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**VERUM – A European Approach for
Successful Venous Leg Ulcer Healing:**

**Implementation of a Comprehensive
Therapy Concept (VERUMI3) in Daily Practice**

PRESSURE ULCERS IN SPAIN



VERUM – A European Approach for Successful Venous Leg Ulcer Healing: Implementation of a Comprehensive Therapy Concept (VERUM¹³) in Daily Practice

ABSTRACT

Background: Successful healing of venous leg ulcers can only be achieved with a combination of compression therapy and moist wound healing¹. Therefore, this treatment strategy is recommended by therapy guidelines; however, implementation in daily practice is thought to be, at the least, complicated or even impossible.

Aim: The main aim of this study was to determine whether a clear treatment strategy is helpful for the implementation of a holistic therapy concept. In order to generate additional information about the practicability and implementation of holistic therapy concepts necessary for successful healing of venous leg ulcers, a comprehensive therapy concept consisting of compression therapy and moist wound care was implemented in daily medical practice in different countries.

Methods: Sixty-three patients from Germany, Italy, and Austria were treated for 12 weeks in daily medical practice with phase-adapted moist wound dressings, bacteria-binding wound dressings, and short-stretch compression bandages in the initial oedema phase, followed by compression treatment using a compression stocking system with high stiffness characteristics.

Findings: Approximately 85% of wounds were significantly reduced in size, and 53% of wounds healed completely within 12 weeks. The patients' well-being was substantially improved, leading to high compliance. As the majority of patients had not experienced any progress in healing for extended periods of time due to their complicated health situation or ineffective treatment, these results were rated very positively by patients and physicians. In addition, the bacteria-binding wound dressing allowed infected wounds to be treated without antibiotics.

Conclusion: Holistic therapy concepts offer significant advantages and can be successfully implemented in daily practice independent of national or local wound care traditions.

INTRODUCTION

Clinical data indicate that compression accelerates the healing process of venous leg ulcers², and wound-healing rates are far superior in patients treated with compression than in those treated without compression^{3,4}. Thus, to improve the healing process, clinical guidelines recommend treatment of venous or mixed venous ulcers (0.6 > ABI < 0.9) with high pressure of 30 to 40 mmHg at the ankle⁵. On the other hand, 50% of all patients with venous leg ulcers heal completely within 3 months following treatment with moist wound healing, and 70% of the cases within 1 year with this strategy⁶. Therefore, the concept of moist wound management in combination with compression is considered the most effective approach; yet, these findings do not receive adequate attention in actual daily practice^{7,8,9,10}.

In Germany in 2002, only an estimated 10%-20% of patients with chronic wounds received moist wound therapy⁸, and as many as 25% of patients with venous leg ulcers failed to receive compression therapy⁷. These findings were confirmed by a survey of 45,975 patients on the use of compression therapy in combination with contemporary moist wound management, as the study showed that patients with chronic leg ulcers did not always receive optimal treatment in Germany⁸.

Even though the general consensus is that successful healing does not depend on the quality of a single product alone but rather on the interaction of all products within a comprehensive therapy concept, such concepts are not consistently implemented in daily practice. Most likely, this occurrence is not due to the complexity of the therapy concepts alone, which can make their implementation difficult, but rather due to the lack of previous experience with the combined use of multiple wound-healing and compression products.

In an effort to gain further experience in the implementation of complex therapy concepts for treatment of venous leg ulcers, 63 patients in Germany, Italy, and Austria were treated with compression therapy and moist wound dressings. The objective of this multicentre evaluation was not only to assess the performance and ef-



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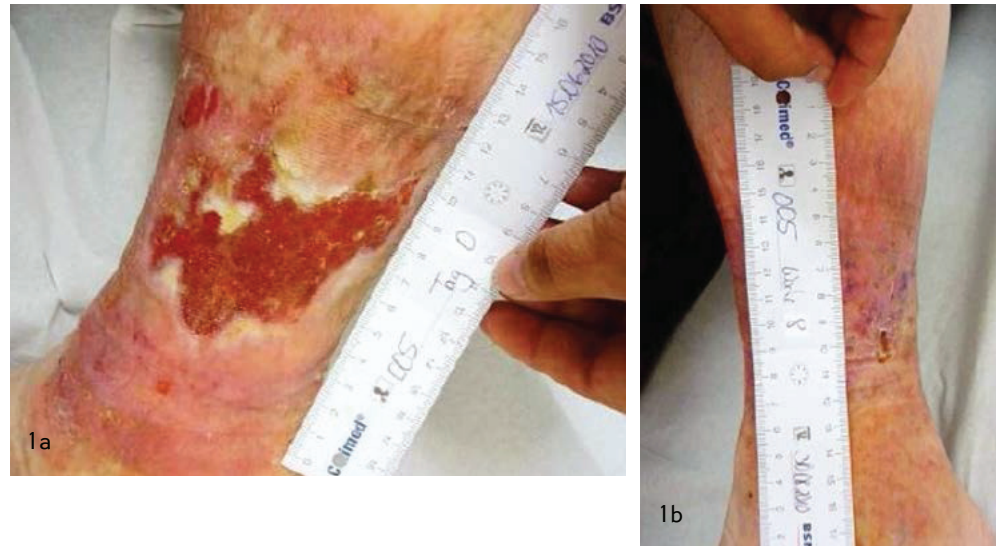
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Figure 1: A 6-month-old *Ulcus cruris venosum* of a 74-year-old patient who was also diagnosed with other risk factors including contact sensitization and obesity. The ulcer showed signs of infection and red wound edges. Treatment was initiated on 15th June 2010 (a). Full wound healing was achieved on 30th August 2010 (b).



fectiveness of the wound care and compression products but also to investigate the efficacy of the overall therapy concept under conditions of routine medical care.

METHODS

Region

The multicentre case studies were conducted on a non-interventional basis at several phlebological surgeries and wound care centres in Italy (Roberto Brambilla, Istituti Clinici Zucchi, Monza; Daniele Aloisi, Poliambulatorio Mengoli, Bologna; and Marco Fioruzzi, Policlinico San Marco, Zingonia), in Germany (Dr. Iris Weingard, Venenzentrum Freiburg, Freiburg; Dr. Thomas Heisterkamp, Dermatologisch-Phlebologische Praxis Gescher, Gescher; and Dr. Edith Janthur, Venenzentrum SAARLOUIS, Saarlouis) and in Austria (Peter Kurz, Wund Pflege Management GmbH, Bad Pirawarth).

Time Frame

In accordance with the predefined observation schedule, the baseline visit was followed by a maximum of five follow-ups within a 12-week period. The total period of observation varied from 6-12 weeks, depending on the status of the individual patient and wound-healing progress.

Aetiology

Only patients with ulcers of venous aetiology were included. Many patients also suffered from other diseases, including diabetes (15.9%), cancer (7.9%), and hypertension (11%). The majority of the patients had additional risk factors, such as allergies. Every patient had at least one chronic ulcer. According to the contra-indications, patients with arterial leg ulcers, recent deep vein thrombosis, or cardiac insufficiency were excluded. The patient ankle-brachial index (ABI) differed from 0.8 to 1.1. None of the patients showed any signs of arterial occlusive disease. In 31.7% of cases, the body mass index (BMI) was $> 28 \text{ kg/m}^2$ (obese patients). Patient age varied between 41 and 92 years, and 58.7% of the patients were women (37/63).

Wound Status

Only venous leg ulcers of less than 1 year were included. The size of the ulcers varied from 10 to 90 mm in length and from 5 to 98 mm in width at baseline (length, $28.3 \pm 21.6 \text{ mm}$ (mean $\pm$ standard deviation); width, $16.7 \pm 16.8 \text{ mm}$; resulting wound surface area, $5.1 \pm 12.0 \text{ cm}^2$). Approximately 43% of the wounds showed signs of infection/biofilm (redness, itching, pain, or odour), and 80% of the wounds exhibited red wound edges.

Data Management

During this evaluation, wound status and healing was documented on the basis of clinical standard parameters. Initial set up of the protocol and questionnaires as well as the data collection was supervised by an external clinical laboratory. The wound status was documented by photo and with a description at the beginning of the study (baseline) and at each subsequent visit. Relevant parameters included the size and appearance of the wound (phases of wound healing, exudation, and signs of infection) as well as the peri-wound skin. Complete healing was defined as full closure of the wound. Furthermore, the evaluation included a patient Quality-of-Life (QoL) survey that was based on the Tübingen Questionnaire¹¹, in which patients were asked about the degree of impairment they experienced in their routine activities, such as lifting and carrying heavy objects, standing for extended periods of time, light/heavy household and gardening chores, and walking and climbing stairs.

At the final visit, the attending physician provided a final assessment of the outcome as well as the therapy concept. The computer-aided documentation during the study was performed by the investigators and evaluation staff at the centres. The data were evaluated by means of descriptive statistics.



Figure 2: A 3-month-old *Ulcus cruris venosum* of a 59-year-old patient who was diagnosed with disturbed perfusion. The ulcer showed signs of infection and red wound edges. Treatment was initiated on 19th April 2011 (a). Wound closure was achieved on 31st May 2011 (b).

Wound Treatment and Compression Therapy

Before applying the high stiffness compression stocking system (JOBST® UlcerCARE™, BSN medical GmbH) the oedema had to be reduced to allow selection of correct stocking size. For this purpose short-stretch compression bandages (in Germany and Austria, Comprilan was used, and in Italy, Comprilan or Tensoplast [BSN medical GmbH] was used) were applied for up to one week depending on the extent of the oedema. The bandages were applied by experienced staff. According to the local protocol, the wounds were always cleaned, and the wound edges protected with a polymeric solution (e.g., Cutimed® Protect, [BSN medical GmbH]) before application of the wound dressing and compression. For exuding wounds, a superabsorbent polyurethane foam dressing (Cutimed® Siltec range, BSN medical GmbH) was used. In the case where signs of infection were noted, a bacteria-binding dressing (Cutimed® Sorbact® [BSN medical GmbH]) was placed directly on the wound and then covered with the foam dressing. In these cases, after normalisation of the wound, the bacteria-binding dressing was applied as a preventive measure. At the beginning, the wound dressings were changed daily, while later, the dressings were changed less frequently depending on the status of the wound (e.g., signs of infection or wound fluid). At subsequent visits following reduction of the oedema, wounds were treated similarly, but a compression stocking system (40 mmHg) was applied instead of the compression bandages. Instructions for use included use of the liner for 24 h and the upper-stocking for 12h. All wounds were treated regularly depending on the status of the wound but the complete questionnaire and patient survey were assessed, and pictures were taken only after 2 weeks (optional) and after 4, 8, and 12 weeks.

RESULTS

At the baseline, the wound status of the majority of leg ulcers was rather complicated: 82% of the wounds showed inflammation, 4% were covered by necrosis, and 59% were covered by slough. Heavy exudate was reported in 24.1% of the ulcers, and moderate exudate levels were observed in 75.9% of the wounds. In addition, 93% of all patients showed a pronounced redness of the wound edges.

During routine examination, infections were suspected in 48% of the patients due to the presence of classical signs, including redness, pain, and odour. In cases of suspected infection, a bacteria-binding dressing was applied during the observation period. The intended therapy was, therefore, implemented without the use of antibiotics. Furthermore, an overall reduction of redness was observed over the course of the wound treatment in these cases.

Individual differences in wound size reduction (length, width, and depth) were observed after 2, 4, 8, and 12 weeks according to analysis with the Wilcoxon test together with photo documentation. In 85% of cases, either a reduction in wound size or complete healing of the wounds was achieved. In cases where complete healing was not achieved, wound size reductions ranged from 43.8% to 92.4%. Examples are shown in Figures 1 and 2.

In addition, 65.5% of the patients reported illness-related limitations in daily activities, and 24.1% even characterized their situation as mostly or completely impaired. The individual illness-related limitations in daily activities varied, likely depending on the severity of the oedema, pain, and wound status. The analysis of the Tübinger Questionnaire revealed a shift from high to low impairment during the period of the observation and from low to no impairment in tasks such as lifting objects, walking, standing, and household and gardening chores. Spontaneous reports of improvement in general were also noted, as patients experienced substantial improvement in

their wound status and well-being. These improvements resulted in a high degree of patient compliance. Only one patient did not comply with the programme, and none of the other patients asked for premature discontinuation of treatment.

Physicians rated the use of a stocking system very positively but pointed out that oedema reduction by means of compression bandages is very important to ensure an optimal fit of the stocking system. As in typical clinical practice, treatment adaptations were necessary for individual patients. Three patients experienced an increase in swelling after initial reduction of their oedema, rendering the compression system too tight. One patient developed an adverse reaction to one of the components of the wound dressing (redness and itching in the contact region of the wound dressing). Two patients developed an infection during the observational period and had to be treated systemically. In two other cases, no healing progress was achieved within 12 weeks. This scenario indicates that the patients were likely resistant to this therapy, and the patients were thus treated differently. Another patient experienced a massive deterioration of his general health status (acute erysipelas) at the beginning of the observation period, resulting in additional treatment; however, no causal relationship with the therapy concept could be established. One patient was considered a drop-out, as he failed to follow the physician's instructions by switching to a different product for one week without permission. As a result, he did not wear the compression stocking system as recommended, which resulted in deterioration in wound status.

Overall, the therapy concept was rated very positively. Both patients and physicians reported that they would use it again. In combination with close monitoring and guidance of the patients, the therapy concept resulted in a high degree of patient satisfaction and compliance.

DISCUSSION

Currently, the combination of moist wound management and compression is acknowledged as the most effective approach for treating venous leg ulcers^{3,4}. Therefore, it is surprising that this therapy concept is given little attention in actual daily practice, even in highly developed countries such as Germany^{7,8,9,10}. To our knowledge, data regarding the implementation of this approach into daily practice in other European countries are not available, and thus, this lack of implementation is presumably not an issue only in Germany. Insufficient knowledge of the selection of compatible compression and wound manage-

ment products may underlie the lack of implementation of this fundamental scientific knowledge in daily practice.

The scope of this evaluation was to determine whether a clear treatment concept is helpful for the implementation of a holistic concept. Therefore, a set of well-adapted products was selected, and application of these products was carefully explained. In our opinion, it is important that the wound care products work reliably under compression. The choice of super-absorbent polyurethane foam dressings with skin-friendly silicone was based on the fact that this type of wound dressing maintains a moist environment in wounds even under compression under 40 mmHg. Indeed, we observed very good fluid handling by the wound dressings (moist wound-healing conditions with no maceration). In addition, atraumatic dressing changes (no pain and no sticking to the wound) were achieved. We also recommend protection of the wound edges for additional safety.

Since wound infections hinder progress in wound healing in our opinion antimicrobial control is a very important part of the treatment concept. Therefore, we included a bacteria-binding wound dressing, which binds bacteria irreversibly via a physical mode of action¹². The bound bacteria are inactive and unable to replicate and are removed with each dressing change, reducing the overall bacterial load without the risk of cytotoxicity or bacterial resistance¹². Our results show that the bacteria-binding dressings work well in concert with the foam dressings even under 40 mmHg. Therefore, the bacteria-binding dressing is a helpful tool for controlling wound infections.

Despite the prevalence of different local treatment protocols, all physicians implemented the treatment concept successfully, and the high number of different products presented no hindrance to implementation of the treatment into daily practice. Positive healing results in 85% of the cases confirmed previous scientific evidence that the combined use of moist wound management and compression systems provides an adequate therapy concept for treating venous leg ulcers³. As the majority of patients had not experienced any progress in healing for extended periods of time before this study, even small improvements were considered a success.

In the many cases where an infection was suspected, the achieved wound healing results can be considered very positive. Also, in these cases, the therapy could be followed without interruption or the use of antibiotics (with exception of two patients). Furthermore, the compression stocking systems, which were easy to don and were operator-independent, were appreciated by both patients and physicians.

In conclusion, we observed that a clear and easy-to-understand therapy concept increases patient satisfaction and QoL and leads to a high patient compliance and acceptance by physicians. With a trend toward shortened hospital stays and ambulant treatment of wound patients, the need for simplified treatment concepts increases. Our example encourages implementation of this therapy concept into daily practice, and additional clinical evidence in support of such concept is warranted in order to increase the number of adequately treated venous leg ulcers. ■

Implications for Clinical Practice

- This therapy concept together with close monitoring and guidance of patients achieves good healing results.
- Even complex therapy concepts can successfully be integrated into daily practice.
- The therapy concept could be implemented independently of local treatment traditions.
- The therapy concept improved patient Quality-of-Life and as a result patient compliance.

Further Research

- Further case studies are planned in the UK and USA to support these observations.
- Further case studies with bigger wounds are planned, keeping in mind the increasing number of ambulant patients with big wounds and the earlier discharge of patients into self-management in the future.

References

1. Dissemmond J. Compression therapy in treatment of *Ulcus cruris venosum*. Dt Ärztebl 2005; 102:2788–2792
2. Klode J, Körber A, Wax C, Dissemmond J. Results of an enquiry concerning the compression therapy and moist wound care including 45 975 patients with *Ulcus cruris venosum*. ZfW 2009; 3:152–158.
3. Wong IKY, Lee DTE, Thompson DR. A randomized controlled study comparing modern wound care alone or in combination with short- or long stretch bandages in treatment of venous leg ulcer. Vasomed 2006; 4: 149–150.
4. Partsch H, Flour M, Smith PC; Indications for compression therapy in venous and lymphatic disease consensus based on experimental data and scientific evidence. Under the auspices of the IUP. International Compression Club. Int Angiol. 2008 Jun;27(3):193–219.
5. Benigni J.P., Echegut P., Mourmaren M. Uhl J. F. and Cornu-Thenard Compression stockings for treating venous leg ulcers FLEBOLOGÍA Y LINFOLOGÍA - LECTURAS VASCULARES:17 / 4 2012
6. Dissemmond J. *Ulcus cruris – Basics, Diagnostics und Therapy*. 3 Auflage. Bremen: UNI-MED Verlag 2009.
7. O'Meara S, Cullum NA, Nelson EA. Compression for venous leg ulcers. Cochrane Database Sys Rev 1,2009; CD000265.
8. Grams LF. Medical care situation in case of chronic wounds: A study analyzing the medical care of patients with *Ulcus cruris* on the basis of therapy guidelines and medical evidence in the area of Hamburg. http://www.sub.uni-hamburg.de/opus/volltexte/2009/4236/pdf/Dissertation_zur_Versorgungsqualitaet_chronischer_Wunden.pdf. 2008.
9. Panfil EM, Mayer H, Junge W et al. Wound care of chronic wounds in the ambulatory treatment – Pilotstudie. Pflege 2002; 15: 169–176.
10. Rüggeberg JA, Golbach U. Medical care of patients with chronic wounds in Germany. Results of an enquiry. BDC Online, www.bdc.de.2007.
11. Klyscz T, Jünger M, Schanz S et al. Lebensqualität bei chronisch venöser Insuffizienz (CVI). Ergebnisse einer Untersuchung mit dem neu entwickelten Tübinger Fragebogen zur Messung der Lebensqualität von CVI-Patienten (TLQCVI). Hautarzt 1998; 49: 372–381.
12. Ljungh Å, Yanagisawa N, Wadström T. JOURNAL OF WOUND CARE 2006; 4, 15
13. Abbreviations VERUM Venous Return Ulcer Management

Venous Leg Ulcer Therapy



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