LEG ULCERS ARE AN UNDERESTIMATED PROBLEM IN PRIMARY HEALTH CARE, PARTICULARLY AMONG ELDERLY PATIENTS. ONE TO 2% OF THE POPULATION WILL SUFFER FROM A POORLY HEALING ULCER OF THE LOWER EXTREMITY IN THEIR LIFETIME.  

PREVALENCE INCREASES WITH AGE (> 80 YEARS) TO ALMOST 20 PER 1000.  

AMBULATORY VENOUS HYPERTENSIOIN IS THE FINAL COMMON PATHWAY, WHICH IN MOST CASES LEADS TO VENOUS ULCER (VU) FORMATION.  

SUBSEQUENTLY, THE SUPERFICIAL VENOUS NETWORK MAY BE EXPOSED TO MUCH HIGHER PressURES THAN NORMAL, UP TO 90 mmHg INSTEAD OF THE NORMAL 30 mmHg. INCREASED PRESSURE CAUSES THE VEINS TO OVER DILATE. THE VALVES BECOME INCOMPETENT LEADING TO REFLUX, WHICH CAN LEAD TO VENOUS STASIS. SLOWER FLOW RATES IN AREAS OF STASIS RESULT IN DEPOSITS OF RED BLOOD CELLS AND INCREASED BLOOD VISCOSITY.  

WHEN VALVES IN THE PERFORATOR VEINS BECOME INCOMPETENT, REFLUX ALSO
Box 8: Clinical pathway used for the study group

Patient presents with a suspected venous leg ulcer.

Assessment (A):
1) Clinical history. 2) Assessment/measurement. 3) Differential diagnosis.

OTHER

yes
no

VENOUS ULCE (B)

no

VENOUS WITH ARTERIAL

yes

Reason for Referral (M)

Allergy; Unable to tolerate compression; uncontrolled pain; no reduction in ulcer size in 1 month; ulcer duration > 6 months; cellulitis unresponsive to treatment; frequent recurrence

Immobile/fixed ankle patient (J)

1) Multi-layer compression (1st line therapy)
2) Multi-layer compression + IPC (2nd line therapy)

OTHER

yes
no

Disease specific treatment

OUTCOME DEFINITION (D)

COMPRESSION (E)

1) Multi-layer (elastic-inelastic)
2) Reduced compression

MEDICAL/SURGICAL TREATMENT (F)

APPROPRIATE DRESSINGS (G)

SKIN CARE (H)

ADJUNCTIVE THERAPIES

EDUCATION (H)

Active/mobile patient (I)

Ulcer is closed post treatment (K)

1) Prevention of recurrence

Ulcer fails to close/no reduction in size after 6 weeks of treatment (L)

1) Refer to specialist
2) Re-evaluation including diagnosis and re-assessment
3) Evaluation for surgical corr. or skin grafting (punch grafting)

EXIT
affects the superficial venous system. Blood flow is reversed and veins become damaged. Venous ulcers are a unique type of wound because the underlying condition usually has developed over several years and is often unknown to the patient. Venous leg ulcers are associated with considerable clinical problems, such as high levels of exudate and disproportionate limb sizes and shapes. It is generally recognized that sustained compression is required to promote leg ulcer closure. Graduated compression is used to counteract venous hypertension, which is the main component of managing venous leg ulceration. 

Effects of compression on microcirculatory levels may include: acceleration of blood flow in the capillaries, reduction of capillary filtration, and increased re-absorption due to enhanced tissue pressure and improved local lymphatic drainage.

Compression has been demonstrated to reduce edema and improve superficial skin lymphatic function, as well as lymph transport within the sub-fascial system. Depending on the parameters measured, higher pressures are suggested to be more effective than lower pressures.

**Materials and Methods**

A clinical pathway (CP) was developed, validated, and implemented, to improve cost efficacy of treatment for patients with venous leg ulcers. The CP and selected products were tested by using case evaluation, looking at clinical efficacy, time to ulcer closure, wound evolution, quality of life (QOL), and cost efficacy. For details on the QOL aspects questionnaire see Table 1. The QOL questionnaire was filled out on a weekly basis by the clinician according to the answers given by the patient. Cost efficacy was assessed through looking at time to ulcer closure, materials used during treatment, clinician’s time and QOL aspects. Clinical examination was performed,

<table>
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<tr>
<th>Table 1. Aspects of QOL included in the questionnaire.</th>
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<td>Aspect of QOL</td>
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<td>Specific aspects regarding the ulcer</td>
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depending on the wound type, upon the start of the treatment and at 2-week intervals for a period of 12 weeks. The patients were then followed until ulcer closure. The study group (SG) received treatment with a short stretch compression system and a dressing, depending on wound condition, as defined in the clinical pathway (Figure 1).

The patients in the control group (CG) received conventional treatment (compression bandages and a wound dressing) before implementing the clinical pathway.

Twenty subjects were included in the study. Data was collected using a questionnaire. Data was entered and verified using a Statistical Package (SPSS). After the questionnaires were completed, each item was analyzed separately and item responses were summed to create a score for a group of items. Responses to a single item on the questionnaire were treated as ordinal data.

Notes:

• The clinician completed the QOL questionnaire once per week according to the patients’ responses.
• A 5-point Likert scale was used for rating the various aspects of QOL. This type of psychometric response scale is often used in questionnaires in survey research. At the end of the study, the completed questionnaires were analyzed looking at separate items, as well as summed item responses to create a score for a group of items.

Tests were carried out at the 5% significance level; the confidence interval (CI) was 95%. Statistic evaluation was performed using StatXact 5.0, double sided ($\alpha = 0.05$), paired sample with Wilcoxon test, and unpaired with Mann-Whitney (N = 20 [10/10]).

The evaluation included structured interviews on how wound management was carried out before implementing the clinical pathway. Available outcomes of the center’s treatment of VU patients were used as a baseline. The clinical evaluation observation period was 12 weeks for each patient. The number of patients who withdrew from the study, of which the ulcer had not closed, were listed in full as well as any adverse incidents.

**Inclusion criteria.** ≥ 18 years old; men and non-pregnant women; diagnosed with a VU; able to understand the terms of the trial and willing to give consent. Inclusion was considered after any infection had resolved.

**Exclusion criteria.** Significant arterial disease (APBI < 0.8); other causes: rheumatoid vasculitis; DFU; malignant ulceration; oral and/or topical corticosteroids; participated in this trial previously; ulcer closed or withdrawn; unable to understand the aims and objectives of the trial and/or poor adherence; clinically infected ulcers where frequent dressing changes are required; ulcers < 4 cm² and circumferential ulcers; known allergy to latex or other contents of the trial products.

Dressing choice was made at the discretion of the clinician regarding local ulcer management. The following materials were tested in the study:

- **Calcium alginate dressing,** available as a wound sheet, for superficial wounds and as wound filler for deep wounds, was used for wounds with high and moderate levels of exudate.
- **Foam (nonadhesive) dressing** with absorbent properties was used for moderate to lightly exuding wounds and was also used as a secondary dressing.
- **Collagen dressing** with absorbent properties was used for stagnating ulcers and combined with a foam dressing as a secondary dressing.

A short-stretch bandaging system was used for compression and consisted of the following:

- Tubular bandage, nonelastic: the tubular bandage was applied on the skin for protection and dressing fixation. A length of 2.5 times the size of the lower limb was used—one half to cover the dressing, the second half to cover the compression bandage to prevent it from slipping.
- Foam bandage: the foam bandage is designed to act as padding underneath compression bandages. The padding bandage facilitates even pressure distribution and will not slip since its open pores interlock. It can be washed at a temperature of 40˚C–60˚C.
- Short stretch bandage.
- Fixation bandage.
- Adhesive, non-elastic fixation tape.
- Optional: foam rubber pads. The kidney-shaped pad can be applied behind the malleoli to support removal of edema.

After the ulcer was cleansed, a dressing was applied and fixed with a fixation bandage. Then the nonelastic tubular bandage was applied. Foam pads were used to provide extra pressure (eg, behind the malleoli) if required. Two foam bandages were used as padding and were applied in a spiral fashion starting at the foot and up the leg to the tibial crest. Finally, two short-stretch bandages were used in a modified Sigg technique—the 8-cm bandage was started at the toes and applied up to the calf base. The 10-cm bandage was applied up to the knee in a figure-
eight fashion. The nonelastic tubular bandage was then folded over the leg and secured with a fixation bandage.

The bandages were applied and washed on average twice weekly. These cotton bandages do not have elastic fibers. Both the bandages and foam padding material can be washed up to 50 times at 90°C, according to the manufacturer’s data on file; the kit contains a special washing bag for this purpose. For each limb, two sets of bandages (short stretch and foam under-padding bandages) are used for a treatment period of 12 weeks (the duration of the trial). All of these materials are included in one treatment kit.

The analysis plan was as follows:

• **Ulcer areas.** Ulcer area (tracing of ulcers margins) on each leg was measured at week 0, at the time of withdrawal and at weeks 2, 4, 8, and 12 if the ulcer was not closed. Ulcer closure rate at 12 weeks was 50% (estimate).

• **Stage of the wound.** DWCS color classification was used to assess local wound condition. The percentage of color present was monitored and indicated on the ulcer tracings and digital photographs at weeks 0, 2, 4, 8, and 12.

• **Patient comfort assessment.** In addition to ulcer closure, assessments are made on patients’ comfort and the level of pain that each patient experiences, at weeks 0, 2, 4, 8, and 12 and also the week the ulcer was closed or the patient withdrew from the study. A specifically designed QOL questionnaire was used to assess patients’ QOL aspects (Table 1).

• **Handling properties of the dressing/bandaging regime.** Handling properties of the dressing were recorded at application and after removal of the dressing focusing on ease of use; ease of removal; patient comfort; pain on removal; durability of the regime; and incidence of leakage.

• **Handling properties of the bandage system was recorded at the application and before the removal.** Following application of the bandages: case of application; appearance of the bandages after application. Assessment before removing the bandages: Perfectly in place; partly slipping, bandages still functional; extensive slipping, bandages not functional.

**Results**

The ulcer area for the SG showed a faster and larger decrease when compared to the CG. The difference was significant ($P < 0.005$, Figure 2).

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**Figure 2.** Evolution in wound area, comparison between SG and CG.

**Figure 3.** Evolution of health scale situation at the beginning and the end of the study.

**Figure 4.** Evolution of wound bed condition difference between SG and CG.

**Figure 5.** Improvement of QOL during the study period when comparing SG and CG.
The number of wound dressings used per patient during the study period for the SG (treated with CP system) was 14 (mean) dressings (range 9–25). For the CG, the number of dressings used per patient was 23 (mean) (range 13–37). The difference between the two groups was significant; \( P < 0.02 \) (difference of the mean).

The evolution in health scale during the study is shown in Figure 3. There was a significant difference between the start of the study and the end of the study regarding the health score for both the SG and the CG. The difference in the SG was larger; however, between the SG and the CG, the difference was not significant.

The DWCS color concept model was used to track the evolution of wound bed condition. The model uses three colors: red = granulation, yellow = sloughy tissue, and black = necrotic tissue. Ulcer tracings and digital photographs were used to indicate changes in the ulcers during the study. The evolution of wound bed condition was better and faster for the SG treated with the CP products (\( P < 0.05 \), Figure 4).

Quality of life evolution during the study was measured using a specifically designed questionnaire (Table 1). An improvement in QOL was noted for the SG (\( P < 0.05 \)) for the combined QOL parameters, as well as for a decrease of pain (\( P < 0.005 \), Figure 5).

Pain evolution during the study period was performed using a specific questionnaire, looking at pain patterns, medication, sleeping patterns, etc. There was a significant decrease in pain during the study period for both groups. The reduction in pain was faster and larger for the study group (Figure 6).

Treatment costs per patient for 12 weeks treatment for the study group was \( \€280.87 \) ($372.64) versus \( \€630.02 \) ($835.88) for the control group. The total cost per healed patient within the 12-week study period was for the SG \( \€262.40 \) ($348.14) versus \( \€100.40 \) ($531.23) for the CG.

Healing rates and cost reduction are shown in Figure 7. The difference between SG and CG was significant (\( P < 0.05 \)). Figure 7A shows the reduction in ulcer size versus costs between the two groups.

The compression system for the CP group was reported as “simple to apply.” As these are short-stretch bandages, the clinicians readily understood how to apply them at full extension. The clinicians noted that the use of foam bandages under the padding helped the bandages stay in place for the intended period and prevented the bandages from slipping.
Discussion

In leg ulcer treatment, there is still little evaluation of treatments used and patient outcomes.

A UK-based project applied a rationalization of community service linked to acute services. The approach of standardized treatment protocols and education improved a liaison between professionals in community leg ulcer clinics. It was suggested that the education should not only promote the use of research-based practice, but is to be developed and evaluated through research.

Although the number of patients included in the present study was limited, the study looked at various relevant aspects of the treatment of patients with leg ulcers and confirmed results shown in the literature. The present study demonstrated an improvement in QOL aspects as well as quality of care. Cost savings are not just due to the application of more effective materials. Treatment outcomes are influenced by the knowledge and motivation of both patients and clinicians. Moreover, an improved level of knowledge and communication between the clinicians involved in the care of patients with venous leg ulcers was instrumental in the demonstrated outcomes.

Conclusion

Communal knowledge and effort can be tuned to the interest of patients and institutions. Clinical pathways applied throughout the continuum of care support overall improvement in the quality of care.

- The CP system used in the SG was shown to be significantly superior regarding evolution of the wound bed and QOL aspects when compared to the CG.
- The CP system demonstrated a trend toward superior performance regarding wound area reduction, health scale, and pain when compared to the CG.

References