OrthoJacket – An active FES-hybrid orthosis for the paralyzed upper extremity

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Abstract
The loss of the grasp function in cervical spinal cord injured patients leads to life long dependency on caregivers and to a tremendous decrease of quality of life. If not enough muscles for surgical rehabilitation are available, Functional Electrical Stimulation (FES) is the only clinically applicable way for functional improvement. However, until now all grasp neuroprostheses are dependent on unrestricted active shoulder and elbow movements, which are not present in very high lesioned patients. Therefore this BMBF funded project aims at the development of a non invasive, modular FES-hybrid orthosis for the upper extremity, which combines the advantages of orthotics in mechanically stabilising joints together with the possibilities of FES for actively eliciting muscle contractions. In patients with limited force generating capacity flexible fluidic actuators will be used to support the movement. Thus the system can not only be used for functional restoration but also for training. The integration of novel user interfaces based on residual muscle activities and detection of movement intentions by real-time data mining methods will enable the user to independently control the system in a natural way.

1 Introduction
In Europe an estimated number of 300.000 people are suffering from a spinal cord injury with 11.000 new injuries per year. The consequences of an injury of the spinal cord, which results in a loss of sensory, motor and autonomous functions, are tremendous for the patients. The loss of motor functions especially of the grasping function - 40% of the total population of the SCI patients are tetraplegics - leads to a life-long dependency on caregivers and hereby to a dramatic decrease in quality of life [1]. Since tetraplegic patients are often young persons due to sport and diving accidents, modern rehabilitation medicine should be aiming at the restoration of the individual functional deficits. However, up to now no pharmacological therapy exists for promoting regeneration of destroyed nerve fibers in the spinal cord [2]. Therefore in case of missing surgical options in the form of tendon transfers the only clinically applicable way of restoring permanently restricted or lost functions to a certain extend is the application of neuroprostheses based on Functional Electrical Stimulation (FES). Some of these neuroprostheses use surface electrodes for external stimulation of muscles of the forearm and hand. Examples are the commercially available NESS-H200 System [3] and other more sophisticated research prototypes [4]. To overcome the limitations of surface stimulation electrodes concerning selectivity, reproducibility and handling, an implantable neuroprosthesis (the Freehand system), where electrodes, cables and the stimulator reside permanently under the skin [5], was developed for use in chronic patients.

Most tetraplegic patients in Europe have a lesion of the spinal cord at the level of C4 or higher with functional restriction not only of the hand and fingers but also of the elbows and sometimes also of the shoulders [6]. This is different to the situation in the US, where the majority of the tetraplegic patients has a lesion at the level of C5 with preserved shoulder and elbow function [7].

Fig. 1: Distribution of the neurological level of injury at discharge from primary rehabilitation (data taken from the European Multicenter-Study about Spinal Cord Injury – EMSCI, www.emsci.org)

All FES systems for grasp restoration have in common that only patients with preserved voluntary shoulder and elbow, but missing hand and finger function may benefit from them. The reason for this limitation
is the occurrence of muscle fatigue due to the relevant weight of the upper limb and the non-physiologic, synchronous activation of the paralyzed muscles through external electrical pulses [8].

One of the main problems in functional restoration of reaching and grasping in tetraplegic patients is the occurrence of a combined lesion of the central and peripheral nervous structures. In almost one third of the tetraplegic patients an ulnar denervation exists due to damage of the motor neurons at the lesion site in the cervical spinal cord [9]. Denervated and therefore flaccid muscles are not responsive to short current pulses typically used in FES applications and even with long pulswidths over 100 ms they do not effectively contribute to a functional restoration because of low force output and low fatigue resistance.

Therefore the main goal of this ongoing project is the development and the clinical validation of a modular FES-hybrid orthosis ("OrthoJacket") for functional restoration of the paralyzed upper extremity, which combines the possibilities of an active, motorized orthosis with the advantage of FES for efficient activation of muscle groups. In patients with very limited force generating capacity the active orthosis will take over the complete support of the movement, thus the system can not only be used for functional restoration but also for training by enhancement of neuroplasticity. Since training has to begin in the very early phase of rehabilitation, when spontaneous neurological recovery may occur, a noninvasive and highly adaptable approach in terms of placement of stimulation and sensor electrodes has to be taken.

2 Basic components of the “OrthoJacket”

In the currently developed "OrthoJacket" device several subsystems are integrated, which consist of surface, self-adhesive stimulation electrodes together with a programmable stimulator unit and adaptable firmware, an orthosis for the upper extremity, which is actively driven by novel fluidic actuators, and sensors for classification of user intentions and determination of internal states of the upper extremity like joint angles, muscle force, fatigue or spasticity.

2.1 Functional electrical stimulation

Most of the activities of daily living can be performed with mainly two grasp patterns, palmar and lateral prehension. Palmar prehension is generated by forming the opposition between the thumb and the palm, whereas the lateral grasp is generated by flexing the fingers to provide opposition followed by thumb flexion. If FES systems based on surface electrodes are intended to be used by patients in their all-day life, a minimal number of electrodes, which have to be individually placed on a daily basis, is a crucial prerequisite. Additionally, electrodes on the thenar or the palm of the hand should be avoided, because they tend to move or to fall off. Since electrodes are needed on the thenar to achieve the thumb abduction necessary for the palmar prehension the primary focus is put on the restoration of a lateral prehension for picking and holding of flat objects like a spoon or a pen. This grasp pattern can be generated by already a few surface electrodes (Fig. 2), namely 3 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). The closing of the fingers with a partly extended thumb can be achieved by implementation of a dedicated activation pattern with utilisation of differently strong cocontractions of the thumb extensors and flexors (Fig. 2).

The main disadvantages of non invasive FES systems are the time consuming and difficult to handle placement and realignment of the surface electrodes and their connection to the cables, which often lead to a refusal by the patients. Therefore considerable efforts are currently undertaken to simplify these processes with the use of custom-built stimulation electrodes (Ø 2.5 cm) with double sided self-adhesive conductive gel surfaces (Axelgaard Manufacturing Co. Inc., Fallbrook, CA, USA), which on the one hand guarantee a proper skin contact and on the other hand can be easily realigned. A textile sleeve made of stretch cloth with integrated cable structures and individually configurable metal plates will be used for contacting the stimulation electrodes and will help to keep donning and doffing as simple as possible.
2.2 Orthotics

A first version of a lightweight orthosis (145 g) for stabilisation of the wrist and support of elbow flexion and extension has been built. The orthoses are individually manufactured for each user and consist of two reinforced half-shells with fixation straps and a custom-built elbow joint for guiding the movements of the elbow. The orthosis effectively restricts joint angles to predefined planes and therefore compensates unwanted movements that may occur due to motion dependent displacements of the stimulation electrodes.

2.3 Fluidic actuators

For external, active support of the joint movements flexible fluidic actuators are being integrated into the orthosis [10]. The innovative fluidic actuators are based on bionic principles and have - compared to conventional electrical drives - the advantages of low weight and high energy density in combination with a high potential for miniaturisation. The latter is an important requirement for this particular application because many actuator elements may be flexibly integrated into the FES-hybrid orthosis. During former research projects mechatronical joint modules with elastic bellows-like force producing elements have been developed and optimised, which are capable of directly producing rotary motions. In parts of the upper extremities like the fingers, where only soft orthotic components can be used, these actuators are ideal for integration into a glove since they are completely made of flexible materials. The biggest advantage of the fluidic technology is their inherent low stiffness, which is an essential feature in order to comply with safety constraints.

2.4 Sensors

A key issue of the “OrthoJacket” is to obtain information about the position and the joint angles of the upper extremity and the orthosis respectively, which is carried out by the integration of a variety of technical sensors, e.g. goniometers and bend sensors. However, these sensors do not provide detailed information about the internal states of the stimulated muscles, e.g. fatigue, and are not able to distinguish between involuntary muscle activation, i.e. spasticity, and preserved voluntary activation of muscles. The latter is of utmost importance since preserved residual muscle functions can be used for determining the users’ movement intentions and can therefore be used for “natural control”. The residual activity of weak muscles can best be assessed by the measurement of the electromyogram (EMG). A mandatory prerequisite for using the EMG for control of a Functional Electrical Stimulation is the possibility to obtain an artefact free signal for real-time processing. This is a technical challenge, since conventional EMG amplifiers react to stimulation pulses with a transient oscillation. Additionally, the poor signal-to-noise ration (1:10000) between the low EMG amplitude of a weak muscle and the high stimulation voltages and their overlapping frequency spectra do not allow to suppress the stimulation artefacts by a fixed filter characteristic.
An existing EMG amplifier based on former research has been adapted to the requirements of the “OrthoJacket” and is currently miniaturised, that is capable of detecting the onset and end of a stimulation pulse generated by stimulation electrodes near the recording site, suppressing the artefacts by switching the amplification factor and the cut-off frequencies of the filters and amplifying the EMG activity within the stimulation pulse pauses (Fig. 5). Recently a setup for a classifier based evaluation scheme based on the analysis of the duration of the electrically induced M-wave has been introduced to determine optimal EMG recording sites and experimentally verified [11].

3 Future Work

In the ongoing project the lightweight orthosis for support of the elbow movements is currently extended to an active orthosis for support of shoulder movements, in particular shoulder abduction, flexion and rotation. Also a control strategy has to be implemented for the coordination of the competitive force generation systems, i.e. the FES and the active orthosis with integrated fluidic actuators.

The EMG-electrodes are currently merged together to electrode arrays in order to investigate, if an automated selection of the most effective recording sites is possible without the need for manual sensor re-alignment. These hardware developments are accompanied by software implementations like the introduction of real-time data mining methods for classification of movement intentions and spasticity.

The “OrthoJacket” is primarily based on the use of preserved voluntary muscle functions of the upper extremity as a “natural” user interface. This also supports the idea of developing a system for bilateral restoration of the arm function. However, in case of complete cervical spinal cord injuries (above C5) not enough residual functions may be preserved for control of the “OrthoJacket”. Within the recently started, EU-funded project TOBI (Tools for Brain Computer interaction, project number 224631) the possibility of using non invasive Brain-Computer Interfaces for the control of grasp neuroprostheses are tested and validated in patients. If these systems prove to provide stable control signals under real world conditions, they may further enhance the currently available conventional user interfaces.

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5 References


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