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Approximately 700,000 Americans suffer from venous ulcers which are associated with a high rate of morbidity and mortality.[1] The most common treatment modalities for lower extremity venous disease are compressive stockings, medicated wraps, elastic bandages, and superficial wound dressings. With the use of these modalities most physicians are frustrated with the rate or complete lack of progression of venous ulcer healing. Studies have shown intermittent pneumatic compression devices IPC to be efficacious in the prevention of postoperative thrombo–embolic disease in high risk patients.[2] IPC improves the venous return in the lower extremities and is believed to improve fibrinolytic activity within the blood vessels.[3,6]

It was the objective of this study to determine if intermittent sequential pneumatic compression which addresses the underlying pathology could expedite the closure of chronic venous ulcers.

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Materials and Methods

Subjects. This was an open label study of male and female outpatients with chronic

venous ulcers. Each patient served as their own control. Subjects were 10 outpatients with chronic venous ulcers as confirmed by past medical history and Doppler ultrasound assessment. All study patients had wounds present for at least one year prior to entry. Eligible patients were all placed on combined elastic wrap and Unna's boot therapy for forty–two days prior to entry. Only those patients without improvement or change in ulcer size in this period of time were accepted into the study. Study group and ulcer characteristics are listed in Table 1. Appropriate Institutional Review Board approval and patient informed consent were obtained.

Table 1

Venous Ulcer Demographic Data

Patient eliminated from the study:
- 1 due to non–compliance
- 1 due to equipment malfunction

Location:

5 patients medical leg
3 patients medial ankle

Average ulcer size in centimeters squared at start of study: 5.70

Range of ulcer size area in centimeters squared at start of study: 3:13 to 10.72

Number of males : 7
Number of females: 1
Average age: 68

Methodology

Upon identification of an appropriate study subject and after obtaining information consent, patients were entered into the study. For patients with more than one ulcer, the most intermediate size (range from 6.25 cm^2 to 64 cm^2) was selected. The wound was then cleansed with sterile saline solution and a compressive dressing was applied consisting of Unna's boot wrap (Moore Paste Bandage, New Britain, CT), Kling® (Johnson & Johnson, New Brunswick, NJ), and Coban® (3M, St. Paul, MN) elastic wrap. The dressing remained in place for one week at which time the patients returned to the clinic and dressing, cleansing, and application were repeated. Patients were required to return to clinic weekly for a 120–day treatment period, or until the wound healed, whichever occurred first. During the initial visit, the patients were given a Sequential Compression Device Therapeutic System (Kendall Healthcare Products, Mansfield, MA) consisting of a controller and thigh–length sleeves. Patients were instructed to use the SCD Therapeutic System daily (one hour AM and 2 hours PM) for the length of the study and to document their use.

Wound status, pain assessments, exudate amounts, and segmental leg volume measurements were assessed before treatment started (Day 0), at weekly intervals during treatment, at total wound closure, and at 6 week post–closure.

At each visit, the wounds were photographed, and leg dimensional measurements were made. Wound area was subsequently determined from photographs using a Kurta IS/ONE Graphics Tablet, Software – VIAS system. The amount of exudate was evaluated and recorded objectively as none, increased, decreased, or no change. Day 0 provided the base line. Pain was assessed on a scale of 0 to 10, zero being no pain and level 10 being intolerable pain.

Statistical Analysis

Effect of Treatment on Wound Healing. The effect of treatment on wound healing was estimated by linear regression, a statistical technique that "fits" a line to observed treatment data. The patient's relative wound areas (as % control) were regressed versus treatment time. All patients were pooled in a single sample for estimating the following regression line:

$A_{i't} = 1 + Bt + e_{i't}$

Where:

"$A_{i't}$" is patient i's wound area in treatment week t as a proportion of their initial, pre–treatment wound area.

"t" is patient i's treatment week, i.e. t = 1 is their first treatment week, t = 2 is their second treatment week, etc.

"B" is the regression coefficient to be estimated.

"$e_{i't}$" is the difference between the patient i's actual relative wound area in treatment in week t, "$A_{i't}$", and the regression estimate, 1 + Bt.

The regression coefficient, B, is the average change, over all patients, in relative wound area per week of treatment. If the treatment were effective, B would be negative and significantly different from zero.

Results

Ten patients were enrolled into the study. There were two dropouts, one due to non–compliance and one to equipment malfunction. The wound area versus treatment time results are given in Figure 1. The data are expressed as the mean–normalized wound area versus week of treatment. We found that daily treatment with the SCD Therapeutic System caused a significant reduction ($P < .01$) in wound area versus time.

Variation among patients did exist in the reduction of wound area during the 120 – day treatment period. Patient #3 demonstrated periods of wound area increase at weeks 28, 40, 44. These increases were related to discontinuity of SCD Therapeutic use and non–compliance. Return to the prescribed treatment resulted in continued area reduction. Patient #10 demonstrated an increase in normalized wound area between week 0 and 12, however, was completely healed at week 18. This apparent lack of response during the initial twelve weeks was attributed to a continued decrease in wound depth without an associated change in wound area. Once the wound filled and became shallow (week 14), the wound surface area decreased until complete reepithelialization at week 18.

While all treated patients demonstrated improvement during the treatment, only one patient healed within the 120–day trial period. All patients were followed for one year post study termination to determine the long–term effects of sequential compression. All patients continued to heal and all, but one, were followed until closure. The exception was a patient who was unable to return monthly post–study and was unable to return for follow–up. Two of the patients discontinued SCD Therapeutic use after their wounds closed, but subsequently reulcerated between three and six months after discontinuation. Returning these patients to SCD Therapeutic treatment resulted in the new ulcers closing.No statistically significant changes in leg volume were noted during the treatment period. No statistically significant changes in exudate amount or pain were noted with treatment. All patients followed were compliant for the entire study period and indicated that the pump was easy to use and did not disrupt their usual daily activities. The patients expressed a consistent belief that overall quality of life was improved through their expedited wound closure.

Discussion

Although compressive stockings, medicated wraps and elastic bandages have been helpful in the prevention of venous ulceration, they have not proved to significantly reduce healing time. Wound dressings have been helpful in the reduction of infection and in the promotion of granulation tissue but are limited in their treatment of venous disease.

Wound closure is best expedited by addressing the underlying pathology. Failure of skeletal musculature, vein valve incompetence, venous thrombosis, vein wall weakness, and hypertension have all been suggested as contributors to venous ulceration.[4,5] The SCD

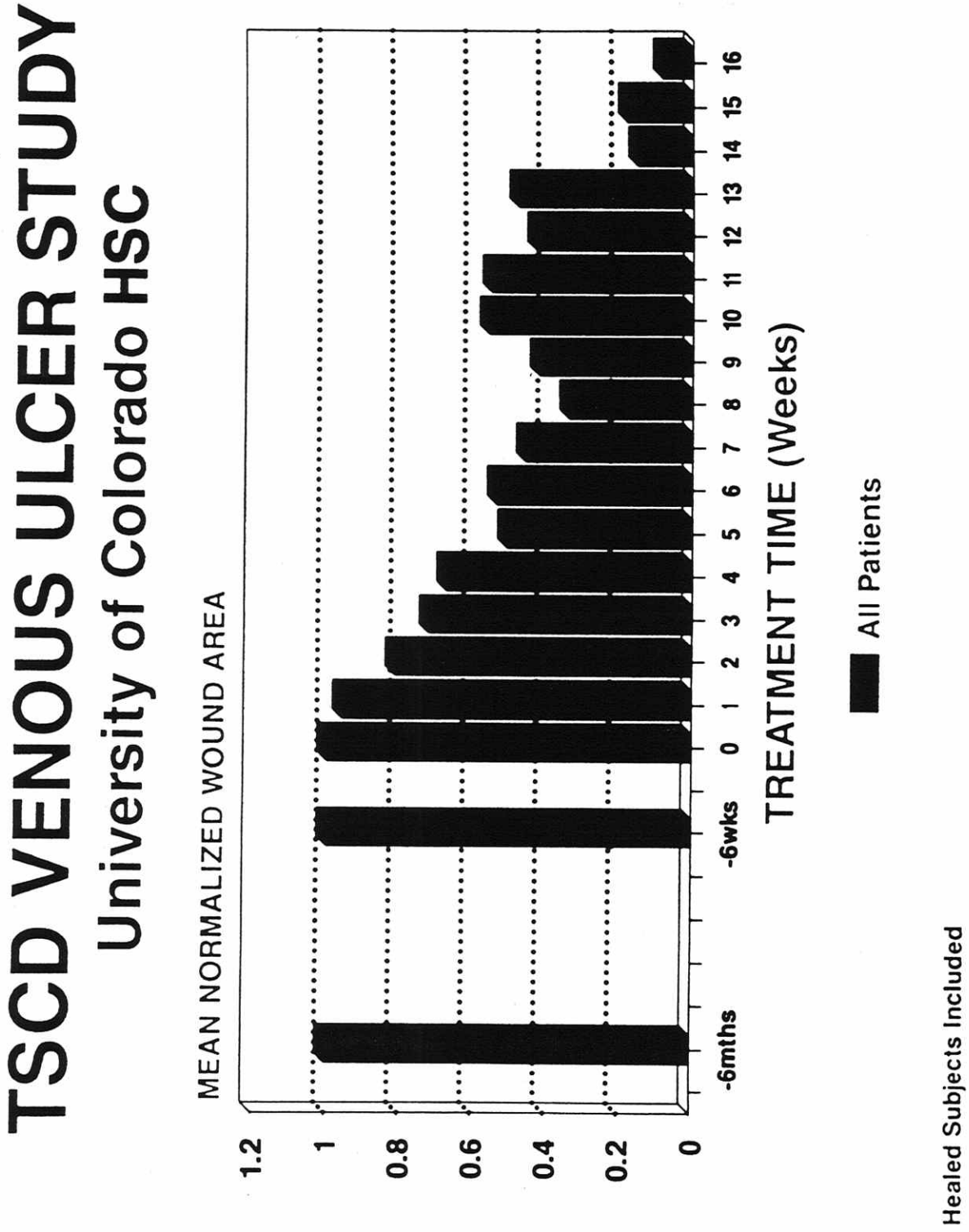
TSCD VENOUS ULCER STUDY
University of Colorado HSC
MEAN NORMALIZED WOUND AREA
1.2
1
0.8
0.6
0.4
0.2
0
-6mths
-6wks
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
TREATMENT TIME (Weeks)
All Patients
Healed Subjects Included

Figure 1

Therapeutic System addresses the underlying pathology by decreasing venous blood pooling and hypertension, and increasing venous return.

Deep venous thrombosis is associated with the occurrence of venous ulceration. The SCD Therapeutic System has been used in the past as a prophylaxis for deep venous thrombosis (DVT) in patients undergoing surgery. Prevention of DVT is believed to occur as a result of reducing venous stasis and increasing fibrinolytic activity.[2] The enhanced fibrinolytic effects of pneumatic compression may reduce the extra–vascular fibrin cuffs surrounding capillaries in the region of venous ulcerations. These cuffs are believed to contribute to ulcer formation by acting as a barrier to nutrient exchange.[7]

It is important to note that gradient sequential compression addresses the underlying pathology, venous hypertension and pooling, but does not cure venous disease. As previously noted, discontinuation of the SCD Therapeutic System resulted in recurrence while re–institution caused closure.

Edema as measured by leg volume changes often associated with venous disease were not significantly changed by the treatment. In our study, leg volume changes were not consistent. This finding may be interpreted to mean that edema was of questionable importance or that the measurement method used was not sensitive enough to pick up small volume changes.

The overall study suggests that venous ulcerations, particularly those chronically, resistant to Unna's boot therapy respond well to treatment with the SCD Therapeutic System. This significant reduction in venous ulcer size is in agreement to previous work done by Coleridge Smith, et al.[6] and Pekanmaki, et al.,[8] who also demonstrated improved healing of venous ulcers with use of intermittent compression pumps.

Conclusion

Daily use of the SCD Therapeutic System resulted in a significant reduction in wound area in venous ulcers which were previously resistant to Unna's boot treatment. This effect surpassed that of conventional compression and our wound dressing modalities used on chronic venous ulcers present for greater than one year. We suggest that closure of these venous ulcers occurred by addressing the underlying pathophysiology. The beneficial treatment effect was due to the daily use of the device because these patients received regular Unna boot treatment but, were not experiencing wound healing before use of the device. Furthermore, the estimated regression coefficient was negative and highly significant. These findings suggest that intermittent pneumatic sequential compression significantly expedites healing of venous ulcers.

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