Improvement of rehabilitation possibilities with the MotionMaker™

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[*] ***Abstract* – "MotionMaker™" is a stationary programmable test and training system for the lower limbs developed at the 'Ecole Polytechnique Fédérale de Lausanne' with the 'Fondation Suisse pour les Cyberthèses'. The system is composed of two robotic orthoses comprising motors and sensors, and a control unit managing the trans-cutaneous electrical muscle stimulation with real-time regulation. The control of the Functional Electrical Stimulation (FES) induced muscle force necessary to mimic natural exercise is ensured by the control unit which receives a continuous input from the position and force sensors mounted on the robot.**

First results with control subjects showed the feasibility of creating movements by such closed-loop controlled FES induced muscle contractions. To make exercising with the MotionMaker™ safe for clinical trials with Spinal Cord Injured (SCI) volunteers, several original safety features have been introduced. The MotionMaker™ is able to identify and manage the occurrence of spasms. Fatigue can also be detected and overfatigue during exercise prevented.

***Index Terms* – Rehabilitation robotics, functional electrical stimulation, closed-loop control, neural plasticity.**

I. Introduction

Many complications impair function and quality of life of Spinal Cord Injury (SCI) patients: muscular atrophy, restriction of joint mobility, spasticity, osteoporosis, poor blood circulation in the affected limbs, bedsores, loss of cardiovascular fitness as well as sphincter problems [1] [2] [3]. From the beginning of the paraplegia, regular mobilization of the paralysed limbs is mandatory in order to prevent secondary damages due to immobility and the resulting circulatory problems. The benefits, of adding functional electrical muscle stimulation (FES) to the mobilization program have been shown during the last 10 years [4] [5] [6]. Moreover, FES can be used to stimulate and develop recovery of some voluntary motor activity especially in incomplete SCI and stroke patients. For optimal gains FES must mimic natural movements as closely as possible. Classical FES systems may be able to follow the natural sequence of activation of the muscles involved in a movement, but are unable to adapt the intensity of stimulation of each muscle as the movement is going on. A closed-loop control of the FES is essential to achieve complex and repetitive movements such as press-leg, cycling and walking similar to those occurring naturally. The closed-loop control technology allows reproducing the kinematics and the dynamics of the natural movements as closely as possible and such movements might have an increased impact on the neural plasticity in the spinal cord and the brain.

Eager to create innovative methods of rehabilitation, the 'Fondation Suisse pour les Cyberthèses' (FSC) initiated a program focused on the development of rehabilitation and overground walking assistance devices based on the association of an orthotic system with the electrical muscle stimulation. This paper deals with the first device developed within this program. The MotionMaker™ (Fig. 1) is a stationary training system which allows to carry out fitness exercises with active participation of the paralysed limbs [7].

The limbs are only attached to the orthoses at the foot level to simulate natural ground reaction forces. The orthopaedic liaisons on the limbs are only guides to avoid hip adduction and abduction and knee overextension.

The calf and thigh segments are adjustable in length for people from 1.50 (4'11") to 1.90 metres (6'3") in height.

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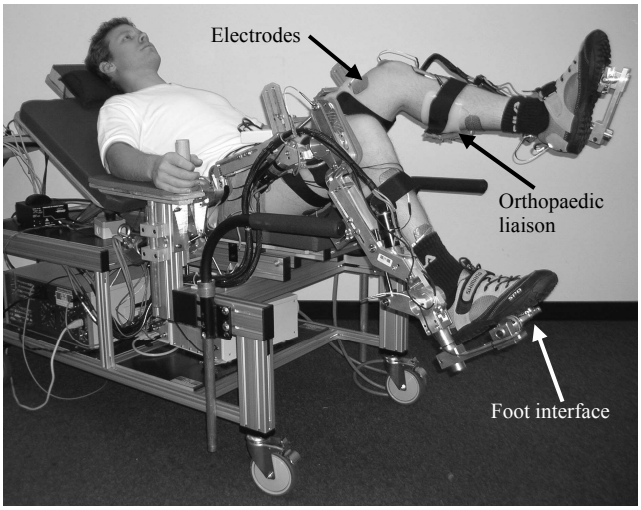

Fig. 1 MotionMaker™ prototype with an uninjured subject.

The two orthoses with 3 degrees of freedom (hip, knee and ankle) are moved by electrical actuators. Position and force sensors (Fig.2) are mounted on each joint to give the information needed for both motion and FES control.

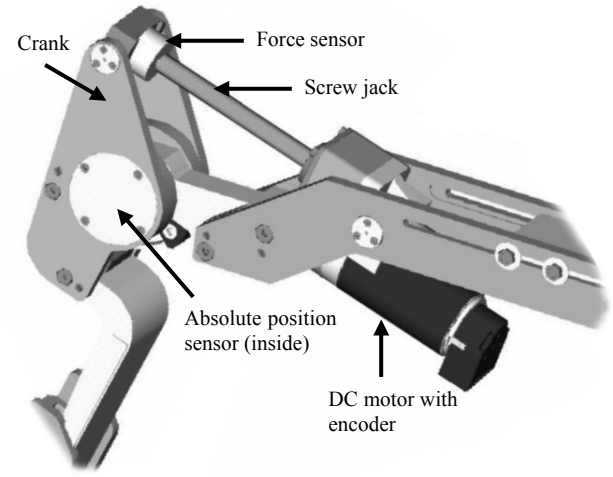

Fig. 2 Detail of the knee joint. Crank and jack architecture with absolute and relative position sensors and force sensor.

The crank and jack solution gives, as it is with human muscles, a maximum torque output depending on the joint angle. The optimisation of the torque–angle characteristic (Fig. 3) allows to follow the shape of human performances with minimisation of the size of the motors.
The same principle has been used for the hip, knee and ankle joint. The maximum output torque and the range of motion specific to the joints guided the adjustment of the dimensions of the crank and of the jack.

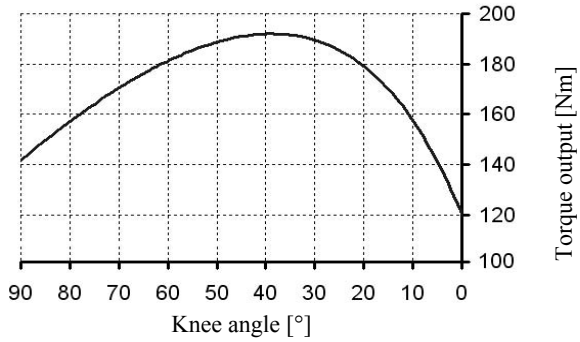

Fig. 3 Torque output of the knee joint regarding the knee angle with a constant motor torque.

The electrical stimulation of the muscles is carried out with our own electrical stimulator "StimWave2", especially designed to match the needs of the MotionMaker™. It allows real-time modification of all the parameters of the stimulation signal for 20 channels with a deterministic rate of 0.5ms per channel. These performances are necessary for our closed-loop control of FES.

II. Preliminary tests

Preliminary tests have been performed with uninjured subjects (Fig. 5) to confirm the feasibility of FES with a closed-loop control of muscle activation. The control algorithm includes a model based feed-forward and a conventional regulator (Fig. 2).

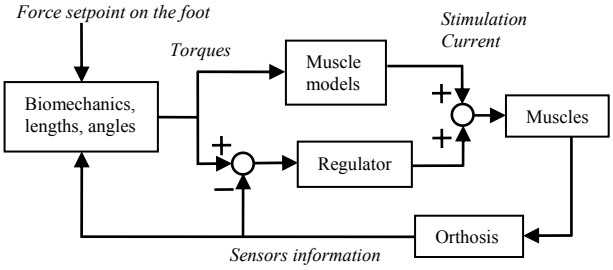

Fig. 4 Functional electrical stimulation control diagram using models of the different stimulated muscles and an orthosis.

This control algorithm was evaluated on press-leg exercises with horizontal movements of the ankle in the cartesian space (X, Y); with the subject lying on dorsal decubitus. The same movement is currently used in the clinical trial. The two following graphs show the result of 3 movements, extension-flexion, with a 30N force setpoint on the foot. In Fig. 5 we see the torques setpoints (HTs, KTs, ATs) and the measured torques (HTm, KTm, ATm) for hip, knee, and ankle. Stimulated muscles are the gluteus maximus and the quadriceps. The same movement is also used in the clinical trial.

Fig.6 shows, for the same exercise, the position of the ankle (Apos), the vertical measured force (FYm) and the horizontal measured force (FXm) following the force setpoint (FXs).

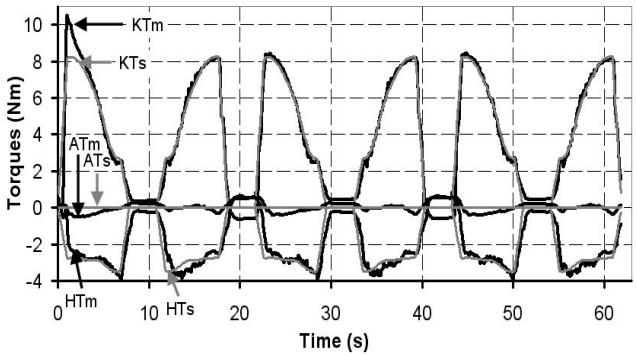

Fig. 5 Torques setpoints for Hip, Knee and Ankle: HTs, KTs, ATs, and Torques measured: HTm, KTm, ATm.

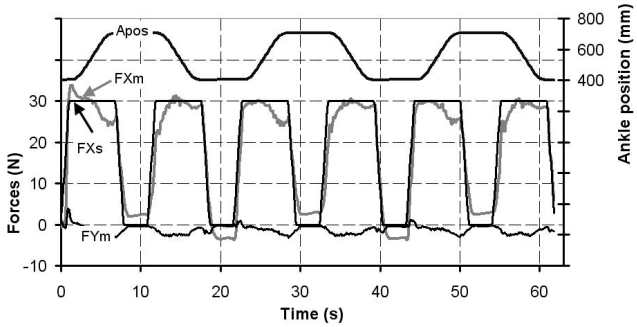

Fig. 6 Horizontal force setpoint (FXs) and measured (FXm), vertical force measured (FYm) during 3 horizontal movements of the ankle (Apos).

The positive results of this feasibility study were a prerequisite for starting a clinical evaluation of the MotionMaker™ with SCI individuals.

Before starting the clinical trial, some modifications have been done to improve safety for the volunteers and to facilitate the work of the therapist.

II. Clinical trial

For the first clinical trial the same leg-press movement as the one described for the feasibility study has been used. The main goals of this trial was to validate the feasibility of performing FES controlled movements with SCI patients, to increase the voluntary strength in patients with incomplete spinal cord lesions and to study the effect of FES induced exercises on spasticity.

The values of torques, forces and power measured during the exercises will be analysed in order to identify objectively increases or decreases of performances along the clinical trial. Benefits in terms of muscle strengthening will be considered significant either if:

a. The enhancement of the electro-stimulated strength is at least 20% between the start and the end of the investigation without significant stimulation amplitude increase. This value will be quantified by the ratio between power output (Watts) and stimulation input (mA).
b. The remaining voluntary strength is increased by 20% between the start and the end of the investigation. This value will be quantified by means of the power output (Watts) by exercise repetition.

The ethical committee of the University Medical Centre Lausanne, Switzerland, examined protocol and risk analysis and approved the trial. The risk analysis concluded that exercising with the MotionMaker™ is safe. The only critical risk identified for the subjects are bone fractures if osteoporotic bone is overloaded by FES induced muscle contractions and occurring spasms. To minimize this risk, the patients recruited for the trial underwent a bone density analysis as described in [8]. Subjects with a trabecular bone mineral density under 148mg/cm3 for the distal femur or under 92mg/cm3 for the distal tibia (worst affected side) have been excluded. We also developed a strategy for detecting and treating spasms to reduce the stress on joints, ligaments, muscles and tendons.

Preliminary results of the trial are now available and given in part V. Clinical reasults.

III. Safety management

A. Spasm detection

Spasms are mostly short, strong, sometimes explosive involuntary muscular contractions. They are a risk because of their uncontrollable nature and their violence. However they might have the advantage of activating the paralysed musculature and putting the bones under stress, thereby maintaining a degree of muscle bulk and reducing bone mass loss.

In some paraplegic subjects the stimulation current used for muscle contraction and the forces applied on the feet can induce spasms. These spasms produce a rapid increase of the torques measured on the orthoses. We observed this phenomenon during previous clinical trial with incomplete SCI subjects on a simpler device, a knee orthosis [9]. More precisely, subject BD (female, lesion C7, impairment C on the American Spinal Injury Association scale) produced quadriceps spasms when stimulated. We stabilised the knee torque by freezing the quadriceps stimulation amplitude (QA) and the knee angle (KA) for 2 seconds after spasm detection (Fig.7).

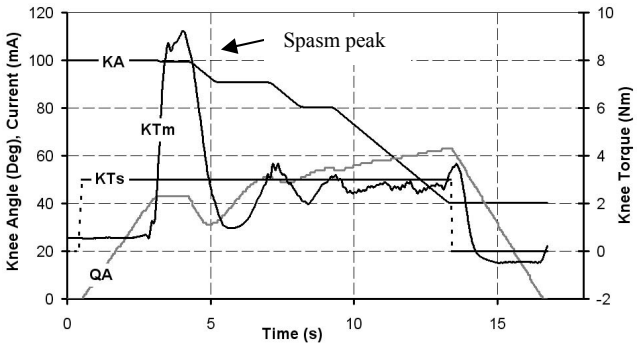

Fig. 7 Spasm management with an injured SCI subject during a closed-loop FES knee extension with a knee orthosis. KA: Knee Angle, KTm: Knee Torque measured, KTs: Knee Torque setpoint, QA: Quadriceps current Amplitude.

This method did not give the high degree of safety expected from a medical exercise device. For the MotionMaker™, we improved the strategy to ensure better stabilisation performances and to reduce joint and bone stresses. After detecting spasm peaks, the MotionMaker™ starts the spasm management program (Fig.8). The stimulation amplitude is reduced to a predefined value, here 15mA, and the motors are controlled in a static position with some compliance to reduce the stresses on bones and joints. The sensitivity of spasm detection and the stabilisation current amplitude can be tuned by adjustable values on the graphical user interface. Moreover, the algorithm unfreezes the robotic joints and restarts the stimulation control only when all the measured torques (HTm, KTm and ATm) return near the torques stepoints (HTs, KTs and ATs).

Fig. 8 shows an uninjured subject simulating a knee spasm and the corresponding MotionMaker™ reaction.

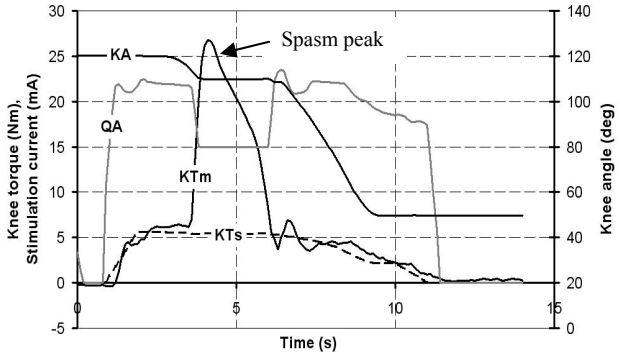

Fig. 8 Management of a knee spasm simulated by an uninjured subject during a press-leg extension with closed-loop FES. KA: Knee Angle, KTm: Knee Torque measured, KTs: Knee Torque setpoint, QA: Quadriceps current Amplitude.

This improved method gives much better performances. Joint and bone stresses are less because the stimulation amplitude is reduced during the spasm and thanks to the joint compliance. Appearance of a spasm is automatically notified in the exercise report to inform the therapist.

B. Fatigue detection

Two variables are used to calculate fatigue. The first parameter is the amplitude of the stimulation current witch defines the spatial recruitment of the muscle fibres. The second parameter is the decrease of power output measured during the exercise.

At the beginning of the exercise only the muscle fibres close to the surface of the members are stimulated. Quickly, the fatigue of these fibres requires an increased stimulation current to recruit deeper muscle fibres and maintain the preset target output torque. As fatigue progresses, higher and higher stimulation currents are needed to recruit deeper muscles fibres. Total fatigue appears after the recruitment of all muscle fibres. At that stage of fatigue, the power output decreases in spite of the increase of the stimulation current up to the maximum level tolerated by the subject. For the clinical trial, we calculate fatigue by comparing the ratio muscle power output / stimulation current (W/mA) of each repetition with the first repetition. Fig. 9 shows an example of 6 repetitions studies on an uninjured subject. Fatigues for both legs are plotted against the number of repetitions.

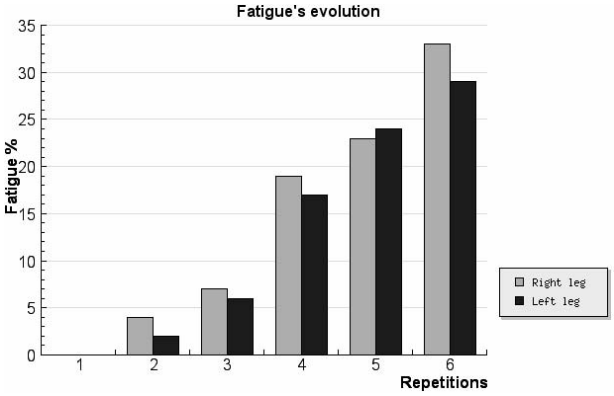

Fig. 9 Fatigue monitoring for a 6 repetitions exercise.

The fatigue of the first movement is 0% by definition and fatigue of 100% means an output power reduced to 0 Watt.

IV. PHYSICIAN'S WORK

This section presents the scenario for the future use of the MotionMaker™ in a clinical context.

Through an electronic link with the MotionMaker™ the physicians or therapists prescribe a set of exercises they can find in a list of predefined exercises designed for specific therapeutic aims, such as growth of the muscular mass, improvement of joint restrictions, stimulation of blood circulation, control of spasticity, etc. Moreover they define the parameters to be used for each exercise such as total number of repetitions, frequency of sessions, torque limits, amplitudes of joint movements, maximum stimulation current, etc.

Before performing a session, patients identify themselves on the MotionMaker™. The system retrieves the exercises that have been prescribed and allows the patient to accomplish them.

The physicians or therapists will then, still from their office, assure the monitoring of their patients, i.e. checking which exercises have been achieved, and for each exercise performed, display a set of graphs summing up the performances of the patients. These graphs can represent the voluntary force developed by the patient, active joint torques, power output, stimulation current amplitudes, evolution of fatigue during an exercise, and the apparition of spasms. This monitoring tool allows the comparison of performances over several weeks (Fig 10.), to measure progress or to modify the treatment if appropriate.

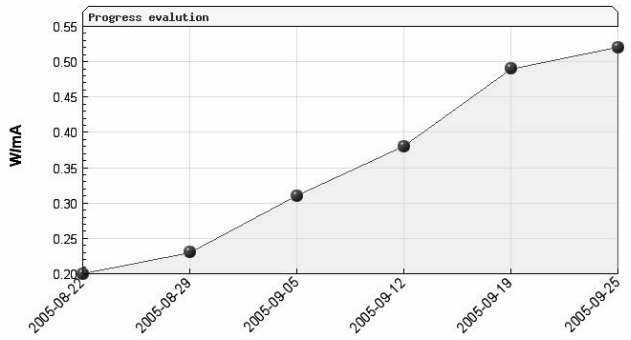

Fig. 10 Simulation example of evolution in output power after 6 weeks of training.

This solution based on distributed applications, (one dedicated to the prescription and monitoring, one dedicated to the execution of the exercises on the MotionMaker™), and communicating through a centralized database provides a very high performing and efficient tool to physicians and therapists for prescription and monitoring the patients. Each prescribed and performed exercise, as well as all the performances of the patients, is stored for as long as desired in the database.

V. Clinical reasults

A first clinical trial is now reaching its end. 5 SCI subjects – 4 with an incomplete and 1 with a complete spinal cord lesion – started a two months training program on the MotionMaker™. They accomplish a one hour press leg training session every 2 days. Press-leg movements were performed by stimulating alternatively the leg extensor muscles (gluteus maximus, quadriceps and gastrocnemius) and the leg flexor muscles (hamstrings and the tibialis anterior).

All subjects were able to complete the whole training program. There was no drop out. The MotionMaker™ demonstrated its excellent capacity to detect and manage the occurrence muscle spasms. None of the participants felt unsafe at any time during the training sessions. They all appreciated the safety features of the MotionMaker™ especially the spasm management program. There was no musculo-skeletal incident during the trial. At the end, all subjects declared to be happy having joined the trial.

A preliminary analysis of the results shows a marked effect of the training on the MotionMaker™ on spasticity. 3 of our 5 subjects are known for a marked hypertonia (levels of 3 to 4 on the modified Aschworth scale [10]) and limbs difficult to be mobilized manually by therapists. After one hour exercise, the hypertonia decreases to levels of 0 to 1 which means an almost normal tonus.

The subjects with incomplete SCI were able to develop more voluntary strength with electrical stimulation than without and noticed an increased awareness for muscle activity during electrically induced muscle contractions. Thus, an increased sensory input to the neuronal circuits involved in motor control might facilitate voluntary motor activity.

After one and a half month of exercise with the MotionMaker™, 3 out of the 4 subjects with an incomplete SCI lesion were able to develop a voluntary force of more than 150N during a leg-press movement without the help of the electrical stimulation. At the beginning of the trial none of them was able to do so. This might be explained by an increased force production by the muscles due to an improved contractile machinery, by an improved function of the spinal motor system related to neuronal plasticity or and an increased central motor drive by reactivation of dormant central motor activation schemes.

These preliminary results are already demonstrating the usefulness of the MotionMaker™ for improvement of function in SCI patients. More detailed results will be presented after the complete analysis of our data.

VI. Conclusion

The MotionMaker™ is a new robotic system providing innovative rehabilitation possibilities for patients with SCI lesions. However, patients with other types of lesions of the central nervous system might also benefit from such a training device. The training programs offer the patient the opportunity to do controlled exercises with electrically induced, voluntary or combined muscle action. This new type of exercising stimulates not only the residual motor function but might also enhance the potential for relearning voluntary activity by inducing neural plasticity. The control of the stimulated muscle force necessary to mimic natural exercise is ensured by a central control unit which receives a continuous input from the position and force sensors mounted on the robot and adjusts in real-time the stimulation currents of the 20 channel stimulator to obtain the desired set-points for force and speed.

A first clinical study with the MotionMaker™ involving 5 SCI subjects is very promising in terms of results and usability of the device.

The development of the MotionMaker™ as a diagnostic tool for measuring joint restrictions, spasticity, muscle force and endurance, etc. is under way. Special training programs for joint restrictions, spasticity, osteoporosis etc. will be created and tested.

Industrialization of the prototype shown in Fig.1 started under the auspices of the FSC and commercialisation of the MotionMaker™ will follow.

Acknowledgment

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