

Design of an Innovative Medical Device to Improve Quality of Life in Lymphedema Patients

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Abstract: Lymphedema is a disease that is a common side effect of breast cancer, affecting up to 70% of breast cancer patients. Currently there is no known curative treatment; management of the disease is based on symptomatic therapy such as Complete Decongestive Therapy (CDT). Current devices and compression garments used in CDT are often heavy and cause discomfort and bacterial infections due to poor skin care. Along with the long-term physical problems, it also causes serious psychological and social problems for patients, affecting their quality of life significantly. There is an urgent need for innovative approaches for the treatment of lymphedema. In this paper we propose a novel solution in the form of a light portable pneumatic device “*Lymphmotion*”, along with a complimentary compression garment designed to reduce bacterial infection to address this problem.


1 INTRODUCTION


Lymphedema is a disease caused by the inability of the lymphatic system to transport lymph fluid out of the affected area, causing accumulation of fluid in interstitial tissues that results in swelling of the affected area (Taghian et al., 2014). Breast Cancer Related Lymphedema (BCRL) is a common side effect of breast cancer treatment, affecting up to 70% of breast cancer patients. The number of individuals coping with this disease continues to increase, estimated to affect more than 120 million individuals worldwide (International Lymphedema Framework, ILF).

It is a leading cause of disability worldwide, yet it remains underdiagnosed, under-researched, and underfunded in most health systems (Douglass and Kelly-Hope, 2019; Keast et al., 2015). The disparity between diagnosis, treatment and funding could be due to a lack of public awareness of the condition, insufficient education and knowledge on management, and limited financial coverage to support appropriate methods and materials. It is suggested that lymphedema may be a common and under-reported morbidity.

Lymphedema patients have chronic, progressive swelling, recurrent infections, and significantly decreased quality of life that affects both physical and psychological aspects of a patient’s life. The progressive nature means that the swelling can lead to disfigurement, disability, decreased limb strength, mobility, pain, heaviness, and in some cases even death (Cemal et al., 2011; Keast et al., 2015; Taghian et al., 2014). Anxiety and frustration are well documented in patients with secondary lymphedema (Hayes et al., 2009). Reduced productivity of the patient, and higher cost of treatment is also a significant socioeconomic burden; treatment cost of breast cancer survivors with lymphedema demonstrated a \$10,000 increase in annual treatment costs compared breast cancer survivors without (Brahma and Yamamoto, 2019; Cemal et al., 2011; Shih et al., 2009).

Treatment of lymphedema is largely palliative, with no cure. The gold standard is Complete Decongestive Therapy (CDT), a treatment programme that includes pneumatic devices. Currently there is no portable pneumatic device for the treatment of lymphedema, and both researchers and physicians agree that there is an urgent need for innovative

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approaches in the treatment of lymphedema.

In this paper, we will give a brief review into the current state of the art treatment and market overview for lymphedema, and the patient perspective. We will also introduce a solution to the current issues with treatment patients face, in the form of a lightweight portable pneumatic compression device and garment named 'Lymphmotion'.

2 STATE OF THE ART TREATMENT AND PATIENT PERSPECTIVES

2.1 State of the Art

Non-invasive Treatments: First line treatment for lymphedema, involves two phases: the reduction therapy and the maintenance therapy. The first one involves Complete Decongestive Therapy (CDT) which is administered by a certified lymphedema therapist, whose goal is to decrease symptoms and limb volume. It is individualized for each patient, but it typically includes Manual Lymphatic Drainage (MLD), aerobic exercise, skin care, patient education and compression strategies; such as using an advanced decongestive pump and compression garments.

Pneumatic devices used in CDT are often heavy and can cause discomfort to the patient; who has to use the devices at least twice per week for 50 minutes per session (Kayōran et al., 2017). Once minimized limb volume is achieved with CDT, after several weeks, maintenance therapy begins. This may include self or caregiver-administered MLD, compression garments, exercise, wound prevention, and skin care. (Gillespie, 2018, Shaitelman, 2015)

While non-invasive treatment remains the standard of care for BCRL, surgical management is another avenue to treat persistent lymphedema, particularly for patients who do not respond to non-invasive treatments. Lymph Venous anastomosis (LVA) is one such method but they are out of scope of this paper.

2.2 Clinical Motivation: The Patient Perspective

Aside from the long-term physical problems, lymphedema also causes serious psychological and social problems for patients. Affected women may have decreased self-confidence resulting from a distorted body image and negative emotions are often

reported including anxiety, frustration, sadness, anger, fear, and increased self-consciousness (Taghian, 2014). As a result, in the last decade there is an increased focus on the quality of life (QoL) and Patient Reported Outcome Measures (PROMs). Most of the Arm Symptom-Specific Questions in Questionnaires on Quality Of Life as well as the ICHOM Breast Cancer Reference guide refer pain, heaviness, swelling/ tightness, loss of strength, tingle/burning/pins and skin problems, elevation of the arm and movement difficulties and the ability of wearing clothes of choice as major everyday problems (Cornelissen, 2018 and ICHOM Breast Cancer Data Collection Reference Guide, 2017)

The necessity to wear compression sleeves are viewed as barriers to daily life and the current products are described as "terrible daily armour", one sized, uncomfortable, tight, affecting clothes wearing and patients' discomfort is described by adjectives such as "aching," "heaviness," and "pulling" (Hayes et al., 2009, O'Toole, 2013). Numbness, dehydration with chapping or sweating with itching, and risk of bacterial or fungal infection are the most frequently mentioned problems concerning the skin because of the absence of pH-neutral moisturizer and antibacterial layer in existent devices (Buragadda, 2015).

We had the chance to work closely with a 24-year-old cancer survivor, who is a representative of the Young Cancer Patient Association Sweden (Ung Cancer). The association was founded in 2010 and supports young cancer patients and survivors, aged between 16-30 years old, as well as young people who have a relative suffering or has died from cancer.

Through several discussions and a presentation by patient representative, we were able to better understand some everyday challenges that the young cancer patients are facing. Given the relationship that we had developed and our interest in the patients' perspective we kindly asked the representative to conduct a small research through the association concerning breast cancer survivors who are suffering from lymphedema. The research included two questions: "Describe your feelings and challenges living with lymphedema" and "Would you use the device we have designed".

Responses received from the community to the first question were all arguing with the findings from the literature while answers concerning our solution, were all positive. Participants highlighted the need for something innovative.

2.3 Lymphedema Market Overview and Economic Burden

According to the first overview of reported direct and indirect patient-borne as well as society-borne costs specifically associated with the treatment of BCRL in literature; BCRL imposes a substantial economic burden which is often neglected. Direct costs include medical and therapeutic consultations, compression garments, medications etc., while indirect costs refer to productivity losses, values of lost income, unpaid help and lost unpaid work. Mean direct costs per year borne by patients ranged between USD\$2306 and USD\$2574. Indirect costs borne by patients ranged between USD\$3325 and USD\$5545 per year. Mean direct treatment costs after 1 year of CDT ranged between €799 (= USD\$1126.60) and USD\$3165 (De Vrieze, 2019). This amount of money mainly depicts what is happening outside the EU and it is difficult to be transferred. However, it remains a strong evidence of BCRL economic burden. Therefore, we need more high-quality, standardized health economic analyses in order to have a clear view of the EU landscape and push to acquire reimbursement.

There is only 1 industrial company per 10 million that is dedicated to lymphedema products in Europe and developing countries are virtually depleted of industrial companies in this field (Schulze, 2018). At the same time Alibaba.com offers 3390 lymphatic drainage air pressure machine products.

We have conducted a small market research to identify some of our direct competitors. FlexiTouch, 4 Chamber Arm Garment and LymphaPress have been identified as the major ones. FlexiTouch, Tactile System Technology, Minneapolis (USA, North America), has an FDA approval and numerous garment and program options but needs a continuous connection to a large external device, it has a non-ergonomic size and non-thermoregulated garment and it costs around 1000€. 4 Chamber Arm Garment, BioCompression Systems, New Jersey (USA, North America), has similar advantages with FlexiTouch. However, the cost varies between 914-3.450€ while the external device has an outdated design, the garment is made of an uncomfortable material and there is an unreliable cable connection. Finally, MegoAFEK Ltd., Afek (Israel, Middle East) is the world's leading innovator in pneumatic compression therapy. LymphaPress is considered the leader in lymphedema and venous insufficiency treatment and it has strong clinical evidence with peer-reviewed publications. Although it has proven positive results its use is limited because of the large in size garment, its heavy weight, lots of wire connection cables and

lack of patients' mobility.

After listening carefully patients' needs and taking in mind the current market solutions, we have concluded that we need a solution that is more compact and non-dependent to external devices in order to reduce fatigue, increase independence and self-confidence.

3 PROPOSAL OF AN INNOVATIVE PRODUCT

3.1 Specifications for Solution

Our solution consists of a device called 'LymphMotion' which comprises of two factors that can be used in conjunction:

A portable pneumatic compression device (PCD) in the form of a sleeve, 'LymphMotion' which the patient can use at home in place of going into a specialized clinic for pneumatic compression (Pressure therapy) or a therapist for manual lymphatic drainage (MLD). The PCD sleeve provides a gentle massage movement to facilitate lymph fluid away from the affected limb.

A complimentary compression garment that is infused with microencapsulated aloe vera and antimicrobial nanoparticles, in order to reduce dryness and prevent bacterial or fungal infection. The compression garment is to be used daily while the patient is awake and during exercise.

During the conception-development procedure of LymphMotion we kept in mind the *IEC 62366 MD-Application of usability engineering to medical devices*.

Intended Use: Alleviation of lymphedema in breast cancer survivors who have undergone mastectomy, and prevention of the disease to progress to more serious stages or develop more serious complications such as infections or cancer.

Intended User: Breast cancer survivors, who have undergone mastectomy (ages 30-80).

User Environment: At home during the day and during exercise.

3.2 Description of *LymphMotion*

The portable pneumatic compression device (PCD), *LymphMotion* consists of a sleeve that is worn over the affected limb (such as the arm) that includes a network of 3D printed pockets designated in zones that can inflate and deflate via air pressure. The network of pockets acts as individual massage actuators. One-

way air pumps and air valves which controls air flow into the next zone of the sleeve in a controlled manner using a microprocessor, in the direction of lymphatic drainage. Air flow enters from the most distal point of the limb away from the body (e.g. wrist on the arm) and is released at the end of the sleeve closest to the body – this direction ensures that the lymph fluid is being drained away from the limb into the blood circulatory system and to be eliminated via natural processes (i.e. urination). A schematic of this can be found in Figure 1. The device would be made in different sizes to accommodate the patient.

Silicone can be used to make the pocket as it is a low-cost, soft, durable material with a high elastic modulus and power to weight ratio. They make safe actuators for direct human interaction owed to their lightweight and lack of rigid parts (Al-Fahaam et al., 2018). This network of silicone pockets can be manufactured using 3D printing methods. One such method is a technique called Rapid Liquid Printing (RLP) (Hajash et al., 2017; Papadopoulou et al., 2017).

A piezoelectric pressure sensor that provides a feedback loop to the microprocessor is used to ensure the correct amount of pressure (mmHg) – depending on which stage of lymphedema the patient is at, is used during the massage on the patient, preventing insufficient or dangerous levels of applied pressure (Elwenspoek and Wiegerink, 2001; Meyer et al., 2006). Gyroscope sensors are used to detect whether the movement of the device is due to patient movement or device inflation; this allows the user to move while wearing the device while not compromising on applied pressure; making the device portable. The device can be powered by rechargeable Lithium ion (Li-ion) batteries, with a lifetime of 2000 cycles – enough cycles to last approximately 5.5 years (Coyle et al., 2010; Gorlatova et al., 2014).

3.3 Description of Compression Garment

Compression garments are used by patients daily from the first moment they wake up, for the duration of the day, and during exercise. A common complication of constantly wearing compression garments is risk of bacterial and fungal infection that results in dermatitis, or if there is a wound in the skin, wound infections. Another issue is that compressive garments can be uncomfortable and result in dry, itchy, cracking skin (Lim and Davies, 2014; Vignes and Arrault, 2009; Xiong and Tao, 2018). The *LymphMotion* compression garment aims to reduce these issues with current compressive garments in the market.

The complimentary *LymphMotion* compression garment (CG) addresses these two problems by incorporating Anti-bacterial nanoparticles (ABNPs) and encapsulated aloe vera into the fabric of the compression garment. ABNPs exhibit antibacterial and anti-inflammatory effects that can significantly inhibit bacterial growth and reproduction. The integration of NPs in the fabric can reduce the risk of wound infection or accelerate wound healing should the skin be injured. Combinations of nanosilver, chitosan (CS), tungsten, and copper have been used in production of textiles that is antibacterial. Fibre fabrication methods such pressurized gyration (Illangakoon et al., 2017; Wang et al., 2017) can be used to create such fibres. Aloe Vera (AV) is stabilized and encapsulated by immersing the fabric into an AV micro-emulsion and inducing ultrasonic waves to encapsulate and load the AV extract onto the fabric (Ghayempour, Montazer and Mahmoudi Rad, 2016).

3.4 Regulatory Aspects

Lymph Motion is an active, non-invasive, non-

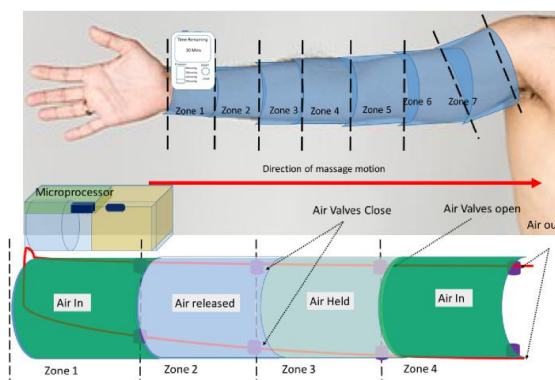


Figure 1: Schematic of the proposed pneumatic compression device LymphMotion and how it works.

implantable Medical Device (MD) that complies with the EC Regulation 2017/745/EU of May 5, 2017 on Medical Devices. According to Article 52, Section 6 and Annex VIII, Rule 9, Section 6.1 of the MDR 2017/745/EU the above-mentioned MD is considered as Class IIa MD.

As our product includes software that collects patients' pressure data, we need to comply with the GDPR (General Data Protection Regulation) EU 2016/679. In collaboration with a DPO (Data Protection Officer) we will take action to reduce data volume collected, the recipients of these data and especially for the clinical studies part, reduce the duration of the process. We will also need to comply with ISO/IEC 27032:2012 Guidelines for cybersecurity.

4 CONCLUSIONS

Lymphedema continues to be clinically and economically underestimated. The current available treatment is insufficient, and data on the improvement of patients' quality of life is missing if not negative. The burden is physical, social and psychological and it is these dimensions that our solution tries to cover.

To bring our idea further, we will need funding to create a prototype. In addition, according to the MDR 2017/745/EU and the new requirements on the Clinical Evaluation of a Medical Device, in order to demonstrate safety and performance requirements of the device when used in accordance with the intended purpose provided by the manufacturer, we will need to proceed with biocompatibility and usability studies and if the results are positive we should continue with a Clinical Investigation. Further issues that would need to be addressed would be the challenge of developing *Lymphmotion* on an industrial scale. A business model canvas is under development. Further options are under consideration.

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