Chapter 11
Advances in Devices that Offer Lower Limb Compression

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Abstract The theme of this book is compression which is a mainstay of treatment for venous leg ulcers. In other parts of this book, there are descriptions of how elasticated garments are used, the evidence of success to heal wounds as well as the shortcomings of this technique that beg questions of how compression may be delivered using other methods. These include surgery to treat incompetence in the superficial veins, advances on traditional bandages and intermittent pneumatic compression (IPC). Initially IPC devices were recommended to treat lymphoedema, later these were used to treat venous conditions. The different uses, range of treatment times were systematically reviewed and reported to be of low level of confidence. Recent developments in devices have been reviewed in this chapter which especially complements Chap. 10 by Mark Richardson that deals with techniques of improving bandaging systems.

Keywords Intermittent compression · Sequential contraction compression · Calf compression · Wound healing

Flowtron™ (Arjo Huntleigh, UK) the first of intermittent pneumatic compression (IPC) devices to be used to manage limb swelling, is described in another chapter in

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this book. It is described how using either a single or more bladders and an air pump designed to quickly inflate/deflate, limb swelling can be managed. Clearly this can benefit treatment of lymphoedema and venous leg ulcers both of which are therapeutic challenges whose standardised clinical management is based on compression and wound care as required [1]. Since IPC was first described, sequential contraction compression devices (SCCD) have been reported. Recent innovations include the Flow Ox™(Otivio Olso, Norway) that works on a modified IPC method as well as Flow Aid (FA)™ (FlowAid Technologies, New York) that is a SCCD and Geko™(FirstKind Medical): the latter two use electrical stimulation to activate muscular contractions.

Early attempts to treat venous leg ulcers using the Flowtron™(Arjo Huntleigh, UK) technique were reported despite the evidence being from different study types (see Table 11.1) [2, 3–17]. The early Flowtron™ devices (in the 1980s) were typically shaped like a cylinder that could be inflated with a limb inside. There were practical difficulties in using these devices and clinical reports to use this device had differing aims, outcome measures and application times. Nonetheless it is clear that controlled mechanical pressure around limb can and does promote venous blood flow as presented in clear review of the physics of the technique [18]. Very recently, Flow Ox™ (Otivio, Oslo, Norway) developed an innovation that uses a modified IPC technique to benefit both macro and micro vascular supply in foot skin and lower limb flow. The Flow Ox™ device is essentially a sealed chamber that connects to an air pump (see Fig. 11.1). In use, a patient would position the lower limb needing treatment in the chamber, resting the foot on the rocker bottom. The top of the chamber is sealed using a flexible cuff to form an air tight compartment before the it (the chamber) is connected to the air pump within the control unit. The seal (flexible cuff) is washable in water, it has a life time of months. Air pressure within the chamber is varied between −40 mmHg below atmosphere and atmospheric pressure. Time of variation can be altered to suit needs: a setting commonly used is 10 s at −40 mmHg and 7 s at atmospheric pressure.

Using these on a group of patients with peripheral arterial disease ($N = 20$, mean age 75 years, statistically significant increases over baseline values were reported in peak arterial flow 46% $p < 0.001$, peak skin blood flow or perfusion 89% $p < 0.001$ while mean blood flow velocity increased by 12% (6.7–75. cm/s) $p = 0.03$ [19]. It is postulated that the device works by modulating the air chamber pressures *without* triggering the arterio-venous reflex. The device has been used to treat chronic lower extremity wounds including a group of patients with spinal cord injury and lower extremity wounds [20]. This cohort included paraplegic and tetraplegic patients. A randomised, single centre, observed-blinded cross over study was done on patients ($N = 9$, age 57 years IQR 52–66 years) with chronic wounds duration 52 weeks (IQR 12–82 weeks). Flow Ox™ plus standardised care was compared against stan-

Table 11.1 Selected reports of Intermittent Pneumatic Compression (IPC) use

Name (year)	Type of study Length of study	*N*=	1. Independent variables 2. Patient group 3. IPC device 4. IPC regime	Results
Alpagut (2005)	RCT 3 months	235	1. IPC + compression therapy vs. control (leg elevation + elastic compression stockings) 2. Patients with post-thrombotic syndrome venous leg ulcers (VLU) 3. Device: Flowtron Plus AC 20002 (Huntleigh Healthcare, UK) 4. Regime: 1 h OD max pressure 70 mmHg	Response to therapy IPC: 100% (76/76) Control: 93.7% (149/159) Time to healing IPC: 20 days (15–35 days) Control: 3 months (20 days–5 months) Return to activity IPC: 7 days Control: 25 days
Alvarez (2012)	RCT 12 months	52	1. IPC + compression bandaging vs. control (compression bandaging alone) 2. Patients with VLU and secondary lymphoedema 3. Device: Sequential Circulator Model 2004 (BioCompression Inc., USA) 4. Regime: 1 h BD 40–50 mmHg	Median time to wound closure by 9 months IPC: 141 days Control: 211 days ($p = 0.031$) Ulcer healing rate (mm/day) IPC: 2.3 mm ±0.08 Control: 1.1 ± 0.04 ($p < 0.05$) Reduction in leg oedema (not significant) IPC: 19.1% Control: 12.0%
Coleridge smith (1989)	RCT 3 months or to healing	45	1. IPC + compression stockings vs. control (compression stockings alone) 2. Patients with VLU 3. Device not stated 4. Regime: Up to 4 h per day, 30–40 mmHg	Number of ulcers healed IPC: 10/21 (48%) Control: 1/24 (4%) Median reduction in area IPC: 19.8%/week Control: 2.1%/week

(continued)

Table 11.1 (continued)

Name (year)	Type of study Length of study	*N*=	1. Independent variables 2. Patient group 3. IPC device 4. IPC regime	Results
Dolibog (2013)	Randomised pilot study 15 days	70	1. IPC vs. compression stockings vs. short-stretch bandages 2. Patients with unilateral VLUs and chronic venous insufficiency 3. Device: Flowtron Hydroven 12 System device (Huntleigh Healthcare, UK) 4. Regime: 1 h OD, 60 mmHg at ankle and 40 mmHg at groin.	Average wound size decrease in patients w/ superficial venous reflux IPC: 9.91 cm^2, 20.12–10.21 cm^2 Stockings: 9.00 cm^2, 19.45–10.45 cm^2 Bandages: 8.77 cm^2, 17.23–8.46 cm^2 Average wound size decrease in patients w/ superficial + deep venous reflux IPC: 9.33 cm^2, 19.35–10.02 cm^2 Stockings: 5.05 cm^2, 25.09–20.04 cm^2 Bandages: 2.78 cm^2, 24.67–21.89 cm^2 Proportion of completely healed ulcers in patients with superficial venous reflux after 15 days IPC: 25% Stockings: 27% Bandages: 10%
Grieveson (2003)	Randomised trial	27	1. IPC vs. control (elevation of legs) 2. Patients with chronic venous insufficiency 3. Device: Flowpac pump (Huntleigh Healthcare Ltd, UK) 4. IPC at variety of pressures 30–70 mmHg—Full strategy not stated	Highest mean reduction in limb volume at 40 mmHg Significant results at 30 mmHg Lower pressures + shorter inflation/deflation times more efficient than higher pressures + long inflation/deflation times
Hazarika (1981)	Case series 44 weeks	21	1. IPC vs. control (compression bandaging alone) 2. Patients with VLU 3. Device: Flowtron (Huntleigh Healthcare, UK) 4. Regime: 2–3 h OD, 30–80 mmHg	Number of improved ulcers IPC: 71.4% (5/7) Control: 8.3% (1/12)

Table 11.1 (continued)

Name (year)	Type of study Length of study	*N*=	1. Independent variables 2. Patient group 3. IPC device 4. IPC regime	Results
Kumar (2002)	RCT 4 months	47	1. IPC + 4-layer bandaging vs. control (4-layer compression) 2. Patients with VLU 3. Device: Not stated 4. Regime: Used for 1 h BD	Number of ulcers healed IPC: 20/23 ulcers (87%) Control: 23/25 healed (92%)
McCulloch (1994)	RCT 6 months	22	1. IPC + standard compression (Unna boot) vs. control (Unna boot) 2. Patients with VLU 3. Device: Not stated 4. Regime: Twice weekly for 1 h each session at 55 mmHg	Number of ulcers healed IPC 12/12 (100%) Control 8/10 (80%) Mean healing rate (cm2/day) IPC 0.15 cm^2/day Control 0.08 cm^2/day ($p = 0.05$)
Mulder (1990)	Cohort study 1 year	10	1. IPC vs. Unna boot 2. Patients with VLU 3. Device: not stated (from Kendall Healthcare, UK) 4. Regime: IPC used OD for 1 h in morning then 2 h in evening	All patients healed 1 patient healed by 4 months ($p < 0.01$)
Nikolovska (2002)	RCT 6 months	80	The efficacy of intermittent pneuma tic compression in the treatment of venous leg ulcers 1. IPC vs. control 2. Patients with VLU 3. Device: not stated 4. Regime: IPC used for 1 h OD for 5 days a week, 40–50 mmHg	Number of ulcers healed IPC: 25/40 (62.5%) Control: 11/40 (27.5%)
Nikolovska (2005)	Randomised trial 6 months/until ulcer completely healed	104	1. Rapid vs. slow IPC 2. Patients with VLU 3. Device: not stated 4. Rapid vs. slow IPC, specific regimes not stated	Complete ulcer healing Rapid IPC 45/52 (86.5%) Slow IPC 32/52 (61.5%) Mean healing rate/day Rapid IPC 0.09 cm^2/day Slow IPC 0.04 cm^2/day ($P = 0.0002$)

(continued)

Table 11.1 (continued)

Name (year)	Type of study Length of study	*N*=	1. Independent variables 2. Patient group 3. IPC device 4. IPC regime	Results
Pekenmaki (1987)	Open clinical trial	8	1. IPC + compression therapy vs. control (compression therapy alone) in post-thrombotic leg ulcers 2. Patients with post-thrombotic syndrome VLU 3. Device: not stated 4. Regime: not stated	IPC + conservative treatment shortened ulcer healing time vs. conservative treatment alone
Rowland (2000)	RCT 6 months	16	1. IPC vs. control (compression therapy using Septopress bandaging) 2. Patients with VLU 3. Device: Flowtron (Huntleigh Healthcare, Australia) 4. Regime: IPC used for 1 h BD (morning + evening)	Ulcer size No significant difference Lower limb volume No significant difference
Schuler (1996)	RCT 6 months	54	1. IPC + elasticated stockings graduated compression stockings vs. control (Unna boot) 2. Patients with VLU 3. Device: HomeRx (Kendall Healthcare, UK) 4. Regime: IPC applied for 1 h each morning and 2 h each evening (40–50 mmHg)	Complete ulcer healing: IPC: 20/28 (71%) Control: 15/25 (60%) Healing rates IPC: 76% Control: 64% – **not significant**
Smith (1990)	RCT 3 months	45	1. IPC + compression stockings vs. control (compression stockings alone) 2. Patients with VLU 3. Device: not stated (provided by Kendall Healthcare, UK) 4. Device: IPC applied for 4 h a day, between 40 and 50 mmHg	Number of VLU healed IPC: 10/21 47.6% Control: 1/23 4.3% ($P = 0$) Median healing rate (area/week) IPC: 19.8% Control: 2.1% ($p = 0.046$)

Fig. 11.1 Shows a subject with his foot resting on the rocker sole of the Flow Ox™ air chamber. The controller housing the air pump is the cylindrical device with a flexible hose to connect to the air chamber. The seal (or flexible cuff) is washable. Used with Permission of Otivio™ (Otivio, Olso, Norway)

dard care alone over 8 weeks. Flow Ox was™ used for 2 h in patients' homes, PWAT (a validated scoring system) was used to assess wound changes.

This pilot study aimed to determine patient compliance and to explore wound healing potential. It reported 90% compliance to Flow Ox™ use, additionally there was a significant trend in wound healing in 4/4 patients while on Flow Ox™ plus standard care. To truly appreciate these findings, one must consider the study group who were paraplegic or tetraplegics a cohort with limited mobility, often have functional venous disease and on whom, compression bandaging is very difficult to use. A few clinical images of wounds are shown in Fig. 11.2.

11.1 Change in Contraction Patterns

A sequential contraction compression device (SCCD) compresses calf muscles in sausage like fashion: top and bottom squeezed while middle is held open: this forces venous flow out of bottom (filling the middle) and top (towards the thigh) while the middle segment fills but neither expels nor allows downward flow. Then the reverse follows with top and bottom segments open while middle is closed forcing flow out of the middle segment but not permitting any inflow at the bottom and no reflux from the top segment. The FlowAid FA100 Sequential Continuous Contraction Device (SCCD) electrically stimulates specific groups of calf muscles. These contractions, which run from distal to proximal along the leg, cause a peristaltic wave of compressions. This compresses the deep veins, causing venous outflow and, secondarily, arterial inflow.

The FlowAid FA100 SCCD system (FlowAid Medical Technologies Corporation, NY, USA) is a handheld unit using four electrodes to deliver electrical currents at three pre-set contraction frequencies to suit such different conditions as Venous, Arterial, Lymphoedema, and Diabetic Neuropathy. It is recommended that the

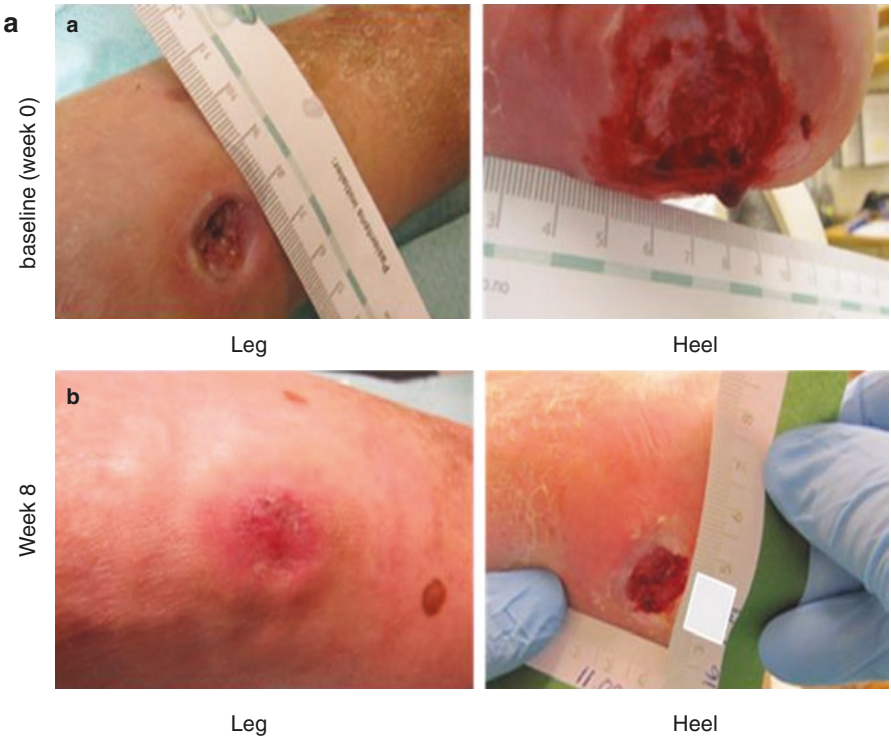

Fig. 11.2 (**a**) Shows four images of two lower extremity chronic wounds both treated with Flow Ox™ for 8 weeks. *A* is the status at baseline and B after 8 weeks treatment with Flow Ox™ in the study. Images on the Left of are of a chronic wound on the medial aspect of the leg while those on the *Right* show a chronic wound on a heel. Notice the Leg *A* wound is deep with rounded edges while the same wound in *B* below, is mostly fully covered with epithelium. The wound the heel on (Right) is extensive as can be seen in *A*. After treatment with Flow Ox™ improvement in size as well as the quality surrounding skin may be observed in *B*. Wounds on heels are difficult to manage. From Sundby ØH, Høiseth LO, Mathiesen I et al. The acute effects of lower limb intermittent negative pressure on foot macro and microcirculation in patients with peripheral arterial disease. PLOSONE https://doi.org/10.1371/jounral.pone.017900 June 2017. Reproduced with permission https://physoc.onlinelibrary.wiley.com/hub/journal/2051817x/about/permissions. (**b**) presents a chronic wound on the forefoot treated with Flow Ox. The patient is diabetic with renal failure. On account of the open wound, he was not offered a transplant. Using the Flow Ox device, resulted in improvement over 26 weeks associated with an increase in ABI (ankle brachial pressure index) in the treated leg. This a classic example of improved macro and microvascular flow resulting from use of Flow Ox. Used with Permission from Otivio, Oslo, Norway

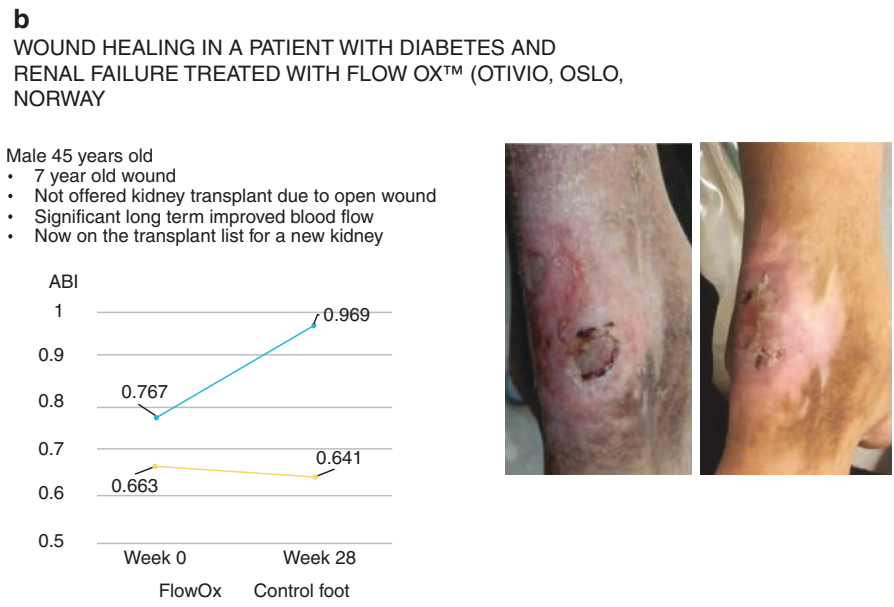

Fig. 11.2 (continued)

device be used for 1.5 h both in the morning and in the evening for optimal performance. Patients may choose a comfortable resting position or be ambulant when the device is in operation. Figure 11.3 shows four electrodes placed on the lower leg over the calf muscles using the FA100 SCCD. The handheld unit houses the controller and the rechargeable power supply.

An evaluation of the FA100 SCCD device to determine effects on popliteal vein blood flow in volunteers (n = 11, 22 limbs (age 25–45 years)) showed that FA100 increases flow in the popliteal vein 317% and active dorsi flexion of the foot 437% compared to the passive resting sitting position [21]. Gimmelreich [22] studied the effect of FA100 SCCD on patients with bilateral chronic venous insufficiency (CVI) to determine the effects of reducing afterload by measuring ankle and calf circumference on patients. Patients with CVI (N = 15) who were being treated with compression to manage their conditions were included. Patients applied FA100 SCCD following their prescribed elasticated stocking or IPC compression. Initially all subjects were treated and had their ankle and calf circumferences measured at baseline and following 2 h FA100 SCCD treatment. Patients on FA100 SCCD plus compression group continued

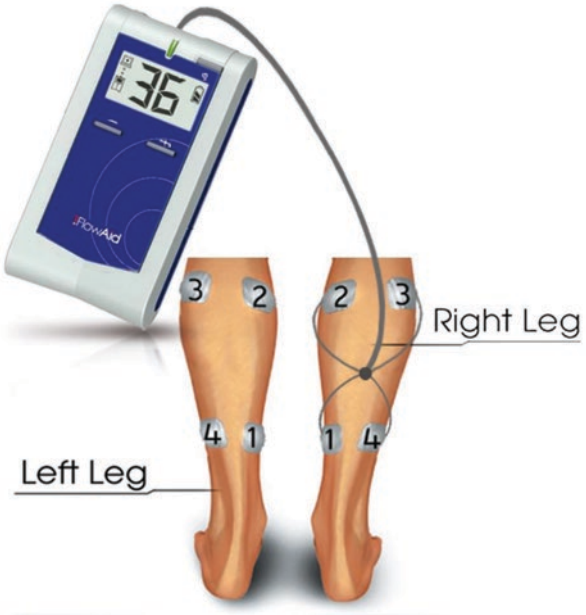

Fig. 11.3 Shows electrodes in situ on a leg using the FA device. The palm top size case houses the controller and the rechargeable power supply for the unit. Used with permission from Flow Aid (Medical Technology, USA)

to use the SCCD treatment for 2 h twice daily for 30 days while others were on compression garments before returning to the clinic for ankle and calf measurements.

In the test limb after 30 days, there were statistically significant reductions in circumference at ankle (21.9%, $p < 0.05$) and calf (19.5%, $p < 0.01$) respectively. Statistically significant trends were evident in the calf even after 2 h of FA100 use. By comparison, using standard compression (elasticated stocking or IPC) there were no significant changes versus the baseline except at the ankle at 30 days, where there was a reduction of 7.23% ($p < 0.05$). This is a very useful objective measure of improved venous outflow activity and helpful surrogate measure of wound healing. Complete compression cycles (distal to proximal) of the FA100 SCCD are far higher than any of the IPC devices in current use.

Two different chronic wounds that responded well to FA100 SCCD use are shown in Fig. 11.4a–d.

11.2 GEKO™ (FirstKind)

The Geko™ device uses neuro-electrical stimulation as described in Chap. 10. The device is small and may be neatly position on the popliteal nerve in the space behind the knee as shown in Fig. 10.4. In use, the level of stimulation current is adjusted to

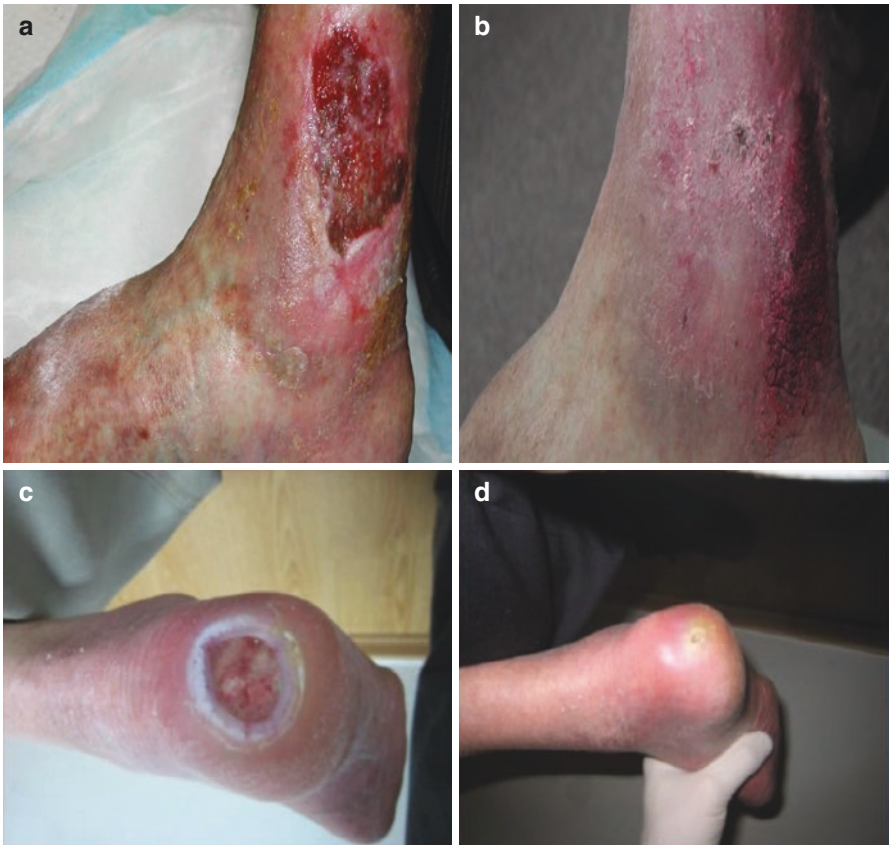

Fig. 11.4 (**a**, **b**) show a chronic venous leg ulcer in the malleolar region of the leg that responded to FA treatment for 4 weeks. This wound was circumferential. Reproduced with Permission from FlowAid Medical Technologies, New York. (**c** (left) and **d** (right)) show healing in a chronic wound on the heel of a 72 year old male that are difficult to treat with success. The wound started as a war injury and was very painful. Use of FA 100 3 h daily resulted in dramatic healing and much decreased pain. Reproduced with Permission from FlowAid Medical Technologies, New York

obtain muscle movements which in turn stimulates venous outflow and arterial inflow. The device is battery powered and is a single use device.

The aim of using the GEKO is to mimic walking: by stimulating the peroneal nerve, muscle groups in the calf are stimulated which in turn increases venous blood flow which has potential to benefit some patients at risk of venous thromboembolism. NICE has "recommended GEKO™ use in patients with a high risk of venous thromboembolism when other mechanical/pharmacological methods of prophylaxis are impractical or contraindicated with the National Health Service in England" [23]. Flowtron™ (Arjo Huntleigh, UK) is also recommended for use to prevent venous

thromboembolism™ especially in maternity hospitals in the UK. Returning to basics, the property to improve venous outflow is a significant step towards better wound health.

11.3 Conclusion

External calf compression using pneumatic and electro-stimulation permit venous outflow to increase which in turn, benefits reduction of oedema. And since reduction of oedema benefits wound healing, this benefits tissue health. There is evidence both laboratory based and from the clinic that Flow Ox™ and Flow (FA) devices have the capacity to improve wound healing.

The study using FlowAid by Gemmerlich [22] et al. measured changes in ankle and calf circumference and found significant reductions in both parameters. This augers well for the device and the use of calf and ankle circumference as a surrogate measure of wound healing. The Flow Ox™ device promoted healing in patients with spinal lesions: every patient who needs compression must get it—the universal question is how to deliver it? These innovative devices have shown their promise. Both Flow Aid (FA) and Flow Ox™ studies have shown high patient compliance. There is a great deal to come from these devices to benefit patients with chronic wounds and limb swelling.

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