

The use of FlowAid FA100, a novel device, for management of DFUs and ischaemic pain, evidenced by a series of case studies

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Introduction

Diabetic foot ulceration (DFUs) is an increasing and considerable burden on the NHS budget with £1 in every £140 now spent on DFUs & amputation and 160 diabetes related amputation per week in England (Kerr 20017). Seeking novel treatment options will be key to contributing to reducing the spiralling costs that the NHS face in the management and interventions of DFUs and diabetes related amputations. FlowAid FA100 (www.FlowAid.com) is an unique, novel device, that treats all forms of circulatory disorders of the lower limbs and their associated complications, such as foot ulceration, preventing tissue atrophy and managing neuropathic and ischaemic pain. The primary mechanism of the FA100 is to activate the calf muscle pump by compressing the deep veins of the lower leg through a number of electrically stimulated controlled contractions. These contractions, which run from distal to proximal along the leg, cause a peristaltic wave of contractions. This compresses the deep veins, which forces the emptying of the deep veins of the lower limb. Secondly, by increasing the venous outflow through the activation of the calf muscle pump, an increase of 'Arterial Inflow' will be created which replenishes the limb with freshly oxygenated blood. This helps treat Arterial Insufficiencies, Chronic Wounds and the complications that may be associated with these conditions.

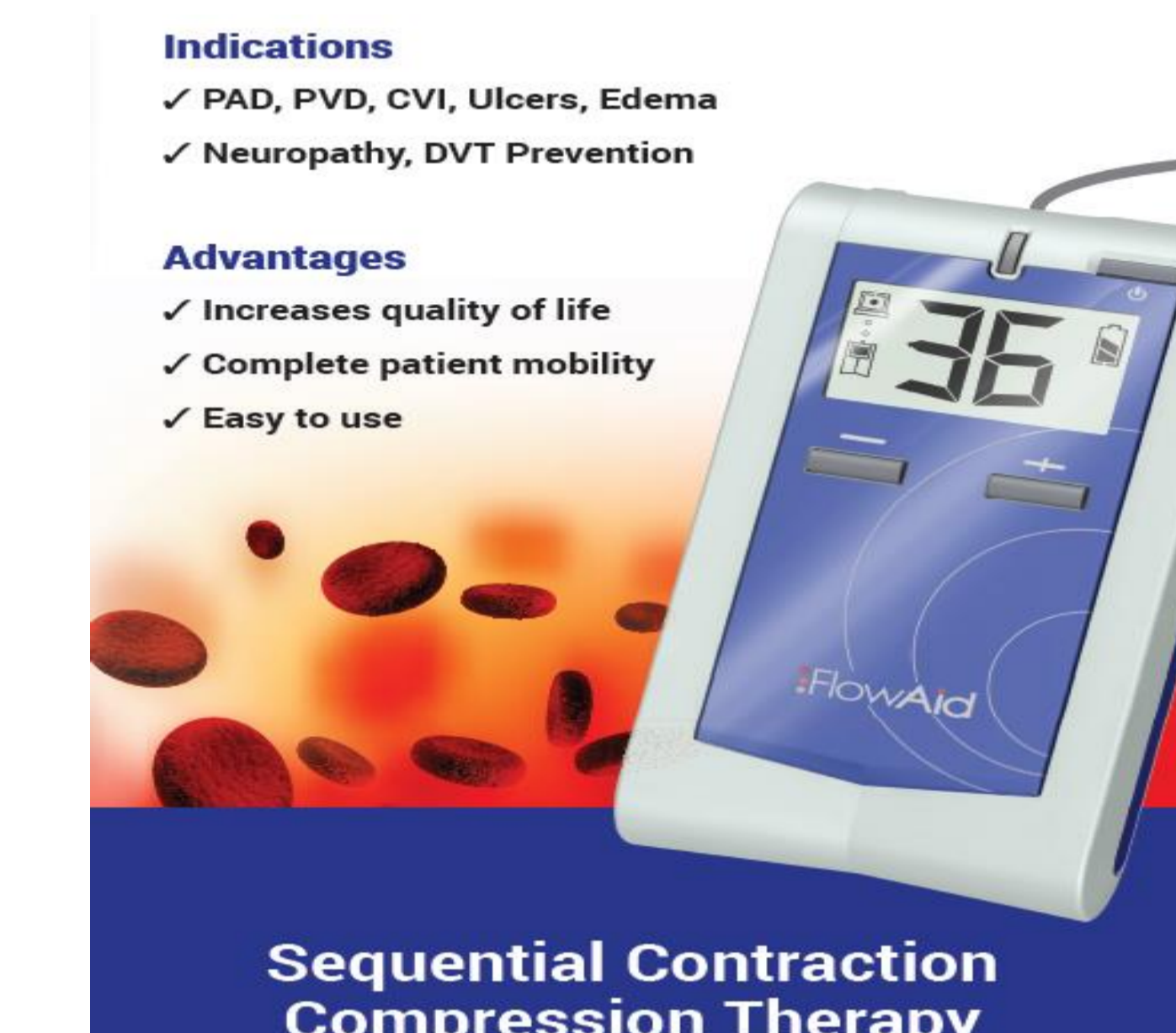
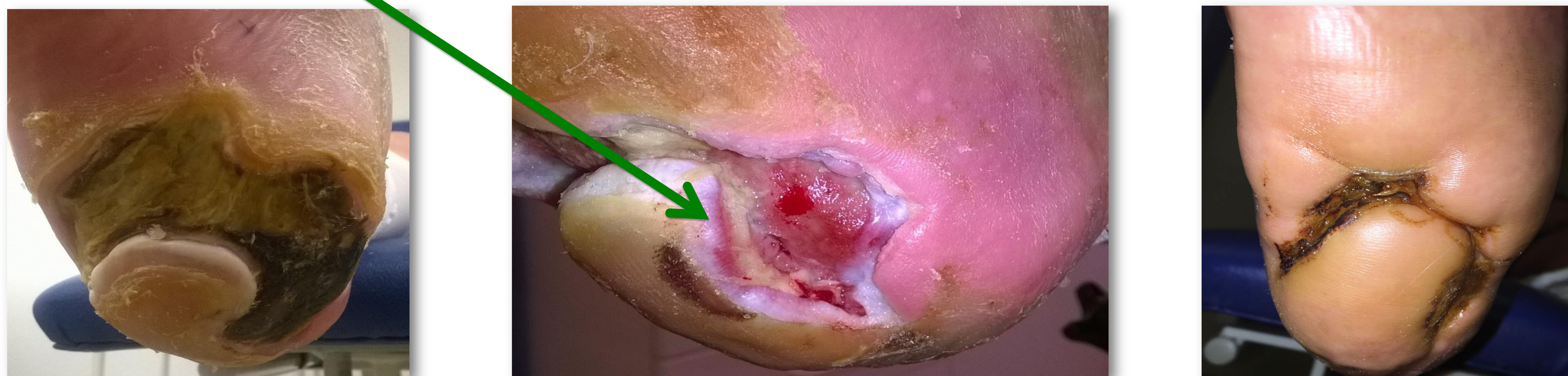
Methods

8 patients, 7 with type 2 and 1 with type 1 diabetes were selected, HbA1c range from 65-112 mmol/mol, who presented with a range of DFUs (neuropathic and ischaemic). Each patient was advised to use the FlowAid FA 100 device for a period of 4-6 weeks, and to use the device 2 twice a day for a period of 1-2 hours. At each Podiatry appointments, DFUs were assessed as per standard care. Each patient was asked to keep a pain diary, by means of a Visual analogue scale (VAS), record any positive or negative experiences and describe any improvements in their quality of life as a result of using FlowAid100.

Results:

- All 8 completed the evaluation with two extending the evaluation period by a further 4 weeks, with one extending to 3 months;
- 2 ischaemic patients reported a reducing in their VAS pain score from 8 to 5.
- 2 patients reported a return of sensation in neuropathy and
- Clinically improvements were noted in wound bed presentation and wound size reduction in all patients selected

One patient 50 years with type 2 diabetes who presented with a significant chronic >12 months heel DFU (SINBAD score of 5) made significant progress to full resolution after starting using FlowAid FA 100 in conjunction with other treatment options. This prevented this patient from being admitted / progressing on to elective amputation. The edge of the wound once FlowAid FA 100 was activated, showed an increase in perfusion and the patient reported his foot feeling warmer.



Discussion:

FlowAid FA100 has a place in the management and prevention of diabetic foot disease. During the vascular assessment of the 8 patients in the evaluation, as soon as the device was activated, there was a significant audible improvement in Doppler sound in all the pedal pulses.

Next Steps:

The study was limited by the size of the cohort and the results were mainly based on patients pain reduction (VAS) and how they felt when using Flow Aid FA100. A larger scale study is indicated to look at the cost benefits of the FlowAid FA100 for a greater range of DFUs. Wider Implications for use of this device would be in those groups of patients identified at Moderate and High Risk (NICE 2016) as the long term benefits of using the device in improving circulation may well yield both significant financial savings in the long term for this group of patients in the management of impaired vascular and neuropathy in the diabetic foot.

References:

1. Marion Kerr (2017) Foot Care In Diabetes – The Human and Financial costs
2. NG19 (2016) Diabetic foot problems: prevention and management NICE