

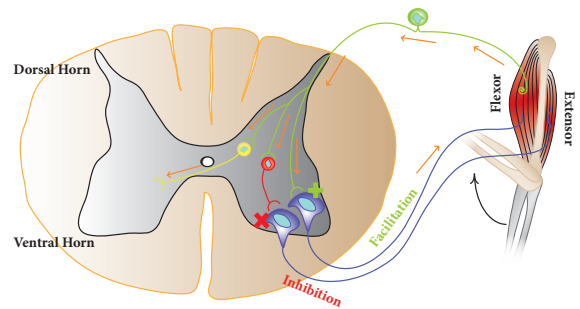
Efficacy and feasibility of the Inventions' method: Using the body's resources as a tool against spasticity

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What is Mollii®?

Mollii® is a multipad electrode system which facilitates selective and localized Electro Stimulation (ES) of the muscles (locally or generally) in order to trigger the reciprocal inhibition which leads to a reduction of spasticity based on the inactivation of the antagonist (spastic) muscle through activation of the agonist muscle^{i,ii,iii,iv}.

The idea of reciprocal inhibition as the cause behind ES came from previous reports describing improvement of gait and other muscle function after training, leading to the hypothesis that sensory feedback is a critical factor for training spinal locomotor networks^{v,vi}. There are numerous evidences in the literature that support the hypothesis of muscle relaxation through reciprocal inhibition, furthermore these evidences describe decrease of spasticity levels and increase of functionality in skeletal muscle movement.

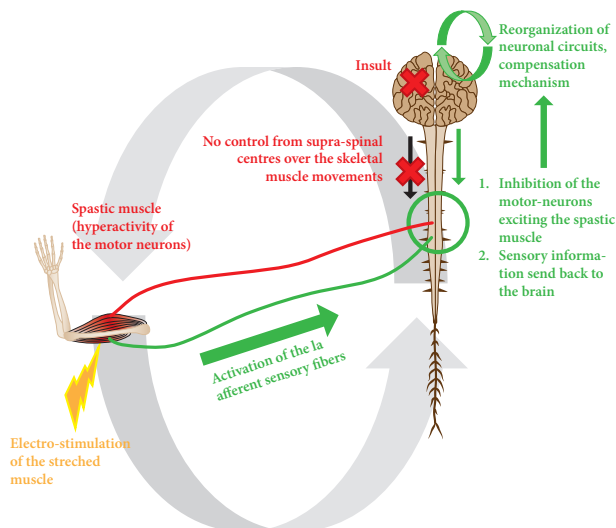


Reciprocal Inhibition

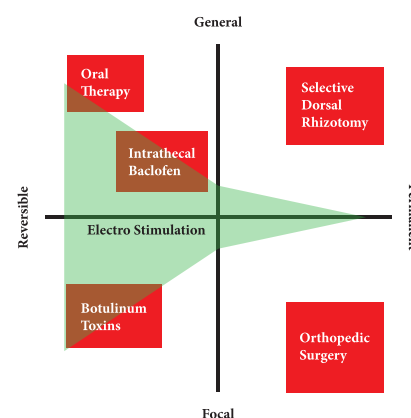
How does Mollii help against spasticity?

ES constitutes a “neural training” therapy. Unlike all other forms of therapy, ES does not inhibit the neuronal signal at any level as baclofen (inhibition of all neurons in the spinal cord) or botulinum toxins (inhibition of the ACh release to the muscle and therefore stopping the muscle contraction) or stops the signal sending process as in SDR.

Thus, ES works in a completely different fashion as it facilitates the synapses of all neurons involved in the spinal circuits.



Neuroplasticity and neural training



Medical management and therapy options

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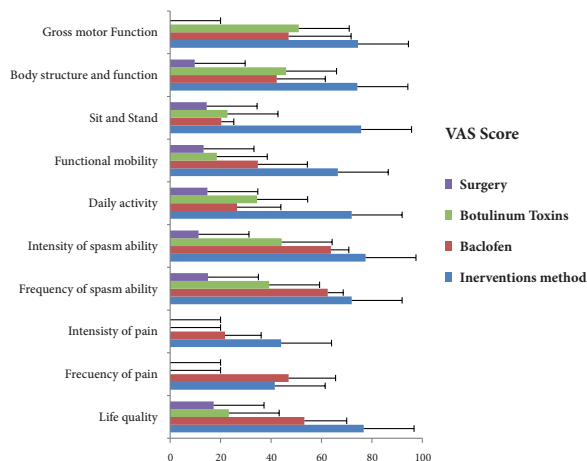
Comparison between available methods for the treatment of spasticity

Inerventions method

- Home based therapy.
- Cheap.
- No withdrawal effect.
- Standarized protocol, easy modulable.
- Activation of cortical areas upon electrical stimulationⁱ.
- Potentially reduces the need for multiple surgical proceduresⁱⁱ.
- Specificity in muscle stimulation (focal application or generalized Molli[®]).
- Irritations, not suitable for some neurodegenerative diseases.

Surgery

- Proves to be a good intervention method, combined with physiotherapy, to increase gross motor function^{xi}.
- Positive effects narrowed to certain population.
- Side effects relate to weight gain^{xiii}.
- Major surgery: infection risk.
- Back pain.
- Weakness in the legs.
- Discouragement in the patient due to the length of on-going therapy.



Example of Mollii[®] 's efficacy:

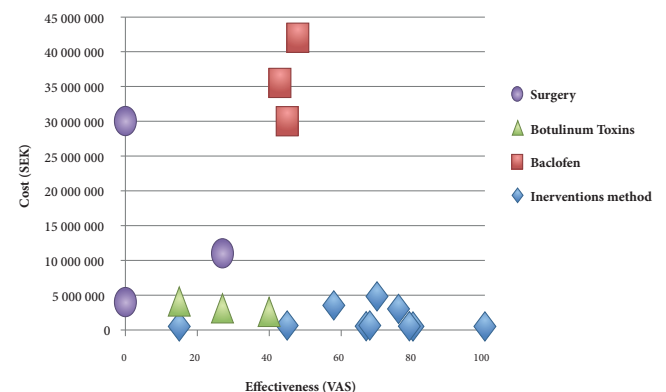
Visual Analog Scale 's scores rating with different method applied as a treatment for children with Cerebral Palsy.

Botulinum Toxins

- Highly effective in combination with other therapies^{vi}.
- Effective delay of surgical methods in muscles with spasm and/or contractures^{vii}.
- Increase of functionality (?)^{viii}.
- Toxin immunogenecity^{ix}.
- "Reflexion is more important than injection" Goal Attainment Scale 51,66±7,51^x.

Baclofen (intrathecal)

- Highly Efficiency at lower doses (Intrathecal 1% of the oral concentration)ⁱⁱⁱ.
- 10 years surveillance reports in increase LSQ^{iv}.
- Common treatment for people with GMFCS IV.
- Major surgery: infection risk (1-9% rates)^v.
- Refilling of the pump is a significant cost to health services.
- Blockade and complete shutdown of neuronal activity: generalized side-effects.



Cost/Effectiveness ratio:

Baclofen: highest price/the highest QOL increase (de Lissovoy et al., 2007; Bensmail et al., 2009): average of 382.000 SEK per quality-adjusted life-year within a total of 455.000-910.000 SEK. Pills reduce the cost to 21.000 SEK/year.
Botulinum: 231.000 SEK per quality-adjusted life-year (Shackley et al., 2012; Ward et al., 2005).
Mollii[®] dress: 48.750 SEK Mollii. 24.375 SEK/year.

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