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New neurorehabilitation technology: A pioneer patient

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Abstract

Spinal cord injury (SCI) often leads to chronic paralysis, which was for a long time considered to be an irreversible condition. Moreover it was unthinkable that any voluntary movement such as walking could be recovered. But recently there has been hope as different studies showed a certain regain of function in rats after spinal cord injury. The group of Prof G Courtine at EPFL has shown with rats, but also translational studies on monkeys that a tri-axial strategy consisting of electrochemical stimulation and active training, enabled by a new robotic system, with the goal of reconnecting the two sections above and below the lesion could lead to improvement of locomotion.

Recently a patient with a cervical spinal cord lesion was involved a similar neurorehabilitation program. The subject, was fully depending on her wheelchair. After being implanted with the electrode array she followed a special rehabilitation program at the gait lab in the CHUV. This training was based on the idea of the triaxial strategy already introduced by the G-Lab, but forwent without chemical stimulation due to the drug's side effects. So after conducting eight months of neurorehabilitation training, consisting of epidural electric stimulation (EES) and active training, the participant was able to walk with just the aid of a walker.

In this master work I am presenting the patient and the evolution of her motor performances during the whole rehabilitation period.

Keywords:

- Spinal cord injury
- Epidural electric stimulation
- Neurorehabilitation
- Versatile robotic interface





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Introduction

Spinal cord injury in Switzerland and the World

Traumatic spinal cord injury (SCI) is a highly life changing incident. It has a high financial, social, psychological and of course a major physical impact on the patients life (WHO, 2013). Also, individuals affected by SCI have a two to five times lower expectancy of life than individuals without SCI, especially in the first year after SCI (WHO, 2013). Historically, spinal cord injury (SCI) is mostly caused by trauma but it can also be caused by neoplastic tumors, degenerative, vascular, autoimmune diseases or Spina Bifida.

Traumatic SCI occurs mainly to young (16 to 30 years old) and elderly (76 years and older) individuals and is primarily caused by falls, sports and leisure-related activities or transport-related injuries. Falls such as tripping or tripping downstairs are age-dependent and can be found most often with elderly patients. Paraplegia results more commonly out of traumatic SCI than tetraplegia however the incidence rate of tetraplegia becomes higher in males after 61 years and females after 76 years (Chamberlain et al. 2015). As observed by Chamberlain et al., "the overall annual incidence rate between 2005 and 2012 was 18.0 per one million"¹ in Switzerland, whereas the worldwide annual incidence of TSCI was estimated to be 40 to 80 per one million according to the WHO. Compared to other European countries the Swiss annual incidence is in the average (Figure 1) (Chamberlain et al. 2015, WHO, 2013).

SCI is associated with high direct costs, such as treatment and rehabilitation service, adapted transportation and adjusted personal care, and indirect costs, which can be of economic and non-economic nature, for example loss of productivity or stress and social isolation (WHO, 2013). Indirect costs can be up to six-fold higher than the direct costs (WHO, 2013). The costs depend on the severity of the SCI and age of onset. They have been estimated to be USS 2.3 million for a 25 years old person with paraplegia (WHO, 2013).

To assess the severity of a spinal cord injury the American spinal injury association (ASIA) has published a classification called the ASIA impairment scale (AIS), which is based on motor and sensory function after the lesion (Annex 1). It is rated from AIS-A, complete motor and sensory impairment, to AIS-D where sensory function is preserved and motor function is preserved below neurological level. AIS-E stands for a normal motor and sensory function. To measure the improvement in walking of SCI patients the Walking Index for spinal cord injury (WISCI II) is very useful. It looks at the assistive devices and physical assistance needed by the patient (Annex 2). The scale goes from 0, the patient is not able to stand and/or walk even with assistance,

¹ Chamberlain et al. 2015





to 20, the patient walks alone without any assistance, such as braces and other assisting devices, for 10 meters (Ditunno et al. 2001).



incidence per million population. Comparison of reported annual incidence rates per million population for European countries with similar methodology.^{*} Indicates estimation based on sub-national survey data. Country references: Greece (Divanoglou and Levi 2009); Iceland (Knutsdottir et al. 2012); Norway (Hagen et al. 2010); Spain (Perez et al. 2012); Sweden (Divanoglou and Levi 2009); France (Albert and Ravaud 2005); Austria (Jazayeri et al. 2014); Netherlands (Nijendijk et al. 2014);

Finland (Ahoniemi et al. 2008); Ireland

(O'Connor and Murray 2006); Denmark

from Chamberlain et al. 2015

(Bjornshave Noe et al. 2015). Reproduced

Fig. 1: European estimates of annual TSCI

Annual Incidence Per Million Population New treatments for spinal cord injury patients

Walking and standing are very important to regain a certain autonomy and quality of life for people with SCI, but current therapies fail to provide a complete rehabilitation of locomotion (Thuret, S. et al. 2006).

But these days there are different strategies in development, trying to achieve that goal. There are the cellular therapeutic interventions, which study the transplantation of different tissues and cells such as a peripheral nerve, Schwann cells, olfactory nervous system cells, embryonic CNS tissue or different types of stem cells (Thuret, S. et al. 2006, Lu et al. 2012). An other strategy is the molecular therapeutic intervention, which aims for example to reduce secondary damage after SCI, to enhance the axonal conduction, to deliver different growth factors or to deliver neurotransmitters (Thuret, S. et al 2006, Musienko et al 2011). But as concluded by Thuret's review "Therapeutic interventions after spinal cord injury", it is not a single therapy that seems to restore function in SCI patients by its own.

However, some of the most advanced strategies are benefiting from spinal cord stimulation (SCS). In a study on healthy humans, the positive effect of transcutaneous electric stimulation at the vertebral level of T11/T12 on involuntarily step-like movements has been established (Gerasimenko, Y. et al. 2015). Also epidural electrical stimulation (EES) has shown good results by using a multi-electrode array in SCI rats and it has proved to facilitate standing and stepping of SCI individuals (Herman, R. et al. 2002, Carhart, M.R. et al. 2004, Harakema, S. et al. 2011, Angeli, C. A. et al. 2014).

Therefore the G-Lab has developed, in the last decade, a new paradigm (Van den





Brand et al. 2012). They conducted a study with a tri-axial strategy in rats, which consists of epidural electric stimulation (EES) combined with active training enabled by a versatile robotic interface and a systemic chemical stimulation, consisting of serotonin receptor agonist and a dopamine receptor agonist (Van den Brand et al. 2012, Dominici et al. 2012). The EES is supplied by a 5-6-5 electrode array implanted at the lumbosacral level, which applies phasic stimulation to the spinal cord. The serotonin agonist drug aims to reactivate the dormant system that lies below the lesion. So the drug and the EES together seek to reactivate the lumbosacral circuits. The active training, enabled by the robot, is added to the program for the same purpose. So the goal of this whole activity-based rehabilitation is to enforce and reconnect the link between the brain and the system below the lesion.

A clinical trial named STIMO is ongoing evaluating the effect of a 6 months intensive neurorehabilitation with closed loop spinal cord stimulation and robotic assistance.

Before STIMO was initiated, we had the opportunity to propose the same type of rehabilitative approach to a pilot patient. This pilot patient is the object of my work.

The pilot patient: MRC

MRC is the 62-year-old pioneer patient upon whom the further thesis is going to center. After a complicated course of disease and treatments, she depended on a wheelchair and suffered from neuropathic pain, which made her a candidate for SCS. And since the electrode array was implanted at the lumbosacral level, which is the placement identified by the G-lab for their rehabilitation paradigm, she was offered to follow, as a pioneer patient, the locomotion rehabilitation program tailored by the G-lab. By enrolling to this pilot study, she became the first patient who underwent a full rehabilitation program that combines EES and an active locomotor training with the versatile robotic interface (Dominici, N. et al 2012).

In this interdisciplinary project, I had the opportunity to do a part of the analysis. More precisely, I tracked selected files containing raw data of MRC's trainings sessions and continued processing the tracked data to finally create the graphs and images shown here in the thesis. In addition to this main part of my thesis, I'd also like to show that collaboration between clinical medical professions and scientists is very important and holds a lot of potential for the future.

Case Report: MRC the pilot patient

Clinical Aspects

MRC is the 62-year-old woman. Her story starts with paresthesia in her arms in April 2013 whereon she was diagnosed with spinal stenosis at the level of C6/C7 (Figure A). Unfortunately, the patient did not respond to conservative treatment and presented herself at the emergency in September 2013 with rapid onset of complete flaccid paraplegia as well as sphincter disorder that appeared shortly after. The patient underwent an emergency C6/C7 discectomy stabilization at the same level.







Fig. A: **Patient history and lesion and array information** shows a short summary oft he patient history and images of the spinal cord lesion and the implanted array.

The patient arose from the surgery freed from the pain for the time being but without recovery of the motor and sensitive deficits and was classed as tetraplegia AIS-B. After 8 months of conventional rehabilitation at the Swiss Paraplegic Center (SUVA, Sion, Switzerland), she was reevaluated as tetraplegia AIS-D. At this point, she had recovered sensitivity below the lesion but was suffering from neuropathic pain. The patient left the rehabilitation in a manual wheelchair, as she had just recovered some motor control in her right leg but hardly any in her left leg.

The surgery (electrode placement)

Finally, in October 2014, she was proposed to receive epidural electrical stimulation at spinal cord level to treat the neuropathic pain. Spinal cord stimulation (SCS) is the most common type of neuromodulation applied nowadays and it has been successfully used for almost the past 50 years (Thomson, S. 2016). Technically, for a successful SCS, electrodes have to be inserted in the epidural area at the appropriate level to treat the pain (Cruccu, G. et al 2007). The main indications for SCS are (refractory) neuropathic pain, which can be found in up to 8% of the population, vascular pain and ischemic pain syndromes respectively, but also SCI is a potential indication (Thomson, S. 2016, Wolter, T. 2014). "High quality, randomised, comparative clinical studies have demonstrated unequivocal clinical and cost effectiveness in the treatment of patients with refractory neuropathic pain"². Therefore, an epidural spinal cord 5-6-5 specify (Medtronic) electrode was implanted and connected to a rechargeable neurostimulator.

² Thomson, S. (2016). Spinal cord stimulation for neuropathic pain. *http://www.neuromodulation.com/spinal-cord-stimulation-for-neuropathic-pain*





The surgery was divided in two steps. Before each step there was cleaning and disinfection of the patient according to the regular procedure and sterile drapes were taped. In the first part the patient was in a supine position and a 5-centimeter midline skin incision was performed. The fascia was opened, the muscle retracted bilaterally and the inferior part of the D12 lamina was removed as well as the superior part to perform the flavectomy. After this the Medtronic 5-6-5 Specify electrode was inserted and its position, which should be located over the midline in a rostro-caudal position, was radiologically and electrophysiologically checked. The electrode was then fixed to the surrounding tissues to avoid shifting and the distal part was hidden under the fascia. The patient was closed up which means that all 3 layers such as fascia, subcutis and skin were closed separately.

For the second step, still under anesthesia and intubation, the subject was put in a lateral position to have access to the abdomen where an additional incision was made for the Medtronic impulse generator, Activa RC. After the implantation of the latter, the back incision was reopened and a cable then was tunnelled from the electrode to the generator and connected. After the incisions were closed up again the patient was woken up and she passed a few hours in the recovery room. During the first 24 hours neurological controls were performed regularly. On day one after the surgery, the patient was allowed to move freely.

Stimulation Program

The stimulation of the spinal cord is achieved through the implanted array, which is connected to the generator. Different stimulation programs can be applied through the generator by combining different patterns of the electrodes in the array.

The functional mapping is the technique that allows to determine which muscle will be activated by each of the 16 electrodes.. During the functional mapping the individual electrodes of the Medtronic 5-6-5 specified electrode array on the spinal cord are stimulated at two hertz and at different amplitudes and the triggered muscle reaction is captured with EMGs. By increasing the amplitude more muscles are recruited. The electrode placement for the EMG is done according to the "EMG placement protocol" (http://seniam.org). The EMG electrodes are each time placed anew so there can be small variations in there localization and the orientation from one session to the other.

. The aim is to find combinations that result in a symbiotic muscle activation for standing or walking. So in the end useful combinations of individual electrodes can be set to stimulation programs used for different situations. Below, Figure B the functional mapping from MRC is shown with three different stimulation programs. All three programs were here applied with the same voltage. Above, the zones of the activated spinal cord segments are shown and beneath, the muscles are color-coded corresponding to the triggered activation.







Fig. B: Functional Mapping of Stimulation shows three different stimulation programs each with activated part of the spinal cord and the activated muscles in de legs.

Rehabilitation

Before the implantation of the array MRC had rehab sessions twice a week. They were increased to three times per week after she recovered from the surgery. In her rehab sessions a physiotherapist always supported her.

After the implantation of the device, the patient underwent a special gait rehabilitation plan. Each session followed the same sequence. Fifteen minutes of treadmill where ensued by about thirty minutes of over ground walking. The training on the treadmill was supported by manual aid as well as epidural electrical stimulation of the lumbar segment, while the over ground walking was assisted by the versatile robotic interface and tonic EES. A physical therapist was always present and assisted and helped with additional exercises and stretching in the end of the sessions.

Rehabilitation room

The gait lab at the Nestle Hospital (CHUV) provides a technical platform to perform and analyze locomotion. This platform consists of a large room, which holds the versatile robotic interface and the associated equipment and computers as well as a treadmill. As shown in Figure 2 the robotic interface is built to provide safety on the one hand by preventing falls, and, on the other hand, to assist the patient by supporting a part of his bodyweight without interfering with his movements. Compared to other robotic systems this one can deliver assistive forces to the patient in the 3 dimensional directions and does not interfere with the movements neither because of added weight nor the size of the strapped on device, as it is necessary by using certain exoskeletons (Hidler, J. M. and Brown, D.A. 2012). Different settings of the vertical bodyweight support (BWS) and forward support (FWD) can be regulated separately and thereby be exactly adjusted to the subjects needs. UNIL | Université de Lausanne Faculté de biologie et de médecine





Fig. 2: Gait lab at **CHUV** with detailed FLOAT system. Kinematic recordings (Vicon, UK), Augmented Reality system (various suppliers), Force Plates (Kistler, CH), Wireless EMGs (Myon, CH), Isokinetic Dynamometer (LMT, CH), Instrumented Treadmill and Support System (Forcelink, NL), Electrical Neuroprothesis (Medtronics, US), **Robotic Postural** Interface (Lutz Medical Engineering, CH). Reproduced from master thesis of C. Le Goff.

The wireless Myon[®] 320 EMG system and the two Kistler[®] force plates as well as the kinematic recording system allow the assessing of different data from the patient who walks back and forth attached to the Float system. The Myon[®] 320 EMG system is able to record 16 surface EMG signals at the same time (the "EMG placement protocol" can be found in the annex). The kinematic recording system consists of fourteen Bonita infrared cameras from Vicon[®] that are evenly spread around the walking path in the room and two video cameras to record the walking area from the front and side view. Everything is connected to the Vicon[®] MX Giganet box that puts the recorded signals together. The real-time signals are displayed on the computer by the Vicon[®] Nexus software.

My Contributions

Introduction

In this part I present my figures and the methods I used to create them. I started by watching the recording of the team of the G-Lab. These recordings were done in the rehabilitation room at the CHUV.. After having decided, on which recording I could base my work, I started to track them. In the following step, I processed them in Matlab[®] and, finally, I created the figures in Adobe Illustrator[®]. In the subsequent





parts I describe how I processed the data and I describe the figures, and consequently the results that emerged.

Methods Processing of the Data

The raw data obtained from the recording sessions had first to be looked through to check the quality such as visibility of the markers and having a good sight of the subject in the video. Then each file had to be tracked in Nexus Vicon[®], which means that all the markers had to be labeled manually so that the trajectories of all the markers were visible trough the whole file. Sometimes to achieve that, the file had to be cut because the cameras did not record all the markers at the far ends of the large room.

The next step was to tag the different gait events in Vicon[®] Nexus. In healthy walking, there are two gait events to mark, one is the "Foot Strike" (first frame when the foot touches the floor) and the other is "Foot move" (first frame the foot starts to move forward). In pathological walking there is an additional gait event to mark, which is "Foot off" (first frame the foot isn't touching the floor anymore). So the time between "Foot move" and "Foot Off" indicates dragging of the foot.

This pre-processed data now underwent further processing through a Matlab[®] interface (Code written by the team of the G-Lab), which enables computing of more than one hundred gait parameters. With its help it was possible to visualize raw and processed electromyographic signals as well as the whole body kinematics for each performed trial.

To create the figures I used the Adobe Illustrator[®], which is a vector-based design program for graphs and drawings. I imported the essential components from Matlab[®] and created some smaller items myself.

Results

Pre Timepoint

According to her medical history, MRC was not able to walk at the end of the standard rehabilitation program and was dependent on her wheelchair to move around. With the help of the versatile robotic interface, she was able to walk as her bodyweight was supported by 70% (Fig. C).







Fig. C: **Pre Timepoint** shows that without assistance no walking is possible and while walking with assistance of 70% BWS and no EES walking is possible. The EMG shows the activation of the Flexor (MG) and Extensor (TA) of the left side while walking, as this is her weak leg. The walking events are color-coded.

BWS Progression

Maybe the most obvious and imposing results can be seen in the changes of the Bodyweight support (BWS) needed by the patient. In figure D the vertical BWS, which is given in percentage of the Patients bodyweight lifted by the versatile robotic interface, is listed for each time interval of four weeks. The patient started each session with more BWS than she would actually need and during the session the BWS was decreased in order to firstly, identify the optimal BWS for training and secondarily, to evaluate the lowest BWS necessary to enable the Patient to walk.



Fig. D: **BWS Progress** shows the decrease in body weight support during the weeks of rehabilitation.

There is a slight increase in BWS from the pre-surgery period to the first week postsurgery that is presumably due to the use of the EES. The Patient had to get accustomed to this new sensation and the effect the EES had on the body.

After Week 24 no more EES was used for the rehabilitation, because MRC could not get used to the feeling of the EES and did even find the sensation disagreeable so she decided not to use it anymore. But even without EES she still made a lot of progress with the help of the versatile robotic system and decreased her need of





BWS from over 20% to 0%. To sum up, in the course of the 34 weeks of Neuro-Rehabilitation the Patient managed to lower her need of BWS from over 80% to 0%, so in the end she was able to walk on her own with only the assistance from a walker.

The Gait Cycle

This section deals with the gait cycles and the EMG results as well as the angles of the hip, the knee and the ankle. This leads us firstly to the gait cycle, which is composed of the three gait events, namely stance, dragging and swing. In healthy walking a gait cycle is made up of just stance and swing whereas in pathological walking, dragging of one or both feet can be observed. A gait cycle is defined as one complete step of one foot, it usually starts with the stance, which begins with the first contact and loading of the foot on the ground and ends with the placing of the foot on the ground. The next part of the step depends on the walking person; whether or not he has a healthy walking pattern. In pathological walking the stance is followed by the drag, which is defined as the moving forward of the foot while still touching the floor. The swing begins in the moment when the toe is lifted from the ground and lasts until the foot is placed on the ground again and a new gait cycle can begin. So drag and swing have both the aim to move the foot forward. In healthy subjects there is no dragging and stance is directly followed by the swing phase. But the dragging is not the only indication for a pathological gait cycle. The change from stance to swing of healthy walkers occurs at approximately 60 percent of the gait cycle, which is clearly not the case in our patients walking.

The sticks schema, as for example shown in figure F, is composed of the schematic positions MRC was in at timely defined intervals. These timely intervals are the same for all the sticks schemas in this paper. First, I would like to show by the sticks schemas, the impact the EES has on the walking pattern. So when we compare the two sticks schemas from the early time point (Figures F and G) the only difference at the time of the recording was that one was recorded without EES (Figure F) and the other was recorded with EES (Figure G). Taking into consideration that the single positions are recorded at the exact same time intervals and looking at the distances between these positions it becomes clear that MRC is walking faster when stimulated with EES in comparison to when she is not stimulated.

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Fig. E, F, G, H and I: In Time Flow each week is represented by a little rectangle and the colorcode is consistent with Figure D. In figures F, G, H and I the BWS is represented by the flash facing upwards and the gait events are colorcoded as follows: grey is the foot stance, red is the dragging of the foot and blue is the swing period. Corresponding to the gait events the EMG of the flexor (MG) and the extensor (TA) is shown. The displayed Angles of the Hip, Knee and Ankle correspond to the average of the angles of several gait cycles and the appending standard deviation (SD). In the Figures H and I no EES is applied whereas in figures G and H the Patient was stimulated by EES.

Second, we can see that at the middle time point of the rehabilitation (Figure H) MRC is able to walk faster then at the beginning of the rehabilitation. Thus even with a decrease of the BWS from 70% to 40% she is able to walk faster. Here it is important to compare the middle time point to the early time point with stimulation as this one was also recorded with stimulation. This leads to the conclusion that the here visible progress, which was made during this first ten weeks rehabilitation program, is due to muscle strengthening which is achieved by the EES stimulation and the walking training in the versatile robotic interface.





At the end of the rehabilitation MRC was able to walk with just the aid of a walker (Figure I). By looking at the sticks figure, the high density of the individual schematic positions implies the slowness of the patient's walking. This slowness results from the effort and the concentration MRC has to display to be able to perform this for her very difficult and tiring task. Adding to that, the overall prolonged time MRC needs for the stance is consistent during the whole rehabilitation and doesn't improve over time.

Muscle Activation

The EMG is the main tool to show muscle activation in a patient. As explained above the EMG is recorded by the Myon[®] 320 EMG system and it records 16 surface EMG. Out of these 16 EMG two were chosen to show here. There are different reasons for the selection of the left musculus gastrocnemius medialis (MG) and the left musculus tibialis anterior (TA). One of them was that I wanted to show a flexor and extensor pair and not just two more or less related muscles. On top of that, the availability and quality of the chosen EMGs throughout the whole rehabilitation had to be taken into account, which excluded for example any pair of agonist and antagonist like the musculus rectus femoris (RF) because it was not recorded during the last recording session. Furthermore all EMG recordings had to be checked for noise and movement artifacts, which can occur in surface EMGs.

It is important to bear in mind that we look at surface EMGs here. The wireless EMG transmitter has to be attached to the patient each session anew and even though this was done corresponding to the "EMG placement protocol", small variations in the placement can occur. This results in the fact that we cannot compare the Amplitude of the EMG but merely the excitation patterns.

Most muscles do not have just the one function for which they are made for. They can act on a single or different joints, interact with other muscle activities and mostly have an antagonist. The M. gastrocnemius medialis (MG) acts as a flexor for the knee and the ankle and is for one antagonized by the M. tibialis anterior (TA), which acts as a dorsal flexor for the ankle. In healthy subjects the MG is activated during stance and in the beginning of the swing phase. The TA is activated during the swing phase in healthy walking.

Looking at the EMG at the pre-rehabilitation time point (figure C), the MG (flexor) does not show a healthy activity pattern. There are different small activations all over the gait cycle but no regular activity over several gait cycles. More activity can be observed when we look at the bursts of TA (extensor) predominately during dragging and swing.

Comparing the EMG at the early time point without EES to the early time point with EES, we observe overall much more EMG activation in the setting with EES. But when we look closer, firstly at the TA, we see that the bursts in the setting without





EES are altogether denser during dragging and swing where as in the setting with EES there seem to be no regular bursts and no obvious pattern. On the other hand, when we have a look at the MG activity, there does not appear to be a lot of activity while not stimulated but with EES there is activity during stance that decreases towards the end of stance (Figure F and G). So the EES seems to increase muscle activation but not at a specific time during gait cycle and not in the same way in the MG/TA muscle pair.

Already in the middle of the rehabilitation time, with applied EES, some progress in the muscle activation can be observed. The EMG of the MG and the TA show clear burst patterns. The MG is activated during stance and TA during the drag and the beginning of the swing. The TA activity in the dragging phase reveals the high effort MRC puts in to extend her foot (Fig. H).

At the end of the rehabilitation the EMG burst pattern advanced even more. Especially the baseline of the TA seems much steadier with evident bursts during the dragging and the beginning of the swing phase. The MG bursts start with the beginning of the stance phase and decrease progressively towards the end of stance. Comparing the beginning and the end of the rehabilitation, a clear amelioration of the EMG burst pattern towards healthier muscle activation can be noticed (Fig. I).

Walking Angles

In order to be able to walk, the whole leg has to move at different levels. To do so we have joints that are moved by the muscles and give the leg its mobility. Looking at the main joints in the leg, which are the hip, knee and ankle, and the changing angles during walking, we can indirectly evaluate muscle activity.

a. Hip angle

In healthy walking the hip is extended during stance and gets even more extended at the end of stance before the leg starts moving forward and the hip goes into flexion for the swing. As MRCs right leg is her strong one the hip angles are mostly conform to healthy walking throughout the rehabilitation even though there is some variation over the different cycles (Figures F, G, H and I). Her left hip angles on the other hand deviate clearly from the norm. When we compare once more the two different conditions at the early time point, the hip angles are closer to the healthy angle pattern when the patient is stimulated with EES, nevertheless the hip does not move enough for healthy walking. In addition there is much less variation (SD) in the angles over multiple gait cycles with EES. At the mid time point, there does not seem to be any improvement in the hip movement but when looking at the late time point some change can be found. The hip moves more and the pattern becomes similar to the right hip angles (Figures F, G, H and I).





b. Knee angle

The knee normally is extended during the weight bearing of the gait cycle. So in healthy walking there is flexion of the knee at the end of stance and in the beginning of swing, so the leg can be moved forward without the foot touching the floor. On top of that there is a minor flexion of the knee at the beginning of stance as the body moves forward and the foot still stands on the same spot. This pattern can be observed on the right knee throughout the rehabilitation and even though at the end time point there is more variation in the angles, the overall pattern resemble healthy walking (Fig. F, G H and I). The EES at the beginning of rehabilitation results in less variation in the left knee angles over multiple gait cycles but MRC starts either way to flex her knee too early to compensate for the low hip movement (Fig. F and G). This early flexion persists at the middle time point but flexion at the beginning of the swing becomes stronger with training (Fig. H). The knee flexion pattern becomes healthier at the end of rehabilitation, the flexion becomes briefer, the smaller flexion at the start of stance appears and the knee movement looks healthier (Fig. I).

c. Ankle angle

Healthy ankle movement is characterized by a plantar flexion of the foot at the end of stance. This flexion comes from the rolling motion of the foot. MRC, particularly in the beginning, has her very distinct ankle-moving pattern. She uses her right foot to compensate for the insufficient flexion of the left leg and to do so; she stands on her right toes during stance to enable the left leg to swing forward without touching the floor constantly. MRC keeps that compensation technique through the whole rehabilitation even though it decreases over time (Fig. F, G, H and I). Also the left leg has his very own course of motion. During stance there is no stable phase where the foot is put even and stable on the ground but the ankle's angle shows an arch. The lack of force to dorsal flex her left foot during swing leads to a pathological plantar flexion. This explains the dragging in the beginning of swing. The only reason why the swing phase is not completely made of dragging, is the above mentioned compensation technique MRC does with her right leg. Not much of a difference can be noticed when comparing the stance phase with and without stimulation at the early time point. During swing the pathological plantar flexion seems to be slightly less prominent while stimulated. But as already observed elsewhere, the angles during the gait cycles deviate less from each other when there is EES (Fig. F and G). Halfway through the rehabilitation the movement pattern of the ankle hasn't changed much. It is mostly superposable with the pattern at the early time point with EES (Fig. H). By contrast the left ankle is more stable during stance in the end of training. On top of that the dorsal flexion of the foot is more pronounced in the swing than before even though there again is also more variation (SD) over the different gait cycles (Fig. I).





To sum up, improvement in all the different movements of the joints can be seen. The stimulation tends to help the reproducibility of the angle patterns and reduces therefore the variability of the angles in the different gait cycles. At the end of the rehabilitation, the motion patterns of the left side have approached the healthy patterns.

Principal components analysis

Until so far some specific improvements have been pointed out, but to show the over all amelioration during MRC's rehabilitation, a principal component (PC) analysis has been developed (Fig. J). For this purpose the collected data of the left leg from six recording sessions at three time points was compared to a collected database of healthy walkers. A schematic graph, where the two different conditions of each time point can be compared to the healthy situation, was therefore created with the help of a code written by the G-Lab.



Fig. J: The **PCA**-**Figure** shows the over all evolution of MRC in a PC analysis and the specific progress in the step length, the drag, the step height and the vertical trunk movement at 3 different time points.

The PC analysis shows us on the y-axis the PC1 that explains 46.36% of the variance. Simplified, the y-axis divides healthy walking and MRC's pathological





walking. On this diagram, the change in walking from the beginning and the mid time point to the late time point as so to the end of the rehabilitation is clearly visible.

After the analysis of the factor loadings on the variables of PC1, some of them are therefore shown in graphs in Figure J. The step length, the drag, the step height and the vertical trunk movements are four examples for variables that are included in the PC1 and contribute to the variance explanation in a significant way.

MRC's step length evolved over time to become closer to the step length from healthy people but did not achieve to catch up with it. Furthermore it is interesting to observe that the step length was slightly longer in the beginning without EES where as at the mid time point the EES seems to improve the step length. On top of that it seems that at the late time point the versatile robotic interface (BWS 25%) enhances the step length as well.

The dragging is the next variable to look at and as we would hope it decreases over time. The decrease is steady for the first two time points but astonishingly it even decreases remarkably more for the last time point, where MRC has the walker as an aid.

Next we take a look at the step height. At the early as well as the mid time point the patients step height is significantly better with EES than without EES. Moreover, MRC is after ten weeks of rehabilitation (mid time point) able to walk with almost the same step height while the Body weight support is reduced from 70% to 40%. Past another 16 weeks of rehabilitation more progress can be perceived. When walking with the walker and without support from the versatile robotic system, she came as close to healthy walking as possible.

The last of the four variables to study here is the vertical trunk movement. The data of last time point shows less movement than a healthy person would show. When thinking about this there is a relatively simple explanation. At the late time point the patient is walking with a walker and it is easily conceivable that MRC uses the walker to steady herself and puts quite some weight on it. This gesture leads to a more rigid upper body posture and consequently to a less vertical trunk movement. This would also happen in healthy subjects but on these grounds it is necessary to keep in mind that here the healthy subjects use no walker. Otherwise, a steady approach to the healthy vertical trunk movement can be observed throughout the first half time of the rehabilitation.

Overall a lot of progress in MRCs walking can be noticed, but we also see that there is still some space for further progress.





Discussion

MRC's progress

At the beginning MRC was totally wheelchair dependent. Due to the spinal cord stimulation, which was put in place to manage the chronic pain she was suffering from, she got the opportunity to participate in this pilot rehab program for paraplegic patients. In the course of time she recovered enough force and reactivated enough lumbosacral circuits to perform sufficient voluntary movement to walk. Through the trial, she increased steadily the percentage of her bodyweight until she was able to bear it fully. She managed to walk faster and more secure the longer she trained with the robotic interface, which led to more reproducible movement patterns and more precise muscle activations.

The stimulation

Tonic stimulation was used in MRC's case, which means that always the same amplitude was applied. Harakema's research group also uses this form of stimulation. But there is also another improved way of stimulation that is called phasic stimulation. In this kind of stimulation different phases, for example extension and flexion, are defined and different amplitudes are applied accordingly. This year the G-Lab made some further progress with phasic electric epidural stimulation that were directly translatable to human beings. They designed a real time control software that takes proprioceptive feedback into account and accordingly modulates the flexor and extensor muscle activity. This so-called spatiotemporal neuromodulation will become an important tool to improve the recovery of motor function in humans (Wenger, N. et al. 2016). In another study they showed that EES modulates muscle spindle feedback circuits. This interaction of EES and the muscle spindle feedback circuit leads to an excitatory drive to the motor neurons. This promotes the alternative recruitment of the respective extensor and flexor muscles (Moraud, EM. et al. 2016).

Robotic interface

Walking with the robotic system opens possibilities for a lot of patients who are not at all able to walk without any kind of assisting device. As the case of MRC so nicely shows a patient who is bound to a wheelchair is able to walk a few steps and gets the chance to feel again how it is to walk. And we don't talk here about the situation after several training sessions; the patient is able to walk at the first attempt. Surely, a high percentage of his weight might be carried by the robotic system but just to have the feeling of walking again can be profoundly reassuring and motivating for the patient. So even if the robot is not used for complete rehabilitation, but just for individual walking session it can be psychologically beneficial for the patient.

The robotic interface has some great advantages compared to existing devices. First there is no additional weight added to the users body compared to the different types





of exoskeletons, such as the AnkleBOT, the Tibion bionic knee or the Lokomat (Hidler, J.M. et al. 2012). But at the contrary a variety of different percentages of the subject's body weight can be lifted by the system. Second, the mobility of the patient is not restricted in any way but at the same time the system provides security by recognizing an incipient fall and by preventing it.

Nevertheless there are also some disadvantages of this new system. The user is restricted to do the training in the gait lab and can just walk as far as the room allows. It does not enable free walking in the patient's natural surroundings or outdoors as it is possible with some types of exoskeletons. Neither does it train the walking on uneven grounds.

My contributions and conclusions

In this multidisciplinary approach, I had the chance to get an insight in the part that is conducted in the laboratory. I analyzed and processed the data obtained out of MRC's gait lab sessions, which were used by the G-Lab for their paper on the robotic interface and for my thesis. Therefore I got to work with different occupational groups and I saw how they worked with each other to achieve one goal. This made me realize how important interdisciplinary collaboration is. Principal component analysis is one example for usefulness of multidisciplinary work. PCA is nowadays just used by scientists and not so much by medical doctors, but it could be a powerful assessment tool in the future. These days big packages of data take sometimes weeks to analyze but thanks to PCA, huge amounts of data can be analyzed in a short time. This could allow medical doctors, in cooperation with scientists, to use this tool to give a patient an immediate, objective feedback about for example the progress made during a training session. A great benefit of this feedback could be the immediate comparison with a huge database of similar cases, which would allow putting the progress into context with other patients in the same situation. This is why incorporating data in the course of treatment could be a very helpful tool in the daily practice of different medical fields.

Another example is the use of the robotic interface. In order to have the possibility of a whole rehabilitation based on the robotic interface a lot of disciplines have to work together. The robot could not just be used for SCI patients but for example also for Parkinson patients to overcome the typical blockage at the beginning of movements. A possible further field of application could be the rehabilitation after orthopedic surgeries of the lower extremities, such as joint replacements or after trauma.

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Annex

1) AISA



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2) WISCI

Scoring Sheet (WISCI II)

Patient Name

Date____

Check descriptors which apply to current walking performance, then assign the highest level of walking performance. (In scoring a level, one should choose the level at which the patient is safe as judged by the therapist, with patient's comfort level described. If devices other than stated in the standard definitions are used, they should be documented as descriptors. If there is a discrepancy between two observers, the higher level should be chosen.)

Descriptors

Gait: reciprocal ____; swing through_____

Devices	Braces	Assistance	Patient reported comfort level
// bars < 10 mtrs	Long Leg Braces- Uses 2 Uses 1	Max assist x 2 people	Very comfortable
//bars 10 mtrs	Short Leg Braces- Uses 2 Uses 1	Min/Mod assist x 2 people	Slightly comfortable
Walker- Standard Rolling Platform	Locked at knee Unlocked at knee	Min/Mod assist x 1 person	Neither comfortable nor uncomfortable
Crutches- Uses 2 Uses 1	Other:		Slightly uncomfortable
Canes- Quad Uses 2 Uses 1			Very Uncomfortable
No devices	No braces	No assistance	

WISCI Levels

Level	Devices	Braces	Assistance	Distance
0				Unable
1	Parallel bars	Braces	2 persons	Less than 10 meters
2	Parallel bars	Braces	2 persons	10 meters
3	Parallel bars	Braces	1 person	10 meters
4	Parallel bars	No braces	1 person	10 meters
5	Parallel bars	Braces	No assistance	10 meters
6	Walker	Braces	1 person	10 meters
7	Two crutches	Braces	1 person	10 meters
8	Walker	No braces	1 person	10 meters
9	Walker	Braces	No assistance	10 meters
10	One cane/crutch	Braces	1 person	10 meters
11	Two crutches	No braces	1 person	10 meters
12	Two crutches	Braces	No assistance	10 meters
13	Walker	No braces	No assistance	10 meters
14	One cane/crutch	No braces	1 person	10 meters
15	One cane/crutch	Braces	No assistance	10 meters
16	Two crutches	No braces	No assistance	10 meters
17	No devices	No braces	1 person	10 meters
18	No devices	Braces	No Assistance	10 meters
19	One cane/crutch	No braces	No assistance	10 meters
20	No devices	No braces	No assistance	10 meters

Level assigned_____

3) EMG placement protocol





01. GM - GLUTEUS MAXIMUS





07. VLAT - QUADRICEPS FEMORIS, VASTUS LATERALIS

Remarks Orientation Test Location Σ on the line from the anterior spins illacs superior to the lateral side of the patella. In the direction of the muscle fibres Extend the knee without rotating the thigh while applying pressure against the leg above the ankle in the direction of flexion.

08. VMED - QUADRICEPS FEMORIS, VASTUS MEDIALIS

		- ×			
Electrode pl	Posture	Location	Orientation	Test	Remarks
Scement	Sitting on a table with the knees in slight flexion and the upper body slightly bend backward.	4/5 on the line between the anterior spinal lists superior and the joint space in front of the anterior border of the medial ligament.	Almost perpendicular to the line between the anterior spina lilaca superior and the joint space in front of the anterior border of the medial ligament.	Extend the knee without rotating the thigh while applying pressure against the leg above the ankle in the direction of flexion.	







ОВ. ТА – ТІВІАLІS АНТЕЯІОР

Electrode pla	Posture	Location	Orientation	Test	Remarks
tement	Supine or sitting.	1/3 on the line between the tip of the fibula $1/3$ on the line between the tip of the medial malleolus.	In the direction of the line between the tip of the fibula and the tip of the medial malleolus.	Support the leg just above the ankle joint with the ankle joint in doesficied on said he foot in inversion without extension of the state costs justices of the foot in the direction of plants flexion of the ankle joint and eversion of the foot.	

SUS			1		
	Electrode pl	Posture	Lociticou	Orientation	fest
	themese	Lying on the belly with the face down and the thigh held down on the table, in medial notation, and the lag medially in tated with respect to the thigh. The knee needs to be flowed to less than 90 degrees.	1/2 on the line between the ischial tuberosity and the medial epycondyle of the tibla.	In the direction of the line between the ischial tuberosity and the medial epycondyle of the tibia.	Press against the leg proximal to the ankle in the direction of knee extension.

Remarks

06.97 - SEMITENDINOSI



Location 1/2 on the line between tuberosity and the late	.sidit	Orientation In the direction of the ischial tuberosity and i of the tibia.	the lege search the leg p to the leg p to the leg p to the direction of kne	Remarks
he line between the ischial ty and the lateral epicondyle of		rection of the line between the Jberosity and the lateral epicon bia.	ainst the leg proximal to the an inection of knee extension.	

le ischial epicondyle of the

Lying and the bally with the sace work with the other balls and the verse shall be wreed fraction of the sace shall be shall be shall be fractioned for last the same shall be shall be the same shall be not be shall be shall be shall be shall be not be shall be

Remarks

05. BF - BICEPS FEMORIS

Orientation Test Location

О4. RF - QUADRICEPS FEMORIS, RECTUS FEMORIS

Posture

Sitting on a table with the knees in slight flexion and the upper body slightly bend backward.

In the direction of the line from the anterior spina illiaca superior to the superior part of the patella. 1/2 on the line from the anterior spins iliscs superior to the superior part of the superior part of the patella.

Extend the knee without rotating the thigh while applying pressure against the leg above the ankle in the direction of flexion.

IO. PERL – PERONEUS LONGUS



1/4 on the line between the tip of the head of the fibula to the tip of the lateral In the direction of the line between the tip of the head of the fibula to the tip of the lateral malleolus. malleolus.

Support the leg above the ankle joint. Everse the focus with jamare frexion of the ankle joint while applying pressure against the lateral locater and ado alo of the foot, in the direction of inversion of the foot and dors/flexion of the ankle joint.

11. PERB – PERONEUS BREVIS



Support the leg above the ankle joint. Everse the foro with landar freason of the ankle joint while applying pressure against the lateral looter and so leo of the foot, in the direction of inversion of the foot and dorsfilted/on of the ankle joint.

placed anterior to the tendon of the peroneus longus at 1/4 of the line from the tip of the lateral malleolus to the fibula-

Sitting with extremity medially rotated.

In the direction of the line from the tip of the lateral malleolus to the fibula-head.

head.

It is difficult to access the peroneus brevis muscle from the surfaces since it is mainly covered by other muscles. Avoid crosstalk / overlap from the extensor digitorum lateralis muscle.

12. Sol - Soleus



Put a hand on the knee and keep / push the knee downward while asking the subject / patient to lift the heel from the floor. 2/3 of the line between the medial condylis of the femur to the medial malleolus. Sitting with the knee approximately 90 degrees flexed and the heel / foot of the investigated leg on the floor. In the direction of the line between the medial condylis to the medial malleolus. Orientation Location Remarks Posture Test

13. MG – GASTROCNEMIUS MEDIALIS



Lying on the belly with the face down, the knee extended and the foot projecting over the end of the table.

placed on the most prominent bulge of the muscle

In the direction of the leg.

Partiar flexion of the foot with emphasis on pullings the lexit word on the cit and public the forefoot downward. For maximum pressure in this position it is necessary to apply pressure against the calciance.

14. LG – GASTROCNEMIUS LATERALIS



GENERAL REMARKS

Electrodes placement Distance 20m Distation (Dou Seference On /	im between the electrodes. uble sided) tape / rings or elastic band. / around the ankle or the proc. spin. of C7.
Reference On /	/ around the ankle or the proc. spin. of C7.
ixation (Dou	uble sided) tape / rings or elastic band.
Distance 20m	nm between the electrodes.
electrodes placement	

European concerted action in the Biomedical Health and Research Program (BIOMED II) of the European Union. The SENIAM project has resulted in European recommendations for sensors and sensor placement procedures and signal processing methods for SENIG, a set of simulation models are ducation and testing, a set of test signals, eight books, publications and a European network for SENG. The SENIAM project (Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles) is a