



Clinical Resources

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Effectiveness of a Novel Static Pneumatic Gradient Compression Therapy Device (SPGC)* for the Treatment of Venous Leg Ulcers (VLU) and Chronic Venous Insufficiency (CVI)

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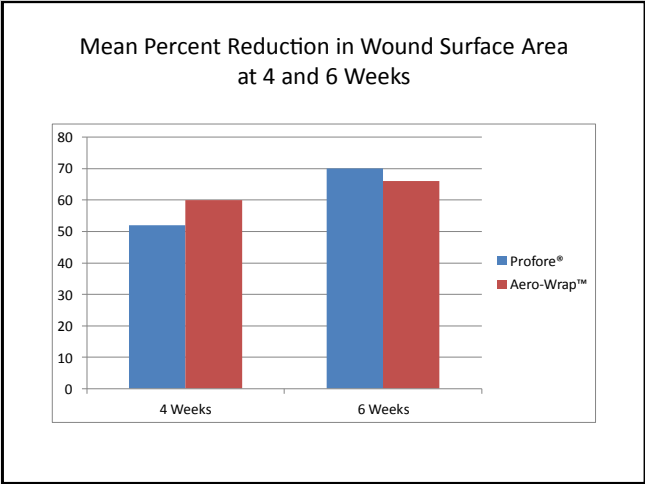


Objectives: To evaluate and compare the effects of SPGC on the healing rate of VLU and to collect clinical information regarding CVI symptom management, ease of use and safety profile.

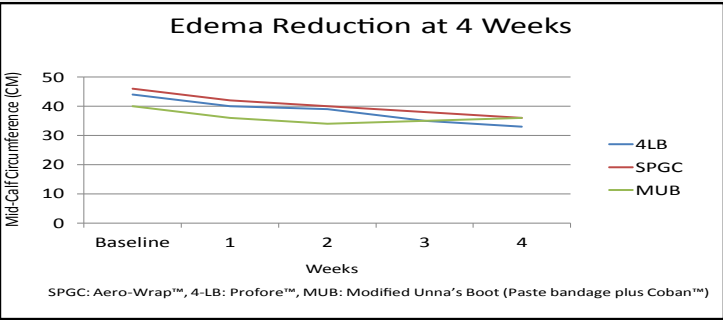
Design: This was a prospective, parallel, 12-week pilot non-inferiority study involving 15 consecutive VLU patients in an outpatient hospital- based wound care center. Healing rates in patients receiving compression therapy with SPGC were compared to healing rates in VLU patients treated with standard of care compression therapy (historical control) consisting of a modified Unna’s boot or 4-Layer Bandage Compression System. (4-LB)**

Endpoints: Wound healing outcomes were graded using Photodigital Planimetry Software*** and a numerical scale of +3 to -3 (+3= complete closure, +2=>50% closure at 4 weeks, +1= 25-49% closure at 4 weeks, -1= 1-24% closure at 4 weeks, -2= no improvement, -3= wound deterioration). Lower leg edema was measured using ankle and calf circumference and local wound pain was measured using a 10-point visual analog scale (VAS).

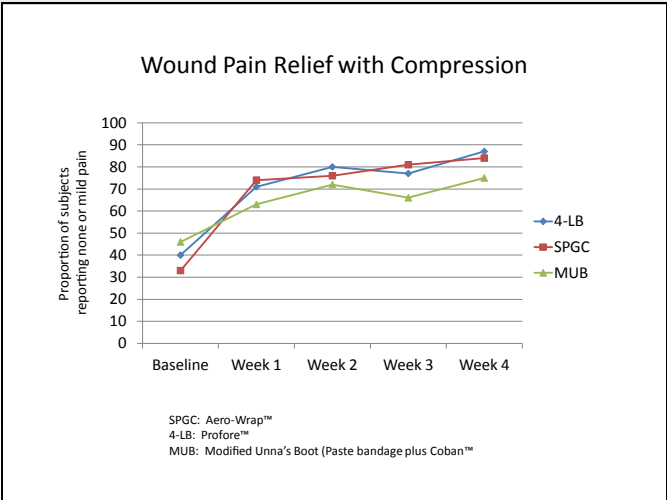
Results: There were no significant differences in the mean wound score between the SPGC group (2.3) and the standard of care controls (2.0). Nine of the 15 patients (60%) in the SPGC group achieved 50% wound healing at 4 weeks compared to 52% in the control group. Reduction of wound pain and edema reduction was also similar between both groups.



Mean Interface Pressure (mm Hg) Ankle Circumference 23-40cm			
Compression Therapy	Ankle	Mid-Calf	Upper Calf
Modified Unna’s Boot	29.5	22.5	19.4
4-LB (Profore™)	42.5	38.8	31.9
SPGC (Aero-Wrap™)	50.0	38.5	31.2



Compression Therapy	Mean Composite Wound Score
Modified Unna’s Boot	1.6
4-LB (Profore™)	2.0
SPGC (Aero-Wrap™)	2.3



*Aero-Wrap™ Gradient Compression System, Sun Scientific Inc. Dobbs Ferry, NY
 **Profore® Smith and Nephew, Largo FL
 ** PictZar® BioVisual Technologies, Inc Elmwood Park, NJ

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Conclusion: In this pilot trial compression therapy with SPCG was as effective as traditional compression bandage therapy. SPCG is easily self applied, can be worn with normal shoes and can be easily removed for showering and sleeping. Although SPCG cannot be used on every CVI patient, it may provide a cost effective alternative for those who don’t want to visit the doctor weekly or want a more active lifestyle.

For more information about Aero-Wrap™
 Visit Booth 439



PFAB Air Bolster Dressing

Home Care of Venous Leg Ulcers Using a Novel, Self-Applied, Inelastic Air Compression Garment and Air-Bolster Wound Dressings.

Compression / Wound Care

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Aero-Wrap Compression Garment

Background

Patients with venous leg ulcers (VLUs) typically come to the office for weekly evaluation and Unna's boot placement. During the pandemic, our VLU patients had a difficult time getting access to care. To overcome this challenge, we developed a VLU home treatment protocol incorporating two novel products, a self-applied inelastic air compression device (Aero-Wrap™) and air-bolster wound dressings (PFAB™).

Methods

Retrospective review of patients with active VLU who underwent our home treatment protocol were included in this case series. Patient demographics were collected, VLU characteristics were recorded, and photographs were reviewed. Inclusion did not have limitation on VLU size or duration. Patients with active infection were excluded from the treatment protocol.

Initial phase of the treatment protocol included a primary layer of Unna's boot, followed by a self-adherent elastic bandage, and then the Aero-Wrap™ applied on top. Patients continued this treatment, returning to the clinic as needed to manage drainage in this initial phase (1-2 weeks). Once the swelling was reduced and the wound progressed in the right direction the VLU home treatment protocol was initiated.

Patients were taught to clean their wound with Dakin's solution after bathing, apply the PFAB™ dressing, and then apply Aero-Wrap™ with 30-40mmHg of compression over it. This was repeated every 2-3 days as dressings became saturated. Patients had a telemedicine visit every 3-4 days and were brought into the clinic every 2 weeks for in-person assessment until healing.

Results

A total of 5 patients were treated with the VLU home treatment protocol. There were 2 men and 3 women with mean age of 65.4 years. Comorbidities included hypertension, diabetes, arthritis, hypothyroidism, and the mean BMI was 35. The average VLU duration at initial treatment was 78 weeks, with a range of estimated wound areas from 5cm²– 161.5cm² with a mean area of 39.6cm². Two of five of the patients had endovenous thermal ablation performed.

All patients were able to self-manage their wound care at home with physician supervision after an initial phase. There were no complications observed. All 5 patients had a significant reduction in wound size and depth and 4 out of 5 patients successfully had their VLU healed within 12 weeks. The mean treatment time was 11.4 weeks. This treatment protocol resulted in an estimated total reduction of 25 clinic visits.

Patient 1



Week 1

Week 15

Week 19

Week 23

Patient 2



Week 1

Week 2

Week 5



Week 7

Post healing

Patient 3



Week 2

Week 3

Week 4

Post healing

Patient 4



Week 1

Week 2

Week 3

Patient 5



Week 1

Week 3

Week 7

Data Table

	Patient					Mean
	1	2	3	4	5	
Sex	F	F	M	F	M	N/A
Age	62	74	40	81	70	65.4
BMI	41.2	46.9	36	23.3	27.7	35.0
VLU Age (weeks)	250	8	26	6	100	78
Est. Initial Ulcer Size (cm ²)	161.5	5.0	14.5	8.0	9.0	39.6
Treatment Time (weeks)	27.1	7.1	8.0	3.9	10.9	11.4
Ulcer Status at Treatment Completion	40cm ²	Healed	Healed	3cm ²	Healed	N/A
Est. Reduced Visits	13	3	3	1	4	5
Venous Intervention	No	EVL	EVL	No	No	N/A

Conclusion

Home treatment of VLU with a self-applied inelastic air compression device (Aero-Wrap™) and an air-bolster wound dressings (PFAB™) is feasible and may reduce weekly patient clinic visits. A larger study will be required to show the efficacy of this approach.

Conflict of Interest

Dr. Ravikumar is the inventor of the Aero-Wrap™ and PFAB™ devices and majority shareholder of Sun Scientific, Inc. the owner of these technologies.

OPTIMIZING LOCALIZED COMPRESSION FOR VENOUS ULCERS: EXPERIENCE WITH A NOVEL AIR-FILLED BOLSTER FOAM DRESSING (P-FAB)*

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Background: The ideal compression pressures for the treatment of venous ulcers remain unknown. Furthermore, local interface pressures provided by short stretch bandages can vary significantly depending on the anatomical location of the wound. The P-FAB wound dressing is an air-filled polyethylene pillow with a medical grade foam wound contact layer that comes in a variety of shapes and sizes. *Localized compression is especially helpful when treating lower leg or foot wounds that are in concave or non-cylindrical areas such as the dorsum of the foot or around the ankle.*

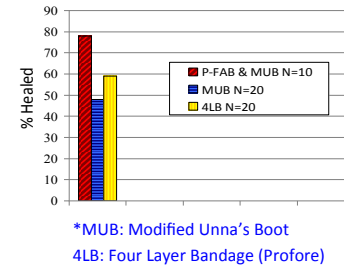


*Pre-Filled Air Bolster (P-FAB) Wound Dressing

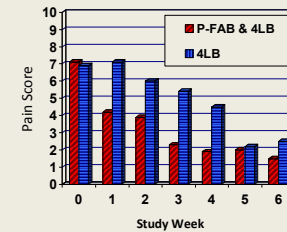


This study was supported in part by Sun Scientific Inc., Dobbs Ferry, NY

Incidence of Wound Closure at 12 Weeks



VAS Wound Pain Scores



Methods: We investigated the healing rates, local interfacial pressures and the wound pain index of 10 consecutive venous ulcer patients treated with P-FAB and either 2 or 4 layer compression bandages. All patients had one or more painful wounds over a concave or non-cylindrical area of the leg. Healing rates and wound pain in wounds treated with P-FAB were compared to retrospectively to historical control patients with wounds in similar locations and compressed without a bolster dressing. All patients were followed for 12 weeks or until healing.

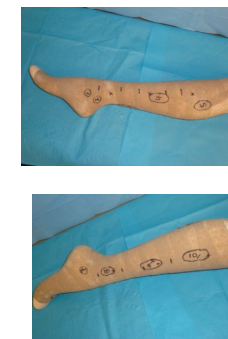


Healing Rates With and Without P-FAB

Treatment	P-FAB & 4LB	4LB Control
Rate of Healing mm/day ± SEM	2.7 ± 0.8	1.5 ± 0.4
N	10	20

Results: All (100%) of the P-FAB treated patients reported pain relief and the mean decrease in VAS score was 3. The incidence of wound closure after 12 weeks was 78% for the P-FAB group and 63% in historical control group. Mean increase in interfacial pressures before and after bolstering with P-FAB was 12.12mmHg.

Interface Pressures mmHg
With and w/out P-FAB



Site	w/ P-Fab	w/out P-Fab
1	56.6	27.6
2	52.3	47
3	60	48
4	63.6	59.6
5	41.6	47.3
6	38	45
7	49.6	39.3
8	65.3	49.3
9	59.6	41.3
10	52.6	51

Conclusion: Although, it has not been formally studied, most experienced wound care clinicians believe that bolstering venous ulcers is helpful. P-FAB is a uniform wound dressing bolster that provides consistent and reproducible local compression. Results of this preliminary study show that P-FAB may be a valuable adjunct to compression therapy in the treatment of venous ulcers