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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 ± 0.93 to 5.8 ± 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 ± 4.03 to 33.2 ± 5.26 in mm Hg, $P = .005$). 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, tissue oxygenation, diabetic neuropathy, amputation, pain assessment, VAS scores, wound assessment

Impaired perfusion is a major factor implicated in the pathogenesis of diabetic foot ulceration, the others being poor glycemic control, neuropathy, and trauma.[1,2] Clinical management of the complications of the diabetic foot is based on treating infection, improving local skin perfusion and oxygenation, while persisting with bettering glycemic control. A significant part of wound healing is neoangiogenesis, whereby new blood vessels are induced to grow in the new tissue, enabling better oxygenation and metabolism within the wound.[3] When ischemia is significant, revascularization is an integral part of this treatment paradigm.[4] FlowAid FA100 (FlowAid Medical Technologies Corporation, New

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