

OUTCOMES OF LOWER LIMB 3D SCANNING AND COMPRESSION HOSIERY

Abstract

Aims: To evaluate the effect of bespoke compression hosiery (Advanced Therapeutic Materials Ltd) on patients who require compression therapy for leg ulceration. **Methods:** An evaluation of clinical outcomes in 16 patients, eight with confirmed venous disease and eight with healed ulceration for whom standard hosiery does not fit, stay in place or is not tolerated. The patients were scanned using a hand-held 3D imaging unit to determine the size and shape of their lower limb. The generation of a 3D image and a pressure map is used to produce bespoke hosiery, and to calculate limb volume. **Results:** All of the patients were able to wear their hosiery and over the course of the study eight patients ulcers improved and eight patients' legs were maintained. **Conclusion:** Bespoke compression hosiery exerts sufficient interface pressure and may be used in the prevention and treatment of chronic venous insufficiency. **Declaration of interest:** No sponsorship has been provided for this study. Advanced Therapeutic Materials Ltd provided the scanning machine and personnel to scan the patients' legs. They also provided the bespoke hosiery.

KEY WORDS

Venous ulcers
Compression
Bespoke hosiery
Prevention

Leg ulceration is a chronic and recurrent condition and a systematic review of international prevalence studies of lower limb ulceration in adults reports a prevalence of 0.12% to 1.1%, with prevalence higher in women (Posnett et al, 2009). Internationally this amounts to 490,000–1.3 million patients and 70,000–190,000 with lower limb ulceration at any one time in the UK (Posnett et al, 2009). The majority of these leg ulcers are due to problems in the veins, resulting in an accumulation of blood in the legs (O'Meara et al, 2009).

IMPACT OF LEG ULCERATION

Patients with leg ulceration frequently experience recurrence, slow healing and a decreased quality of life, including pain, restricted mobility and depression (Price and Harding, 1996; Franks et al, 2003; Persoon et al, 2004; Franks et al, 2006). Additionally, its significant impact on body image is acknowledged by Day and Hayes (2008).

Persoon et al (2004) reviewed 37 studies,

which identified the impact of leg ulceration as causing:

- ▶▶ Reduced physical functioning
- ▶▶ A negative impact on psychological and social well-being due to pain and sleep disturbance
- ▶▶ Reduced energy
- ▶▶ Limited work and leisure
- ▶▶ Worry
- ▶▶ Frustration
- ▶▶ Lack of self-esteem.

Moffat et al (2007), in a study of 95 patients with leg ulceration, identified that patients experience poor psychological health with a greater risk of depression, less perceived social support and greater social isolation. It is recognised that patients with leg ulceration have complex needs (RCN, 2006; Scottish Intercollegiate Guidelines Network, 2010) and the delivery of care is challenging and costly (Callam et al, 1985; Bosanquet, 1992).

Eklöf et al (2004) offer the following categorisation of clinical, aetiological, anatomic and pathophysiological (CEAP) venous disease:

- ▶▶ C0 — No signs of venous disease

JACKIE STEPHEN-HAYNES

Visiting Professor in Tissue Viability,
Professional Development Unit,
Birmingham City University and
Consultant Nurse, Worcestershire Health
and Care NHS Trust Stourport
Health Centre

LOUISE TONER

Associate Dean, Birmingham City
University

The consequences of inappropriate measurement can lead to ill-fitting hosiery and even limb amputation, due to an inappropriately high level of compression being applied (RCN, 2006; SIGN, 2010).

Evidence base for compression hosiery

A Cochrane systematic review of randomised controlled trials of venous ulcer recurrence reports that there is weak evidence to show that compression hosiery reduces recurrence and the report recommends further research (Nelson, 2001; Jungler et al, 2004). However, the use of compression hosiery in the care of patients with active venous leg ulceration achieves similar healing rates to those achieved by using compression bandages (Hendricks and Swallow, 1985; Burgess and Robinson, 1993; Samson, 1993; Horakova and Partsch, 1994; Samson and Showalter, 1996).

An additional advantage is the consistent and reproducible pressures that are obtained when using compression hosiery, which are viewed as an advantage over other methods of compression (Mulder et al, 2001; Bale and Harding, 2005). It is important that the compression hosiery is tolerated in order to achieve the outcomes identified by Bale and Harding (2005), including:

- ▶▶ Healing
- ▶▶ Tolerance by patient
- ▶▶ Comfort
- ▶▶ Mobility
- ▶▶ Financial considerations.

Compression stockings are considered essential in preventing the recurrence of leg ulceration or the treatment of chronic venous disease (CVD) to prevent leg ulceration (Bale and Harding, 2005).

While compression stockings are commonly used to prevent the development or recurrence of venous ulcers, elastic bandages and multi-layer bandaging systems remain the principal forms of treatment for active ulceration (EWMA, 2003). To be effective, compression bandages need to be applied according to manufacturers' instructions and this is reported as being a variable in clinical practice (Bale and Harding, 2005). Keachie (1993) suggests that elastic compression hosiery has certain advantages over bandages as it maintains a high level of compression

consistently over time, it can be taken off at night and reapplied in the morning or left on 24 hours a day and is available as a sock or stocking in a choice of colours.

However, hosiery is not always effective and this is predominantly due to patients being unable or unwilling to use them as prescribed. Raju et al (2007) undertook research on the use, compliance, and efficacy of compression stockings among a large cohort of patients referred to a tertiary venous practice.

A total of 3144 new CVD patients were seen between 1998 and 2006. Only 21% of patients reported using the stockings on a daily basis, 12% used those most days, and 4% used them less often. The remaining 63% did not use the stockings at all or abandoned them after a trial period. The primary reasons given for non-usage were:

- ▶▶ Not prescribed by the primary physician, 25%
- ▶▶ Did not help, 14%
- ▶▶ Binding or 'cutting off' circulation, 13%
- ▶▶ Too hot to wear, 8%
- ▶▶ Limb soreness, 2%
- ▶▶ Poor cosmetic appearance, 2%
- ▶▶ Inability to apply without help, 2%
- ▶▶ Contact dermatitis or itching, 2%
- ▶▶ Other (cost, work, etc), 2%
- ▶▶ Multiple factors were cited by 8%.

There was no difference in compliance between men and women (39% versus 38%) or among different age groups. Compliance was relatively better (50%) in patients who gave a prior history of deep vein thrombosis (n = 675) compared with 35% in those without a prior history (n = 2,437) (p < 0.0001).

Compliance was poor in all CEAP classes and overall compliance with stockings was low and did not differ statistically in several subsets with significant symptoms, including pain and swelling. Compliance was better in patients who had a longer duration of symptoms although symptoms were still persistent in about one-third (37%) of the patients despite apparent compliance with prescribed stockings.

According to Raju et al (2007), compressive stockings are inapplicable in about one-quarter of patients due to the condition of the limb or the general health of the patient. They are ineffective despite

References

- EWMA (2003) *Position Document. Understanding Compression Therapy*. MEP, London
- Franks P, McCullagh L, Moffatt C (2003) Assessing quality of life in patients with chronic leg ulceration using the medical outcomes short form questionnaire. *Ostomy Wound Manage* 49: 26–37
- Franks PJ, Moffatt CJ, DoHerty DC, Williams AF, Jeffs E, Mortimer PS (2006) Assessment of health-related quality of life in patients with lymphedema of the lower limb. *Wound Repair Regen* 14(2): 110–18
- Hendricks WM, Swallow RT (1985) Management of stasis leg ulcers with Unna's boots versus elastic support stockings. *J Am Acad Dermatol* 12(1): 90–8
- Horakova M, Partsch H (1994) Venous leg ulcers: are compression bandages indicated? *Phlebologie* 47: 53–7
- Husband L (1995) the management of the client with a leg ulcer: precarious nursing practice. *J Adv Nurs* 24: 53–59
- Jungler M, Wollina U, Kohen R, Rabe E (2004) Efficiency and tolerability of an ulcer compression stocking for therapy of chronic venous ulcers compared with a below knee compression bandage: results for a prospective, randomised multicentre trial. *Curr Med Res Opin* 20(10): 1613–23
- Keachie J (1993) A cheaper alternative to the four-layer bandage system. *J Wound Care* 2: 133
- Knight S (2008) Could leg ulcer service provision in the community be improved? *Br J Community Nurs* 13(Suppl 6): S39–44
- Moffatt C, Martin R, Smithdale R (2007) *Leg Ulcer Management. Essential Skill for Nursing*. Blackwell Science.
- Morison M, Moffatt C (1999) Leg ulcers. In: Morison M, Moffatt C, Bridel-Nixon J, Bale S, eds. *A Colour Guide to the Nursing Management of Chronic Wounds*. Mosby, London

being worn by approximately one-third of patients seen. In the remainder, non-compliance with prescribed compressive stockings is an apparent major cause of treatment failure. Non-compliance is very high in patients with CVD regardless of age, sex, aetiology of CVD, duration of symptoms, or disease severity. The reasons for non-compliance can be grouped into two interdependent major categories (Raju et al, 2007):

- ▶▶ Wear comfort factors
- ▶▶ Intangible sense of restriction imposed by the stockings.

There is a clinical need for hosiery with improved application, comfort and which will encourage an increase in the time the patient will wear it.

The Darzi report (Department of Health [DH], 2008) challenges healthcare professionals 'to put patients at the centre of care delivery and increase the input of patients into care delivery'. There are several reports within the literature that suggest that care is less than optimal (Moffatt et al, 2007), particularly in relation to care delivered in practice settings. This is attributed to the lack of support, time and appropriate education/training and is similarly reported by Husband (1995), Schofield (2000) and Knight (2008). The impact of this on patients and staff and their view of care delivery have not been reported in the literature.

THE PROGRAMME

Bespoke hosiery using 3D scans

Initial research into developing a 3D scanning unit and performing an evaluation was conducted at the University of Manchester and supported by a grant from the Wellcome Trust Foundation.

Aim

The aim of the programme was to develop an innovative solution to the challenges of leg ulcer care in the NHS. The main objective was to evaluate the efficacy of bespoke hosiery in preventing leg ulceration or the recurrence of leg ulceration in patients with confirmed venous disease at level C2, C3 or C4 who were unable to tolerate standard hosiery. The evaluation was commissioned on behalf of Birmingham City University

and carried out in Worcestershire Health and Care NHS Trust following clinical governance approval.

Method

The scanning of a patient's limb generates a 'point cloud output file' (a set of 3D vertices), which appears as a scanned image of the leg. An assessment was made of the patients' limbs using the scanner and a pressure map was produced, which demonstrated the patient's limb volume and was used to provide accurate measurements and produce appropriately fitting bespoke hosiery. The hosiery was Class 1, 2, or 3 (European and British standard hosiery classifications) and provided a seamless, compression garment made using a flat-bed knit on a specifically developed knitting machine. This delivers the prescribed pressures accurately and reliably over the whole of the treatment area and allows for an easy application and fit.

The evaluation featured 16 patients with confirmed venous disease at C2, C3 or C4 or healed ulceration (C5) for whom standard hosiery did not fit, stay in place or was not tolerated.

The patients underwent 3D scanning using a hand-held imaging unit. It was performed by a representative from the manufacturer. The scans were undertaken in a variety of healthcare settings across the primary care organisation. The 3D scanned image was then used to develop the bespoke hosiery, which was then worn by the patient. The evaluation lasted for 16 months and patients wore the hosiery for 12 weeks to 12 months.

Inclusion criteria

All 16 patients that met the inclusion criteria agreed to take part and were able to give their consent. Any patients not wishing to participate would have been advised that they could continue with their current hosiery regimen. The inclusion criteria were:

- ▶▶ Patients with confirmed venous disease who had an ankle to brachial pressure index (ABPI — ratio of blood pressure in arms to legs) of 0.8 or greater (n=16)
- ▶▶ Subjects had a confirmed venous leg ulcer with duration less than 24 months and size ranging between

References

- Mulder GD, Brazinsky BA, Faria D, et al (2001) Clinical aspects of healing by secondary intention. In: Leaper DJ, Harding KG (eds). *Wounds: Biology and Management*. Oxford University Press, Oxford
- Nelson EA (1997) Compression bandages for venous ulcers. *Prof Nurse* 12 (7): S57–9
- Nelson E (2001) Systematic reviews of prevention of venous ulcer recurrence. *Phlebology* 16(1): 20–3
- Compression bandages and stockings to aid the healing of venous leg ulcers. *Cochrane Review*. DOI: 10.1002/14651858.CD000265.pub2
- Persoon A, Heinen M, van der Vleuten C, de roooij M, van der Kerkof P, Van Achterberg T (2004) Leg ulcers: a review of their impact on daily life. *J Clin Nursing* 13: 341–54
- Posnett J, Gottrup F, Lundgren H, Saal G, (2009) The resource impact of wounds on health-care providers in Europe. *J Wound Care* 18(4): 154–61
- Price P, Harding K (1996) Measuring health-related quality of life in patients with chronic leg ulcers. *Wounds* 8(3): 91–94
- Raju S, Hollis K, Neglen P (2007) Use of compression stockings in chronic venous disease: patient compliance and efficacy. *Ann Vasc Surg* 21(6): 790–5
- RCN (2006) *Clinical Practice Guidelines. The nursing management of patients with venous leg ulcers*. 2nd edn. RCN, London
- Samson RH (1993) Compression stockings and non-continuous use of polyurethane foam dressings for the treatment of venous ulceration. A pilot study. *J Dermatol Surg Oncol* 19(1): 68–72

- ▶▶ C1 — Telangiectasies or reticular veins
- ▶▶ C2 — Varicose veins
- ▶▶ C3 — Oedema
- ▶▶ C4 — Pigmentation or eczema
- ▶▶ C5 — Healed venous ulcer
- ▶▶ C6 — Active venous ulcer.

The bespoke compression therapy featured in this audit, may be used in patients with C2–C6.

COMPRESSION THERAPY

Compression is the direct application of pressure to a limb, measured in mmHg. The amount required to achieve the therapeutic effect of compression to prevent or manage venous hypertension is determined by the patient's underlying pathologies. The main treatment for chronic venous hypertension is the use of a compression garment (bandage or stocking) in order to aid venous return and reduce the superficial venous pressure by exerting external pressure on the interstitial tissue (Moffatt et al, 2007; World Union of Wound Healing Societies [WUWHS], 2008; O'Meara et al, 2009).

In 1969, Stemmer proposed that an external pressure of between 30–40mmHg pressure was required at the ankle to reverse chronic venous hypertension. While there has been debate regarding the optimum level of compression pressure required to reverse venous hypertension, 40mmHg is clinically effective (Nelson, 1997). The achievement of graduated compression is a key component of any compression therapy, aiming to provide 40mmHg of pressure at the ankle with a gradual reduction in the pressure up the leg with 30mmHg at the calf and 20mmHg towards the knee. This graduated compression is achieved due to the natural increase in the circumference of the limb. Sub-bandage pressure can be calculated using Laplace's law, which states the pressure produced beneath the bandage is directly proportional to the tension within the fabric and the number of turns applied, but inversely proportional to the circumference of the limb (Thomas, 2003). Therefore, the larger the limb the greater the pressure required from the bandage to affect the interstitial tissues.

A Cochrane review (O'Meara et al, 2009) of all the randomised controlled trials on

the clinical effectiveness of compression bandage/stocking systems in the treatment of venous leg ulceration concluded that compression is better than no compression and that multi-component bandages worked better than single-component systems. However, acknowledgement is not given to patient tolerance and the bulkiness of the system, which can lead to non-concordance. The application of hosiery fulfils the physiological needs and has the additional benefit of being more easily tolerated by the patient (O'Meara et al, 2009). It provides consistent and reproducible pressures and it is cost-effective as it can be washed several times and will continue to provide effective compression therapy.

The main aim of leg ulcer treatment as identified by Morison et al (1999) is to:

- ▶▶ Correct the underlying cause of the ulcer, for example by improving the underlying venous or arterial flow
- ▶▶ Create an optimal local environment for wound healing
- ▶▶ Improve the wider intrinsic factors that may delay healing, such as poor mobility, malnutrition and psychosocial issues
- ▶▶ Prevent avoidable complications such as infection, dermatitis and bandage trauma
- ▶▶ Maintain healed ulcers.

Compression has a number of effects (Moffatt et al, 2007). It is suggested that it:

- ▶▶ Reduces the distension of the blood vessels, thereby increasing the velocity of blood flow within the vessels
- ▶▶ Enables absorption of fluid back into the veins and lymphatic vessels
- ▶▶ Facilitates the calf muscle pump
- ▶▶ Influences endothelial function and affects cell mediators involved in the local inflammatory response
- ▶▶ Relieves the symptoms associated with venous disease and improves healing rate of venous ulcers.

While compression has been shown to improve microcirculation and decrease capillary filtration and oedema (RCN, 2006), the pressure exerted varies according to the brand of compression therapy.

The use of compression hosiery requires adequate knowledge on the part of the practitioner to correctly identify, measure for, and fit appropriate hosiery.

References

- Bale S, Harding K (2005) A pilot study to evaluate the potential of SurePress Comfort*. *Wounds UK* 1(2): 19–29
- Bosanquet N (1992) Costs of venous ulcers from maintenance therapy to investment programmes. *Phlebology* 1: Suppl 44–6
- Burgess B, Robinson B (1993) Wound care. Comparative benefits. *Nurs Times* 89(13): 90–92
- Callam MJ, Ruckley CV, Harper DR, Dale JJ (1985) Chronic ulceration of the leg: extent of the problem and provision of care. *Br Med J* 290: 1855–56
- Coull A, Clarke M (2005) Best practice statement for compression hosiery. *Wounds UK* 1(1): 70–6
- Day J, Hayes W (2008) Body image and leg ulceration. In: Lindsay E, White R, eds. *Leg Ulcers and Problems of the Lower Limb: An holistic approach*. HealthComm UK Limited, Aberdeen: 21–4
- DH (2010) *Equity and Excellence: Liberating the NHS*. DH, London
- Eklöf B, Rutherford RB, Bergan JJ, et al (2004) Revision of the CEAP classification for chronic venous disorders: consensus statement. *J Vasc Surg* 40(6): 1248–52

The consequences of inappropriate measurement can lead to ill-fitting hosiery and even limb amputation, due to an inappropriately high level of compression being applied (RCN, 2006; SIGN, 2010).

Evidence base for compression hosiery

A Cochrane systematic review of randomised controlled trials of venous ulcer recurrence reports that there is weak evidence to show that compression hosiery reduces recurrence and the report recommends further research (Nelson, 2001; Jungler et al, 2004). However, the use of compression hosiery in the care of patients with active venous leg ulceration achieves similar healing rates to those achieved by using compression bandages (Hendricks and Swallow, 1985; Burgess and Robinson, 1993; Samson, 1993; Horakova and Partsch, 1994; Samson and Showalter, 1996).

An additional advantage is the consistent and reproducible pressures that are obtained when using compression hosiery, which are viewed as an advantage over other methods of compression (Mulder et al, 2001; Bale and Harding, 2005). It is important that the compression hosiery is tolerated in order to achieve the outcomes identified by Bale and Harding (2005), including:

- ▶▶ Healing
- ▶▶ Tolerance by patient
- ▶▶ Comfort
- ▶▶ Mobility
- ▶▶ Financial considerations.

Compression stockings are considered essential in preventing the recurrence of leg ulceration or the treatment of chronic venous disease (CVD) to prevent leg ulceration (Bale and Harding, 2005).

While compression stockings are commonly used to prevent the development or recurrence of venous ulcers, elastic bandages and multi-layer bandaging systems remain the principal forms of treatment for active ulceration (EWMA, 2003). To be effective, compression bandages need to be applied according to manufacturers' instructions and this is reported as being a variable in clinical practice (Bale and Harding, 2005). Keachie (1993) suggests that elastic compression hosiery has certain advantages over bandages as it maintains a high level of compression

consistently over time, it can be taken off at night and reapplied in the morning or left on 24 hours a day and is available as a sock or stocking in a choice of colours.

However, hosiery is not always effective and this is predominantly due to patients being unable or unwilling to use them as prescribed. Raju et al (2007) undertook research on the use, compliance, and efficacy of compression stockings among a large cohort of patients referred to a tertiary venous practice.

A total of 3144 new CVD patients were seen between 1998 and 2006. Only 21% of patients reported using the stockings on a daily basis, 12% used those most days, and 4% used them less often. The remaining 63% did not use the stockings at all or abandoned them after a trial period. The primary reasons given for non-usage were:

- ▶▶ Not prescribed by the primary physician, 25%
- ▶▶ Did not help, 14%
- ▶▶ Binding or 'cutting off' circulation, 13%
- ▶▶ Too hot to wear, 8%
- ▶▶ Limb soreness, 2%
- ▶▶ Poor cosmetic appearance, 2%
- ▶▶ Inability to apply without help, 2%
- ▶▶ Contact dermatitis or itching, 2%
- ▶▶ Other (cost, work, etc), 2%
- ▶▶ Multiple factors were cited by 8%.

There was no difference in compliance between men and women (39% versus 38%) or among different age groups. Compliance was relatively better (50%) in patients who gave a prior history of deep vein thrombosis (n = 675) compared with 35% in those without a prior history (n = 2,437) (p < 0.0001).

Compliance was poor in all CEAP classes and overall compliance with stockings was low and did not differ statistically in several subsets with significant symptoms, including pain and swelling. Compliance was better in patients who had a longer duration of symptoms although symptoms were still persistent in about one-third (37%) of the patients despite apparent compliance with prescribed stockings.

According to Raju et al (2007), compressive stockings are inapplicable in about one-quarter of patients due to the condition of the limb or the general health of the patient. They are ineffective despite

References

- EWMA (2003) *Position Document. Understanding Compression Therapy*. MEP, London
- Franks P, McCullagh L, Moffatt C (2003) Assessing quality of life in patients with chronic leg ulceration using the medical outcomes short form questionnaire. *Ostomy Wound Manage* 49: 26–37
- Franks PJ, Moffatt CJ, DoHerty DC, Williams AF, Jeffs E, Mortimer PS (2006) Assessment of health-related quality of life in patients with lymphedema of the lower limb. *Wound Repair Regen* 14(2): 110–18
- Hendricks WM, Swallow RT (1985) Management of stasis leg ulcers with Unna's boots versus elastic support stockings. *J Am Acad Dermatol* 12(1): 90–8
- Horakova M, Partsch H (1994) Venous leg ulcers: are compression bandages indicated? *Phlebologie* 47: 53–7
- Husband L (1995) the management of the client with a leg ulcer: precarious nursing practice. *J Adv Nurs* 24: 53–59
- Jungler M, Wollina U, Kohen R, Rabe E (2004) Efficiency and tolerability of an ulcer compression stocking for therapy of chronic venous ulcers compared with a below knee compression bandage: results for a prospective, randomised multicentre trial. *Curr Med Res Opin* 20(10): 1613–23
- Keachie J (1993) A cheaper alternative to the four-layer bandage system. *J Wound Care* 2: 133
- Knight S (2008) Could leg ulcer service provision in the community be improved? *Br J Community Nurs* 13(Suppl 6): S39–44
- Moffatt C, Martin R, Smithdale R (2007) *Leg Ulcer Management. Essential Skill for Nursing*. Blackwell Science.
- Morison M, Moffatt C (1999) Leg ulcers. In: Morison M, Moffatt C, Bridel-Nixon J, Bale S, eds. *A Colour Guide to the Nursing Management of Chronic Wounds*. Mosby, London

being worn by approximately one-third of patients seen. In the remainder, non-compliance with prescribed compressive stockings is an apparent major cause of treatment failure. Non-compliance is very high in patients with CVD regardless of age, sex, aetiology of CVD, duration of symptoms, or disease severity. The reasons for non-compliance can be grouped into two interdependent major categories (Raju et al, 2007):

- ▶▶ Wear comfort factors
- ▶▶ Intangible sense of restriction imposed by the stockings.

There is a clinical need for hosiery with improved application, comfort and which will encourage an increase in the time the patient will wear it.

The Darzi report (Department of Health [DH], 2008) challenges healthcare professionals 'to put patients at the centre of care delivery and increase the input of patients into care delivery'. There are several reports within the literature that suggest that care is less than optimal (Moffatt et al, 2007), particularly in relation to care delivered in practice settings. This is attributed to the lack of support, time and appropriate education/training and is similarly reported by Husband (1995), Schofield (2000) and Knight (2008). The impact of this on patients and staff and their view of care delivery have not been reported in the literature.

THE PROGRAMME

Bespoke hosiery using 3D scans

Initial research into developing a 3D scanning unit and performing an evaluation was conducted at the University of Manchester and supported by a grant from the Wellcome Trust Foundation.

Aim

The aim of the programme was to develop an innovative solution to the challenges of leg ulcer care in the NHS. The main objective was to evaluate the efficacy of bespoke hosiery in preventing leg ulceration or the recurrence of leg ulceration in patients with confirmed venous disease at level C2, C3 or C4 who were unable to tolerate standard hosiery. The evaluation was commissioned on behalf of Birmingham City University

and carried out in Worcestershire Health and Care NHS Trust following clinical governance approval.

Method

The scanning of a patient's limb generates a 'point cloud output file' (a set of 3D vertices), which appears as a scanned image of the leg. An assessment was made of the patients' limbs using the scanner and a pressure map was produced, which demonstrated the patient's limb volume and was used to provide accurate measurements and produce appropriately fitting bespoke hosiery. The hosiery was Class 1, 2, or 3 (European and British standard hosiery classifications) and provided a seamless, compression garment made using a flat-bed knit on a specifically developed knitting machine. This delivers the prescribed pressures accurately and reliably over the whole of the treatment area and allows for an easy application and fit.

The evaluation featured 16 patients with confirmed venous disease at C2, C3 or C4 or healed ulceration (C5) for whom standard hosiery did not fit, stay in place or was not tolerated.

The patients underwent 3D scanning using a hand-held imaging unit. It was performed by a representative from the manufacturer. The scans were undertaken in a variety of healthcare settings across the primary care organisation. The 3D scanned image was then used to develop the bespoke hosiery, which was then worn by the patient. The evaluation lasted for 16 months and patients wore the hosiery for 12 weeks to 12 months.

Inclusion criteria

All 16 patients that met the inclusion criteria agreed to take part and were able to give their consent. Any patients not wishing to participate would have been advised that they could continue with their current hosiery regimen. The inclusion criteria were:

- ▶▶ Patients with confirmed venous disease who had an ankle to brachial pressure index (ABPI — ratio of blood pressure in arms to legs) of 0.8 or greater (n=16)
- ▶▶ Subjects had a confirmed venous leg ulcer with duration less than 24 months and size ranging between

References

- Mulder GD, Brazinsky BA, Faria D, et al (2001) Clinical aspects of healing by secondary intention. In: Leaper DJ, Harding KG (eds). *Wounds: Biology and Management*. Oxford University Press, Oxford
- Nelson EA (1997) Compression bandages for venous ulcers. *Prof Nurse* 12 (7): S57–9
- Nelson E (2001) Systematic reviews of prevention of venous ulcer recurrence. *Phlebology* 16(1): 20–3
- Compression bandages and stockings to aid the healing of venous leg ulcers. *Cochrane Review*. DOI: 10.1002/14651858.CD000265.pub2
- Persoon A, Heinen M, van der Vleuten C, de roooij M, van der Kerkof P, Van Achterberg T (2004) Leg ulcers: a review of their impact on daily life. *J Clin Nursing* 13: 341–54
- Posnett J, Gottrup F, Lundgren H, Saal G, (2009) The resource impact of wounds on health-care providers in Europe. *J Wound Care* 18(4): 154–61
- Price P, Harding K (1996) Measuring health-related quality of life in patients with chronic leg ulcers. *Wounds* 8(3): 91–94
- Raju S, Hollis K, Neglen P (2007) Use of compression stockings in chronic venous disease: patient compliance and efficacy. *Ann Vasc Surg* 21(6): 790–5
- RCN (2006) *Clinical Practice Guidelines. The nursing management of patients with venous leg ulcers*. 2nd edn. RCN, London
- Samson RH (1993) Compression stockings and non-continuous use of polyurethane foam dressings for the treatment of venous ulceration. A pilot study. *J Dermatol Surg Oncol* 19(1): 68–72

KEY POINTS

- ▶▶ Use of compression hosiery has been demonstrated to be effective in both the treatment of leg ulceration and the prevention of recurrence.
- ▶▶ Bespoke compression hosiery exerts sufficient interface pressure that may be used in the prevention and treatment of chronic venous insufficiency.
- ▶▶ The application of British standard hosiery classifications bespoke hosiery on 16 patients has demonstrated a positive clinical outcome due to the accuracy of the fit and tolerance of the compression.
- ▶▶ The achievement of graduated compression is a key component of any compression therapy.

References

O'Meara S, Cullum N, Nelson E (2009) Samson RH, Showalter DP (1996) Stockings and the prevention of recurrent venous ulcers. *Dermatol Surg* 22(4): 373–76

Schofield J, Flannagan M, Fletcher J et al (2000) The provision of leg ulcer services by practice nurses. *Nurs Stand* 14(26): 54–58

Scottish Intercollegiate Guidelines Network (2010) *The Care of Patients with Chronic Leg Ulcer. A National Clinical Guideline*. SIGN, Edinburgh

Thomas S (2003) The use of the Laplace equation in the calculation of sub-bandage pressure. *World Wide Wounds* <http://www.worldwide-wounds.com/2003/june/Thomas/Laplace-Bandages.html> Last accessed: 27th July 2010

WUWHS (2008) *Principles of best practice: Compression in venous leg ulcers. A consensus document*. MEP Ltd, London

5cm²–7.5cm², or a healed venous ulcer or was at risk of developing a venous ulceration

- ▶▶ Subjects had to agree to have their leg scanned and to wear bespoke compression therapy
- ▶▶ Subjects had to be over 18 years and able to provide written informed consent.

Exclusion criteria

The following subjects were not included in the study:

- ▶▶ Subjects with a history of skin sensitivity to any of the components of the study product
- ▶▶ Subjects whose leg ulcers were clinically infected; had erysipelas; had malignant changes; those who had a DVT; or those who had undergone venous surgery within the past three months
- ▶▶ Subjects who had a progressive neoplastic lesion being treated by radiotherapy or chemotherapy, or who were undergoing ongoing treatment with immunosuppressive agents or high-dose corticosteroids.

At the time of writing, 16 patients had been wearing bespoke hosiery for six weeks to nine months. Eight patients who had not worn standard hosiery wore the bespoke compression to prevent recurrence. The other eight patients wore the bespoke compression for the treatment of leg ulceration. They all fulfilled the eligibility criteria. The 16-month evaluation period allowed for clinical governance and trust approval, the recruitment of patients, scanning of the lower limb, and the wearing of the compression hosiery over a three, six or nine-month period.

RESULTS

All of the patients' skin was maintained in a healthy and viable condition. Patients also verbally evaluated the hosiery as comfortable and their leg ulcers had not recurred. Concordance was improved compared with standard hosiery. Patients were confident that their ulcer could be therapeutically treated or prevented when wearing the bespoke compression hosiery. Ease of application and removal was reported by all patients and the impact has been a reduction in district nurse visits. The study found that patients who

were non-concordant and did not wear their standard fit hosiery remained in the bespoke hosiery and there was no recurrence of ulceration noted.

Cost-effectiveness

The scanning machine for the assessment and production of bespoke hosiery will enable patients to wear a £30 garment which will last for up to at least six months, the same as standard hosiery. This offers a significant saving over non-wearing of the hosiery or the wearing of compression bandaging, which can cost £150 per week when the price of multi-component bandage kits, dressing packs, low-adherent dressings and nursing time is considered. Therefore, bespoke hosiery offers the NHS both improved patient outcomes and economic benefits.

Other uses

The scanning equipment can be used to guide the manufacture of bespoke hosiery but can also be used to measure limb volume. It can also track the progress of treatment for patients with confirmed venous leg ulceration, chronic oedema and lymphoedema by measuring limb volume before and after the application of compression.

CONCLUSION

The addition of bespoke hosiery that can be tolerated by patients allows for greater patient choice and the appropriate application of compression in patients who have confirmed venous disease. The alternative treatment frequently used within clinical practice is the continued application of compression bandaging, which is time-consuming for community staff. Additionally, any untreated venous hypertension can lead to ulcer recurrence (RCN, 2006).

The White paper (DH, 2010) identifies that healthcare will be measured in outcomes and that patients' views of services will be sought. The size of this evaluation limits generalisability but this exploratory data identifies the positive effects of bespoke scanning and fitting of hosiery and this does warrant further exploration — as does the prevention of recurrence and the use of lifelong compression which is an important issue that is often neglected. **WUK**