The Effectiveness of FlowAid FA 100 Muscle Pump Activation System (MPA) at increasing microcirculation velocity in PAD Patients.

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Background

Critical Limb Ischemia manifests itself in the lower extremity of approximately 3% of the US population. Smokers, Persons with Diabetes, and patients receiving Dialysis are at high risk of developing this complicated condition. Patients report pain, coldness of the limb and difficulty walking. The disease affects the medium and small size arterial vessels of the lower limb with specific anatomic placements depending on the underlying cause. Residual deficits in the microvasculature of the distal parts of the extremities predispose these individuals to ulceration and a higher risk of amputation.
Current treatments, both pharmacological and surgical, aim to improve all facets of the circulation with the ultimate goal of reperfusion of the distal aspects of the feet.
Muscle Pump Activation System (MPA), FlowAid FA 100 is a new technology whereby a circular circuit of electrodes is placed on the muscles of the calf causing a sequence of contraction causing an increase circulation.

Materials and Methods

5 patients with a primary diagnosis of Peripheral Arterial Disease were admitted into this open labeled self controlled n of 1 case series. In addition 8 healthy subjects were evaluated as healthy controls. IRB approval and informed consent was obtained. All subjects were screened for the presence of any contraindication to Muscle Pump Activation System (MPA), with the FlowAid FA 100 device and were then asked to sign Informed consent. All subjects were place in the sitting positions with their legs at 90 degrees to their bodies. FlowAid FA 100, MPA system was applied to one of their calves and they underwent a 2 hour treatment period. Laser Doppler Flowmetry (Perimed) was used to measure their microcirculatory velocity in the capillary bed in the 1st interspace of the foot of the treated limb. Recordings were made continuously beginning before treatment and including a one hour rest period after treatment was ceased. In addition limb circumference measurements were made on the patients with PVD both around the upper and lower electrodes and pain was measured using a VAS both before and after treatment with the FlowAid FA 100 device.

Results

Table 1 represents the tabulated changes of the five subjects in the PVD group. All showed a significant decrease in pain. All patients showed an improvement in velocity as well as a decrease in the edema. The most marked change was in the microcirculatory velocity as measured by laser Doppler. Table 2 represents the tabulated results of the healthy control group. All subjects in the healthy control group showed a significant increase in their microcirculatory velocity. All subjects in both groups related subjective relief from some symptomatology with the healthy subjects relating the feeling as "feeling lighter on their feet".

Table 1 Tabulated Result for PVD Patients

Patient no.	% change flow treated	% change pain	% change edema upper	% change edema lower
1	49.27	87.5	16	14
2	16	30	4.7	8
3	15	0	5.2	0
4	40.6	82	2.2	4.8
5	27.58	96	2.33	3.45

Table 2 Tabulated Results for PVD Patients

Patient no.	% change flow treated
1	33.53
2	3.27
3	4.69
4	63.55
5	12.44
6	6.32
7	82.55
8	42.27

Conclusions

The FlowAid FA 100 device is effective at increasing microcirculatory velocity. In patients with symptomatic PVD and claudication it is effective in reducing the symptoms associated with the disease .The benefit of the treatment is felt after cessation of the treatment and over the course of a resting period. Further studies must and are being performed to evaluate how long this effect lasts and to thereby determine maximalized treatment dosages.