A pilot study to measure the effects of BioEnergiser ElectroFlex electrical stimulation device on lower limb circulation.

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BioEnergiser™ ElectroFlex™
**Introduction**

Neuromuscular electrical stimulation provides well documented therapeutic benefits in two distinct areas. In conditions where there is prolonged loss or prevention of movement, the resultant muscle wasting can be at least partly prevented by using electrical stimulation to exercise the muscle passively. As muscle activity increases local perfusion, this in turn allows neuromuscular electrical stimulation to be used to treat circulatory problems including leg ulcers and poor circulation in the legs, and to reduce the risk of deep vein thrombosis.

We undertook a pilot study to measure the effects of a novel neuromuscular electrical stimulatory device on lower limb circulation, using high resolution thermography to monitor alterations in perfusion and a series of physical and feedback probes to assess changes in lower limb function and patient responses.

The device is called, variously, Bioenergiser ElectroFlex, Circulation Massager, Circulation Doctor and Circulation Enhancer. In the following report it is referred to simply as Bioenergiser ElectroFlex.

**Authors**

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**Methodology**

A group of 16 subjects was selected for trial according to a pre-agreed set of criteria (below). They were treated with the BioEnergiser ElectroFlex for a period of 25 minutes. Somatoinfra scans and lower limb parameters (diameter, degree of function, degree of pain and/or discomfort) were scored at baseline and after treatment.

**Inclusion criteria:** intermittent claudication, ‘restless leg’, leg ulcers, oedema, lower limb pain and/or restriction of movement unrelated to joint or neuronal disease, ages 50 to 75.

**Exclusion criteria:** arthritis of the hip, knee or ankle, neurological disorders, concomitant uncontrolled disease.

**Thermographic monitoring system:** Somatoinfra Hi-Res scanning system.

**Thermographic monitoring and analysis:** Prof Mihaly Szacsky

**Patient treatment and scoring:** Dr Szabolcs Ladi

**Trial coordination, analysis and reportage:** Dr Paul Clayton
Results

The effects of a single treatment with the BioEnergiser Electroflex were marked and consistent, with very positive results. Somatoinfra scanning showed significantly improved circulation in affected limbs in 15 of the 16 cases, and symptom scores also improved significantly in 15 cases. Global scores for lower limb heaviness, coldness and pain were reduced in all subjects, with an average initial global score of 6.19 falling to 3.44 after treatment. It is worth noting that these are the best responses to therapy that Prof. Szacsky has recorded. Lower limb oedema (assessed by direct measurement of calf circumference) was slightly reduced in several subjects but we believe that additional treatments will be needed to achieve significant improvements in this latter parameter. The individual results are attached in a separate file (results 1a), as are the imagery (images).

10 of the 16 subjects expressed a wish to either return to the clinic for further treatment and / or to buy Bioenergiser Electroflex equipment for their own use. Two subjects who had lost the ability to bend their legs at the knee were able to tie their own shoelaces for the first time in several years. It will be noted that several of the test subjects were medical doctors; these individuals were initially sceptical but were convinced by their own responses to treatment.

There were no adverse effects.

Discussion

In healthy adults, TENS treatment at a level that produces visible muscle contractions increases blood flow significantly in the stimulated muscle. A change in sensation was experienced with lower frequency TENS that did not induce muscle contractions, but this had little effect on blood flow. [Sandberg 2007] Muscle contractions induced by motor-level 2-Hz TENS appear to be a prerequisite for increasing blood flow in the muscle. [Sandberg et al 2007] Other groups have published similar findings (i.e. Miller et al 2000).

In patients with leg ulcers and/or restricted lower limb perfusion, electrical stimulation to the calf muscle increases blood flow in the lower leg and increased ulcer healing [Moloney et al 2006, Augustinsson et al 1985]. The increase in blood flow is somewhat less than that caused by voluntary contraction of the muscle but electrical stimulation is better tolerated [Moloney et al 2006]. Treatment with NMES may be particularly useful in immobile or reduced mobility patients with venous ulceration who do not use their calf muscle pump optimally [Moloney 2006], and in those who are therapy-resistant [Junger et al 2008]. In patients at risk of DVT due to lower limb venous stasis, there is indirect evidence of improved venous circulation [Scheffler & Chae 2007].

Our group of patients included diabetics, patients with Metabolic Syndrome and chronic smokers. All had lower limb circulatory problems presenting as oedema, pain, restlessness and reduced function. Although their underlying pathology was somewhat diverse, their
response to Bioenergiser treatment was consistently positive. Thermographic and symptomatic improvements were internally consistent, and consistent also with improved circulation. They were also consistent with the literature.

Summary

We conclude that acute treatment with BioEnergiser Electroflex is a simple and effective way to improve lower limb perfusion, and the symptoms associated with this condition. Our findings indicate that it may be used both in the clinical management of designated patients, and to achieve symptomatic relief in non-clinical and pre-clinical subjects.

Declaration of Interest

Professor Szacsky and Dr Szabolcs have no conflict of interests. Dr Clayton provides occasional consultancy services to BioEnergiser Ltd.

References


Summary (results)

RESULTS 1a

1. Farkas András
   Although there was not significant change in circulation (it might be obscured by the signs of the active veins) the patient experienced robust subjective changes. Feels lighter legs and relief of the calves after treatment. Before: 7 After 4

2. Dr. Ocskovszky Jánosné
   The saturated vein remained active but the local activity decreased. Measurable and sensible improvement of the circulation after 25 minutes. The patient feels more heat in the lower limbs. Before: 6 After 3

3. Dr. Jenitsek Tiborné
   There is an asymmetry in the circulation between the left and the right lower limbs. The asymmetry between the left and right side has disappeared; the circulation improved on both sides and became homogenous. Her legs became much lighter after the treatment. She is very satisfied with the treatment. Before: 7 After 3

4. Dian Viktória
   Inactivity in the arteria femoralis region, asymmetry in the circulation at the knees, the tibial regions are symmetric. The arteria femoralis region is inactive on the right on the back photographs. Improved circulation, the asymmetry had disappeared and the projection of the limbs became saturated. She did not feel major changes. Before: 6 After 5

5. Bornemissza Károlyné
   Always feels coldness in the legs. She can walk but cannot stand. Her legs started to prickle after treatment. The legs became less cold after the treatment. The somatoinfra photos show difference in circulation before the treatment. The difference disappeared after the treatment and generally became better. Before: 7 After 4

6. Pospa Gézáné
   Numbness in the right leg, gets tired easily. Sometimes cramps in both calves even when resting. Feels heaviness in the legs after walking a longer distances. The somatoinfra photos show better circulation towards the periphery after the treatment. The difference disappeared. The patient feels lighter legs. Before: 6 After 3

7. Pécsi Sándorné
   Feels numbness in the legs even during rest and during the night. She feels a burning pain when going up stairs. Cramps usually occur, even when she does not walk. The somatoinfra investigation shows measurable improvement in circulation after the treatment, the difference between the two legs disappeared. The patient feels much lighter legs, she could not even cower (bend) before the treatment, now she can bend down. Before: 8 After 3

8. Nagy Péter
   There are cramps in both calves in cold weather or when walking. He cannot walk long distances. Constant numbness in both legs. The duration of the treatment was just 15 minutes! After 15
minutes just mild changes can be seen on the photos which show the calves from the back. The patient did not feel significant improvement. Before: 6 After 6

9. Márkus Mária
If she is walking longer distances her legs become very tired after only a few hundred meters. If she lies down after walking the calves start to cramp. When walking up a 3 storey building her calves are aching. When sitting, the oedema can occur very quickly. The somatoinfra photos show mild differences in the circulation between the left and the right side. After the treatment the difference disappeared and the circulation became much better on both sides. The patient feels much lighter legs, even more on the left side after the treatment. Before: 7 After 6

10. Zabari József
If he walks longer distances, his legs become tired easily. The somatoinfra photos show mild differences in the circulation between the left and the right side. After the treatment the differences disappeared, the circulation became better on the periphery, both sides. The patient reports mild changes, he said, his legs became „fresh”. Before: 5 After 4

11. Zabari Józsefné
When she is walking more, she feels pain in both thighs and the calves start to cramp. The photos show obvious improvement in circulation, the peripheral circulation improved both sides and the differences became significant. The patient describes lighter legs and „freshness”. Before: 6 After 4

12. Szabados Éláné
She has just mild symptoms. She feels heaviness in both legs when she walks more than one kilometer. The photos do not show huge disturbances in the circulation, but the differences between the left and the right sides disappeared after the treatment. The patient feels much lighter lower limbs after 25 minutes treatment. Before: 4 After 2

13. Szabados Éláné
If he walks more, his legs become heavy but does not feel cramps in the calves. The photos show active venous projection in the right tibialis region. Differences between the circulation on the right and left hand side. After the treatment the differences disappeared, the circulation became balanced, the projection of the vein remained the same. The patient could not bend before the treatment, afterwards he can bend and feels much lighter and fresher legs. Before: 6 after 2

14. Dr. Décsiné Kiss Györgyi
Her superficial veins on both legs are distended. She does not experience cramps when walking, she feels as if her legs were made of lead after walking 1 kilometer. The activity of the veins became less different from the surroundings after the treatment. The circulation improved on both sides. The patient reported a „refreshing” feeling in her legs. Before: 6 After 3

15. Párragh Jánosné
Her legs are always cold. She does not walk more than 2-300 meters without stopping. During rest she feels numbness in both legs. After the treatment the activity of the vascularity became compensated, the relative difference in the spectral emission also became equalized between the left and the right side with marked changes in general circulation. The patient said, the numbness has disappeared and she feels her legs are lighter. Before: 7 after 3
She cannot walk longer distances because of the left hip pain (not the calf pain). The main complaint is that when she is standing for a long time, her legs become swollen with the feeling of heaviness. The pictures show significant improvement in the peripheral circulation on both sides. The patient reported „lighter” legs and feeling of freshness after 25 minutes. Before: 5 After 3
Patients treated with the BioEnergiser ElectroFlex for a period of 25 minutes. Somatoinfra scans and lower limb parameters (diameter, degree of pain and / or discomfort) were scored (at baseline and after treatment) out of 10.