A single center, open, non-controlled pilot investigation to evaluate the effects of intermittent negative pressure on spasticity and concomitant pain in patients with multiple sclerosis

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Objective:

To assess the safety and potential clinical benefit of intermittent negative pressure treatment on spasticity, pain, and quality of life in patients with MS.

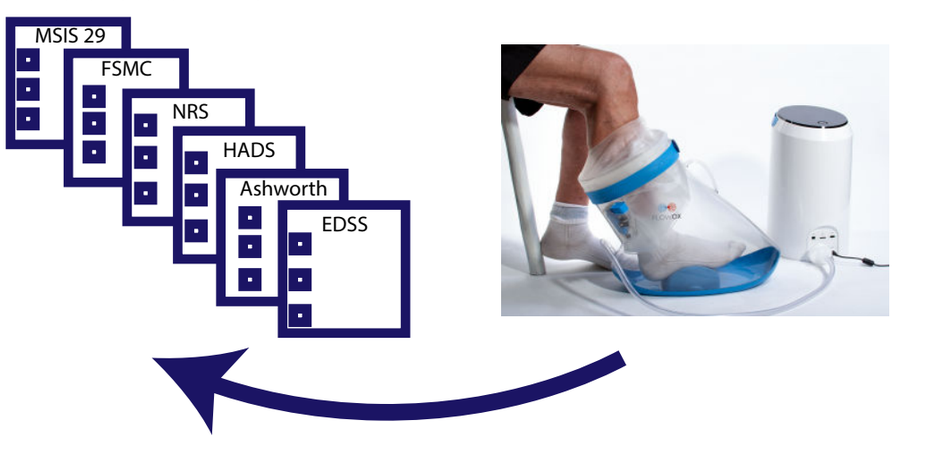
Background:

A novel non-invasive medical device applying intermittent negative pressure to the lower leg have shown promising effects on spasticity and pain in single patients with multiple sclerosis (MS).

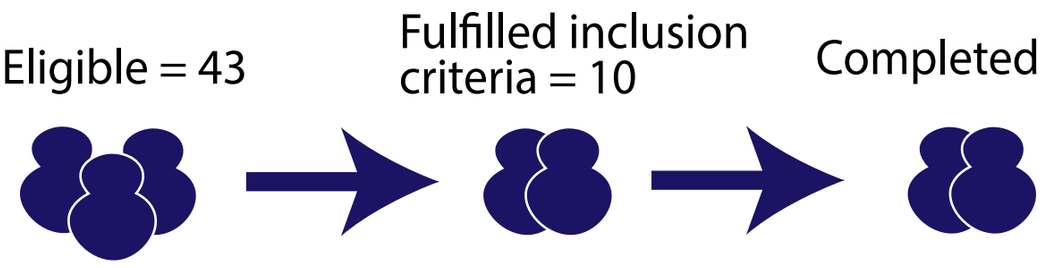
Method:

This was a prospective, non-controlled clinical pilot investigation. Patients with a numeric rating scale (NRS) reported spasticity ≥ 4, combined with pain in the lower extremities were included. Assessed at baseline and after 4 weeks of treatment were:

- Self-reported spasticity, pain, and sleep (NRS) over the last 24 hours and 7 days
- multiple sclerosis impact scale (MSIS 29)
- hospital anxiety and depression scale (HADS)
- fatigue scale formotor and cognitive function (FSMC)
- modified Ashworth spasticity scale
- expanded disability status scale (EDSS)
- two-minute and 25-foot walk tests



Results:



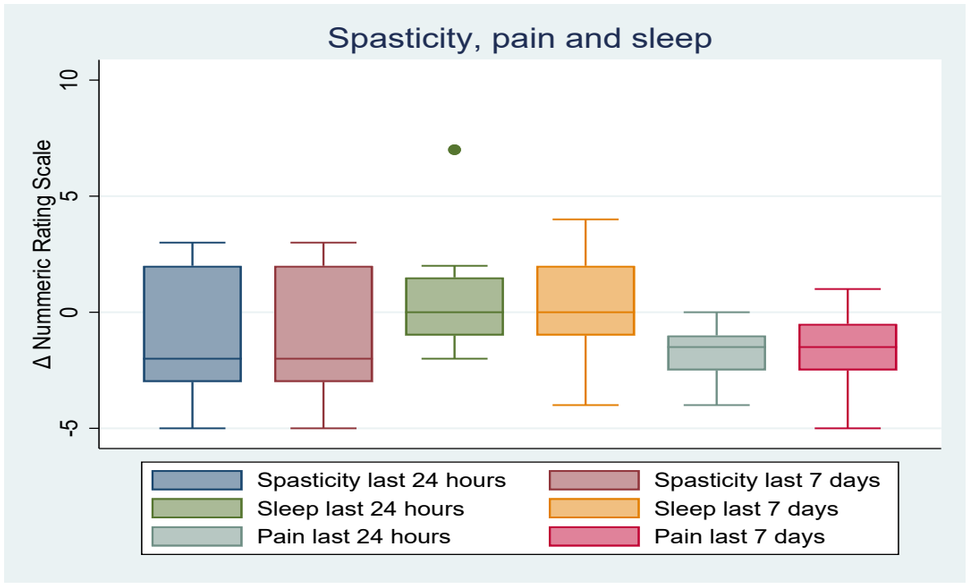


Figure 1: spasticity was reduced by -2 (-5, 3) NRS points reported over the preceding 24 hours and 7 days. Pain was reduced by -1.5 (-4, 0) points reported over the preceding 24 hours, and -1.5 (-5, 1) points over the preceding 7 days. Sleep remained unchanged.

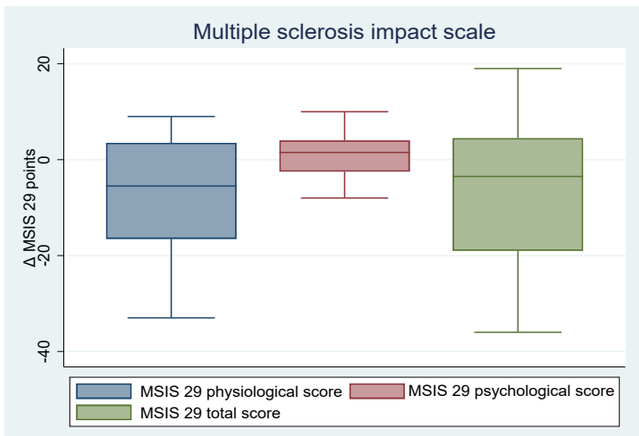


Figure 2: Boxplot showing the change in Multiple Sclerosis Impact Scale (MSIS 29) total score of -3.5 (-36, 19) from baseline to week 4.

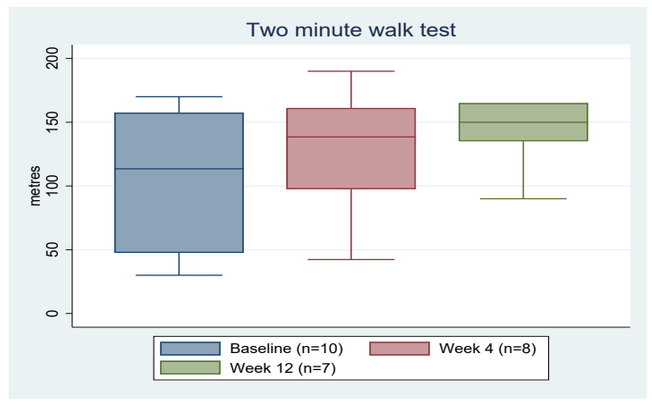


Figure 3: Boxplot showing an improvement in the two-minute walk test with a median distance of 8.5 m (-20, 75) from baseline to week 4.

Conclusion:

Intermittent negative pressure treatment may improve spasticity, pain, quality of life and walking ability in patients with MS. The treatment seems to be safe and well tolerated in this patient group.

Disclosures:

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