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Int J Low Extrem Wounds. 2020 Jun 11;1534734620917918. doi: 10.1177/1534734620917918. Online ahead of print.

Regular Use of FlowAid FA100 SCCD Reduces Pain While Increasing Perfusion and Tissue Oxygenation in Contralateral Limbs of Amputees With Diabetic Neuropathy and Peripheral Arterial Disease: Results of an Open, Pre-Post Intervention, Single-Center Study

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## Abstract

Patients with diabetic neuropathy and peripheral arterial disease often suffer pain, develop foot wounds, and go on to lose limbs leaving them with a painful limb. Electrical stimulation is one possibility open to physicians. In this study, the effects of the FlowAid FA100 SCCD, a sequential contraction compression device, were tested. The FA100 device is noninvasive; it uses 4 electrodes to sequentially stimulate the calf muscles in a modified intermittent pneumatic compression manner. A total of 14 patients with diabetic neuropathy, peripheral arterial disease, unilateral amputation, and a painful limb were treated with FlowAid FA100 (FlowAid Medical Technologies Corporation, New York, NY) with prior ethical approval. The study design was open, pre-post intervention comparison, and nonrandomized. Pain perceived was measured using Visual Analogue Scale (VAS) scores. Assessments of ankle brachial index (ABI), ultrasound color Duplex, and tissue oxygen using the transcutaneous oxygen technique were done at baseline and 2 successive follow-ups 4 weeks apart. Three out of 14 patients dropped out on account of distances involved in traveling to the clinic. Eleven out of 14 patients experienced statistically significant reduction in pain mean VAS scores (7.5  $\pm$  0.93 to 5.8  $\pm$ 1.47, P = .002) associated with increase in ABI (0.64 ± 0.06 to 0.69 ± 0.04, P < .001) and transcutaneous oxygen tension measured on the dorsum (29.4  $\pm$  4.03 to 33.2  $\pm$  5.26 in mm Hq, P = .005). When pain scores were regressed against ABI and transcutaneous oxygen tension values, there was a significant association between these (r = 0.8, P = .002). The reduction in pain following regular use of FlowAid was accompanied by beneficial and statistically significant increases in perfusion and oxygenation.

**Keywords:** FlowAid; VAS scores; amputation; diabetic neuropathy; pain assessment; tissue oxygenation; wound assessment.

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