The Effectiveness of FlowAid FA 100 Muscle Pump Activation System (MPA) for pain reduction

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Introduction

Ischemia of the Lower extremity affects approximately 2,000,000 individuals in the United States alone. Peripheral Arterial Disease is one of the foremost complications of Diabetes and is the preeminent risk factor associated with development of foot ulcerations and the need for amputation. One of the grave complaints of patients suffering from PAD is significant pain either intermittent claudication which expresses itself during ambulation or in more advanced stages claudicant pain even during rest. Many medical and surgical therapies are on the market for the treatment of this condition. Pharmacologic treatment bears a large number of side effects and complications and surgical intervention carries with it extensive surgical risk. Physical Medicine including compression devices has recently been employed for the treatment of PAD with varying degrees of success. This study looks at the effect of the FlowAid FA 100 Muscle Pump Activation System (MPA) on the symptomatology associated with PAD.

Materials and Methods

14 patients with a diagnosis of PAD were treated with the FlowAid FA 100 MPA device. All patients had an ABI between 0.35 and 0.70 with decreased waveforms on Doppler Ultrasound examination. IRB approval and informed consent was obtained. Subjects were given one two hour treatment with the FlowAid FA 100 device. Patients were asked to remain in the supine position during treatment. This was due to other measurement devices and was not related to the treatment device which can be used even during ambulation. Amplitude and width were adjusted until a visual muscle contraction was seen and then kept at a level well tolerated by patients.Subjects were asked to use a VAS to evaluate their pain both pre-treatment and post-treatment and these results were tabulated.

Results

Table 1 represents the responses of the subjects both for the treated and non-treated limbs. The mean difference in the treated group between pre and post treatment was 3.58 with a standard deviation of 2.41. The mean difference in the non treated group between pre and post treatment was 1.27 with a standard deviation of 2.07. Wilcoxon test on the difference, with a p-value=0.007(very significant) in favor of treated group.

Table 1: Recorded Pain Data

Tx side	Tx pre VAS	Tx post VAS	non Tx pre VAS	non Tx post VAS
R	4	0.5	0.2	0.2
L	2.3	1.6	2	2
L	1	1	0.5	2
L	8.7	2.3	8.6	5.4
L	8.4	0.3	7.2	0.3
R	6	4.2	4.2	4.2
L	7	3.4	5.1	3
R	2.7	0.2	0.2	0.2
R	9.3	6.3	0.5	0.5
L	9	2.8	8.1	5.7
R	7.3	0.5	2.1	2.1
R	4	0.7	2	1
R	2.8	0.5	2.2	0.5
L	3.5	1.5	3.5	1.5

Table 2 Graphic Representation of Average VAS Responses