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Lymphoedema is a chronic, progressive condition that results in swelling of the tissues as a consequence of lymphatic failure (Mortimer and Rockson, 2014). Its causes can be genetic, referred to as primary lymphoedema, which results in malformation or under-development of the lymphatics, or secondary, as a result of trauma, surgery, radiotherapy or obesity among other causes (Hardy, 2012).

Regardless of cause, lymphoedema can affect any part of the body with an accumulation of protein-rich fluid building up in the tissues, and, if not treated early or managed effectively, it can lead to disability and complications, such as cellulitis (Moffatt et al, 2016). Management strategies can form part of a two-phase approach (International Society for Lymphology (ISL), 2013); however, both decongestion and maintenance of a limb can be used interchangeably with patients stepping up and down between phases, depending on how the oedema is responding. Furthermore, decongestion and maintenance will involve the use of compression therapy, skin care, exercise and manual lymphatic drainage, all being adapted to each patient's needs, depending on which approach is being used, with further treatment modalities added where necessary (Wigg and Lee, 2014).

The focus of this article is to introduce the reader to the use of Comfiwave in all phases of the treatment process. Case studies will demonstrate how versatile Comfiwave is at reducing and maintaining limb volume either as a stand-alone treatment or as part of combination treatment.

Although optimisation of compression therapy is not a new concept, the use of 24-hour compression therapy as part of the maintenance phase of treatment has not been standard practice in the UK, and, until recently, it has only been adopted by certain specialist centres. A modality that has been considered in the process of optimisation is the use of products that are classed as 'reduced compression' or 'night time garments'. These are not traditional flat- or circular-knit garments, but are made of various components to include foam and, more recently, knitted cotton fabrics. Haddenham Comfiwave is a new product that has recently been brought to market. Although it does not yet feature in the literature, it is a unique product in its own right and fits within the groups of products discussed previously. Furthermore, from the studies highlighted in the subsequent literature review, it can be argued that, although classed as night-time garments, these products clearly fall into two categories: devices used as stand-alone treatment, used mainly at night-time, and those that are used in conjunction with other products, such as bandaging for decongestive treatment.

Evidence for 24-hour compression

There are few studies using randomisation that address both the safety aspects and performance of those products

ABSTRACT

Compression therapy is the mainstay of treatment in venous and lymphatic diseases. Optimisation of compression therapy is not a new concept, but, in the UK, the use of 24-hour compression therapy as part of the maintenance phase of treatment has not been standard practice and, until recently, has only been adopted by certain specialist centres. One such modality in the process of optimisation is the use of products that are classed as 'reduced compression' or 'night-time garments'. These are not traditional flat- or circular-knit garments but are made of various components to include foam and, more recently, knitted cotton fabrics. Haddenham Comfiwave is a new product that has recently been brought to market and does not feature in the literature reviewed. Although a new unique product in its own right, it has been demonstrated to fit within the common groups of products discussed.

KEY WORDS

- Comfiwave
- Reduced compression
- Night-time compression
- Combined compression therapy

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classed as night-time compression garments. Of the literature reviewed in the present study, there are no randomised controlled trials, with some studies being comparative, retrospective or experimental. These studies use devices as part of combined treatment or for stand-alone treatment for night-time compression, and they evaluate the efficacy of the products on the basis of limb-volume changes. Some studies discuss adverse events; however, these are classed as mild and do not result in discontinuation of treatment or are not directly related to the devices. Much of the literature are case studies from clinical practice. The literature will be discussed detailing how devices perform, as well as the safety of the devices when used in practice.

In the Polit study (Quere et al, 2014), the aim was to evaluate the two arms of long-term lymphoedema management and observe limb volumes pre- and post-decongestive therapy and then 6 months after, during maintenance therapy. The study did not evaluate one particular product, although a predecessor product was used as part of the multi-component bandaging system in 55.6% of participants. Retrospective analysis of 306 patients demonstrated that limb heaviness reported prior to treatment with multi-component bandages reduced from 75% to 42%, and median excess limb volume reduced by 31% but then increased by 16.5% over the following 6-month maintenance period. The study was of good quality, demonstrating acceptable participant numbers for statistical significance and confidence intervals. Furthermore, the authors detailed adverse events and documented redness and compression marks on the skin of 18.4% and 15.7% of participants, respectively; however, there was no information on which products the patients affected were using (Quere et al, 2014).

Riccioni et al (2014) compared treatment with the same product and inelastic bandages to inelastic bandages alone in 40 participants. Participants were divided into two groups based on stage and location of oedema, but randomisation was not used, in order to ensure that each group had similar patients in them. They were evaluated at baseline and after 40 days of treatment, and exercise was recommended for both groups. Outcomes measured were limb volume, venous Doppler ultrasound, measurement of venous pressure in the orthostatic position and laser Doppler of veno-arteriolar reflex (VAR), to measure limb volume reduction, reduction in skin thickening and a reduction in interstitial pressure. After 40 days, the results demonstrated that all participants had limb-volume reduction, but this was more so in the combined product group. Furthermore, a reduction in skin thickening and improvements in VAR were also demonstrated. According to the participant questionnaires, all patients reported improvements in quality of life and better function and that the product had positively impacted self-management. There were limitations with regard to the data collection in this study, in that the raw data were not given, and no tests for standard deviations or statistical analysis were carried out Riccioni et al (2014).

Another study (Mestre et al, 2016) demonstrated the use of a predecessor device, namely, Mobiderm Autofit, as a night-time garment. Following decongestive therapy, limb-volume increase was less in the 24-hour compression group than that in the group that used daytime compression alone. After 30 days, all participants were treated with night-time compression, which resulted in the second group experiencing limb-volume reductions. This pilot, prospective, open-label randomised study directly observed reduced limb volumes as a primary outcome, together with compliance, quality of life and improved functional symptoms using a validated quality-of-life assessment tool. A sample of 40 women with breast cancer-related lymphoedema was included in the study, 20 randomly selected for each group. The results were clear, in that they showed data ranges with the median and mode and included standard deviations, but, although statistical calculations were carried out, no information on the statistical significance of differences between groups was documented. Qualitative data demonstrated 82% satisfaction with the product. Furthermore, the study discussed adverse events that occurred, finding that these were mild redness or irritation, which did not result in discontinuation of use. Two serious adverse events occurred, which were not directly related to the product. Mild indentations could be seen on the skin following removal of the device, but, again, this was not serious and did not result in discontinued use.

Bertsch (2018) conducted a longitudinal observational study on 91 participants to evaluate a predecessor product, Jobst Relax, where continuous variables were described along with the absolute number of observations, to present outcomes. Although no statistical analysis was performed, mean and standard deviations, percentages and frequencies were used to describe nominal or ordinal values. Participants' overall response demonstrated that they achieved good quality of sleep while wearing the product. Some 75% stated that night-time compression had helped manage their oedema 'a lot'/'great deal', and patient satisfaction was 94%, with the product rated as 'good' or 'very good'. As with the previous study, this study, too, observed for tolerability and skin problems associated with the device, with 76.9% not experiencing itching and 85.7% not experiencing pressure marks. Again, those who did experience either did not discontinue treatment.

Toccafondi et al (2017) conducted a retrospective study on 145 participants with breast cancer-related lymphoedema, to analyse the effect of a predecessor product, Mobiderm made-to-measure night-time compression sleeve, on volume reduction and maintenance when worn at night. Comparisons were made between affected and unaffected arms, as is normally the case for such limb-volume measurements. Statistical significance was observed in correlation ($p<.001$) between limb volumes before the night-time compression was administered and those after 6 months of treatment with night-time compression. The authors observed that the reduction in limb volume

was greater in newly diagnosed lymphoedema patients than in those who had received night-time compression for 6 months (56.6% to 49.6% vs. 50.6% to 49.3%). In comparison with other studies, this study did not observe quality-of-life indicators to determine the efficacy of the device; another limitation was the retrospective nature of the study. In contrast, Whitaker (2016) used telephone interviews to question 94 participants across five countries. The circumferential measurements of the ankle, calf and thigh in the lower limb and wrist in the arm were recorded in 66 participants. These were monitored at bedtime and in the morning, for a total of 315 nights, with 214 nights for legs and 101 for arms. The findings showed that the swelling was reduced or maintained at the same level in 86% of the thigh, 87% of the ankle, 83% of the arm and 86% of the wrist measurements when the participants used night-time garments. Where night-time compression was not used, an increase in swelling was experienced by 89% of participants. The subjective findings were that night-time compression improved sleep and reduced discomfort. In a second study evaluating a different predecessor product, Tribute Wrap, Chohan et al (2019) demonstrated that it reduced oedema, increased blood flow, reduced venous stasis and increased tissue oxygenation, all of which lead to healthy tissues. Tissue oxygenation tests were performed in 28 subjects prior to, during and after wearing the device for 20 minutes in each scenario and in three positions, namely, chair-sitting, long-sitting and supine. Increased tissue oxygenation was demonstrated significantly in chair-sitting while wearing the device. This has implications for the management of mixed aetiology oedema and where reduced compression therapy is required or full compression therapy is contra-indicated, as a reduced compression device of this kind has been found to improve circulation. However, a limitation of this study was that it was conducted on healthy subjects, and the authors stated that, to demonstrate clinical significance, a sample of the actual patient population should be tested (Chohan et al, 2019).

Although case studies rank low in the hierarchy of evidence, several have been published detailing the efficacy of reduced compression products in the treatment and management of lymphoedema. Grabsch (2018) presented a case study where Mobiderm Bandaging system was used as part of combination treatment to reduce limb volume and tissue changes in a patient with an underlying genetic disorder leading to connective tissue problems and oedema. The treatment consisted of the product and short-stretch bandaging for 2 weeks, with clinic visits twice per week. On the third visit to the clinic, circumferential measurements taken at 30 cm up the leg had reduced by 14.3 cm, and tissue softening and reduced fibrosis were also noted. In the article by Todd et al (2018), significant data on limb volume reduction were not provided, but improvements in skin softening were noted, and quality of life markers improved. Case studies showed that the product was comfortable, with one patient showing a further reduction following 11 nights of wearing the garment after decongestive lymphatic treatment (DLT), demonstrating maintenance of limb volume reduction post-DLT. Similar outcomes were noted in an article in the *British Journal of Community Nursing* (2017), where eight case studies demonstrated the efficacy of compression products worn at night in controlling and reducing oedema. In contrast, there are several case studies that demonstrate the efficacy of predecessor products as part of combination treatment. In a case series with four participants (Elwell, 2018), the use of foams and pads in conjunction with MLD, compression or multi-layer bandaging resulted in tissue softening and reduced oedema. This was shown using tissue dielectric constant (TDC) and limb volume measurements. Furthermore, this was also demonstrated in the case study by Lawrance (2018), who demonstrated limb-volume reductions when using a reduced compression device underneath a Velcro wrapping system.

Comfiwave

Comfiwave is a patented compression garment intended for use in primary or secondary lymphoedema and chronic oedema as a stand-alone treatment or as part of combination treatment where a reduced compression system is indicated. Comfiwave is designed to be worn at any point throughout the 24-hour period and can stay in situ for 24 hours per day, although it can be removed to perform skin care. Comfiwave consists of a non-traditional flat-knit, highly elastic, uneven, mesh fabric, designed to provide a reduced level of therapeutic compression to the patient. Comfiwave is composed of a single layer of knitted fabric that delivers therapeutic compression by using highly elastic yarn and highly breathable cotton and is latex free. Due to the elastic nature, it aims to be easy to apply and is available as an arm, combined arm with mitten, below knee or full-leg garment.

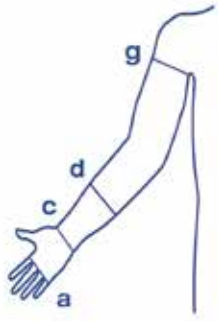
The upper limb garments are available in three sizes with two lengths, accommodating hand circumferences between 16 and 26 cm and axilla ranges from 25 to 50 cm. The lower limb garments have four sizes and three leg lengths, accommodating ankle circumferences from 17 to 35 cm and thigh circumferences from 40 to 75 cm. All garments are extremely easy to measure for, and many patients will fit into standard sizes (*Figures 1* and *2*).

Since its launch, Comfiwave has already demonstrated how effective and versatile a product it can be during all phases of lymphoedema treatment. The following case studies demonstrate this further.

Case study 1

Mrs S is an 84-year-old woman with breast cancer-related upper limb lymphoedema. She was diagnosed with left breast cancer in 2015, and was treated with wide local excision surgery and radiotherapy. She had no problems with lymphoedema until late 2019, when she developed secondary disease. This involved her lungs, supraclavicular nodes and a soft tissue mass extending from the anterior chest wall into the left axilla.

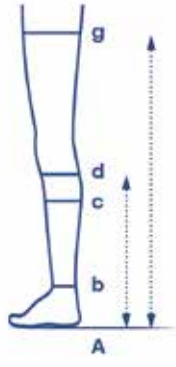
	Circumferences cm	S	M	L
g	AXILLA	25-30	30-40	40-50
d	MID-POINT OF FOREARM	23-26	26-30	30-38
c	WRIST	13-18	18-22	22-28
a	PALM AT BASE OF FINGERS	16-22	18-24	20-26



	Lengths cm	SHORT	REGULAR
c-g	WRIST TO AXILLA	36-42	40-46

Figure 1. Comfiwave sizing chart: upper limb

	Circumferences cm	S	M	L	XL
g	THIGH TOP	40-48	46-56	54-65	62-75
c	WIDEST CALF	25-32	30-38	36-46	44-56
b	ANKLE	17-22	20-26	22-30	27-35



	Lengths cm	SHORT	REGULAR	LONG
A-d	BELOW KNEE	32-37	37-42	42-48
A-g	THIGH HIGH	64-70	70-77	77-84

Figure 2. Comfiwave sizing chart: lower limb

Mrs S presented in clinic with an oedematous left arm and hand with reduced range of movement and poor grip ability. On examination, the skin on her arm was intact, but the tissues were soft and pitting. Further examination revealed tight contracted tissue on the chest wall extending into the left axilla, palpable supraclavicular nodes and distended veins across the chest wall. A computed tomography (CT) scan confirmed the tumour was compressing the axillary vein and brachial plexus nerve, accounting for the reduced range of movement and soft, pitting nature of the oedema.

The initial assessment comprised a discussion on skin care, passive and active movement and limb positioning to reduce any dependency oedema. It was felt that the oedema was too soft and pitting for her to wear a traditional arm sleeve, so a Comfiwave combined arm garment was chosen. Mrs S was also fitted with a Haddenham Pertex Light, flat-knit class 1 glove to manage the very soft dependent hand/finger oedema that was developing. It was also decided to provide an arm sling for use when she was walking around, to reduce the dependent oedema. The Comfiwave was fitted easily by Mrs S, with some assistance from her husband, and initial feedback was that it felt comforting to have some support on the arm.

Mrs S returned 2 weeks later for review, where it was found that there had been a marked improvement in her arm. The size had reduced by 8%, the shape was better (previously, there had been 'pooling' of dependent oedema around the hand and elbow) (*Table 1*), and there was a slight improvement in her hand function due to the reduction in hand/digit oedema. There remained a small area of peau d'orange tissue around the mid-forearm, but this was minimal considering the extent of the axillary mass.

The regime Mrs S is on is to use the Comfiwave at home and overnight. She tends to remove it when going out, as she finds that some clothes are too tight to wear over the top of the garment. The more 'normal' arm shape and size could probably be managed now in a conventional

Table 1. Mrs S's limb volume and circumference measurements at baseline and 2 weeks after using Comfiwave

Circumference (cm)	A	C	D	F	G	Limb volume A	Unaffected	% difference
Baseline	17.5	17.5	25	29	31.5	2329	1954	+16%
After 2 weeks	17	15.8	24	27.5	31	2139	1953	+8%

Figure 3. Mrs S wearing Comfiwave

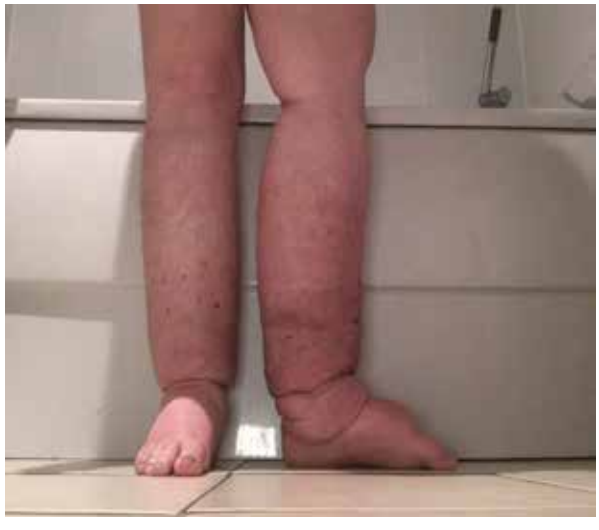


Figure 4. Miss H's legs before treatment

flat-knit class 1 sleeve, but she prefers to continue using the Comfiwave as her first choice of garment: 'my arm feels safe and it is comforting to wear' (*Figure 3*).

Case study 2

Miss H, aged 29 years, was diagnosed with Milroy's disease at age 11 years. Following diagnosis, there seems to have been no treatment intervention, and the patient struggled through her teenage years with bilateral lower leg oedema and recurrent episodes of cellulitis.

On initial assessment, there was evidence of bilateral lymphoedema below the knee, with both feet showing positive Stemmer's sign, mild hyperkeratosis and post-cellulitis skin discolouration on the left gaiter area. The left leg was 30% bigger than the right, with an ankle circumference of 51 cm and calf of 65 cm. There were distinct skin folds distorting the shape around her left ankle, as well as foot oedema, which was restricting footwear (*Figure 4*). The limb size also restricted clothing, and the patient was only able to wear very loose trousers or long skirts.

Initial advice of skin care, exercise, elevation and weight management were discussed, and 2 weeks of daily treatment were booked. Miss H was signed off work by her GP to enable her to attend the sessions. Daily treatment commenced in October 2018 and involved alternating days of MLD or intermittent compression using Haddenham LymphFlow Advance, followed by below-knee multi-layer compression bandaging. Due to the extensive fibrotic nature of the left leg, the compression layers included Bande Mousse foam bandage under Clinistretch bandages (8 cm and 10 cm) and Haddenham Microfine toe caps.

In advance of her return to work in week 3, Haddenham E garments (foot and below knee) were ordered to enable her to continue treatment independently and maintain optimum compression. This was combined with a Mobiderm leg garment to provide night-time compression.

Miss H was fitted with a Haddenham Goldpunkt, class 3, below-knee garment for her right leg after 4 weeks. However, due to the extent and duration of the oedema in her left leg, there was an excess of skin around the ankle, making Easywrap the most appropriate garment to use. The skin fold was lifted using Kinesio tape strips, in order to reduce the skin sagging under the wrap.

At 6 months, both legs were fitted with Haddenham Goldpunkt, class 3, custom, below-knee garments. To maintain optimum reduction, the night-time compression system was continued. Miss H alternated between Easywrap and Mobiderm garments depending on the condition of her leg. This gave her full autonomy over the management of her condition. However, this combination was bulky and hot during the summer, so she offered to trial the Comfiwave leg garment. The structure and compression of Comfiwave provided reduced compression compared with the level she was used to. Understandably, she was concerned about preventing the oedema from recurring, having experienced so many problems and finally getting a 'normal leg' back. It was agreed that she would use the

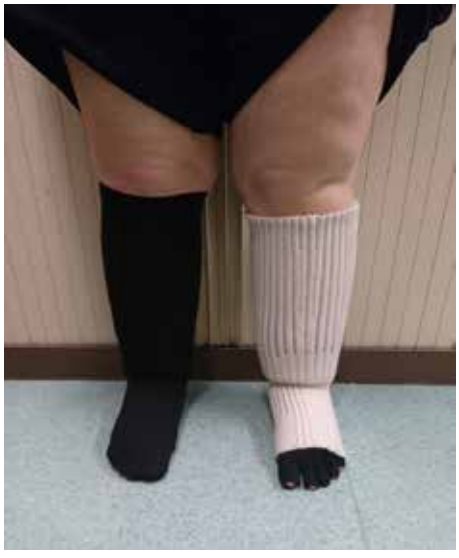


Figure 5. Miss H wearing Comfiwave on the left leg

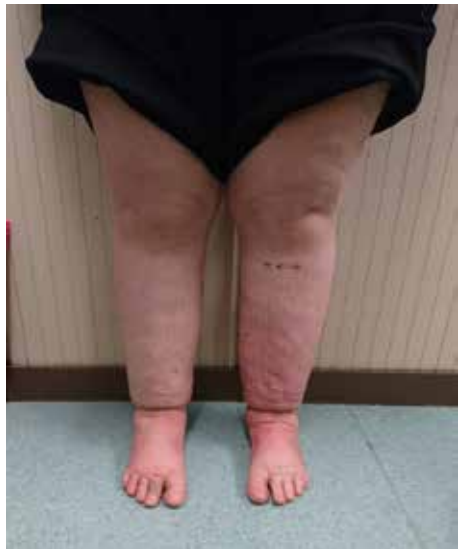


Figure 6. Miss H's legs after using Comfiwave for 2 weeks

Comfiwave under Easywrap for 2 weeks to compare this with the previous Mobiderm/Easywrap combination (*Figure 5*).

The feedback after 2 weeks was that it was a much more comfortable garment combination to wear, and the Easywrap over the top gave as good compression as the combined Mobiderm/Easywrap combination did. It was easier and quicker to apply and more flexible when worn in the evening, so Miss H was able to walk easier. Measurements after 2 weeks showed further volume reduction by 5% (*Figure 6*).

Miss H felt her leg shape was better, and she is now using the Comfiwave without Easywrap at night. If there is any increase in the oedema, she has the tools to self-manage and return to using Easywrap or an older compression garment over the Comfiwave if required. The limbs have both maintained well, with day garments and Comfiwave at night. Overall, her left leg has reduced by 2702 ml since September 2018. Miss H is now much more confident in her physical appearance and has returned to wearing straight leg jeans and ankle boots.

Case study 3

Ms Mc is 48 years old and presented with bilateral below-knee oedema secondary to cellulitis and chronic lympho-venous disease. The oedema had been present for several years but was not treated until she developed cellulitis in the left leg, which required antibiotics and onward referral from her GP.

Ms Mc felt it would be difficult to treat both legs with a wrap or bandage system at the same time due to her work commitments. Since the right leg had good limb shape, self-maintenance using a Haddenham Goldpunkt flat-knit class 2 garment was decided on, with a view to reducing the compression if needed at a later date with a wrap system. The left leg was bigger due to the previous cellulitis with some distorted shape around the ankle, so a Haddenham Easywrap was selected, with which she could self-manage. A few days later, she contacted the clinic for an earlier appointment as there was a 'problem' with her skin.

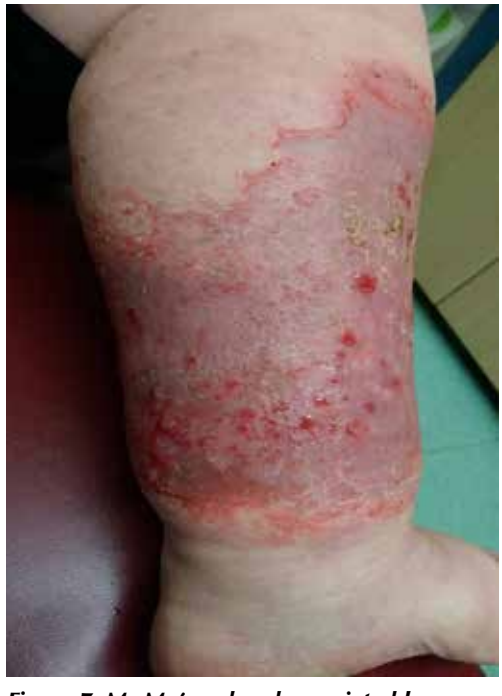


Figure 7. Ms Mc's red and excoriated leg

On removal of the wraps, the right leg was found to be red and excoriated (*Figure 7*). The cause was unknown, but it was possible that she was sensitive to the silver in the Easywrap liner garment (although she had no known previous allergy to silver). After consultation with the dermatologist, non-adherent dressings, emollient and extra padding were used, and Ms Mc continued with Easywrap as the compression layer (without the liner garment). After 10 days, the skin had significantly improved. The limb shape had improved, and a custom-made Haddenham Goldpunkt garment was fitted for daytime use. It was felt that she

Figure 8. Ms Mc's leg after using Comfiwave

needed to use some sort of night-time garment due to the extent of the initial problems and the fact that there was a slight increase in the oedema after removal of the daytime compression garment in the evening or overnight. She was fitted with a below-knee Comfiwave and booked for a 2-week review.

At 2 weeks, the left leg had reduced a further 1–2 cm, the tissues were softer and the shape was well maintained (*Figure 8*). There was a reduction of 119 ml, with excess volume reduction from 11% to 8% between limbs. The patient commented that: 'It is really easy to put on and very comfortable, I found it fine to sleep in, I thought it would be too warm, but it wasn't'.

KEY POINTS

- Comfiwave can be used as part of decongestive or maintenance compression therapy
- Compression therapy can be left in situ for 24 hours per day in patients who meet certain criteria
- Comfiwave can be used as stand-alone treatment or combined with other compression therapy
- Comfiwave promotes self-management among patients with lymphoedema/chronic oedema

CPD REFLECTIVE QUESTIONS

- At what point would you deem it appropriate to introduce 24-hour compression?
- How would Comfiwave be used as part of combined treatment during the decongestive phase?

Conclusion

Across all case studies in the literature review, and within the case studies related specifically to the use of Comfiwave presented in this article, benefits were noted to the patients' quality of life, and there were no negative responses to the use of any of the devices. Patients reported that they were comfortable and easy to use, which itself would improve concordance with treatment and self-management of oedema. Furthermore, the evidence suggested that this type of product can be used for stand-alone treatment or as an adjunct to other treatment modalities and for 24 hours a day if needed. Comfiwave has demonstrated efficacy in reducing and maintaining limb volumes, thus decreasing the incidence of complications associated with oedema and the burden of oedema management on the patient, family and the health service. **BJCN**

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