Lymphoedema management with the LymphFlow Advance pneumatic compression pump

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Lymphoedema is a chronic condition, that has been present for longer than 3 months, where there is an accumulation of fluid in the tissue space (Lymphoedema Framework, 2006) caused by lymphatic failure (Mortimer, 2013). Classified as primary or secondary (Hardy, 2012), it is suggested that in some areas of the UK the prevalence of lymphoedema is between 2.29 and 3.59 cases per 1000 of the general population (Cooper and Bagnall, 2016).

In primary lymphoedema, Browse et al (2003) state that genetic abnormalities can cause malformation of the lymphatic system. Furthermore, according to Harding (2012) lymphoedema can present at birth or develop later on in life, and in some instances at the same time as hormonal changes such as puberty, pregnancy or menopause. According to Connell et al (2009) if primary lymphoedema is suspected, regardless of age of onset, it is suggested that a classification using phenotype is made as patients who present with a secondary lymphoedema may have underlying genetic abnormalities which predispose them to lymphoedema (Mortimer, 2013).

Secondary lymphoedema can develop following trauma to the lymphatics either through surgery used to treat cancer, injury of other causes, infection, or secondary to other underlying pathologies such as obesity or venous disease (Mortimer, 2013). In all cases, if the lymphoedema is left untreated skin changes will occur, resulting in thickening and fibrosis of tissues, leakage referred to as lymphorrhoea, and increased risk of infections such as erysipelas and cellulitis (Lymphoedema Framework, 2006).

Intermittent pneumatic compression has formed part of long-term lymphoedema management for several years (Lymphoedema Framework, 2006) and is seen as a main component of treatment in Europe (Wigg, 2009b). With a number of different pneumatic compression devices available and used (Olszewski et al, 2011), pneumatic compression systems allow the application of external pressure to actively compress the limb, using single or multi-chamber garments that are inflated with air (Camerota and Aziz, 2009).

Historically, intermittent pneumatic compression pumps used either sequential or peristaltic cycles. With sequential cycles, each chamber inflates in turn and maintains the pressure on the limb until the final chamber inflates and then all chambers deflate together. The peristaltic cycle usually initially inflates three chambers in turn, deflating the previous chamber as the next one inflates, creating a wave motion as it moves up the limb. One disadvantage of traditional devices is the failure to perform cycles in a proximal to distal motion, mimicking the movements therapists would use when performing manual lymphatic drainage. According to Camerota and Aziz (2009) this would ensure the emptying of the proximal lymphatics before the fluid from the distal lymphatics reached the area. However, according to Fife et al (2012) evidence to support the advantages of using these devices as an adjunct to treatment is lacking.

ABSTRACT

There are many intermittent pneumatic compression devices available for use in the management and adjunct treatment of lymphatic, venous and arterial disease. This article discusses the development of a new advanced pneumatic compression device, the LymphFlow Advance, which can perform focussed treatment on the lymphoedematous area using a variety of different cycles. Case studies with therapist and patient feedback are used to demonstrate the use of the LymphFlow Advance in the lymphoedema clinic, with a discussion of the evidence to underpin recommended treatment regimes.

KEY WORDS

• advanced pneumatic compression • oedema • lymphoedema • active compression • LymphFlow Advance

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Figure 1. LymphFlow Advance Pump

Intermittent pneumatic compression pumps have been modified in recent years to provide treatment for different medical conditions such as critical limb ischaemia (Tawfick et al, 2013) and chronic wounds (O'Sullivan-Drombolis and Houghton, 2009). All applications are concerned with the reduction of oedema in some way, based on hypothetical possible physiological effects during treatment (Morris, 2008). Furthermore, with developments in the use of indocyanine green (ICG) imaging techniques using lympho-fluoroscopy to visualise the lymphatic function in real-time (Giacalone et al, 2011), clear evaluation of the effects of these advanced pneumatic compression devices on lymphatic function is now taking place.

Benefits of advanced pneumatic compression devices

The Lymphoedema Framework (2006) suggests that when compression therapy is applied, lymph reabsorption is increased as capillary fluid filtration is counteracted. Cooper (2013) states that compression therapy enables movement of fluid to an area where drainage is less compressed. Further benefits have been demonstrated for the use of intermittent pneumatic compression devices, which offer a retrograde or manual lymphatic drainage cycle – Wigg (2009a) demonstrated tissue softening and limb volume reductions when compared to manual lymphatic drainage, stating that the device provides an easy to use alternative to manual lymphatic drainage. Small scale studies have demonstrated, using limb volume reductions and imaging with lymphoscintigraphy, that home use of intermittent pneumatic compression can increase lymphatic flow by aiding re-establishment of lymphatic pathways (Furnival-Doran, 2012). Furthermore, using near infrared fluorescence imaging, Adams et al (2010) demonstrated a statistically significant improvement in lymphatic function and increased propulsion rates of lymph flow.

There may be benefit for patients who have lipoedema (Fetzer, 2016), which manifests as disproportionate accumulation of fat in the tissues (Fife et al, 2010). Often pain, discomfort and bruising can present as debilitating symptoms of lipoedema which can be life-limiting for patients (Dudek et al, 2015). Although research is limited and there are no standard guidelines in treatment of lipoedema using intermittent pneumatic compression, some patients who have received this treatment have reported the benefits of and express symptom relief through the use of low pressure intermittent pneumatic compression. Furthermore, use of intermittent pneumatic compression on larger limbs can reduce the risk of injury to the therapist (Wigg, 2009b) while promoting self-management or home-based treatment for those with lymphoedema (Ridner et al, 2008) or lipoedema.

An added benefit is a reduction in episodes of cellulitis, with one study demonstrating a reduction by as much as 79% in those with cancer-related lymphoedema (Karaca-Mandic et al, 2015). This impacts directly on clinic resources by reducing costs related to hospital admissions. In addition, pneumatic compression can be supervised by health-care assistants without the need for a trained specialist, which further promotes appropriate use of resources (Wigg and Lee, 2014).

Development of the LymphFlow Advance

The LymphFlow Advance (*Figure 1*) has been developed taking into account research and changes in the understanding of fluid exchange and lymphatic function. According to Levick and Michel (2010), research suggests that minimal transient fluid returns from the interstitium via the venous circulation, with fluid now returning to the circulation via the lymphatic system. Furthermore, Belgrado et al (2014) stated that filling of the initial lymphatics occurs as a result of changes in tissue pressure caused when muscles are activated or when aiming to fill the lymphatics with pressure achieved using manual therapies.

The identification of the glycocalyx layer within the venous capillary is thought to be responsible for the change in fluid exchange theories. Levick and Michel (2010) state that the glycocalyx theory demonstrates that reabsorption through the venous capillaries does not occur, as a result of the change in oncotic pressure and the protein layer of the glycocalyx repelling the reabsorption of interstitial fluid into the capillary. In addition, Mortimer and Rockson (2014) suggest that the capacity at which the lymphatic system functions is greater than previously thought, as all fluid is filtered through this system whereby lymph becomes more concentrated as it passes back into the venous system through the venule exiting the lymph nodes in the normal situation.

Table 1. Treatment modes

Mode number	Mode type
Mode 1	Intensive distal
Mode 2	Intensive proximal
Mode 3	Intensive whole
Mode 4	Intensive hand/foot
Mode 5	Sequential
Mode 6	Peristaltic
Mode 7	Midline

The LymphFlow Advance has seven cycles (*Table 1*) to enable the clinician to focus treatment on a particular area. Many of the pumps currently available only treat the whole limb, but the LymphFlow Advance will work intensively on the whole limb, or on the proximal or distal areas, or on the hand or foot. It has a retrograde action working from proximal to distal on the limb, as is the case when performing manual lymphatic drainage. This allows the therapist to offer a more focused treatment as the device concentrates on the area that requires more intensive treatment.

The LymphFlow Advance could be considered an advanced pneumatic compression system because of the ability to target specific areas. Fife et al (2012) states it is difficult to compare new advanced pneumatic compression devices with standard devices as many studies, over 10 years old, lack details regarding the devices studied. There is also a lack of consistency in treatment regimens and duration across the studies (Olszewski et al, 2011). In comparison to other pumps the LymphFlow Advance may be more effective as it uses a retrograde cycle in modes 1–4 while focussing on the specific area and then uses a sequential clearance. According to Belgrado et al (2016) the use of sequential pneumatic compression can achieve clearance of the superficial lymphatic collectors during chamber inflation. This could be seen as a more effective treatment, ensuring clearance of the vessels following the use of retrograde sequences which focus on the specific area. Furthermore, Fife et al (2012) argue that the use of specific garments, such as those which clear the trunk, are comparable to the underpinnings of clinical training for manual lymphatic drainage, which promote truncal clearance. Adams et al (2010) suggest the use of garments that treat the truncal area before treating the limb demonstrate an improved propulsion rate in lymph flow. Further consideration has been given to a theory proposed by Belgrado et al (2016) which states that knowing the occlusion pressure of the lymphatics will allow improved treatment between occluding and improving flow.

Figure 2. Standard arm garment

Figure 3. Standard leg garment

Optimal pressures

Olszewski et al (2011) state that more knowledge is required detailing the optimal pressure that should be applied, manually or by compression devices, to provide sufficient pressure to move tissue fluid from a swollen area to that which is not swollen. There are no agreed guidelines on the treatment of lymphatic or venous disease using intermittent pneumatic compression but Camerota and Aziz (2009) suggest that the higher the pressure the better the outcome of treatment. In contrast it has been documented that when used at high pressures for long periods, intermittent pneumatic compression can induce genital oedema (Boris et al, 1998). However, Wigg (2013), who replicated this retrospective study, found no genital or midline oedema in patients receiving a modern and advanced pneumatic compression therapy at a pressure of 30-40 mmHg in a stated treatment protocol.

It is important to consider the pathology of the condition when treating with intermittent pneumatic compression. Morris (2008) states that those with lymphoedema secondary to cancer may not tolerate higher pressures, although Camerota and Aziz (2009) suggest that those with lymphoevenous oedema may tolerate higher pressures. Morris (2008) states that compression pumps that allow adjustment of treatment regimens according to individual conditions are beneficial. Haesler (2014) states that there is insufficient evidence to recommend treatment regimens using intermittent pneumatic compression and Mayrovitz (2007) states that pressure should not exceed that needed to produce a therapeutic result while minimising the risk of injury.

While analysing the pressures of two pneumatic compression devices, significant differences in the applied pressures were identified (Mayrovitz, 2007). According to Segers et al (2002) pressures greater than 30 mmHg should not be used with a sequential compression cycle because of the interaction between each chamber, which causes an increase in pressure in the most distal chamber, leading to the pressure being greater than that shown on the control unit. In contrast Belgrado et al (2016) suggests that more pressure over the oedematous part of a limb will improve the transport of lymph to an area where it is free to drain

into functioning lymphatic collectors. He demonstrated that the average occlusion pressure of superficial lymphatic collecting vessels is 84 mmHg in the arms of healthy subjects.

Treatment protocols

In light of the available research, it is advised that the pressure is set at 30 mmHg when using the lymphoedema cycles of the LymphFlow Advance on the upper limb. This is to minimise the risk of reverse flow through incompetent initial lymphatics, rerouting and causing dermal backflow. During each inflation, pressure may become concentrated on the specific area being treated, so oedema may be forced in a reverse direction through the dermis. The sequence of the pump takes account of this by clearing each area after inflation. This advised pressure setting is a precautionary measure, as Adams et al (2010) demonstrated distal movement in the control group and the asymptomatic untreated arms of patients with breast cancer-related oedema. This was interpreted as a negative velocity of lymphatic propulsion and although this was demonstrated during treatment, post treatment all subjects had a statistically significant ($P<0.05$) increase in propulsion rate, demonstrating that any overall distal movement had been reversed. The development of the LymphFlow Advance included consideration of the possibility of reverse flow by including sequential clearances in the lymphoedema cycles which focus on proximal regions of the limb.

The different modes used to treat are listed in *Table 1*. A standard arm or leg garment (*Figures 2* and *3*) can be used for modes 1 and 4 which concentrate more on the distal portion of the arm or leg, which would be useful in instances where there is post-traumatic lower limb oedema or in some primary lymphoedemas where lower limbs or just feet are oedematous.

Where the oedema extends into the shoulder or hip, the LymphFlow Advance has the added benefit of either a garment with a shoulder cap or a thigh-high garment with a waist attachment (*Figures 4* and *5*), which can be used for modes 2, 3, 5 and 6.

The extent of the oedema should be considering when selecting modes. For example if the oedema is mainly in the upper portion of the limb and trunk then the mode which focuses proximally should be selected; however, the intensive whole mode can also be selected as the whole limb or proximal cycles will ensure clearance of the truncal area before treating the limb. If the patient has bilateral leg oedema extending into the genital area or midline then there is the option to select trousers (*Figure 6*).

All lymphoedema modes will clear first but using the proximal modes will ensure truncal clearance first. The duration of treatment will vary depending on limb size, garment selection and th emode used to treat the patient. However, the cycles have been developed to reflect the time that would be spent performing manual lymphatic drainage in the clinical setting, because there is a lack of consistency across research studies and a lack of evidence to recommend a treatment regime (Haesler, 2014). Therefore

Figure 4. Arm with shoulder cap

Figure 5. Thigh with waist attachment

Figure 6. Trousers

KEY POINTS

- The development of the LymphFlow Advance allows for a more individualised treatment using intermittent pneumatic compression.
- Treatment can be targeted to a specific area and can include treatment of midline oedema which was previously not possible.
- The combination of sequential and retrograde cycles may enhance treatment when using intermittent pneumatic compression.
- A wider range of garments are available to extend treatment to those patients who were excluded previously.

each full treatment lasts between 35 and 50 minutes. When using the trouser garment for bilateral leg oedema, depending on variables such as limb size and nature of oedema, the cycle may last up to 60 minutes.

Treatment can be used as part of decongestive lymphoedema therapy, where patients would attend clinic daily for 2 weeks, if using traditional bandaging techniques, and for reducing sessions following implementation of compression hosiery. The LymphFlow Advance can also be used as stand-alone treatment as part of maintenance therapy or as part of a supervised self-management regime which incorporates home use.

Evaluation of LymphFlow Advance

Evaluation is ongoing and has included collecting data on limb volume, tissue type, garment suitability and suitability of the LymphFlow Advance cycles. Both patient and therapist comments are also being collated. Below are case studies of patients who have received treatment using the LymphFlow Advance, which focus on initial feedback from both therapists and patients. Limb volumes and quantitative data will be used in future publications, when more data have been collated and analysed, along with further information on the impact of this treatment on quality of life.

Initial feedback

Case study 1

Mr J attended the lymphoedema clinic following episodes of cellulitis and swelling to both legs. He was diagnosed with lymphoedema secondary to infection and mild venous disease with the right leg presenting bigger than the left. He reported that his oedema impacted on his quality of life and social circumstances, as he was unable to wear appropriate footwear, which meant he had become more isolated.

Mr J had received standard decongestive lymphoedema therapy using a predecessor device but indicated he would like to compare both pumps at the same time, as he felt he could evaluate all aspects of the experience. Therefore the LymphFlow Advance was used on his right leg with the predecessor device on the left leg. After one session the patient reported that he felt the LymphFlow Advance was giving a better treatment and felt firmer, even though the pressures were set the same. He reported that the garment felt more comfortable as it was not as heavy as the garment on his left leg and that it focussed more on the problematic area of the lower leg. Ongoing evaluation and therapist feedback found that, compared to the previous pump, LymphFlow Advance seems to maintain results of decongestive lymphoedema therapy better than previously noted as the skin around the patient's ankle remained wrinkled, where this had previously refilled, and the tissues remained softer following reducing sessions of treatment on the leg that was treated with the LymphFlow Advance.

Case study 2

Mrs S is a 40-year-old who presented with right arm oedema following metastatic breast cancer. She had previously attended her local lymphoedema clinic where she had undergone two full courses of decongestive lymphoedema therapy consisting of multi-layer bandaging and intermittent pneumatic compression using a predecessor pump. With limb volumes ranging from 30–57% her oedema is now being maintained with fortnightly sessions of advanced pneumatic compression. Recently her treatment has been changed to incorporate the new LymphFlow Advance set to a pressure of 30 mmHg using a standard sleeve on the whole limb cycle and fluoroscopy guided-manual lymphatic drainage performed to the shoulder region. A garment with a shoulder cap is now being evaluated as this was not used initially. Early results demonstrate that the arm is softer proximally than when using the previous device, suggesting that there is improved clearance of congestion of the upper arm and shoulder. The patient reports that the treatment 'seems to be doing more' and she is pleased with how soft and comfortable her arm feels following treatment.

Further feedback

Reports from two further clinics who trialled the pump on four patients in total report limb volume reductions in all patients, with tissue softening apparent. Feedback from all patients states that, when compared to the predecessor device, selected garments are more comfortable. Both arms and legs were treated using a variety of cycles with all patients reporting that limbs felt 'much better' and that the LymphFlow Advance is an improved device to use. One patient reported that swelling around the pubis reduced while using the garment with a waist attachment.

Therapists report that the pump is easy to use, with easy fitting connectors from garments to the pump and tubes that are more flexible. Therapists also state that it is useful to have different cycles, with one therapist stating that it was beneficial to have a cycle that focused more on the hand, which was one patient's problem area. All therapists felt that the availability of different garment styles and treatment cycles were beneficial to enable individualised care.

Conclusions

LymphFlow Advance has been carefully designed to take account of the changing knowledge in anatomy, physiology and pathology of the venous and lymphatic systems and conditions. Existing and ongoing studies and knowledge have allowed this latest redesign in intermittent pneumatic

compression. It is reported to improve skin texture and give a faster response to treatment. It helps the therapist with the ever-increasing pressures of the clinical workload and with health and safety issues through providing some relief of symptoms without the repetitive stress of physical therapy. Although previous reports suggest that intermittent pneumatic compression can increase fibrosis and thickening of the tissue (Földi and Földi, 1985), the ongoing assessment of retrograde pumps demonstrate softening of the tissues (Wigg, 2009b) as do the case studies from the use of the LymphFlow Advance. The LymphFlow Advance gives the therapist a combination of tools assisting with patient outcomes and clinic requirements. Although more research is required to demonstrate and develop clear treatment protocols, the current knowledge and evidence demonstrates a secure position of advanced intermittent pneumatic compression devices in the treatment of lymphoedema and other lymphatic conditions. **BJCN**

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