



Evidence review: Efficacy and reproducible compression of the KTwo bandage system

Contents

Foreword	S3
Efficacy and reproducible compression of KTwo	S4
Evidence for practice	S4
Implications for clinicians	S5
Aetiology	S5
Sustained graduated compression therapy	S7
How compression therapy works	S7
Compression bandage systems	S8
The static stiffness index (SSI)	S8
The KTwo compression bandage system	S9
Literature review	S10
Alternative evidence	S14
Conclusion	S16
References	S16



Declaration of interest

This supplement was commissioned and supported by Urgo Medical.

Maureen Benbow is an independent consultant who received a fee for her contribution



MA HEALTHCARE LIMITED

© 2013 MA Healthcare Ltd

All rights reserved. No reproduction, transmission or copying of this publication is allowed without written permission. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, mechanical, electronic, photocopying, recording, or otherwise, without the prior written permission of MA Healthcare Ltd or in accordance with the relevant copyright legislation.

Although the editor, MA Healthcare Ltd and Urgo have taken great care to ensure accuracy, neither MA Healthcare Ltd nor Urgo will be liable for any errors of omission or inaccuracies in this publication.

Published on behalf of Urgo by MA Healthcare Ltd.

Publishing director: Anthony Kerr

Editor and Associate Publisher, Med Ed: Tracy Cowan

Sub-editor: Peter Bradley

Designer: Alison Cutler

Published by: MA Healthcare Ltd, St Jude's Church, Dulwich Road, London SE24 0PB, UK

Tel: +44 (0)20 7501 6726 **Email:** anthony.kerr@markallengroup.com **Web:** www.markallengroup.com

Foreword

Humans are upright living animals and therefore victims of gravity. This explains the fact that most wounds are situated on the distal part of the lower extremity and that compression, counteracting gravity, will remain the basic management for treating these conditions.

Concerning the mode of action of proper compression therapy, some fresh insights have emerged over the past few years, leading to better understanding of this important, but frequently still underestimated, treatment modality.

However, all our theoretical knowledge has had only modest beneficial influence regarding better care of our patients.

The fact that too many patients in the community are still suffering from long-term leg ulcers is mainly due to inadequate care of these patients.

In spite of a general conviction that good compression plays a crucial role, this treatment is often delegated to clinicians who have never been shown good compression bandaging techniques and who handle different systems incorrectly.

There is obviously a need for compression products that are effective and which can be easily and safely applied without intensive training.

As demonstrated in this evidence review, the KTwo system (Urgo Medical) seems to fulfil these requirements. Good evidence is presented that this system is effective and safe.

It is proven that pressure indicators on the bandages make it easy and safe to apply the correct pressures and to maintain the applied pressure for several days.

The combination of a short-stretch (inelastic) first component containing wadding, together with a cohesive long-stretch (elastic) bandage, produces a compression system that provides relatively high stiffness.

As explained in this review, stiffness is defined by the increase of compression pressure when leg muscles contract; for instance, by standing up from the recumbent position, by dorsiflexions or by walking. This parameter of stiffness has decisive importance for the haemodynamic action of compression during walking and characterises the

relationship between tolerable resting pressure and high working pressure.

The seeming paradox that elastic material may achieve compression with high stiffness can be explained by the high friction between the different layers, especially when adhesive surfaces are used.

One practical consequence of these considerations is the proposal of an international consensus to use the terms of 'elastic' and 'inelastic' only in connection with single bandages, while the elastic property of composite bandages would instead be characterised by using the expressions more or less 'stiff'.¹ *In vivo* measurements of the bandage pressure following a standardised protocol are able to quantify stiffness.

The KTwo system certainly belongs to the category of a rather stiff bandaging system. This explains the convincing clinical results that are nicely compiled and documented in this supplement, following the principles of evidence-based medicine.

Enjoy your reading!

Reference

1 Partsch, H., Clark, M., Mosti, G. et al (2008) Classification of compression bandages: practical aspects. *Dermatol Surg* 34: 5, 600–9



Hugo Partsch, MD
Emeritus Professor of Dermatology
Medical University of Vienna, Austria

Efficacy and reproducible compression of KTwo

To achieve good patient outcomes, clinicians must ensure that clinical decision making is informed by valid and reliable evidence. This review examines the evidence on the clinical efficacy and reproducibility of compression applied by the KTwo bandage system. Its aim is to describe the evidence, not critique it. However, it clearly shows there is a body of evidence, from simple comparative evaluations to a randomised controlled trial, demonstrating the effectiveness of this system

In view of the increasing incidence of leg ulceration¹ and chronic oedema as the population ages, and the high financial and psychosocial costs associated with the condition, clinicians have a professional and ethical responsibility to ensure that treatment is evidence-based.² This involves searching and evaluating the evidence to determine the safety, efficacy, cost-effectiveness and potential acceptability of treatments to patients. In essence, sound, reliable and valid research evidence should be used to inform clinical decision-making, including product selection and formulary inclusions

Over the past decade, numerous research studies have highlighted the positive and dramatic benefits of compression therapy, with patients reporting reduced pain, improved mobility and generally better quality of life.³ Our understanding of the pathophysiology of chronic venous leg ulceration, chronic oedema and lymphoedema, as well as the physiological basis of compression therapy has increased, and the focus is now on choosing the most appropriate therapy for the patient, applying it correctly and improving the patient experience.



Maureen Benbow, MSc, BA, RGN, HERC,
Senior Lecturer, University of Chester

The need to establish and maintain therapeutic levels of compression has led to the development of innovative hosiery and bandages, such as the KTwo system (Urgo Medical). KTwo was designed to surmount the problems associated with elastic bandages and as an alternative to four- and three-layer systems and other two-layer inelastic systems.

This is the first of two evidence reviews on the KTwo bandage system and focuses on the efficacy and reproducibility of the compression applied. The second review, to be published in 2014, will focus on tolerance to and acceptability of KTwo, along with patients' and clinicians' experience of its use.

Evidence for practice

Traditionally, evidence hierarchies have been used to determine which types of evidence were most suitable for implementation into practice. However, some focused on study design, with emphasis on those at the top of the hierarchy (meta-analyses and randomised controlled trials (RCTs)) (Table 1), but without sufficient regard for the rigour and quality of the findings.⁴ Furthermore, due to the strict inclusion and exclusion criteria, it can be difficult to generalise the findings of RCTs to heterogeneous patient populations.⁵

To address this, strength of evidence grading systems have been introduced. These not only consider the study design, but also other aspects such as study conduct, presence or absence of bias, quantity of evidence (the number of relevant studies), directness (the link

between the diagnostic outcome and a clinical outcome), consistency of evidence (the degree to which reported findings from included studies are similar) and precision of estimates to ensure a more comprehensive evaluation.⁶ An example is the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system, which aims to standardise approaches to grading evidence and thereby facilitate clinical decision-making, for example that relating to wound-care guidelines and formularies.^{7,8,9} GRADE is used by a number of respected organisations, including the Cochrane Collaboration.¹⁰

Implications for clinicians

For clinicians, implementing evidence into practice is an ongoing and dynamic process, with 5 main stages¹¹

The first step is to determine what question to ask. In leg ulcer management, the question may be whether healing is evident or whether the patient is satisfied with the treatment.

Second, the clinician has to find the most reliable and trustworthy evidence that will answer the question. The evidence must then be appraised to determine its validity and usefulness. Resources, such as the Critical Appraisal Skills Programme (CASP, www.casp-uk.net) are available to assist with this. A decision should then be taken on whether to act on the evidence and, if so, how to incorporate it into clinical practice.

The final stage of this dynamic process is evaluation and reflection, to determine whether the actions taken have produced the desired outcomes. However, if the right question has not been asked or is not specific and focused (for example, what is the correct management of a patient with an ABPI of 0.7?), it is unlikely that reliable, valid and generalisable results will follow.

Evidence is most likely to be successfully implemented if done in consultation with the patient,¹² as this will help promote concordance.

The most important task is to critically evaluate the quality and trustworthiness of the evidence. Key sources of possible bias need to be identified. These may include: selection bias (biased allocation to comparison groups); performance bias (unequal provision of care apart from the treatment being evaluated); detection bias (biased assessment of outcome measures); or attrition bias (biased occurrence and handling of deviations from protocol and loss to follow up).¹³ Research evidence, therefore, must be carefully and systematically examined to judge its trustworthiness, value and relevance in a particular context. The value of the clinician's and patient's knowledge and experience must also not be underestimated.

Aetiology

Leg ulceration

Venous valve insufficiency is one the most common causes of leg ulceration,^{14,15} with an estimated population

Table 1. Levels of evidence for intervention studies⁹⁵ (Scottish Intercollegiate Guidelines Network, 2002)

1++ High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+ Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1– Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias*
2++ High-quality systematic reviews of case-control or cohort studies. High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2– Case-control or cohort studies with a high risk of confounding bias, or chance and a significant risk that the relationship is not causal*
3 Non-analytic studies (for example, case reports, case series)
4 Expert opinion, formal consensus
*Studies with a level of evidence '1–' should not be used as a basis for making a recommendation

prevalence of 1.2–3.2 per 1000.^{16,17} Over half will be affected for more than a year¹⁸ and despite appropriate treatment with graduated compression therapy, recurrence rates are about 28%.¹⁹ The cost, mostly in primary care, is estimated as £168–198 million per annum.²⁰

To counteract the force of gravity, when an individual moves, muscles in the foot, calf and thigh squeeze the veins, forcing the blood to move upwards and back to the heart. One-way valves in the veins close to prevent backflow of blood²¹ and increased hydrostatic pressures.²²

Normal valve function relies on functioning leg muscle pumps and is therefore impaired by inactivity, paralysis, and damage to the deep veins due to venous thrombosis, trauma or obstruction. Venous valve incompetence in the superficial or deep perforating veins of the legs can lead to constant venous hypertension. This results in a backflow of blood, slowing blood flow through the capillaries and veins, increasing the permeability of the blood vessels and resulting in leakage of red cells, protein and fluid into the tissues.²³ This, in turn, leads to swelling (oedema) and damage to the skin and other tissues. The damage may manifest as hyperpigmentation from haemosiderin deposition, lipodermatosclerosis (subcutaneous tissue fibrosis), *atrophie blanche* (small avascular areas of

scarring on the skin) and varicose eczema, which is characterised by itching and skin scaling.²⁴ Chronic venous hypertension can present as varicose veins, which, along with the discomfort and skin changes described above, can be early indicators of leg ulceration.²⁵

Atherosclerotic disease is responsible for the development of arterial leg ulcers. This occurs when the bloodflow through the arteries is obstructed in the medium and large-sized arteries, usually by atherosclerotic plaque narrowing the lumen of the artery. Tissue perfusion and the delivery of oxygen and nutrients are reduced, placing individuals at risk of ulceration (the reduced arterial blood supply results in tissue hypoxia and tissue damage). Thrombotic and atheroembolic episodes may also contribute to tissue damage and ulcer formation after apparently trivial trauma.²⁶ In addition, atheroembolic and thrombotic episodes may also contribute to tissue damage and ulceration associated with hypoxia.²⁶

Mixed-aetiology leg ulceration is due to a combination of longstanding venous disease and inadequate arterial flow. The underlying factors need to be identified, and a comprehensive clinical assessment undertaken, before treatment can be initiated.²⁷ Patients with an ABPI of <0.8 should therefore be referred for specialist assessment.

Chronic oedema

The aetiology of chronic oedema is complex, but can be simply described as tissue swelling in the limbs and/or mid-line structures such as the trunk, head and neck or genitalia that has been present for at least 3 months.²⁸ This is due to underlying causes, ranging from immobility-associated 'dependency' oedema, to venous hypertension, and/or lymphoedema.²⁹ Various causes of chronic oedema are given in *Table 2*.

Chronic oedema is frequently associated with venous leg ulceration, as the lymphatic system is unable to drain the excess fluid leaking from the capillaries into the interstitial spaces.³⁰ Many patients with venous ulcers will, therefore, suffer from chronic oedema (also known as lymphovenous disease), which can delay wound healing due to the ensuing reduced oxygenation of the affected tissue.³¹ A characteristic of chronic oedema is non-reduction of swelling with leg elevation.³²

Lymphoedema

Lymphoedema is defined as swelling of a limb or part of the body resulting from failure of the lymphatic system,³³ and occurs when the lymph drainage system fails to adequately drain fluid from the interstitial spaces back into the venous system. It leads to the accumulation of fluid and proteins in the tissues, resulting in swelling or oedema, usually affecting the limbs and/or the adjacent quadrant of the body.

Lymph fluid performs the important immunological function of transporting foreign particles and cellular debris back to the lymph nodes, where macrophages clear the lymph of bacteria, debris and other substances before the fluid returns to the bloodstream.³⁴ As a rule, lymphoedema typically occurs in the presence of an abnormality such as valvular incompetence in the lymphatic vessels³⁵ or physical damage to the lymphatic system associated with oedema.³⁶ This results in stretching of the epidermis, elevated numbers of fibroblasts and collagen fibres in the tissues, lymphatic dilatation and increased inflammatory agents.³²

Table 2. Common causes of chronic oedema

'Dependency' oedema (associated with immobility)
Oedema due to heart failure
Venous oedema, resulting from venous disease, such as post-thrombotic syndrome or severe varicose veins
Oedema associated with obesity
Lymphoedema: primary and secondary
Oedema related to advanced cancer

Table 3. Causes of oedema and lymphoedema²³

Physiology	Possible cause	Effect
↑ Capillary permeability (c)	Cellulitis, arthritis, hormonal cyclic oedema	Inflammatory oedema, 'idiopathic oedema'
↑ Venous (capillary) pressure (P _c)	Heart failure, venous insufficiency, dependency syndrome	Cardiac, venous oedema
↑ Oncotic tissue pressure (π _t)	Failure of lymph drainage	Lymphoedema
↓ Oncotic capillary pressure (π _c)	Hypoalbuminaemia, nephrotic syndrome, hepatic failure	Hypoproteinaemic oedema

In patients with venous insufficiency, pre-fascial lymphatic drainage is intact or even increased. However, it is reduced or absent in patients with deep vein thrombosis and deep venous incompetence due to a post-thrombotic syndrome resulting in oedema.²³

The various causes of chronic oedema and lymphoedema are given in *Table 3*. Effective management of chronic oedema and lymphoedema depends on correct diagnosis. It aims to enhance the function of the lymphatics, stop the swelling from getting worse and gain long-term control of the condition.³⁰

Sustained graduated compression therapy

Compression bandages aim to correct the effects of valvular incompetence and reverse the effects of chronic venous hypertension. Sustained graduated compression therapy from the toes (highest applied pressure) to the knee (lowest applied pressure) is now accepted as ‘the cornerstone of venous leg ulcer treatment’. It has been shown to improve venous leg ulcer healing rates, decrease recurrence rates and prolong intervals between recurrences.³⁷⁻³⁹ Healing rates of more than 50% after 12 weeks of compression therapy are achievable.^{40,41}

It has been demonstrated that adequate levels of compression reduce the diameter of major veins, pushing blood into the central areas of the body.⁴² Meanwhile, blood velocity in the deep veins is increased, reducing pressure within the superficial veins and improving their capacity for venous return. Combined with the ensuing reduction in venous hypertension, this results in a significant increase in venous return to the heart.⁴³ In addition, the pressure difference between the capillaries and surrounding tissues decreases, resulting in less leakage from the capillaries and the return of fluid to the vascular space. The improved absorption of fluid by the lymphatic and vascular systems will reduce oedema and exudation and, similarly, the improvement in the circulation will minimise or reverse skin changes.⁴⁴

In patients with chronic oedema and lymphoedema, the aim is to remove fluid from the congested tissues, encourage the movement of fluid through the lymphatic pathways and reshape the oedematous limb and/or trunk region, thus ‘decongesting’ the affected area.³² As stated above, compression therapy removes oedema by reducing capillary filtration, increasing lymphatic drainage, transporting fluid to non-compressed body areas and breaking down fibrosclerotic tissue.³²

How compression therapy works

The modified equation of Laplace’s law is used to calculate or predict sub-bandage (interface) pressures (*Table 4*). The pressure exerted immediately after bandage application is determined by the tension (initial force on application and its sustainability) in the fabric,

Table 4. Laplace’s Law¹⁹

Pressure	Tension of bandage multiplied by the number of layers which is divided by the circumference of the limb (cm) multiplied by the bandage width
Laplace's law	Sub-bandage pressure is proportional to: $\frac{N \times T}{C \times W}$
Where	N – Number of layers of bandage T – Bandage tension C – Limb circumference W – Bandage width



the number of layers and the degree of curvature of the limb, with the relationship being determined by the interaction of these factors.⁴⁵

To explain, if the number of bandage layers (N), bandage width (W) and the tension (T) at which the bandage is applied to the leg are kept constant, then the pressure (P) applied is inversely proportional to the limb circumference (C) — that is, the smaller the leg circumference, the greater the pressure. This explains why the pressure graduation decreases from the toes upwards. Any variation in one of these factors in the equation will affect the pressure delivered. It must be remembered that this concept is based on a mathematical equation, and while the principles behind it are clearly correct, it cannot determine the precise sub-bandage pressure needed at the ankle to achieve a therapeutic effect; furthermore, sub-bandage pressure is rarely measured in clinical practice.

Factors that will influence the pressure gradient achieved include the severity of venous disease and the size and shape of the leg, as it can be difficult to achieve uniform distribution over the curvature of the limb contours. The patient’s level of activity will also affect sub-bandage pressure, particularly when walking; other influencing factors include poor measurement and poor application technique.⁴⁵

Compression bandage systems

Compression bandages are classified according to their strength and function, and are generally categorised as either elastic (long stretch) or inelastic (short stretch). Bandage performance is determined by: the tension; the extensibility (its ability to stretch); the amount of force needed to achieve a predefined increase in length of an elastic bandage;⁴⁶ and its elasticity (its ability to return to its original unstretched length).⁴⁵

Elastic bandages contain elastomeric fibres that can be stretched by over 100% and then return to their original size. Due to their elasticity, they can accommodate changes in the patient's limb shape during movement.⁴⁵ In contrast, inelastic bandages contain few or no elastomeric fibres and so have a minimal extensibility of less than 90%. They maintain a semi-rigid cylinder that does not yield when the calf muscle contracts and expands against them during activity. This causes the sub-bandage pressure to rise. Inelastic bandages therefore achieve high pressure during movement and revert to low resting pressures when the patient is immobile.⁴⁷

The static stiffness index (SSI)

Resting pressure is the force exerted by the bandage when the leg is at rest; it is dependent on the elastic stretch of the material and the method of application. Working pressure describes the internal force that is directed towards the applied bandage when the calf muscles expand during activity. A pulse-pressure (massage) effect is generated by the difference between resting and working pressure during activity.⁴⁸

The static stiffness index (SSI) is the difference between the sub-bandage pressure on the distal lower leg when the person is standing and lying down. The muscle contraction that occurs during dorsiflexion or standing causes the calf to expand to its full circumference, at which point the SSI is at its greatest. This can be measured by placing a pressure transducer between the compression system and the limb. It is suggested that bandages with a high SSI may be better at compensating for the increased hydrostatic pressure that occurs when the patient is standing up, when accumulation of blood in the lower extremities increases pressure within the venous system.⁴⁹ Inelastic bandages have a high SSI and, therefore, higher working and lower resting pressures, which enhance the function of the veins and the lymphatics.²³

Multilayer systems with an inelastic component are classified as inelastic, having a higher pressure when the individual is standing up and a lower one when lying down. Elastic bandages are rarely used in isolation these days, as they provide little or no stiffness.

Given their high SSI, inelastic bandages are likely to reduce oedema, which will in turn reduce limb size. This can, however, cause slippage, highlighting the importance of regular assessment.

Bearing in mind the principles of Laplace's law, good application technique is essential, and attention must be paid to the size and shape of the limb. Padding can be used to artificially increase the circumference of the limb if the curvature is irregular and will protect the bony prominences, which are more at risk of damage due to the smaller radius of curvature.

The evidence to support the use of compression therapy is strong. Systematic reviews have repeatedly shown that

compression therapy heals more venous leg ulcers than not using compression (dressing only, non-compressive treatments, palliative regimens).⁵⁰⁻⁵² This was reiterated by a later (2009) Cochrane review⁵³ on compression, for which healing time was the primary outcome. Once again it was found that the application of compression increased healing rates when compared with no compression, and that multi-component bandage systems were more effective than single component systems. While an earlier systematic review by Cullum et al.⁵⁰ did not recommend any particular compression bandaging system, it did highlight the importance of delivering high pressure, which can only be achieved by correct application. According to Partsch and Partsch,⁵⁴ the sub-bandage pressure necessary to counteract venous hypertension caused by venous disease should exceed 40mmHg at the ankle, with the required range being 40–50mmHg when the legs are dependent.²³

The Royal College of Nursing⁵⁵ suggests that, for uncomplicated venous leg ulcers (ABPI >0.8), the first-line treatment in all settings should be a graduated multilayer high-compression bandage system, with an elastic component capable of sustaining high compression at the ankle for at least a week. This should be applied with padding to protect any bony prominences. The 2009 Cochrane review supported this, stating that multi-component systems containing an elastic bandage appeared to be more effective than those composed mainly of inelastic components.⁵³

Efficacy is achieved through a complex set of interactions involving the physical structure and properties of the compression bandage system, size and shape of the leg, the skill and technique of the applicator and the patient's level of activity.^{45,55} Cullum stressed the importance of assessment, correct interpretation of the assessment, appropriate choice of system and meticulous application.⁵⁶

It has been suggested that the ideal compression bandaging system should:

- Be clinically effective
- Provide sustained compression,
- Enhance calf-muscle function,
- Be non-allergenic, comfortable and conformable and durable⁴⁷
- Also be easy to train staff on its application and removal.

The type of bandage chosen will depend on a number of factors, such as its clinical and cost-effectiveness, efficacy, availability, local protocols and guidelines, and the nurse's knowledge and skills. Patient preference and the likelihood of concordance are also key determinants.⁵⁷

The KTwo compression bandage system

KTwo was designed to provide safe, consistent compression over time and during repeat applications. As well as being



Fig 1a. KTwo unstretched (left) and KTwo stretched correctly (right)



Fig 1b. Correct application of KTwo

Patient assessment

Patients with leg ulcers must undergo a comprehensive, holistic, clinical assessment, including Doppler ultrasound assessment, to identify the aetiology.^{2,55,57,96} The patient's ankle brachial pressure index (ABPI) should not be used as a diagnostic indicator for venous or any other leg ulceration, but may be of value in defining what is a safe level of compression bandaging for each individual patient.⁹⁷



easy to apply and acceptable and tolerable to patients, it aims to provide effective compression, while improving patient comfort and promoting concordance.

KTwo is a two-layer, high-compression bandage system designed to ensure the even distribution of pressure between two dynamic bandages: KTech, an inelastic bandage, and KPress, an elastic bandage. It applies the therapeutic pressure required to treat active or healed venous leg ulcers and associated symptoms such as severe oedema in chronic venous insufficiency. KTwo is also indicated for the treatment and maintenance of lymphoedema as its inelastic component provides a high SSI and massage effect.

The first layer, KTech, is an inelastic, short-stretch bandage combining a viscose and polyester wadding with a polyamide and elastane knitted layer. It has an extensibility of approximately 75%. KTech provides the benefits of an inelastic bandage, facilitating improved haemodynamics and oedema reduction with high working and low resting pressures. KTech donates 80% of the overall bandage pressure delivered by the system. The even application of the bandage redistributes the pressure uniformly to prevent

damage to the bony prominences, and the wadding provides good absorbency where there is excess exudate.

KPress, the second component, is applied over KTech. It is a cohesive elastic bandage made of acrylic, polyamide and elastane, which facilitates stretchability. It provides the extra compression necessary to facilitate the optimal therapeutic pressure at the ankle for healing venous leg ulcers. Being an elastic bandage, it gently squeezes the leg, helping to maintain therapeutic pressures, which is especially important for patients who are immobile or have limited mobility. It also maintains the position of the KTwo system for up to 7 days. The KPress component contains low levels of natural latex to give it cohesion; however, a latex-free option is available. The manufacturers state that KTwo provides the correct level of pressure at every application due to the guidance of its pressure indicator.

The KTwo system incorporates the PresSure system. A pressure indicator is printed on each bandage to aid stretch and overlap. By choosing the correct kit size for the ankle, stretching the pressure indicator from an oval to a circle and overlapping to just cover it, optimal compression levels are achieved at each application, in line with the law of

Laplace (Fig 1). According to the manufacturer, this ensures safe and effective application every time, regardless of the experience of the clinician applying the system, as long as the instructions for use are followed.

KTwo is contraindicated in patients with an arterial or predominantly arterial ulcer, or known or suspected arterial disease, characterised by an ABPI of <0.8. However, KTwo Reduced provides a lower level of ankle pressure (20mmHg) and is suitable for delivering compression when the ABPI is 0.6–0.8, depending on vascular opinion and local protocols. KTwo Reduced also provides a lower level of pressure for patients who are unable to tolerate full compression despite having an ABPI of >0.8. This can be ‘stepped up’ to the full compression kit once the patient has become accustomed to wearing compression bandages, to allow for the full benefits of healing.

Literature review

The above section describes how the KTwo compression system was designed to ensure safe application and consistent levels of high pressure (40mmHg at the ankle). However, claims have to be substantiated with evidence, as only then can they inform clinical decision-making. The rest of this review therefore outlines the evidence supporting the clinical efficacy and ability of KTwo to reproduce consistent and accurate pressure. Results relating to ease of use, tolerability and patient concordance will be discussed in full in Part 2, to be published in 2014.

Efficacy

The first clinical evaluation was published in 2007, shortly after the launch of KTwo,⁵⁸ and had a prospective, non-comparative design. Its primary endpoint was efficacy

of the KTwo bandage compression system in the local management of venous ulcers. Efficacy was defined as the reduction in wound surface area over a 6-week period.

The sample comprised 42 adult outpatients from 12 outpatient centres in France. Inclusion criteria were venous leg ulceration (confirmed by Doppler) measuring 2–20cm² with a duration of 1–24 months; a wound bed with at least 50% granulation tissue; and previous treatment with other compression systems. Exclusion criteria included clinical signs of infection, ankle circumference >28cm and diabetes mellitus.

The treatment protocol allowed the physicians to use a primary dressing (UrgoCell Non-Adhesive or Urgotul, both produced by Urgo Medical).

To ensure consistency, the same investigator followed up the patients throughout the evaluation. At baseline, the mean ulcer size was 6.97cm² and the mean ulcer duration was 8.1 months (standard deviation [SD] ± 10.4; range 1–60). Most of the ulcers (n=26, 62%) were recurrent, and over two-thirds (69%) of the patients had oedema in the ulcerated limb. Although the investigators had been applying other compression systems to all but one patient prior to the evaluation, nearly 55% of the ulcers had failed to improve. Previous systems comprised: single bandage (long stretch) (32%); two-layer system (39%); three- or four-layer system (29%).

No patients were lost to follow-up. By the end of the 6-week evaluation period, the mean surface area, measured objectively by planimetry and photography, had reduced from 6.97 ± 6.43cm² (median 4.96cm²) to 2.42 ± 3.60cm² (median 1.05cm²) (p<0.0001). The mean reduction in wound surface area was 58.51% (median: 72.5%) after 6 weeks (Fig 2).

Ten ulcers healed (24%) in a mean of 25.9 ± 9.46 days (range 7–41). The baseline mean surface area of these ulcers was 6.2cm² with a baseline mean duration of 6.7 months. Of the remainder, 26 ulcers improved.

The impact of KTwo in the reduction in surface area for the sample as a whole is evidenced by the fact that the baseline mean surface area reduced by more than 40% in 32 of the 42 patients in a mean of 18.8 days. Only 6 ulcers did not improve: 4 stagnated and 2 increased in size.

One of the evaluation’s secondary endpoints was an improvement in the clinical condition of the wound. At week 6, only five patients (12%) had clinical oedema of the lower limb compared with 29 (70%) at baseline. Ten ulcers (30%) had a healthy surrounding skin compared with only three (7%) at baseline.

A 6-week follow-up period was chosen because the endpoint was not total wound closure. Nevertheless, the authors noted that the mean reduction in ulcer surface area observed at 6 weeks (58.51%) was at least comparable with data recorded at 6 weeks in venous leg ulcer studies using other compression systems⁵⁹⁻⁶¹ or compression

Fig 2. Benigni evaluation:⁵⁸ mean percentage reduction in ulcer surface area over the 6-week treatment period with KTwo (n=42)

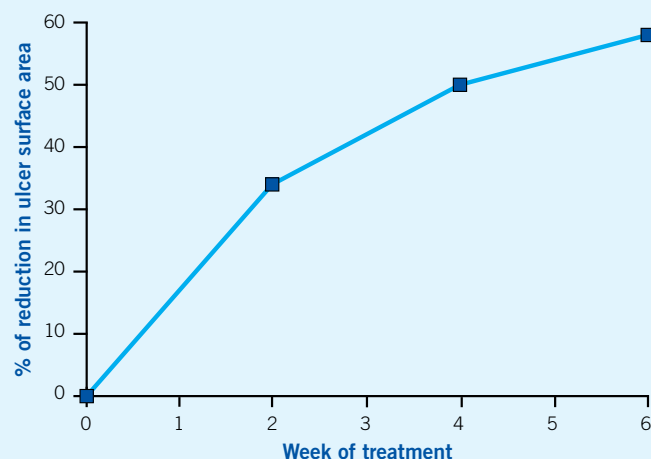


Table 5. Hanna evaluation:⁶⁵ distribution of the interface pressures achieved by the nurses

Percentage of nurses achieving interface pressures						
Bandage system	<29 mmHg	30–35 mmHg	36–44 mmHg	45–50 mmHg	>51 mmHg	% between 30–50 mmHg
KTwo bandage	6%	28%	44%	13%	9%	85%
Four-layer bandage	6%	16%	34%	19%	25%	69%
Inelastic bandage	75%	12%	13%	0%	0%	25%

bandaging plus lipidocolloid primary dressings⁶²⁻⁶⁴ where the baseline leg ulcer surface areas and durations were similar. They proposed that, given that compression was used in combination with the lipidocolloid dressing in the latter 3 studies,⁶²⁻⁶⁴ the positive outcomes recorded in this KTwo evaluation were due to the addition of the KTwo compression system and not solely to the use of the primary dressing.

Reproducibility

Once efficacy had been evaluated, the next step was to ascertain the level of interface pressure achieved with KTwo in comparison with that of other compression systems. A healthy volunteer study design was chosen to elicit individuals' experience of wearing the bandages. A comparative study was therefore undertaken in which 32 nurses with experience of using compression bandages applied a four-layer bandage system (Profore, Smith & Nephew), an inelastic bandage system (Actico, Activa Healthcare) and the KTwo system to a healthy female volunteer.⁶⁵

As none of the 32 nurses (9 tissue viability nurses and 23 district nurses) had previously used KTwo, they received training in its application technique in the form of a short video. The evaluation protocol required each nurse to apply the three bandage systems, in a random order, to the same healthy volunteer: a 28-year-old woman with an ankle circumference of 21 cm. As the nurses were unfamiliar with KTwo, they applied it twice to reduce potential for bias.

Following application, the interface pressure achieved by each nurse was recorded with the volunteer sitting upright, with her leg bent at 90 degrees at the knee and her foot flat on the floor. This was to increase the size of the calf-muscle pump and also the sub-bandage pressure. Interface pressures were measured using a Kikuhime pressure monitor at position B1 — 10 cm above the medial malleolus.

While it was expected that all of the systems would achieve a therapeutic pressure of 40 mmHg, it was decided that, for the purposes of this study, the therapeutic range would be 30–50 mmHg at the ankle, as this would reduce venous hypertension⁶⁶ without causing undue discomfort.

The results showed that both the four-layer bandage system and KTwo were applied within the required therapeutic interface pressure range (30–50 mmHg), but, as expected, lower pressures were achieved with the inelastic system:

- KTwo: 39.8 mmHg SD ± 11.2 (first test) and 39.8 mmHg SD ± 10.1 (second test)
- Four-layer bandage: 44.1 mmHg SD ± 12.4 mmHg
- Inelastic bandage: 23.2 mmHg SD ± 9.5

Table 5 illustrates the percentage of nurses who achieved the required therapeutic interface pressure. The majority of nurses (85%) applied KTwo at the required therapeutic pressure, but the percentages were lower for both the four-layer and inelastic systems, being 69% and 25% respectively. Some 75% of the nurses generated an interface pressure of <29 mmHg with the inelastic bandage system, whereas 25% achieved pressures of ≥51 mmHg with the four-layer system.

The reproducibility of compression applied by KTwo is illustrated by the fact that the mean interface pressure remained the same (39.8 mmHg) at both consecutive applications. The authors concluded that this indicated that KTwo could be applied correctly and consistently by nurses who are unfamiliar with the system. They suggested this was due to construction of the bandages and the presence of the pressure indicator aiding bandage stretch and overlap.

Follow-up evaluation

In 2009, Jünger et al.⁶⁷ set out to produce further evidence on the reproducibility of KTwo. As with the Hanna et al. evaluation,⁶⁵ this also had an open, randomised design and compared KTwo with a four-layer system (Profore, Smith & Nephew) and an inelastic system (Actico, Activa Healthcare). However, in this evaluation the systems were applied by a single experienced investigator to 24 healthy volunteers, who wore the bandages for 7 days. Furthermore, to eliminate any risk of bias resulting from incorrect application of compression at baseline, the pressure indicator icon printed on KTwo was also printed on both comparator systems.

The primary outcome measure was the loss of interface pressure after 1, 3 and 7 days. The secondary outcome was the reduction in volume of the lower limb.

To be included in the evaluation, the healthy volunteers had to be aged 18–60 years and have healthy intact skin with no signs of dermatological conditions, such as eczema and psoriasis. Exclusion criteria were: peripheral arterial occlusive disease, diabetes mellitus, cardiac insufficiency, history of disease of coronary arteries such as myocardial infarction, cerebrovascular disease, liver or kidney disease, use of diuretics, antihypertensives or drugs that influence capillary filtration; comorbidities that could affect compression therapy, particularly diseases that cause oedema.

The investigating physician was familiar with the three bandaging systems, which were randomly allocated using the closed envelope method. The 24 volunteers were told not to shower during the test period or participate in ‘excessive sports’, but otherwise continued with their day-to-day activities.

A statistician determined that each bandage system would need to be applied to 12 legs to produce meaningful results, and therefore, in the event, 36 legs were used in

the evaluation. Interface pressures were measured, using the Eclat air sensor system, in the same location (B1, 10cm above the medial malleolus) as in the earlier Hanna study.⁶⁵ The measurements were performed immediately after bandage application and on day 0 and then on days 1, 3 and 7 with the volunteers in the following positions:

- Supine
- Sitting
- Active standing (standing absolutely straight).

Maximal working pressure was then measured: the volunteers underwent ankle dorsal extension and plantar flexion 10 times over a period of 15 seconds. The mean of 10 peak values was defined as the maximal working pressure. Each bandage type was tested on the right and left leg an equal number of times.

In addition, the volume of the lower limb was determined using a three-dimensional imaging system (Image 3D; Bauerfeind Phlebologie) before bandage application on day 0 and after removal on day 7.

The 24 volunteers comprised 7 males and 17 females with a mean age of 27.58 SD ± 6.9 years. Three volunteers (all randomly allocated to the four-layer bandage) dropped out on day 3 due to intolerance caused by pain.

Baseline interface pressures and maximal working pressure values are given in *Table 6*. The results showed that KTwo maintained a similar level of sub-bandage pressure to the four-layer system and was partially better than the inelastic system over one week. Specifically, the inelastic system had a significantly bigger percentage reduction in maximal working pressure on day 3, when compared with KTwo and the four-layer bandage, although there was no significant difference between them on day 7 (*Fig 3*). There was no significant difference in loss of maximal working pressure between KTwo and four-layer system throughout the 7 days (mmHg data not given).

The relative decrease in interface pressure values from baseline for KTwo and the inelastic system was similar for the supine, sitting and active standing positions throughout the 7-day evaluation. However, the relative loss was smaller for the four-layer bandage, when compared with the other two systems, on day 7 for the active standing and sitting positions, but not for the supine position (data not given).

Concerning reduction in volume of the lower limbs, there was a significant reduction compared with baseline for all three systems on day 7 ($p < 0.024$; data not given), even though there was no apparent oedema in these healthy volunteers. Again, there was no significant difference between KTwo and the four-layer bandage, whereas KTwo achieved a statistically significant difference ($p = 0.0485$) compared with the inelastic bandage. These confirm the results of the Benigni et al. study,⁵⁸ where only 12% of the recruited patients were still presenting with leg oedema

Fig 3. Jünger evaluation:⁶⁷ relative maximal working pressure on days 3 and 7, compared with baseline

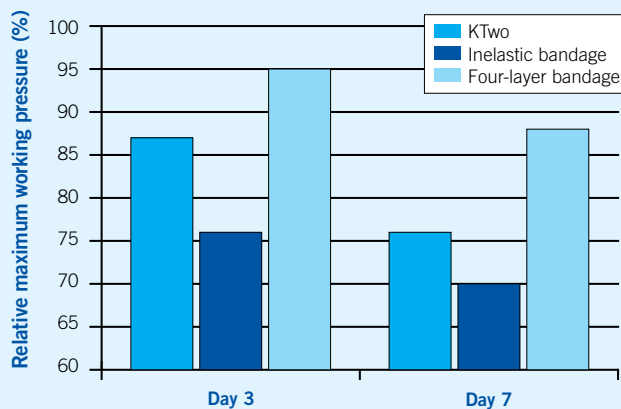


Table 6. Jünger evaluation:⁶⁷ median baseline interface pressure values and maximal working pressures (mmHg)

Position layer	KTwo	Inelastic bandage	Four-layer bandage
Supine	47.81	48.47	51.54
Sitting	49.44	47.97	54.02
Active standing	55.81	64.72	62.08
Maximal working pressure	61.62	71.46	78.97

after 6 weeks of treatment, indicating that KTwo is suitable for the treatment and management of leg oedema.

RCT evidence on efficacy

Although both the Hanna et al.⁶⁵ and Jünger et al.⁶⁷ papers showed that KTwo provided comparable therapeutic interface pressures on healthy volunteers, further evidence on the bandage system's efficacy when used on patients was needed. In order to achieve the most rigorous and robust evidence, it was decided to undertake a randomised controlled trial (RCT), considered to be the 'gold standard' and the most objective test of an intervention in research.⁶⁸ Given the findings of the Hanna⁶⁵ and Jünger⁶⁷ evaluations, and the fact that its efficacy has been demonstrated in so many randomised trials⁶⁹⁻⁷⁵ and in meta-analyses,^{50,53} Profore was chosen as the comparator.

The RCT⁷⁶ study was designed as a clinical demonstration of non-inferiority between two compression bandaging systems: KTwo and Profore. (A non-inferiority trial is designed to demonstrate that one treatment is no less effective than another treatment by a specified margin — in this case, 15%.) The hypothesis was that the KTwo system was as effective as the Profore system in healing venous leg ulceration which provided the accepted 'gold standard' level of compression (40mmHg).

The RCT therefore evaluated the efficacy of both compression bandage systems in the treatment of venous leg ulcers. The primary endpoint was the number of ulcers that healed (defined as 100% epithelialisation) after 12 weeks of treatment with either KTwo or Profore. Secondary endpoints related to efficacy were:

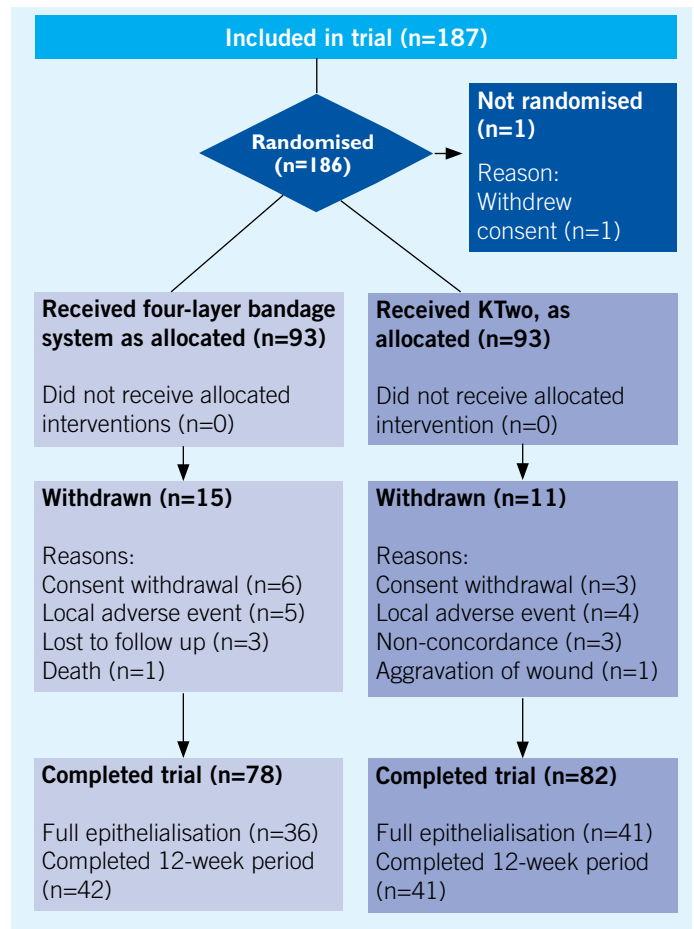
- Absolute wound area reduction (measured in cm²) over the 12-week period
- Relative wound area reduction (percentage reduction)
- Percentage of patients who had a relative wound area reduction of at least 40%, compared with baseline, by week 4 (considered a predictor of complete wound closure at 20–24 weeks);⁷⁷⁻⁸²
- Time taken to reach complete epithelialisation
- Other secondary outcomes measured were tolerability and acceptability.

The RCT was a large multicentred European study. All subjects were either inpatients or outpatients with venous or mixed aetiology ulcers with an ABPI of 0.8–1.3. For inclusion purposes, they had to be aged 18 years or over and already receiving treatment with a multilayer compression bandage (two, three or four layer). Other inclusion criteria were:

- Ankle circumference 18–25cm²
- Target ulcer surface area 2–5cm²
- Ulcer duration 1–24 months.

If the patient had more than one leg ulcer, then the ulcer that best met the selection criteria was chosen.

Fig 4. Lazareth et al.⁷⁶ RCT: flow of participants through each phase of the trial



Primary exclusion criteria were: suspected infection of the ulcer; scheduled surgery for the ulcer; presence of dry fibrinous tissue or malignancy; history of venous thrombosis in the 3 months prior to entry; bedfast patients; those receiving radiotherapy or chemotherapy; and those with known hypersensitivity to any of the bandage components.

After obtaining written informed consent and confirmation of the ABPI measurement, participants were randomised (using a centralised randomisation list provided by the statistician) to either the KTwo or Profore group. Demographic information, the patient's medical, surgical and leg ulcer history, and a detailed wound description were recorded.

The bandage systems were applied in accordance with the manufacturers' instructions over a 12-week treatment period or until the ulcers healed (application frequency was not specified). The wounds were cleansed with sterile saline and the clinicians were asked to use a non-impregnated neutral primary dressing of their own choice. If there were clinical signs of high bacterial colonisation, use of an antimicrobial dressing was permitted.

The investigator assessments were carried out every 2 weeks and comprised a clinical examination, planimetric measurements and digital photography. Tracings were evaluated by two blinded, non-participating clinicians. Bandage change frequency, pain and ease of application were also evaluated.

Statistical analysis was conducted using SPSS by an independent company. Non-inferiority analyses were performed on the intention-to-treat (ITT) and per-protocol (PP) populations; conclusions were only drawn if the two analyses had similar results. To evaluate comparability of the groups at baseline, Student's t-test or non-parametric test was used for continuous data and Chi-squared test or Fisher's exact test for categorical data. The Kaplan-Meier test and later the log-rank test were used to analyse time to closure. The ITT population was defined as all patients who received at least one application of the randomly allocated compression therapy. The PP population was defined as subjects who did not deviate from the protocol and were treated with compression therapy for at least 4 weeks.

A non-inferiority margin of 15% was considered acceptable, as both systems produce similar, effective interface pressures⁵⁸ with an anticipated wound closure rate of 80%.^{77,83-88}

A total of 187 patients were recruited into the study. Following one immediate withdrawal, there were 93 patients in each study arm. The population distribution was heterogeneous, in that 70% were from France, with the rest from the UK and Germany, but there was no significant difference between groups in terms of either patient or wound characteristics. At baseline, the mean ABPI was 1.06 SD \pm 0.13 mmHg and the median ankle circumference was 23cm (same for both groups). Seventy-two per cent were reasonably mobile and 73% had ankles that were reasonably flexible. Both groups had similar baseline mean wound surface areas, with a combined mean of 10.0 SD \pm 11.2 cm² (median 6.0) and a combined mean ulcer duration (6.6 SD \pm 6.7 months, median 4), which is important as both variables are prognostic factors for healing.⁷⁷

In all, 160 subjects, mostly treated as outpatients, completed the trial. Reasons for withdrawals are given in *Fig 4*. In the ITT group (n=186), 41 ulcers (44%) in the KTwo group healed, compared with 36 (39%) in the control group. In the PP group (n=128; 62 and 66 in the test and control groups), 30 ulcers (48%) and 25 ulcers (38%) healed, respectively.

Regarding the secondary endpoints, the final median absolute wound area value at week 12 was 0.48 cm² for KTwo and 1.33 cm² for the control group (compared with 5.9 cm² and 6.1 cm² at baseline). These figures support the findings of the previous studies.^{58,67}

The percentage of wounds that had \geq 40% reduction in wound surface area by week 4 was 47% for KTwo and 44% for the control group.

Finally, healing times were similar in both groups, with a median value of 91 days for complete closure for both the ITT and PP groups.

On analysis, KTwo was not found to be inferior to Profore in terms of leg ulcer management and wound healing. However, KTwo was considered to be easier to apply (supporting the results of Hanna et al.⁶⁵ and well tolerated. The equivalent efficacy of KTwo to the well-established four-layer bandage system indicates that, combined with easy application and the good tolerance of the KTwo two-layer system, patient concordance would be increased.

Alternative evidence

The above studies, taken from the literature, provide various levels of evidence demonstrating the efficacy and reproducibility of KTwo. Here, they are supported by clinical accounts, written by nurses in the form of poster presentations.

Tissue viability nurses (TVNs) Sylvia Stanway et al.⁸⁹ described the use of KTwo on prisoners, many of whom have venous or mixed aetiology leg ulcers as a result of drug dependency and a history of heavy drinking. Given the restrictions of a prison setting, with the TVNs only being allowed entry once a week for 90 minutes, it was decided to train the prison health-care staff to apply compression bandages, thereby reducing the prisoners' dependence on the formal health-care system. KTwo was chosen for its simplicity and ease of application, as minimal training was required and the pressure indicator ensured the correct pressure was applied. As a result, compression bandages were changed more frequently than was the case when application was only possible during the TVNs' weekly visit. Stanway et al. say this resulted in four improved outcomes:

- Prisoners could be treated appropriately at the 'point of need'
- Leg ulcers healed more quickly
- Prison staff had greater job satisfaction
- The TVNs were subsequently able to rationalise their visits to 3 hours every 2 weeks.

Sally Ridpath,⁹⁰ a tissue viability nurse from Seaford Health Centre, Sussex, UK, faced the challenge of a female patient with longstanding, painful, bilateral, non-healing venous leg ulcers, whose bandages kept slipping as a result of her thin ankles. A combination of topical dressings, compression hosiery and inelastic bandages had been tried previously, but severe pain precluded concordance. The ulcers were wet and strikethrough was evident. The KTwo bandage system was applied and successfully healed the leg ulcers in less than 8 weeks due to improved comfort and concordance.

G O'Sullivan,⁹¹ a community staff nurse from Hastings, described how KTwo was used on an obese 40-year-old mother of six whose ulcers on both legs were so bad she had become housebound. Apart from the obesity,

there were no other comorbidities. The patient had previously been treated with a basic dressing and non-compression bandaging (wadding, type 2 bandage and a tubular bandage) and then, when the ulcers became circumferential, with inelastic bandages. However, the pain was now so bad that the patient required Oramorph. By the time KTwo was applied, the leg ulcers were 4 years old, measured 176cm² and 127.5cm², and were inflamed and

infected. The KTwo bandages were initially changed twice weekly, and then weekly once the infection had cleared. The two ulcers reduced in size by 30% and 21% within 3 weeks, and the pain levels fell dramatically, with only mild pain at dressing change. The patient did not require analgesia after 2 months of treatment with KTwo and could wear normal shoes after 3 months. One wound healed in 14 weeks and the other in 16 weeks.

Table 7. Summary of the main outcomes of studies on the efficacy of KTwo

Study	Study design	Sample size	Wound type	Products used	Outcome measures	Key results
Lazareth et al. ⁷⁶ (2012)	RCT	186 patients	Venous leg ulcers	KTwo and four-layer bandage (Profore)	% of leg ulcers healed after 12 weeks, with secondary endpoints of absolute wound area reduction; relative wound area reduction; and the % with relative wound area reduction of \geq 40% at 4 weeks	KTwo no less effective than Profore and was easier to apply.
Benigni et al. ⁵⁸ (2007)	Prospective, non-comparative, open-label, phase III, multicentre clinical study	42 patients	Venous leg ulcers (some with concomitant chronic oedema)	KTwo	Reduction in ulcer surface area over 6 weeks; secondary endpoints included improvement in clinical condition of wound, including surrounding skin and presence of oedema in lower limb	KTwo reduced the surface area by a mean of 58.5%, with 10 wounds (24%) healing in a mean time of 25.9 SD \pm 9.46 days
Junger et al. ⁶⁷ (2009)	Single-centre, open, randomised trial	24 healthy volunteers	N/A	KTwo, four-layer bandage (Profore) and inelastic bandage (Actico)	Reduction of sub-bandage pressure after 1, 3 and 7 days; secondary outcome was reduction in volume of the lower limb	KTwo maintained, over one week, a sub-bandage pressure similar to a four-layer system and was partially better than the inelastic system
Hanna et al. ⁶⁵ (2008)	Comparative evaluation	32 nurses who applied compression bandages to one healthy volunteer	N/A	KTwo, four-layer bandage (Profore) and inelastic bandage (Actico)	Sub-bandage pressure applied	The nurses achieved consistent sub-bandage pressures with KTwo (39.8mmHg); KTwo and the four-layer system were applied within the therapeutic range (30–50mmHg)

The community staff nurse team at Hastings and Rother primary care trust⁹² reported a small case series involving six patients with seven venous leg ulcers. Mean age was 89 years (range 82–95); the mean duration was 6 weeks; mean size was 8.5 cm². Previous treatment comprised inelastic and multilayer systems.

After 4 weeks' treatment, three wounds had healed, four had reduced in size by a mean of 36%, five had healthy surrounding skin (compared with three at baseline) and all had reduced in pain levels, with five patients experiencing minimal or no pain at all.

Sanderson,⁹³ a vascular clinical nurse specialist, described how use of KTwo in four patients with lower-limb wounds (two pre-tibial lacerations and two skin tears) resulted in a mean healing time of 10 weeks.

Finally, Doherty and Moffatt,⁹⁴ from the Centre of Research and Implementation of Clinical Practice, described 10 cases in which KTwo was used on patients with chronic oedema secondary to venous disease. They found the system was associated with a reduction in limb volume. The average reduction at the ankle was 1.9 cm (1.4–3.4 cm) and that at the calf was 1.4 cm (0.4–3.1 cm).

Conclusion

Treatment of chronic venous leg ulcers and chronic oedema is more likely to be effective if the compression bandages applied are able to consistently reproduce the correct therapeutic pressure, maintain the therapeutic pressure over time, and is acceptable to both clinicians and patients. Thus, a bandage system that facilitates this is required. While RCTs demonstrating clinical efficacy are essential, successful healing outcomes rely on the clinician's knowledge, skill and experience. Ongoing patient compliance to treatment and their ability to continue what they consider to be a relatively normal life is also of great importance with regard to concordance and quality of life.

Part 1 of this evidence review demonstrates the research findings on the efficacy and reproducibility of the pressure applied by KTwo. The results give clear, firm evidence that its use can promote the healing of venous leg ulcers. All the included (*Table 7*) studies also showed that KTwo is well tolerated by patients and acceptable to both patients and clinicians.

Part 2, due out in 2014, will explore this evidence in depth, with a view to determining whether the combined effect of the system's appeal to patients and clinicians, along with its proven efficacy, are likely to result in more frequent positive patient outcomes and improved patient quality of life.

References

- 1 Palfreyman, S. Assessing the impact of venous ulceration on quality of life. *Nurs Times* 2008; 104: 41, 34–7
- 2 Scottish Intercollegiate Guidelines Network (SIGN). SIGN 120. Management of Chronic Venous Leg Ulcers. Scottish Intercollegiate Guidelines Network, 2008. Available at: <http://www.sign.ac.uk/pdf/sign120.pdf>
- 3 Moffatt, C.M. Understanding compression therapy. In: European Wound Management Association (EWMA) Position Document. Understanding compression therapy. MEP, (2003). Available at: <http://tinyurl.com/87rg9cr>
- 4 Greenhalgh, T. How to read a paper: getting your bearings (deciding what the paper is about). *BMJ* 1997; 315: 7102, 243–6
- 5 Rothwell, P.M. External validity of randomised controlled trials: 'To whom do the results of this trial apply?' *Lancet* 2005; 365: 9453, 82–93
- 6 Owens, D.K., Lohr, K.N., Atkins, D. et al. Grading the strength of a body of evidence when comparing medical interventions. In: Agency for Healthcare Research and Quality. *Methods Guide for Comparative Effectiveness Reviews*, 2009. Available from: <http://tinyurl.com/q5tpwhu>
- 7 Estabrooks, C.A. Will evidence-based nursing practice make practice perfect? *Can J Nurs Res* 1998; 30: 1, 15–36
- 8 Estabrooks, C.A. Translating research into practice: implications for organisations and administrators. *Can J Nurs Res* 2003; 35: 3, 53–68
- 9 Gerrish, K. Promoting evidence-based practice: an organizational approach. *J Nurs Manage* 2004; 12: 114–23
- 10 GRADE Working Group (2009) Grading of Recommendations Assessment, Development and Evaluation. Available at: www.gradeworkinggroup.org/toolbox/index.htm
- 11 Evidence Based Nursing Practice (2003) The Five Stages of Evidence Based Practice. Available at: <http://tinyurl.com/q4cwtch>
- 12 Muir Gray, J.A. *Evidence-Based Healthcare: How to Make Health Policy and Management Decisions*. Churchill Livingstone, 1997
- 13 Burls, A. What is Critical Appraisal? Hayward Medical Communications, 2009. Available at: <http://tinyurl.com/2685sct>
- 14 Ruckley, C.V., Dale, J.J., Callam, M.J., Harper, D.R. Causes of chronic leg ulcer. *Lancet* 1982; 2: 8298, 615–6
- 15 Nelzen, O., Bergqvist, D., Lindhagan, A. Leg ulcer aetiology: a cross sectional population study. *J Vasc Surg* 1991; 14: 4, 557–64
- 16 Graham, I.D., Harrison, M.B., Nelson, E.A. et al Prevalence of lower-limb ulceration: a systematic review of prevalence studies. *Adv Skin Wound Care* 2003; 16: 6, 305–16
- 17 Bergan, J.J., Schmid-Schönbein, G.W., Coleridge-Smith, P.D. et al. Chronic venous disease. *N Engl J Med* 2006; 355: 488–98
- 18 Moffatt, C.J., Franks, P.J., Doherty, D.C. et al. Prevalence of leg ulceration in a London population. *QJM* 2004; 97: 7, 431–7
- 19 Moffatt, C., Harper, P. *Leg Ulcers*. Churchill Livingstone, 1997
- 20 Posnett, J., Franks, P.J. The burden of chronic wounds in the UK. *Nurs Times* 2008; 104: 3, 44–45
- 21 Anderson, I. Venous leg ulcers: methods and devices in compression therapy. *Nurse Prescribing* 2006; 4: 6, 224–9
- 22 Eberhardt, R.T., Rafetto, J.D. Chronic venous insufficiency. *Contemporary Reviews in Cardiovascular Medicine. Circulation* 2005; 111: 2398–2409. Available at: <http://tinyurl.com/nq8ospu>
- 23 Partsch, H. Understanding the pathophysiological effects of compression. In: European Wound Management Association (EWMA) Position Document: Understanding compression therapy. MEP, 2003. Available at: <http://tinyurl.com/87rg9cr>
- 24 Collins, F., Hampton, S., White, R. *A–Z Dictionary of Wound Care*. Quay Books, 2002
- 25 Valencia, I.C., Falabella, A., Kirsner, R., Eaglstein, W.H. Chronic venous insufficiency and venous leg ulceration. *J Am Acad Dermatol* 2001; 44: 3, 401–21
- 26 Grey, J.E., Harding, K.G., Enoch, S. Venous and arterial leg ulcers. *BMJ* 2006; 332: 7537, 347–350
- 27 Johnson, S. Compression hosiery in the prevention and treatment of venous leg ulcer. *J Tissue Viability* 2002; 12: 2, 67–74
- 28 Moffatt, C.J., Franks, P.J., Doherty, D.C. et al. Lymphoedema: underestimated health problem. *QJM* 2003; 96: 10, 731–8
- 29 Lymphoedema Support Network (2010). How to Recognise Lymphoedema. Available at: <http://tinyurl.com/no2bvds>

- 30** Lymphoedema Framework. Best Practice for the Management of Lymphoedema. International consensus. MEP, 2006. Available at: <http://tinyurl.com/cqo5rfa>
- 31** Burns, J.L., Mancoll, J.S., Phillips, L.G. Impairments to wound healing. *Clin Plastic Surg* 2003; 30: 1, 47–56
- 32** Williams, A. An overview of non-cancer related chronic oedema: a UK perspective. *World Wide Wounds*, 2003. Available at: <http://tinyurl.com/nqoucnrb>
- 33** Board, J., Harlow, W. Lymphoedema 1: components and function of the lymphatic system. *Br J Nurs* 2002; 11: 5, 304–9
- 34** Mortimer, P.S. Swollen lower limb 2: Lymphoedema. *BMJ* 2000; 320: 7248, 1527–9
- 35** Mortimer, P.S. The pathophysiology of lymphoedema. *Cancer* 1998; 83: 12 (Suppl), 2798–802
- 36** Földi, M., Földi, E. Lymphostatic diseases. In: Földi, M., Földi, E., Kubik, S. (eds) *Textbook of Lymphology*. Urban and Fischer, 2003
- 37** Brem, H., Kirsner, R.S., Falanga, V. Protocol for the successful treatment of venous ulcers. *Am J Surg* 2004; 188: 1A (Suppl), 1–8
- 38** Sibbald, R., Contreras-Ruiz, J., Coutts, P. et al. Bacteriology, inflammation, and healing: a study of nanocrystalline silver dressings in chronic venous leg ulcers. *Adv Skin Wound Care* 2007; 20: 10, 549–58
- 39** Blair, S., Wright, D., Backhouse, C. et al. Sustained compression and healing of chronic venous leg ulcers. *BMJ* 1988; 297: 6657, 1159–61
- 40** Vowden, K.R., Barker, A., Vowden, P. Leg ulcer management in a nurse-led, hospital-based clinic. *J Wound Care* 1997; 6: 5, 233–6
- 41** Barwell, J.R., Davies, C.E., Deacon, J. et al. Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. *Lancet* 2004; 363: 9424, 1854–9
- 42** Christopoulos, D.C., Nicolaides, A.N., Belcaro, G., Kalodiki, E. Venous hypertensive microangiopathy in relation to clinical severity and effect of elastic compression. *J Dermatol Surg Oncol* 1991; 17: 10, 809–13
- 43** Eagle, M. Compression bandaging. *Nurs Stand* 2001; 15: 38, 47–52
- 44** Venous Forum of the Royal Society of Medicine. Recommendations for the referral and treatment of patients with lower limb chronic venous insufficiency (including varicose veins). *Phlebology* 2011; 26: 3, 9–3. Available at: <http://tinyurl.com/7jx75z4>
- 45** Clark, M. Compression bandages: principles and definitions. In: *European Wound Management Association (EWMA) Position Document: Understanding compression therapy*. MEP, 2003. Available at: <http://tinyurl.com/87rg9cr>
- 46** Thomas, S., Nelson, E.A. Graduated external compression in the treatment of venous disease. *J Wound Care* 1998; 7: 8 (Suppl), 1–4
- 47** Marston, W., Vowden, K. Compression therapy: a guide to safe practice. In: *European Wound Management Association (EWMA) Position Document: Understanding compression therapy*. MEP, 2003. Available at: <http://tinyurl.com/87rg9cr>
- 48** Partsch, H., Moffatt, C.M. An overview of the science behind compression bandaging for lymphoedema and chronic oedema. In: *The international Lymphoedema Framework in association with the World Alliance for Wound and Lymphoedema Care*, 2012
- 49** Partsch, H. The static stiffness index: a simple method to assess the elastic property of compression material *in vivo*. *Dermatol Surg* 2005; 31: 6, 625–30
- 50** Cullum, N., Nelson, E.A., Fletcher, A.W., Sheldon, T.A. Compression for venous leg ulcers. *Cochrane Database Syst Rev* 2001; 2: CD000265. Available at: <http://tinyurl.com/nnuhcm5>
- 51** Fletcher, A., Cullum, N., Sheldon, T.A. A systematic review of compression treatment for venous leg ulcers. *BMJ* 1997; 315: 576–9
- 52** Palfreyman, S.J., Lochiel, R., Michaels, J.A. A systematic review of compression therapy for venous leg ulcers. *Vasc Med* 1998; 3: 4, 301–1
- 53** O'Meara, S., Cullum, N.A., Nelson, E.A., Dumville, J.C. Compression for venous leg ulcers. *Cochrane Database of Syst Rev* 2012; 11: CD000265. Available at: <http://tinyurl.com/pkfkx5f>
- 54** Partsch, B., Partsch, H. Calf compression pressure required to achieve venous closure from supine to standing positions. *J Vas Surg* 2005; 42: 4, 734–8
- 55** Royal College of Nursing (RCN). The Nursing Management of Patients with Venous Leg Ulcers. RNC, 2006. <http://tinyurl.com/2nzx2q>
- 56** Cullum, N. The Nursing Management of Leg Ulcers in the Community: A Critical Review of Research. Available from: Department of Nursing, University of Liverpool, 1994
- 57** Scottish Intercollegiate Guidelines Network (SIGN). Management of Chronic Venous Leg Ulcers: a national clinical guideline. SIGN 120. SIGN, 2010
- 58** Benigni, J.P., Lazareth, I., Parpex, P. et al. Efficacy, safety and acceptability of a new two-layer bandage system for venous leg ulcers. *J Wound Care* 2007; 16: 9, 385–90
- 59** Vin, F., Téot, L., Meaume, S. The healing properties of Promogran in venous leg ulcers. *J Wound Care* 2002; 11: 9, 335–41
- 60** Hansson, C. The effects of cadexomer iodine paste in the treatment of venous leg ulcers compared with hydrocolloid and paraffin gauze dressing. Cadexomer Iodine Study Group. *Int J Dermatol* 1998; 37: 5, 390–6
- 61** Thomas, N.A. Comparison of two dressings in the management of chronic wounds. *J Wound Care* 1997; 6: 8, 383–6
- 62** Fays, S., Schmutz, J.L., Vin, F. et al. Leg ulcers and the Urgocell Non-Adhesive wound dressing. *Br J Nurs* 2005; 14: 11, S15–20
- 63** Smith, J., Hill, J., Barrett, S. et al. Evaluation of Urgotoll plus K-Four compression for venous leg ulcers. *Br J Nurs* 2004; 13: 6 (Suppl), S20–8
- 64** Meaume, S., Ourabah, Z., Cartier, H. et al. Evaluation of a lipidocolloid wound dressing in the local management of leg ulcers. *J Wound Care* 2005; 14: 7, 329–34
- 65** Hanna, R., Bohbot, S., Connolly, N. A comparison of interface pressures of three compression bandage systems. *Br J Nurs* 2008; 17: 20 (Suppl), 16–24
- 66** Taylor, A., Taylor, R., Said, S. Using a bandage monitor as an aid in improving bandaging skills. *JWC* 1998; 7: 3, 131–5
- 67** Jünger, M., Ladwig, A., Bohbot, S., Haase, H. Comparison of interface pressures of three compression bandaging systems used on healthy volunteers. *J Wound Care* 2009; 18: 11, 474, 476–80
- 68** Torgerson, D.J., Torgerson, C. *Designing Randomised Trials In Health, Education, And The Social Sciences: An Introduction*. Palgrave Macmillan, 2008
- 69** Moffatt, C.J., Simon, D.A., Franks, P.J. et al. Randomized trial comparing two four-layer bandage systems in the management of chronic leg ulceration. *Phlebology* 1999; 14: 4, 139–42
- 70** Moffatt, C.J., McCullagh, L., O'Connor, T. et al. Randomized trial of four-layer and two-layer bandage systems in the management of chronic venous ulceration. *Wound Repair Regen* 2003; 11: 3, 166–71
- 71** Ukat, A., König, M., Vanscheidt, W., Münter, K.C. Short-stretch versus multilayer compression for venous leg ulcers: a comparison of healing rates. *J Wound Care* 2003; 12: 4, 139–43
- 72** Polignano, R., Bonadeo, P., Gasbarro, S., Allegra, C. A randomized controlled study of four-layer compression versus Unna's boot for venous ulcers. *J Wound Care* 2004; 13: 1, 21–4
- 73** Partsch, H., Damstra, R.J., Tazelaar, D.J. et al. Multicentre, randomised controlled trial of four-layer bandaging versus short-stretch bandaging in the treatment of venous leg ulcers. *Vasa* 2001; 30: 2, 108–13
- 74** Moffatt, C.J., Edwards, L., Collier, M. et al. A randomised controlled 8-week crossover clinical evaluation of the 3M Coban 2-layer compression system versus Profore to evaluate the product performance in patients with venous leg ulcers. *Int Wound J* 2008; 5: 2, 267–9
- 75** Iglesias, C., Nelson, E.A., Cullum, N.A., Torgerson, D.J. Venus I: A randomised controlled trial of two types of bandage for treating venous leg ulcers. *Health Technol Assess* 2004; 8: 29, 1–105
- 76** Lazareth, I., Moffatt, C., Dissemond, J. et al. Efficacy of two compression systems in the management of VLU: results of a European RCT. *J Wound Care* 2012; 21: 11, 553–65
- 77** Margolis, D.J., Allen-Taylor, L., Hoffstad, O., Berlin, J.A. The accuracy of venous leg ulcer prognostic models in a wound care system. *Wound Repair Regen* 2004; 12: 2, 163–8
- 78** Prince, S., Dodds, S.R. Use of ulcer size and initial responses to treatment to predict the healing time of leg ulcers. *J Wound Care* 2006; 15: 7, 299–303
- 79** Phillips, T.J., Machado, F., Trout, R. et al. Prognostic indicators in venous ulcers. *J Am Acad Dermatol* 2000; 43: 4, 627–30
- 80** Margolis, D.J., Berlin, J.A., Strom, B.L. Risk factors associated with the failure of a venous leg ulcer to heal. *Arch Dermatol* 1999; 135: 8, 920–6

- 81** Meaume, S., Couilliet, D., Vin, F. Prognostic factors for venous ulcer healing in a non-selected population of ambulatory patients. *J Wound Care* 2005; 14: 1, 31–4
- 82** Gilman, T., Kantor, J., Margolis, D.J. A multicentre study of percentage change in venous leg ulcer area as a prognostic index of healing at 24 weeks. *Br J Dermatol* 2003; 149: 4, 896–8
- 83** Vin, F., Benigni, J.P. Compression therapy. International Consensus Document Guidelines according to scientific evidence. *Int Angiol* 2004; 23: 4, 317–45
- 84** Nelson, E.A., Iglesias, C.P., Cullum, N., Torgerson, D.J. Randomized clinical trial of four-layer and short-stretch compression bandages for venous leg ulcers (Venus I). *Br J Surg* 2004; 91: 10, 1292–9
- 85** Miller, C., Kapp, S., Newall, N. et al. Predicting concordance with multilayer compression bandaging. *J Wound Care* 2011; 20: 3, 101–12
- 86** Duby, T., Hoffman, D., Cameron, C. et al. Randomized trial in the treatment of venous leg ulcers comparing short-stretch bandages, four layer bandage system, and a long stretch paste-bandage system. *Wounds* 1993; 5: 276–9
- 87** Scriven, J.M., Taylor, L.E., Wood, A.J. et al. A prospective randomized trial of four layer versus short-stretch compression bandages for the treatment of venous leg ulcers. *Ann Rev Coll Surg Engl* 1998; 80: 3, 215–20
- 88** Haute Autorité de Santé (HAS) Report (2010) Compression devices for single use medical use in vascular disease. Revision of the list of reimbursable products and services. Service evaluation of devices [in French]. Available at: tinyurl.com/99se6mt
- 89** Stanway, S., Coup, R., Gasiorowski, D., Foy, E. Developing a Tissue Viability Support Service for Compression Bandaging in a Prison Environment. Poster presentation, Wounds UK, Harrogate 2012
- 90** Ridpath, S. Overcoming Compression Intolerance with the KTwo Bandage System. Poster presentation, Wounds UK, Harrogate 2011
- 91** O'Sullivan, G., Connolly, N. Returning to 'Normal Family Life' with the Help of the KTwo Compression Bandage System. Poster presentation, Wounds UK, Harrogate 2010
- 92** O'Sullivan, G., Warren, J., Wheatley, H., Connolly, N. Evaluating the KTwo Compression Bandage System on Six patients to Assess Ease of Application, Patient Comfort and Concordance. Poster presentation, Wounds UK, Harrogate 2010
- 93** Sanderson, S. Managing traumatic lower leg lacerations with the K Two compression bandage system at Southend Wound Management Unit. Poster presentation, Wounds UK, Harrogate, 2011
- 94** Doherty, D., Moffatt, C. Ten Case Studies on the Use of KTwo in the Treatment of Chronic Lymphovenous Oedema. Poster presentation, Wounds UK, Harrogate 2009
- 95** Scottish Intercollegiate Guidelines Network (SIGN). SIGN 50. A Guideline Developer's Handbook. SIGN, 2002. Available at: www.sign.ac.uk/pdf/sign50.pdf
- 96** World Union of Wound Healing Societies Document. Principles of Best Practice: Compression in venous leg ulcers. A consensus document. MEP, 2008
- 97** Vowden P, Vowden, K. Doppler assessment and ABPI: interpretation in the management of leg ulceration. *World Wide Wounds*, 2001. Available at: <http://tinyurl.com/6crar8>

