

A novel device for the management of venous ulcers caused by chronic venous insufficiency



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The aim of this evaluation was to investigate the effect of a Sequential Contraction Compression Device (FlowAid FA-100; FlowAid Medical Technologies Corp; New York, USA) on patients with chronic venous insufficiency who had developed venous leg ulcers on their lower limbs. Patients were assessed, cleansed, debrided and standard dressing protocols were followed. FlowAid was used as an adjunctive therapy to compression on the affected limbs.

Venous stasis ulcers or venous leg ulcers (VLUs) are chronic wounds that take a long time to heal and present a clinical challenge for healthcare professionals. VLUs are mostly caused by macro- and micro-circulatory dysfunction (Coleridge-Smith et al, 1988; Falanga and Eaglestein, 1992). The Cleveland Clinic (2019) defines venous insufficiency as “a failure of the valves in the veins of the leg that causes congestion and slowing of blood circulation in the veins”. Symptoms include swelling, pain, itching and the recurrence rate can be as high as 70% (Hansson et al, 1987; Falanga, 1999; Abbade et al, 2005; McDaniel et al, 2002; Finlayson et al, 2015).

Guidelines and consensus vary throughout the world with regard to assessment, referral, investigation and treatment modalities (Scottish Intercollegiate Guidelines Network, 2010; Australian Wound Management Association and New Zealand Wound Care Society, 2011; Kelechi TJ et al, 2012; Neumann et al, 2014; O'Donnell TF Jr et al, 2014; Wittens et al, 2015; Franks et al, 2016; Dutch College of General Practitioners, 2016; Franks et al, 2016).

Compression is recommended in all VLU cases, along with wound bed preparation during various stages of wound healing (Sibbald et al, 2007). A meta-analysis of VLU compression found that compression increases ulcer healing rates compared with no compression, and multi-layer systems were more effective than single-component systems (O'Meara et al, 2012). Although four-layer bandage is regarded as the gold standard, a recent comparison randomized control trial between compression hosiery compared

with two-layer and four-layer compression bandaging showed that there is no significant difference in time to healing between hosiery and compression (Ashby et al, 2019). It was recognised that the amount of compression delivered might be compromised by poor application technique. The study also showed hosiery to be an effective and economical option. It is well recognised that patient's compliance remains the major determining factor for the effectiveness of the compression therapy (Nelson et al, 2014). Patients living in tropical regions face more challenges with regard to compression compliance due to weather-related heat and humidity, resulting in a raised core temperature and increased rate of sweat (Ting Xie et al, 2018).

Advanced surgical endovascular vein procedures can be performed by surgeons in many cases, but waiting times in hospitals can be long, appointments often unattainable and costly if done privately.

Of late, Intermittent Compression Devices (ICDs) are used in the treatment of chronic ulcerations of the lower limb (Fraccia et al, 2010) but there is still the issue with compliance and its use is not without complications (Brown et al, 2014; Harding et al, 2016). A new device, Flowaid FA-100 Sequential Contraction Compression Device (SCCD), has a similar function as an ICD but a different mode of action. SCCD works by sending a specific sequential pattern, timed electric pulse into the muscles of the leg. It causes a peristaltic series of contractions of the leg muscles, compressing the veins in the leg to increase in venous outflow. When the pulse ceases the muscle relaxes, resulting in arterial

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inflow. This will help to send static blood back to the upper leg and back to the central mass, reducing pooling of blood, oedema and leg circumference (Gimmelreich et al, 2016). It raises the foot temperature (Rosenblum et al, 2016) and improves popliteal blood flow (Shashar et al, 2016), thereby helping the healing of wounds.

Methodology

An evaluation was conducted in Hospital Kuala Lumpur. Five patients with VLUs were selected. These patients had been new referrals to Kuala Lumpur Hospital from local clinics that had applied the standard protocol of treatment for wounds. Patients with VLUs for at least 30 days with an ankle brachial pressure index (ABPI) of 0.9–1.2 (CEAP 3–6) to confirm there is no arterial component involved were included.

All five eligible patients were recruited to receive SCCD treatment on a single leg with an ulcer. The treatment regimen consisted of applying SCCD for 1½ hour ± 15 minutes twice

per day, alongside the standard advance wound treatment as per hospital protocol. Patients received weekly wound care visits, where the wound size was measured and pictures taken every week to chart the wound healing progress. Emollients creams were used on the periwound area during each dressing change. All patients were followed for up to 4 weeks.

Results

The patients were assessed, cleansed, debrided and standard dressing protocols applied. As the pooling of blood was the cause for a reduction in venous return in these patients, Flowaid proved to be an effective adjunctive therapy on the affected limb. The wound area decreased in all five patients and the wound bed showed clear signs of improvement.

Table 1 and *Case studies 1–5* summarize the results. These are preliminary, preceding a bigger study of 30 patients, to be conducted after this evaluation.

Table 1. Summary of case study results

Case	Pre-treatment (cm ²)	Post-treatment (cm ²)	Percentage of reduction (%)
1	8.8	2.2	74.3
2	63.0	21.0	66.7
3	55.0	28.8	47.6
4	24.8	18.0	27.3
5	260.0	198.0	23.8

Case study 1

59-year-old male, VLU for 5 months

The area of ulcer at pre-treatment measured 8.8cm² and at post-treatment 2.2cm². The results showed that there was a significant percentage of ulcer reduction (74.3%).

Wound size

Sept 19: 3.5 x 2.5 cm

Oct 19: 1.5 x 1.5 cm



17.09.2019



14.10.2019

Case study 2

37-year-old male,
VLU since 2016,
recurrent wound

The area of the ulcer at pre-treatment measured 63 cm² and at post-treatment 21 cm². The results showed that there was a significant percentage of ulcer reduction (66.7%).

Wound size

Sept 19: 14 cm x

4.5 cm

Oct 19: 7 cm x 3 cm



23.09.2019



11.10.2019

Case study 3

73-year-old male,
VLU for 6 months

The area of the ulcer at pre-treatment measured 55 cm² and at post-treatment 28.8 cm². The results showed that there was a significant percentage of ulcer reduction (47.6%).

Wound size

Sept 19: 11 cm x 5 cm

Oct 19: 6 cm x 4.8 cm



10.09.2019



14.10.2019

Case study 3

60-year-old female,
VLU for 9 months

The area of ulcer at pre-treatment measured 24.7 cm² and at post-treatment measured 18 cm². The results showed that there was a significant percentage of ulcer reduction (27.3%).

Wound size

Sept 19: 5.5 cm x 4.5 cm

Oct 19: 4.5 cm x 4 cm



2.10.2019



14.10.2019

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Case study 5

66-year-old male, VLU for 3 months

The area of ulcer at pre-treatment measured 260 cm² and at post-treatment 198 cm². The results showed that there was a significant percentage of ulcer reduction of 23.8%.

Wound size

Sept 19: 20 cm x 13 cm

Oct 19: 18 cm x 11 cm



20.09.2019



14.10.2019

Discussion

A number of previously conducted studies showed that FlowAid FA-100 aided patients in the reduction of oedema and leg circumference (Gimmelreich et al, 2016), raised the foot's temperature (Rosenblum et al, 2016a) and improved popliteal blood flow (Shashar et al, 2016). Other studies suggested that FlowAid helped to reintroduce blood flow in venous insufficiencies, relieved symptoms of diabetic peripheral neuropathy, lowered pain as well as increased the maximal walking distance in patients with peripheral arteries disease (Rosenblum et al, 2016b). There was a ulcer reduction of 23.8–74.3%, which is notable when compared with standard of care.

Conclusion

The current case series showed wound healing progression in patients with chronic VLUs as a result of venous insufficiencies. It is important that patients with venous insufficiency or venous ulcer receive the standard of care. Compression therapy was used in all of these cases, along with adjunctive therapies, such as FlowAid SCCD, which can improve healing and shorten healing time. The main objective is to ensure that the wound is healed with minimum or no complication. The FlowAid SCCD may help patients who are unable to secure surgical intervention and those who can not comply with compression. There was improvement of more than 20% in all five patients, which is comparable with international standard. **WAS**

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