



The Inventions Method

- follow up and long term use of a new possible therapy for patients with spasticity

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Facts about the Inventions method

- The principle of the method is based on reciprocal inhibition.
- It reduces muscle tonus and improves locomotion in patients with spasticity.
- It is effective in relieving spasticity caused by cerebral palsy, stroke, multiple sclerosis as well as other forms of brain injury.
- 100% of the patients in the present study experienced improvements of function or quality of life and 90% were overall positive to the therapy.
- Only few and mild side effects have been reported.

Introduction

Spasticity is a sign of upper motor neuron dysfunction caused by brain injury and it results in paresis, immobilization and adaptive shortening of joints and muscles (Gracies, 2005). The chronic disuse of paretic muscles is accompanied by long-term adjusting rearrangements of the central and peripheral nervous systems. For patients with spasticity, the physical limitations caused by the condition often have severe impact on daily living and it will result in high societal costs due to sickleave and expensive treatments. However, a paretic limb may in some cases also be beneficial for the patient since it facilitates activities such as standing or walking which in turn protects against formation of deep venous thrombosis.

Electrical stimulation has previously been shown to be effective in reducing spasticity and increasing mobility (Robertson et al., 2006). Based on this finding, the Inventions method was developed as a new and refined strategy for treating patients with spasticity. The principle of the method is based on reciprocal inhibition, i.e. upon contraction of a muscle, the antagonistic muscle will relax to not counteract the movement. Through stimulation of antagonistic muscles, the Inventions method will hence reduce tonus of the spastic muscles. The majority of patients using the Inventions method today have been diagnosed with spastic or dyskinetic cerebral palsy, however, it has also been used to successfully reduce spasticity in patients with multiple sclerosis, spinocerebellar ataxia, dystonia, stroke and other forms of acquired brain injury. The device is easy to apply and can readily be used

at home, at care centers or at work as well as during physical exercise or rehabilitation. To obtain optimal effect, the recommended use of the Inventions method is approximately 60-90 min every other day which in most patients will result in reduced spasticity and improved locomotion for up to 48 hours.

Materials and Methods

The Inventions method

The Inventions method is used to stimulate skeletal muscles (antagonistic to the spastic muscles) at a frequency of 20 Hz, and a pulse width of 30 μ s. The electrodes cover both the upper and lower part of the body. The selection of stimulation sites is dependent on clinical diagnosis and the voltage applied to the electrodes is adjusted to suit every patient individually. A map of representative electrode positions is shown in Fig 1. The recommended use of the Inventions method is 60- 90 minutes/day, 3-4 times a week, and 80% of the patients has used it weekly during the study period (Fig 2A). For optimal effect, the method can be used in combination with conventional physiotherapy and it may continue as long as a positive effect of the method is obtained.

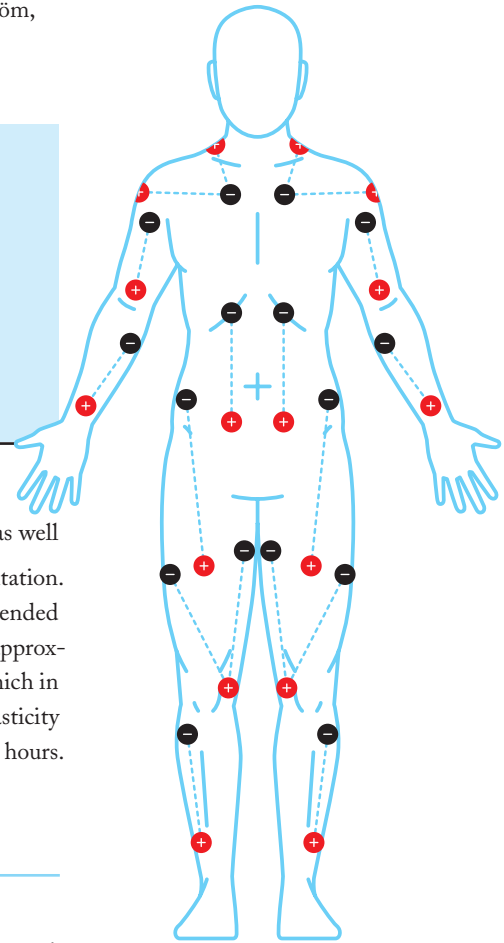
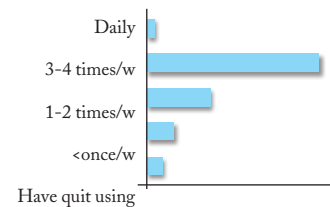


Fig 1. Representative map of the electrode positions used by the Inventions method.

Reported use of the Inventions method



Diagnoses

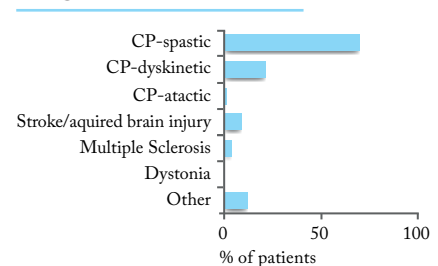


Fig 2 A,B. A) Reported use of the Inventions method by the subjects participating in the study. B) Diagnoses included in the study. The data is presented as percentage of the total number of patients (n=117). w=weeks.

Study group

We evaluated the use of the Inventions method in 117 male and female subjects with different neurological diagnoses covering cerebral palsy (79%), acquired brain injury or stroke (8%), and other diagnoses (13%) such as dystonia and multiple sclerosis (Fig 2B). The majority of the subjects participating in the study were children or young adults, however, some subjects above the age of 50 were included (Fig 3). All included subjects have used the method 6-24 months at the time of the survey (average 12-15 months) also included. The patient's physical condition at the start of the therapy was defined as baseline level and all positive and negative changes observed thereafter were registered. The survey was completed by the Inventions method users themselves or when necessary, by an assisting caregiver.

Results

Based on the finding that low frequency electrical stimulation can reduce spasticity, we evaluated the use of the Inventions method in patients with spasticity. The results from the study showed an overall improvement of the general condition in 90% of the patients. Studying individual parameters (Fig. 5), the most pronounced effect was seen on locomotion which improved in 61% of the patients, while general spasticity was reduced in 60%. The ability to straighten the hand/fingers was improved in 46% and 34% of the patients respectively. In addition, the patients also reported improved balance, trunk stability, range of motion, mobility, speech, digestion, better mood, reduced pain, improved sleep quality, and an overall improved quality of life.

Age of patients

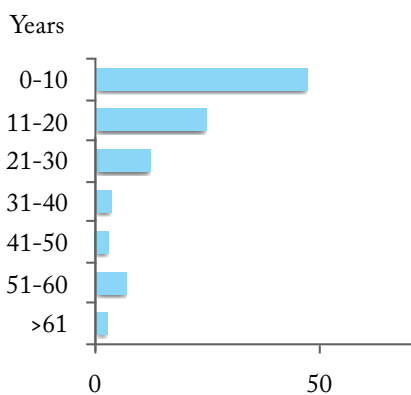


Fig 3. Age distribution of the subjects participating in the study evaluating the Inventions method. The data is presented as percentage of the total number of patients (n=117).

32% of the patients had planned spasticity treatments at baseline, and 90% of these patients could cancel these treatments due to improvement (fig 4A-B & 4D). 24% of the patients could stop using one or more assistive devices, such as wheelchair and walker (fig 4C and 4E). Interestingly, 100% of the patients participating in the study reported some form of improvements on either physical function or quality of life after being treated with the method. Only as little as 4% reported negative effects on digestion, mobility, spasticity and/or pain. In summary, the results from the present study showed that 90% of the patients were positive to therapy with the Inventions method, whereas only 3% were negative and 7% were neutral (Fig 4).

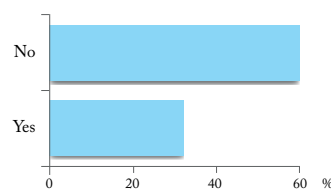
Discussion

The Inventions method offers a new strategy for treating patients with spasticity caused by brain injury. By applying low frequency electrical stimulation to antagonistic muscles, the tonus of a spastic muscle can be reduced. The method can be used as single therapy or in combination with other forms of treatments such as conventional physiotherapy. Several beneficial effects of the method have been reported such as improved mobility, reduced muscle tonus and pain as well as higher quality of life. The primary effects of the therapy may also be accompanied by secondary effects such as less need of personal

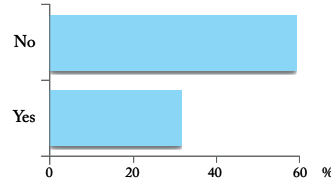
assistance, medication and surgery as well as lower societal costs.

The strategies commonly used for treating spasticity today involve different forms of medication, surgery, botulinum toxin injections and physiotherapy. These treatments may be effective in reducing spasticity, but they all have limitations and are associated with negative side effects. Baclofen for example, modulates pain by binding to gamma-aminobutyric acid (GABA) receptors however, an undesirable side effect of the treatment is muscular weakness, sedation and respiratory problems and not all patient benefit from the treatment (Ørsnes et al., 2000). Moreover, the drug has limited capacity to cross the blood-brain barrier and has to be administered through intrathecal injection into the cerebrospinal fluid to reach high concentrations. Tizanidine on the other hand acts as an alpha-2 adrenergic receptor agonist and has been shown to exert positive effects on spasticity in patients with stroke (Milanov et al., 1994). It is easy to use since it can be administered orally however, like baclofen, tizanidine is associated with undesirable side effects such as sedation, dry mouth and prolonged QT interval and in some cases also hallucinations (Brashear et al., 2008; Montane et al., 2004). Botulinum toxin injection is another form of treatment commonly used in patients with spasticity. It causes inhibition of acetylcholine release at the neuromuscular

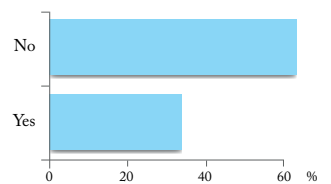
Planned spasticity treatments



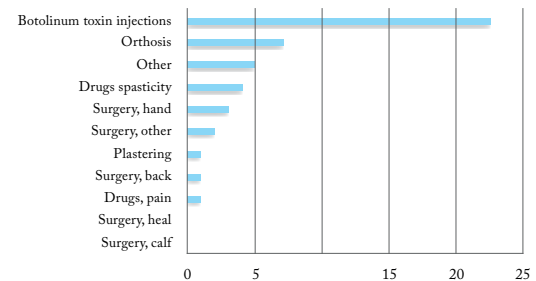
Cancelled spasticity treatments



Reduced need of assistive devices



Which treatment was cancelled?



Which assistive device was removed

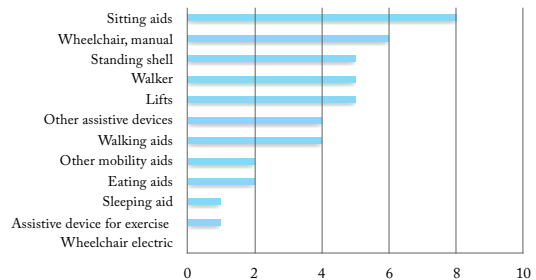


Fig 4A-E. A Percentage of patients with planned spasticity treatments, B Percentage of patients with one or more cancelled spasticity treatments, C Percentage of patients with one or more removed assistive devices, D Type of treatment cancelled, E Type of assistive device removed.

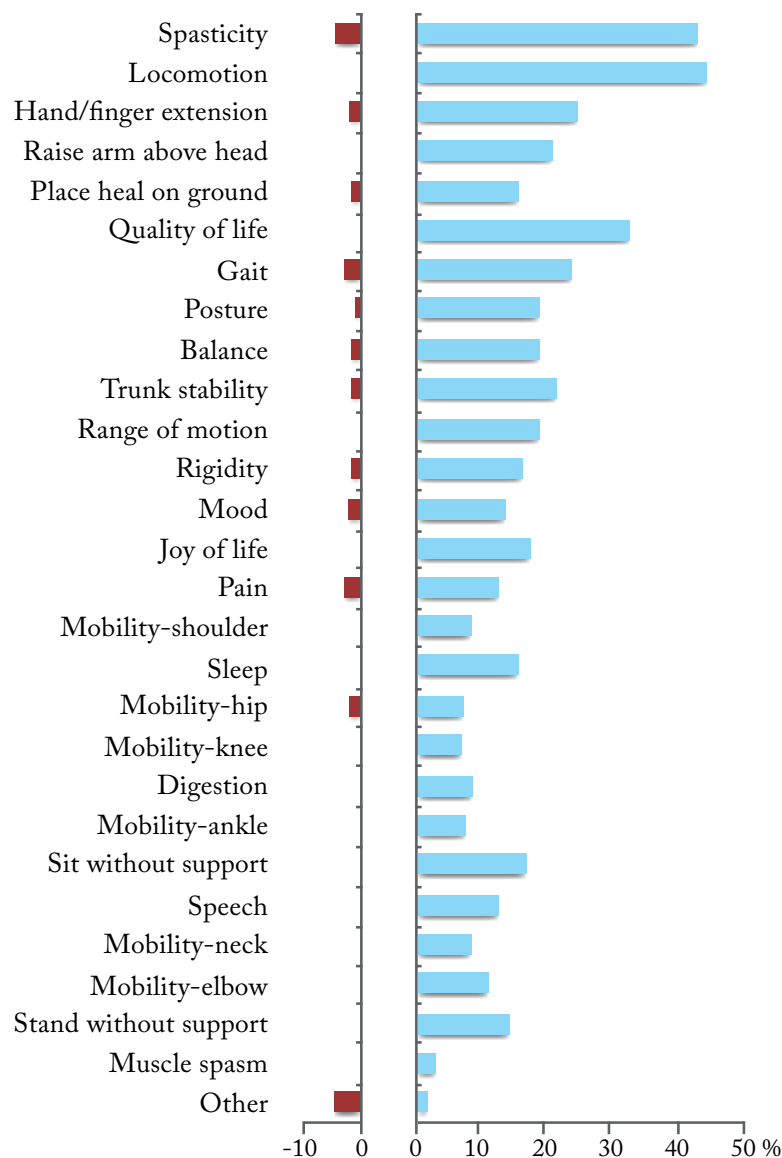


Fig 5. Reported effects of the Inventions method. Blue bars represent the percentage of patients reporting positive effects of the therapy whereas red bars represent patients reporting negative effects.

junction and a reversible block of synaptic transmission. The therapeutic effect is most pronounced two months after injection and the procedure has to be repeated as the effect wears off. Moreover, long-term treatment with the toxin may also result in formation of antibodies (Müller et al., 2009).

The Inventions method has been shown to have several beneficial effects in patients with spasticity and at the same time, it is associated with relatively few side effects. The effects of the therapy are evident already after 5–20 minutes which gives a direct quality control of the method. It is also highly motivating for the patient to observe such an instant effect of the therapy. Since the degree of spasticity may vary between patients depending on the clinical diagnosis as well as in a patient over time, it is important to treat every subject individually and adjust the device accordingly. The effect of the Inventions method usually lasts for 24–48 h (range

4–72 h) after which it gradually wears off. To obtain optimal effect, the therapy should be repeated 3–4 times/week. The Inventions method is not exclusive. It can be used in parallel with other treatments such as medication or botulinum toxin injections. It can also be used in combination with physiotherapy and physical exercise to reduce the activity of the α -motor neurons in the spinal cord (Gracies, 2001). Since the Inventions method was introduced in 2009 only few and relatively mild side effects such as urticaria around the site of the electrodes have been reported. Attention should be given to patients with different forms of heart conditions and it is not recommended to use the therapy in patients with heart failure or a pacemaker.

The mechanisms responsible for the direct effects of the Inventions method may partly be explained by reciprocal inhibition and possibly also by other reflex mechanisms. Preliminary unpublished data from

our studies have also indicated long-term effects of the therapy. By following the patients for several months, a gradual improvement of mobility has been observed. The underlying mechanism of this effect is still unknown, however it has been suggested that synchronized firing of neurons can result in increased synaptic strength according to the Hebbian theory ('cells that fire together, wire together').

In conclusion, the Inventions method has been shown to be successful in reducing spasticity, particularly when used in combination with physical activity. This can result in increased mobility, reduced pain and an overall improved quality of life for the patients. Based on the many positive effects and the relatively few side effects, we suggest the Inventions method as a new possible therapy for patients with spasticity.

References

- Brashear A, Lambeth K. Spasticity. *Curr Treat Options Neurol* 2009;11:153–61. Gracies JM. Pathophysiology of impairment in patients with spasticity and use of stretch as a treatment of spastic hypertonia. *Phys Med Rehabil Clin N Am* 2001;12:747–68. vi. Gracies J-M. Pathophysiology of spastic paresis I: paresis and soft tissue changes. *Muscle Nerve* 2005;31:535–51. Milanov I, Georgiev D. Mechanisms of tizanidine action on spasticity. *Acta Neurol Scand* 1994;89:274–9. Montane E, Vallano A, Laporte JR. Oral antispastic drugs in nonprogressive neurologic diseases. *Neurology* 2004;63:1357–63. Müller K, Mix E, Saberi FA, Dressler D, Benecke R. Prevalence of neutralizing antibodies in patients treated with botulinum toxin type A for spasticity. *J Neural Transm* 2009;116:579–85. Robertson V, Ward A, Low J, Reed A. *Electrotherapy Explained: Principles and Practice*, Elsevier 2006. Ørnes GB, Sørensen PS, Larsen TK, Ravnborg M. Effect of baclofen on gait in spastic MS patients. *Acta Neurol Scand* 2000;101:244–8.

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Inerventions is a company in the field of medical technology that has developed a new and unique assistive device for people with spasticity, immobility and increased muscle tension.

Mollii provides electrical stimulation through a specially designed garment and helps the body to relaxation, increased movement through activity.

Mollii is an assistive device for people with spasticity and increased muscle tension due to cerebral palsy, stroke, Multiple Sclerosis, Parkinson's disease, spinal impairment or other neurological impairment. Mollii can also be used for rehabilitation in pain management.

Mollii previously called Elektrodress.

Throughout the development of Mollii, Inerventions has worked together with researchers at CTMH, Centre of Medical Technology and Health, Smart Textiles, MedTech West.

CTMH Centre is a collaboration between the Karolinska Institutet, Kungliga Tekniska Högskolan and Stockholms läns landsting.

Smart Textiles is a center of expertise on textile innovation and textile solutions.

MedTechWest is a collaboration between Chalmers Tekniska Högskola, Sahlgrenska Universitets sjukhuset and Västra Götalandsregionen.



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