

The Use of a Glycerine-Based Stable Hydrogel as a Primary or Secondary Dressing in the Treatment of Painful Venous Ulcers

Oscar M. Alvarez and Catherine B. Fahey
University Wound Healing Clinic
New Brunswick, New Jersey

ABSTRACT

We have evaluated the use of a glycerine-based, stable hydrogel (*Elasto-Gel™*) as either a primary dressing or as a bolster to provide additional localized compression in the treatment of lower leg ulcers secondary to chronic venous insufficiency. Fifteen (15) patients who had chronic (>1 year history of non-healing), painful ulceration of the medial or lateral dorsum of the foot were enrolled in the evaluation. This type of ulceration is particularly difficult to manage because of unbearable localized pain and ulcer location, making it difficult to provide the necessary compression.

The use of *Elasto-Gel™* as a primary dressing combined with compression resulted in an immediate and long-lasting relief of pain, as determined by a categorical analog scales ($p < 0.05$ compared with hydrocolloid dressings and impregnated gauze). *Elasto-Gel™* used as a bolster (secondary dressing) to provide more uniform compression to sites with a large radius of curvature (e.g., depression behind the ankles) was also studied. This hydrogel, because of its consistency and conformability, is ideal for providing additional compression to difficult to compress areas of the lower leg and foot. Several case studies will be presented and methods of using *Elasto-Gel™* with compression will be illustrated.

INTRODUCTION

Most venous ulcers are irregular, are located on the medial aspect of the leg on or around the ankle and are surrounded by dermatitis and hyperpigmentation. Often, these ulcers are not exquisitely painful. However, a substantial number of venous ulcers are located on the lateral and posterior aspect of the leg, often below the malleolus. Such ulcers are often small, they are accompanied by varicosities and hyperpigmentation and are around these venous ulcers is burning pain frequently making an analogy of a “hot iron being place over the wound” or “steel wool pad being rubbed over the wound”. In our clinical experience, like all venous ulcers, these ulcers also respond well to standard compression but the painful component has been difficult to manage.

The following is our experience with a stable, flexible, thick hydrogel to provide pain relief by protecting the nerve endings over the wound and increase local supplemental counter pressure to the local area.

DESIGN

Prospective, open label, evaluation of *Elasto-Gel™* for the treatment of painful venous ulcers.

Evaluable Patients:	15
Duration:	8 weeks or until healing
Evaluations:	Local wound pain Wound closure Interfacial pressures

METHODS

Fifteen patients who had chronic (> 1 year history of non-healing) painful ulceration of the medial, lateral, or posterior inframalleolar region of the lower leg were enrolled in this evaluation.

Inclusion Criteria

1. Patient must be over the age of 21 years.
2. Ulceration must be secondary to chronic venous insufficiency, exquisitely painful and below or behind the ankle bone.
3. Level of local ulcer pain must be a 4 or 5 as determined by visual analog scale.
4. Patient signed informed consent.

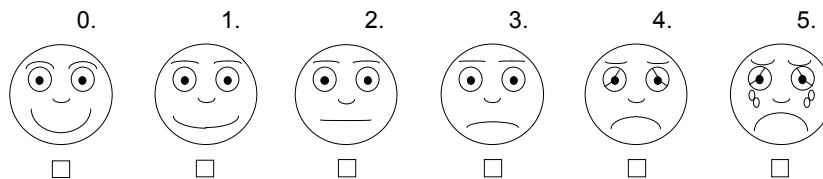
Exclusion Criteria

1. Ankle to brachia index <0.70
2. Cellulitis or wound infection
3. Necrotic or avascular wound bed
4. Uncontrolled diabetes
5. Ulcer exposing bone, tendon or fascia
6. Cortecosteroids, chemotherapy, radiation or any other immusuppressive agents
7. Rheumatoid arthritis

EVALUATIONS

Wound Pain

Localized wound pain was determined prior to treatment on day 0 (enrollment day) and once weekly for eight weeks or until the wound healed. Pain was graded using the following subjective scale of 0 to 5 (0 = no pain, 5=severe pain).



Explain to the patient that each face is for a person who feels either happy because he or she has no wound pain or sad because either he or she has some or a lot of wound pain. Face 0 is very happy because he or she does not have any wound pain. Face 1 hurts just a little bit. Face 2 hurts a little more. Face 3 hurts even more. Face 4 hurts a whole lot. Face 5 hurts as much as you can imagine, although you do not have to be crying to feel this bad. Ask the patient to choose the face that best described how he or she is feeling.

Wound Healing

Acetate Tracings, Measurements (L, W + D) wound assessment, serial photographs.

Interfacial Pressure

Counter compression of the bandage with and without the use of *Elasto-Gel*[™] was evaluated using a Lotus pressure meter PR 38. The sensor probe was placed against the skin adjacent to the ulcer prior to applying the compression bandages.

Statistics

Chi-square tests were used to assess between group differences for pain and healing.

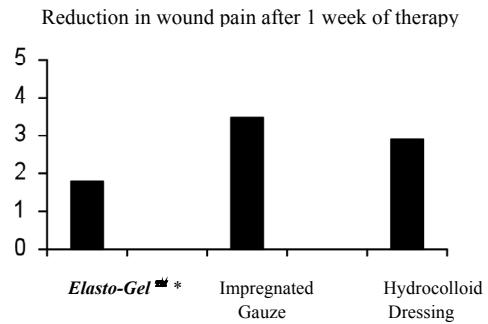
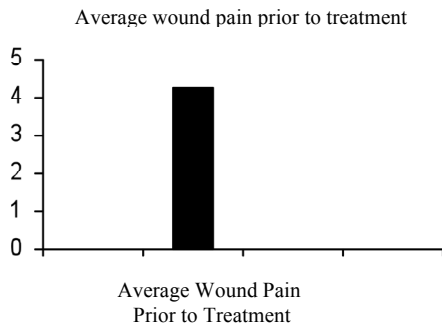
How *Elasto-Gel*[™] Was Used

Eight of the 15 patients had *Elasto-Gel*[™] applied only as a primary wound dressing. The *Elasto-Gel*[™] was cut in an oval shape to completely cover the wound.

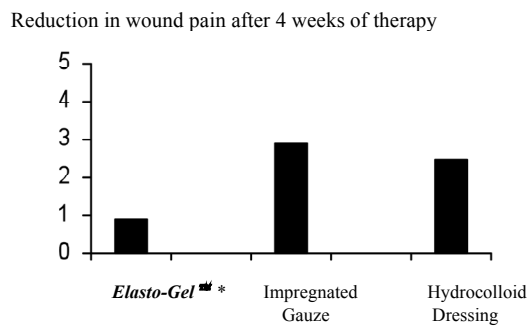
Three of the 15 patients had adaptic (petrolatum emulsion impregnated gauze, J&J Medical, Inc.) applied directly over their ulceration as a primary dressing.

Four of the 15 patients had their ulcers treated with a hydrocolloid dressing (DuoDERM®, CGF, ConvaTec). When either the impregnated gauze dressing or the hydrocolloid dressing was used as the primary wound dressing, an *Elasto-Gel*[™] bolster to provide localized supplemental pressure was used over the primary dressing. The *Elasto-Gel*[™] bolster was cut in an oval and placed on top of the primary dressing. The Unna's Boot and cohesive bandage were then applied.

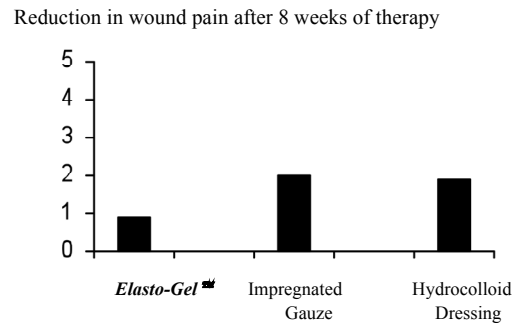
RESULTS



*p<0.05 compared with impregnated gauze and pain prior to treatment.



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HEALING

Frequency of Ulcer Healing by 4 Weeks and 8 Weeks

Treatment	Percent Healed	
	4 Weeks	8 Weeks
<i>Elasto-Gel</i> TM	(2/8) * 25%	(5/8) 62%
Hydrocolloid	(1/4) 25%	(2/4) 50%
Impregnated Gauze	1/3 33%	(2/3) 66%

*healed / # total

COMPRESSION

Interfacial pressure with and without supplemental counter compression.

Treatment	Mean Interfacial Pressure
<i>Elasto-Gel</i> TM * Primary Dressing	28.2 ± 5
<i>Elasto-Gel</i> TM Secondary Dressing	34.0 ± 7
No Supplemental Counter Compression	21.7 ± 6

SUMMARY

- ◆ Fifteen patients with painful venous ulcers participated and completed this preliminary evaluation.
- ◆ A significant and lasting reduction of local wound pain was observed after one week of treatment with *Elasto-Gel*TM as a primary wound dressing.
- ◆ Less pain was noted by patients treated with *Elasto-Gel*TM than those treated with impregnated gauze or hydrocolloid dressings
- ◆ Ulcer healing was comparable within the three treatments evaluated.
- ◆ *Elasto-Gel*TM provides pain relief and supplemental counter pressure for the treatment of venous ulcers which are difficult to compress.

Poster
Advances in Wound Care Symposium
April 1, 1997
New Orleans, LA