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RehaMove®

Medical Benefits of FES Cycling in Complete Paraplegic Individuals

- A scientific Overview -

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Hardware and Software for Medicine

A spinal cord injury (SCI) is an incident that causes significant changes for a patient within a relatively short time span. These changes happen on a physiological, histological and morphological level.

They can lead to muscle atrophy, a reduction in muscle mass, a decreased ability of the muscle to contract as well as transformations of type I muscle fibers to type II muscle fibers. Apart from that a higher muscle tone in terms of spasms can occur due to a damage of the first motor neuron.
Secondary diseases as in the cardiovascular system and a reduced cardiopulmonary endurance and fitness are also developed more frequently (Bauman WA, 1992).

At the moment, Functional Electrical Stimulation (FES) is the only option for an adequate non-compensatory training of affected extremities. The regular passive motion therapy of the lower extremities that is performed as prophylaxis against contractures and thromboses has in fact no significant impact on the muscle.

The original intention for the use of electrical stimulation in paraplegics was described by Newham (2007) as restoring the ability to walk. From a technical point of view this was, however, difficult to achieve due to the manifold degrees of freedom in the human gait as well as the factor of balance.

For that reason HASOMED GmbH made the products RehaMove and RehaBike available. Both systems enable the user to actively train their muscles empowered by electrical stimulation.

Today electrical stimulation is used to minimize further damages after a spinal cord injury, i.e. to stop mentioned changes, as muscle atrophy, or even reverse them. Furthermore, an increased efficiency in the rehabilitation process plays a significant role. Functional Electrical Stimulation can help to achieve therapy goals more rapidly and thereby minimize running costs.

Operating principles of the RehaStim device

The method of electrical stimulation makes use of surface electrodes attached to the skin in order to stimulate nerve endings with electrical impulses. These finally produce a smooth contraction of the relevant muscle.

The electrodes are connected with a cable to a portable stimulator which generates electrical pulses. These pulses trigger the nerves of the paralyzed muscle in a way that it contracts. The contraction generates a movement which again has a beneficial impact on the metabolism and the blood circulation.

With such combined respectively synchronized stimulation of various muscle groups, physiological effects associated with muscle activity can be multiplied and functional movements (=Functional Electrical Stimulation) be generated. Furthermore, motion sequences can be programmed and exercised in combination with a movement exerciser.

Therapy goals of the Functional Electrical Stimulation with the RehaMove

- Build-up of muscle mass, strengthening of muscles and increase of endurance for relevant extremities
- Prevention of atrophy in affected extremities
- Support of metabolic processes: blood pressure stabilization, promotion of blood circulation and metabolism, improvement of the cardiopulmonary capacity
- Reduction of spasms

All studies listed below describe the method of Functional Electrical Stimulation in combination with cycling, so called FES-cycling or FES-leg cycle ergometer (FES-CE), a term commonly used in literature. Sorted by therapy goals, they provide an overview of the effectiveness of Functional Electrical Stimulation with the RehaMove. Please take precise information on effects and level of significance from the full texts which are provided on request.

Goals of the Functional Electrical Stimulation with RehaMove

1. Build-up of muscle mass, strengthening of muscles, increase of endurance for arms or legs

In a study overview published in 1998, Janssen, Glaser and Shuster confirmed the assumption that FES supported training has a promising therapeutic benefit for SCI patients. They describe a physical and mental growth of fitness as well as a reduced risk of secondary damages. At the same time they argue that it is necessary to carry out controlled longitudinal studies with the largest possible sample size to have clearer evidence for the effectiveness of FES supported therapy.
In the field of muscular performance the authors indicate significantly improved work performance (work respectively power output), an improved working against resistance, an improved torque in the quadriceps muscle as well as a significantly improved isometric force. As possible (causal for this) adaptation processes, muscle hypertrophy, transformation of FT to ST fibers in the muscle, an increased concentration of oxygen enzymes and mitochondria, a higher density of capillaries and increased arterial blood flow are described.

Demchak (2005) examined in a controlled study the effects of FES on the muscle performance and muscle morphology. He was able to prove an increased efficiency (power output) ($p<0.05$) as well as a smaller loss of the muscle fiber cross section ($p=0.05$) in the FES-CE experimental group.
Comparison groups consisted on the one hand of SCI control patients, on the other hand of healthy subjects. The sample size contained only 5 persons per group– a possible limitation in quality mentioned by the authors themselves. Here, too, an early intervention for achieving stated results is emphasized (4-6 weeks after trauma).

In the multi-centred study carried out by Duffell at al. (2008), FES-supported therapy shows highly significant improvements of the muscular strength (quadriceps muscle) in paraplegic patients. A group of 11 SCI patients exercised over a period of one year 5x60 minutes/week. The comparison group consisted of 10 healthy subjects. The resulting parameters maximal torque (increase about 673% after 12 months, $p = 0.012$), fatigue resistance and performance (power output, improvement after 6 months about 177%, $p < 0.05$) partly show highly significant improvements.

Relevant is the work of Duffell because it examines a period of one year combined with a stronger intensity (5h/week). Other studies mentioned here work with lower intensities. In comparison with, e.g., the study generated by Mohr and colleagues, the authors mention that in that study - in spite of a lower intensity - a greater overall improvement exists.

Mohr et al. (1997) carried out a study with 10 SCI patients being exercised with FES-CE over a period of one year up to 3x30 minutes/week. It involved a stimulation of the following muscles: gluteus maximus, quadriceps, hamstrings (surface electrodes). At the conclusion of the investigation, significant improvements in all parameters are visible: the performance increased from 4 KJ to 17 KJ ($p < 0.05$) and max. oxygen uptake (VO2) from 1.2 liter to 1.43 liter ($p = 0.05$). Furthermore, an increase in muscle mass of 12% ($p < 0.05$) as well as changes in muscle fiber composition were noticed.

In a clinical study carried out by Sloan and colleagues (1994) it was shown that a three-month stimulation program in combination with physiotherapy can cause a significant improvement of muscular strength, endurance and mass of the muscle. During the study, 12 SCI patients were treated over a period of three months (<1 year post-trauma, complete paraplegia) 3x/week with FES supported cycling.

The training was personalized depending on the current performance level of the patient (individual time unit, max. 30 minutes). The outcome variables arbitrary isometric force, isometric force (stimulation) and endurance (stimulation) improved significantly ($p<0.033$, $p<0.011$, $p<0.014$). The quadriceps muscle also showed a significant increase of the cross section ($p<0.002$). The arbitrary isokinetic force and the biceps muscle, however, showed no statistically significant changes. The authors mention that due to the small sample size no separate statistical analysis of patients <1 year after trauma and patients >1 year trauma could be done. Therefore no statements can be made in this context about the period of time elapsed since the trauma as an influence on the results.

2. Prevention of atrophy at relevant extremities

Janssen, Glaser und Shuster (1998) mention in the article on page 6 a significant hypertrophy of the stimulated muscles. This statement is based on the research work of Sloan et al. (1994) and Baldi et al. (1998).

Wilder, Jones, Wind and Edlich describe in a review of 2002 a hypertrophy of the stimulated muscles and recommend to exercise 3x30 minutes/week. Furthermore, changes of the muscle fiber types in favor of fatigue resistant fibers are mentioned. The authors refer to the works by Mohr (1997), Baldi (1998) and Sloan (1994) that will be discussed below.

The authors emphasize the importance of FES supported cycling for SCI patients. The prevention of secondary problems (and therefore fewer hospital stays), the preservation of manpower as well as a better self-perception are important parameters for patients in terms of their individual quality of life.

3. Support of metabolic processes: blood pressure stabilization, promotion of blood circulation and metabolism, improvement of cardiopulmonary capacity

Davis, Nur and Fornusek published a systematic review (2008) whereby a systematic research in electronic databases (1900-2007) as well as a manual search in journals and conference proceedings was conducted. Since a sufficient number of randomized controlled studies respectively quasi randomized studies had not been found during search, the authors also included non-randomized and controlled studies. 177 publications met the inclusion criteria. The authors summarize that there existed positive effects of the FES induced exercise in the fields of health and fitness. Although the improvements were lower than those of healthy subjects, the tendency to an improvement in the field of muscle morphology (muscle size) and metabolism (aerobic fitness, higher exercise capacity) was visible.

In the field of cardiopulmonary fitness, Janssen, Glaser and Shuster (1998) describe improvements of the oxygen uptake (VO2) as well as of the stroke volume (significant) and the heart rate. From the author's point of view, an FES supported training for quadriplegics is, with regard to the mentioned improvements, more effective than a (compensatory) training of both arms. The peripheral blood circulation would also be improved by FES supported cycling and thus the risks of thromboses, edema and orthostatic complaints could be reduced.

Wilder, Jones, Wind and Edlich describe in their review (2002) the need for SCI patients to carry out an aerobic training program. According to the authors, the FES ergometer is the only FES combination that allows patients to exercise cardiopulmonarily in sufficiently high intensities. Furthermore, the FES ergometer offers the possibility to improve even the circulation of the lower extremities. For best possible results, Wilder and colleagues recommend a training intensity of 3x30 minutes/week.
Regarding the parameters oxygen uptake (VO2) and work performance, the authors refer to clinical studies carried out by Mohr (1997) and Hooker (1995) (see below).

The study carried out by Mohr et al. (1997) has been mentioned more detailed in point 1 (Build-up of muscle mass, strengthening of muscles and increase of endurance of the muscle on relevant extremities). In a group of SCI patients, the authors were able to prove an increase in oxygen uptake (VO2) from 1.20 liter to 1.43 liter (after 12 months). These results are statistically significant ($p<0.05$) and therefore very important.

Against the common opinion to exercise at least 3x/week, Hooker et al. (1995) prove that even a training performed 2x/week causes significant improvements of the cardiorespiratory function. Here, 8 male SCI patients exercised over a period of 19 weeks 1-2x/weekly 30 minutes with the FES ergometer. However, significant improvements were visible for the parameter maximum oxygen uptake only (VO2) (+10%, $p \leq 0.05$).

In a 6 week training program, Gerrits and colleagues (2001) show significant improvements in the fields of arterial blood circulation (A. femoralis, A. carotis communis) ($p<0.01$), systolic flow volume (peak) ($p<0.01$) and flow volume on average ($p<0.05$). In the clinical study 9 male SCI patients were treated with FES-CE over a period of 6 weeks. According to the authors a relatively short training program can also improve the arterial diameter and the blood circulation of the legs.

As shown in a publication of 2008 by Berry et al., FES supported training can also be accomplished successfully at home. A training performed at home with 9 male and 2 female SCI patients showed improvements in the variables max. oxygen uptake (VO2) (increase of 52%, $p<0.001$) and O2 uptake/heartbeat at rest (increase of 34%, $p=0.002$). These highly significant improvements occurred within the first 6 months after training.

The authors conclude that an intensive training with an FES bike at home under mentioned conditions can effect a significant improvement of the cardiorespiratory fitness and of the performance (power output= increase of 132%, $p=0.001$).

4. Reduction of spasticity

In the field of the reduction of spasticity after electrical stimulation a lot of research has been done. However, many studies report a treatment with TENS or other electrotherapeutic methods without a functional component. Robinson (1988) mentions positive effects on the tonus of relevant extremities due to the treatment with TENS.

Granat (1993) worked with FES for gait training. As a consequence, the spasticity of 4 out of 6 patients was reduced. Campbell (2002) of the International Functional Electrical Stimulation Society (IFESS) concludes from the previous research results:

- The use of surface electrodes for the stimulation of muscles resulted in reduced spasticity and improved function
- If electrical stimulation was not sufficient to cause a reduction of the tonus, a combination of electrical stimulation and drug therapy made sense
- The maximum benefit of electrical stimulation in the reduction of the tonus would be achieved after a period of 1-3 months (daily stimulation for 1-2 hours)
- An improved situation of the muscle tonus would improve the voluntary muscle control and extend the active range of motion

http://www.ifess.org/Services/Consumer_Ed/SCI.htm

Krause, Szecsi and Straube (2008) examined the effects of FES cycling on spasticity in 5 SCI patients. In a crossover study the authors compared FES cycling to passive cycling on the ergometer. Here, significant improvements of the examined parameters Ashworth Scale and pendulum test for the FES cycling intervention were shown. Even after a purely passive exercise, the patients improved significantly on the Ashworth Scale but in the pendulum test only in one field of the measurements. The differences between the groups are significant.
The authors discuss their results and mention that the period during which the effects of the stimulation persist is still uncertain. In addition, there would be a divergence between objective measurements and subjective impressions of the patients being asked for the reduction of spasticity. Furthermore, they describe a relatively small sample size (5 persons) as a limiting factor.
The authors come to the conclusion that FES supported training on the ergometer is an effective method to reduce the muscle tonus of SCI patients, and in this context it seems to be superior to a purely passive motion training. During the investigation no side effects occurred.

Van der Salm and colleagues (2006) examined in 10 SCI patients the influence on spasticity during the application of 3 different electrotherapeutic methods. They stimulated either agonist, antagonist or in the dermatome of the triceps surae muscle.
They concluded that the stimulation of the agonist (i.e. of the triceps surae muscle), in comparison to the placebo controlled comparison group, may lead to a reduction of spasticity ($p<0.001$). The spasticity had been measured using the Modified Ashworth Scale.

Summary

As a summary it can be said that for the population of SCI patients considerable effects for described target parameters can be observed in different studies. These prove the effectiveness of FES in this patient group. From presented research it can be concluded that a stimulation taking place 3x/ week for about 30 minutes already causes significant improvements.

The requirement for starting the treatment with functional stimulation as early as possible in the acute phase becomes apparent. Further research is necessary to confirm the effects shown above. The implementation of randomized and blinded high quality studies as well as larger sample sizes is also preferred. With further randomized- controlled studies it would be possible to create e.g. meta-analyses or systematic reviews on a considerably high level of evidence.

Apart from that there is the necessity to find out what kind of stimulation parameters provide best results to improve health and fitness (Wilder 2002, p. 171).

One further task is the broadening of FES treatment programs to patients with other medical conditions e.g. stroke or traumatic brain injury (ibid.).

Last but not least FES cycling plays an extremely important role for each individual. It enables – in addition to described beneficial effects - the implementation of a physical activity and thereby, in terms of an improved participation, leads to a better quality of life.

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Your notes

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