A. *Ulcus crusis venosum* prior to the application with JOBST® Compri2 compression system.

B: Directly after the application of JOBST® Compri2 compression system (5.12.2014).

C. After 3 days of application of JOBST® Compri2 compression system (8.12.2014).

Fig. 3: A 61- year old patient with history of a non-healing *ulcus crusis venosum* for 17 years, was treated with moist wound care and compression therapy using JOBST® Compri2 for 3days. In this case additional padding was used for the toes. This patient had been treated previously with several other compression systems e.g. short stretch bandages and recently (1.4.2014) with the two-layer compression system Rosidal TCS (Lohmann&Rauscher).

References

1. Klode J, Körber A, Wax C, Dissemond 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
2. Dissemond J. Compression therapy in treatment of Ulcus cruris venosum. Dt Ärztebl 2005; 102:2788–2792
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. O´Meara S, Cullum NA, Nelson EA. Compression for venous leg ulcers. Cochrane Database Sys Rev 1,2009; CD000265.
6. 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 Versorgungsqualität chronischer Wunden. pdf. 2008.
7. Panfil EM, Mayer H, Junge W et al. Wound care of chronic wounds in the ambulatory treatment – Pilotstudie. Pflege 2002; 15: 169–176.
8. Rüggeberg JA, Golbach U. Medical care of patients with chronic wounds in Germany. Results of a enquiry. BDC Online, www.bdc.de. 2007.
9. Margolis DJ, Bilker W, Santanna J, et al. Venous leg ulcer: incidence and prevalence in the elderly. J Am Acad Dermatol 002;46(3):381-6. PMID: 11862173. Venous leg ulcers constitute the majority of all ulcers seen in the United States.
10. Lamel SA, Kirsner SR (2013) New approaches to enhanced wound healing: future modalities for chronic venous ulcers. Drug Discovery Today: Disease Mechanisms, Dermatology Vol. 10, No. 3–4, pg e71 – e77.
11. Rajendran S, Rigby A, Anand S (2007) Venous Leg Ulcer Treatment and Practice-Part 3: The Use of Compression Therapy Systems, Journal of Wound Care, 16, 107-109.
12. Tang J, Marston W, Kirsner R (2012) Wound Healing Society (WHS) venous ulcer treatment guidelines: What's new in five years? Wound Repairs and Regeneration, vol 20, p 619–637
13. Rockson, S, Rivera, K (2008) Estimating the Population Burden of Lymphedema. Annals of the New York Academy of Sciences, 1131: 147-154.
14. O´Meara S, Cullum NA, Nelson EA . Compression for venous leg ulcers. Cochrane Database Sys Rev. 3 2013.

Authors:
C. Hampel-Kalthoff, ORGAMed Dortmund GmbH, Breierspfad 159, 44309 Dortmund, Germany
J.B. McGuire, Leonard Abrams Center for Advanced Wound Care, Temple, University School of Podiatric Medicine, 3340 North Broad Street, Philadelphia, PA 19140, USA
K.C. Münter, Bramfelder Chaussee 200, 22177 Hamburg, Germany
S. Ehmann, Stanly Regional Medical Center - Edema Management Program, 301 Yadkin Street, P.O. Box 1489 Albermarle, NC 28002 USA
K. Will, BSNmedical GmbH, Quickbornstr. 24, 20253 Hamburg, Germany
N. Sinclair, BSN medical, Inc., 5825 Carnegie Blvd, Charlotte, NC, 28209, USA

BSN medical Inc. 5825 Carnegie Blvd. Charlotte, NC 28209-4633
Tel. (+1) 704 554 9933 Fax (+1) 704 358 4558 www.bsnmedical.com
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Compression Treatment for Patients with Venous Edema or Phlebolymphedema - Clinical White Paper

Implementation of the new two-layer compression bandage system JOBST® Compri2

Hampel-Kalthoff, C.; McGuire, J. B.; Munter, K. C.; Ehmann, S.; Will, K.; Sinclair, N.

March 2015

I) Objective

To provide evidence that the newly developed two-layer compression system , JOBST Compri2, can be easily implemented in the daily practice by treating patients with chronic venous insufficiency (CEAP classification class 6) or phlebolymphedema with/without leg ulcers in daily medical practice in different countries. Ease of application and wearing comfort will be observed.

II) Introduction

Compression therapy is the cornerstone of the treatment for venous edema, venous leg ulceration and lymphatic disorders. Compression, in addition to moist wound therapy, has been shown to be superior for healing of venous leg ulcers.[1-4] Furthermore it has been demonstrated that high compression levels (30 to 40 mmHg) produced by bandaging and strong compression stockings are most effective at healing leg ulcers and preventing progression of post thrombotic syndrome.[4] Nevertheless, these findings are given too little attention.[5-8]

Venous leg ulcers are extremely common in the United States and affect between 500,000 to 2 million people annually.[9]

Advanced wound dressings regulate moisture found at the wound surface through moisture retention or exudate absorption, protecting the wound base and periwound tissue. Additionally, maintaining moisture balance minimizes patient discomfort before, during, and after dressing changes. Venous stasis ulcers are often difficult to heal because of a combination of the underlying disease (venous insufficiency/hypertension), edema, the production of large amounts of exudate and (the potential for) bacterial contamination and infection. Exudate from this type of lesion is known to harbor bacteria and to contain compounds such as metalloproteinases, some of which are not beneficial to the wound healing process.
Today, the principle of moist wound healing is well accepted as the therapy concept of choice for chronic wounds. It has been confirmed that moist wound healing has various beneficial effects in the wound bed.
Treating a venous leg ulcer requires a 2-pronged approach: edema, a consequence of venous hypertension, needs to be managed and venous stasis, essentially the primary reason for a venous leg ulcer to occur, needs to be counteracted. It has been established that compression serves both purposes: indeed, proper compression by itself has been shown to contribute significantly to the healing of venous leg ulcers.[10-12]

Prevalence estimates for lymphedema are relatively high, yet its prevalence is likely underestimated. Attempts to identify the population impact of lymphedema are hampered by the fact that this chronic, debilitating disease is frequently under recognized or misdiagnosed: treatment delays are common and many patients never receive treatment.[13]

Compression bandages help blood to return to the heart from the legs, and there are a variety of types of bandage systems available; some are just a single bandage, while others require the application of several different types of bandages to the leg.[14]

Many compression systems are commercially available, but these systems may have significant practical problems: the traditional bandaging systems are difficult to apply and tend to slip down over time. Moreover, when bandaging systems are improperly used an inconsistent or even worse, reversed pressure gradients may occur.

More training and education are needed to increase knowledge of the appropriate materials and application compression systems. In addition easy to understand and to apply products, which are well accepted by the patient will help to treat patients adequately in daily practice.

III) Introduction

The use of compression for the management of lower extremity edema and venous leg ulcer is well documented in the medical literature. However there is inconsistent use and application of appropriate compression. The ideal compression system is one that can be easily and consistently applied, reduces venous hypertension thereby promoting venous and lymphatic return enhancing edema reduction and/or management, and is comfortable and tolerable to the patient requiring minimal alterations in daily routine. The major criticism of compression therapy of today is the high therapy burden leading to poor patient compliance. To reduce this burden a new two-layer compression system, JOBST® Compri2, was developed and implemented into the daily practice in USA and Germany.

IV) Methods

Twenty-one patients with chronic venous insufficiency (CEAP classification class 6, edema and active venous leg ulcers) and five phlebolymphedema (three with leg ulcers, two without leg ulcers) were treated for 3 or up to 7 days with the two-layer compression bandage system JOBST® Compri2, depending on the wound status and patient specific medical needs.

The compression bandage system, JOBST® Compri2, was applied following the instructions for use (IFU) and the wounds were treated according to the medical protocol of each center.
In the U.S. the following clinicians/centers were used:

- McGuire J. B. Leonard Abrams Center for Advanced Wound Care, Temple University School of Podiatric Medicine, 3340 North Broad St., Philadelphia, PA 19140
- Ehmann S., Stanly Regional Medical Center, 301 Yadkin Street, P.O. Box 1489 Albemarle, NC 28002
- Athens Regional Medical Hospital, 1199 Prince Ave, Athens, GA 30606
- 1515 N Madison Ave, Anderson, IN 46011,

In the Germany the following clinicians/centers were used:

- Hampel-Kalthoff, C, ORGAMed Dortmund GmbH, Breierspfad 159, 44309 Dortmund
- Münter K.C., Bramfelder Chaussee 200, 22177 Hamburg

Product performance (e.g. slippage) and the satisfaction of the participants (wearing comfort and mobility of the patient) as well as usability of the product (e.g. ease of application) were monitored and a questionnaire was completed to document the results. As a part of the regular clinical routine in the German centers the circumferences at the B and C point were measured before and after treatment to analyze the effect of the compression treatment on the extent of the edema.

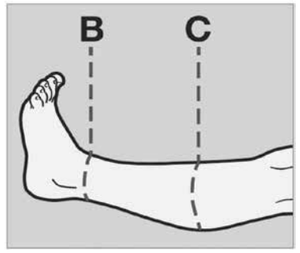

Fig. 1: Measurements of the circumference at B the ankle and C the calf

(V) Conclusion

Effective compression bandage systems like the new JOBST® Compri2, which can easily be applied and provide high wearing comfort, are well accepted by patients, physiotherapists, nurses and physicians. JOBST® Compri2 can be easily implemented in the daily routine in the clinics and at home.

(VI) Results

In an effort to gain further experience in the implementation of a new two-layer compression bandage system JOBST® Compri2, 21 patients with chronic venous insufficiency (edema and active venous leg ulcers) and five with phlebolymphedema (three with, two without leg ulcers) were treated for 3 or up to 7 days a part of their daily medical practice in the USA and Germany. The age of the patients ranged from 43- 90 years (10 men, 16 women). Since the majority of patients (only one exception) had ulcers which had to be controlled regularly the wound dressings and the compression system were reapplied after 3 days or if possible after 7 days. Prior to the reapplication the fit of the compression system was analyzed

analyzed revealing no or only slight slippage (less or comparable to other compression systems) after 3 and 7 days of treatment. Only three cases of obvious slippage were reported probably due to heavy usage (e.g. active daily activities). By measuring the circumferences at points B and C of the legs of the patients, edema reduction (up to 4.5 cm) or no change of circumferences after three days of application of JOBST® Compri2 were observed (Fig. 1). The extent of the edema reduction varied depending on the individual patient's health condition and former compression treatment.

In addition to the assessment of the effectiveness of JOBST® Compri2, usability of the compression system was analyzed by monitoring the ease of application. All practitioners rated the ease of application with excellent, very good or good independently of their former experience using other systems, e.g. UrgoK2 (Urgo GmbH), Rosidal TCS (Lohmann&Rauscher) or country specific modalities (Germany, USA) and expressed their satisfaction. Furthermore, the patients were asked about their restriction of movement linked to use of the compression system and about the wearing comfort, which revealed high patient satisfaction (see Fig. 2). They reported that they could wear their own shoes.

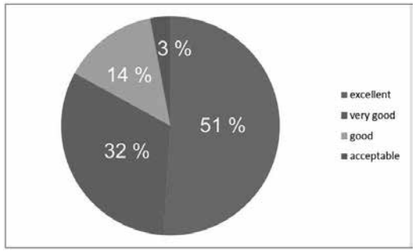

Fig. 2: Summary of the wearing comfort using JOBST® Compri2 rated by patients (including wearing time 3 days and 7 days)

Only in one case was the patient (4%) not satisfied (mentioned that the compression system is too tight). In contrast to this patient, other patients wanted to continue the compression therapy using JOBST® Compri2 after the end of this evaluation . For example, the patient shown in Fig. 3 liked the JOBST® Compri2 very much and even preferred this two-layer compression bandage system to recently used products. In addition some patients greatly favored JOBST® Compri2 because they had experienced itching under the compression bandage system Rosidal TCS (Lohmann&Rauscher), which did not occur with JOBST® Compri2. In conclusion, practitioners and patients readily accepted JOBST® Compri2 compression techniques and successfully integrated the new system in their medical routine.

(VII) Discussion

The use of compression for the management of lower extremity edema and venous leg ulcer is well documented in the medical literature. However there is inconsistent use and application of appropriate compression. The ideal compression system is one that can be easily and consistently applied, reduces venous hypertension thereby promoting venous and lymphatic return enhancing edema reduction and/or management, and is comfortable and tolerable to the patient requiring minimal alterations in daily routine.

In this evaluation edema was reduced or recurrence prevented in all cases which demonstrates the efficacy of JOBST® Compri2 for the management of edema in this patient population.

Since most of the patients (n=25) were treated with other compression systems or compression garments prior to the compression with JOBST® Compri2, this outcome received a very positive rating by the practitioners. High comfort and excellent mobility during the application of JOBST® Compri2 resulted in high patient satisfaction and compliance.

Furthermore, the high comfort and excellent mobility during the use of JOBST® Compri2 resulted in high patient satisfaction and compliance.

Although this is only a first and preliminary report on JOBST® Compri2, it already provides valuable insights into the use of this compression system. Monitoring of the efficiency and performance of the systems will be continued.