Biosystems & Biorobotics

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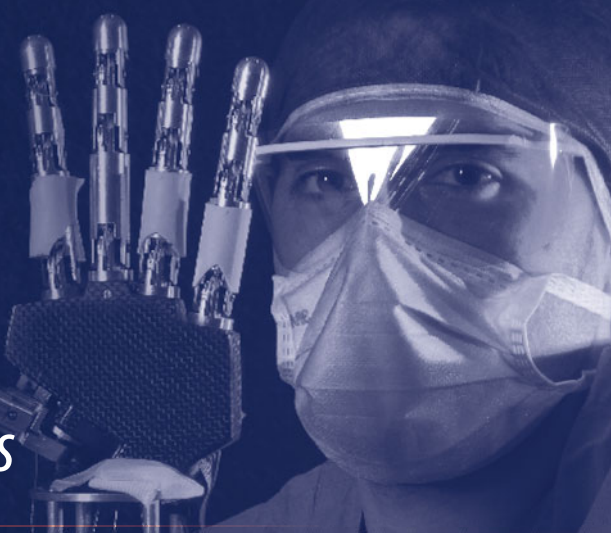

Converging Clinical and Engineering Research on Neurorehabilitation III

Proceedings of the 4th International Conference on NeuroRehabilitation (ICNR2018), October 16–20, 2018, Pisa, Italy

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Biosystems & Biorobotics

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Aims & Scope

Biosystems & Biorobotics publishes the latest research developments in three main areas: 1) understanding biological systems from a bioengineering point of view, i.e. the study of biosystems by exploiting engineering methods and tools to unveil their functioning principles and unrivalled performance; 2) design and development of biologically inspired machines and systems to be used for different purposes and in a variety of application contexts. The series welcomes contributions on novel design approaches, methods and tools as well as case studies on specific bioinspired systems; 3) design and developments of nano-, micro-, macrodevices and systems for biomedical applications, i.e. technologies that can improve modern healthcare and welfare by enabling novel solutions for prevention, diagnosis, surgery, prosthetics, rehabilitation and independent living.

On one side, the series focuses on recent methods and technologies which allow multiscale, multi-physics, high-resolution analysis and modeling of biological systems. A special emphasis on this side is given to the use of mechatronic and robotic systems as a tool for basic research in biology. On the other side, the series authoritatively reports on current theoretical and experimental challenges and developments related to the "biomechatronic" design of novel biorobotic machines. A special emphasis on this side is given to human-machine interaction and interfacing, and also to the ethical and social implications of this emerging research area, as key challenges for the acceptability and sustainability of biorobotics technology.

The main target of the series are engineers interested in biology and medicine, and specifically bioengineers and bioroboticists. Volume published in the series comprise monographs, edited volumes, lecture notes, as well as selected conference proceedings and PhD theses. The series also publishes books purposely devoted to support education in bioengineering, biomedical engineering, biomechatronics and biorobotics at graduate and post-graduate levels.

About the Cover

The cover of the book series Biosystems & Biorobotics features a robotic hand prosthesis. This looks like a natural hand and is ready to be implanted on a human amputee to help them recover their physical capabilities. This picture was chosen to represent a variety of concepts and disciplines: from the understanding of biological systems to biomechatronics, bioinspiration and biomimetics; and from the concept of human-robot and human-machine interaction to the use of robots and, more generally, of engineering techniques for biological research and in healthcare. The picture also points to the social impact of bioengineering research and to its potential for improving human health and the quality of life of all individuals, including those with special needs. The picture was taken during the LIFEHAND experimental trials run at Università Campus Bio-Medico of Rome (Italy) in 2008. The LIFEHAND project tested the ability of an amputee patient to control the Cyberhand, a robotic prosthesis developed at Scuola Superiore Sant'Anna in Pisa (Italy), using the tf-LIFE electrodes developed at the Fraunhofer Institute for Biomedical Engineering (IBMT, Germany), which were implanted in the patient's arm. The implanted tf-LIFE electrodes were shown to enable bidirectional communication (from brain to hand and vice versa) between the brain and the Cyberhand. As a result, the patient was able to control complex movements of the prosthesis, while receiving sensory feedback in the form of direct neurostimulation. For more information please visit http://www.biorobotics.it or contact the Series Editor.

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A Wearable Hand Neuroprosthesis for Hand Rehabilitation After Stroke: Preliminary Results of the RETRAINER S2 Randomized Controlled Trial

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Abstract. Stroke is the main cause of permanent and complex long-term disability in adults. RETRAINER S2 is a system able to recover and support person's ability to perform Activities of Daily Living (ADL) in early stage after stroke. The system is based on exercises for hand and wrist performed using Neuro Muscular Electrical Stimulation (NMES). This work describes the preliminary results of a multi-center Randomized Controlled Trial (RCT) aimed at evaluating effectiveness of the system. The preliminary results were calculated on 18 patients who completed the protocol. Data is promising, the RETRANER S2 system seems to be a good tool for stroke rehabilitation. Data confirms also a general good usability of the system.

1 Introduction

Stroke is the main cause of permanent and complex long-term disability in adults and has implications for patients, caregivers, health professionals and society in general [1]. There is common agreement in the literature that functional recovery after stroke is positively influenced by goal-specific sensorimotor input through training or everyday use of the arm and hand [2]. Neuro Muscular Electrical Stimulation (NMES) is one of the treatments used to recover the use of paretic limb after a stroke and improve grasp capability. NMES systems have been tested extensively with chronic patients, but rarely in a coherent way on acute or sub-acute patients [3] for inherent limits of epidemiology.

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RETRAINER S2 is a system able to recover and support person's ability to perform Activities of Daily Living (ADL) in subjects with upper limb impairment due to a stroke at the sub-acute or early chronic stage. This work describes the preliminary results of a multi-center Randomized Controlled Trial (RCT) aimed at evaluating effectiveness of the system in the recovery of hand functions. The RCT was registered on ClinicalTrials.gov registration number NCT03199833.

2 Materials and Methods

2.1 Participants and Sample

Subjects were selected within a cohort of stroke patients meeting the following inclusion criteria. A subject was considered eligible if his/her brain hemispheric lesion was unilateral, if s/he had no history or evidence of previous neurological and/or psychiatric disorders, if s/he was vigilant, collaborative and without global cognitive impairment. Other inclusion criteria were: age between 18 and 85 years, a distance from the acute event between 2 weeks and 9 months, Motricity Index (MI) lower than 80%, Medical Research Council (MRC) at least 1 for the target muscles, no limitation for using the system due to impairment of Passive Range of Motion PROM and/or Pain due to Spasticity evaluated using Modified Ashworth Scale, muscle response to NEMS and comfort (VAS $\leq$ 3) with the possibility to perform the required actions.

Sample size of 68 subjects was defined on the basis of ability to detect a Minimally Clinically Important Difference for primary outcome measure Action Research Arm Test (ARAT). The clinical trial was performed in two clinical centers: Valduce in Italy and Asklepios in Germany. The clinical trial compared one group of post-acute stroke survivors using the RETRAINER S2 system in addition to conventional therapy, and a second one treated only with conventional therapy. The subjects were randomly assigned to either the conventional or the RETRAINER S2 therapy group. Block randomization was applied to maintain the two groups balanced.

In Table 1 is shown the patients' characteristics.

Table 1. Patient' characteristics

	Control group	RETRAINER group	p‡ value
Age*	64(12)	63(15)	0.915
Time since Event* (days)	100(74)	81(61)	0.412
Gender* (Male/Female)	9/9	9/9	
Aetiology* (Ischemic/hemorrhagic/Mixed)	14/4/0	11/5/2	
Affected Side (left/right)	10/8	9/9	

*Mean (standard deviation) - ‡ t-test for independent sample.

2.2 System Description

The system is a wearable hand neuroprothesis composed by a splint used for constrain wrist and finger motion plus electrode arrays able to stimulate the target muscles. In companion paper [4] the system is fully described.

2.3 Exercises Description

RETRAINER S2 system proposes two different groups of exercises. The first group is performed with the wrist and the thumb fixed by an orthosis whilst the second one is setting with free wrist and thumb.

The first group includes four different exercises: (i) Flexion and extension of fingers - the subject has to open and close the fingers alternatively; (ii) Grasp and release objects - the subject has to grasp and release cylindrical objects with different size (Small, Medium and Large) and weight; (iii) Grasp, move and release objects on a plane - the subject is seated in front of a desk, the height of the desk is adjusted in order to have the elbow at 90° of flexion and no compensation of shoulder in frontal plane. The subject must move an object on the desk in three different positions reaching, grasping and releasing it each time; (iv) Grasp, move and release objects in space – activities mimic the previous exercise but the subject, in order to move the object to the new position, has to lift it at the shoulder level.

The second group includes just one exercise of flexion and extension of the wrist and fingers. The subject has to flex and extend the wrist and the fingers alternatively, and the anti-slacking stimulation is activated only in case of insufficient voluntary response.

The grasping exercises require from the subjects to be able to reach the objects, this means that patients must have good functional ability at both shoulder and elbow joints.

2.4 Description of Training Program

The treatment included three sessions a week for nine weeks for each patient. Each treatment session consisted of 30 min of RETRAINER S2 treatment or conventional treatment as a supplement to the standard allocation of 60 min of treatment. The patients were evaluated before the treatment (T0), at the end of treatment (T1) and four weeks after the end of treatment. Additionally to the main outcome measure, usability was measured by System Usability Scale (SUS).

The rationale behind the selection of each single exercise, for each patient, is clinically driven. In fact, the clinician selects the set of exercises from the available according to two factors: the residual functional ability of each subject and the rehabilitation goals.

3 Results

The preliminary results were calculated on 18 patients who completed the protocol. In Table 2 is shown the data (mean about the primary outcome ARAT for the complete test and for the gross Movement Items (gMT).

Table 2. Trial Results

	Group	T0	T1	T2	p‡ group effect	p‡ time effect	p‡ group* time effect
ARAT (0–57)*	Control	30.6 (21.3)	36.6 (22.2)	40.7 (20.8)	0.675	0.075	0.044
	RETRAINER	26.4 (20.8)	42.3 (18.8)	42.0 (18.2)			
ARAT gMT* (0–9)	Control	6.4 (2.3)	6.7 (3.1)	7.2 (2.5)	0.282	0.623	0.02
	RETRAINER	5.0 (3.6)	7.6 (1.9)	7.6 (1.5)			

*Mean (standard deviation) - ‡ Linear mixed model analysis for repeated measures.

Usability data, evaluated using the System Usability Scale (SUS), is shown in Fig. 1 and indicates a quite good usability perception.

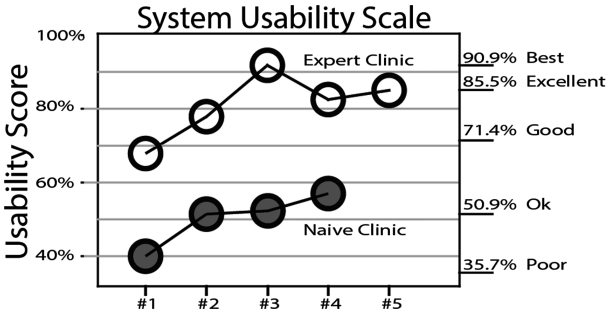

Fig. 1. RETRAINER Usability. Different levels of usability are perceived by operators of different clinics, both showing different initial levels of confidence with the used technology. In both cases is visible positive trend in the SUS rating, suggesting that a learning phase is required to use the device with effectiveness.

4 Discussion

The preliminary results show that RETRAINER group patients have improved more than Control group patients. Data confirm a general good usability of the system by all patients, with a difference between the two center maybe due to the fact that one of them was more skilled at the beginning of the trial. The sample size at this stage is not

enough to generalize the results to the target population. The study is ongoing and the complete sample should provide more robust information on the effects of the treatment.

5 Conclusion

The preliminary results are promising and RETRANER S2 system seems to be a good tool for stroke rehabilitation in early stage.

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The Role of Industry in a H2020 Innovation Action – Transferring Research into Products

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Abstract. Collaborations between universities and industry are a driving force for innovation. While the benefits for both parties involved in such collaboration are numerous, so are the challenges that come with it. This paper shines a light on both – benefits and challenges - experienced in the H2020 project RETRAINER, a multi-national project in the strongly regulated field of medical devices.

1 Introduction

There is no doubt that collaborations between universities and the industry are important for both industrial and scientific innovation. Nevertheless, these collaborations in practice often turn out to be challenging due to a number of factors. One is a deviating focus between the parties involved. While companies want to gain a competitive advantage, universities have an obligation to educate and create new knowledge that they generally also want to use openly. These differences in opinion and focus are often called "orientation-related barriers".

There are also so-called "transaction-related barriers", such as conflicts over IP. Bruneel et al. have shown, that prior experience of collaborative research and trust reduces these barriers between partners [1].

In a different study – investigating a low-tech industrial perspective – Maietta has found that geographical proximity has a positive effect, while increasing codified knowledge in the universities has a negative effect on knowledge transfer [2].

Agrawal has identified four categories of challenges in any given knowledge transfer [3]. Besides the already mentioned geographical relationship, they identified difficulties of channels of knowledge transfer, university specific characteristics, and company specific issues such as internal organization and resource allocation.

Within Horizon 2020 the European Union/Commission has developed the instrument "Innovation Actions". "Innovation Actions" are specifically targeting the transfer of knowledge from academia to industry.

The project RETRAINER is such an innovation action with the goal of implementing a full technology transfer, based on results of the FP7 project MUNDUS [4].

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In this paper we will discuss the topics that arose in this academia-industry collaboration within an international consortium from the perspective of a big industrial partner that was not part of the previous project.

2 Main Advancements of the Project

2.1 Clinical Evidence

In RETRAINER a special focus and interest was and still is on the completion of a large clinical trial. Rehabilitation of the upper extremity following stroke with a complex technical system raises many questions, starting from the clinical efficacy up to patient and therapist acceptance. In an age of decreasing healthcare budgets and increasing demand for evidence-based medicine, favorable results of a clinical trial are a crucial pre-requisite for a successful transfer of research into a product.

2.2 New Technology

The RETRAINER system integrates a number of interesting technologies that are also applicable to other areas of research or products. As such, again the clinical trial was a perfect testbed to better understand the technological readiness of these technologies in a daily clinical routine.

2.3 Networking- LEAD Users

Use as a rehabilitation device or use as a home-care device during daily living are two different aspects of the ReTrainer system. Both require different sales channels and impose different requirements on the system. For either of them though it is of importance to develop the best fit of the system with the requirements and to ask the right people for their opinion. In ReTrainer the consortium developed a deep understanding of the processes involved in rehabilitation with a complex technical system.

2.4 Distribution of Knowledge

Development of medical devices is a strongly regulated business. Each product has to comply with numerous standards, some of which underlie a specific interpretation depending on the system in question. In ReTrainer the commercial partners transferred some of their expertise in the commercialization of products to the academic partners. Special focus was given to the regulatory environment that has to be fulfilled. In this context it should be noted that there are two aspects that need to be considered. One aspect is the sheer number of regulatory standards and the second aspect are the underlying processes that need to be implemented. Finally the industrial partners also focused on the development of market strategies.

2.5 Shared Production Resources

During the development of the RETRAINER prototypes a practical aspect of joint innovation was revealed: On the one hand, the university partners were testing and using new innovative technologies not available to industrial partners (e.g. 3D-printing). On the other hand, industrial partners shared well-tried technologies and know-how (e.g. mills, anodisation). This way, fast iterative prototyping cycles using 3D-printing combined with the access to established traditional manufacturing, lead to a robust prototype.

3 Challenges

3.1 Difficulties of Knowledge Transfer

During the runtime of RETRAINER it emerged that a full transfer of technology to a finished product is a challenging endeavor at least. In our experience compliance with a development process and full control of documents is probably not achievable within a distributed project and independent sites that are not certified to defined quality standards (e.g. ISO13485). As a result, it seems, at least for medical products to be very challenging (or near impossible) to achieve market availability within the typical time-frame of H2020 projects.

Apart from the pure technical side there also exist managerial questions in the handling of intellectual property rights and possible license payments.

3.2 Company Specific Challenges

In comparison to Departments at Universities which tend to have a rather flat hierarchy, companies are often a complex construct of legal entities, subsidiary companies and areas of expertise. Company internal structures and processes as well as company internal restructuring (e.g. due to market strategic decisions) may thus pose an extra challenge to university-industry cooperation.

Due to a restructuring, a subsidiary company involved in the RETRAINER project was dissolved. Only clear and timely communication from the company side, a well-planed redistribution of funds and an orderly handing-over of responsibilities enabled the project to handle this issue without causing any major disruptions.

3.3 Occupation Specific Language

Coming from the medical device industry it was already known to us that “the language” partners use is not the same. Nevertheless the differing background of industrial, academic and clinical partners also were visible in this project. As before, it required intense personal contact and willingness to understand each other to overcome this challenge.

3.4 Entering a Well-Established Consortium

We also observed that entering an existing project creates extra effort. The project-history as well as the personal relationship between partners and people is unknown to the entering partner. As a consequence the dynamic in a project is difficult to grasp in such a setting. As suggested earlier, it is therefore important to invest time and money into establishing a good relationship with all involved. Doing this was key to the good progress made in RETRAINER.

3.5 Geographical Distance and Cultural Differences

The RETRAINER consortium consists of nine partners from four countries. Although nowadays modern communication technologies can somewhat reduce the difficulties of long distance collaboration it still cannot compensate personal meetings. Only by investing time and money in creating personal relationships can an international project such as RETRAINER become a success.

4 Discussion and Conclusion

We believe RETRAINER to be a very fruitful project for all partners involved. On the one hand the project has impressively demonstrated the benefits of university-industry collaborations: two prototype systems were developed and are currently under investigation in a clinical study. The project did not only generate new knowledge, but also clinical data usable for market approval.

On the other hand most challenges were tackled successfully due to investments of time and money for the goal of establishing good relationships between the partners.

The particular project might not achieve market availability due to the strongly regulated market. Nevertheless the European Commission is very interested to support this kind of action. We thus suggest that groups interested seek this collaboration actively, yet possibly refrain from framing their projects in the medical device domain.

For all involved, arguably the biggest benefit however, is the network that has been built, expanded and stabilized; A network and personal trust that can later on be used to receive feedback from the market or to develop new products.

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Smart Objects in Rehabilitation

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Abstract. Stroke is a leading cause of disability worldwide, and home-based solutions at low costs are required to provide effective rehabilitation to patients and decrease the economic burden. The interactive objects are one of the components of the RETRAINER system, and we exploited them to produce a stand-alone home rehabilitation tool. Patients own objects are equipped with RF sensitive tags and an antenna connected to a RF reader is placed on patient's hand. Using the relation between the distance of RF sources and the RSSI the contact with the object is detected and the task completion is identified. A backend system autonomously guides the execution of the exercises designed by therapists and record the data about the performance of the execution. Preliminary results demonstrate the feasibility of the approach and show a good degree of acceptability by patients and clinicians.

1 Introduction

Stroke represents the major cause of disability worldwide [1], and motor impairment of the contralateral arm affects 80% of the stroke survivors [2]. This leads to a high burden for providing rehabilitation therapies.

To cope with these needs, research is highly investing in ICT supported aids for rehabilitation aimed at increasing the effectiveness of the therapy as well as to reduce the personnel costs. However, between the patients' needs and the current technological offer there is still a huge gap in devices' costs, ready availability and easiness of use. Rehabilitation needs extensiveness to reach patients at local premises or directly at home. This asks for low cost devices, high ease of use, proved reliability and efficacy, with the potential to move the rehabilitation provision from hospitals to homes.

One of the components developed for the RETRAINER systems consist of the interactive objects, that are used, in the context of RETRAINER, to automatically recognize the completion of a task and guide the execution of the exercise. In this paper it will be shown how this concept has been translated to produce an effective and low-cost stand-alone tool for home rehabilitation of the upper limb.

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2 Working Principle

2.1 Overview

High-intensity, repetitive and task-oriented practice is a key element for an effective rehabilitation programme. Upper extremity impairments are a significant cause of disability in terms of both incidence and impact on the performance of Activities of Daily Living (ADLs) and working engagement. Physical and occupational therapy plays a specific role in reducing such an impact and facilitating return to ADLs and job-related tasks performing [3]. Home-based rehabilitation may gain advance by the repetition of occupational tasks in the user's own environment thanks to the "specificity of learning" concept stating that the learning or relearning of a skill is empowered by practice conditions matching real life tasks. Task-specific training, i.e. practicing movement within a complete action, is gaining evidence as an effective tool in neurological rehabilitation of the upper limb [4].

The system described in this paper implements a home-based physical therapy aimed at motor recovery, by providing a rehabilitation program based on user's habits and ADLs. The exercises composing the rehabilitation session are designed by the therapist, who set a sequence of reaching and grasping tasks involving patient's own objects, and a number of repetitions to be completed during the session. To perform the rehabilitation session, the patient wears an RF reader, placing its antenna in correspondence of the his/her hand, and sits in front of the objects selected for the session. By starting the session, the system, running on a PC, suggests the first action to be completed (i.e. reach an object or a position in space); the task completion is automatically detected, the user is acknowledged of the correct execution and the next task to be performed is prompted. The iterations go on until the completion of all the tasks in the exercise, and the exercise is repeated a number of times decided by the therapist.

2.2 System Components

The proposed system is built around three main components: smart objects, UHF RF reader and backend system, as shown in Fig. 1.

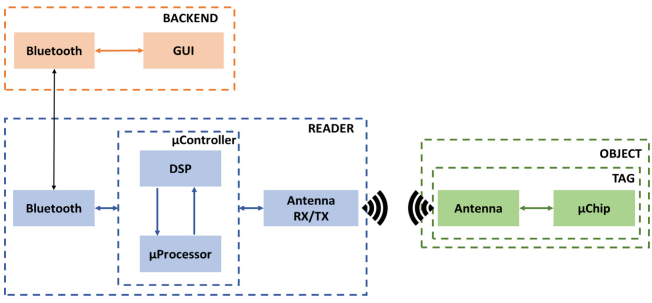

Fig. 1. System components. In green the objects and the tag mounted on it. In blue the RF reader with the Bluetooth module. In orange the backend system.

The smart objects are everyday objects equipped with RFID UHF passive tags, that are thus able to provide information about their characteristics and space location. When the RF reader scans the environment, all the tags and thus the objects, will respond providing their Unique Identifier (UID) and, for each identified tag, the Received Signal Strength Indicator (RSSI) is retrieved. The RSSI is defined as:

$$RSSI = \left(\frac{\lambda}{4\pi d}\right)^4 \chi G_r(\vartheta)^2 G_t(\vartheta)^2 \left|1 + \sum\nolimits_i H_i\right|^4 \quad (1)$$

Where d is the distance between tag and antenna, λ is the wavelength, χ is the reader-tag polarization mismatch, $G_r(\vartheta)$ is the reader's antenna gain, $G_t(\vartheta)$ is the tag's antenna gain ϑ is the main path incidence angle and H_i is the contribution of the ith multipath.

It is clear from Eq. (1) that the RSSI value is inversely proportional to the distance between the antenna and the tag. The lower the distance, the higher the RSSI.

By positioning the antenna on the patient's hand and exploiting the above concept, the contact between the hand and the object is detected, and the next task is triggered.

Because of non-idealities such as multipath effect and damping effect of the body, affecting the relations previously described, it is not possible to exploit a complete deterministic relation between distance and RSSI. To cope with these issues, an online pre-processing of the signal is performed. A first stage of the processing is performed to take into account the directionality of the movement. Indeed, the direction from which the object is reached by the patient's hand can vary from repetition to repetition and the radiation pattern of both the tags and the antenna is not omnidirectional. To overcome this limitation, multiple tags have been placed on the objects' surface, and a weighted mean of the RSSI values obtained from the object's tags is computed. The weights are computed as ratio of the RSSI of each detected tag to the sum of all the RSSI values. The weights are then inversely assigned to the RSSI values (the higher the RSSI, the lower the weight). The second processing stage is aimed at the stabilization of the signal over time. To remove the high frequency signal variations related to noise, a moving average is applied using a five samples window.

Non-idealities also imply the impossibility to compute *a priori* a value of the RSSI corresponding to the contact. A calibration phase is then required to estimate the threshold values before the execution of the exercise, during which the patient performs a walkthrough of the exercise and the RSSI value obtained in correspondence to the contact of the hand with the object is saved for each object involved. The walkthrough also acts as training of the patient.

The backend system consists of a PC or a tablet that communicates via Bluetooth with the reader, manages the processing and the storage of the signal, the sequence of the tasks in the exercise, the database to associate the UIDs and the objects, and the management of the users. During the execution, data describing the performance are stored (e.g. RSSI values, task completed, task skipped, etc.) and, at the end of the rehabilitation session, an overview of the execution performance is provided to the patient to increase his/her awareness.

3 Results

From the technical point of view the system stability and reliability have been demonstrated. The application of the described configuration and processing algorithm resulted in a sensitivity of antenna-tag distance measurement of 5 cm, while a sensitivity of 15 cm has been obtained from raw RSSI consideration. The contact between hand and object, detected using the calibration and processing methodology previously described, is reported at a mean hand-object distance of 2.05 ± 2.00 cm.

Interviews have been conducted with therapists after showing them the system and its application. The outcomes revealed that the system is perceived as useful and shown the interest of the clinicians in introducing the system in their daily practice.

5 hemiplegic patients have been asked to use the system and to score its usability through the System Usability Scale. A mean score of 95.5 ± 4.8% has been obtained, showing a very high usability of the proposed system in real clinical conditions.

4 Conclusion

In this paper we have described how the smart objects concept implemented in the RETRAINER system are successfully deployed to implement a new stand-alone system for home rehabilitation.

The field tests and the interviews confirmed the expected interest in the adoption of the system, starting the path to the commercialization of the system.

Refinements are still needed to fully address the clinical requirements, as highlighted by the therapists, but it is evident that the proposed solution well fits with the current requests of the rehabilitation market and trends, providing a reliable, flexible and low-cost system for home-based therapy.

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Wireless IMU- and EMG-Sensors for Controlled Functional Electrical Stimulation

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Abstract. This contribution describes wireless IMU- and EMG-sensors for the control of Functional Electrical Stimulation that have been developed within the European project RETRAINER. Combined IMU- and EMG-sensors shall be integrated into the RETRAINER exoskeleton (S1 system) for estimation of the arm posture and for EMG-triggered stimulation. IMU-sensors shall be used within the RETRAINER hand neuroprosthesis (S2 system) to estimate the finger and hand motion. Both sensor types are Bluetooth 5 ready and incorporate a powerful Cortex M4F processor. Data preprocessing, like orientation estimation and adaptive linear prediction EMG filtering for estimating residual volitional muscle activity, can be implemented directly on the wireless sensors. This reduces the data rate significantly down to the stimulation frequency.

1 Introduction

The combined use of Functional Electrical Stimulation (FES) and robotics is advocated to improve rehabilitation outcomes after stroke. Therefore, a hybrid arm rehabilitation system, called RETRAINER S1, has been developed within the European project RETRAINER that combines both technologies [1]. Additionally, a hand rehabilitation system, called RETAINER S2 has been built, that can be used separately from S1 [3].

The arm rehabilitation system consists of a passive 4-degrees-of-freedom exoskeleton equipped with springs to provide gravity compensation and electromagnetic brakes to hold target positions. An EMG-triggered stimulation controller is included in the RETRAINER S1 system. Up to two arm muscles can be stimulated simultaneously. For each muscle, the residual volitional EMG signal is detected by means of an adaptive linear prediction filter [2] and used to trigger the onset of a predetermined stimulation sequence applied to the same muscle.

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Once the system automatically recognizes that the target is reached, the brakes are activated, and the stimulation is switched off. During the stimulation phase, the volitional EMG signal is continuously monitored in order to provide a visual feedback about the patient's volitional involvement at the end of the execution of each task. The arm motion is currently assessed by means of encoders at the exoskeleton's joints for monitoring the progress of therapy, e.g., via the achieved range of motion.

The S2 hand rehabilitation system consists of an array electrode in combination with a wrist/hand orthosis with integrated wired IMU sensors [3].

At the current state, the EMG sensor of the S1 arm rehabilitation device as well as the IMU sensors of the S2 system are connected via wires to an ARM Linux-based embedded control system (ECS). The raw data are sent at 100 Hz (IMU) and 4 kHz (EMG) with full resolution to the control system where the preprocessing and the control strategy is executed. The developed wireless sensors firstly aim at an improved usability and flexibility of the system by reducing the amount of required cabling and weight of the systems. Furthermore, the estimation of the arm posture shall be enhanced by the integration of combined IMU- and EMG-sensors into S1. The sensors must run all signal processing on board to allow a reliable, real-time capable data exchange at the stimulation frequency with Bluetooth low-energy.

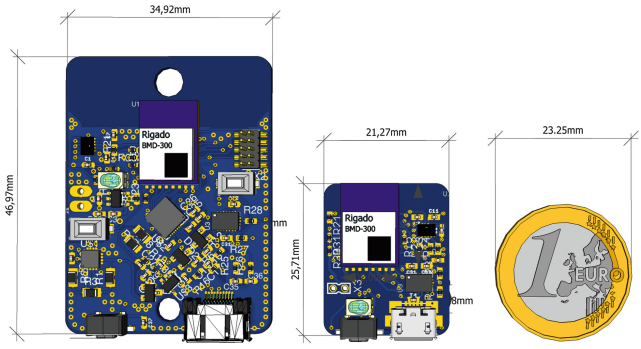

Fig. 1. PCB 3D export of the built IMU/EMG sensor (left) and IMU sensor (right) with dimensions.

2 Methods

One combined IMU/EMG sensor and one pure IMU sensor have been developed. The PCB of the two sensor types and the dimensions are shown in Fig. 1. Both sensors are using the FCC certified module BMD-300 by Rigado (USA). The module combines a Bluetooth 5 compliant 2.4 GHz transceiver with an ARM Cortex M4F CPU. Due to the powerful CPU the preprocessing of the raw sensor

data, i.e. orientation estimation and the adaptive linear prediction filtering of the volitional muscle activity, can be executed directly on the sensors. The block diagram of the IMU/EMG sensor is displayed in Fig. 2. Both sensors employ the IMU module BMX055 by Bosch (Germany).

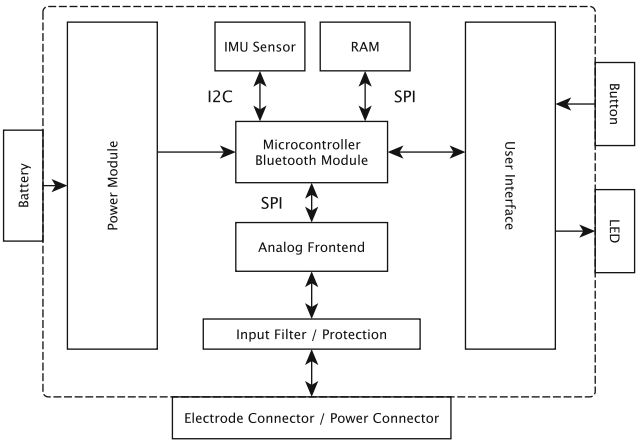

Fig. 2. Block diagram of the IMU/EMG sensor. The pure IMU sensor does not contain the analog front-end, filter and protection circuits, and has a reduced power module.

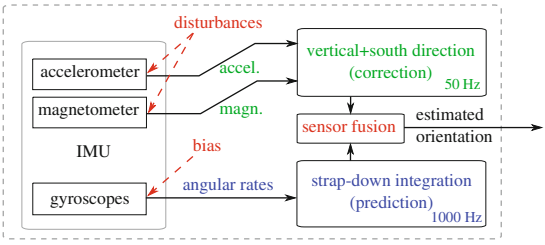

Fig. 3. Orientation estimation algorithm according to [4] with increased sampling frequency for the strap-down integration.

The applied method for orientation estimation is displayed in Fig. 3. We implemented the orientation estimation algorithm from [4] directly in the interrupt routine of both sensors. Hence, it is possible to run the strap-down integration of the angular rate at 1000 Hz which increases the accuracy. The resulting orientation estimate can be transferred as a quaternion or Euler angles to the controller. The angles will then be used within RETRAINER S1 and S2 to estimate joint angles of the human arm and hand, respectively.

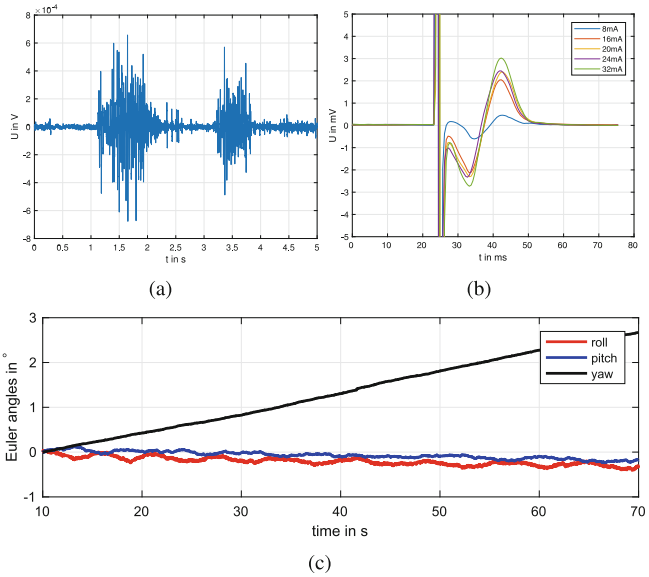

Fig. 4. (a) Volitional EMG measurement of healthy subject at 2 kHz at the wrist extensor. (b) M-wave at different stimulation intensities at the wrist extensor. (c) Obtained Euler angles for the IMU sensor resting on a table.

The IMU/EMG sensor possesses an input filter and a protection circuit which makes it possible to measure the EMG signals while stimulation is applied to the same muscle up to a stimulation voltage of 150 V. The analog front-end ADS1292 by Texas Instruments (USA) is used which incorporates active shielding, common mode rejection via a reference electrode driver and a resolution of 24 bit at up to 8 kHz. To store raw data for calibration routines an external RAM is integrated with 1 MB. Galvanic isolation is guaranteed via a battery which can be only charged if no electrode cable is connected.

Both sensors are powered with a small Lithium polymer battery which allows an operation of up to 8 h.

3 Preliminary Experimental Results

With the first manufactured prototypes of the IMU/EMG and IMU sensors, several experiments have been executed with healthy subjects. In Fig. 4(a) and (b) the measured volitional EMG activity at the wrist extensor of one healthy subject and the resulting M-wave (FES-evoked EMG-response) for different stimulation intensities also at the wrist extensor are shown, respectively. The resulting signal-to-noise ratio is sufficient to detect the onset of a volitional movement. Furthermore, Fig. 4(c) shows the low drift of the IMU sensor orientation. Here the sensor was resting on the table and the orientation was estimated with the

algorithm described in [4] without using the magnetometer information (advisable for indoor measurements). The maximum drift of the resulting Euler angles is less than 2.5°/min.

4 Conclusions

The sensors are ready for integration into S1 and S2 using a customized Bluetooth dongle with a Rigado module at the embedded control system. Only final EMC tests need to be performed before using the sensors inside clinical environments. A study with healthy subjects is planned to compare the EMG signal processing for the wireless and cable-based solutions. Afterward, exploratory trials with stroke patients will be performed to assess the entire functionality of the wireless sensor system.

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Passive Light-Weight Arm Exoskeleton: Possible Applications

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Abstract. Upper extremity exoskeletons are useful for humans in different ways: for motor rehabilitation, as assistive devices, or for the reduction of work-related loads on the musculoskeletal system. This paper describes the design of a passive modular and light-weight arm exoskeleton with gravity support and discusses possible fields of application. Tests, carried out with enabled gravity support show reduced muscle activations and forces compared to the same movements with disabled gravity support, indicting the effectiveness of the design.

1 Introduction

Exoskeletons were first described in animals as external, hard supporting structures for protection, support and defense [1]. In the last decades exoskeletons became more important for humans, used in rehabilitation or as assistive devices for physically injured persons, or to support the musculoskeletal system while carrying heavy loads or working in physically demanding postures as e.g. overhead work. Work-related musculoskeletal disorders in the upper extremity are an important issue in the modern workplace, and there is still a lack of assistive devices that do not restrict a worker's mobility, such as could be used in situations requiring a worker to move with an object (e.g. a car on an assembly line) or to be inside an object (e.g. an aircraft fuselage) [2]. Exoskeletons can be classified as active and passive orthoses. In active exoskeletons additional joint moments are generated by active actuators as electrical motors, passive exoskeletons mainly use gravity compensation mechanisms to enable movements with reduced muscular effort.

Here we present the RETRAINER passive lightweight upper limb exoskeleton with integrated adjustable gravity-compensation and a modular structure that facilitates easy adaption to different requirements. The effectiveness of the built-in gravity compensation is determined and possible applications beyond rehabilitation are discussed.

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2 Materials and Methods

2.1 Exoskeleton

The described upper limb RETRAINER exoskeleton is a modular, light-weight passive device with 5 degrees of freedom (DoF) [3]. Humeral rotation and wrist pro/supination are either controlled by residual muscle forces or locked at customized positions. Shoulder elevation in sagittal and frontal planes as well as elbow flexion are actuated by residual muscle forces and additionally by neuromuscular electrostimulation (NMES) if needed and can be locked at any chosen position during the movement. The exoskeleton consists of six basic modules - wrist module, elbow module, humeralrotation module, shoulder module, inclination module and mounting module (Fig. 1).

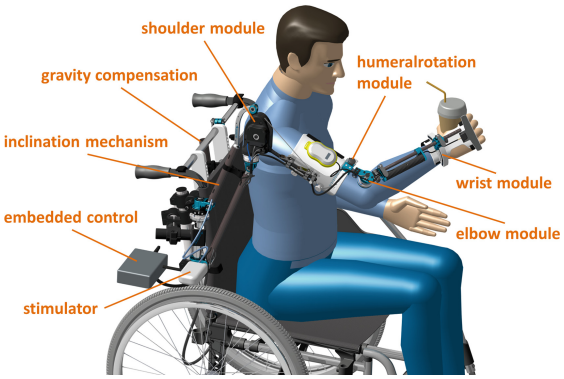

Fig. 1. Exoskeleton structure and modules: For stroke rehabilitation, the exoskeleton is mounted on a wheelchair and arm movements are facilitated through gravity compensation and if needed, additional actuation by NMES. Due to the flexible modular design single modules can be omitted if not needed.

The spring-based gravity compensation mechanisms integrated into the shoulder and elbow joint modules, provide compensation torques as a function of the respective joint angles.

Main element of the shoulder joint gravity compensation (Fig. 2) is a special alignment of rope pulleys, which guide a Dyneema rope fixed to the end of the shoulder elevation lever. Pre-tensioned springs are connected to the shoulder module and the Dyneema rope via a Bowden cable. If the shoulder joint angle changes, the spring tension and consequently the compensation torque changes. Gravity torque is not fully compensated so that the arm slowly moves down by gravity when relaxed.

The gravity compensation is designed for users with anthropometric measures between 5th female and 95th male percentiles. Fine tuning of the gravity support is done by a stepper motor combined with a timing belt and a driven thread that changes the pre-load of the spring package.

The weight relief for the forearm is also realized by a spring linked with a cable pull, which is manually adjusted. The applied compensation torque at the elbow does

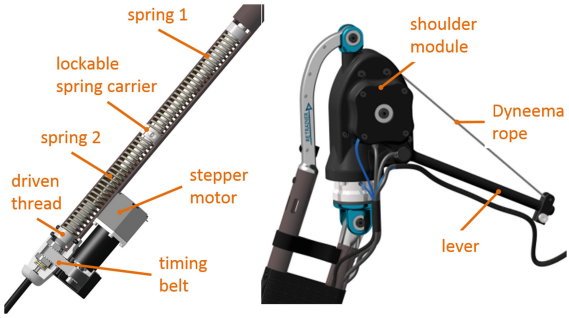

Fig. 2. Shoulder module with external compensation spring unit. For higher gravity compensation, it is possible to change from two-spring to one-spring mode. Changing to one-spring mode results in a higher total spring stiffness and consequently in a higher gravity compensation torque at the shoulder joint.

not change with upper arm position. For movement sequences with elevated upper arm and flexion/extension of the elbow in a more or less horizontal plane where gravity does not have a large impact on the movement, the compensation can be disabled by inserting a clip.

2.2 Experimental Setup and Measurements

Measurements were done to determine the effectiveness of the gravity support. Trajectories of 8 reflective markers, placed on the subject's torso and left upper limb, were collected with a camera motion analysis system (Motion Analysis Corporation). Electromyographic (EMG) signals were recorded with a wireless EMG signal detection system (Delsys Trigno Lab), the electrodes were placed on the skin above the muscles *Deltoideus ant.*, *Deltoideus med.*, *Deltoideus post.* and *Biceps brachii*. Maximum isometric joint torques were recorded using a force sensor (K6D40, ME Messsysteme).

Five healthy subjects were instructed to carry out two different motions - shoulder elevation in parasagittal plane and shoulder elevation in frontal plane (elbow neutral) - with an additional weight of 0.5 kg in the hand to enhance muscle excitations. Each movement was repeated three times. Two sets of data were recorded, one with enabled and one with disabled gravity compensation. The gravity compensation was adjusted so that gravity slowly moved the fully extended arm (neutral elbow joint angle) downwards from an initial shoulder elevation angle of 90°. For each subject maximum isometric joint torques and maximum voluntary contractions (MVC) of shoulder muscles and biceps were measured in isometric test routines [4].

2.3 Simulation

For performing the simulations and estimating muscle activations and forces the software package OpenSim was used [5]. From motion data joint angle trajectories for each movement were computed using the Inverse Kinematics tool. The computed muscle control (CMC) algorithm [6] was then used to determine muscle forces and activations.

3 Results and Discussions

Experiments on the RETRAINER arm exoskeleton have shown, that muscle activations could be significantly reduced during shoulder elevation movements when gravity compensation was enabled. Muscle activations determined by the simulations showed similar behavior as the measured EMGs, indicating the validity of the musculoskeletal model. The estimated muscle forces (Fig. 3) indicate highest rates of force reduction due to the gravity compensation between 20°–80° of shoulder elevation (60% *Deltoideus ant.*, 80% *Deltoideus med.*, *Deltoideus post.* 75%).

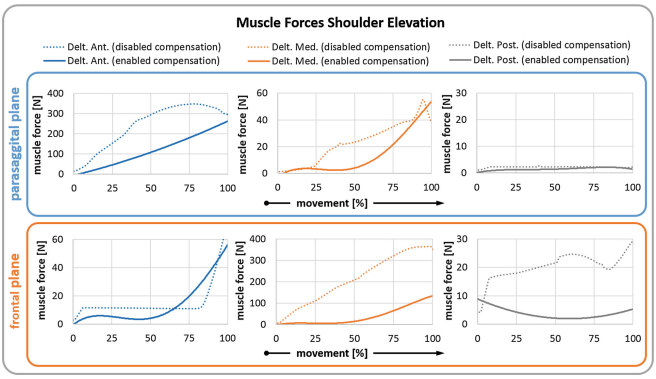

Fig. 3. Comparison of predicted shoulder muscle forces from simulation for enabled (full lines) and disabled (dashed lines) gravity compensation for one subject as a representation of the whole group.

The region between 20°–80° of shoulder elevation is optimal for rehabilitation and most activities of daily life. For an application as gravity compensating device for overhead work, modifications of the shoulder joint module would be necessary to move the region of optimal compensation to higher elevation angles. A body shell for mobile use has been developed and tested, which allows to mount the exoskeleton directly on the trunk and fix it at the hip similar to a backpack. However, as [7] have shown, also loads on body parts that are not the primary design focus of the technology have to be considered for safe application.

4 Conclusion and Outlook

Beside its compact and lightweight design, this study indicates that the gravity compensation of the RETRAINER exoskeleton can significantly reduce required muscle forces for arm movements. This exo was primarily developed for effective support in the rehabilitation process, but due to its modular structure, it can, with minor adaptions, also effectively be used to avoid work-related musculoskeletal disorders, especially in case of overhead work.

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RETRAINER Project: Perspectives and Lesson Learnt on Clinical Trial in Rehabilitation Robotics to Foster Industrial Exploitation

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Abstract. The RETRAINER (Reaching and grasping Training based on Robotic hybrid AssIstance for Neurological patients: End users Real life evaluation) project is an Innovation Action funded by the European Commission under the H2020 research framework programme. The project aims at a full technology transfer of the results of a previous FP7 project, MUNDUS, aimed at the development of upper limb assistive technologies, to a robotic system for upper limb and hand rehabilitation to be tested in a wide clinical trial with stroke survivors in two clinical centers. The final result of the project is the design of a validated system suitable to address the rehabilitation market. Along this project's path, several issues affecting both development and validation have been pointed out and are here summarized to serve as lesson learnt for prospective projects and challenges.

1 Introduction

REHABILITATION robotics plays a key role in reducing the personal and social burden of disability and it may represent an important contribution in coping with chronic disabilities. Its main advantages are: (1) intense controlled training with reduced supervision by clinical operators, (2) repetitive exercises management through gaming and immersive training to foster patient's involvement and engagement, (3) exercises execution in safe conditions, even in case of severe disability, (4) continuous monitoring of performances, (5) therapy personalization, scaling the required effort on current performances, (6) proper reward delivery [1]. All these aspects are extremely promising and represent a huge change with respect to conventional therapy, even though the supervision of the therapist encouraging and stimulating the patient remains a key point.

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The diffusion of robotic devices in rehabilitation is however still minimal, partly because of initial costs, partly because of learning difficulties in the use of the systems and partly because of limited support of scientific evidence. The adoption of randomized controlled trials to gather proper scientific evidence of new treatments with respect to conventional therapy is not yet widely spread in rehabilitation. One of the major limitations is the personalization of therapies, that affects the comparability of treatments and patients. There is a clear need to improve the current limited evidence-based approach, to assess and promote the diffusion of robots in rehabilitation practice. Further, the relationship between functional rehabilitation and brain plasticity is still under investigation [2–4].

RETRAINER [5] is an Innovation Action funded by the European Commission (EC) under the H2020 research framework programme aimed at the technology transfer of the results of a previous EC funded FP7 project, MUNDUS [6], dealing with the development of upper limb assistive technologies, to upper limb and hand rehabilitation to be tested in a wide clinical trial with stroke survivors in two clinical centers. The project is now close to its end and it is time for summarizing main achievements and lessons learnt.

2 What Does "Moving a Research Prototype Outside of the Lab" Mean?

Several issues need to be taken into account moving a system from research to clinics. The main ones are:

Usability: One of the major assets, often highly neglected by researchers, is usability in its multiple facets: easiness of donning and doffing, time to set up, time for calibration, clarity of instructions, but also user interface both for the operator and the patient. Definition of usability requirements must be accomplished in strict collaboration among patients, therapists, clinicians and technicians. User centered design is still encountering difficulties in entering robotic research, often still heavily technically driven, not equally involving all the actors of the entire value chain.

Reproducibility: Pre-series prototypes are to be used in the controlled trials with as many patients as those required to get scientific evidence of effectiveness. A suitable number of devices has to be properly produced and spare parts have to be promptly available. A parallel patients' recruitment using multiple devices and possibly multiple clinics to compensate the potential inter-operator biases is required.

Pilot Tests: It is mandatory to move the device to clinical sites only after a thorough testing by system engineers. A continuous iterative process involving designers and system integrators is necessary not only to fix bugs, but to improve usability and reliability of the system before the transfer to clinics. Otherwise, with a direct transfer from developers to clinics, clinicians are frustrated by the burden of these preliminary tests and their engagement immediately fails.

Full Ethical Clearance: Moving a new prototype to clinics for testing with patients implies an ethical approval by relevant local authorities. When the CE mark is missing,

as in the case of a prototype, existing directives on medical devices require specific steps to ensure safety and performance. Devoted competences are required from early design phases to assure full compliance with the regulations.

Therapists Involvement: The success of a clinical trial strongly bases on the conduction of the trials by clinical operators, not technicians. The relation between the therapist and the patient is different in conventional and robotic therapy, but it still plays an essential role. Therapists need to be committed in using the device and in supporting the patients during the exercises. The best way to assure positive commitment of the therapists is to make them completely confident in using the device. A strong and effortful training is essential as well as a continuous remote support, but engineers must not to be physically on-site.

Faults Managements: The efficiency of the technical support in solving possible failures is crucial to sustain the engagement of clinicians, to compress the time of the trials and to avoid losing patients across the treatment.

3 What Are the Main Aspects of a Proper Clinical Trial of Rehabilitation Treatments Based on Robots?

To make effective a clinical trial addressing robotic rehabilitation, given the fulfillment of the standard rules, such as randomization, lack of bias, proper sample sizes, etc., two additional aspects need to be properly considered:

Clear Design: The design of the trial has always to choose the happy medium between a clear definition of the target population, which is the most promising one in getting the best statistical significance, and a larger view to assure proper recruitment and relevant potential market size.

Trial Homogeneity: The compromise between comparability of the provided training and the essential tailoring of the treatment to the single user is a key point. Personalizing the treatments is one of the most important features of rehabilitation and the adoption of robotic devices opens a potentially huge possibility of adaptation to the single user. However, some common clear rules of the treatment need to be set equally for all patients and centers, in order to assure the comparability of outcomes.

4 What Are the Most Important Elements to Evaluate the Trial?

The effectiveness of the trial has to be assessed both by standardized clinical outcome measures as well as by indicators derived by the sensors embedded in the system.

Outcome measures need to be very well acknowledged and clearly focused on the primary and secondary expected outcome of the treatment as well as patients' quality of life.

On the other side, it is also important to investigate the use of the robotic device by each patient. One of the advantages of using robots in rehabilitation is that there are

plenty of *sensors monitoring the performance during each session*. Unfortunately, most of these data are not yet exploited, but, at least in controlled clinical trials, the way the single user works with the device as well as the changes across sessions is a key information to understand the results, improve the personalization of treatment and learn more on the possible benefits and limitations of the device.

5 And the Industrial Exploitation?

Once moved out of a research lab and validated in a clinical trial, a system is expected to be ready for industrial exploitation, but several aspects need to be addressed in order to prepare the process:

The Gap Between Research and Market: An Innovation Action is expected to run activities leading to innovation through development of new solutions rather than research. However, even when a project is building on already existing research prototypes, obsolescence of the components as well as new clinical requirements and scientific achievements have to be taken into account and, still, the prototypes used in the clinical trials are far from engineered solutions exploitable on the market or even ready for certification. Time constraints need to be clearly kept in mind and the release of a final product is not feasible in a project's time frame.

The Role of Companies in Research Consortia: Cooperation of academies and companies is expected to lead to more industry-oriented projects. Indeed, this strongly depends on the maturity of the initial idea or prototype. Companies may play different roles: suppliers of modules, observers of the solution's potential, integrators of research results, all of them pointing out new issues to cope with. Technology transfer is not a straightforward process.

The Dissemination of the Results: Scientific dissemination is only one component of a strategy aimed at the market exploitation of a project's results. Prototypes need to be made visible and demonstrations in congresses and exhibitions are also required to investigate any potential exploitation pathway.

The property of the Results: A mandatory Consortium Agreement manages roles, rights and duties in H2020 funded projects. However, this agreement ceases at the end of the project's life. As soon as results come, existing as well as newly generated IPRs need to be carefully investigated to prepare any exploitation action. Shared agreements need to be put in place to foster future exploitation of the results. While the most suitable solution is expected to be a pre-commercial agreement with one partner planning to tackle the market (at the end of a successful project), also stand-alone modules are worth of consideration.

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Clinical Benefits and Acceptability of Two Commercial Arm Exoskeletons for Patients with Muscular Dystrophy

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Abstract. Restore a lost function is a special experience for people affected by neuromuscular evolutive diseases as muscular dystrophy. Upper limb stiffness and activity limitations have a crucial role in reducing patients' autonomy and worsening quality of life. Even if the commercial products might assure a benefit to some users and meet most of their requirements, so far a validation of the use of such devices by people with neuromuscular diseases is missing. We aim at field-testing the improvement in arm functions provided by the use of two commercial devices (Jaeco Wrex and Armon Ayura) and assessing their impact on users' quality of life and independence. This step is essential to assure a widespread access to these devices for most of the potential users, possibly presenting direction and guidance to health providers. The results acquired from the first three subjects, with a different disease progression, showed that the functional improvements gained with the use of these exoskeletons are limited and largely depends on the user's impairment. Results showed that if the patient is severely impaired, the exoskeletons are not sufficient to gain functional movements. In contrast, if the patient is moderately impaired, both devices help the subject, even if some limitations of the movements occur. Finally, if the subject is slightly impaired, both devices decrease the performance. However, all the patients have appreciated the good usability of both devices.

1 Introduction

NOWADAYS, technology advancements can produce a high impact on people with disabilities. However, people with Muscular Dystrophy (MD) could remain slightly on the side and only partially benefit. The reduced number of patients

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has limited the research specifically aimed at bridging the gap between the availability of new technologies and the peculiar condition of these subjects. Most effort has been reasonably devoted to wheelchairs, so to assure autonomous mobility, and respiratory assistance, essential for survival [1]. On the contrary, few efforts have been devoted to the assistance of upper limb functions. With the increased life expectancy, upper extremity function becomes more and more important for people affected by MD [2]. MD encompasses more than 40 inherited myopathies characterized by progressive muscle wasting and weakness, among those the main forms are: Duchenne MD (DMD); Becker MD (BMD) and Limb Girdle MD type 2 (LGMD2). Although the various MDs vary in their severity and progression, all are progressive and disabling over time. Very little is known about severity, course and impact of upper limbs limitations in MDs, and only recently scales have been validated to detect modifications during time [3] but even less is known about adequate and effective aids able to reduce functional upper limb limitations. The key concept of the USEFUL project (funded by Telethon foundation) is to contrast the everyday experience of MD people of losing functions by providing them with a system able to exploit their own residual capabilities in arm movements so to keep them partially autonomous as long and as much as possible. Nowadays, the absence of an extensive validation of such anti-gravity assistive devices prevents the health-care systems to recognize these devices in the accreditation lists, limiting their accessibility.

2 Material and Methods

This project aims at validating a system consisting of an arm exoskeleton mounted on a wheelchair, comparing two commercial devices for arm gravity compensation, to measure their impact on the independence and quality of life of people with MD.

Clinical Trial Design. The study (registered on ClinicalTrails.gov, GUP 15021) proposes on-field validation of Jaeco Wrex, a passive exoskeleton, and Armon Ayura, a motorized arm exoskeleton, in a randomized controlled trial with crossover design (Table 1). The clinical study is multicentric and received the Ethical Committee approval.

Table 1. Technical details of the two exoskeletons

Name	Assisted Degrees of Freedom (DoFs)	Overall DoFs	Weight [kg]
Wrex	2 (shoulder and elbow flexion)	4	2
Ayura	2 (shoulder flexion and tilt)	3	6.4

The Two Exoskeletons. One exoskeleton is the Wrex by Jaeco. It is a passive solution for gravity compensation, which uses elastic bands to support the

patient arm; the number of bands varies depending on the weight of the patient arm and his/her strength. The other exoskeleton is the Ayura by Armon Products. It is an active (motorized) solution for gravity compensation, provided with buttons that enable the tilt and shoulder elevation movement. Ayura can be electrically connected to patient's wheelchair if the patient is using a motorized wheelchair, otherwise, it has to be connected to a standard domestic power line.

Inclusion Criteria and Outcome Measurements. Patients with DMD, BMD, and LGMD, wheelchair bounded, have to sign informed consent and need to comply with the study. They must have a score at the Medical Research Council (MRC) scale for upper limb muscles ranging from 2 to 4 for at least one muscular district (proximal, middle or distal) and they must not show additional diseases. Here, we show the results obtained from the first three patients who have been enrolled in the trial and who have completed the assessment with both devices. Table 2 reports patients' details. It is possible to notice that the three patients are affected by different forms of MD and different levels of impairment in the residual force of their arm. P1 is the most severely impaired patient, P2 is in an intermediate situation, while P3 has still a sufficiently good force in his upper limb. For both devices, the assessments have been performed at baseline, without the device (T0), wearing the exoskeleton, after a 3-days training (T1), and wearing the exoskeleton, after a 2-weeks home training (T2). As a result, the complete protocol with the two devices lasts more than one month. The primary outcome measure is the Performance of the Upper Limb (PUL)[1] [4], while other outcome measures evaluate the usability of the two devices (System Usability Scale - SUS).

Table 2. Clinical details of the patients

Patient code	Age	Sex	Pathology	MRC Muscle Scale		
				Proximal	Middle	Distal
P1	18	M	DMD	1	1	2/3
P2	52	M	LGMD 2A	1/2	1/2	3
P3	57	M	BMD	3/3+	3/3+	4

3 Result

We have analyzed the PUL scores divided into muscular districts (shoulder, elbow, and wrist). P1 did not show improvements of the shoulder with both

[1] PUL provides an overall score capable of characterizing motor performances of the upper limb in multiple tasks or "items", the protocol can assess the three major level dimensions (shoulder, elbow, and wrist levels).

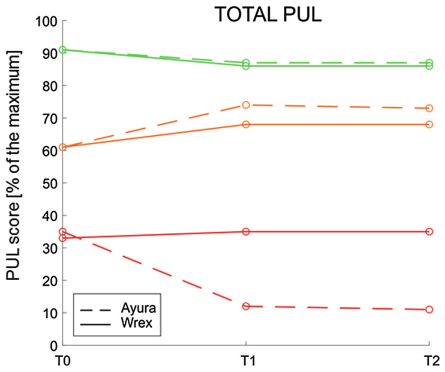

Fig. 1. Total PUL score for a severely impaired (P1 - red), for a moderate impaired (P2 - orange) and for a slightly impaired (P3 - green) subject. T0 evaluation is without the device, while T1 and T2 are performed with the device, the Wrex (continuous lines) or the Ayura (dashed lines)

devices (0%), only Ayura improved the elbow movements (from 6% at T0 to 21% at T1 and T2) and for the wrist Ayura decreased the initial performance (80%) to 9%, while Wrex did not significantly change it. Also P2 did not show improvements of the shoulder with both devices (0%), but both Ayura and Wrex improved the elbow movements (from 63.5% at T0 to 85% at T1 and T2) and for the wrist Ayura slightly increased the initial performance (87.5%) to 92.5%, while Wrex slightly decreased it (83%). P3 showed a decrease of the shoulder performance with both devices (from 63% to 50%), unchanged elbow movements (100%) and slightly decreased wrist performances with both devices (from 94% to 91%). Analysis of the overall PUL scores showed that the improvement gained with the use of these exoskeletons depends on the subject. Specifically, if the patient is severely impaired (P1), the Wrex is not sufficient to gain functional movements while Ayura improves elbow performance, but impedes wrist movements. In contrast, if the patient is moderately impaired (P2), both devices help the subject, with a better improvement provided by Ayura, even if some movement limitations occur. Finally, if the subject is slightly impaired (P3), both devices decrease the performance since they mostly limit subject's movements rather than assist him/her. Fig. 1 shows the overall PUL results (as percentage of the maximum possible score). The SUS showed that both systems have a good usability, with a score of $84\% \pm 10\%$ for Wrex and a score of $76\% \pm 16\%$ for Ayura. As in the PUL results, the usability of both devices was higher for P2 ($91\% \pm 4\%$) with respect to P1 ($76\% \pm 7\%$) and P3 ($76\% \pm 21\%$).

4 Discussion

We observed that for similar muscular strength, evaluated by means of MRC, it is possible to have very different benefits from the use of the devices. Moreover, we

perceived that even very impaired subjects in terms of MRC may take advantage of the devices if they have good trunk control and/or have developed abilities to compensate a low MRC value. This is particularly true for LGMD2, that thanks to the slow disease progression, are able to learn how to compensate the weakness. We have also observed that in all the evaluated patients who completed the tests, no differences between T1 and T2 in terms of PUL scores are present, suggesting that a short training is sufficient to reach maximal gain. This is also confirmed by the high usability indexes obtained by both devices. In order to have a more robust and statistical interpretation of the clinical trial, the number of recruited subjects has to increase.

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Prosthetics – Computer Models in the Design of Neurotechnologies and Rehabilitation Tools (SS3)

Model-Based Analysis of Spinal Cord Stimulation for Chronic Pain

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Abstract. Spinal cord stimulation (SCS) is a widely-used therapy for chronic pain management. Computational models provide a valuable tool to study the effects of SCS on the nervous system. However, it is critical that these models include sufficient detail to correlate model predictions with clinical effects, including patient-specific data. Therefore, in this study, we developed a patient-specific computer model for a patient undergoing SCS to treat neuropathic pain. The patient-specific model predicted sensory threshold estimates that were consistent with the corresponding clinical measurements. These results demonstrate the potential for patient-specific computer models to quantitatively describe the axonal response to SCS and to address scientific questions related to clinical SCS.

1 Introduction

SPINAL cord stimulation (SCS) is a common neurostimulation therapy for neuropathic pain conditions that are refractory to conventional treatments [1]. To improve the efficacy of SCS, we need to better understand the electric fields generated by SCS and their direct effects on the nervous system. In the past, several groups have used computational models to help improve lead design, stimulation configurations, waveform parameters, and programming procedures as well as investigate the potential mechanisms of action of SCS [2, 3]. However, these studies utilized canonical models that largely ignored the interpatient variability in anatomy and electrode locations.

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To successfully correlate model-based predictions with clinical effects, it may be necessary to incorporate three-dimensional (3D) patient-specific anatomy and electrode locations in computer models of SCS. Therefore, the goal of this study was to develop a 3D patient-specific computer model of SCS. We compared model-based predictions to clinical measurements (e.g. sensory threshold) across several sets of stimulation parameters.

2 Materials and Methods

2.1 Clinical Measurements

This study was reviewed and approved by the institutional review board at the Cleveland Clinic (Cleveland, OH, USA). We recruited one patient who was being treated with SCS as part of his standard clinical care and who provided informed consent to participate in the study. We performed all clinical testing procedures at a single visit approximately 6 weeks after implantation of the SCS system. To localize the electrode array relative to the spine, we obtained a postoperative computed tomography (CT) scan of the lower thoracic spine. We measured the patient's sensory threshold (ST) to SCS for several sets of stimulation parameters.

2.2 Model Analysis

The first step in our model analysis was to estimate the extracellular voltages generated in the spinal cord during SCS. We used preoperative magnetic resonance imaging (MRI) to segment the participant's spinal cord, cerebrospinal fluid (CSF), epidural fat, and spine. We used the postoperative CT scan to localize the SCS electrodes and segment the participant's spine. We then co-registered the segmented 3D surfaces from the preoperative and postoperative images and defined a patient-specific finite element model (FEM) (Fig. 1(a)). To assess the need for a patient-specific approach, we also performed simulations with a canonical FEM with the same type of SCS array placed on the dural surface along the spinal cord midline. We assigned electrical conductivities to each domain using experimental data available in the literature [3]. For the patient-specific FEM, we adjusted the encapsulation layer conductivity until the FEM produced average electrode impedances that matched the clinical impedance measurements. We applied 1 V and 0 V boundary conditions at the cathode and anode(s), respectively, and solved Laplace's equation.

The next step was to define multi-compartment cable models of both dorsal root (DR) and dorsal column (DC) fibers in the spinal cord (Fig. 1(b)) [3]. In both the patient-specific and canonical models, we generated axon populations that covered a range of diameters (i.e. 5.7–11.5 μm) to match the axon diameters and densities measured in the human spinal cord [4]. Due to computational demand, we only used $\sim$1% of the true anatomical densities. We also defined DR fibers that entered the spinal cord and branched into a daughter fiber within the DC.

The final step was to assess the axonal response to SCS. We applied the extracellular voltages defined by the FEM to the axon models (Fig. 1(c)). We then

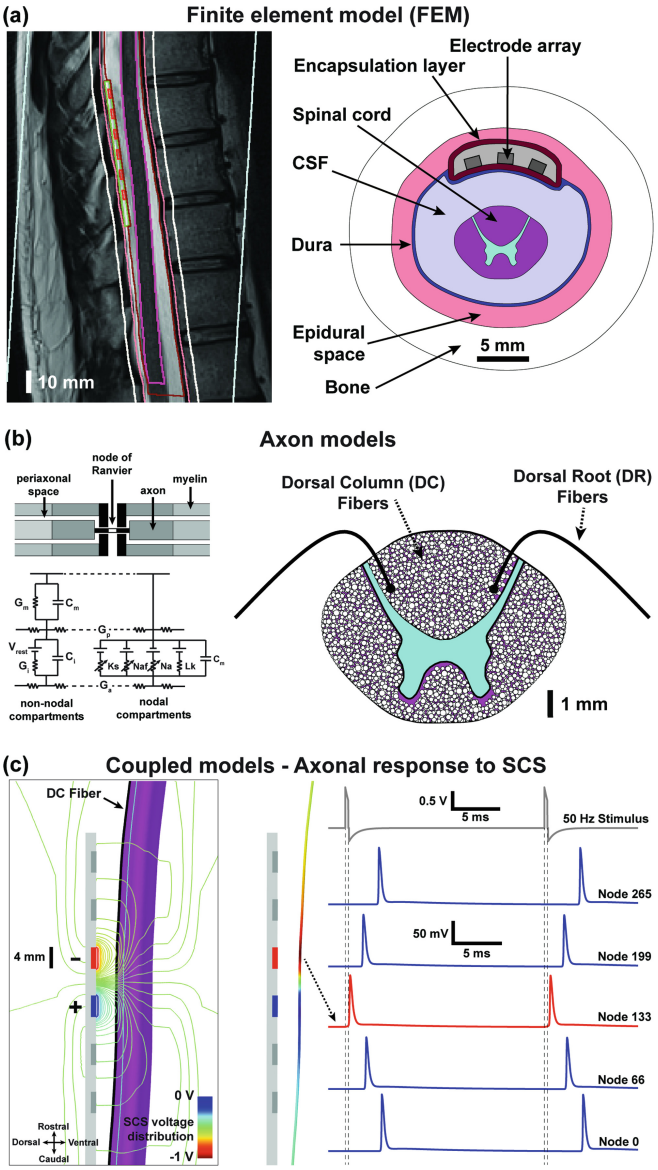

Fig. 1. Patient-specific FEM. (a) We used preoperative MRI scans to define the participant's anatomy (e.g. spinal cord, CSF, spine) and a postoperative CT scan to define the 3D electrode locations. We coregistered the 3D objects segmented from the preoperative and postoperative images to define a patient-specific FEM. A general thorax domain surrounding the bone is not shown in the figure on the right. (b) In our analysis, we included multi-compartment cable models of myelinated axons [7] running through the white matter of the spinal cord. We also included dorsal root (DR) fibers that consisted of a mother fiber and a bifurcated daughter fiber running along the dorsal columns. (c) Sagittal view of isopotential lines of the extracellular voltage distribution generated by SCS as calculated from the patient-specific FEM. To estimate the direct axonal response to SCS, we interpolated the SCS-induced extracellular voltages onto the axon models. The figure shows the time-dependent transmembrane voltages at several nodes in a DC axon and illustrates action potential generation with a 50 Hz SCS waveform.

calculated the activation thresholds and a model-predicted ST for each parameter set and compared these model estimates to the corresponding clinical ST. Model ST was the minimum pulse amplitude required to activate $\geq 10\%$ of the DC axons.

3 Results

Clinical studies have demonstrated that increasing the pulse width can increase total paresthesia coverage, pain relief, and comfort [5, 6]. Therefore, we used the patient-specific and canonical models to estimate the ST as a function of pulse width. Both of the models and the clinical data exhibited an exponential decrease in ST with increasing pulse width. The clinical ST was 6.6, 3.3, 2.7, 2.5, and 1.9 V for pulse widths of 60, 210, 300, 450, and 1000 μs, respectively. The patient-specific model ST was 7.5, 3.1, 2.6, 2.3, and 2.1 V. The canonical model ST was 3.9, 1.6, 1.4, 1.3, and 1.2 V. Relative to the clinical ST, the patient-specific and canonical models produced mean absolute percentage errors of 8.9% and 44.9%, respectively.

4 Conclusion

In this study, we implemented a patient-specific computer modeling approach of SCS to investigate the direct neuromodulatory effects of SCS. By accounting for patient-specific anatomy, electrode locations, and impedances, theoretical estimates of SCS-induced neuromodulation closely matched the corresponding clinical measurements. This proof-of-concept study suggests that patient-specific models can potentially provide quantitative descriptions of the neural response to SCS and serve as a tool to address scientific questions related to clinical SCS as well as inform the development of tools that may guide SCS implantation and programming.

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Anatomically Realistic Computational Model to Assess the Specificity of Epidural Electrical Stimulation of the Cervical Spinal Cord

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Abstract. Spinal cord injury (SCI) disrupts the communication between the brain and spinal sensorimotor circuits below the lesion, leading to paralysis. Epidural electrical stimulation (EES) applied dorsally to the spinal cord modulates the activity of spared spinal circuits by supplying excitatory inputs via the direct recruitment of large myelinated afferent fibers running in posterior spinal roots. EES applied at the cervical level could promote upper-limb function after SCI, but its ability to engage specific arm and hand muscles remains largely unknown. Here we developed an anatomically realistic computational model to evaluate the influence of electrode positioning on the recruitment of cervical afferent fibers. Our results show that laterally-positioned electrode active sites recruit specific dorsal roots with higher selectivity than centrally-positioned active sites, opening a development path for efficient epidural electrode arrays tailored to the cervical cord.

1 Introduction

Initially developed to alleviate chronic back pain, EES has rapidly emerged as a promising technique to restore sensorimotor function in patients suffering from para- and tetraplegia following SCI. During the last decade, it has successfully been used to restore motor tasks such as overground walking and standing and promote recovery of volitional control over joint-specific movements in completely paralyzed animal models and humans [1,2]. The relative contributions of the seemingly countless mechanisms underlying these outcomes are still to be uncovered [3], nevertheless, the current view is that EES brings the spinal sensorimotor circuits into a state of increased excitability, enabling residual descending

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and sensory inputs to initiate and coordinate movement [4]. However, increasing the excitability of restricted cervical circuits modulating the motor pools of specific arm and hand muscles during different phases of movement might be essential to promote upper-limb function after SCI. Previous computational studies [5,6] have identified the large myelinated proprioceptive and cutaneous fibers running in posterior roots and in the dorsal columns as the primary targets of this type of stimulation, suggesting that the artificial afferent inputs generated through these pathways contribute majorly to the increased excitability of spinal circuits, though other routes of excitability may also play a significant role [3]. Using EES, the ability of targeting specific motor pools is thus likely subordinated to the ability of selectively engaging posterior roots [6]. Here we show with computer simulations that, due to the anatomy of the cervical spinal cord, EES delivered at lateral locations leads to higher selectivity than that achieved by centrally-positioned contacts. These computational insights foster the development of novel epidural electrode arrays tailored to the cervical spinal cord.

2 Hybrid Computational Model

To assess the influence of electrode positioning on the recruitment of cervical posterior roots using EES, we developed a hybrid computational model adapted to the non-human primate cervical cord combining a Finite Element Method solver and a validated biophysical model of myelinated nerve fiber.

2.1 Realistic 3D Conductor Volume

We modelled a 3D structure including 9 distinct compartments representing: the grey matter (GM), the white matter (WM) and spinal roots, the intradural space filled with cerebrospinal fluid (CSF), the dura, the epidural fat, the vertebral column, the metallic electrode active sites, the silicone matrix embedding the active sites, and the tissue surrounding the spine represented by a homogeneous saline layer (Fig. 1A). The electrode active sites (5 positionned centrally over the dorsal columns, and 5 more laterally, $\sim$3 mm away from the midline) were put in direct contact with the dura. Each compartment was provided with a homogeneous isotropic conductivity tensor except for the WM and spinal roots, which were assigned an anisotropic conductivity tensor [6].

2.2 Realistic Group-Ia Fibers

We modelled realistic trajectories of group-Ia fibers following the morphological characteristics described by [7], namely: bifurcation upon entering the cord into one ascending and one descending branches running in the dorsal funiculus, and transversal collaterals projecting towards the motor nuclei in the GM (Fig. 1B). The number of Ia-fibers in each dorsal root exceeded $n = 50$. Biophysically realistic representative electrical circuits (MRG model, [8]) were thus

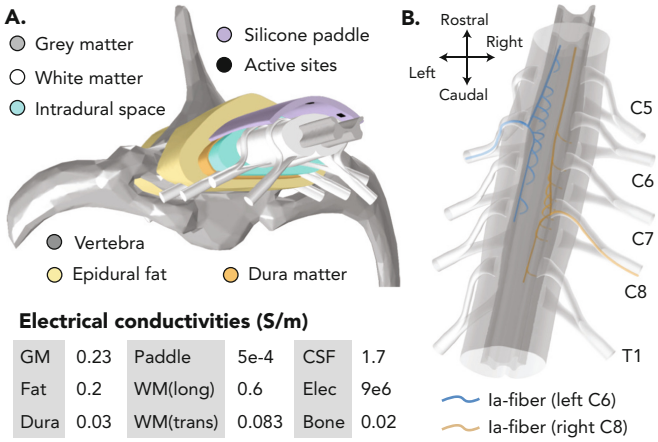

Fig. 1. Hybrid computational model of EES applied to the cervical spinal cord of non-human primates. A. 3D conductor volume. Electrical conductivities from [6]. GM: grey matter. WM: white matter (long = longidtudinal, trans = transversal). CSF: cerebrospinal fluid. Elec: eletrode contacts. B. Group-Ia fibers trajectories.

driven by the simulated voltages derived from the FEM model to evaluate their responses to 200 µs biphasic current pulses. A fiber was declared recruited when an action potential travelled all the way up to the last node of a collateral. For a given stimulation amplitude, we computed the fiber recruitment of spinal root j as $\mathrm{R}_j(\mathrm{amp}) = \#\text{fibers recruited in root } j / \#\text{fibers in root } j$. We evaluated the selectivity for spinal root j using the index $\mathrm{SI}_j = f\left(\mathrm{R}_j - \frac{1}{N-1}\sum_{i\neq j}\mathrm{R}_i\right)$ where N is the number of roots (=5), and f = max or mean over the amplitude range. Statistics were obtained using a boostrap approach whereby $n = 1000$ populations of fibers were formed by sampling the same initial fiber population with replacement.

3 Results

We unified detailed anatomical features collected from literature, direct measurements performed during dissection, and CT-scan and MRI-acquisitions into a computational framework to assess the propagation of electromagnetic fields elicited by EES in the cervical spinal cord of non-human primates and the responses of afferent nerve fibers to this stimulation. Our simulation results indicate that (i) the direct recruitment of group-Ia fibers is restricted to the spinal root closest to the active site of stimulation at low supra-threshold amplitude, but (ii) increasing the amplitude progressively recruits more distant roots (Fig. 2A). Furthermore, lateral electrode active sites systematically led to significantly higher selectivity for specific roots compared to central active sites (Fig. 2B). Group-Ia fibers belong to the class-A fibers, the thickest and thus most excitable afferent fibers during external stimulation, and they innervate

mono-synaptically alpha-motoneurons, implying that their recruitment is followed monotonically by the excitability of their targeted motor-pools. Therefore, the increased ability to recruit specific afferent pathways reported here should translate into a similarly increased modulation selectivity of spinal motor-control circuits.

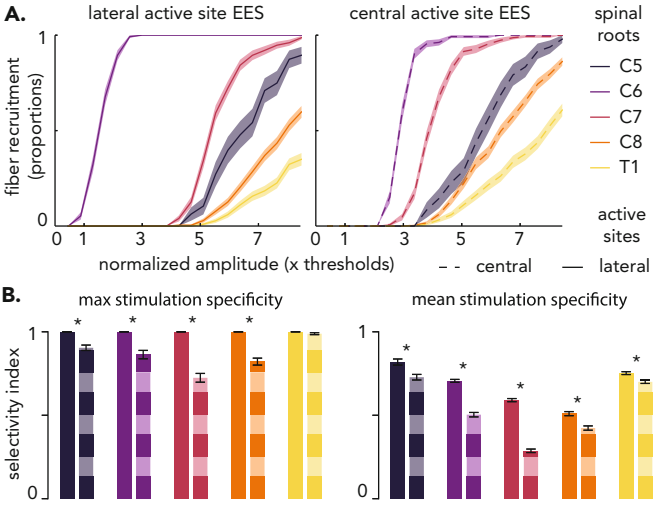

Fig. 2. Simulation results. A. Example recruitment curves using a lateralized compared to a centrally-positioned electrode active site. B. Influence of electrode laterality on the selectivity of specific dorsal roots (*, $p < 0.005$, statistical significance of index reduction obtained using bootstrapping).

4 Conclusion

Our simulations suggest that stimulation specificity in the cervical spinal cord is tightly bound to the anatomy of the cervical enlargement. Specifically, rostro-caudal projections of primary afferents in the dorsal columns limit the specificity of centrally located contacts. These results provide novel insights for the design of selective EES implants.

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A Computational Model for the Design of Lower-Limb Sensorimotor Neuroprostheses

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Abstract. Leg amputees suffer the lack of sensory feedback from a prosthesis, which is provoking their low confidence during the walking, falls and low mobility. Electrical peripheral nerve stimulation (ePNS) of upper-limb amputee's residual nerves has shown the ability to restore the sensations from the missing limb into the proper sensorimotor scheme. Physiologically plausible stimulation protocols targeting lower limb sciatic nerve holds promise to induce sensory feedback restoration that should facilitate close-to-natural sensorimotor integration and therefore fall avoidance and walking corrections. The sciatic nerve, innervating the foot and lower leg, has very different dimensions and density/disposal of mechanoreceptors, respect to upper-limb nerves. Therefore there is a need to develop a computational model of its behaviour. Different types of neural interfaces and their different designs have been implemented. This computational modelling suggests the optimal interface to use in human subjects.

1 Introduction

The lower-limb amputees suffer from: low confidence during the walking and balance, asymmetrical gait pattern, 20% lower walking speeds [1] and higher energetic effort. Over 50% of all lower-limb amputees suffer from falls in the first year after receiving their prosthesis [2]. The introduction of the feedback could enhance the balance and symmetry during the walking and it should help in the prevention of falls, especially when unexpected obstacles or holes are encountered. Neural pathways between the brain and the peripheral nerves proximal to the amputation are anatomically still present, permitting sensory functionalities restoration, by means of peripheral neural interfaces (PNIs) [3]. Indeed, the stimulation of median and ulnar nerves using transversal intraneural electrodes (TIME) [4] and epineural flat interface neural electrode (FINE) [5] allowed amputees to feel close-to-natural touch sensations from

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missing hand and to exploit them in a prosthesis bidirectional control. PNIs can have different geometries, number of stimulating contacts, placement within the nervous system, and stimulation protocols. This high-dimensional problem is not tractable by empiric brute-force approach, but urges for a development of exact computational models. Implantation of PNS electrodes in the sciatic nerve for lower-limb amputees could be beneficial for many of the problems above, but the optimal device has to be designed. Such a neural interface should have: (a) High selectivity: discrete areas and single type of sensation elicitable; (b) Low invasiveness; (c) Low activation thresholds permitting smaller tissue damage and longer battery life. Realistic model of the human sciatic nerve is constructed in order to compare the TIME and FINE electrodes in terms of efficiency (selectivity) and efficacy (the threshold values), and to propose the optimal design.

2 Materials and Methods

2.1 Computational Model

In order to implement the effects of ePNS on the sciatic nerve we coupled a realistic Finite Element Model (FEM) of the human sciatic nerve to axons models of the different populations of axons present. Voltage fields induced by ePNS are simulated with the FEM model and used to predict the recruitment of large sensory fibers. The position and size of the axons has been varied, in order to emulate the anatomical variability. Quantification of the induced responses is performed on the simulated populations recruitment. Simulations of ePNS were applied at the most-distal position of an amputated thigh-level (transfemoral) amputee. Sel_i (spatial selectivity) and Sel_s (functional selectivity) [6] have been used to estimate the selectivity of a device. The current amplitude at which 10% of fibers within the fascicle were activated represents the threshold [7].

2.2 Modeling of Different Geometry and Design of Devices

First we implemented the comparison of two electrodes, which were successfully used in human sensory feedback restoration: TIME [5] and FINE [6]. FINEs were implemented with 16, 20, 24, 32 active sites equally distributed over the substrate. TIME was implemented in 3 configurations: 16, 20 and 24. Then, for the TIMEs we also studied the case in which the active sites were not placed symmetrically on the two sides of the substrate, but rather shifted, which is congruent to the transversal somatotopographic disposition of the peripheral nerves.

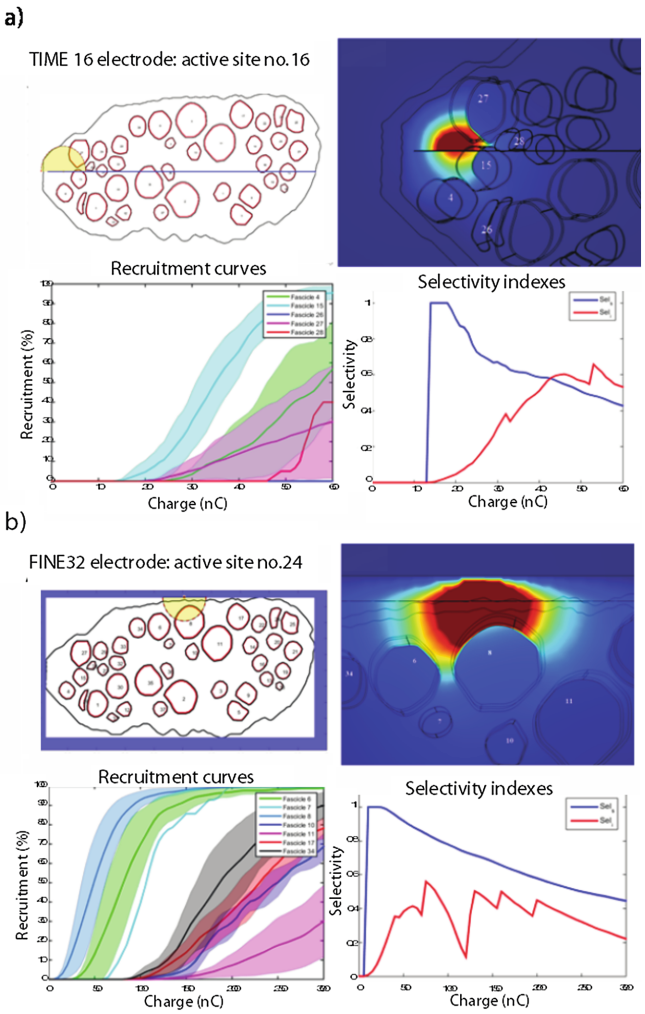

Fig. 1. (a) Solution of the model for TIME: a single active site voltage induced, recruitment curves, and selectivity indexes calculated. (b) Solution of the model for FINE: voltage induced, single recruitments and selectivity indexes. These data is used for the comparison.

3 Results

In Fig. 1 is represented the direct comparison of results for a single active site of TIME versus FINE electrode. The voltage induced by the current injection, together with the corresponding population recruitment and both selectivity indexes computation is shown.

Intraneural electrodes provide higher selectivity and efficiency (estimated as the number of elicitable fascicles versus number of electrode's active sites) than epineural

(Table 1). Direct electrode comparison shows the best overall effectiveness of TIME20 neural interface.

Table 1. Comparison of different devices

	TIME20	FINE20	TIME24	FINE24
Sel_i	0.69	0.22	0.76	0.25
Sel_s	0.90	0.3	0.95	0.30
Fascicles recruited	10	7	9	8
Fascicles activated/sites	0.5	0.35	0.375	0.33

The threshold current necessary for intraneural electrodes is significantly smaller than the one needed for epineural electrodes (Table 2). This result indicates the better TIME's performance regarding induced neural damage and implantable battery longevity.

Table 2. Threshold currents comparison

Electrode type	TIME	FINE
Threshold [μA]	119 ± 69.8	533.3 ± 234.5
Saturation [μA]	283 ± 184.2	1044.3 ± 497.8

Asymmetrical design results into the slight improvement of device function (Table 3). Indeed both the number of the elicitable fascicles and selectivity estimated are found to be higher for the case in which the active sites are not placed symmetrically on two sides of the substrate.

Table 3. Electrode geometry change

	TIME16	TIME16 shift	TIME20	TIME20 shift
Sel_i	0.74	0.76	0.69	0.73
Sel_s	0.89	0.92	0.90	0.95
Fascicles recruited	7	8	10	10
Fascicles activated/sites	0.4375	0.5	0.5	0.5

4 Discussion and Conclusion

We implemented a realistic computational model of the human sciatic nerve stimulation. It indicated the optimal type and geometry of the device to use. Model limitations include: needs for additional validation with different anatomy, implementation of fibrosis and consideration of the electrodes bending. In-vivo validation experiments are

currently undergoing. These results provide a computational framework to develop the effective devices for the functional recovery in amputated human subjects.

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Decoding Phantom Limb Neuro-Mechanical Function for a New Paradigm of Mind-Controlled Bionic Limbs

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Abstract. Mind controlled bionic limbs promise to replace mechanical function of lost biological extremities and restore amputees' motor capacity. State of the art approaches use machine learning for establishing a mapping function between electromyography (EMG) and joint kinematics. However, current approaches require frequent recalibration with lack of robustness, thus providing control paradigms that are sensitive to external conditions. This paper presents an alternative method based on the authors' recent findings. That is, a biomimetic decoder comprising a computational model that explicitly synthesizes the dynamics of the musculoskeletal system as controlled by EMG-derived neural activation signals.

1 Introduction

Upper limb loss substantially impacts the quality of life of thousands of individuals worldwide. Current advanced treatments rely on prostheses controlled by electromyograms (EMG). Solutions employ model-free machine learning for creating macroscopic mappings between EMG and prosthesis joint angles, disregarding the underlying neuromusculoskeletal processes [1]. However, current solutions are associated with lack of robustness leading to substantial rejection rates (40–50%).

This perspective paper presents an alternative method based on the authors' recent findings. That is, a data-driven model-based decoder that synthesizes the mechanics of the musculo-skeletal system as controlled by EMG-derived neural activations to muscles. This enables recording muscle high-density electromyograms (HD-EMGs) and reconstructing the non-linear transformations that lead to the production of musculoskeletal forces in the human upper extremity.

We present and discuss how this procedure can be used to establish intuitive human-machine interfaces (HMIs) for controlling robotic upper limb prostheses. We provide quantitative results showing that neuro-mechanical modelling can be

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successfully used offline and online to decode the three-dimensional mechanics of trans-humeral and trans-radial amputees' phantom limbs.

These developments may create new opportunities for providing amputees with truly intuitive and robust control paradigms, thereby reducing the current large rejection rates of myoelectric prostheses.

2 Methods

2.1 Experimental Procedures

The University Medical Center Göttingen Ethical Committee approved all experimental procedures. One individual (age: 51 years, weight: 82 kg; height: 172 cm) with left arm transhumeral amputation volunteered for this investigation along with one individual with right transradial amputation (age: 50 years, weight: 75 kg, height: 168 cm). Both individuals provided signed informed consent. The trans-humeral amputee underwent targeted muscle reinnervation procedure (TMR) four years and four months before the experiments. This resulted in the medianus, ulnaris, and radialis nerves being reinnervated into the brachialis, caput breve bicipitis, and caput laterale tricipitis muscles respectively.

2.2 Neuro-Mechanical Modelling and Control

We used the open-source software OpenSim [2] to scale a generic upper extremity model of the musculoskeletal geometry [3] to match each subject's anthropometry. The musculoskeletal geometry model had seven upper extremity degrees of freedom (DOFs) and incorporated a total of 12 muscle-tendon units (MTUs) spanning the shoulder, elbow, wrist and hand joints as previously described [4].

The HD-EMG bio-electric activity of muscle fibers in the TMR trans-humeral amputee's stump was recorded via 192 monopolar channels and clustered according to the DOFs it contributed to actuate. Clustering was obtained by applying a 80% threshold on normalized EMG linear envelopes across all channels. Above-threshold envelopes were converted into neural activations using a twitch model based on a time-history dependent recursive filter and a non-linear transfer function. Single-channel EMG bio-electric activity was recorded from sevefrom the trans-radial amputee's stump via eight bipolar channels. Raw EMGs were converted into normalized linear envelopes as previously described [5].

EMG data were processed and prescribed to all MTUs having moment arms about the multiple selected DOFs using the open-source software CEINMS as we previously proposed [6]. The neuro-mechanical model was calibrated to map neural activations to individual MTUs and account for physiological and force-generating differences across individuals.

After calibration, estimated elbow and wrist motions were converted into prosthesis low-level control commands for online control. Experiments encompassed online prosthesis control tasks for the transradial amputee and offline motor tasks for the transhumeral amputee.

3 Results

Figure 1 shows the transhumeral amputee who underwent targeted muscle reinnervation. The figure also shows how neurally controlled muscle-tendon forces, computed across all muscle-tendon units in the model, enable the blinded reconstruction of the resulting net joint moments in the intact limb as well as in the amputee's phantom limb with substantial accuracy during validation trials. Squared Pearson product moment correlation coefficient (R^2) and the normalized root mean squared difference (RMSD) displayed high values across all joints and tasks for the amputee ($R^2 = 0.8 \pm 0.2$, RMSD = 0.4 ± 0.1). Figure 1 also shows how the trans-radial amputee could control prosthesis wrist pro-supination and hand opening-closing simultaneously. This enabled completing a clothespin test, which consisted in grasping 12 pins located on horizontal bars and placing them onto a vertical bar. The amputee's speed performance was 5.5 ± 0.4 pins per minute or ppm. Remarkably, the individual completed the test with substantially better performance than when he used the commercially available sequential control scheme based on co-contraction. For this, average speed performance was 2.3 ± 0.4 ppm.

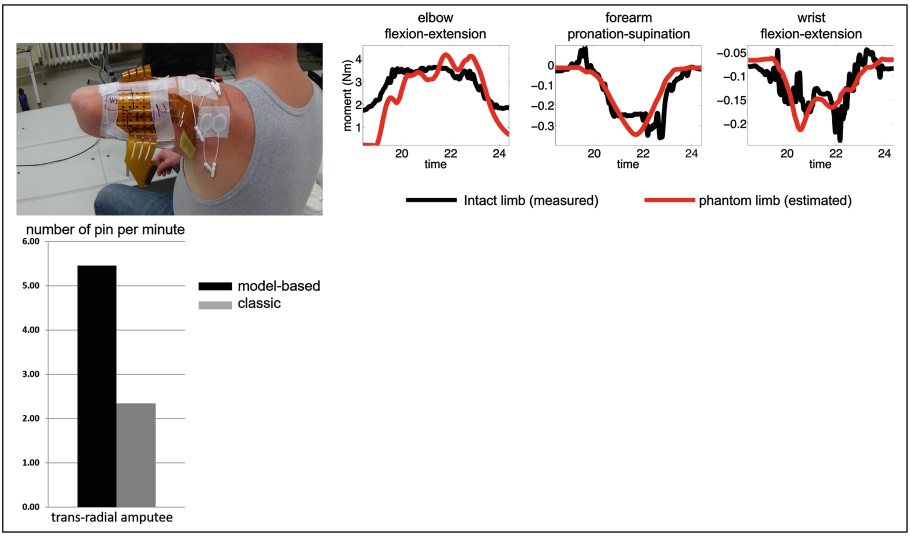

Fig. 1. Above: estimation of phantom limb mechanics. Transhumeral amputee who underwent targeted muscle reinnervation. The figure depicts bi-dimensional grid electrodes used to record high-density electromyograms. Joint moments predicted in the phantom limb are depicted together with those experimentally measured from the intact limb during a bi-lateral mirror task involving simultaneous elbow flexion, forearm pronation and wrist flexion. Torque decoding results derived from [5]. Bottom: Real-time control of a multi-functional prosthesis. Speed performance during clothespin test using our proposed system (model-based) and the commercially available system (classic). Tests were performed using a powered multi-functional wrist hand prosthesis (Michelangelo Hand, Ottobock HealthCare GmbH, Duderstadt, DE) equipped with wrist rotation and hand opening-closing motors.

4 Conclusion

We developed an interface that synthetizes the musculoskeletal function of amputees' phantom limbs as controlled by neural surrogates. For the first time, we show this new model-based approach enables simultaneous and proportional control of multiple degrees of freedom in bionic limbs during functionally relevant tasks. The development of man-machine interfaces that account for an individual's neuromusculoskeletal system creates unprecedented opportunities to address clinically relevant rehabilitation challenges via biomimetic wearable assistive technologies.

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A Simple and Complete Model of Thalamocortical Interactions for Neuroengineering Applications

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Abstract. The thalamus tends to be presented as a sensory gateway, a relay where little computation takes place. This view, combined with the difficulty of accessing this area related to cortex or peripheral nervous system, resulted in a relative paucity of thalamic computational models being detailed, complete and efficient enough to subserve neuroengineering applications. Here we present a novel model of thalamocortical interaction where both areas are simulated with adaptive integrate and fire spiking neurons. The model is able to reproduce information transfer from thalamus to cortex in both awake and asleep state, as shown by the local field potentials matching those observed experimentally in the two dynamics regimes. The applications in neuroengineering of such a simple and complete model range from simulations of sensory feedback injected directly in the thalamus for tetraplegic patients, to simulations of the effects on cortical activity of DBS stimulation delivered in the basal ganglia or directly in thalamus.

1 Introduction

The first thalamic network models date back to more than 20 years ago [1,2]. In this span of time a wealth of thalamic models have been developed to account for specific experimentally and clinically observed phenomena [3]. Nevertheless, most of them are not suited for neuroengineering applications, for reasons due to the spatial scale and level of details. Among them, a seminal thalamocortical model is [4], consisting of a network of a few conductance-based thalamic neurons (e.g, [1] and [5]), to investigate the prominent role of rebound currents in the thalamus [6,7]. Other papers have focused on a larger scale, adopting rate models [8] or mass models [9] in order to develop mean field approximations of the thalamic activity. We demonstrated [10] that rebound properties of thalamic neurons can be easily reproduced using Adaptive exponential Integrate and Fire

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neurons (AeIF) [11]. Here we extend previous results by linking the thalamic network to an AeIF model of the cortex reproducing the basic features of cortical information processing [12] and analyzing the relationship between thalamic and cortical Local Field Potential (LFP) both when the thalamus is isolated and when is receiving external inputs.

2 Materials and Methods

Neuron dynamics is described by an AeIF model with different set of parameters for every populations in order to capture intrinsic dynamics of thalamocortical cells. Thalamic TC and RE neurons are tuned to exhibit rebound spiking interplay, leading to spindle oscillations. Regular spiking neurons display adaptation in response to depolarizing inputs, while fast spiking interneurons do not.
Synaptic currents are described by a conductance-based double-exponential model. We used different values of synaptic conductance, decay and rise times for thalamic and cortical network. Time delay modelling axonal propagation is also used.

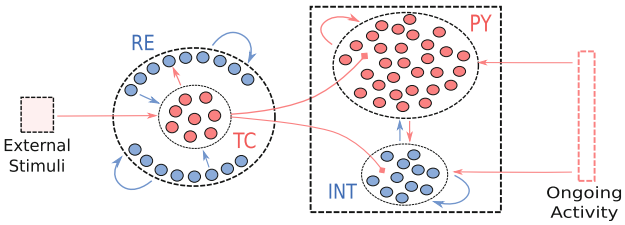

Fig. 1. Graphic representation of the network structure.

Network Design. The network consists of four neuronal populations divided into two different excitatory-inhibitory subnetworks, see Fig. 1. We consider 250 thalamocortical relay (TC) neurons and 250 reticular (RE) neurons for thalamic subnetwork, while 4000 pyramidal (PY) neurons and 1000 interneurons (INT) for cortical subnetwork. Ratio between populations are compatible with anatomical findings. Excitatory and inhibitory projections between TC and RE neurons have connection probability $p_e = 0.01$ and $p_i = 0.04$, respectively. We build RE-RE connections starting from a ring network and then randomly rewiring with probability RP $= 0.25$. A small world-like arrangement is essential for spindle oscillations, as discussed in [10]. Cortical subnetwork is more dense, with $p = 0.2$ as connection probability for excitatory and inhibitory projections. Furthermore, we consider thalamic relays to cortical subnetwork: TC neurons project sparsely with $p = 0.07$ to both excitatory and inhibitory populations [13].

External Inputs. For simulating asleep behaviour, during the first 50 ms we initiate self-sustained thalamic activity stimulating the network with injected

currents. We do not consider external stimuli on thalamic network. In the awake regime instead, after 3000 ms of self-sustained activity thalamic network receives Poisson spike trains simulating sensory stimuli. We use Poisson processes with different constant rate ν_0. In both regimes we consider also cortical ongoing activity as external inhomogeneous Poisson spike trains entraining cortical circuit. These excitatory presynaptic potentials have an event rate $\nu_n(t)$ that varies following an Ornstein-Uhlenbeck process:

$$\tau_n \dot{\nu}_n(t) = -(\nu_n(t) - \bar{\nu}_n) + \sigma_n \sqrt{2\tau_n}\eta(t) \tag{1}$$

with mean value $\bar{\nu}_n$ and standard deviation σ_n. τ_n is the characteristic time of the process and η(t) is a Gaussian white noise.

LFP and Coherence Computation. We computed cortical LFP as a linear combination of GABA and AMPA currents to pyramidal neurons, following methods of [14]. Instead, for computing thalamic LFP we considered linear combination of currents to TC neurons and between RE neurons. To compute LFP power spectrum, we used Fast Fourier Transformation with the Welch method (pwelch function in Matlab), dividing the time window into eight subwindows with 50% overlap. We computed the estimated coherence as the ratio $\Gamma_{tc}(\nu) = |G_{tc}(\nu)|^2/(G_{tt}(\nu)G_{cc}(\nu))$ between cross-psd estimate and psd-estimate of thalamic and cortical LFP signals.

Numerical Methods. We used second order Runge-Kutta integration scheme for numerical simulations, with time step $h = 0.05$ ms. Total simulation period was $T = 5000$ ms for every trial considered.

3 Results

To investigate how thalamic network communicates with the cortex, we concentrate on oscillatory behaviour of Local Field Potential deriving from our AeIF network model. Figure 2 shows LFP power spectrum during *asleep* state (absence of sensory input entraining thalamic network) and *awake* state (presence of sensory inputs).

Thalamic Oscillations. During asleep state thalamic activity is characterized by θ/spindle-oscillations [7–14 Hz] and 2 Hz δ-oscillations with higher amplitude. The latter emerge from a wax-and-wane behaviour of faster θ/spindle rhythms. On the other hand, during awake state a fraction of TC neurons change their dynamics to tonic firing with linear response to sensory stimuli [10]. So thalamic LFP shows enhancement of β-rhythms, while an amplification in lower frequency range is also visible.

Thalamocortical Relays. We then insert thalamic relays into cortical network. We find out that cortex synchronizes in the 2 Hz δ-rhythm and filters out θ/spindle-oscillations. Thalamic network modulates cortical activity through this slow mechanism of δ-rhythm embodied by cortical network. This occurs during both asleep and awake states. Instead, intermediate θ/spindle-oscillations are not

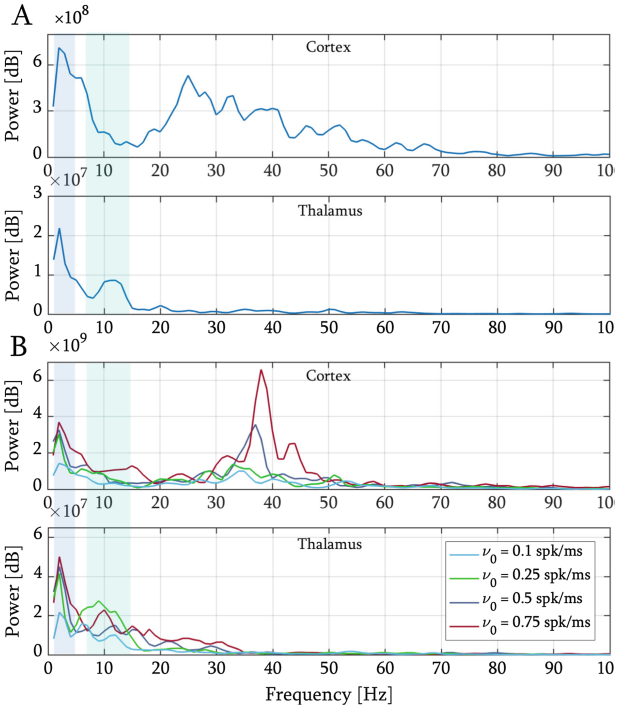

Fig. 2. LFP power spectrum during asleep state (A) and awake state (B) for both subnetworks. Legend shows different input rates ν_0 we used as sensory inputs to thalamic network. Colored stripes indicate δ and θ/spindle frequency range, in blue and green respectively.

incorporated into cortical rhythms. Rather, low spindle inputs from thalamus enhance intrinsic cortical excitation-inhibition rhythms in the high-β [20–30] Hz range during asleep state. Estimated coherence for δ-oscillations is relevant (Γ_{tc} = 0.62) while is not for θ/spindle range ($\Gamma_{tc} \in [0.18, 0.24]$).

When sensory inputs intensify thalamic activity, cortical oscillations encode strength of thalamic afferents into amplified and faster γ-rhythms [35–40 Hz]. Even during awake state spindle frequencies are not embodied by cortical activity. Low-frequencies coupling is present but almost not correlated ($\Gamma_{tc} = 0.24$), while θ/spindle oscillations are not correlated at all ($\Gamma_{tc} < 0.1$). Consequently, they seems to be a relay mechanism rather than an informative coupling between networks.

4 Discussion

The main limitation of our thalamocortical network is the absence of corticothalamic feedback (only a static version of it was discussed in [10]), which will be considered in an extended version of the model. The next step will be to

embed morphological characteristics of the thalamus in the model and couple the network with available model of thalamus stimulation [15], to explore their effects on the thalamus and the propagation on the cortex, for designing better therapies.

5 Conclusions

We presented a model of thalamocortical dynamics capturing the processing of spectral information. This paves the way to in silico test of thalamic stimulations.

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Prosthetics – New Perspectives in Upper Limb Prosthetics: from the Robotics Laboratory to Clinical Use (SS4)

A Synergistic Behavior Underpins Human Hand Grasping Force Control During Environmental Constraint Exploitation

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Abstract. Despite the complex nature of human hands, neuroscientific studies suggested a simplified kinematic control underpinning motion generation, resulting in principal joint angle co-variation patterns, usually called postural hand synergies. Such a low dimensional description was observed in common grasping tasks, and was proven to be preserved also for grasps performed by exploiting the external environment (e.g., picking up a key by sliding it on a table). In this paper, we extend this analysis to the force domain. To do so, we performed experiments with six subjects, who were asked to grasp objects from a flat surface while force/torque measures were acquired at fingertip level through wearable sensors. The set of objects was chosen so that participants were forced to interact with the table to achieve a successful grasp. Principal component analysis was applied to force measurements to investigate the existence of co-variation schemes, i.e. a synergistic behavior. Results show that one principal component explains most of the hand force distribution. Applications to clinical assessment and robotic sensing are finally discussed.

1 Introduction

The human hand is a very complex biomechanical system, with high capabilities in terms of dexterity and force control. However, the Central Nervous System (CNS) seems to deal with such a complexity by leveraging on dimensionality

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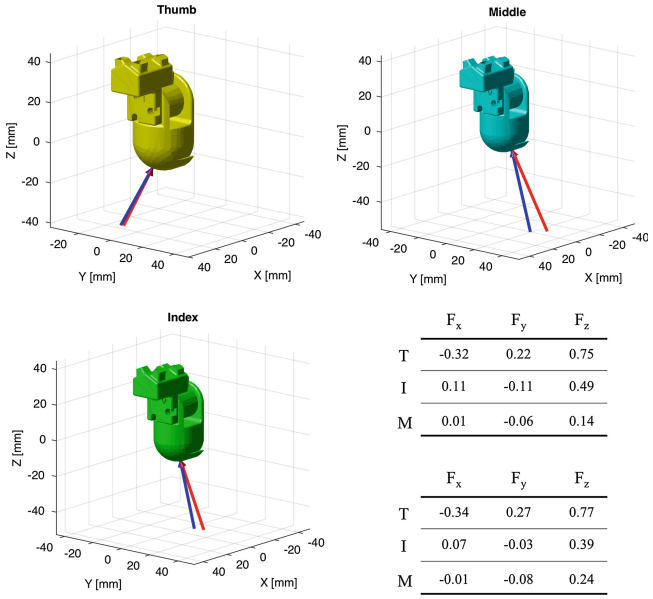
reduction strategies. Indeed, several neuroscientific studies reported on an underlying low-dimensionality control, typically referred to as *synergies*, which can be observed at different levels, e.g. kinematic [1], muscular [2], and neural [3]. From a kinematic point of view, while a lot of effort has been devoted to describing the synergistic control that modulates hand movements during grasp [1], the relationship between postural hand synergies and contact force distribution and how the interaction with the external environment shapes synergistic control is still debated [4–6]. In a previous work we studied how kinematic synergistic control is modified when the hand interacts with the environment to grasp an object [5], and proposed a consequent unsupervised clustering of principal hand approaches [7]. In this paper we further extend this analysis to the force domain. Our analysis is based on force and torque (F/T) measurements at fingertip level for thumb, index and middle fingers during grasping of a set of objects from a flat surface, and uses Principal Component Analysis (PCA) to identify the principal force directions or synergies. This investigation is motivated by the need of developing new tools for the evaluation of physiological and pathological behavior in object grasping and manipulation. More specifically, some pathologies such as stroke can alter subject grasping capabilities in everyday-life, eventually resulting in different synergistic behavior in force distribution. At the same time, the study reported in this work could inspire simplified sensing guidelines for robotic hands and prostheses. The latter point is particularly important when considering soft robotic devices, which deform with the environment as humans actually do.

2 Materials and Methods

Experiments. We asked six able-bodied, right handed volunteers (three females; age 25.17 ± 2 years) to reach and grasp objects, which were a set of 21 items suitably selected to force the interaction with the environment (a complete list, here omitted for the sake of space, can be found in [5]). Each finger was endowed with a ThimbleSense [8], which consists of two rigid shells assembled around a force and torque sensor, allowing to retrieve contact point information through Intrinsic Tactile Sensing. For each trial, participants were asked to reach and grasp the object placed at the center of a flat surface, lift and hold it for one second, then put it back on the table. Two trials were performed for each of the 21 objects.

Pre-processing. We extrapolated two ranges of interest from the whole task execution: (A) in which the hand is in contact with the table and (B) in which the hand has lifted the object (see Fig. 2). Regarding phase (A), during which the interaction with the object has the goal of obtaining a stable grasp, we analyze the last five frames, which contain information on the force exchange immediately before lift. These F/T vectors are then averaged to get a single vector for each acquisition. Regarding phase (B), we extract a single F/T vector as mean between all the frames. With this procedure we extrapolate, for each



	F_x	F_y	F_z
T	-0.32	0.22	0.75
I	0.11	-0.11	0.49
M	0.01	-0.06	0.14

	F_x	F_y	F_z
T	-0.34	0.27	0.77
I	0.07	-0.03	0.39
M	-0.01	-0.08	0.24

Fig. 1. First force synergy for the three fingers. In blue the contact phase, in red the flight phase. On the right-bottom, in top table we report the numerical values of the first synergy in the contact phase while in the bottom table we report the values for the flight phase. Each row refers to one finger, each column refers to the direction. Please note that all coefficients are dimensionless.

task, for each subject and for each experimental phase (A,B), one representative F/T vector $\in \mathbf{R}^m$, containing 3D forces at fingertip level. Note that, although we recorded forces and torques during the experiments, for the analysis we used only the force components (i.e. $m = 9$), since the torques appear to be negligible w.r.t. the forces.

Data Analysis. For each experimental phase (A,B), we collected the F/T vectors in a matrix $X_{A,B} \in \mathbf{R}^{n,m}$, where $n = 252$ is the number of trials. Principal Components (PCs) are calculated as eigenvectors of the covariance matrix $S = X_{A,B}X_{A,B}^T - \mu\mu^T$, where $\mu = \text{mean}(X_{A,B})$. The variance explained by each PC is calculated as the normalized corresponding eigenvalue.

3 Results and Discussions

Principal Component Analysis (PCA) on the two experimental phases shows that one predominant Principal Component exists and explains over the 60% of the total dataset variability (see Fig. 3). In Fig. 1 we plot the first PC as direction of forces insisting on thumb, index and middle fingers (in blue the contact phase (A), in red the flight phase (B)). As expected the first PC appears with a strong

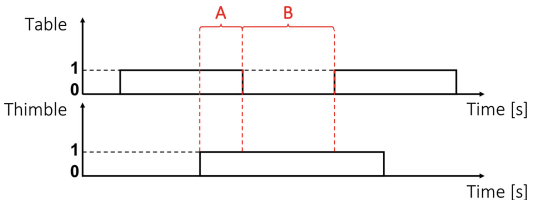


Fig. 2. In the top graph we show an ideal plot of signal presence on table sensor (1 if over a threshold, 0 otherwise), while in the bottom graph we report the analogous for ThimbleSense recordings. We identify two main regions of interest for our analysis: (A) in which the hand is in contact with the table; (B) in which the hand has lifted the object.

dominance of direction along the axis normal to the fingertip surface. What is noticeable is that the coordination between fingers appears maintained in both the experimental phases, with slight variations mainly on index and middle finger probably due to the effect of the object weight.

These results suggest that a coordination between finger forces exists in grasping tasks, and that this behavior is preserved also in case of interaction with the environment. This hypothesis is further confirmed by the fact that the first PC plays a crucial role in explaining the force distribution, with an explained variance higher than 60% in both the experimental cases. We believe that these finding could be used to develop new assessment procedures, e.g. in post-stroke patients, where the pathology could alter the synergistic behavior thus resulting in different principal components. At the same time, the co-variation in force distribution could be employed to suggest optimal sensing strategies for soft robotic hands, that deform as human hands actually do, when constraints on the number and quality of sensors are present, similarly to what was done in [9] for kinematic under-sensing techniques of hand poses relying on postural synergies.

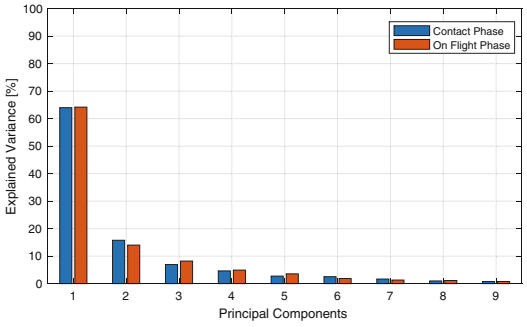


Fig. 3. Variance explained by each PC. In blue the contact phase, in red the flight phase. A predominant first synergy explaining more than the 60% of the data can be observed in both phases.

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Online Simultaneous Myoelectric Finger Control

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Abstract. State-of-the-art prosthetic hands allow separate control of all digits. Restoring natural hand use with these systems requires simultaneous and proportional control of all fingers. Regression algorithms might be able to predict any combination of degrees of freedom after training them separately. However, to the best of our knowledge, this has yet to be shown online. Twelve able-bodied participants were instructed to reach predefined target forces representing either single or combined finger presses, following a system training session consisting of only individual finger presses. Myoelectric control was implemented using linear ridge regression. The results demonstrated that myoelectric control allowed participants to reach both single finger, and combination targets, with hit rates of 88% and 54% respectively. These findings suggest that simultaneous control of multiple fingers is possible, even when these movements are not included in the training set.

1 Introduction

Regression techniques allow for the different degrees of freedom (DoFs) to be trained individually, after which these can be predicted simultaneously and proportionally [1]. This is especially interesting for finger control, where dexterous control of combined finger motions could be achieved even when the training is restricted to single finger

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movements, limiting the training time. Both Castellini and Koiva [2], and Krasoulis, Vijayakumar, and Nazarpour [3] showed that offline generalization to untrained finger movements is possible. They also illustrate that linear and non-linear regressors perform similarly when estimating unknown movements, even when the non-linear regressor outperforms the linear regressor on trained movements [3]. However, these results have yet to be corroborated in an online paradigm as it has been shown that online evaluation is far more relevant for the assessment of myoelectric controller performance [4]. Here, we conducted an online myoelectric control experiment, where single finger data were used in the training, and the participants were then asked to perform both single, and combined finger target hitting tasks.

2 Methods

2.1 Subjects

Twelve able-bodied subjects participated in the study (age 26.5 ± 2.4, 6 male and 6 female). The study was approved by the Imperial College London Research Ethics Committee.

2.2 Experimental Setup

The participants were seated with their index, middle, ring, and little finger resting on 4 individual force sensors (Fig. 1C; CZL635, Phidgets Inc., Canada). Forces were sampled at 10 Hz. Electromyography (EMG) was recorded using two high-density 8 × 8 monopolar surface electrode grids with a 10 mm inter-electrode distance (Fig. 1A, B; ELSCH064NM3, OT Bioelettronica, Italy). The signals were amplified (subject specific gain of 500 or 1000; OT Bioelettronica EMG-USB2 amplifier), and sampled at 2048 Hz with a resolution of 1.44 μV per least significant bit. Matlab 2016b (The Math Works Inc, USA) was used to develop custom software allowing for the real-time presentation of visual feedback.

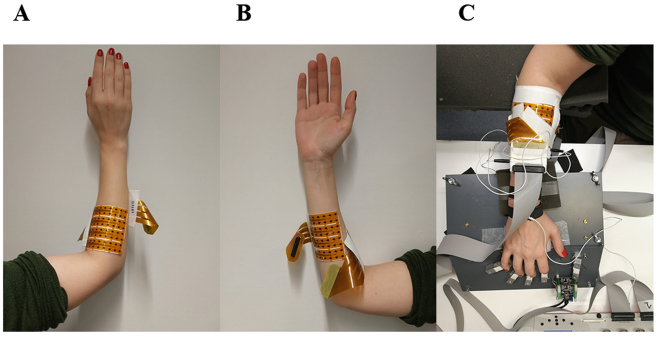

Fig. 1. Experimental setup. (A) Placement of HD-EMG grid on extensor, and (B) flexor muscles of the lower arm. (C) Custom made force device.

2.3 Experimental Protocol

Maximum voluntary contraction (MVC) trials were performed for all fingers, allowing subsequent measurements to be normalized. The training data for the regressor consisted of 3 repetitions of presses with each individual finger. The subjects were required to match a 15 s trapezoidal cue with the plateau at 25% MVC.

The myoelectric controller used linear ridge regression of the EMG signals. Both for training and online application, the EMG signals were filtered (10–500 Hz bandpass filter, 4^{th} order Butterworth; and 45–55 Hz bandstop filter, 2^{nd} order Butterworth), and segmented into intervals of 200 ms with an overlap of 100 ms. EMG amplitude was calculated by taking the root mean square of each interval. Forces were normalized with respect to the MVC.

In the online EMG control session, subjects performed target reaching tasks in which the force bars on the screen were updated every 100 ms based on the estimated forces calculated by the myoelectric controller. The session consisted of 5 repetitions of all single finger and combination tasks. The participants were instructed to reach a target force in the range of 20% to 30% MVC as fast as possible, while the forces of the non-instructed fingers remained below the threshold of 10% MVC. In order to complete the trial, the participants had to keep the force within the target window for 0.5 s. Participants were timed out if they did not reach the target within 15 s.

2.4 Data Analysis

The Shapiro-Wilk test indicated that hit rate and completion time results for the EMG controlled trials were not normally distributed. As a result, the Kruskal-Wallis test was used in order to determine whether samples of different groups were derived from the same distributions. Post-hoc pair-wise comparisons were performed with the Wilcoxon signed rank test, using the Bonferroni error correction. The threshold for significance was set to 0.05. Statistical analysis was performed with IBM SPSS Statistics version 21 (IBM Corporation, USA).

3 Results

Participants hit on average 88% of single finger targets, completing trials in 4.2 s (±3.0 s; Fig. 2A). There was no statistically significant difference in hit rate for the different fingers ($p = 1$). The Kruskal-Wallis test showed a significant difference in completion time of the single finger trials ($p = 0.002$), with the little finger (3.7 s ± 2.4 s) reaching the targets faster than the index (4.2 s ± 3.1 s; $p = 0.003$), and the middle finger (4.7 s ± 3.5 s; $p = 0.01$). There were substantial differences between participants, with the single finger hit rate ranging from 65% to 100%, and the average completion time ranging from 2.1 s ± 0.9 s to 8.2 s ± 4.8 s ($p < 0.001$).

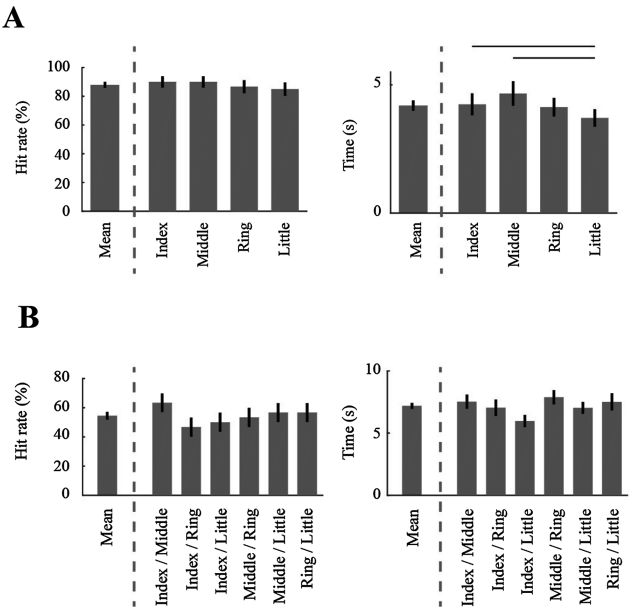

Fig. 2. Online performance of (A) single finger, and (B) combined finger control (mean ± standard error). The horizontal lines indicate statistical differences between instructed fingers.

The combination targets proved to be more challenging to reach, with an average hit rate of 54% over all participants (Fig. 2B). The average completion time was 7.2 s (±3.3 s). The instructed finger combinations had no influence on hit rate ($p = 0.53$) or completion time ($p = 0.28$). The difference between participants increased for the combination trials, with the hit rate ranging from 10% to 97%, and the completion time ranging from 5.4 s ± 1.6 s to 10.6 s ± 2.0 s ($p = 0.001$).

4 Discussion

In order for myoelectric control to be applicable for clinical translation, the amount of time necessary to train the controller should be limited. Therefore, regression strategies, which allow for the controlling combination of DoFs while training only of on single DoFs [1], are a viable candidate for myoelectric finger control. We demonstrated the feasibility of online simultaneous myoelectric finger control, even when the myoelectric controller was trained based on single finger data. Our training set was limited to twelve trials, resulting in a short setup. The differences in hit rate between participants suggest that generalization in myoelectric control is for the most part depending on the ability of the user to adapt to the control. Future research should investigate if participants that show a low hit rate initially are able to adapt to the control when given more time.

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Preliminary Results Toward Continuous and Proportional Control of a Multi-synergistic Soft Prosthetic Hand

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Abstract. State of art of modern hand prosthesis is populated by sophisticate hi-tech poly-articular hands which usually offer a broader set of movement capabilities, with the possibility to control up to 4 or 5 motors and achieve several different postures. Unfortunately these device are not so easy to control. A novel emerging trend is oriented towards a strong simplification of the mechanical design (through i.e. underactuation mechanisms), but still maintaining a good level of performance. A successful example is the SoftHand2 Pro, a 19 Degrees of Freedom (DoF) anthropomorphic hand which, using two motors, can move along two different synergistic directions, to perform either power grasp, precision grasp and index point. The combination of this multi-synergistic prosthetic hand with advanced controls, as myoelectric pattern recognition algorithms, allows to get promising results toward a more natural and intuitive control, introducing novel features as the possibility of a continuous switch between gestures. Preliminary experimental results are presented, demonstrating the effectiveness of the idea.

1 Introduction

Despite notable advances in technology and research, function of prosthetic hands and satisfaction of users still remain low [1]. The state of the art of prosthetic hands is divided between very simple hook-like systems, easy to control but not anthropomorphic, and more complex solutions, that try to match the functions of human hands [2]. These devices use a combination of multiple motors

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and are controlled using surface electromyographic (sEMG) sensors. However, the problem of controlling multi-DoF hands is very complex. Novel trends are leading the hand mechanical design towards a heavy simplification of the actuation mechanism. An example is the SoftHand2 Pro [3]. From the control side, a significant improvement over conventional control methods (i.e. co-contraction, smart-phone control) is the use of sEMG pattern recognition control strategy [4], based on the information content and the classification of muscles group to identify different movement intentions. Nevertheless, pattern recognition strategies used to control commercial prosthetic hands still requires the full re-opening of the device in order to switch between different grips. In this paper we propose an approach that, combining the SoftHand2 Pro with a myoelectric pattern recognition control, allows to get the control more intuitive, through a continuous switching between gestures. The system was preliminary tested on 6 able-bodied subjects (Fig. 1).

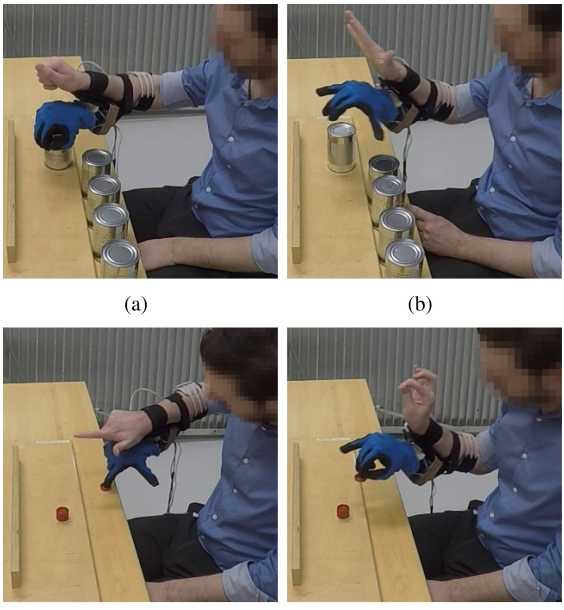


Fig. 1. SoftHand2 Pro used by an able-bodied subject during the JTT experiment. The pictures show the main hand postures: power grasp (a), hand open (b), index point (c) and fine pinch (d).

2 Materials and Methods

SoftHand2 Pro is an anthropomorphic robotic hand with 19 DoF evolving the Pisa/IIT SoftHand [5] by the introduction of a friction mediated Degree of

Actuation (DoA). The hand is actuated using a single tendon that moves from the palm base through all the fingers and two motors, placed on the back of the hand. While keeping strong similarity with the SoftHand original design, the additional actuation mechanism equips the SoftHand2 Pro with various novel skills, such as good level of dexterity and in-hand manipulation capabilities. To test the extended functionalities of the novel prototype and check the possibility of applying it over the prosthetics contexts, a myoelectric pattern recognition using linear discriminant analysis (LDA) classifiers [6], was used to operate the SoftHand2 Pro in a natural and intuitive way.

Two different control modalities were implemented and tested:

- Control 1 (used as a benchmark): that consist on the full re-opening of the hand to switch between one class to another. This modality is used in commercial prosthetic device controlled using myoelectric pattern recognition.
- Control 2: a novel control modality that allows to switch in a continuous way between one gesture and another, without the need to full re-open the hand and in a more natural way.

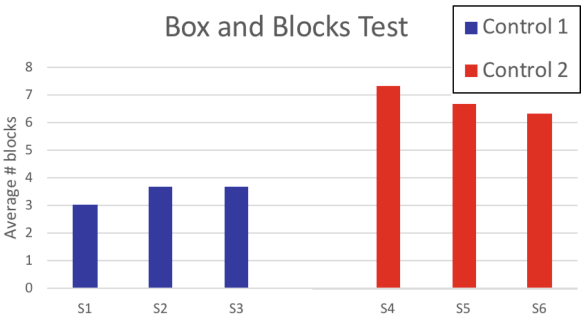
Thanks to the intelligence embodied in the design of the SoftHand2 Pro, a continuous switch control between pinch grasp and index point allows also to implement in-hand manipulation skills, without the introduction of an additional class. To test the effectiveness of the novel solution each control was tested on 3 able-bodied subjects. The following experiment was approved by the Northwestern University Institutional Review Board and all participants gave their informed consent. Each subject was wearing a cuff, embedded with eight equally-spaced pairs of stainless steel dome electrodes and one reference electrode, and a wearable mechanical interface to connect the SoftHand2 Pro to the human operator forearm. The classifier was trained with three repetition for each class, selected choosing the hand movements that more closely matched the movements performed by the SoftHand2 Pro: hand open, power grasp, fine pinch and index point.

3 Results

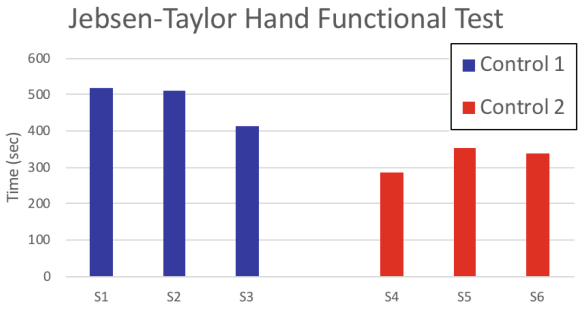
The experiment consisted of two sessions held on two different days. On the first day, after 1 h and 30 min of training, the subjects were performing the Box and Blocks Test (BBT) [7] in three repetitions of 1 min. The second day, the hand functions for activities of daily living were evaluated through the Jebsen-Taylor Hand Functional Test (JTT) [8]. This test consists on 7 sub-tasks and were started after an initial training of 15 min. The results, showed in Fig. 2, demonstrate the effectiveness of Control 2 (in red) compare to the classical control method (in blue).

4 Discussion

Results from the preliminary test of the continuous switching control on the SoftHand2 Pro were quite satisfactory and interesting to show the potentiality of



(a)



(b)

Fig. 2. Results of the BBT (a) and JTT (b) using Control 1 (in blue) and Control 2 (in red) on six able-bodied subjects (three for each control). The score of the BBT is the average score of the three repetition of 1 min, while for the JTT the total time required to complete all the sub-tasks is reported.

the system. Control 2 allows to be faster and more natural in grasping, reaching (in average) of double of the performance in BBT (allowing in example to move a block using the index point and switch directly to power/pinch to grasp it) and requiring less time to complete all the JTT sub-tasks.

5 Conclusion

This paper presents a multi-synergistic prosthetic hand, the SoftHand2 Pro, controlled using pattern recognition algorithms. A continuous switching control was implemented and compered with the classical control method used in commercial devices. Some preliminary promising results on able-bodied subjects are presented in the paper. Future work will be addressed on the validation of the system on amputee subjects.

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X-Limb: A Soft Prosthetic Hand with User-Friendly Interface

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Abstract. We have developed a soft prosthetic hand with features addressing the need of upper-limb amputees using soft robotics techniques. The designed hand is ultra-light and easy to manufacture. It is readily customisable for different hand size due to parameterised CAD design and using 3D printing techniques. The user-friendly control of the hand is achieved by using combination of designed-in behaviour of the finger and optimised movement of the fingers. This enables users to grasp a wide range of objects in one specific hand preshape eliminating the need for multiple switching between different grasps. The performance of the designed hand is evaluated through evaluation criteria used for prosthetic hands.

1 Introduction

The advances in myoelectric hand prostheses showed the potential to return independent living for people with upper limb loss. Despite the recent advances, the heavy weight of the prosthetic hands and lack of user-friendly control of the hand are still major shortcomings [1]. The weight is a major problem causing not only fatigue but also potential damage to the remainder of the body. The lack of non-fatiguing command interface in multifunctional prosthetic hands is also one of the main factors that significantly affects their acceptability. Currently, state-of-the-art prosthetic hands are controlled through electromyographic (EMG) signals using surface electrodes due to their non-invasive nature and long-term stability. Since extracting more than two reliable EMG signals from the residual muscle contractions required more complicated methods, current sophisticated commercial prostheses such as Bebionic are relying on only these two signals to provide 17 grasps and postures. This results in the increase of control complexity, long training periods and unnatural command interface such as using complex

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timing and pulse sequences of the required EMG command signals, or using the other (able) hand for preshaping the prosthesis.

In this study we conducted the design of the X-Limb with focus on a low complexity and user-friendly interface, to allow robust and reliable control in addition to light weight. This is done by firstly focusing on providing only the most common grasps for the activities in daily living and secondly using 3D printing techniques to manufacture the overall hand with low infill in the structure to reduce the weight.

2 Method

As shown in Fig. 1, we have realised the two most commonly used grasps: pinch grasp and power grasp. Combined, these grasps will cover more than 70% of the daily activities as reported in [2]. In pinch grasp, thumb moves to the abduction position and the index finger moves with the slower displacement (per unit change in EMG command) and they will meet in the 'centre' to form the tip pinch. In power grasp, all fingers will move together with the same speed to full flexion position. Considering the underactuation and compliance features of the hand, the actuation system of the hand consists of five DC motors for flexion of each finger. There is no return tendon in the fingers and compliant flexure joints returns the finger to the original position.

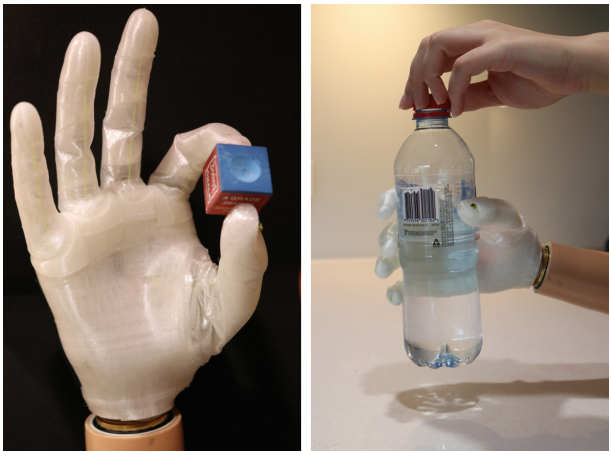

Fig. 1. X-Limb prosthetic hand with pinch grasp (left) and power grasp (right)

Fingers of the hand are designed using flexure joints and hinges with monolithic structure. Monolithic manufacturing eliminates a good portion of the need for assembly and the inadvertent misalignments associated. Furthermore, flexure based articulation provides little friction losses, continuous displacement

and a relatively light-weight and compact design. Compliance in the joints also improves the adaptability to the objects being manipulated (potentially improving grasp robustness), highly simplifies the mechanical design and enables safe interaction with humans. Thumb design is done with one flexure joint instead of two to provide stable structure for pinch grasp. The axis of rotation of the thumb is designed in such a way that by pulling the cable moves the thumb from adduction to abduction position. This eliminates the need for adduction and abduction of the thumb for different grasps and therefore simplifies the overall structure.

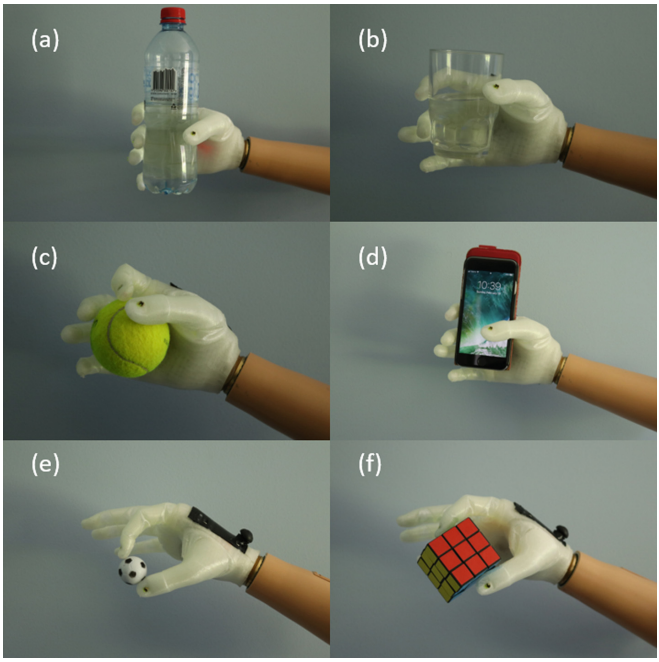

Fig. 2. X-Limb performance in grasping wide range of objects with only two grasp types: power grasp (a, b, c, d) and pinch grasp (e, f).

The transmission mechanism from motors to fingers is tendon. Actuation configuration is intrinsic and all the actuators, motor drivers and the controller are embedded in the hand structure as shown in Fig. 2. The hand is controlled by using only two sEMG (surface electromyography) signals provided by most of commercial EMG electrodes for opening and closing the hand and one simple tactile button located below the thumb towards the back of the hand to switch between pinch and power grasp. An average male hand size (breadth 9 cm and length 19 cm) is adopted in the design of hand.

The X-Limb is specifically designed and customised for fabrication using additive manufacturing techniques and 3D printing of soft material. Additive manufacturing allows realisation and fabrication of complicated features (e.g.

hollow space) which are not possible with conventional manufacturing methods. For fabrication of the whole hand, we used a commercially available 3D printer (FlashForge Dreamer) to print TPU90 (Thermoplastic Polyurethane with Shore 90A).

In order to have a stable pinch grasp while keeping the mechanism simple, a designed-in feature is considered in design of the index finger and thumb. This feature is the air bubble in fingertips of index and thumb. The air bubble is a thin layer of TPU printed on the fingertip to increase the interaction between fingertip and objects in pinch grasp.

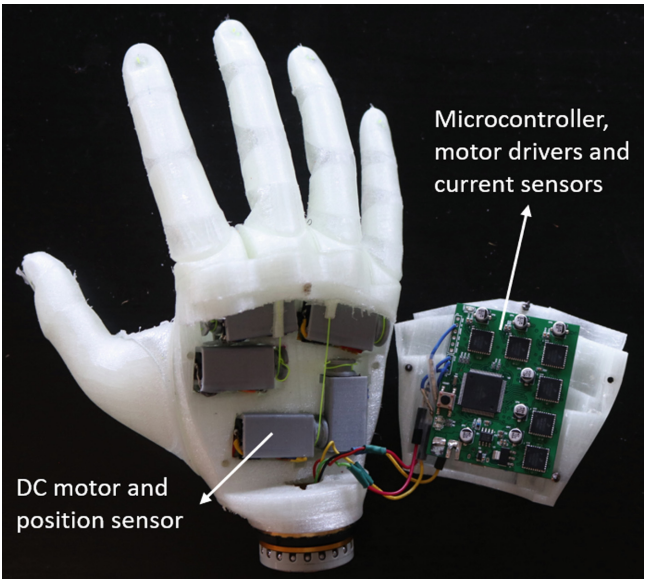

Fig. 3. X-Limb actuation mechanism

3 Results and Discussion

The overall weight of the X-Limb hand including the embedded actuators and universal quick disconnect wrist is 292 g which is half of the weight of existing commercial hand prostheses such as Bebionic. The required functionality for the hand is determined through evaluation criteria for prosthetic hands proposed in [3]. This includes a set of tasks for food preparation, dressing, holding cup, pouring bottle water, opening cap of bottles and picking small items. The capability of the X-Limb in grasping different objects and its application in performing ADLs is shown in Fig. 3. A video from the X-Limb demonstration is provided in YouTube (https://youtu.be/vIF9QH0ojzg).

As shown in Fig. 3(b) and (l), in power grasp mode, the X-Limb fingers can adapt to the cylindrical (water bottle) and spherical (tennis ball) shaped objects without requiring specific grip type. This significantly simplifies the prosthetic hand control interface for users and demonstrates effectiveness of the optimally designed hand prostheses. The designed-in air bubbles in fingertips of the index and thumb fingers also allows grasping small spherical objects as shown in Fig. 3(j) and (k).

4 Conclusions

The results of this study showed that X-Limb design is able to address the current issues with the state-of-the-art hand prostheses through the soft robotics techniques. The light weight and simple control interface of the X-Limb would potentially increase the use time and acceptability of the hand prostheses by upper-limb amputees.

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Prosthetics – Poster Session

Development of a Hand Neuroprosthesis for Grasp Rehabilitation After Stroke: State of Art and Perspectives

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Abstract. Stroke disrupts motor and sensory pathways, affects the ability to sense without distorsions body and peripersonal space, to decide to act, and to control efficiently the body. This paper describes the contextual requirements for the design of a grasp rehabilitation system for goal directed exercises. An implementation of a compatible system is shown.

1 Introduction

Grasping an object, although apparently a simple and natural action, is a highly specialized set of tasks involving the ability to stabilize the shoulder, perform counter-gravity movements, stabilize arm and wrist during reaching and grasping, preshape the hand as desired, and grasp with the desired strength. The altered skeletal muscle performance is a multi-segmental combination of paralysis, increased tendon reflex activity and hypertonia.

The search for an effective rehabilitation lies on the rebalancing motor, sensory, and cognitive skills in a coherent and contextual fashion. However, the development of a grasp rehabilitation system general enough is still a matter of investigation. The reasons of such complexity depend on the variability of the cortical damage, and the variability of its impact on the person's motor and sensory function.

Neuro Muscular Electrical Stimulation (NMES) is one of the treatments proven to recover the use of paretic limb after a stroke and improve grasp capability [1,2]. If compared to passive splinting or active robotic solutions, NMES evokes sensory rich afferent informations, and is a means of active muscle reconditioning in patients with partial or absent volitional recruitment. NMES can be combined with splints and exoskeletons as means of mechanically stabilizing weak or poorly responding segments while providing goal-directed contextual training. For neuroprostheses using robotics and NMES, the discriminants for effective clinical use can be summarized in portability, weight, fast calibration procedures, range of motion achievable with limited anti-gravitary muscle

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strength, comfort, and practicality for usage and cleaning. Active glove solutions such as the GloReha (Idrogenet s.r.l.) satisfy those requirements [3] from a mechanical perspective. Within this line of thought, we designed a goal-directed grasp rehabilitation system which includes multi-electrode NMES, a novel grasp orthosis, and a rehabilitation protocol with interactive objects for contextual grasp assistance.

2 Materials and Methods

The system described in this paper aims at recovering and supporting person's ability to perform Activities of Daily Living (ADL) in subjects with upper limb impairment due to a stroke at the sub-acute or early chronic stage. A set of passive wearables are used for selectively constrain wrist and finger motion, while electrode arrays target selectively hand opening and closing without the need of complex agonist-antagonist stimulation tuning.

2.1 User-Centered Design

The collection of requirements for the design of the orthoses proceeded over multiple meetings with prototypes look-like, and orthoses aimed at assisting power grasp. Focus groups with patients, physicians and neurologists, and on-field tests with prosthetists and therapists aimed at determining the number of necessary sizes, the amount of mechanical support needed for patients with limited spasticity (Modified Ashworth Scale ≤ 2), and with the need to sustain the wrist in subjects with null stabilization capability. Differently from the conventional splinting solutions, the hand palm was minimally covered with cloth-like material to allow the hand to conform to the objects used for the exercises, and to avoid any reduction on afferent tactile information. If not designed properly, rigid wrist locking can cause high pressures in localized areas. Goodness of fit and comfort of use were addressed by conforming the orthosis to common variability of hand and wrist; areas associated to potentially prominent exostoses were shaped to minimize the risk of direct contact. The material was chosen to allow, if needed, a quick reshaping of the wrist compensation angle and of the degree of opposition of the thumb. Selectively constraining of fingers is obtained with custom rubber-like clasps; a first clasp constrains proximal phalanges to move planar along the MCP joint, a second clasp joins the middle phalanges.

2.2 Active Modules

Topographically mapped multiple electrode arrays (Fig. 1) allow to provide dynamically reconfigurable stimulation maps. The device is designed to provide electrical stimulation on extrinsic hand flexors and extensors with independent sets of electrode arrays. The RehaMove Pro (Hasomed) [4] is used to deliver stimulation through custom produced 3 electrode arrays, each with 16 independent active sites. In this implementation Virtual Electrodes (VEs) are implemented

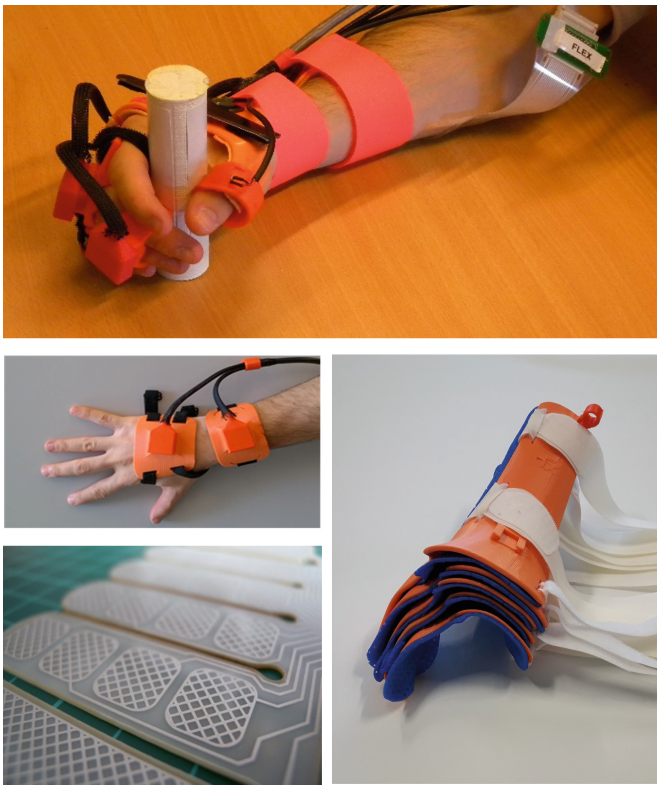

Fig. 1. For exercises requiring to grasp objects, the wearable is designed to lock the wrist at standard extension angles, and to monitor the opening and closing of the hand. Top: the worn system with the orthosis used to perform the grasp exercises. Bottom: details of the orthosis for wrist exercises, of the electrode array, and of the variability of fitting covered with the different size.

through the synchronous activation of single or multiple active sites each with sizes ranging from 1×1 to 2×2 electrodes. The VE centroid on the grid determines electrode size, direction, and location thus providing a set of positions and a varying depth encoding of the field of activation as a consequence of the dynamically changeable electrode size. The maximal stimulation intensity is limited for each VE to 30 mA and 300 µs. The VEs positions are personalized through a reactive GUI [5] to elicit functional grasp, to obtain whole muscle conditioning, and to produce open-loop or closed-loop grasp control. This approach diverges from the auto-tuning procedures proposed by other authors because it implicitly includes stimulation acceptance information. Moreover, stimulation maps deriving from previous sessions or other users can be transferred to the current session, reducing the manual search to 2–3 min. An anti-windup PID controller, fed with the desired metacarpal joint angle or grasp force, implements a simple

anti-slacking stimulation scheme. Clasps contain force sensors and inertial sensors to estimate grasp force and hand kinematics. Objects, used for mimicking daily life tools, weight up to 600 g, and the force sensors measure up to 15N. The objects are labelled with Radio-Frequency IDentification (RFID) tags, a reader filters by proximity the selected objects among several ones. The robotic system is fed with information on the objects proximal to the hand (e.g. physical characteristics, expected sequence of use) to drive exercises execution and stimulation activation.

3 Results and Discussions

The hand neuroprosthesis described in this paper is able to recover and support person's ability to perform exercises based on ADL in subjects with upper limb impairment due to stroke at the sub-acute and at the early chronic stage. Pilot tests with with previous embodiments of the device [6] proved to be insightful in defining anthropometric requirements and practicality requirements usually not needed in healthy populations. The current set of wearables allows to fit the target population, and to functionally constrain the movement for the exercises as needed. The functional constraining implemented in the orthosis is fit with the execution of the exercises and allows to host the electrode arrays for targeted NMES. A Randomized Controlled Trial (RCT) aimed at evaluating the effectiveness of the system in recovering of hand function is registered (Clinicaltrials.org, NCT03199833) and currently ongoing.

4 Conclusions

The preliminary results suggest that this wearable allows performing goal-driven exercises in a population that otherwise would be targeted either with splinting, passive external mobilization, or with repetitive NMES. In the companion paper [7] are described the exercises implemented with this device and a preliminary assessment on efficacy and usability.

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