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ORIGINAL ARTICLE

Evaluation of the performance of a new compression system in patients with lymphoedema

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Key words
Bandaging; Comprehensive decongestive therapy; Limb swelling; Lymphoedema; Volume reduction

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Abstract

In the acute phase of lymphoedema, patients require comprehensive decongestive therapy (CDT), which includes skin care, an exercise regimen, manual lymphatic drainage (MLD) and regular bandaging. This study was established to determine the effectiveness of a new system of bandage therapy, the 3M™ Coban™ 2 compression system. In total, 24 patients were entered into the study (12 from UK and 12 from Canada) with a variety of clinical presentations. The mean age of the groups was 57·4 years, which varied from 26 to 79 years. Body mass index (BMI) averaged 38·9 kg/m^2, with a range from 22·7 to 67·5 kg/m^2. Of the total, eight were women with arm lymphoedema, the remainder being men and women with lymphoedema of the lower limb. All were considered to be in need of CDT. After 19 days, the reduction of limb volume was measured, which indicated a mean limb volume reduction of 1210 ml (95% confidence interval, CI, 780–1641, $P < 0{\cdot}001$). Leg affected patients experienced greater reduction than arm affected patients (1596 ml versus 438 ml), although both groups experienced significant reduction in limb volumes (both $P < 0{\cdot}001$). Mean percentage changes in limb volume were 14·9% and 16·1% for legs and arms, respectively. The Measure Your Medical Outcome Profile questionnaire indicated significant improvement in symptoms considered important by the patient ($P < 0{\cdot}0001$), which also led to improvements in skin quality by reducing skin thickness and firmness. The Coban 2 compression system provides good oedema reduction in both arms and legs to reduce limb volume and improvements in symptoms associated with lymphoedema.

Introduction

Lymphoedema is a chronic swelling caused by regional accumulation of lymphatic fluid because of an insufficient lymphatic system. The increased size and restricted mobility of the affected limb influence quality of life. Daily activities at work, home and with personal care activities are influenced, and the risk of developing anxiety and depression is therefore increased (1,2).

Key Messages

- lymphoedema is a chronic swelling caused by regional accumulation of lymphatic fluid because of an insufficient lymphatic system
- in the acute phase, treatment is focused on volume reduction and breakdown of fibrosclerotic tissue via decongestive lymphatic therapy, a combination of

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bandaging, manual lymphatic drainage (MLD), exercises and skin care
- historically, much of the evidence *regarding* how compression works is based on research in venous disease and was extrapolated to lymphoedema
- the aim of this study was to gain further clinical experience on the effectiveness of the Coban 2 compression system in the treatment of patients with lymphoedematous legs and arms
- the primary objective was to determine the volume reduction in the treatment of lymphoedema of legs and arms with the Coban 2 compression system in a cohort of selected patients
- secondary objectives included assessment of:
  - comfort of the Coban 2 compression system
  - differences across patient groups
  - frequency and reason for withdrawal
  - bandage application frequency using the Coban 2 compression system
- as arm lymphoedema occurs almost exclusively in women, it was not thought practicable to collect information on men with this indication
- as this was a two-country study (UK and Canada), each provided 12 patients into the study
- this study was not powered to detect a statistically significant result, as the magnitude of the effect was unknown using this compression system
- these results were used to indicate trends in the patients most likely to benefit most from the use of the Coban 2 compression system
- this study has shown that there are substantial reductions in limb volume associated with a 3-week treatment period of comprehensive decongestive therapy (CDT) incorporating the Coban 2 compression system
- this effect was noted with patients with arm and leg lymphoedema
- these results are encouraging in that they provide objective assessments of both clinical and symptomatic improvements to patients with lymphoedema
- this is a phase I study to evaluate the performance of the new bandage system in a real world environment, with minimal restrictions on entry criteria
- further work has being undertaken to extend the evaluation of the product within a pilot study that examines bandage change frequency
- this has indicated that changing the bandage twice weekly gives slightly better volume reduction than more frequent changes, contrary to current practice using other bandage materials
- the results from these two studies may be used as a precursor to a full phase III randomised controlled trial and health economic analysis

In the acute phase, treatment is focused on volume reduction and breakdown of fibrosclerotic tissue via decongestive lymphatic therapy, a combination of bandaging, manual lymphatic drainage (MLD), exercises and skin care. The European Wound Management Association published a consensus paper 'Lymphoedema bandaging in practice', which underlines bandaging as an important intervention in the management of lymphatic disease (3). A Cochrane systematic review has examined the role of compression in the management of patients with lymphoedema (4). Although meta-analysis was not performed because of the poor quality of the trials, the authors concluded that wearing a compression sleeve is beneficial. For this conclusion, they focused on three randomised-controlled trials (5–7). The publication provides evidence that bandaging plus hosiery resulted in a greater initial and sustained volume reduction than hosiery alone (6). Historically much of the evidence on how compression works is based on research in venous disease and was extrapolated to lymphoedema. Therefore, currently available compression systems, which are originally intended for the treatment of chronic venous disease, are also in use for the treatment of lymphoedema.

Table 1 Patients recruitment into the study

Leg lymphoedema, including phlebo-lymphoedema (total $n = 16$)	Arm lymphoedema (total $n = 8$)
Patients with ISL stage II lymphoedema ($n = 8$)	Patients with ISL stage II lymphoedema ($n = 4$)
Two men in work	Two women in work
Two men not working	Two women not working
Two women in work	
Two women not working	
Patients with ISL stage III lymphoedema ($n = 8$)	Patients with ISL stage III lymphoedema ($n = 4$)
Two men in work	Two women in work
Two men not working	Two women not working
Two women in work	
Two women not working	

ISL, International Society of Lymphology.

The 3M™ Coban™ 2 compression system (Coban 2 compression system) was initially developed for the treatment of chronic venous leg ulcer and has proven to be effective for this indication. The advantage of this system is its comfort and low slippage potential. The bandage system has been adapted for the needs of patients with lymphoedema who have more extreme limb shapes and sizes. The sub-bandage pressure applied is related to the bandage tension, width, number of layers and radius of the limb. Taking into consideration different circumferences for arms and legs, the Coban 2 compression system is provided in two versions for the upper (3M™ Coban™ 2 Lite) and lower extremities (3M™ Coban™ 2). The Coban2 system is designed to be applied without padding to achieve a thin and comfortable system allowing the patient a high degree of independence and mobility. The system has the ability to provide a high working pressure and low resting pressure, features considered important in a compression system.

Study objectives

The aim of this study was to gain further clinical experience on the effectiveness of the Coban 2 compression system in the

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treatment of patients with lymphoedematous legs and arms. The primary objective was to determine the volume reduction in the treatment of lymphoedema of legs and arms with the Coban 2 compression system in a cohort of selected patients (Table 1).

Secondary objectives included assessment of:

- Comfort of the Coban 2 compression system.
- Differences across patient groups.
- Frequency and reason for withdrawal.
- Bandage application frequency using the Coban 2 compression system.

Methods

The study was a prospective cohort study to evaluate the use of the Coban 2 compression system in a group of 24 patients over a 19-day period. The study aimed to recruit 24 patients with specific indications for the use of bandaging.

In most study designs, the aim is to provide information on the 'average' patient by drawing on a sample that represents the general population of patients with a certain condition. The study design was chosen to allow us to specifically target factors that were likely to influence the outcome of treatment or impact on the patients' ability to comply with treatment. These were explicitly gender, lymphoedema stage and current work status. By selecting patients who fitted certain criteria, it was possible to examine the influence of these factors in a relatively small sample before more detailed investigations of the bandage system in larger cohorts and trials. As arm lymphoedema occurs almost exclusively in women, it was not thought practicable to collect information on men with this indication. As this was a two-country study (UK and Canada), each provided 12 patients into the study (Table 1; See Appendix for clinical areas).

The protocol was submitted to and agreed by the relevant research ethics committees, institutional review boards and health provider organisations undertaking this research. All patients were provided with written information about the study, and all gave written informed consent before entry into the study.

Patients were drawn from existing lymphoedema services within the designated health care providers collaborating on this study. All patients within the services were considered for inclusion into this trial. Patients were assessed using a standard procedure, which included a medical history, swelling details and clinical assessment of the cause of the lymphoedema. Both existing and patients who newly presented for treatment within the clinical areas of the collaborating health care providers were considered for entry.

The following criteria were met before a patient was recruited to the study:

- Age: at least 18 years of age.
- Sex: males and females
- Presentation: clinical need for intensive bandage therapy.
- Administrative: the patient was able to understand the trial and willing to give written consent to the study.

There were no specific exclusions. As this was a case series, with patients being assessed for the need for intensive bandage therapy, the decision to include the patient was determined by the clinician based on their own clinical experience and any guidelines that were in use within their clinical area. This was to allow a 'real world' view of the use of the bandages.

Materials

The Coban 2 compression system consists of a comfort layer comprising medical foam laminated to an adherent wrap and an adherent compression. The comfort layer is applied without tension, whereas the compression layer is applied at full stretch. For anatomical areas with small circumferences including arms, fingers and toes, 3M™Coban™ 2 Lite was used, whereas for legs, 3M™ Coban™ 2 was applied.

Treatment regimen

At the initial assessment, the patients were questioned regarding their medical history that related to their lymphoedema. The limb volume was assessed by means of sequential circumference measurements on both affected and unaffected limbs, using a standard methodology (8). Limb volumes were calculated by assuming that each interval between measurements was a truncated cone. The volume of each interval was estimated using the following formula:

$$V = (h)(C^2 + Cc + c^2)/12(\pi)$$

where C and c are the respective circumferences at the two measurement points, and h is the distance between them (in this case 4 cm). Measurements were taken to the axilla in women with arm lymphoedema and as high up the leg as possible. Patients with below knee swelling were measured to the knee.

All clinical staff involved in this study received instruction on how to apply the bandages by recognised experts. Bandages were replaced according to clinical need and the protocol of the centre undertaking this study. Reasons for re-bandaging including bandage slippage were noted at each bandage change. Patients received MLD according to the protocol adopted in the clinical area where the patient was seen. A skin care regimen appropriate for the patients' needs was provided and all patients were informed of the importance of exercise.

The secondary objectives were assessed at the first and last visits. The 'Measure Your Medical Outcome Profile' (MYMOP) questionnaire was used to determine changes in symptomatic well-being of the patients from initial visit to final visit (9). This is a well-validated patient-centred outcome measure to evaluate changes in symptoms as chosen by the patient. The comfort of the products was assessed by asking the patient at the end of the study.

The durability of the compression system and patient compliance was assessed by the investigator by inspecting the bandages at each bandage change. Slippage was assessed by measuring the change in bandage length from the previous application to the length before removal. Skin status (dry, firm, infected, intact, itchy, moist, thickened, etc) and pain were assessed at each visit.

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Statistical analysis

Data were entered onto a secure Internet-based database system developed specifically for this study (Axon TeleHealthCare). At the end of the study, the data were downloaded to an Excel file, which was then read into the statistical package for analysis (STATA 10).

The principal outcome measure was volume reduction following 19 days of treatment using the Coban 2 compression system. Sequential circumference measurements were taken at each visit and analysed using both univariate and multiple regression methods to determine the outcome of treatment.

This study was not powered to detect a statistically significant result, as the magnitude of the effect was unknown using this compression system. Moreover the subgroup risk factor analysis produced small samples and as such was not expected to determine a statistical difference between groups. Instead, these results were used to indicate trends in the patients most likely to benefit from the use of the Coban 2 compression system. Ninety-five percent CI were generated where appropriate. Summary tabulations allowed inspection of data by covariate and overall.

Results

There was complete recruitment into all cells of the sampling frame as identified in Table 1. As expected, this meant that there were 16 women and 8 men, with 16 legs and 8 arms for evaluation. Twelve patients were currently working, with 12 patients with stage II lymphoedema (including late stage II) and 12 with stage III severity as assessed using the International Society of Lymphology classification.

The mean (SD) age of the groups was 57·4 (14·0) years, which varied from 26 to 79 years. Body mass index averaged 38·9 kg/m^2, with a range from 22·7 to 67·5. Of those recruited, 12 were left limbs and 12 right limbs. A total of 5 patients were considered to have primary lymphoedema, 18 secondary and one with lipoedema. Most cases of secondary lymphoedema were trauma related to cancer treatment (ten) with a variety of other causes including non cancer trauma (two), immobility (two), infection (two) and venous disease (two).

Only 17/24 (71%) were receiving skin care, 20/24 (83%) exercise and 10/24 (42%) were receiving MLD. Ten patients were currently not receiving treatment from a health care professional on a weekly basis, although six (25%) were receiving daily care. Before the study, 12 patients were receiving class II hosiery (8 flat knit, 4 circular knit), with a further 4 receiving class III hosiery (2 flat knit, 2 circular knit). Four patients were receiving bandaging (two elastic, three inelastic), one patient receiving both inelastic and elastic bandaging. The application frequency ranged from one to seven times per week with a mean of 3·75 applications/week.

Table 2 gives the absolute reduction in limb volumes given by site of lymphoedema. Although there were 16 patients with leg lymphoedema, five had lymphoedema only below

Table 2 Absolute reduction in limb volume (ml) over study and percent change in limb volume

		Start	End	Difference				Percent			
	n	Mean (SD)	Mean (SD)	Mean	95% CI	*P* value	*n*	Mean	SD	Minimum	Maximum
Total	24	7869 (6006)	6659 (5203)	1210	780 to 1641	<0·0001	24	15·3	8·5	−12·9	27·8
Arm patients	8	2608 (623)	2169 (454)	438	264 to 613	0·0006	8	16·1	4·7	10·7	23·6
Leg patients	16	10499 (5744)	8903 (5028)	1596	1039 to 2153	<0·0001	16	14·9	9·9	−12·9	27·8
Below knee	5	5784 (3669)	5068 (3338)	716	−201 to 1633	0·096	5	12·2	15·0	−12·9	22·9
Full leg	11	12643 (5286)	10646 (4772)	1996	1373 to 2620	<0·0001	11	16·2	7·3	3·0	27·8

Table 3 Absolute limb volume reduction and percent limb volume reduction (ml)

	N	Mean (SD)	Difference	95% CI	*t*-value	*P* value
Absolute limb volume reduction						
Canada	12	824 (233)	−772	−1585 to 41	−1.97	0·062
UK	12	1596 (315)				
Arm	8	438 (209)	−1157	−1941 to −375	3·07	0·006
Leg	16	1596 (1046)				
Working	12	1010 (335)	−399	−1263 to 464	−0·96	0·348
Not working	12	1410 (247)				
Stage II	12	1284 (333)	147	−733 to 1026	0·35	0·733
Stage III	12	1137 (263)				
Percent limb volume reduction						
Canada	12	14·6 (10·6)	−1·4	−8·7 to 5·8	−0·41	0·686
UK	12	16·1 (6·0)				
Arm	12	16·1 (4·7)	1·2	−6·5 to 9·0	0·33	0·747
Leg	12	14·9 (9·9)				
Working	12	11·5 (9·4)	−7·7	−14·2 to −1·2	−2·45	0·023
Not working	12	19·2 (5·4)				
Stage II	12	16·1 (5·7)	1·5	−5·8 to 8·8	0·43	0·674
Stage III	12	14·6 (10·8)				

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Table 4 Multivariable analysis of volume reduction by key variables

	Mean	SD	*z*-score	*P* value
Regression of absolute reduction in limb volume (ml)				
Limb (arm/leg)	1157	345	3·36	0·003
Working	399	325	1·23	0·235
Stage II/III	−147	325	−0·45	0·657
Canada/UK	772	325	2·37	0·028
Regression of percentage reduction in limb volume (ml)				
Limb (arm/leg)	−1·2	3·5	−0·35	0·733
Working	7·7	3·3	2·31	0·032
Stage II/III	−1·5	3·3	−0·45	0·657
Canada/UK	1·4	3·3	0·43	0·669

knee and were measured only to this point. Overall, there was a mean reduction in limb volume of 1210 ml, although this varied greatly according to the site of the lymphoedema. Patients with full leg lymphoedema experienced the greatest mean reduction (1996 ml), with arm patients experiencing the lowest volume reduction (438 ml). All categories of patients experienced statistically reduced limb volume with the exception of below knee patients, which just failed to show a statistically significant reduction (716, 95% CI −201 to 1633). Changing the measure to percent reduction had the effect of reducing the difference between affected limbs (arm or leg) with mean values ranging from 12·2% below knee to 16·2% in the full leg (Table 2).

Potential risk factors for limb volume reduction were investigated and presented in Table 3. As expected, there was a large difference between arm and leg lymphoedema, and also some evidence to suggest a difference between the two countries (UK and Canada). However, normalising the results using percentages reduced the difference between arms and legs (1·2%) and between the two countries (−1·4%), so that neither result approached a standard level of statistical significance. One effect of this normalisation was the difference between working and non working individuals, with significantly greater reduction in those not working compared with those in work (difference = 7·7%, $P = 0{\cdot}023$). Multivariable analysis confirmed these results, Table 4. MLD was categorised according to whether at least 50% of visits included MLD versus <50%. The addition of the MLD variable made little difference to the overall mean changes as they appeared in Table 4, with a mean increase of 48 ml ($P = 0{\cdot}89$) when MLD was included in the treatment regimen.

Slippage measurements were determined by comparing the height of the bandage on application with that experienced before removal. The mean difference between visits varied between 1·8 and 3·4 cm for arm bandaging and 4·7 to 6·4 cm for leg bandaging. Greater slippage was associated with larger volume reductions in the patients with arm and leg lymphoedema, although this only achieved a standard level of statistical significance in the arm patients (−260 ml, $P = 0{\cdot}007$) for those with an average slippage >2·9 cm, Table 5.

Evaluations of pain on the visual analogue scale indicated substantial change with a mean reduction of 2·17 on the 10-point scale ($P = 0{\cdot}007$) over the treatment period (Table 6). Most of this effect was noted in the patients with leg lymphoedema. Interestingly, perceived pain at the start of the study was significantly higher in patients with stage II rather than stage III class of lymphoedema.

The MYMOP questionnaire was used to determine changes in symptoms that were important to the patient. Patients most frequently reported tightness (four), swelling (three) and heaviness (three) as their most important symptoms. Table 7 illustrates how the symptoms improved following the bandage treatments, together with self-assessments of activity and well-being. MYMOP scores were significantly improved after treatment, for symptoms and activity, with only well-being failing to achieve a standard level of significance. This also corresponded to improvements in skin quality with reductions in skin thickness (eight patient versus one patient, Fisher's exact test $P = 0{\cdot}023$) and firmness (12 versus 2 patients $P = 0{\cdot}003$) with a slight increase in the number reporting itching (6 versus 10, $\chi^2 = 1{\cdot}5$, 1 df, $P = 0{\cdot}221$), Table 8.

As part of the evaluation process of this study, patients were asked to consider a number of comfort aspects of the Coban 2 compression system following treatment on a 0- to 10-scale, the results of which are presented in Table 9. In general, the

Table 5 Limb volume reduction by slippage

	n	Mean (SD)	Difference	95% CI	*t*-value	*P* value
Arm						
Absolute volume reduction by average slippage (±median)						
<2·9 cm	4	308 (123)	−260	−557 to 31	−2·19	0·007
≥2·9 cm	4	568 (203)				
Percent volume reduction by average slippage						
<2·9 cm	4	13·4 (3·3)	−5·4	−12·3 to 1·5	−1·92	0·104
≥2·9 cm	4	18·9 (4·6)				
Leg						
Absolute volume reduction by average slippage						
<4·4	8	1283 (789)	−626	−1730 to 479	−1·22	0·244
≥4·4	8	1909 (1225)				
Percent volume reduction by average slippage						
<4·4	8	17·2 (7·0)	4·6	−6·1 to 15·3	0·92	0·374
>4·4	8	12·6 (12·3)				

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Table 6 Changes in pain over the study and pain score at start by ISL stage

		Start	End	Difference		
	n	Mean (SD)	Mean (SD)	Mean	95% CI	*P* value
Changes in pain over the study						
Total	24	3·08 (3·32)	0·92 (2·12)	2·17	0·66 to 3·67	0·007
Arm patients	8	2·63 (2·92)	1·75 (3·41)	0·88	−2·90 to 4·65	0·60
Leg patients	16	3·31 (3·57)	0·50 (0·97)	2·81	1·24 to 4·38	0·002
	n	Mean (SD)	Diff (mean)	95% CI	*t* value	*P* value
Pain score at start by ISL stage						
Stage II	12	4·5 (3·5)	2·8	0·2 to 5·4	2·27	0·033
Stage III	12	1·7 (2·6)				

ISL, International Society of Lymphology.

Table 7 Changes in MYMOP scores

		Start	End	Difference		
	n	Mean (SD)	Mean (SD)	Mean	95% CI	*P* value
Total	23	3·52 (1·25)	1·85 (1·15)	1·67	1·06 to 2·28	<0·0001
Symptom 1	23	3·91 (1·20)	1·65 (1·34)	2·26	1·44 to 3·08	<0·0001
Symptom 2	21	3·95 (1·32)	1·86 (1·06)	2·10	1·28 to 2·91	<0·0001
Activity	24	3·96 (1·55)	2·46 (2·04)	1·50	0·62 to 2·38	0·002
Well-being	24	2·02 (1·96)	1·54 (1·38)	0·67	−0·11 to 1·44	0·088

MYMOP, Measure Your Medical Outcome Profile.

Table 8 Skin quality at first and final visits

Skin quality	First visit, *n* (%)	Final visit, *n* (%)	Chi-squared (df)	P value
Intact	17 (70·8)	21 (87·5)	2·02 (1)	0·155
Dry	14 (58·3)	11 (45·8)	0·75 (1)	0·386
Itchy	6 (25·0)	10 (41·7)	1·50 (1)	0·221
Thickened	8 (33·3)	1 (4·2)	*	0·023
Firm	12 (50·0)	2 (8·3)	*	0·003
Moist	3 (12·5)	3 (12·5)	*	0·999
Lymphorrhoea	4 (16·7)	1 (4·2)	*	0·348

*Fisher's exact test.

Table 9 Patient assessments on a 0–10 scale

	Mean	SD
Comfort of the bandage	7·0	2·3
Ability to wear own shoes	6·4	3·6
Ability to walk	8·6	1·7
Slippage	7·5	1·8
Ability to bend arm	7·2	2·5
Appearance	7·4	2·5
Overall view on product	8·1	2·1

bandage appeared to be well evaluated by patients, the highest mean scores being for the ability to walk (8·6) with an overall score of 8·1.

Reasons for bandage change were recorded on the case report form. Of the total 153 follow-up visits, four were for reasons other than routine changes. These were due to sores developing under the bandage (two), irritation from the bandage in an arm crease (one) and some redness developing between the toes (one). All were treated with appropriate skin care and patients continued in the study.

Discussion

This study was designed to determine major responders to a new compression therapy by evaluating the reduction of limb volume in patients with lymphoedema across different patient groups. This was a non comparative study and is described as a phase I study within the framework for development and evaluation of complex interventions as defined by the UK MRC (10). This phase includes the ability to vary the components within the intervention to determine their impact on the outcome measure. It has shown that there are substantial reductions in limb volume associated with a 3-week treatment period of comprehensive decongestive therapy (CDT) incorporating the Coban 2 compression system. This effect was noted with patients with arm and leg lymphoedema. The mean arm volume reduction of 438 ml in this study compares favourably with other published studies that have investigated the value of an intensive bandage phase within the management of lymphoedema. Johansson et al. recorded limb volume reductions of approximately 235 ml following 3 weeks of short stretch bandaging (11). A similar mean volume reduction was noted in 50 women treated with short stretch bandaging over a 4-week period which included either MLD (241 ml) or simple lymphatic drainage (SLD) (244 ml) (12).

Although stage III is typically more associated with fibrosis, similar reductions in volume have been observed in stage II and stage III lymphoedema. It has been observed that symptoms of fibrosis of the skin (skin thickness and firmness)

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were reduced at the end of the study, which might be related to the previously found reduction in volume. Moreover, the results indicated subjective improvement in symptoms considered important to the patients before the application of the new bandage system. These results are encouraging in that they provide objective assessments of both clinical and symptomatic improvements to patients with lymphoedema. Patient assessments of further markers including pain and comfort were also positively rated.

As indicated, this is a phase I study to evaluate the performance of the new bandage system in a real world environment, with minimal restrictions on entry criteria. Further work has being undertaken to extend the evaluation of the product within a pilot study that examines bandage change frequency. This has indicated that changing the bandage twice weekly gives slightly better volume reduction than more frequent changes, contrary to current practice using other bandage materials (13). The results from these two studies may be used as a precursor to a full phase III randomised controlled trial and health economic analysis.

References

1. Pereira de Godoy JM, Braille DM, De F, Longo JO. Quality of life and peripheral lymphedema. *Lymphology* 2002;**35**:72–5.
2. Passik SD, McDonald MV. Psychosocial aspects of upper extremity lymphedema in women treated for breast carcinoma. *Cancer* 1998;**83**(12 Suppl 2):2817–20.
3. European Wound Management Association. *Focus document: lymphoedema bandaging in practice.* London: MEP Ltd,2005.
4. Preston NJ, Seers K, Mortimer PS. Physical therapies for reducing and controlling lymphoedema of the limbs. *Cochrane Database Syst Rev* 2004;CD003141. DOI: 10.1002/14651858.CD003141.pub2.
5. Andersen L, Hojris I, Erlandsen M, Andersen J. Treatment of breast-cancer-related lymphedema with or without manual lymphatic drainage – a randomized study. *Acta Oncol* 2000;**39:**399–405.
6. Badger CMA, Peacock JL, Mortimer PS. A randomized, controlled, parallel-group clinical trial comparing multilayer bandaging followed by hosiery versus hosiery alone in the treatment of patients with lymphedema of the limb. *Cancer* 2000;**88**:2832–7.
7. Hornsby R. The use of compression to treat lymphoedema. *Prof Nurse* 1995;**11**:127–8.
8. Lymphoedema Framework. *Best practice for the management of lymphoedema.* International Consensus. London: MEP Ltd,2006.
9. Paterson C. Measuring outcomes in primary care: a patient generated measure, MYMOP, compared with the SF-36 health survey. *BMJ* 1996;**312**:1016–20.
10. Medical Research Council. *A framework for development and evaluation of RCTs for complex interventions to improve health.* London: MRC Health Services and Public Health Research Board, 2000.
11. Johansson K, Albertsson M, Ingvar C, Ekdahl C. Effects of compression bandaging with or without manual lymph drainage treatment in patients with postoperative arm lymphedema. *Lymphology* 1999;**32**:103–10.
12. McNeely ML, Magee DJ, Lees AW, Bagnall KM, Haykowsky M, Hanson J. The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial. *Breast Cancer Res Treat* 2004;**86**:95–106.
13. Moffatt CJ, Franks PJ, Hardy D, Lewis M, Parker V, Feldman J. A randomised controlled trial to determine the application frequency of a new lymphoedema bandaging system. *Br J Dermatol* 2012;**166**:624–32.

Appendix

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