. the footplates, and the primitives. At the same time the synthesis from simple convex primitives allows for the flexible design of complex static and dynamic training scenarios, as e.g. a treadmill with or without obstacles, a slope or an escalator. Two example scenarios are shown in Fig. 2. As can be seen most scenes can even be synthesized using cubic objects.
Physical properties are assigned to the objects, namely mass, damping and stiffness, resulting in forces acting during contact of probes with objects. The maximum stiffness used in the design of the underlying admittance controller, as described in [5], corresponds to the maximum object stiffness. In case two or more superposed objects are partly or completely collocated, only the largest stiffness is used for the haptic simulation according to \( k_r(x) = \max_i k_i(x) \) (1).

Thereby the stable interaction with collocated, overlapping objects is preserved.

2.2 Adjustable training assistance

The assistance provided during robot assisted gait training can be divided into two subtasks. These are 1) guidance, constraining the deviation perpendicular to the nominal trajectory, and 2) support, promoting the tangential motion along the trajectory according to the therapist chosen training velocity. The proposed approach utilizing a moving window for assistance, solves both subtasks with a single assistance element. An elliptic tolerance window is moving along the task specific trajectory with a velocity chosen by the therapist. Fig. 3 a shows the window with its assigned physical properties and Fig. 3 b the virtual tunnel resulting from the window’s motion. As stated above the moving elliptic window ensures both guidance on and support along the training trajectory.

In the present approach the window is assigned a pure stiffness. The assistive forces generated by the moving window are determined by its stiffness given in 2 and the kinematic error corresponding to the
distance between current probe position and center of the window \( d_{\text{act}} \).

\[
k_w = \gamma(d_{\text{act}}) \cdot \lambda \cdot \hat{k}_w
\]

The weighting function is defined as stated in 3.

\[
\gamma(d_{\text{tp}}) = \begin{cases} 
0 & d_{\text{act}} < \delta, \\
1 & d_{\text{act}} > d_{\text{max}}, \\
\frac{(d_{\text{act}} - \delta)}{(d_{\text{max}} - \delta)}^2 & \text{else}.
\end{cases}
\]

Here \( \delta \) is the distance from the center of the ellipse to its boundary along the vector \( d_{\text{act}} \). That means that inside the ellipse its stiffness is 0 while outside it presents a progressive spring-like behaviour ranging from 0 to \( \hat{k}_w \). The factor \( \lambda \) ranging between 0 and 1 is used for the adjustment of the assistance level, e.g. by the therapist.

Figure 3: Assistance window and virtual tunnel created by the window moving along a nominal task-specific trajectory

3 Results

Figure 4: Mean measured forces and metatarsal trajectories during free (a, c) and assisted (b, d) treadmill walking
To evaluate the stable rendering of the training environment, free motion on a virtual treadmill was tested in healthy subjects. A second trial addressed the functionality of the assisted training mode. The results presented here are preliminary results from one healthy subject. To assess the weight bearing during haptic simulation, as well as the capability to render free motion, measured forces in the sagittal plane averaged over all measured steps and the corresponding trajectory of the metatarsal joint are plotted. Fig. 4 a shows the mean vertical (dash-dotted black) and horizontal (solid blue) force of the free motion trial measured at the footplate with respect to one gait cycle, Fig. 4 c the measured metatarsal trajectories for all performed steps. Mean vertical (dash-dotted black) and horizontal (solid blue) force of the assisted walking trial, as well as the corresponding metatarsal trajectories, are shown in Fig. 4 b and Fig. 4 d respectively.

4 Discussion

4.1 Stable rendering of training environments
The first scenario, i.e. free walking on a virtual treadmill, shows that the interaction with stiff dynamic environments remains stable and the simulated environments are capable of bearing the users full bodyweight. Further by continuously adapting the haptic interfaces admittance controller parameters, as detailed in [5], it is possible to achieve a relatively low impedance in free motion (swing phase), compared to the device’s inertia and damping. Yet for fast movements in completely unguided mode the resistance felt by the user is still considerable. During unguided walking on the haptic display the observed stepping pattern is not very consistent, i.e. step length and height vary considerably and the user moves back and forth on the virtual treadmill. This might result from the remaining minimum impedance in free motion needed to stabilize the haptic interaction.

4.2 Assisted, task-specific training mode
To compensate for the remaining minimum impedance in the presence of a given training task, the subject is then provided assistance along the task specific trajectory using a moving elliptic window. As seen in the results the assistance in fact partly compensates for the remaining device impedance, if the subject attempts to follow the nominal trajectory. Forces measured at the footplate during swing phase are considerably smaller with assistance than without assistance. Further the resulting metatarsal trajectory is much more consistent. Yet the slopes of the vertical force in stance phase are less steep when walking with end-effector based assistance. This is consistent with the results from [6], if and how this effect correlates with the level of assistance provided, should be matter of further investigation.

4.3 Future work
The next step will be to perform more trials with healthy subjects to ensure the robustness of the haptic simulation and assistance, as well as to investigate the influence of different levels of assistance. Based on the presented approach a method to automatically adapt the assistance level to the patient’s performance, measured e.g. by the kinematic error, is to be developed and tested. When the robustness of the haptics enhanced training is ensured, first trials with patients and further tuning of the assistance parameters will be performed.

References


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Assistive Acting Motion Therapy Devices with Rotary Soft Pneumatic Actuators
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Abstract
This paper describes control strategies and realization of assistive motion therapy devices for upper and lower limbs, using novel soft (i.e. inherent compliant) pneumatic actuators with rotary elastic chambers. Due to natural back-drivability of actuators, interaction forces between human and therapy device can be estimated without using expensive torque/force sensors. These compact and cost-effective devices with low inertia provide a gentle treatment and allow individual adapted assistance to complete desired movements. The actuator specific assistive force control in combination with visual feedback motivates patients to maximize their effort. Precondition for effective assistive control is active model-based compensation of gravity influence with experimental parameter determination. The knee/hip motion therapy device has been extensively tested with healthy persons and is being tested in Klinikum Stuttgart (Clinic for Orthopaedics and Trauma Surgery); shoulder motion therapy device is in progress.

1 Introduction
Recent studies confirm the effectiveness of robot assisted therapy in neurorehabilitation after stroke or surgical intervention [1]. It is assumed, that this should be valid in orthopedic rehabilitation too, where mainly the position controlled CPM-machines are in use. In assistive motion therapy devices (MTD) based on conventional electrical drives [2]–[4], required compliancy has been achieved using precise (and mostly expensive) force/torque sensors as well as different variations of impedance controllers to regularize interaction force and position simultaneously [5]. Demonstrating well performance, such MTD are mostly voluminous and really expensive. Soft actuators like linear pneumatic muscles possess inherent compliancy and therefore, they are well suitable to achieve the interactive behavior between patient and MTD [6]. This kind of actuators allows light-weight construction of MTD, however the realization of revolute joints requires more or less complex transmissions. In contrast, the novel soft fluidic actuators with Rotary Elastic Chambers (REC-actuators) enable compact modular design of motion therapy devices, interacting with patients [7].

This article describes briefly the control, safety and handling concept of assistive acting MTD with pneumatic REC-actuators. Recently a first prototype for assistive knee MTD has been developed and was successfully tested with healthy persons. The prototype is now being tested in Klinikum Stuttgart to prove the concept in real-life conditions. The same control law is implemented for a 2 DOF shoulder MTD; clinical trials of this device are upcoming.

2 Soft motion therapy devices
Because treatment times of physiotherapists are limited and expensive, state of the art in orthopedic rehabilitation for more than thirty years are treatments with electromechanical continuous passive motion (CPM) therapy devices. To develop assistive MTD, the key idea was the replacement of electromechanical drives by pneumatic soft-actuators to achieve inherent compliancy. Prototypes are presented in Figure 1.
fire flat hose. Compared to the formerly used pleated elastic chambers (pREC), especially produced from polyurethane foil [7], the main advantages are slim design as well as reduction of costs. The basic construction of bREC-actuator consists of two parts, one fixed and one moving part, centrally connected through a rotary axis. By pressure variations the buckled working chambers expand crosswise and a direct rotary movements can be achieved. The working range is about 110° with maximum torque of about 40 Nm at standard pressure of 6 bar.

The design of knee MTD is based on the exoskeleton-like mechanics of a common CPM-machine. Equipped with two parallel working slim bREC-actuators in knee joints and additional bRECs in hip joint, the prototype provides a strong but soft behavior. The design of shoulder MTD is also based on common CPM devices; the prototype consists of one bREC-actuator for transversal and one for sagittal movements. The combination of abduction/adduction and anteversion/retroversion movement patterns allows circular motions of human shoulder. Due to basically back-drivability of REC-actuators, interaction between patient and therapy device can be estimated using position and pressure sensors only. Thus, no expensive force/torque sensors are needed. A touch-screen interface with intuitive handling assures a simplified usage for therapists and patients and a visual feedback for human-machine cooperation shall motivate patients to maximize effort.

3 Assistive control

Specific properties of physiotherapist’s behavior during treatment provide the base for development of the assistive control concept for the soft MTD. In general, therapists ensure discharge of extremity weight, guidance of motion and assistance relative to muscular strength of patients. Because the control concept is developed for orthopedic rehabilitation, it provides the opportunity for patients to move into requested direction of motion without generation of counteraction, but they are still supported at any position by the therapy device. Thus, patient’s get the opportunity to generate own muscular strength to perform desired movements, which shall activate remaining muscle energy. The assistive joint-based control concept is basically applicable for multi-DOF robots (Figure 2). It has been implemented for fully functional 1-DOF knee MTD and will be realized for 2-DOF shoulder MTD afterwards.

![Figure 2. Structure of assistive control](image_url)

To ensure discharge of mechanics weight and extremity weight, gravity compensation can be used. Currently widely used are passive solutions like elastic bands or springs, whereby one example is the famous neurologic rehabilitation device Armeo®Spring provided by Hocoma. Due to low stiffness and weight of REC-actuators and because of low velocity and acceleration, during motion therapy an active model-based gravity compensation of human robot combination has been developed. Weight of patient’s extremity is estimated by measuring air pressure inside of customized air pad sensor. To compensate model inaccuracies due to unknown influence of patients, an optimization method has been developed and implemented, that automatically adjusts individual parameter inaccuracies and adapts model parameters online during treatment for every patient specifically.
To ensure guidance of motion and assistance relative to muscular strength of patients an assistive controller is realized in outer loop of control concept. The control law is based on corresponding desired trajectories, actual distances to target positions plus desired and estimated direction of patient’s motion. Assistive controller only generates torque if patient is not able to accomplish requested movement or moves into opposite direction. If patient’s movements into requested direction are sufficient, no counteraction should be generated and therefore the assistive torque has to be reduced to zero. If the patient behaves passive or is not able to accomplish requested movements, the controller generates appropriate assistive torque to guide patient towards the targets.

4 Human-Machine Interaction Detection

Additional to the human-machine interaction (HMI) detection for the applied control concept, another separate HMI detection algorithm was developed which is solely to estimate interaction and to indicate visual feedback for patients. The intention is to rate patients’ activity (excellent/well/poor/bad cooperation) with colored continuously variable displays for prompting them to accomplish desired movements across the whole motion range on their own. Keeping in mind the idea of low-cost, a simple air pad in conjunction with standard pressure sensor is used. The air pad consists of special soft and hardly expandable polyurethane-nylon foil which is very suitable for direct contact between human and robot. It is filled with air at initial pressure of 33 mbar and directly connected to a proximity located small pressure sensor to avoid compressibility and delay effects during measurement of air pressure variations. There are two air pads in the knee MTD, one arranged inside the foot cup below the patient’s foot and the other one placed inside of the lower leg rest. The purpose is to estimate contact forces, not muscle activity. Using an inverted model to eliminate the slight non-linear correlation between payload and air pressure, the air pad can be used to determine leg weight and physical interaction, quite well independent from contact force location compared to conventional force sensors. Caused by patients’ movements, the resulting pressure variations are evaluated with respect to amplitude, slope rate and peak-to-peak values. They are observed for one half motion cycle each and combined with measurement values of actuator torque (i.e. pressure) and position. All these characteristic values are considered for the calculation of the rating system, before the visual feedback is finally shown on screen.

5 Safety Concept and Handling the Device

After basic control algorithms have been developed and patient-cooperating motions were realized, the next step was to develop and integrate the safety and handling concepts. The functionality of motion controller is influenced by the safety control depending of system status and patient’s behavior.

General safety is assured due to the following reasons: the bREC-actuators have been extensively tested for stress and endurance, only low voltage components and normally closed valves are used. Furthermore, due to redundant position and pressure sensors with permanent software supervision, in case of emergency (hand switch activation/hardware error/current loss/pressure supply damage), an automatic shutdown is triggered with mechanical break activation. Simplified safety and handling concept for knee motion MTD is shown in Fig.3.
Handling becomes simple, if only few buttons are needed to control a device and only most important easily understandable information is displayed to the user. Therefore a user interface was designed in close cooperation with professional therapist advice and many function routines are implemented in a manner to work autonomously and imperceptible in the background. According to Fig. 3, motion settings are done by therapists who get status information as A/V-feedback on screen. The air pad sensors are used to estimate the leg weight for model-based gravity compensation and supervise presence of a patient after an initialization phase at the beginning of therapy. In case of unexpected exit of patient, gravity compensation parameters are instantly reset to compensate mechanic only, for preventing high accelerations. During first start a gravity compensation optimization method is done hidden as warm-up mode in the background. Therefore the static actually provided torque, respectively pressure, is measured and stored at several positions within the desired motion range. Switching between initial and corrected model is realized using bumpless transfer method, which is a non-linear variation from actual to desired torque values by minimum jerk trajectory. Bumpless transfer is used as well for pressure supply switching and in case of operation mode changes e.g. stop/continue.

Conclusion
An assistive controller for novel MTD especially for orthopedic rehabilitation is described. Utilizing inherent compliant soft-actuators with rotary elastic chambers, interaction control is realized without using expensive force/torque sensors.

In case of orthopedic rehabilitation in comparison to neurorehabilitation patients are able to set motion more precisely, but typically have a very small amount of muscular strength and limited range of motion. To activate their remaining muscle energy, the assistive controller allows patients to move into therapeutic requested direction without generating of counteraction, but still with support of therapy device due to torque of active gravity compensation. The long-term goal is to simulate behavior of physiotherapists during treatment.

The application of new pneumatic soft-actuators for motion therapy requested a detailed identification of possible danger and system faults. All implemented safety features like redundant sensors, permanent monitoring of sensor signals as well as usage of low voltage components and pressure proof tubes contribute to a harmless usage with sufficient safeguard for an assistive rehabilitation therapy. The graphical user interface allows easy handling with audio-visual information and patient cooperation feedback. The prototype of knee MTD is currently being used for clinical trials in the Clinic for Orthopaedics and Trauma Surgery of Klinikum Stuttgart. After verification of assistive control concept for shoulder MTD, which is now in progress, the device will be committed for clinical trials to the Clinic as well.

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Literature

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Application of a tracking task assessment tool for adaption of upper extremity FES-orthosis

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Abstract

The BMBF funded project 'OrthoJacket' aims at functional restoration of a restricted shoulder-arm-hand function in high lesioned spinal cord injured (SCI) individuals by a novel neuroorthosis. This assistive system integrates Functional Electrical Stimulation (FES) for intrinsic and fluidic actuators for external support of movements. A major challenge in its setup is the adaption to the individual biomechanical neurological and functional status of the user. Therefore an instrumented assessment tool for quantification of upper extremity kinematics based on real-time tracking of standardized movement tasks has been developed. With the proposed method different parameter variations of the neuroorthosis can be directly assessed with the 'patient in the loop'. The first application in a tetraplegic SCI subject with weak elbow extension shows that the effects of different FES control modes can be precisely analyzed. This may serve as a good starting point for further individualized optimization of the user interface of the neuroorthosis.

1 Introduction

The loss of the grasp and reaching function in cervical spinal cord injured (SCI) subjects leads to a tremendous decrease of quality of life. Functional Electrical Stimulation (FES) is a promising method for functional improvement because it compensates for the loss of supraspinal control of paralyzed, but innervated muscles of the upper extremity. In the project 'OrthoJacket' a combination of FES together with an active orthosis driven by fluidic actuators is proposed to overcome the problem of a limited force generation capability of denervated muscle fibers, which are often present in the potential user group. Beside the design of powerful and reliable miniaturized actuators and of user-friendly FES components the personalized implementation of an intuitive user interface forms a major challenge in the development of a complex neuroorthosis like OrthoJacket [1].

For initial setup of an appropriate control method a precise documentation of the neurological and functional status of the potential end-user is mandatory. As a first step several clinical examinations are performed to assess the patients’ overall status, which include the assessment of the residual grasp function (grasp-and-release test, GRT [2], van Lieshout test, VLT [3]). The GRT and VLT score the performance of grasping, but do neither account for the actual movement pattern nor to which degree compensatory movements are responsible to fulfill the task. Manual testing of single muscles in predefined postures is a routinely used examination, but this provides no information about coordination of multiple muscles in goal-directed movements. A problem related to the application of the FES is the undesired crosstalk to neighboring muscles that occurs when several muscles are stimulated together. Furthermore the FES might trigger spasticity.

In summary, while all the tests give an overview of the mainly static, isolated residual capabilities of an SCI individual they do not provide detailed information about the dynamics of the activation and kinematic patterns occurring during the attempt of performing goal-directed movement tasks. Due to the biomechanical and bioelectrical complexity of the upper extremity no deterministic model of the partially nonlinear processes exist, which can be used for the optimal placement of the FES electrodes or for the selection and adaption of the parameters of the fluidic actuators. Therefore a heuristic approach has to be chosen for the implementation of an appropriate actuator scheme and user interface capable of sufficiently identifying the users’ movement intention.

As a basis a method for an objective and automated documentation of kinematics and myoelectric activities of upper extremity movements based on realtime instrumented movement analysis of a standardized tracking task has been recently introduced. This work aims at the extension of this method by allowing for realtime detection of deviations from normal kinematic patterns and for automated adjustment of stimulation parameters and control variables and thereby putting the ‘patient in the loop’ of the optimization process.

2 Methods

2.1 Algorithm for initial component selection of the active FES-orthosis

Based on the manual assessment of joint ranges of motion, voluntary force of single muscles, electrical excitability of (partly) paralyzed muscles and of the overall functional capabilities (GRT, VLT) an algorithm for setup of a stimulation training has been derived. In addition a cyclic tracking task
(eight shaped movement of the hand lying on a table) has been defined, in which an alternating activation of extension and flexion muscles have to be present for correct task completion. Based on the results of this assessment scheme (Fig. 1) a first compilation of sites of electrical stimulation, requirements for fluidic actuators and a selection of control muscles can be defined (Fig. 1).

This can be further refined by the application of the instrumented assessment tool described in the following chapter. If patients’ joint angles are not in the same range than the reference angles, FES will be applied to train the weak muscles until the desired range of motion is achieved. If this cannot be achieved sufficiently over a few months of training fluidic actuators have to support the missing muscle function. In the extreme case of a totally paralyzed muscle the motor function has to be completely substituted by external actuators.

### 2.2 Assessment of a feedback controlled cyclic tracking movement task

In an instrumented version of the cyclic tracking task a cursor following the trajectory of a Lissajous figure (LF) at preselected speeds is presented to the subject on a frontal projection screen (Fig. 2). The subject tries to virtually follow the cursor position transversally on a table. The hand movement is tracked with a motion analysis system and fed back as a crosshair cursor on the projection screen [4]. The crosshair position is transformed from the three dimensional space of the motion analysis laboratory coordinate system into the two dimensional space of the table reference plane. Four markers placed on the table define and limit the reference plane for tracing the LF (Fig. 2).

The subject is instructed to match the movements of the cursor (obtained by tracking of movement of 10 healthy volunteers) with the crosshair in a challenging range of speeds as good as possible. The LF shape is qualitatively evaluated by visual inspection of the LF plots. At present the mean Euclidian Distance (D) between cursor and crosshair is used for quantification of the deviations.

### 2.3 Data acquisition system

The core component of the assessment system is a commercially available, optical marker based motion analysis system (Motion Analysis Corp., Santa Rosa, CA), which consists of 8 Hawk infrared cameras and the Cortex software environment. Cortex calculates joint angles in real-time based on a biomechanical model of the upper extremity (32 reflective spherical markers of 12 mm diameter placed on anatomical landmarks of the upper extremity [4]). In addition Cortex also coordinates the acquisition of analog data like EMG signals, which are digitized by an USB-6218 DAQ device (National Instruments, Austin, TX, USA). A proprietary eight channel EMG system with a stimulation artifact suppression circuit [1] is used for EMG recordings nearby electrical stimulation electrodes accompanied by a 16 channel Trigno™ Wireless EMG system (Delsys Inc., Boston, MA). An 8-channel electrical stimulator ‘Motionstim8’ (Krauth+Timmermann, Hamburg, Germany) with surface electrodes is used for FES.

### 2.4 Software development

A proprietary C++ software tool called ‘EightFB’ was developed using the Cortex’ software to track the position of markers and to visualize the cursor and the crosshair in the LF. It processes marker

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**Figure 1:** Flowchart of the FES adaption process

**Figure 2:** Experimental setup consisting of a worktable and projection screen, Lissajous-figure (grey) with cursor (black point) and round crosshair (orbital)
trajectories, joint angles, EMG raw data and controls the Motionstim8 stimulator in real-time. The motion is captured with a sampling frequency of 120 Hz, the raw EMG is sampled with 2400 Hz and EMG activities are calculated every 100 samples (24 Hz), which are instantaneously used to update the FES amplitude (1/24 sec). The standard deviation of the raw EMG serves as an EMG activity estimator in disjunctive windows of 1/24 s length. The sample frequency of the analog data is synchronized with the motion capture clock to ensure a correct data processing and storage. The computer-generated imagery is produced with Nokia’s QT Toolkit. The Motionstim8 electrical stimulator was equipped with a dedicated self-developed firmware, which allows the programming of the currents and pulse widths of each channel over the serial interface. The implementation of a compact bidirectional serial protocol with minimal data overhead ensures a fast update of stimulation parameters. For safety reason the FES device and the control PC have been electrically decoupled. Offline analysis was performed using Matlab R2009b (The Mathworks Inc.).

2.5 Pilot experiments for system evaluation

A 46 year old male tetraplegic individual with a traumatic incomplete spinal cord injury (ASIA Impairment Scale C, neurological level of injury C5, Muscle grades of elbow extensors right 4/5, left 4/5; elbow flexors right 3/5, left 3/5) took part in the first evaluation of the novel system. The feasibility experiment was conducted in the subacute rehabilitation phase 10 weeks after injury. Within the proposed framework for assessment of upper extremity function (Fig. 3) a method for setup of an FES-based support of a weak elbow extension has been implemented. FES electrodes were positioned on right triceps brachii muscle to support elbow extension. Two separate control options of the FES have been foreseen: In the first operation mode (position controlled mode) the timing of the FES pattern is selected by the position in the LF, in which the triceps muscle is active in the healthy control group. In the second operation mode (EMG trigger mode) the FES is triggered by the residual EMG activity of the patient’s right trapezius muscle. The FES pattern is active when the EMG activity of this muscle exceeds a configurable threshold. The FES pattern itself consists of two square wave gating impulses which mimic the natural activation pattern of the triceps muscle during a LF cycle. The experiments started with determination of a challenging LF speed, since the difficulty of the cyclic movement has a linear dependency to LF speed [4].

After a first reference trial without FES the stimulation parameters (fixed 300µs biphasic pulse width) were personalized regarding timing and amplitude in order to allow for a completion of the whole LF cycle (position controlled mode). In a following step the EMG trigger mode has been selected and the results compared to the position controlled mode in terms of deviations D from the ideal cyclic movement.

3 Results

Fig. 4 shows the results of the feasibility experiment. Each row represents a single trial of twelve rounds. One LF period length is 3.14 s. The first trial (a) without FES served as reference. The mean D of 44.7 px is about twice as high as in healthy subjects [4]. The second trial ((b) middle row of Fig. 4) represents the FES supported elbow extension in position controlled mode. FES pulse timing is derived from the EMG of healthy subjects and depicted as black circles on the LF and as impulses of the EMG-chart. The amplitude of the first FES pulse of each LF round has been set to 22 mA in a time window of 17-28 % LF cycle. It supported the elbow extension in the lower right part of the eight shaped movement, whereas the second impulse (20 mA, 68-75% LF cycle) supported the elbow movement in lower left part. The mean D score of 42.1 px was slightly better compared to the reference trial. In contrast to the first trial (a) the movement trajectory is due to the support of the FES more stable, as indicated by the narrow most left part of the LF. In the last trial ((c) EMG trigger mode) the activity of the EMG without stimulation artefacts has been used as a trigger signal for generating the FES pattern. The impulse generation started, when the EMG activity exceeded the predefined threshold (marked as vertical line in the activity chart). Stimulation events appeared at 7-18% and 58-
65% LF cycle. Currents were fixed at 20mA and 22mA. The maximum trapezius activity occurred at 10% LF cycle. Therefore the stimulation timing has been shifted by this offset. For most of the twelve rounds the stimulation periods (circles) appeared within the reference time windows of trial (b). In two rounds (around frame 500 and 3200) triggering failed. The mean D of 58.6 px was worse than in the previous two trials. Like in trial (b) the movement trajectory was more stable than in the reference trial without FES. False trigger events next to the LF crossing point decreased the movement precision the LF shape compared to trial (b).

5 Discussion
With the instrumented assessment tool based on the real-time tracking of movement tasks an objective analysis of the upper extremity function is possible. The difficulty level is controllable by the LF speed for a wide range of impairments and movement disorders. A good selectivity of the assessment has been shown by the fact, that even in apparently well performing tetraplegic SCI subjects significant differences in the mean deviation D compared to healthy subjects were found. The feasibility experiment in a patient with a weak voluntary elbow extension revealed that the LF movement task can be slightly improved by triceps FES support when using a position control. Nevertheless, a more sensitive assessment parameter focusing on spatial precision rather than timing is needed since noticeable differences in precision in LF shape within the trials do not transfer in appropriate changes in D. Additionally, the EMG of the trapezius muscle has been identified to be suitable for triggering a supportive FES. Further investigations will show, if a combination of position and EMG triggered modes may add more precision and if adaptive thresholds in the EMG triggered mode lead to a more natural control.

Conclusion
The combination of real-time instrumented motion analysis, EMG recordings and closed-loop FES control opens novel possibilities for setup of a heuristic approach allowing for implementation of an appropriate actuator scheme of the neuroorthosis ‘OrthoJacket’. Additionally, it is a prerequisite for reliably identifying the users’ movement intention during goal-directed movements.

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Control of OrtoJacket – an intelligent hybrid orthosis for the paralyzed upper extremity

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1 Abstract

Through to the loss of the active movement of the upper extremity, for example a spinal cord injury, patients loose the major part of their autonomy and of their live quality. This leads to a lifelong dependency on caregivers. In the BMBF funded project OrthoJacket a modular, active orthosis for the upper extremity is developed. The System consists of an electrically powered shoulder support, a fluid-actuated elbow and a grasping function, realised by functional electrical stimulation (FES). The control of the neuroorthosis is realised by electromyography (EMG) signals from individually positioned surface electrodes. If there are no measurable EMG-signals, the movement of the orthosis is managed by using a shoulder or neck joystick. OrthoJacket can be used for functional restoration and training at home. By stabilizing the shoulder and the elbow the orthosis relieves the joints, the FES prevents further muscle degeneration and through the active animation joint stiffness is prevented.

2 Introduction

Every year about 1800 new people in Germany suffer from a spinal cord injury, 40% of these are tetraplegic [1]. These patients frequently possess remaining functions of parts of the shoulder and elbow [2], but cannot use them, as these possible movements are not sufficient to autonomously execute smaller activities. There exist various systems for assistance for persons with a tetraparesis or tetraplegia. They focus on stationary rehabilitation and therapy with the assistance by medical expert staff [3, 4, 5]. The project OrthoJacket is aimed at developing a lightweight, inconspicuous, mobile support system for the upper extremities to support the patients and to give them more autonomy and independence in everyday life. For this purpose, the movements of the upper extremities are supported actively and guided by an orthosis. For the patient to use this system not only for training purposes, but also in everyday life, the system has to be usable on a mobile basis contrary to other rehabilitation systems [6, 7]. As the injury and the resulting functional deficiency varies for every patient, the system has a modular design, such that it can be adapted easily to the individual needs of every patient.

3 Components of OrthoJacket

OrthoJacket consists of three modular parts, which can be used individually and together with the other parts [8]. The movement of the wrist and the grasping function of the hand are achieved by Functional Electrical Stimulation (FES). This type of actuation uses the body muscles to generate the movement. Stimulation is accomplished from outside by special electrodes fixed to the skin above the muscles. Rapid fatigue [9] of the hand is not so critical, because the movements take only very short and no large forces have to be applied. Grasp function can already be generated by a few surface electrodes, namely three pairs of electrodes for stimulation of the finger extensors (M. ext. digitorum communis EDC), the thumb extensors (M. ext. pollicis longus EPL) and one pair for common stimulation of the finger (M. flex. digitorum superficialis FDS und profundus FDP) and thumb flexors (M. flex. pollicis longus FPL) [10]. The muscles controlling the wrist and fingers are located closely to each other in the forearm. Due to the electrode size and inaccurate positioning of electrodes, not only the relevant muscles, but also adjacent muscles are stimulated. As a result, the wrist direction cannot be adjusted to the desired position. This effect frequently occurs when a simple stimulation system with one electrode pair is applied. The problem is eliminated by the use of several electrode pairs or multi-electrode arrays [11].

At the elbow, the system consists of a lightweight active orthosis that is partly integrated in a jacket. It supports the elbow function and the inner rotation of the shoulder with up to 100% of the force needed. For reasons of weight and due to the excellent integrability of FFAs [12, 13, 14], the orthosis is equipped with these drives. Based on the multibody simulation results, a torque to be applied by the elbow orthosis to move the arm was specified. The actuator meets the required minimum torque amount of 7Nm. Exact pressure adjustment is accomplished continuously by a proportional valve between -100 and 400kPa. The orthosis consists of two composite shells connecting the points of rotation of the actuator with the support area for the upper arm and forearm [15].

The shoulder function is supported by a linear axle system attached to the wheelchair. The shoulder is actuated by two stepper motors, as the torques to be applied are larger than those at the elbow. The relatively high weight of these drives is compensated by intelligent positioning near the center of rotation of the shoulder system. Shoulder actuation is achieved by a vertical rotation axis for the rotation of the shoulder. Adduction and anteversion are accomplished by an actively driven linear axle fixed to the center of the upper arm to raise the arm.
4 Control of the orthosis

As the OrthoJacket represents a system with up to 6 degrees of freedom, control is rather complicated for paraplegic patients who have a limited number of usable random signals only. Two different types of random signal sensors are used. If possible, OrthoJacket is controlled by electromyography signals (EMG-signals) measured at the skin surface of the patient [16]. There are two approaches to control the orthosis via EMG-signals. If the patient has some remaining voluntary movement in his muscles, for example in the musculus biceps brachii, then the EMG-signal is measured at the muscle the patient wants to move. This kind of control is very intuitive but not always possible, because not every patient has remaining voluntary movement in the arm or shoulder muscles.

For these patients it is still possible to control OrthoJacket via EMG-signals. Here the signals will be taken from muscles with remaining voluntary movement, like the musculus frontalis at the forehead. With a headband with textile EMG-electrodes [17] a frown can be detected and can be translated in a movement of the Orthosis.

A second possibility of signal acquisition is to use a joystick fixed on the shoulder or neck. This joystick can detect even smallest movements. As it is impossible to extract a target value for the desired end position from these signals, a speed-proportional control is implemented. When the random signal exceeds a certain patient-specific limit value, the corresponding actuator is activated. The more the current value of the signal exceeds the limit value, the more quickly the orthosis will move. This process is illustrated by an EMG signal in figure 1 below.

There are three different modes for the joystick control, depending of the patient spinal cord injury level:

- In the first control mode, the orthosis is moved via a speed-proportional control. With the 1-D joystick a special movement path is controlled, for example, in the one direction the hand moves to a drinking vessel and grasps it, in the other direction the hand moves to the mouth. This control concept has the advantage of being very intuitive and rapid to learn. Its drawback consists in the fact that only certain, stored programs can be run and that the hand cannot be positioned freely in space. If the drinking vessel cannot be grasped, as it is located too far on the left or right, the wheelchair has to be repositioned by the patient or the patient has to change the control mode for a short term to exactly position the hand.

- In the second mode the currently chosen actuator is moved in accordance with the measured random signal. By means of this program, the hand can be positioned exactly in space. For this purpose, the patient can operate only one degree of freedom of the orthosis with the joystick and switch among the degrees of freedom. This works as follows: The joystick moves the shoulder rotation only. If the patient makes a rapid left-right movement with the joystick, the rotation is blocked and the patient is able to raise or lower the upper arm. If the patient wishes to move the elbow, he has to make a rapid left-right movement again. In this way, all degrees of freedom can be positioned individually. As this is a relatively complicated and slow control mode, it shall only be used for fine positioning. Normal operation is controlled by the first mode.

- The third mode requires the patient to have three independent random signals. With them, the patient shall be enabled to control the speed of his/her hand in the three dimensions of space.

![EMG signal at the biceps](image)

Fig. 1. Interpretation of the EMG signal
The required angular velocities of the shoulder and elbow actuators are calculated by software. The complete system is monitored and controlled by a microcontroller. The controller monitors the filling level of the pressure and vacuum tanks. It activates the actuators, and monitors the position of the orthosis via various sensors. In addition, it evaluates the movement detection sensors and plans the movement tracks.

5 Evaluation

First tests of the system were made with healthy subjects. In these tests, it was determined how large the movement space of persons of variable size is and system operation with limbs of variable weight was evaluated. Three persons with complete movability were chosen to represent a very large group of persons. Their weights ranged from 63 to 95kg, their size varied between 1.84 and 1.92m. The results obtained were very good, as you can see on table 1.

In case of adduction, the wheelchair to which the system was fixed prevented further rotation to the outside. Tests on patients focused on the elbow orthosis. The patient has a lesion below C4 and voluntary movement of the biceps was very difficult. Voluntary activation of the triceps was impossible. With the orthosis flexion and extension of the elbow was between 0° to 90°. The elbow orthosis was controlled by a shoulder joystick. In the patient test, it was checked how intuitive the control of the orthosis is and how reliably it can be moved. When the joystick signal exceeded a certain threshold value, the pressure in the actuator was increased slowly. When the signal dropped below the value, the movement stopped. The results were satisfactory, but also showed that the patient first requires a training phase to learn to control OrthoJacket.

6 Conclusion

First experiments showed that the elbow orthosis is considered helpful and useful by the patients. Now, the complete OrthoJacket system with the shoulder actuators remains to be evaluated on healthy subjects and on tetraplegic patients. For this purpose, a test scenario was designed with activities frequently occurring in everyday life. The test person is sitting in his wheelchair in front of a table and wishes to grasp a drinking vessel and move it to his mouth. This movement that is important in everyday life is repeated several times using the different operation modes of the OrthoJacket. Various problem levels will be distinguished. With this, it will be tested whether the system will also work reliably in the human environment. After this, the patient will be asked how he has experienced the system, what he felt during the test, whether it was comfortable or too complicated, and what he did not like.

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Abstract

The clinical implementation of osseointegrated limb prosthesis is still limited due to infections at the side of the percutaneous passage. In our concept this issue is addressed by designing antimicrobial, biocompatible surface coatings for an permanent aseptic interface.

In this study different copolymers with surface active phosphate and antimicrobial cationic groups are designed. Thus coated titanium samples are cultured in vitro with bacterial strains or fibroblasts, respectively. The antimicrobial impact is evaluated imaging the reduction of bacterial adherence. The biocompatibility is displayed by fibroblast proliferation and morphology. Furthermore an in vivo animal model with transcutaneous pin samples is developed and analyzed regarding the interface morphology and occurrence of infection.

To date three generations of copolymer surface coatings are developed. The optimized polymer coating shows a reduction of adherent bacteria up to 95%, but an equal adherence of human fibroblast compared to blank titanium samples.

In a short term follow up in vivo we could see no significant differences in wound heeling or bacterial load between the titan and the polymer-coated samples, however, the long term follow up are ongoing studies. In this study we could demonstrate the basic antimicrobial and biocompatible capability of polymer surface coatings at the same time. We consider this to be a promising technology for the realization of a permanent aseptic percutaneous passage as needed for the advancement of osseointegrated limb prosthesis.

1 Introduction

Osseointegration of amputation limb prosthesis as it was introduced in the 1990ies by Branemark and coworkers appears to be a promising approach to improve quality of life and mobility of amputees in comparison to conventional socket attached devices [1]. As an alternative docking system for exoprosthesis attachment, the percutaneous osseointegrated implant system is currently under clinical evaluation in selected patients with limb loss. A European survey indicates a high degree of satisfaction among patients using this skeletal prosthesis docking system with improvement seen mainly in the areas of mobility, limb function and the ability to perceive terrain changes when ambulating. However, the clinical implementation of those bone anchored transcutaneous systems is still limited due to infections at the side of the percutaneous passage.

To date, their center has treated more than 150 patients with femoral, tibial, humeral, or ulnar/radial implants. In their concept the skin is attached directly to the bone stump [2]. The used polished titanium implants inhibit an attachment of the dermal and soft tissue layers to the devices. Even though treatment failures could be reduced over the time by implementing a standardized treatment protocol in 1999, infection is still a major problem. In a study published by Tillander, Branemark et al. [2] in 2010 seventeen of thirty-nine amputees show a probable or definite implant infection (n=6) or at least a soft tissue infection at the side of the transcutaneous passage (N=11) in a 2-3 year follow-up. Additionally, from the clinician’s point of view the direct attachment of the skin to the bone is not ideal particularly with regard to required revision surgery.

Other research groups working on the realization of osseointegrated transcutaneous limb prosthesis are focusing on the implementation of a stable and direct attachment of the skin to the implant [3,4]. In theory such a stable attachment of the dermis to the implant is crucial for a permanent aseptic interface and to prevent implant failure due to infection. This issue is addressed by macro porous titanium alloys or fibronectin coatings, respectively. However, it was observed that the macro porous implants used in animal experiments enable the dermal attachment to the implants and a fibroblast migration into the structures, a slow epithelial down growth was still detected over the time [4]. Moreover, the porosities can abet a bacterial adhesion as well. So, the main challenge facing percutaneous implant technology is the superficial infection due to insufficient epithelial integration at the skin/implant interface, which allows sinus tract formation and subsequent microbial invasion into the depth.

In our concept of osseointegrated limb prosthesis we address this issue by designing surface coatings with an antimicrobial impact – to prevent bacterial adhesion to the implant - and biocompatible characteristics – to assist the dermal attachment - at the same time. We hypothesize that polymer coatings could
be designed combining said characteristics and that these would improve the maintenance of a physiological skin seal at the skin-implant interface.

2 Methods

Different copolymers with surface active phosphonate groups and antimicrobial cationic groups are designed and coated on titanium samples. The evaluation of the coatings itself is performed via ellipsometry and contact angle measurements. Their characteristics regarding their antimicrobial impact and biocompatiblility are screened in vitro. Coated samples are cultured with S. epidermidis, S. aureus and E. coli under static and dynamic conditions or with human dermis fibroblasts, respectively (n=10 for each group). Polished blank titanium discs serve as controls. Bacterial adherence is evaluated via live/dead assay at 1 or 5 hours of cultivation. The biocompatibility is displayed by fibroblast attachment and cell morphology in electron microscopic analysis at 24h. Cell proliferation of the fibroblasts is monitored at 72h via a modified LDH assay. Suitable polymers are selected and optimized in composition to accomplish the contrarily requirements best. The optimized antimicrobial capability and biocompatibility of those copolymers is evaluated in vitro as mentioned. The copolymer with the best combination of antimicrobial activity and good biocompatibility is selected for the subsequent in vivo experiments.

In the second stage an animal model with transcutaneous pin samples is developed as shown in figure 1 to evaluate the effect of the coatings in vivo. Coated or blank titanium pins are implanted at the back of hairless mice (n=30 per group). A wound dressing is only applied for the initial three postoperative days, after that no further specific wound care or disinfection is performed. The implant-skin-interface is monitored daily regarding clinical sights of infection. At 1, 2 and 3 weeks after implantation the animals are sacrificed. Initial wound healing at the dermal-implant-interface is analyzed regarding the clinical occurrence of infections and the bacterial load. At the time of explantation the bacteria adhered to the implant surface are displayed with acridin-orange staining in confocal laser scanning microscopy. Additionally swab cultures are taken to verify the bacterial stains. Histological methods are establish for contemplate analysis of the implant-skin-interface.

Figure 1: Sketch of the percutaneous titanium sample for the in vivo experiments (left) postoperative picture 3 days after implantation (right)

3. Results

To date ten copolymer surface coatings are developed, characterized and evaluated in vitro. Thereupon three generations of optimized copolymers are designed and tested in vitro. A layer thickness of 4.3 to 6.2, or 5.5 to 9.0 nm is detected. In the vitro evaluation the 1st generation polymers already show an antimicrobial capacity with an oust effect and subsequent aggregation of germs but no reduction in the overall bacterial load as shown in figure 2b. The 2nd generation as well as the 3rd generation show a significant reduction of adherent bacteria up to 95% compared to blank titanium samples in vitro [Figure 2a,c+d]. Similar results can be reproduced in static and dynamic culture systems with a variety of species. The adherence and proliferation of human dermis fibroblasts on the 2nd generation polymer show a slight decrease compared to the control titanium samples, but is not significant (p=0.512), whereas the 3rd generation polymer coatings are worse (p=0.000). [figure 3] The cell morphology is not affected by the polymer coatings of the 2nd generation as well [figure 4]. As a result of the in vitro tests the 2nd generation copolymer coating was defined to match the requirements best and was chosen for the subsequent in vivo experiments.
As mentioned an animal model with percutaneous titanium pin samples is established for the in vivo evaluation of the polymer coatings [Figure 1]. The implantation technique can be reproduced in a highly standardized protocol. In the short time follow up we used in the first stage to assess the initial wound healing, clinical apparent infection occurred in two mice of the blank titanium group but none in the polymer group. A bacterial migration along the transcutaneous pin is found in three cases – two in the blank titanium group and one in the polymer group. All other samples show no adherent bacteria to the implants. Overall we are not able to demonstrate significant differences in the bacterial load in the polymer coated group compared to the blank titanium controls. Contemplate histological analysis are still in progress.

Figure 2: *S. aureus* adhesion on A) blank titanium controls, B) 1. generation polymers, C) 2. generation polymers, D) 3. generation polymers at 5 hours of cultivation, Live/Dead Assay.

Figure 3: Fibroblast coverage on the surface of the blank titanium controls, 2. and 3. generation polymers compared to cell culture plastic (= 100%) at 72h of cultivation.
4. Discussion

The main challenge facing percutaneous implant technology is the superficial infection due to insufficient epithelial integration at the skin/implant interface, which allows sinus tract formation and subsequent microbial invasion. A stable dermal attachment to the implant has to be installed as well as the bacterial migration into the depth has to be prevented.

In our study we were able to design a copolymer surface coating for implant materials with antimicrobial and biocompatible properties at the same time. This appears to be suitable for the skin-penetrating region of transcutaneous devices with the perspective to achieve a permanent aseptic skin seal. Compared to the mentioned single biocompatible character of the other surface coatings [3] the antimicrobial surface functionalisation implies an interesting new approach. We can demonstrate a high antimicrobial impact to different clinical relevant pathogens in vitro. The biocompatibility of the 2nd generation polymers to human dermis fibroblasts shows no significant difference to the titanium controls in vitro.

Admittedly, our preliminary results in vivo, showed no significant benefit of the polymer coatings compared to blank titanium. Though, infection was not a major problem in the short time follow up, we used in this study to determine the initial wound healing. In this context the long term evaluation of the surface characteristics and the dermal-implant-interface in vivo would be much more relevant for our clinical setting. This is currently addressed in ongoing experiments using the same animal model.

Overall we consider the proven basic characteristics of the polymers to be a promising technology for the realization of a permanent aseptic percutaneous passage as needed for the advancement of osseointegrated limb prosthesis. Probably this needs to be combined with porous surfaces and subdermal anchorage systems as introduced by others [4].

5. Acknowledgements

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Transcutaneous Energy Transfer System (TET) drives German Artificial Sphincter System

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I. Introduction
Faecal and urinary incontinence are conditions that have a strong impact on the quality of life. In recent years, the German Artificial Sphincter System (GASS) project has developed an innovative system capable of substituting a dysfunctional sphincter [1]. GASS is a highly integrated prosthesis system, working as a hydraulic muscle, for treatment of the faecal and urinary incontinence [2]. The system features a high performance peristaltic micropump pumping a working fluid from a reservoir into a compression cuff system which is implanted around the damaged sphincter muscle or urethra to restore a normal functional capability [3].

After the proof of concept was provided in a prior project, the current objective is to develop a transcutaneous energy and data transfer system for the device. Percutaneous drivelines that are used to power active implants create a serious risk for infections. The TET technology improves therapy and enables sustainable enhancement in the quality of life. A convenient external carrier system was designed for correct positioning of the charger module during the recharging process.

II. Materials and Methods
A. TET Components
The TET is equipped with a pair of inductively linked coils to transfer energy to implants without percutaneous drivelines (Fig. 1). The transmitter coil is placed on the skin surface, while the receiving coil is implanted either in the subcutaneous tissue or between outer muscle layers.

The standard voltage for the energy supply of implants is in the range of 24 Volts and is adjustable to the required energy supply of the electric components.

![Transcutaneous Energy Transmission](image)

The amount of the transmitted energy is controlled by the energy demand of the implant. This reduces the strength of the magnetic field, thereby sparing the tissue. Wireless data transfer is realized by RF transmission and a proprietary protocol at a rate of up to 500 kbit/s.

B. External Components
The patient is equipped with a handheld device that allows wireless opening and closing of the cuff. A further external component for recharging the internal accumulator is the charging unit including the external transmission coil (see Fig. 2). The wireless data transmission performance was verified in vitro in a body phantom. The textile carrier system to lock the charging unit into position during the charging process has the shape of an expanded belt (see Fig. 3).
C. Implanted Components
The artificial sphincter system consists of a cuff that is placed around the bowel/urethra and an implantable module that includes the micro pump, the RF-transmission module, the pump driver and an accumulator. The micro pump is used to pressurize the cuff that is filled with fluid and thus closes the bowel/urethra. An implantable reservoir is necessary for buffering the cuff-fluid during defecation/micturition. The reservoir is located inside the receiver coil of the TET to keep the number of implanted components as small as possible (see Fig. 4).

D. Micropump and Actuators
The pumping process is realized by piezo actuated silicon membranes (see Fig. 5). The core of the system is a bidirectional piezoactuated micropump [2] consisting of three actuated membranes: two active valves and one pumping actuator. In typical operating conditions, it can reach a flow rate of 1.1 ml/min and a maximum backpressure of 400 mbar. This performance is sufficient to pressurize and depressurize an elastic compression cuff in a few minutes, therefore emulating the contraction/relaxation of human sphincters [4]. Fluid can be propelled with an appropriate actuation sequence of the pump and valve membranes from the inlet to the outlet or vice versa. The piezoelectric membrane actuators flex upward and downward due to an electrically induced in-plane strain of the piezo disks mounted on top of the silicon membranes. This strain is caused by the electric field strength in the piezo material via the inverse piezoelectric effect [3].
An effective reduction of the actuation voltage can be achieved by the use of multilayer piezoelectric actuators. They use the fact that the electrical field strength in the piezoelectric material remains constant in a multilayer with intersected electrodes. Therefore a customized multilayer piezoelectric actuator was manufactured by Morgan Electro Ceramic [5]. This actuator consists instead of only one active piezo layer of nine active piezo layers each with a layer thickness of 15 µm (see Fig. 6) to sum up the generated in-plane forces [3].

III. Results

A. The Transcutaneous Energy Transmission System (TET)

Bi-directional data communication is improved to a rate of 500kbits/sec, where the handheld device is allowed to be a distance up to 3 m from the patient. The maximum efficiency of the system with no horizontal displacement is 74% at a distance of 13 mm between the coils and 57% at a distance of 33 mm.

Horizontal displacement of 30mm of the coils reduces the efficiency to 62% at a distance of 13 mm and to 40% at a distance of 33 mm (see Fig. 7). Displacement of the coils also leads to warming of the external transmitter electronics. Warming within permitted limits was measured between the coils and implanted components under normal operating conditions [6]. The system is able to run for up to 60 hours without external power. After this period, the system must be recharged for two hours.

B. The Micro Pump and Driver PCB

The operating voltage and driving power of the micro pump could be reduced for safety reasons and to reduce the energy consumption which determines the size of the accumulator and there-
fore the size of the implant. The reduction of the driving voltage from a bipolar signal of +250 V/-
100 V to +30 V/-10 V was obtained by using a multilayer piezoelectric actuator instead of a sim-
ple piezo disc. Along with this, efficiency of the electronic driver could be increased, because
the voltage gain from accumulator voltage level to driving level was reduced by a factor of 10.
The current fluidic power was reduced to about 1 ml/min and a maximum sustainable backpres-
sure of 40 kPa, compared to about 4 ml/min and 60 kPa for the high voltage pump. A further re-
duction of the size of the micro pump system was obtained by minimizing the electronic driver.
This is mainly a side effect of the voltage reduction, as the size of the electronic components
could be reduced due to lower voltage requirements.

IV. Conclusions
Due to the voltage reduction the multilayer piezo technology is capable to be used in medical
implants [3], but further research is necessary to increase the maximum flow rate of the micro
pump to values above 2 ml/min. Also the driving frequencies should be decreased in order to
reduce step-up converter losses which are significantly dependent on the driving frequency [7].
The battery has to provide enough energy in order to monitor the status of the system during
stand-by (e.g. to control the pressure inside the cuff or to check for communications from the
remote controller) and to drive the piezo actuators during the pumping phase. This clearly
implies that power consumption is a major concern in the design in order to keep the dimension of
the battery as small as possible while maintaining sufficiently long battery duration [4].
The TET showed reliable transmission of energy at horizontal and vertical displacements up to
30 mm. Transmitted energy is automatically adapted to the demand of the implanted device.
The temperature of the implanted components did not exceed critical values. The setup worked
reliably during in-vitro testing. All electronic components shall be further miniaturized to reduce
the size of the implant and the external components. Further research is necessary to increase
the efficiency of the energy transmission.

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Appendix

List of BMBF funded projects:
Innovative aids in rehabilitation and for the disabled

Forschungsprojekte im Verbund „Innovative Hilfen in der Rehabilitation und bei Behinderung“

1.1 Modellbasierte Hörsysteme: Entwicklung und Evaluation innovativer modellbasierter Techniken für technische Hörhilfen
(HörTech gGmbH, Oldenburg, Prof. Dr. Dr. B. Kollmeier)

1.2 Bus-ID: Barrierefreier Zugang blinder und sehbehinderter Menschen zum öffentlichen Nahverkehr durch Einsatz von RFID
(Helmut-Schmidt-Universität der Bundeswehr, Hamburg, Prof. Dr.-Ing. A. Fay)

1.3 Entwicklung einer innovativen Gleichgewichtsprothese
(Unfallkrankenhaus Berlin Holding GmbH, Prof. Dr. A. Ernst)

1.4 Funktionelle, periphere Magnetstimulation (FMS) zur Rehabilitation der Motorik in Patienten mit zentralen Paresen, insbesondere halbseitigen Lähmungen
(Klinikum der Universität München, Prof. Dr. A. Straube)

1.5 Sphärisches Rundfensterimplantat für Schwerhörige
(RW-Implant, Eberhard-Karls-Universität Tübingen, Prof. Dr. H.-P. Zenner)

1.6 RehaRobES: Regelungsverfahren für Endeffektorbasierte Reha-Robotik in Kombination mit elektrischer Stimulation in der Gangtherapie nach Schlaganfall
(Fraunhofer-Institut für Produktionsanlagen und Konstruktionstechnik Berlin, Prof. Dr. J. Krüger)

1.7 Kompakte assistiv-restaurative Bewegungstherapie - Geräte neuer Generation auf Basis fluidischer Soft-Antriebe mit elastischen Rotationsarbeitskammern (KoBSAR)
(Friedrich-Wilhelm-Bessel-Institut, Bremen, Dr. O. Ivlev)

1.8 OrthoJacket - Eine intelligente Hybrid-Orthese für die gelähmte obere Extremität auf Basis der Funktionellen Elektrostimulation und innovativer Fluidfaktoren als Therapie- und Unterstützungssystem
(Stiftung Orthopädische Universitätsklinik Heidelberg, Dipl.-Ing. Rüdiger Rupp)

1.9 TExoPro: Technische Realisierung von transkutanen, knochenverankerten Extremitätenprothesen zur Verbesserung der Mobilität und Sicherheit bei amputierten Patienten
(Medizinische Hochschule Hannover, Prof. Dr. H. Windhagen)

1.10 German Artificial Sphincter System - Eine intelligente, telemetrisch bedienbare Schließmuskelpresse zur Kontrolle der Blasen- und Darmentleerung
(GASS, Albert-Ludwigs-Universität Freiburg, PD Dr. H.-J. Schrag)

1.11 Entwicklung einer osseointegrierten biophasischen Mittelohrprothese zur Optimierung der Rehabilitation hörbehinderter Patienten
(MOP, Technische Universität Dresden - Universitätsklinikum "Carl Gustav Carus", PD Dr. Th. Zahnert)