Design of a Wearable Vibration Therapy Device for Relieving Plantar Fasciitis Pain, Based on the Input of Clinicians

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Farshid Sarmast

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Abstract

This study explored the technical and design aspects and requirements underpinning the design process of a new wearable vibration therapy device for home users to reduce the pain caused by plantar fasciitis. The device has the potential to help reduce demands on health practitioners' time while ensuring a consistent level of ongoing treatment. In this research Myovolt Ltd., a Christchurch-based, company was the industry sponsor, and Callaghan Innovation funded the study.

The process followed in this project consisted of four steps including 1. Problem identification 2. Idea generation 3. Prototyping and 4. Evaluation. A combination of literature review, asking experts' advice and feedback (on the outcome of the design process), creative idea generation methods (mind mapping, mood board, sketching, etc.) and prototyping informed the design process with useful data.

To develop a deeper insight into the problem in the primary stages of the study and to get feedback on the design outcome of the project, the researcher interviewed some physiotherapists and podiatrists. Similarly, the academic supervisors and Myovolt managers gave beneficial information that helped the researcher in different stages of the project.

The outcome of the project was a device consisting of a vibration therapy unit in two sizes (one for small-medium feet, and the other for medium-large feet) and a knitted wrap (in two versions) to enclose the unit. The reason for choosing this approach from other design concepts generated was to enable users to hold the vibration units on the foot more easily and comfortably. The entire knit development and prototyping process was done at AUT's Textile and Design LAB.

As no similar product for the same purpose exists on the market, this research and its outcome are the first endeavours to create a user-centric wearable device for domestic users to manage the pain caused by plantar fasciitis at home. The iterative design process adopted in this project and consultation with experts at the beginning and the end of the research process helped the researcher decide the considerations for the final design solution and to understand to what extent the outcome corresponds to the design requirements.

This research will be useful for prospective researchers/designers in the design of user-oriented products, especially healthcare and therapeutic products. The overall feedback given by the experts confirmed the outcome of the project and helped identify what to improve through future development.

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Attestation of authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

Signed by Farshid Sarmast, 01/04/2019

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I also have to offer my special thanks to my father, who, although no longer in the world, his memories will remain in my heart forever.

Finally, I would like to thank my family: my wonderful mother and my supportive wife Sara for their permanent support, encouragement and kindness throughout my life.

Intellectual Property Rights

According to the agreement between the researcher and Myovolt Ltd., the researcher assigns the intellectual copyright over the creative work contained in this thesis to Myovolt Ltd. All rights are reserved to Myovolt Ltd.

In return, Myovolt Ltd. recognises the researcher as the designer of the work in all their marketing media including website, brochures, etc. The researcher will have the right to write about the work (including the design process phases and outcomes) in his master's thesis. He will also have the right to publish the project in his CV, portfolio, website, etc. (including general information such as the design process, pictures displaying the project phases and the final prototype and manufactured product), respecting issues of commercial confidentiality.

Signed by Farshid Sarmast, 01/04/2019

1. Introduction

1.1 Introduction

A large number of diseases may affect the foot and ankle in general, and the heel specifically. Plantar fasciitis is the most prevalent type of heel pain (Buchanan & Kushner, 2018) and is very commonplace among active people (either athlete, particularly runners, or non-athletes) and middle-aged or older individuals. Rehabilitation involves regular and prolonged treatment (such as massage, taping, shockwave etc.) at clinics and by clinicians. However, such treatment is costly and time-consuming. Hence, people need new tools that can help them manage their condition more independently at home.

Myovolt, the sponsor of the project defined the focus of this project, to design and develop a wearable home rehabilitation device for people with plantar fasciitis, using vibration as the therapeutic method. In this thesis, the researcher adopted an iterative design process consisting of problem identification, idea generation, prototyping and evaluation. A literature review, a review of similar products already on the market, and consultation with experts for advice and feedback on the design development informed the design process.

1.2 Project background and objectives

A personal interest in designing a real product addressing an actual human need and being motivated to work in the field of healthcare products design guided the researcher to look for New Zealand companies that were proactively endeavouring to create novel healthcare products. This search led to approaching Myovolt Ltd. in Christchurch.

Myovolt has been manufacturing and marketing vibration therapy devices since 2015 (www.myovolt.com/products). Their products utilise a vibrating module, which is attached to different body parts (including leg, neck, arm, etc.) using a Neoprene[1] wrap.

USA-based podiatrist Dr Neil Goldberg contacted Myovolt asking for product samples to test and evaluate their vibration system. His investigation affirmed the efficacy of Myovolt's Core product for Plantar fasciitis treatment, provided the product was redesigned to fit the form of the foot. Dr Goldberg's suggestion prompted Myovolt to rethink their current product and develop an application for the foot.

This research aimed to investigate how a design thinking approach to wearable technology could facilitate the development of a device for rehabilitation and pain management for people with plantar fasciitis. This study explored the interaction between patients and the therapy device to improve the design outcome.

A literature review, an analysis of similar products on the market, and medical experts' (physiotherapists and podiatrists) interviews formed a context and theoretical background for the project. Through experts' interviews and learning about the rehabilitation process, current methods utilised by physical therapists and podiatrists to alleviate plantar fasciitis were assessed to understand better how users interact with the existing rehabilitation products and how they feel about them. Although having potential end users (people currently with plantar fasciitis) as participants in the research could assist in better realising the users' needs and formulating the design requirements, due to time restrictions, the scope of a Masters project, and limitations regarding ethics approval, the researcher and the supervisors decided interviewing only medical experts could produce the required information. The results of the interviews informed the design parameters which were then used during the design process and in the evaluation of the designs.

At the final stage of the design process, the researcher invited some medical practitioners and product design experts to participate in interview sessions, evaluate the prototype of the final design, and give feedback on its usability, comfort, and ease of use. Participants in this step of the project were requested to only assess the product design attributes such as comfort and usability. Myovolt will take up medical testing at a further stage of the process, outside the scope of the design process and this design research project.

[1] A family of synthetic rubbers

1.3 Significance of the research

Plantar fasciitis is the most common type of heel pain (Buchanan & Kushner, 2018; Radwan et al., 2016). The incidence of this condition in adults older than 18 years is between 17–24%, and in adults older than 65 years, this number is as high as 42%. In more than half of older adults with foot pain, this condition causes disability, imbalance and gait control problems (Chatterton, Muller, & Roddy, 2015).

Plantar fasciitis is a big issue in most countries. For example, a national survey conducted in the USA shows that about 1% of American adults suffer from plantar fasciitis, and among those, 85% have pain. This survey also states that the least number of people with plantar fasciitis (0.53 per cent) are individuals aged 18-44, while people aged 45-64 make the most significant percentage (1.33 per cent). According to this survey, plantar fasciitis occurs mostly among American women than men (Nahin, 2018).

People with foot and ankle disorders such as plantar fasciitis may have difficulty in doing their daily work and relaxing after it, due to the pain or the lack of function. The condition not only makes life very hard and unpleasant for these people but also costly for the patients and society. For example, a study reports that in 2007, in the USA, people with plantar fasciitis have paid a total amount of between $192 to $376 million for treatment (Belatti & Phisitkul, 2014). The only reliable resource giving information about the prevalence of plantar fasciitis in New Zealand is a report by ACC[2] (Barry, 2016). According to this report, in the period of 2010-2015, 34,138 claims were lodged to ACC for plantar fasciitis, among which 1,705 (5%) were accepted (as most cases were diagnosed as “Gradual Process”). This report also shows that the total cost (for all paid and unpaid claims) for the treatment of plantar fasciitis (Ex GST) over this period has been $602,628.

A range of treatments are currently suggested and used to treat plantar fasciitis, such as relative rest, stretching, night splints, strengthening exercises, anti-inflammatory therapies (like NSAID[3]s), arch supports, specific shoes, extracorporeal shockwave therapy (ESWT) and surgery (as the last option (Dyck & Boyajian-O’Neill, 2004). To get these treatments, people need to see medical practitioners for a prolonged period, and this is usually costly.

On the other hand, wearable technology offers a multidisciplinary approach that opens doors to designers and inventors and gives them the chance to create new user-centred solutions for many longstanding problems. Such technology has found applications in areas like health and medicine (for example in cardiac or infant monitoring), fitness (tracking devices), education, gaming and leisure, and entertainment (such as VR headsets). However, the opportunities are numerous. Some examples of wearable devices designed for therapeutic purposes are discussed in section 2.4 Similar existing products to treat foot problems (with or without using vibration therapy), p. 18.

For this project, which has involved the design of a personal vibration therapy device that gives people with plantar fasciitis independence in managing their condition, the researcher deemed wearable technology most appropriate, as it allows for the development of small, lightweight, comfortable and easy-to-use products.

[2] Accident Compensation Corporation
[3] Nonsteroidal anti-inflammatory drugs

1.4 Research questions

This study set out to identify parameters and requirements to inform the design and development of a wearable device that could help domestic users in personal rehabilitation, particularly for plantar fasciitis, using vibration as the therapeutic method. It involved research through design as an iterative process of concept and prototype development. This research aimed to address two main research questions:

1. What are the most critical considerations including users' needs, technical requirements, market and financial restrictions in the design of a wearable vibration therapy device for domestic users to improve plantar fasciitis, using Myovolt's existing technology?

2. How can the design process and specific design methods be employed to answer users' needs and design requirements in the form of an easy-to-use product for the purpose of the project?

2. Background Review

2.1 Plantar fasciitis

Plantar fasciitis, also called jogger's heel, tennis heel, calcaneodynia, and gonorrhoeal heel (an inappropriate name which was the most dominant term for the condition in the early 20th century) (Crawford & Thomson, 2003), is a disease of the plantar aponeurosis, that is most commonly seen at the proximal insertion[4] on the medial tubercle[5] of the calcaneus[6] (Figure 1) (Riddle & Schappert, 2004). The majority of the clinicians believe that the pain caused by plantar fasciitis is worse when the person starts walking in the morning, and when weight bearing (Riddle & Schappert, 2004).

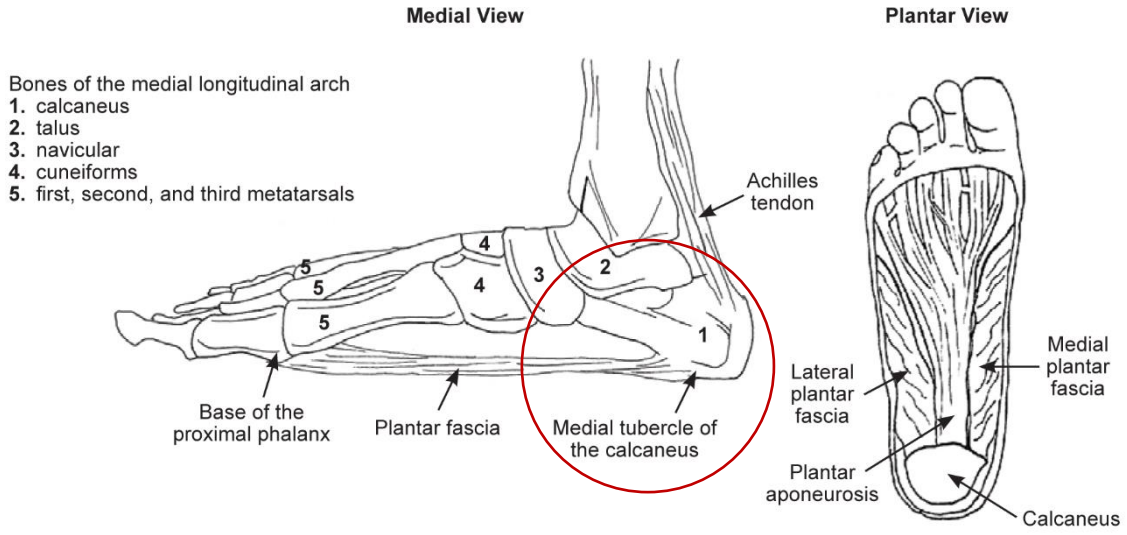


Figure 1 The origin of plantar fasciitis Reprinted with permission from (Thompson, Saini, & Reb, 2014)

A range of risk factors can cause plantar fasciitis. Overuse and overstretching of the plantar fascia (for example when walking or running for a long time) are the most important causes (Premkumar, 2004). Furthermore, other researchers believe that plantar fasciitis, which causes the pain in the heel, is a syndrome with an unknown reason (Wright, 2009). Wright claims injuries that happen to the plantar fascia[7], either acute or chronic, at the medial tubercle of the calcaneus, can be the cause of several slight traumas and degenerative changes. Some other researchers also have stated that plantar fasciitis consists of degenerative changes, rather than inflammation of the fascia (Lemont, Ammirati, & Usen, 2003). The other important factors can be age, excessive foot pronation[8], obesity and limited ankle dorsiflexion[9] (Scher, Belmont, & Owens, 2010).

In a study within the United States Armed Forces (a highly active population), researchers have concluded that the overall incidence prevalence of plantar fasciitis has been 10.5 per 1000 person-years (Scher et al., 2009). These researchers also discovered women, black people, junior enlisted[10], senior enlisted and senior officer rank groups, of the Army or Marines, and older people have had higher risk factors for plantar fasciitis.

Plantar fasciitis is thought to be the most prevalent cause of heel pain in athletes, active people, and also in individuals with sedentary lifestyles (Riddle & Schappert, 2004). Different studies show

[4] "The point of attachment of a muscle (e.g. to a bone) that is relatively movable when the muscle contracts" (Martin, 2015)
[5] "A small rounded protuberance on a bone" (Martin, 2015)
[6] "The large bone in the tarsus of the foot that forms the projection of the heel behind the foot. It articulates with the cuboid bone in front and with the talus above" (Martin, 2015).
[7] "The plantar aponeurosis, or fascia, is a fibrous layer in the subcutaneous tissue of the sole extending from the calcaneus to the deep soft tissues of the forefoot, to the proximal phalanges, and superficially to the skin. It provides stability to the arch of the foot and assists in raising the arch when the toes are extended" (Kitaoka, Luo, Growney, Berglund, & An, 1994, p. 557).
[8] This happens when the foot is rolled inward, which causes the external part of the heel move towards the ground and the feet flatten too much (Figure 2).
[9] The motion of the ankle joint to move the upper part of the foot towards the shin (Figure 3).
[10] The definitions of the US Army ranks can be seen in https://www.military.com/hiring-veterans/resources/military-enlisted-rank-structure.html

contradictory results about the incidence of plantar fasciitis among different genders. A group of studies claim an almost equal rate for both women and men (Riddle & Schappert, 2004), some suggest a higher prevalence in women (Taş, 2017; Reb, Schick, Karanjia, & Daniel, 2015; Nahin, 2018), and others have found a higher probability of plantar fasciitis for male individuals (Sinclair, Chockalingam, & Vincent, 2014). However, a more significant number of studies think of plantar fasciitis as more common among women of middle age and male athletes (Juliano & Harris, 2004; Scher et al., 2009).

Although plantar fasciitis is common in active people older than 40 (nearly 30% of adults over the age of 65 years have the condition), it also occurs in active children and adolescents aged 8-13. Heel pain rarely occurs in both heels bilaterally. In most cases, the left heel is affected first, and the other heel may show similar symptoms after a while (Agyekum & Ma, 2015).

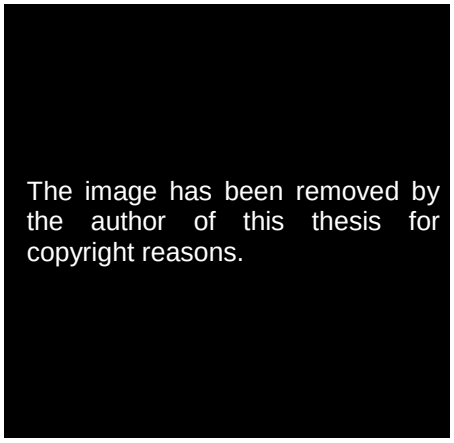


Figure 2 Over-pronation or excessive foot pronation Reprinted from ("Overpronation," 2018)

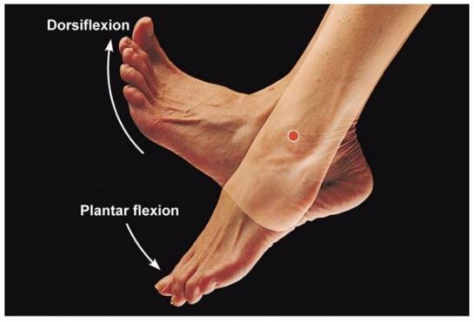


Figure 3 Ankle dorsiflexion and plantar flexion Reprinted with permission from ("The Importance of Ankle Mobility and Dorsiflexion," n.d.)

As Figure 4 and Figure 5 demonstrate, plantar fasciitis can affect an area from the midfoot to the hindfoot. This area is the region to apply the therapy (i.e. the vibration motors location).

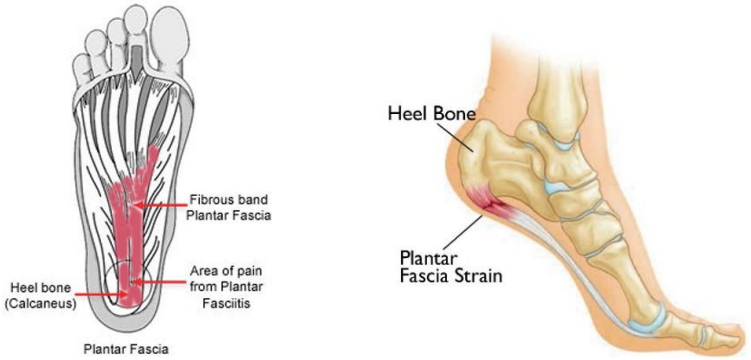


Figure 4 The area of plantar fasciitis Reprinted with permission from OrthoInfo © American Academy of Orthopaedic Surgeons. http://orthoinfo.aaos.org ("Plantar Fasciitis and Bone Spurs - OrthoInfo - AAOS," n.d.)

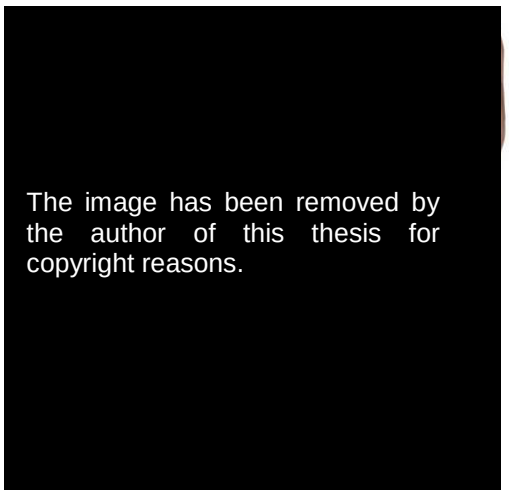


Figure 5 The percentages of the most common pain areas related to plantar fasciitis Reprinted from (Pappas & Tholl, 2013)

Medical literature generally describes plantar fasciitis pain as progressively increasing, sharp and localised close to the origin of the plantar aponeurosis on the medial plantar tubercle of the calcaneus. The pain can be worse in the morning when the person begins to walk, or after a long rest. The other symptoms are pain and tenderness under the heel on weight bearing, with an associated limitation of activity (Gudeman, Eisele, Heidt, Colosimo, & Stroupe, 1997).

Plantar fasciitis is the most prevalent and disabling musculoskeletal disease of the foot (Chawla, Goyal, & Samuel, 2015) and has an incidence of more than 2 million in the USA (Rompe, Furia, Weil, & Maffulli, 2007). This disease comprises 11–15% of clinical visits related to foot pain, and occurs in up to 10% of the US population (Rompe et al., 2007). It is very common, especially among active people either athlete (particularly runners with an incidence of 10%) or non-athlete (Kibler, Goldberg, & Chandler, 1991).

Management of plantar fasciitis includes invasive (surgical) and non-invasive (conservative) treatments. Surgery is usually not necessary and in most cases, conservative management using nonsteroidal anti-inflammatory drugs (NSAIDs), heel pads, night splints, and prolonged physical therapy, and as secondary treatment, corticosteroid injections work well (Razzano et al., 2017).

2.2 Vibration therapy and its applications for foot and ankle

Variable and oscillatory motion forms vibration (Griffin, 1996). The use of vibration as a therapeutic method dates back to ancient Rome and Greece in the form of riding horses or specially-designed vehicles or devices (Calvert, 2002). Vibration was the first therapeutic method presented as a mechanical device, which was devised to produce gentle and constant movements (not possible through hand massage). This device (invented in 1886) was a portable hand-cranked machine and had an applicator similar to a hand drill (Figure 6). Battery-operated vibrators were developed later and replaced the first generation machines (Calvert, 2002).

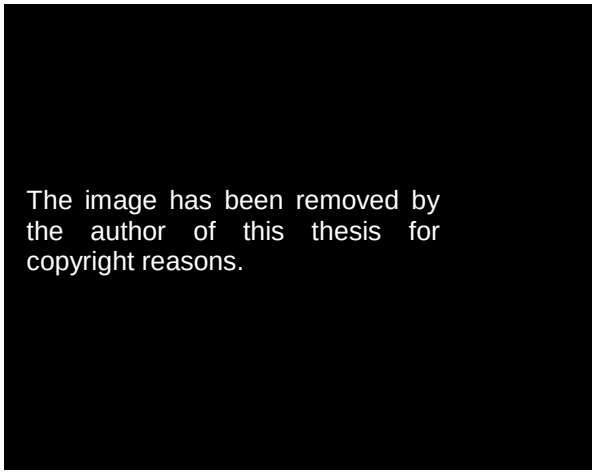


Figure 6 The first mechanical vibrator Reprinted from (Calvert, 2002)

Vibration has found different applications from improving the imbalance caused by Parkinson's to preventing astronauts' bones and muscles from degeneration as well as increasing athletes' performance (Albasini, Krause, & Rembitzki, 2010).

The following parameters determine the intensity of vibration:

- "Amplitude: the extent of the oscillatory motion, peak-to-peak vertical displacement in millimetres
- Frequency: the number of impulses delivered per second (repetition rate of the cycles of oscillation), in hertz (Hz)
- Magnitude: the acceleration of the movement, in g(s) (where 1g is the acceleration due to the Earth's gravitational field or 9.81 m/s^2)" (Albasini et al., 2010, p. 6)
- Duration: the total amount of time of applying vibration, in seconds or minutes

The two main ways of applying vibration therapy are the whole body (WBV) and focal (segmental, regional or localised) vibration. The latter has been the first way of using vibration (Albasini et al., 2010). However, the majority of the clinical usages and studies on vibration so far have aimed at WBV (using platforms or plates with lateral or horizontal movements around a centre). Focal vibration therapy devices include two main groups of handhelds (the leading group) and wearables.

Vibration has proved to be useful in various applications such as improving muscle strength, power, flexibility and coordination (Albasini et al., 2010), reducing spasticity, improving muscle contraction, gait, attention in hemineglect[11] and making motor control tasks easier (Murillo et al., 2014), increasing electromyography activity and intra-muscular temperature (effective in improving muscles performance, preventing injuries and rehabilitation exercises) (Cochrane, 2011), and improving blood circulation (Nakagami et al., 2007).

[11] "The syndrome of hemi-spatial neglect is characterised by reduced awareness of stimuli on one side of space, even though there may be no sensory loss" (Parton, Malhotra, & Husain, 2004).

2.3 The use of vibration therapy for musculoskeletal disorders: a review of the current research

This section reviews the studies that have evaluated the use of focal vibration as an intervention for musculoskeletal disorders, including plantar fasciitis. The objective of this systematic review was defined using the PICO (Patients, Intervention, Comparison, Outcomes) method.

- **Methodology**

The researcher carried out a thorough search for a combination of the terms vibration, vibration therapy, local vibration, localized vibration, segmental vibration, vibration training, vibratory exercise, vibratory stimulation, rehabilitation, plantar fasciitis, balance, power, strength, pain, performance and musculoskeletal disorder using electronic databases Medline, PubMed, Scoups, ScienceDirect, Elsevier, The National Center for Biotechnology Information (NCBI), EBSCO, CINAHL (Cumulative Index to Nursing and Allied Health Literature), AMED (The Allied and Complementary Medicine Database), SPORTDiscus, Rehabilitation and Sports Medicine Source, Psyc INFO, Cochrane, SciELO, Web of Science, Embase, Physiotherapy Evidence Database (PEDro), BMJ (formerly the British Medical Journal) and Science Citation Index.

Articles were primarily checked for their relevance, and only case studies, pre and post testing or controlled or randomised controlled trials published within the ten years (2008-2018), written in English were included. Reviews and studies on laboratory animals were also excluded. Moreover, studies that examined vibration for conditions other than musculoskeletal disorders (for example diabetic ulcers) were excluded.

The population were adults with acute or chronic musculoskeletal disorders and healthy adults, and intervention consisted of studies that used whole body vibration and focal vibration. Outcomes included any outcome that measured health-related diseases. The quality of the studies included in this review was not assessed. Papers were summarised under the headings of Population, Intervention, Comparator, Outcome measures (PICO).

2.3.1 Focal vibration applications in healthy adults

Twelve studies examined the use of focal vibration (FV) in healthy adults (Table 1). The most common aim of these studies was to evaluate the effect of FV for increasing muscle strength when combined with exercise (Dickerson, Gabler, Hopper, Kirk, & McGregor, 2012; Drummond, Couto, Augusto, Rodrigues, & Szmuchrowski, 2014; Drummond, Szmuchrowski, Simão, Maior, & Couto, 2017; Goebel, 2017) and/or reduce post-exercise muscle soreness (delayed onset muscle soreness) (Custer, Peer, & Miller, 2017).

- **Focal vibration parameters (frequency, amplitude and treatment duration):**

The frequency used in these studies ranged between 5-100 Hz, with the most common being 30Hz. The average vibration amplitude was 3.8 (varied between 0.2-12mm), and the maximum treatment duration was 10 min (ranging between 2 and 10).

Most of these studies assessed the immediate effect of FV on healthy volunteers (Couto et al., 2013; Custer et al., 2017; Dickerson et al., 2012; Drummond et al., 2014, 2017; Filippi et al., 2009; Goebel, 2017; Imtiyaz, Veqar, & Shareef, 2014; Siegmund, Barkley, Knapp, & Peer, 2014). These investigations did not demonstrate a reasonable advantage of FV on muscle strength when added to exercises in these healthy, active younger people. In contrast, the most extensive study (Celletti et al., 2015) examined the effect of FV on lower limb function in older women. This study did show a beneficial impact on lower limb function of FV when added to leg muscle contraction exercises.

Table 1 Papers evaluating the effects of focal vibration on healthy adults

	Participants		**Intervention**					**Comparison group**	**Outcome measures**	**Results**	**Study design**
Author(s)	**Description**	**Number**	**Vibration method & intervention description**	**Vibration frequency (Hz)**	**Vibration amplitude (mm)**	**Treatment Duration (Min)**	**Treatment frequency and times**				
(Celletti et al., 2015)	Older women	350	Focal Vibration (FV) to voluntarily contracted quadriceps muscles. Aim: to investigate the likelihood that a new protocol based on the focal mechanical muscle vibration may decrease the danger of falling of older ladies	100	0.2–0.5	10m (total 30 min/day)	3 times/day, 3 days	Sham vibration	– Performance-Oriented Mobility Assessment (POMA) test assessed before (T0) and 30 (T1) and 180 (T2) days after the intervention	– A significant change in POMA in the intervention group – No significant change in POMA in control group at T1 and T2	Randomised controlled, triple-blind trial with a 6-month follow-up after the intervention
(Couto et al., 2013)	Healthy male volunteers	32	FV applied through the Cable Lat Pulldown machine during lateral pull down training at 55% Maximum Voluntary Contraction (MVC) Aim: to verify the acute effects of the application of local vibration on upper limbs during resistance training on the number of maximum repetitions, metabolic and hormonal responses	20	12	Not stated	4 sets	Lateral pulldown training at 55% MVC without FV	– Number of lateral pull down reps – blood lactate concentrations – testosterone concentrations – creatine kinase concentrations – cortisol concentrations – urea concentrations	– A significant increase in blood lactate and testosterone concentrations in the FV group compared with the control group. – Blood lactate (& testosterone) is a marker for training intensity. – No significant changes in creatine kinase, cortisol or urea concentrations (indicative of muscle damage)	Crossover trial- acute effects study
(Custer et al., 2017)	Healthy moderately active subjects	19	FV applied to relaxed muscles (triceps surae, quadriceps, hamstrings, and gluteals) post exercise Aim: to examine the effect of FV on muscle fatigue and acute muscle soreness after exercise	5 to 35	2	2	2 sessions	Sham	– Static and dynamic balance – Leg power – Self-reported pain at baseline, after the vibration intervention, and 24 hours post-exercise	– No differences between the active and sham vibration conditions.	Single-blind crossover study. Laboratory-based acute effects
(Dickerson et al., 2012)	Healthy university students	30	FV (Thumper Versa Pro Massager) to the relaxed right hamstrings Aim: to determine whether FV affects hamstrings and quads performance	30	6	5	Not stated	Sham – massager, turned off – subjects solved puzzles	– right and left isometric hamstrings and quadriceps strength using hand held dynamometer – maximal horizontal hop distance of each lower extremity	– No significant differences in means between vibration and sham treatment for any outcomes	Repeated measures cross-over design – acute effects study

	Participants		Intervention					Comparison group	Outcome measures	Results	Study design
(Drummond et al., 2014)	Healthy male volunteers	20	FV applied through the cable during isotonic strength training to right elbow flexors Aim: to investigate the chronic effects of dynamic strength training (ST) with local vibration on the maximum strength of elbow flexor muscles	30	6	Throughout the strength training	4 sets 8-10 RMs, 3 times/week, 12 weeks	Conventional exercise with no vibration	– 1 RM strength for elbow flexors (kg) – MVC s(N)	– No significant differences in outcomes between groups.	Randomised parallel group design
(Drummond et al., 2017)	Healthy male volunteers	20	FV applied through the cable during isotonic strength training to right elbow flexors Aim: to investigate the chronic effects of dynamic strength training (ST) with local vibration on the maximum strength of elbow flexor muscles	30	6	Throughout the strength training	4 sets 8-10 RMs, 3 times/week, 12 weeks	Conventional training with no vibration	– Muscle hypertrophy (cross-sectional area) of the elbow flexors	– The cross-sectional area of the distal arm was higher in the control group versus the FV group	Randomised parallel group design
Filippi et al., 2009	Healthy older women	60	(a) FV applied to quadriceps while contracted. (b) FV applied to quadriceps without contraction Aim: To determine the effect of FV on stance and lower-extremity muscle power	100	0.2 to 0.5	10	3 consecutive days, 3 times/day	Sham stimulation	– Centre of pressure (sway) (mm/s) on a force platform – Vertical jump height (cm) – Leg power (Nm/s/kg)	– In the FV with contraction group, Centre of pressure, vertical jump height and leg power increased significantly. – No significant change in outcomes for FV without contraction or control group	Randomised controlled trial
(Goebel, 2017)	Healthy collegiate students	27 (17 males, 10 females)	Isotonic strength training of right elbow flexors. FV applied to the triceps muscle (antagonist) of the right arm during training Aim: To determine whether FV applied to the antagonist improved the isometric MVC of the agonist (elbow flexors) of the same arm.	18, 24, 30 and 36	4	Not stated	4 sets, 12 repetitions, 3 times/week, 4 weeks	Left-arm strength training	– Isometric MVC of the elbow flexors	– Significant improvement in MVC in the FV group in compared to the control group	Arm to arm comparison model Laboratory-based acute effects
(Imtiyaz et al., 2014)	Healthy female non-athletes in three groups	45	FV applied to the belly and the tendons of biceps brachii post exercise Aim: To compare the effects of FV and massage to prevent DOMS.	50	Not stated	5	1	a. Massage therapy b. No intervention	– Muscle soreness (pain perception) – Range of Motion (ROM) – Maximum Isometric Force (MIF) – 1RM – Blood lactate dehydrogenase and Creatine Kinase (CK)	– Muscle soreness was significantly less for both FV and the massage groups. – No significant difference in Range of Motion – MIF between groups – CK at 48 hours of post-exercise in the vibration group and massage group showed a significant difference as compared to the control group.	Pre-test and Post-test Control-Group Design Laboratory-based acute effects

	Participants		Intervention					Comparison group	Outcome measures	Results	Study design
(Pournot, Tindel, Testa, Mathevon, & Lapole, 2016)	Physically active adults	11	FV applied to elbow flexors post barbell curls Aim: to investigate the effect of FV as a recovery modality from exercise-induced increased stiffness	55	0.9	10	Not stated	Passive recovery of opposite arm	– Acute changes in biceps brachii passive stiffness measured with ultrasound	– No differences between passive and FV recovery.	Arm to arm comparison model Laboratory-based acute effects study
(Sağiroğlu, 2017)	Male soccer players	22	Vibrating foam roller equipment (localised) Aim: to investigate the effects of an FV foam roller device on lower extremity muscle power and flexibility in soccer players	38	Not stated	Not stated	10 repetitions (rolling), for 30 seconds	Foam roller without FV	– Vertical jump (muscle power) – Sit and reach (flexibility)	– No difference observed between the 2 interventions	A randomised crossover study design
(Siegmund et al., 2014)	Healthy populations Three groups: a) college-aged non-athletes (n=19) b) college-aged athletes (n=10) c) physically active older adults (n=15)	44	"Swisswing segmental vibration device" applied to the low back, hamstrings and gluteal muscle groups Aim: to investigate the effect of FV on low-back and hamstring flexibility and perceived low back stiffness	20	Not stated	11	1 session	Seated for 10 minutes with no FV (college-aged non-athletes group only) Control group: college-aged non-athletes received no BMS treatment	– Sit and reach test (flexibility) – Self-perceived low back stiffness (Likert scale).	– Significant improvement in sit-and-reach performance and perceived stiffness after treatment in intervention compared to control groups.	Pre-test post-test design. Laboratory-based acute effects study

Note: Abbreviations: FV, Focal vibration; MVC, Maximum voluntary contraction; RM, Repetition maximum; WBV, Whole body vibration

2.3.2 Focal vibration applications for people with musculoskeletal disorders

Three studies were found that evaluated the effect of focal vibration in people with musculoskeletal disorders (Benedetti et al., 2017; Kitay, Koren, Helfet, Parides, & Markenson, 2009; Pietrangelo et al., 2009). The two disorders studied were knee osteoarthritis (OA) and sarcopenia (muscle wasting) (Table 2). The purpose of using the focal vibration for people with OA was to relieve pain and for people with sarcopenia was to increase muscle strength.

- **Focal vibration parameters (frequency, amplitude and treatment duration):**

The frequencies used in the studies that evaluated FV for pain relief were 150 Hz (Benedetti et al., 2017) and 300 Hz (Pietrangelo et al., 2009), and in Kitay et al. (2009), sets applied at 10, 27, 42 Hz. The treatment duration used in both studies that used FV for pain relief was 15 or 20 minutes.

Table 2 Papers reviewing the effects of focal vibration on the people with musculoskeletal disorders

	Participants		**Intervention**					**Comparison group**	**Outcome measures**	**Results**	**Study design**
Author(s)	**Description**	**Number**	**Vibration method & intervention description**	**Frequency (Hz)**	**Amplitude**	**Treatment Duration (Min)**	**Treatment frequency and duration**				
(Benedetti et al., 2017)	Patients with knee OA; randomly assigned to a) FV over the quadriceps muscles b) Neuromuscular electrical stimulation (NMES)	30	FV (Vibra Plus) at high frequency and low-amplitude Aim: (a) to investigate the clinical effectiveness of high-frequency FV on quadriceps muscle in patients with knee OA (b) to disentangle, using surface Electromyography (sEMG), the underlying mechanism.	150	Not stated	20	5 days/week, 2 weeks	NMES	– the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) – Visual Analogue Scale (VAS) – Knee range of motion (ROM) – Timed Up and Go test (TUG) – Stair Climbing Test (SCT) – Isometric knee extensor strength	– FV group showed significantly higher improvements in WOMAC score, VAS score, TUG test, SCT, and knee ROM compared with the NMES group. – No significant differences in the isometric knee extension strength between the two groups or before and after the treatment	A randomised, controlled, single-blinded pilot study
(Kitay et al., 2009)	OA Knee patients Randomised into 2 groups	71	FV: using the “Kineticure” system: knee brace composed of stretchable textile support placed around the knee and a polyurethane case housing the vibration motor + Heating pad inserted into the brace + CPM (continuous passive motion) Vibration delivered above and below the knee	10s at 10 Hz 10s at 27 Hz 10s at 42 Hz 10s of no vibrations	0.1	20	2 times/day, 4 weeks	The sham device was similar to the active device but consisted of a non-vibrating knee brace with no heating pads	– Western Ontario and McMaster Universities (WOMAC) OA index using a Likert scale – VAS of pain	– WOMAC and VAS significantly decreased for patients receiving active treatment compared to sham treatment	A prospective, randomised, controlled, double crossover study
(Pietrangelo et al., 2009)	Older adults with diagnoses of sarcopenia	9 (four males and five females)	Local mechanical vibrations applied to the thigh muscles Aim: to evaluate the efficacy of combined mechanical vibrations, continuous passive motion (CPM) and heat on the severity of pain in the management of osteoarthritis of the knee	300	Not stated	15	1 to 3 sessions/ week, 12 weeks	No control group	– Cellular and molecular analysis of muscle biopsies – Muscle fibres, mechanical characterisation – Electrophoretic separation and quantification of myosin – heavy chain (MyHC) isoforms – Gene expression profile	– Isometric strength increased, but no significant variations in muscle mass accompanied increases in muscle strength.	Pre-post test design

	Participants		Intervention					Comparison group	Outcome measures	Results	Study design
									– The maximal isometric strength of knee extensor muscles – Muscle fibre cross-sectional area and specific tension – Myosin isoform composition of biopsy samples – Genes involved in energy metabolism – Genes involved in oxidative stress		

- **Summary**

In summary, no studies have yet examined the effect of FV on plantar fasciitis. However, FV has been tested and shown to be beneficial for pain relief in people with OA (Pietrangelo et al., 2009); as well as for improving lower limb function in older people when combined with exercise (Celletti et al., 2015). Similar to OA, the main issue with plantar fasciitis is the pain.

The first and the main task a therapy device for plantar fasciitis has to perform is relieving pain. As stated previously, Myovolt as the sponsor company in this project defined “plantar fasciitis” as the main application for the designed product; hence, it has been the most crucial focus of the research phase. On the other hand, as the studies demonstrate, no clinical trial has thoroughly investigated the efficacy of focal vibration therapy to relieve plantar fasciitis pain. Therefore, such enquiries will be necessary for the future. Clinical trials will be organised by Myovot, using the prototype developed in this research. However, clinical trials are not a component of this master’s research project.

2.4 Similar existing products to treat foot problems (with or without using vibration therapy)

Published materials explaining the design process of a user-friendly therapy device specified to foot diseases (especially plantar fasciitis) are rare; however, a range of commercial products exists in the market to reduce different foot/ankle problems, such as heel pain, imbalance, or diabetic ulcers. The researcher has categorised these products into the following groups according to their configurations and applications:

2.4.1 Foot and ankle wraps, braces, orthoses, night splints, etc. with no electronic part (Figure 7).

Figure 7 Foot orthoses Reprinted with permission from https://www.betterbraces.com.au/procare-prowedge-plantar-fasciitis-night-splint

2.4.2 Vibrating insoles are designed and studied to improve stability, balance and gait control for healthy people or patients with some walking impairment. For example, a study has explained the effect of using a specially designed urethane insole with two piezoelectric actuators delivering vibratory stimulation and argues it has helped improve the balance of healthy people (Lipsitz et al., 2015).

- VibraThotics® (Figure 8) is an insole that delivers vibration to foot and ankle to reduce pain and fatigue (https://vibrathotics.com).

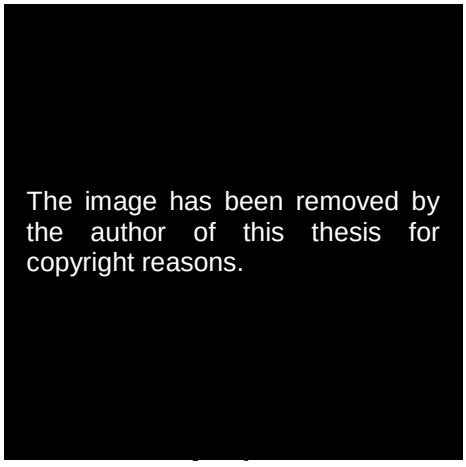
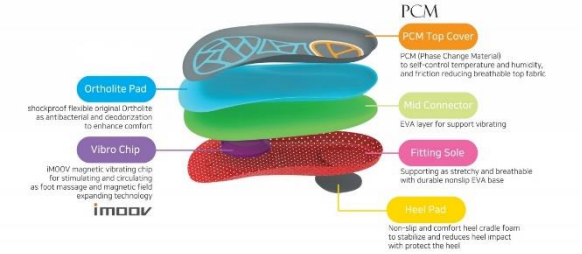


Figure 8 VibraThotics® Reprinted from https://fsastore.com/Vibrathotics-Vibrating-Shoe-Insole-Large-P25867.aspx

- Engineers at the Wyss Institute (a division of Harvard University) have designed a vibration insole (Figure 9) to improve motor control and balance in seniors ("Improving Balance and Gait Control," 2016).

Figure 9 The Wyss Institute's vibrating insoles use piezoelectric actuators to deliver mechanical vibrations to the feet Reprinted with permission from ("Improving Balance and Gait Control," 2016)

- Vibro Orthotics® is another similar vibration insole available in four different sizes of S, M, L, and XL (Figure 10) (http://vibroorthotics.com).



Size Chart		S	M	L	XL
Women	CM	225-240	245-255	260-270	
	US	5.5-7	7.5-8.5	9-10	
	UK	3-4.5	5-6	6.5-7.5	
	EU	36-38	38.5-40	40.5-42	
Men	CM		245-255	260-270	275-285
	US		6.5-7.5	8-9	9.5-10.5
	UK		5.5-6.5	7-8	8.5-9.5
	EU		39-40.5	41-42.5	43-44.5

Figure 10 Vibro Orthotics® structure and its sizes Reprinted with permission from http://vibroorthotics.com

2.4.3 Handheld devices that deliver different kinds of therapies such as shockwave (Figure 11), electrical impulses or vibration (Figure 12). These devices usually need an operator (such as a physiotherapist) to position the device correctly and use on a patient's foot, so, they are not home-based therapy devices.

Figure 11 Shockwave for Plantar Fasciitis and Tendonitis Reprinted with permission from https://www.ems-dolorclast.com/en/17-testimonial-plantar-fasciopathy

Figure 12 Hypervolt handheld vibration therapy device Reprinted with permission from https://hyperice.com

2.4.4 Stationary foot massagers that usually deliver a combination of different therapies such as infrared, compression, vibration, kneading or mimicking oriental therapy methods such as acupuncture, reflexology, shiatsu, etc. (Figure 13).

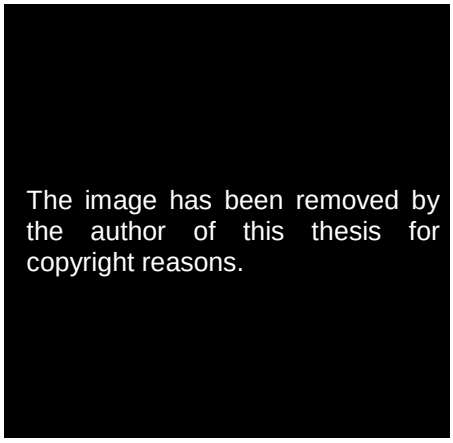


Figure 13 Stationary foot massager Reprinted from http://www.massageronline.com

2.4.5 Foot/leg wraps that usually produce pneumatic (air) compression, which is believed to improve blood circulation (Figure 14). These devices are available in different types for the neck, arms, and legs/feet.

Figure 14 Triple Play® VT Ankle Orthotic Reprinted with permission from http://compressionsolutions.us

2.4.6 Wearable therapy devices: These devices are typically general-purpose therapy devices that are also usable for foot/ankle.

- Heelease® employs low energy extracorporeal shockwave therapy (ESWT) to treat heel pain (plantar fasciitis), reduce pain, and improve the blood circulation ("Easy home treatment for Plantar Fasciitis," n.d.). Medical Technology Ltd. has designed this device; the company that also has developed and marketed Kneease® (a device that produces high-frequency vibration to deliver shockwaves through the skin to the tendon). These

two products are similar products (in terms of function and appearance). However, they come under two different names (Figures Figure 15 and Figure 16).

Figure 15 Kneease Reprinted with permission from https://kneease.com

Figure 16 Heelease Reprinted with permission from https://heelease.co.uk

- Quell® (Figure 17) is a TENS[12] unit developed by NeuroMetrix and designed by IDEO ("A Drug-Free Alternative to Chronic Pain Relief," 2015) which automatically adjusts the intensity of therapy for patient using a patented technology called OptiTherapy™[13] ("Wearable pain relief that is drug free," n.d.).

Figure 17 Quell pain relief device Reprinted with permission from https://www.quellrelief.com

[12] Transcutaneous Electrical Nerves Stimulation is the use of any electrical current through the skin to reduce pain, using moderate to high frequency current between 40-150 Hz and 50-100 µsec pulse width (Rutjes et al., 2009).

[13] This technology calibrates to users' optimal stimulation levels to ensure they receive maximum relief (Kilgore, 2017).

- ActiPatch® (Figures Figure 18, Figure 19 and Figure 20) is a wearable Pulsed Shortwave Therapy (PSWT)[14] device applicable for foot and ankle, and also other parts of the body ("ActiPatch® Muscle & Joint Pain Relief | ActiPatch® Pain Relief," n.d.).

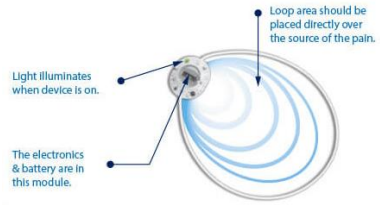


Figure 18 ActiPatch® PSWT device Reprinted from ("ActiPatch® Muscle & Joint Pain Relief | ActiPatch® Pain Relief," n.d.)

The image has been removed by the author of this thesis for copyright reasons.

Figure 19 ActiPatch® on foot

The image has been removed by the author of this thesis for copyright reasons.

Figure 20 ActiPatch on the ankle

- Wearable Therapy™ is a TENS, NMES[15], and FES[16] therapy product useful for persons with neurological impairments including spinal cord injury, stroke, traumatic brain injury, multiple sclerosis, and cerebral palsy and helps them to revive their body and power and reduce their pain (Figure 21) ("Wearable Therapy® Technology | Axiobionics, LLC," n.d.).

Figure 21 Wearable Therapy™ for the leg, foot and ankle Reprinted with permission from http://axiobionics.com/pain-relief/

[14] Pulsed shortwave therapy uses intermittent high-frequency electromagnetic energy to change the behaviour of tissues (Al-Mandeel & Watson, 2010).
[15] Neuromuscular Electrical Stimulation: the use of non-invasive sensitive electrical stimulation to contract muscles with no need for the patient to attempt (Wageck, Nunes, Silva, Damasceno, & de Noronha, 2014).
[16] Functional Electrical Stimulation involves the application of electrical stimulation to activate paralyzed muscles and fix movement disorders for people with upper motoneuron injuries (Chou & Binder-Macleod, 2007).

- VibraCool® (Figure 22) uses vibration and cold therapy at the same time and has been claimed to alleviate neck, shoulder, lower back pain and plantar fasciitis (“VibraCool® for Neck and Shoulder and Plantar Fasciitis,” n.d.).

Figure 22 VibraCool Reprinted with permission from https://vibracool.com

- Intellinetix® is a vibration therapy device available in the forms of gloves (Figure 23) and facial mask (Figure 24), but it is not available for foot and ankle.

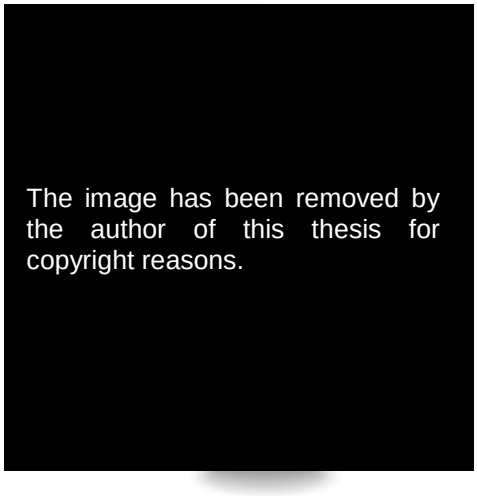


Figure 23 Intellinetix Gloves Reprinted from https://www.intellinetixvibration.com

Figure 24 Intellinetix Mask Reprinted from https://www.intellinetixvibration.com

- Myovolt™ markets a therapy device that combines vibration and warmth in a module which can be wrapped around different body parts (shoulder, back, knee, and leg) using particular fabric bands (Figure 25) (“MYOVOLT | Wearable Vibration Therapy,” n.d.).

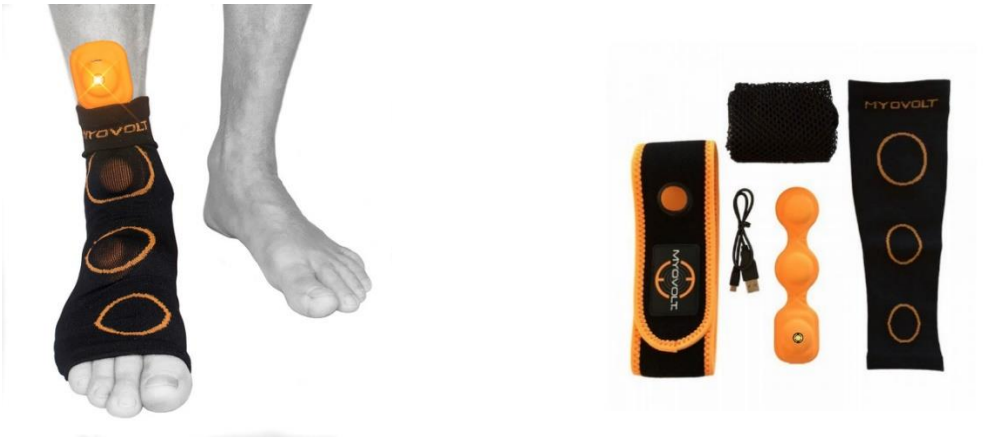


Figure 25 The MYOVOLT Core Kit Reprinted with permission from (“MYOVOLT | Wearable Vibration Therapy,” n.d.)

2.4.7 New smart accessories: Researchers and engineers have been trying to invent new solutions to reduce patients’ foot problems more easily and smartly. A group of scientists from the Hebrew University of Jerusalem has actively worked in this field. They have teamed up to develop a machine-washable sock with a large number of tiny pressure sensors, called SenseGO (Figure 26), which is aimed to prevent developing of diabetic ulcers. SenseGO works by detecting “changes in pressure due to incorrect posture, anatomical deformation or ill-fitting shoes” and sending proper signals and alerts to the patient’s smartphone app (Paz-Frankel, 2016).

Figure 26 SenseGO Reprinted with permission from (“To Help Diabetics, Intelligent Socks Are Paired With Smartphones | האוניברסיטה העברית בירושלים | The Hebrew University of Jerusalem,” n.d.)

In another project, the researchers in EPFL[17]'s Integrated Actuators Laboratory (LAI) have invented a different product with the same purpose. They have designed a new type of shoe sole having 50 electronic valves (filled with suspended iron micro-particles reacting to an electromagnetic field applied to them) that control the pressure on the arch of the foot, hence helping to alleviate diabetic ulcers (Figure 27,Figure 28Figure 29) (Perrin, 2016).

[17] École Polytechnique Fédérale de Lausanne

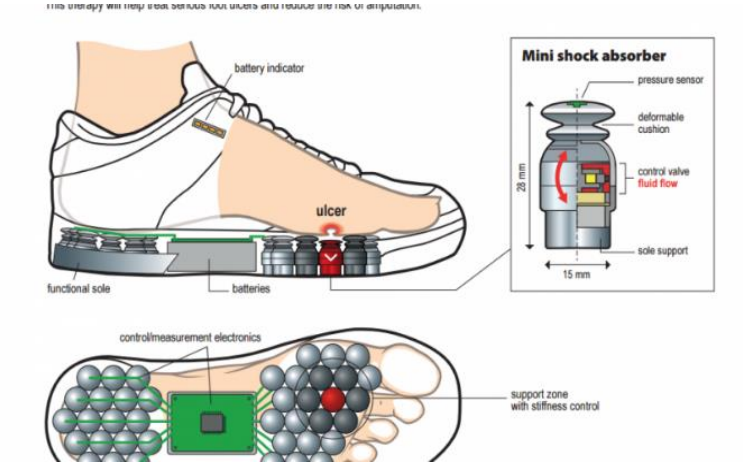


Figure 27 Shoe sole having 50 electronic valves Reprinted with permission from (Perrin, 2016)

Figure 28 Shoe sole having 50 electronic valves Reprinted with permission from (Perrin, 2016)

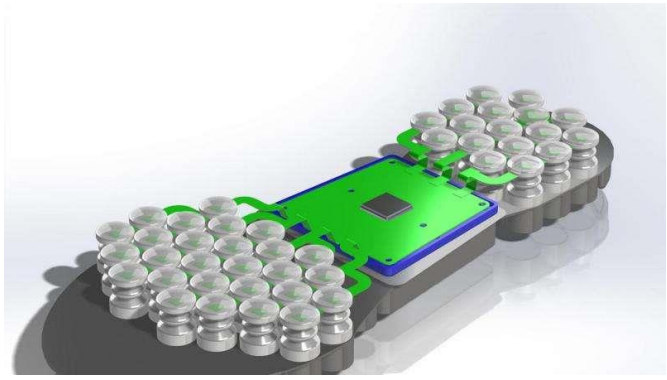


Figure 29 Shoe sole having 50 electronic valves Reprinted with permission from (Perrin, 2016)

Among the products mentioned above, VibraCool® seems more relevant and akin to the purpose of this project (a vibration therapy device that is attachable to the foot). Although as Figure 22 shows, this product does not cover the entire area affected by plantar fasciitis (from the midfoot to the hindfoot). Moreover, this device does not take into consideration different foot sizes or slimness affecting the fit comfort and usability expected from a wearable device. Heelease® and ActiPatch® have similar restrictions.

The review of existing products on the market confirmed the lack of any similar wearable vibration devices to treat plantar fasciitis and supported the opportunity for research and product development for this market.

3. Research Methodology and Design

This investigation was an applied research project and involved both qualitative and practice based research. It followed a product design process involving a close-knit sequence of explorative, experimental, testing and problem-solving activities. As a research project it also involved reflection on and in the design process as the project progressed (Schön, 2011). The researcher adopted a qualitative approach to help frame and answer the research questions. A literature review, an analysis of existing similar products and interviewing a number of medical practitioners and experts helped the researcher in data collection for the study.

Moreover, in this project, a non-linear four-step process was used based on the suggested design process by Vijay Kumar (Kumar, 2013) with slight modifications (Figure 30). This process allowed the iteration of one or more of the previous phases when needed until the desired outcome was achieved.

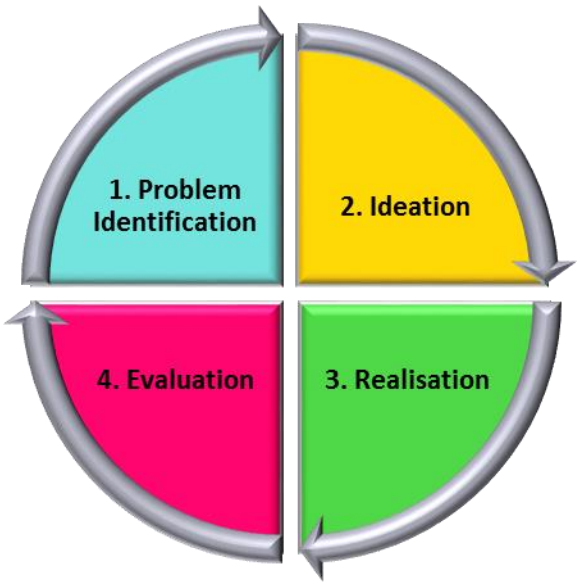


Figure 30 The Design process phases Adapted from (Kumar, 2013)

3.1 Problem Identification

Charles F. Kettering, the American inventor, stated: "A problem well stated is a problem half-solved" (“Charles Kettering Quotes,” n.d.). It is necessary to understand a design problem and the experiences of people involved in it properly, to develop relevant design solutions. In this stage of the project, the researcher tried to seek answers to questions and to establish a theoretical base for the next steps by pursuing two parallel paths, outlined in the following two sections.

3.1.1 Knowing the problem

A literature review surveyed topic areas including the history of vibration therapy, vibration parameters, studies on the efficacy of vibration therapy for musculoskeletal disorders, etc. and an analysis of some similar existing products, helped to view the problem from different perspectives, understand previous work done in the field and the identification of areas that would benefit from creativity and innovation.

3.1.2 Field study

Aim

To develop new medical devices, a multi-disciplinary collaboration between researchers (industrial designers) and physicians is necessary (Freudenthal, Stüdeli, Lamata, & Samset, 2011).

This stage of the project aimed to explore the views of medical practitioners about plantar fasciitis, the use of vibration therapy for plantar fasciitis, learning about potential users (people with plantar fasciitis), and how they might interact with the proposed product.

Ethical Issues

At first, it was intended to carry out qualitative structured interviews to obtain information from physiotherapists and podiatrists about their views of vibration therapy and from people with plantar fasciitis about their experience of this condition. This required applying for an ethics approval to the AUT Ethics Committee (AUTEC). The requisite forms and documents were submitted to AUTEC. They reviewed the application in their meeting on 11/05/2018 and did not approve it due to the issues raised concerning patient insurance and their ruling that the proposed device was a Class IIa medical device. This was in spite of the purpose of the intended interviews with people with plantar fasciitis being to gather information to inform the design requirements, rather than for any medical insights or evaluation. Hence, they asked that an application to the Health and Disabilities Ethics Committee (HDEC) be submitted.

On supervisors’ advice, the research proposal was modified to include only clinical experts (podiatrists/physiotherapists), rather than patients (See Appendix 1). It was recognised that this would provide a robust but broader overview than patient-specific responses and would be sufficient to inform the initial design requirements. A revised proposal was submitted to HDEC with a modified methodology. While interviews with both end users and expert clinicians would have been preferable, people with plantar fasciitis were not included, to ensure the field study section was manageable within the scope and timeframe of this Master’s research project. Interviewing people with plantar fasciitis would have required a significantly more extensive ethics application. Given the considerable experience of the clinical experts, the strict research timeframe, and the project’s focus on proof of concept prototype development, this revised approach was supported by the supervisors and by Myovolt. HDEC confirmed there was no need to get their approval.

AUTEC then confirmed it was possible to resubmit the revised documents. They also noted the accident insurance would not be necessary, as the study would only focus on clinicians’ interview and observation. The ethics application was resubmitted with the required amendments (See Appendix 2) to AUTEC, and in their meeting on 23 July 2018, they approved the application (See Appendix 3).

Participants

On getting approval from AUTEC, some Hamilton and Auckland based podiatrists and physiotherapists with experience in treating plantar fasciitis were contacted to ask if they were able to participate in two interviews. These health professionals were identified through online searches and in consultation with one of my supervisors. The criteria for inclusion of participants included their having at least three years' experience in treating plantar fasciitis and willingness to participate in two interview sessions of up to 30 minutes per session. The desired number of participants was five to ten. Six experts (four based in Hamilton and two in Auckland) agreed to participate in the research. The desired range for the number of participants was suggested by my supervisors as being the minimum for providing some diversity of expertise and opinion to inform the design prototype development, while keeping the scale of this phase of the research manageable within the project timeframes.

Procedure

'Consent forms' and 'Information sheets' were sent to the participants to sign off, before each interview (See Appendix 4 and Appendix 5). Interviews were conducted at the physicians' place of work.

The first round of interviews consisted of 15-20min casual conversations. The participants were requested to fill out a questionnaire (See Appendix 6) first, and then, freely talk about their experiences and knowledge on plantar fasciitis, the treatment methods for it, and what they thought a new therapy device might offer. Afterwards, to follow up on the interview, they were asked further questions related to their responses.

Data analysis

The outcomes of the interviews were thematically analysed[18], summarised and categorised to form the design requirements that were then used in the design phase. The criterion used in the categorisation was based on the relevance of the information to the purpose of the project. According to these criteria, two categories were established: 1. General ideas about plantar fasciitis, and 2. The points that could help in the design of a new vibration therapy device. The first category covered the aspects that corresponded to and enhanced the findings of the background review, and the latter gave insights for the design phase.

A brief explanation of the main findings of the research and their relationship to the device design is given here, as this information helped in the next, problem identification phase.

General thoughts about plantar fasciitis:

Plantar fasciitis is the most common complaint people have when they start to walk in the morning or after a period of rest. Its symptoms progress as the day goes on.

Plantar fasciitis comes under the umbrella term of heel pain or arch pain and mostly happens to very active people such as athletes (higher impact sports), or (in New Zealand) to the people standing on the ground and even doing Haka. Most of the patients find plantar fasciitis very frustrating.

Comments identified as usable in the design phase:

According to the experts, most patients (in New Zealand) are over 50, non-athletes, and can be either men or women. This fact reinforces 'ease of use' as an essential characteristic of a therapy device. The ability to put it on, take it off quickly, and operate it efficiently will be necessary for users.

Understandability of how to use the device is very important for users. It should have accessible, simple and easy to use controls. It is critical for the therapy device to be easy to apply, simple,

[18] "Thematic analysis is a method for identifying, analysing and reporting patterns (themes) within data. It minimally organizes and describes your data set in (rich) detail." (Braun & Clarke, 2006)

secure and straightforward. There should be no need for many controls or timers. Straightforward and accessible user instructions would be necessary for users.

Another fact stated by experts was that the origin of plantar fasciitis is in the calcaneal part (heel or back foot) to midfoot. Most of the time, the pain starts where plantar fascia originates (calcaneal part or heel bone), and sometimes, it is in the mid-section of the foot. Most patients have pain in the middle of the heel, and rarely the pain goes towards the toes unto their arch. Mid-band of the foot is the most crucial part for applying treatment (vibration therapy device). There is no need to extend to the whole foot (lateral bands of fascia). This information helped to specify the location of vibration motors and their distance from each other.

Experts also said patients generally have a limited budget, and as plantar fasciitis is not ACC covered and treatment may be required over an extended period, many people stop treatment (or going to a specialist) after a while. The pain relief device has to be cost-effective and affordable for average users to address this issue.

Treatments that clinicians usually use or suggest to heal plantar fasciitis include rest, strapping, stretching, changing footwear and using better shoes, ice therapy (cryotherapy), shockwave, and ultrasound. Shockwave therapy is effective but very painful and expensive as well. Vibration is not a conventional therapy for plantar fasciitis at present (See section 2.3 The use of vibration therapy for musculoskeletal disorders: a review of the current research). Therefore, if medical trials prove this method's efficacy, as being both safe and effective, it can compete well with other available therapies.

Most experts believed patients could see the result of a rehabilitation programme in between a few weeks to months. According to them, 70% of people have improvement after three months, but others may have a prolonged problem even for years. Users should be informed about such differences in response times due to the level of their conditions, through a therapist, user's manual or company website.

The other important point that experts mentioned was a user's need to be able to adjust the intensity of the device easily. Deep, broad and slow strokes can be more effective than fast vibration. Vibration therapy should be applied deep into the foot. The full contact of the soles is vital. Moreover, for the experts having properly sized devices for patients, hygiene (ease of cleaning), safety (not causing heat, burning, or any other undesired sensation), and durability were important factors, in the experts' opinions.

3.1.3 Design requirements

Wearable technology (sometimes called 'wearables') includes "electronic technologies or computers that are incorporated into items of clothing and accessories which can comfortably be worn on the body" (Tehrani & Michael, 2014), para. 1. Wearables include a range of products from smart glasses (like Google glasses) and smartwatches (such as iWatch and Samsung Galaxy Gear) to smart health bracelets (like Fitbit and Jawbone). The initial uses of wearable devices were for military application (Tehrani & Michael, 2014), but today we find wearables across extensive areas of application.

Two main types of wearable healthcare products include:

1) Fitness (tracking) devices (such as Fitbit) which are used to monitor daily activities such as steps, the distance walked, calories burned, sleep, and diet. Young, healthy and active people usually like these products (Alley et al., 2016).
2) Medical (therapy) devices that are mostly used by seniors or patients (Peltola, 2017).

   As a wearable technology project, this research is focussed on the development of a medical therapy device.

For any wearable device, comfort is a vital characteristic. Comfort is a subjective concept (Miller, Nigg, Liu, Stefanyshyn, & Nurse, 2000) and has been defined as a pleasant state consisting of physiological, psychological, and physical aspects in which the person is in harmony with the environment (Slater, 1985) and feels no pain or discomfort (Hatch, 1993).

The following list was concluded from the literature review and experts' interviews to summarise the factors affecting the degree of comfort and convenience of the device in this project, and other factors to consider in the design phase (design requirements).

1. **Weight:** The maximum weight of the device should be light (potentially under **400gr**[19]).

This requirement was mentioned by clinicians and was found in the literature about ergonomics.

2. **Texture:** The texture of the outer skin of the device (where touches the body skin) should be both non-slippery and smooth.

This requirement was mentioned by clinicians and was found in the literature about ergonomics.

3. **Flexibility:** The device material should be flexible to fit the foot comfortably.

This requirement was mentioned by clinicians.

4. **Thermal comfort:** The device should also be breathable. It should not make the user's foot sweat. The device's main body materials should have a low thermal conductivity (to prevent getting very cold or hot).

This requirement was found in the literature about ergonomics.

5. **Foot measurements:** The device should cover an area from midfoot to back foot (9-17cm[20]).

This requirement was found in the literature about ergonomics.

6. **Being equally applicable for both the right and left foot (symmetrical and reversible)**

This requirement came from the industry partner.

7. **Rounded edges:** Sharp edges can cause cuts, scrapes, scratches, and punctures on the skin; therefore, smooth edges are preferable when and where technically possible.

This requirement was found in the literature about ergonomics.

8. **Secure yet comfortable fixing to the foot:** The design should enable a fixation system that prevents the device from movement when working (vibrating) and is effortlessly and conveniently adjustable by users.

This requirement was mentioned by clinicians and Myovolt.

9. **Easy to understand how to use:** Using the least possible functional elements and preventing complexity can help users easily realise how to run, utilise and stop the device with least or no need of asking other people for help or referring to a long user's manual.

This requirement was mentioned by clinicians and was found in the literature about ergonomics.

10. **Deep stimulation:** The device should enable applying vibration deep into the foot. In other words, the device needs to allow tight (but comfortable) attachment to the foot.

This requirement was mentioned by clinicians.

[19] The maximum weight for handheld tools that must be manipulated precisely has been stated up to 400gr (Cushman & Rosenberg, 1991; Government of Canada, 2018). While the informal brief was for a wearable rather than a hand held device, this recommendation of weight could be seen as proximate in terms of requirements for holding and attaching a device on the body.

[20] See Appendix 8

11. Safety: The device should cause no heat, burning, irritation, etc.

This requirement was mentioned by clinicians and was found in the literature about ergonomics.

12. Hygiene: The device should be easily cleanable. Cleanliness is essential to consider through both material choice and the form of the product.

This requirement was mentioned by clinicians and was found in the literature about ergonomics.

13. Price: The final cost of the product should be under **US$150**[21].

This requirement came from the industry partner.

14. Durability: As a domestic consumer product, the device should last and work smoothly for a long time.

This requirement was mentioned by clinicians and Myovolt.

[21] Defined at the beginning of the project by the sponsor company. It was based on the price range they have identified as appealing to the target market that purchases other wearable health technology vibration devices they produce. For example, the Myovolt Wearable Massage Technology for Shoulder/Vibration Therapy Device retailed for US $129.00 in April 2019.

3.2 Idea generation

A mix of creative idea generation techniques was used to help create new design ideas. This process included the four following steps:

3.2.1 Initial ideation

Three creative idea generation methods helped to develop the initial design concepts in this project; Mind mapping, Mood board, and Sketching.

At the beginning of this phase, a mind map was formed to help to look at the different aspects and attributes of the product to be designed (Figure 31).

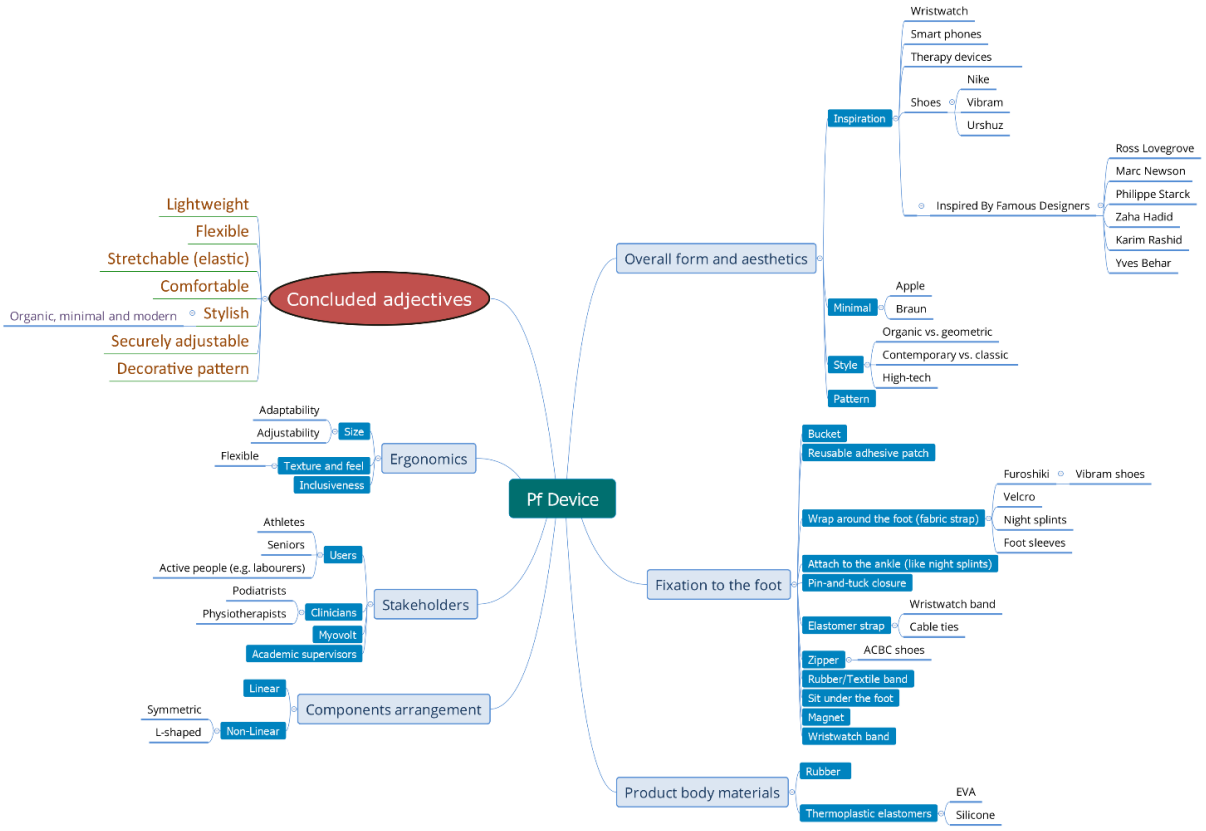


Figure 31 Mind map

The researcher also created a mood board based on some keywords extracted from the mind map, to explore the potential opportunities including form, function, materials, etc. (Figure 32).

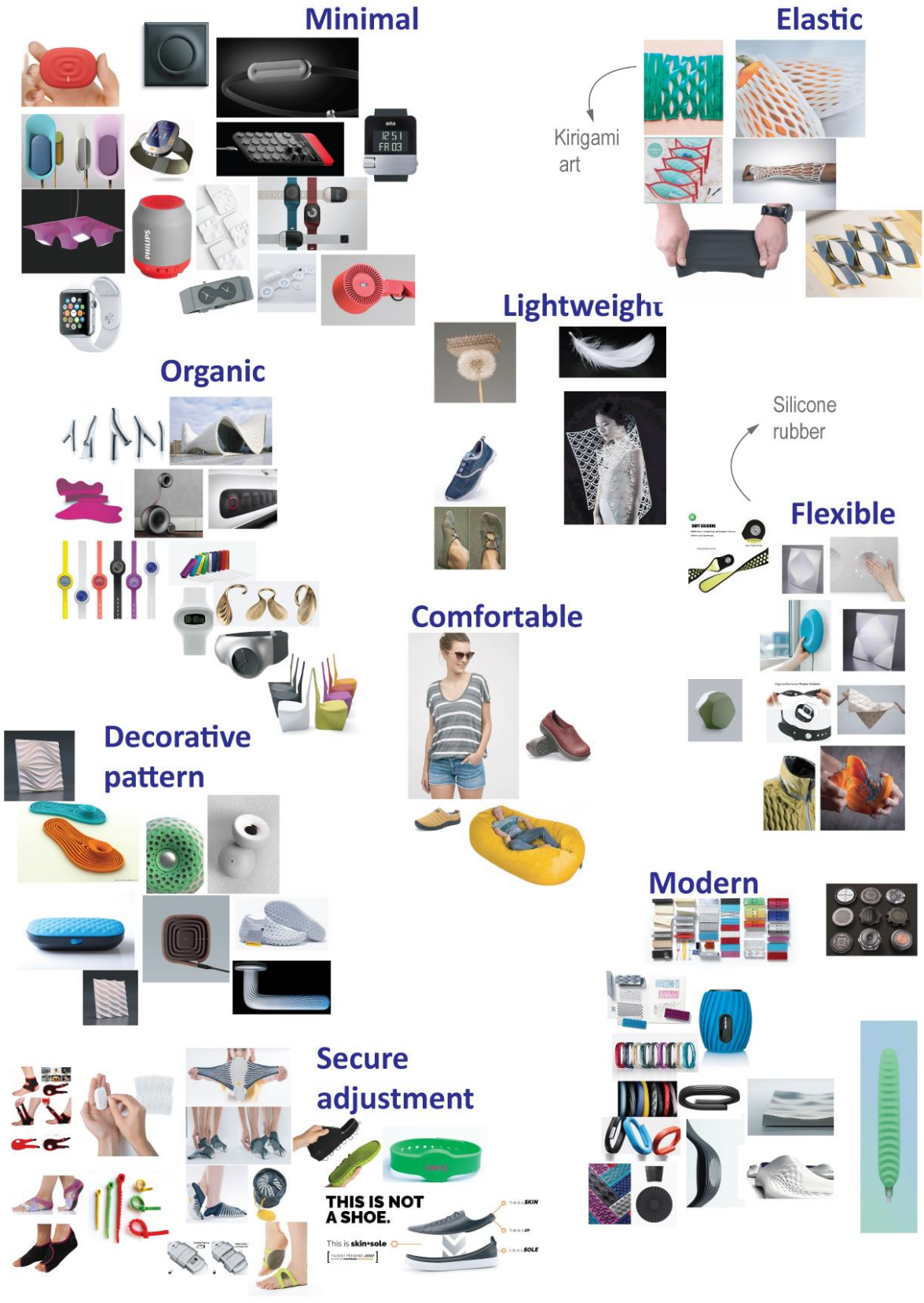


Figure 32 Mood board

Moreover, the researcher studied the possible configurations for the product (Figure 33) using the current vibration motors and the electronic controller circuit (Figure 34 and Figure 35) and the possibilities around the ways to attach the device to the foot (Figure 36).

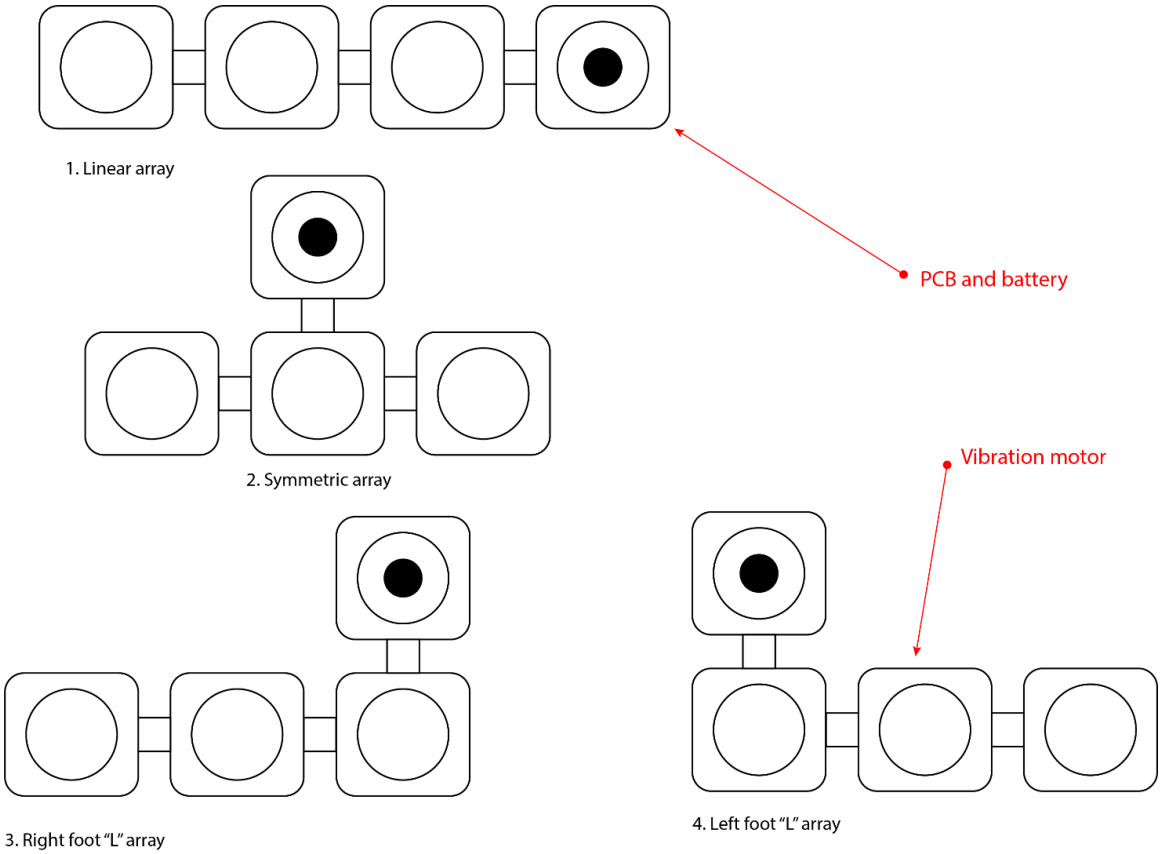


Figure 33 Different possible configurations for vibration motors and PCB

Figure 34 Vibration motor

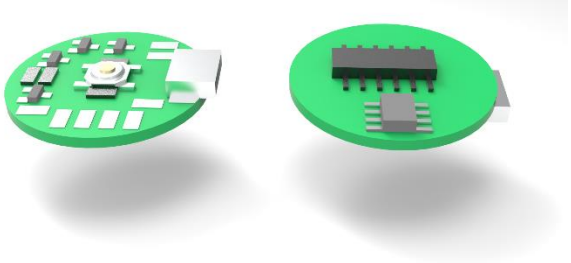


Figure 35 Electronic controller circuit

Figure 36 Means of attachment

The researcher drew some sketches, incorporating the information gained through the research and the inspiration taken from the previous stages of the idea generation process, to explore and communicate the product's form and structure (Figure 37).

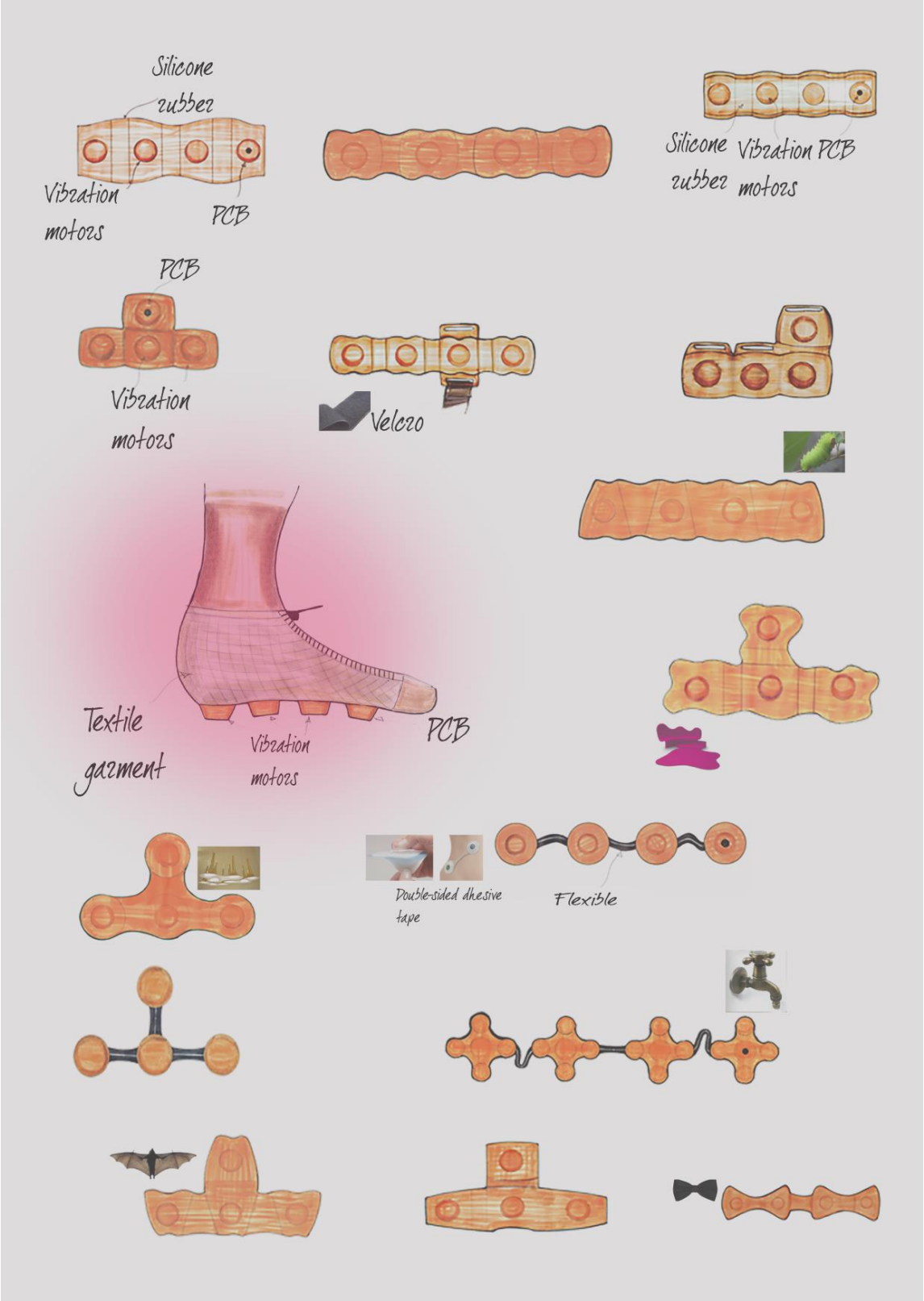


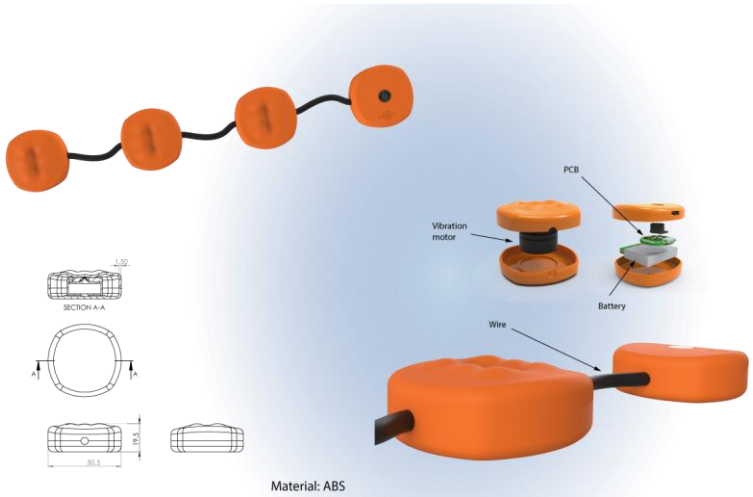
Figure 37 Initial design sketches

3.2.2 Primary evaluation of ideas:

Following discussion with my supervisor, these design concepts were evaluated and three ideas were selected, to present to and ask the sponsor company's managers for feedback. The selection process involved analysing the different design concepts in relation to the previously identified design requirements (3.1.3 Design requirements) and identifying those concepts seemed to have greater development potential, from a designer's perspective. From my experience in working on product design projects in collaboration with the other designers, three designs are normally considered the optimum number of ideas to be selected, from among a number of potential design ideas. One way to select the 3 design concepts is screening all concepts and putting aside the ones that seem less desirable until only 3 remain.

3.2.3 Refining ideas:

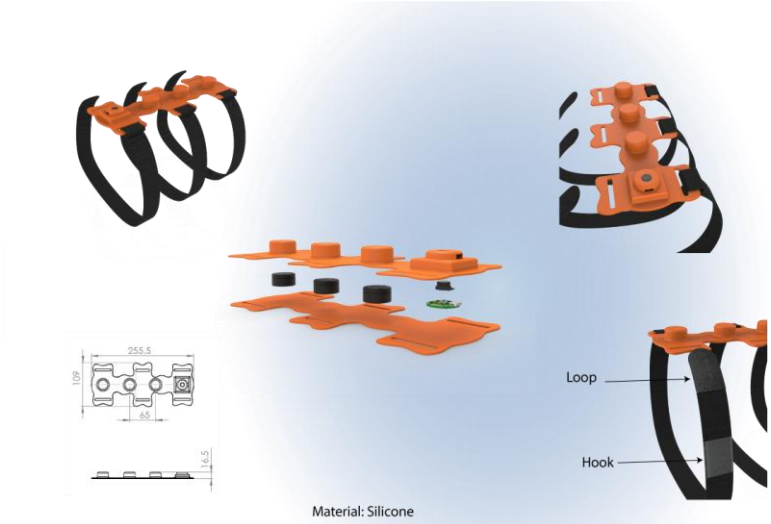
These three primarily selected design concepts were further developed with visuals and technical details to present to supervisors and the sponsor company for a decision on a final selection for prototype development (Figure 38-A, B, and C).



Design idea A

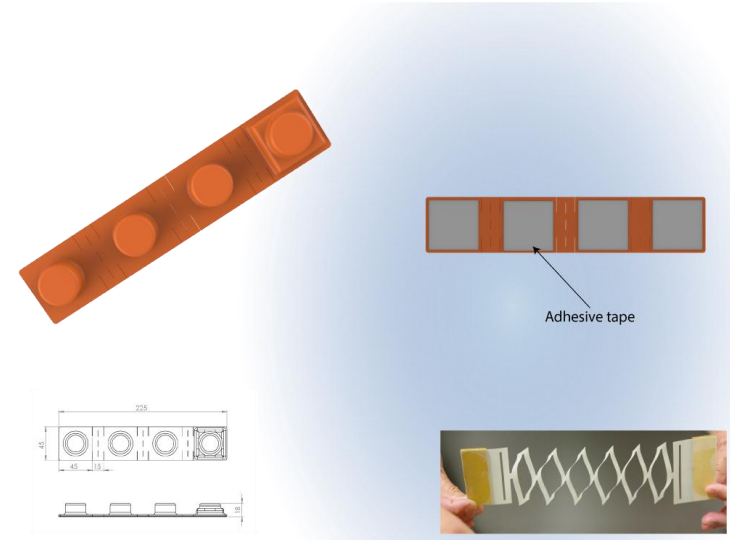
Design idea A consists of separate units connected to each other using electric wires (that also make electrical connection between units). This allows users to locate the units on different areas of their foot and adjust the product's length according to their foot size.

Each unit sticks directly to the foot skin using a piece of 'double-coated medical grade adhesive tape'.



Design idea B

Design concept B, a one-piece unit made out of silicone rubber that encloses vibration motors and the PCB can be wrapped around foot using neoprene straps and can be securely fixed using Velcro fasteners. As in this concept, vibration motors and PCB have fixed locations the product should be made in different versions to fit different foot sizes.



Design idea C

Design idea C was inspired by Japanese Kirigami art to enable the product to be stretchy and correspond different foot sizes. The product was intended to be made of silicone rubber and stick directly to the foot skin using 'double-coated medical grade adhesive tape'.

Figure 38 The primarily selected design ideas

3.2.4 Final evaluation and choosing the final design:

T The selection of the final design for prototyping occurred in a meeting with Myovolt managers and academic supervisors. The researcher presented a summary of the research findings and the initial design ideas to get feedback from the sponsor company managers and ask them to select a design idea to prototype.
Myovolt managers expressed they were interested in exploring new methods/approaches for attaching their vibration therapy technology, especially on parts of the body with complex curvatures, like shoulders and feet. They were interested in looking at ways of attaching the device to the body without straps, which is what they currently use. They were also ikeen to explore new manufacturing technologies for wearables, including AUT's seamless knit machines. These factors led them to choose one design idea among the initial design ideas to refine and prototype, which was closer to their current products form and structure, but with a new approach for attachment: a knitted garment. This idea, however, was not among the primarily selected design ideas, but came from them looking through the sketches for other design ideas.

The selected design idea was developed and modified based on the 'symmetric array' vibration unit in Figure 33 to help users use the device more comfortably (Figure 39).

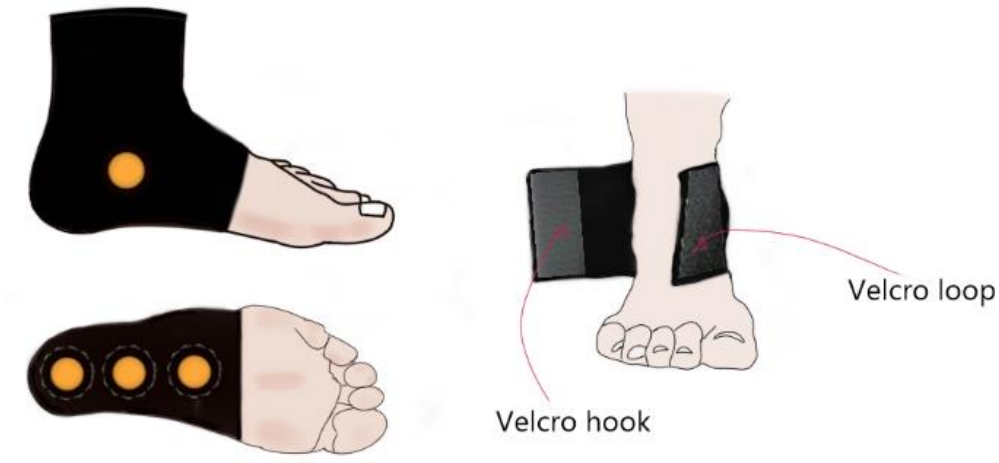


Figure 39 Selected design concept development

The next step in the design process (detailed in the next chapter) involved making prototypes of the selected design concept. Prototyping is a method for testing design ideas before investing a lot of capital, time and energy on the mass production of a product. Spending a limited amount of money on making prototypes, allows designers and manufacturers to explore options and evaluate design ideas on a small scale and modify them until they achieve the desired result. There are different types of prototyping, and prototyping can be used at various stages of the design process and for different purposes.

Prototyping allows for the clarification of the production expenses and manufacturing issues and exploring ways to minimise them. Prototypes can also help to present and sell design ideas to potential customers or investors (Christie et al., 2012).

Also, materials made of fibres especially knitted textiles are heterogeneous in their micro or middle structures. Therefore, they have very anisotropic and nonlinear mechanical characteristics. The integral fibres' attributes and their complex interactions affect the mechanical behaviours of knitted fabrics in a macroscopic level profoundly. Accordingly, it can be tough to model, simulate and predict the actions and properties of knitted textiles (Dinh, Weeger, Kaijima, & Yeung, 2018). In textile and garment design and development process, particularly with new technologies like digitally shaped knitwear, it can be difficult to predict the form, texture and other qualities of a final product without making prototypes, as there are no predictive models or formulae yet available.

4. Prototype Development and Evaluation

4.1 Prototype development

The final selected design idea consisted of a textile wrap to enclose the foot from back to the middle (similar to a toeless sock) and with holes to insert the vibration units. The wrap would be adjusted onto the foot using a hook and loop (Velcro™) fastener at the back and front. Once the final design was selected, four variations (with different decorative patterns) of that design were made up and presented to Myovolt managers to choose from and subsequently one was picked for further prototyping. Myovolt were interested in the potential of using new textile fabrication technologies to develop a more comfortable and wearable product and new manufacturing options (Figure 40,Figure 41, Figure 42 and Figure 43).

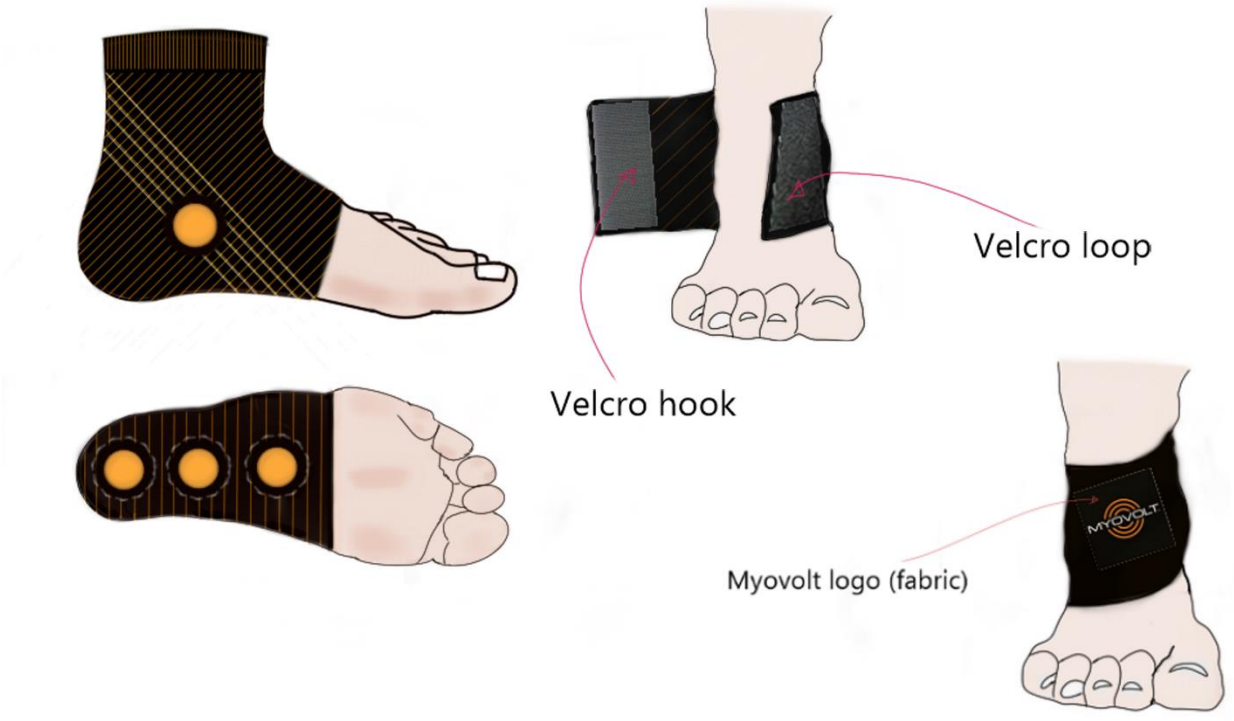


Figure 40 Wrap design 2, with diagonal lines pattern

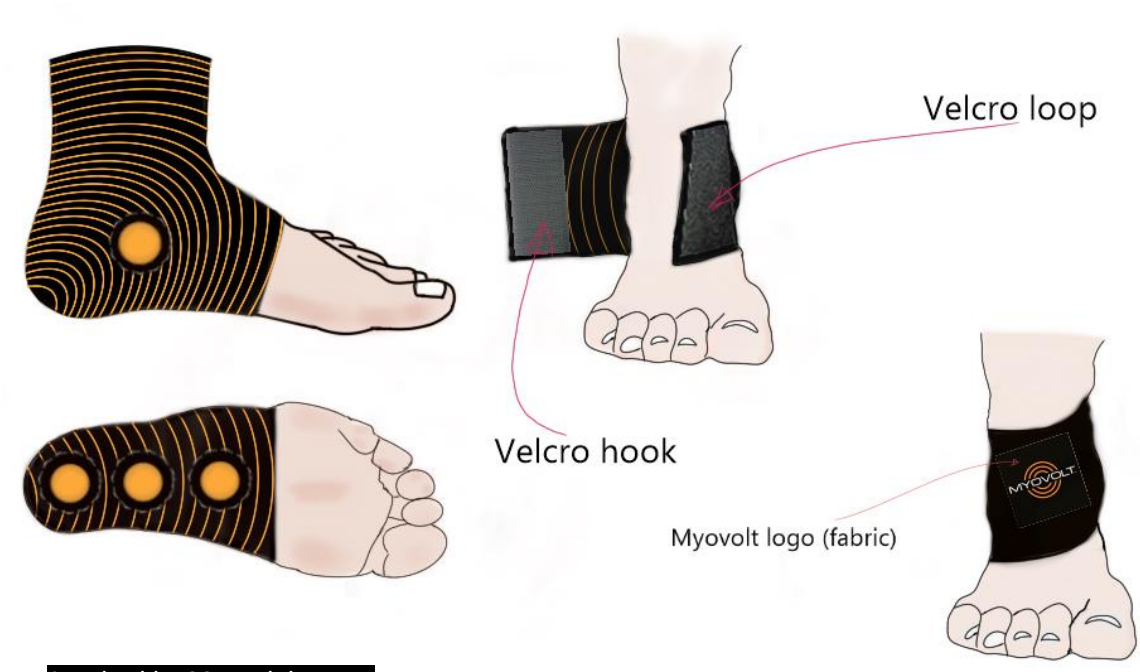


Figure 41 Wrap design 2, with concentric lines pattern

Figure 42 Wrap design 3, inspired by Reebok Les Mills™ Circuit Trainer Ultraknit pattern

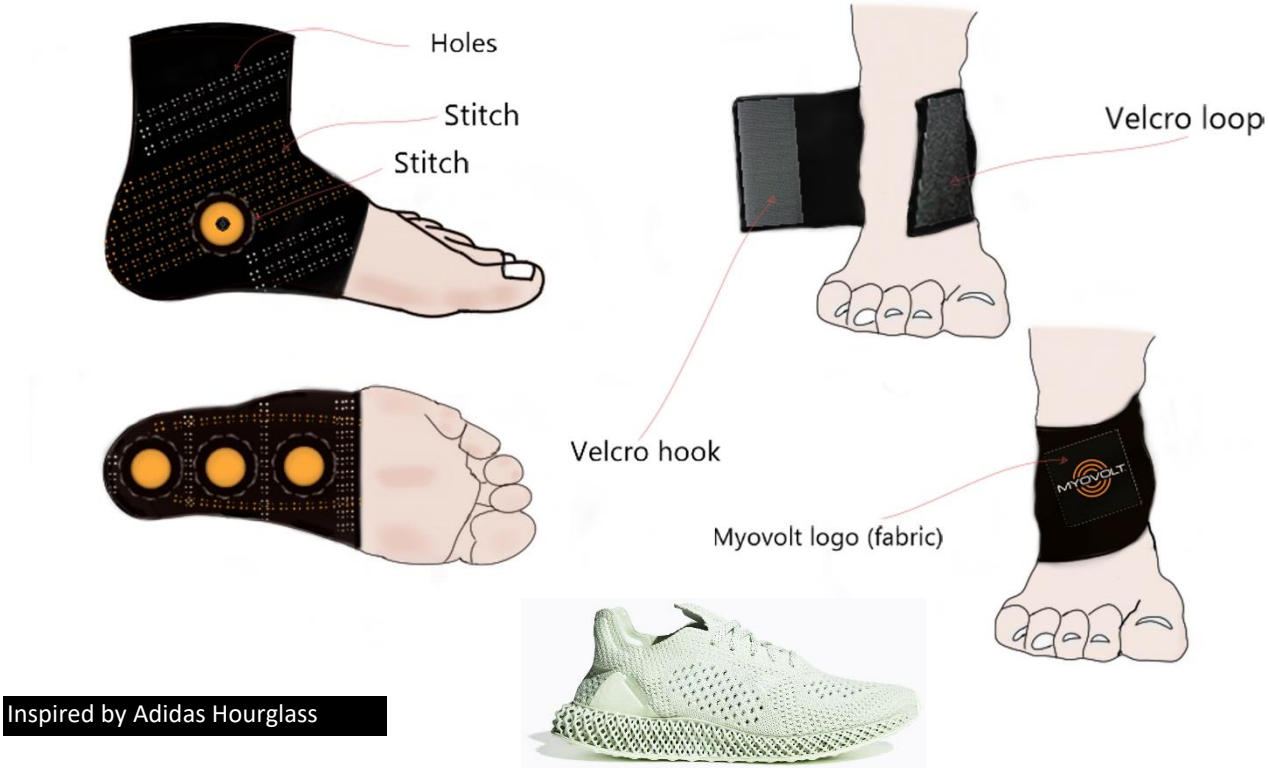


Figure 43 Wrap design 4, inspired by Adidas Hourglass pattern

Due to variations in foot sizes, it was decided to design and make the vibration unit for this product in two versions: Size 1, with two vibration motors (called a Double unit) to suit small-medium foot sizes, and Size 2, with three motors (called a Triple unit) to suit medium-large foot sizes (FiguresFigure 44Figure 45). In Size 1, the motors' ends have a distance of 11cm from each other, and in Size 2 this distance is 15cm (*See Appendix 8* for more details on how these dimensions were specified).

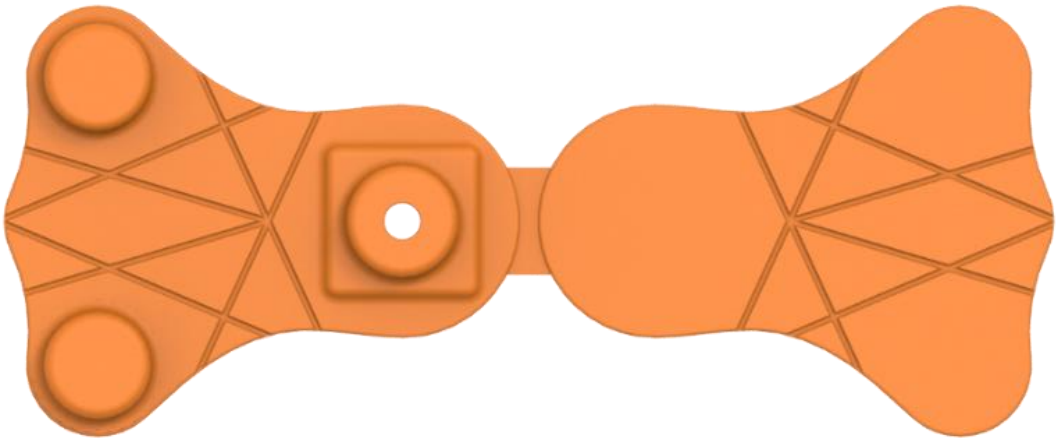


Figure 44 The unit with two vibration motors (Double unit), unassembled

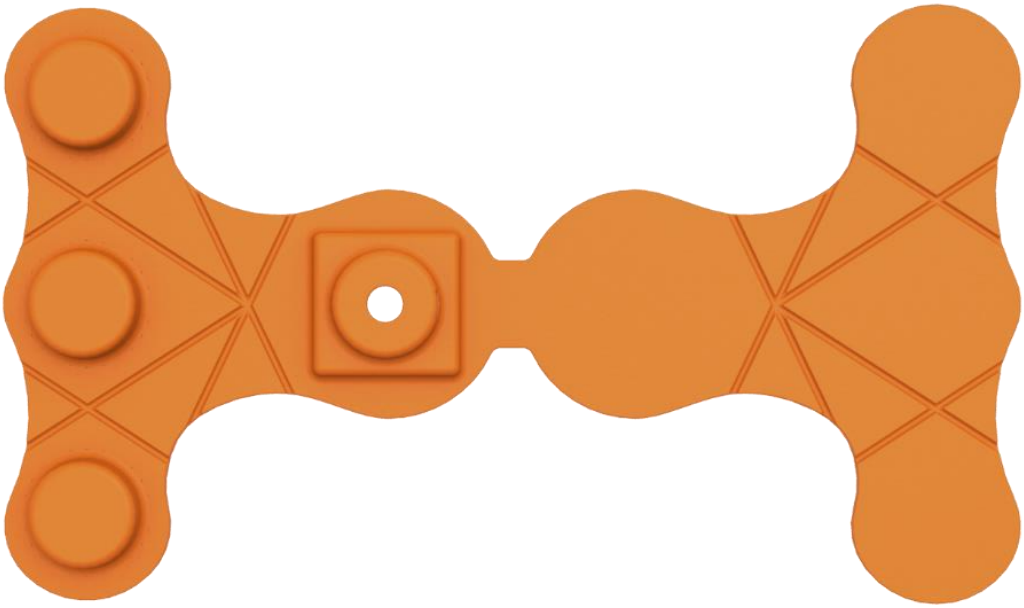


Figure 45 The unit with three vibration motors (Triple unit), unassembled

As Figure 48Figure 49 show, vibration units have a T-shaped configuration. This outline design allows vibration motors to sit in a linear arrangement on the foot sole and the PCB (and the power button) on foot inside (either right or left) above the foot sole. In this manner, the user can see and push the power button straightforwardly.

The prototyping process for vibration units included preparing 3D CAD models and fabrication drawings, material selection and specifications definition, and building prototypes.

The material used to make the main bodies of vibration units is EVA, which is an elastomer, hence soft and flexible. The use of this material was suggested by Myovolt managers, as they had experience using it for their previous products, and prototyping new vibration unit configurations using this material was easy for them.

The process of making the vibration units was performed at Myovolt's plant in Hong Kong and with the help of their manufacturing engineers. The process started by sending 3D CAD files of the vibration units to one of Myovolt's manufacturing engineers and he requested some changes he found necessary to achieve the best quality and with no moulding or fabrication issues. After a few such iterations, he confirmed the final drawings (Figure 46Figure 47) and started the prototyping process. The entire vibration unit prototyping process took about three weeks. The prototypes arrived in New Zealand a week later (Figure 48Figure 49).

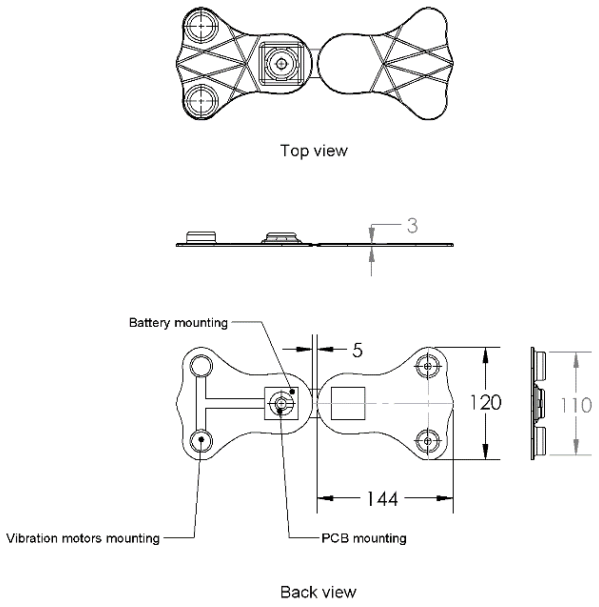


Figure 46 Double unit drawing

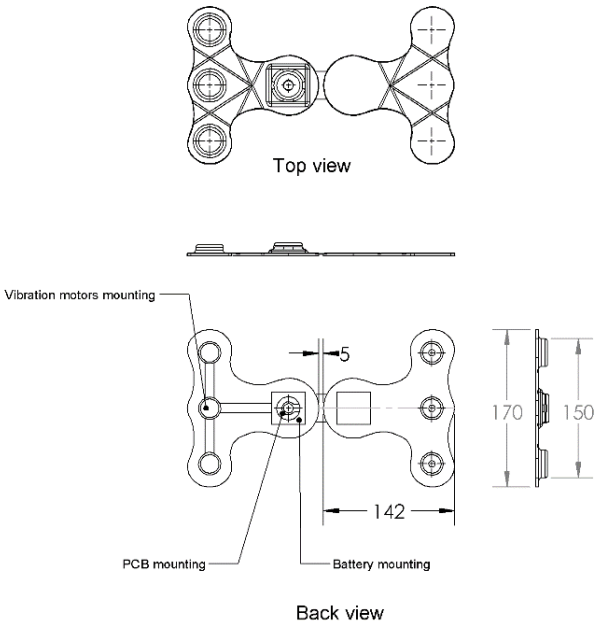


Figure 47 Triple unit drawing

Figure 48 Double unit prototype

Figure 49 Triple unit prototype

The textile design and knitting of the textile wrap structure were done in consultation with the knit technician at AUT's Textile and Design Lab, Gordon Fraser. This process started in parallel with making the vibration units and consisted of several trials to develop and achieve the final form of the wrap.

The type of knit technique was not envisaged at the beginning of the design ideation process. However, in having selected the design to be developed and in consultation with the first supervisor and the knit technician at AUT's Textile and Design Lab, this approach was found to be the most suitable method to create a versatile textile wrap. The challenges to overcome during this process included:

1. Forming a firm yet flexible and lightweight structure

2. Achieving exact dimensions (for the overall shape of the panel, the holes for vibration motors, and the slot to slide in vibration units) and distances between the hollows

3. Knitting a pocket into the textile wrap back (at each side) to house the vibrating unit

3. Making panels reversible (symmetric to be usable for both left and right foot)

4. Making the wrap in two yarn colours (black for background, and orange for pattern)

5. Comfortability of the textile wrap.

The knit technician chose two-colour rib jacquard for the area that required limited stretch and knitted in a cotton yarn. This technique allowed the wrap to be firm and (to some extent) stretchy.

The holes were knitted using two yarns. One of the yarns, Porte®[22], shrinks and locks when steamed whereas the other yarn, Grilon®[23], melts. This keeps the resulting fabric from unravelling, once the hole was formed.

The pocket was knitted using two-colour float jacquard on both the front needle bed and the rear needle bed. The pocket was knitted to the shape and size of the vibration unit to allow easy insertion and removal of the unit.

The overlapping flaps in the front of the wrap had to be knitted longer on one edge to allow the areas to cross over when the panel was constructed. This longer/shorter edge was achieved by utilising a knit technique known as "short row knitting".

A knit-to-shape technique using a Shima Seiki SRY 123LP ™ flat-knitting machine (http://www.shimaseiki.com/product/knit/sry/) helped to knit the textile wrap. The knit gauge was 14, and the knit structure was a mix of all knit jacquard[24] and tubular float jacquard[25]. The reason for this was the machine needle beds have 14 needles per inch – with full jacquard, intarsia, inlay & shaping capabilities.

The Shima Seiki SDS design system was used to create the knitting program for the knitted piece.

[22] A product of Nittobo Niigata Co., Ltd. (https://www.nittobo.co.jp/english/index.htm)

[23] A brand name of EMS Griltech (https://www.emsgriltech.com/cz/products-applications/markets-applications/bonding-yarns/)

[24] Patterned fabric knitted on a jacquard knitting machine. The pattern can be distributed either all over the fabric or on specific sections (Tortora, Johnson, & Merkel, 2014).

[25] In this process, the pattern is created by adding an extra yarn of a different colour to the stitches across the knitted panel or only in a particular area. ("FabricLink: Sweater Knit & Yarn Resource," n.d.)

A number of prototypes were produced in developing the textile wrap design. At first, an elementary rectangular-shaped textile panel was knitted with two holes on it using 2/36s NM grey merino yarns. The structure of this initial version was not robust enough; hence, the next trials aimed to knit a stronger textile panel. After attaining the desired strength for the panel (Figure 50), the next step was to create the panel with the final form (Figure 51).

Figure 50 The first knitting sample with an acceptable strength

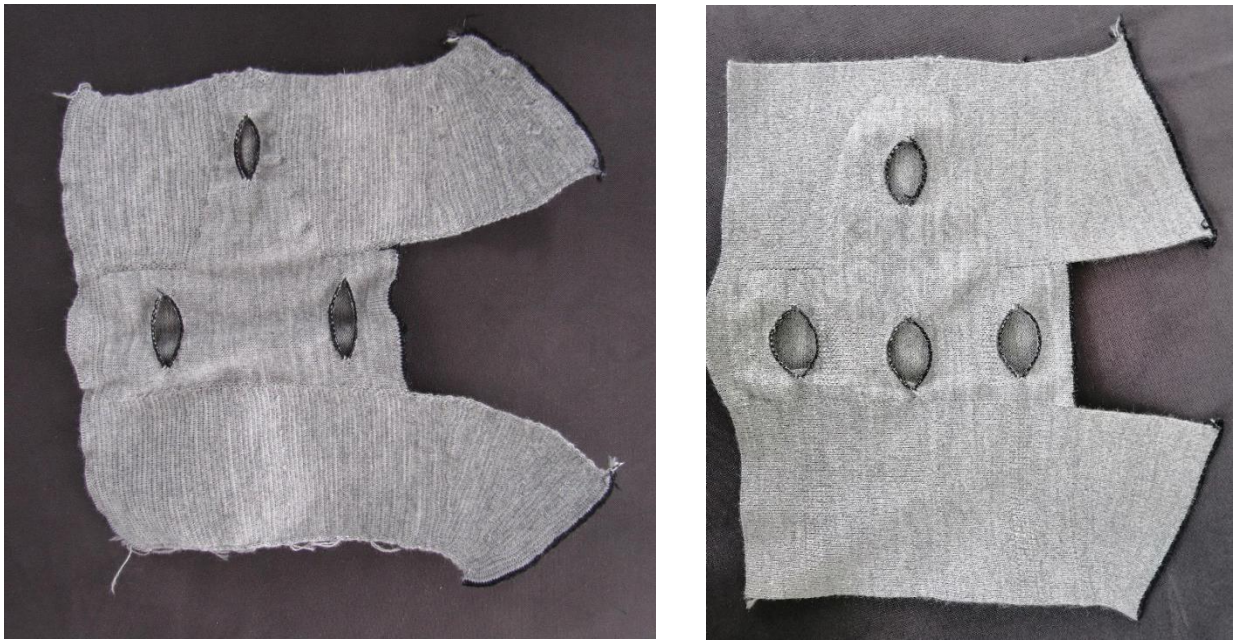


Figure 51 The first trials for creating the overall shape for the wrap

To create the final form of the panels, the *shoe last taping* method was borrowed from the shoemaking industry (based on the previous experience of the designer in working with a shoe manufacturer) to help the technician create the desired shape for the wrap (Figure 52,Figure 53 and Figure 54).

Figure 52 Shoe last with masking tape on it

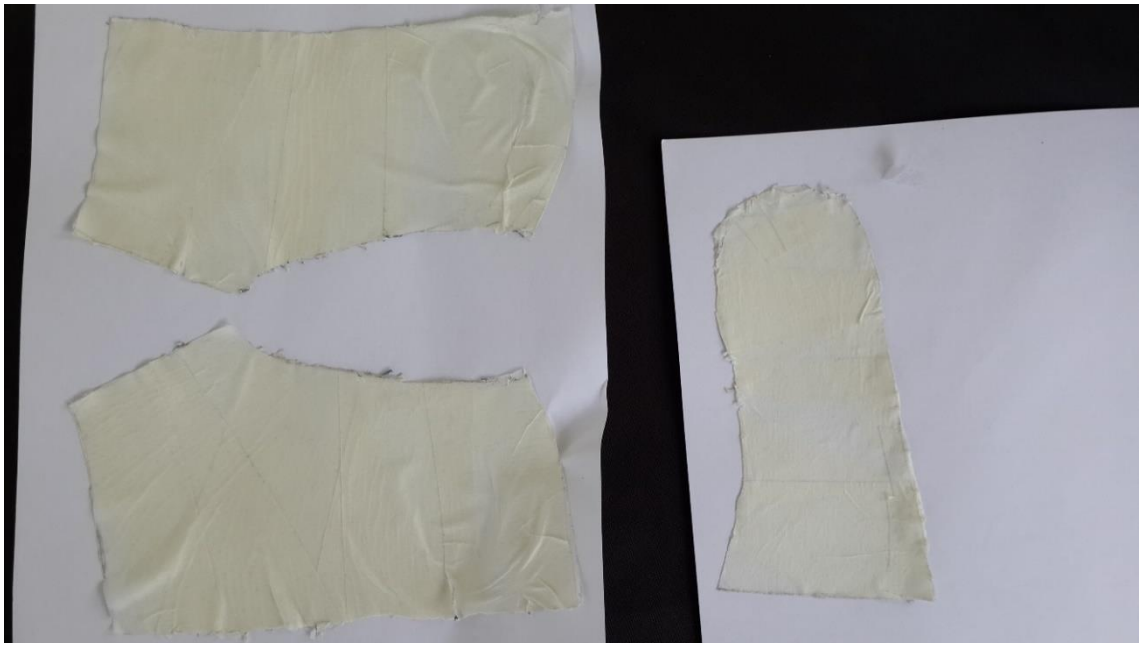


Figure 53 Using the shoe last taping technique to create the overall shape of the wrap

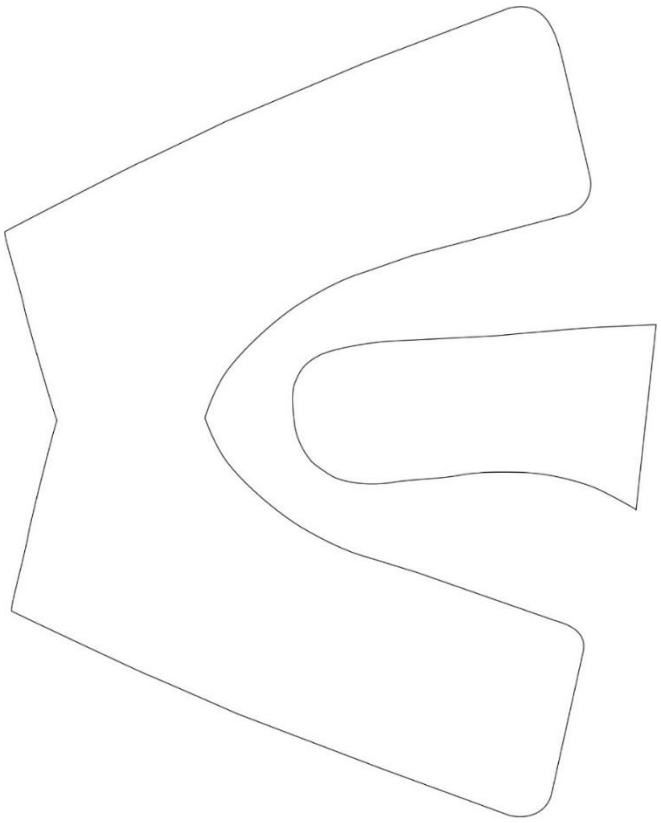


Figure 54 The 2D shape of the wrap created using the shoe last taping technique

The next step was to add an extra hole to the panels and make them symmetrical/reversible (Figure 55).

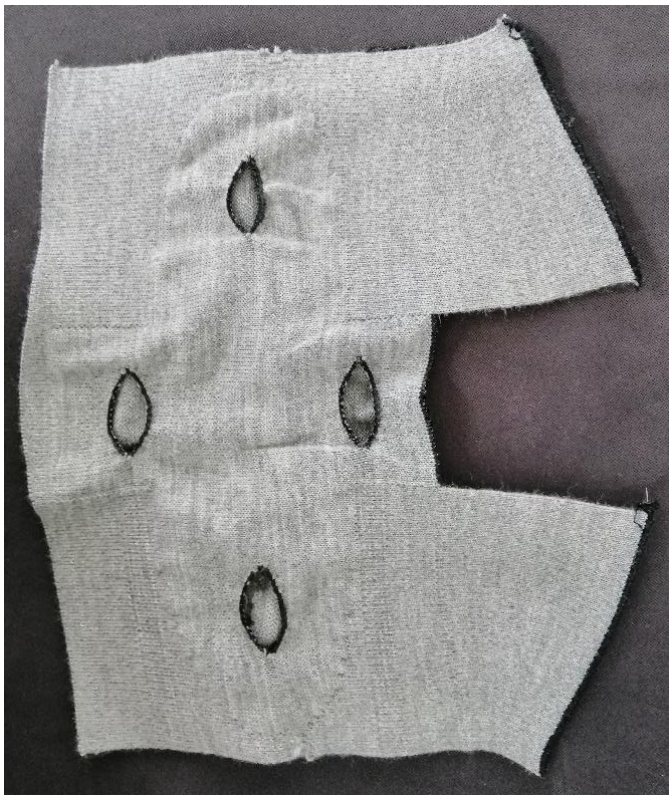


Figure 55 Panels with an additional hole (symmetrical and reversible)

After achieving the desired overall shape for the wrap, fabric panels were made in black and orange using cotton yarn, in the final stage. Cotton fibre has characteristics that fit well with the design requirements of the project. Cotton is soft, absorbent and breathable, and a good conductor of heat. It is non-allergenic and chemical free and cannot hold an electric charge, hence makes no static adherence (“Fact Sheets | Cotton Australia,” n.d.). In this step, a mixture of a 2/20s cotton count and a 2/60s cotton count were used to make the panels. Figure 56, Figure 57 and Figure 58 demonstrate the Shima Seiki programme patterns used to knit t both wraps.

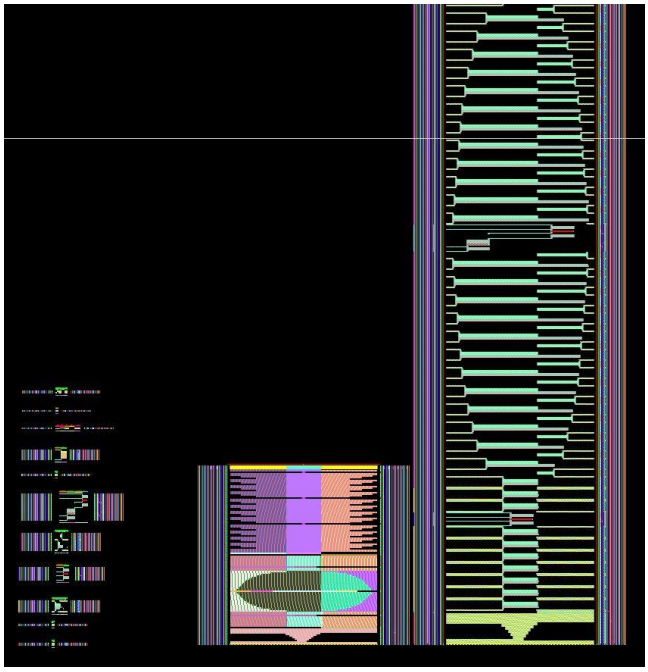


Figure 56 Shima Seiki programme pattern for the wrap pf the double unit

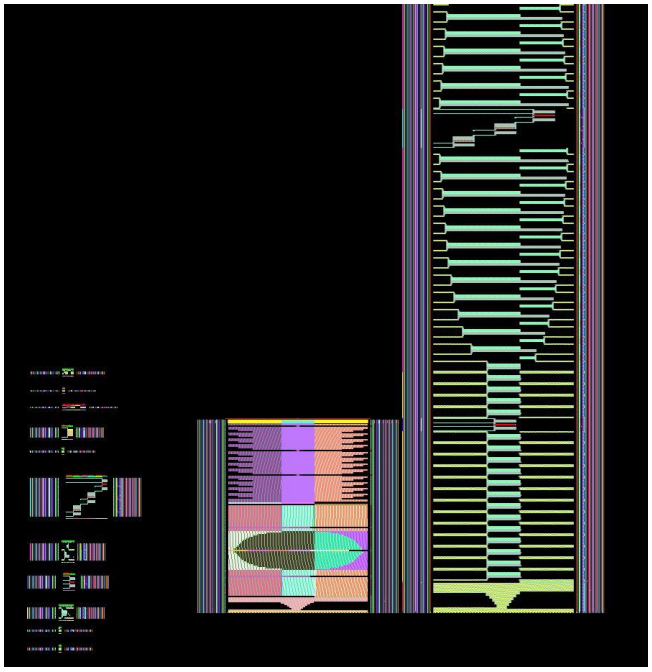


Figure 57 Shima Seiki programme pattern for the wrap of the triple unit

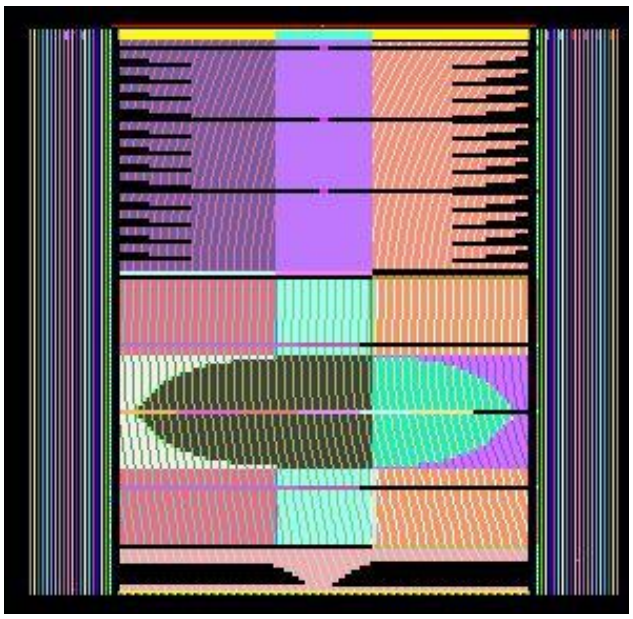


Figure 58 Shima Seiki programme pattern for the wrap of the triple unit

Each horizontal line in the drawing is made up of a combination of colours. The different colours represent packages that contain the knit instructions relevant to that line of knitting. The purpose of using packages is to give the technician the ability to construct complex knit programs in a simplified form, which to the trained eye are reasonably easy to decipher.

When the program is complete and ready to be converted into a knit file, the compressed image is developed using software that expands the packages into detailed knit instructions. The developed file is prepared to be processed by the software to be converted into a file type that can be used on the knitting machine.

The advantages of using compressed files in conjunction with package software become apparent here. The developed file requires a high level of technical expertise to understand. Therefore, if there is a knitting problem, it can be difficult and time-consuming to alter using the developed file. This is especially true if an alteration must be repeated many times throughout a generated file. By using package software, the technician can alter the relevant package, and this change is applied to every use of the package. There is a colour code that borders the developed file that helps the user identify the package used, as there are usually several packages being used to construct a file.

Figure 59 illustrates a Free Colour Package. Packages can be used when programming on the Shima Seiki SDS design System. They offer a range of advantages over Automatic software, especially for complicated garments.

When using automatic software to program knit panels the user will select their desired choices according to a menu-based format. The menus allow the user to choose from several functions, which can help with the knitting of the product. However, there are cases where the choices contained within automatic software are not extensive enough to produce the item required. In these cases, the technician can use package software. When utilising package software, the technician can select knit processes on an individual needle and apply these processes to selected groups on needles.

The package shown in Figure 59 has a possible colour combination of up to fourteen colours. Each colour shown on the horizontal bar underneath the package informs the knitting machine to carry out the knit process assigned to that colour. The number of colours in this package was

increased during the sampling process. At the beginning of the process, there may have been a few colours used, but to change any area of knit it may be vital to add additional colours.

The use of packages makes it easier to change specific areas in the panel, as is often required in prototyping and development of new garments. Numerous packages can be used in the building of a knit program, each with their particular colour combination.

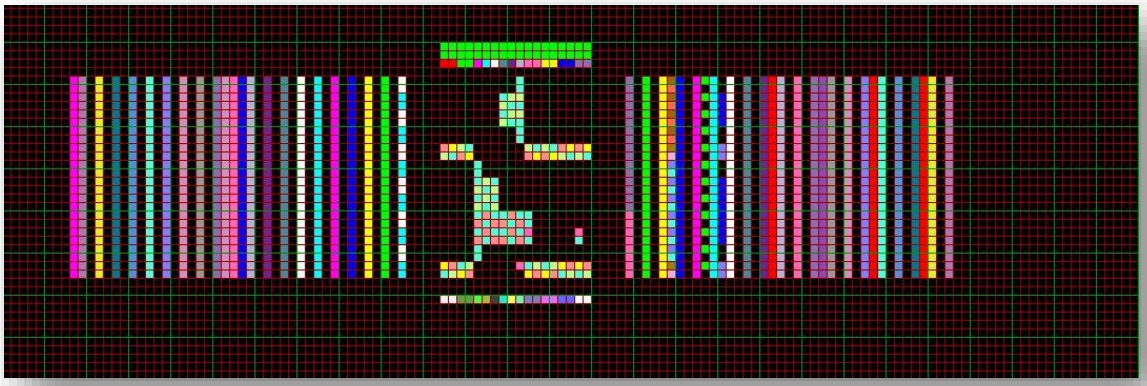


Figure 59 A Free Colour Package

Once the knit process was complete, and the knitted panels were ready, Velcro pieces and the company logo badge were attached to the wrap to complete it (Figure 60).

Figure 60 The complete textile wrap for the double unit.

4.2 Evaluation

This phase of the project involved asking medical experts for the assessment of the prototype of the final design to find out how successful the design process and the outcome have been while they were audio recorded. Through this second round of interviews, in a series of 20-minute meetings, the clinicians who participated in the first round of interviews were invited to comment on the prototype. They were provided with the built prototype for giving feedback and evaluating in terms of product design features such as appearance, comfortability, and usability via oral comments and using a Likert Scale Questionnaire[26] (See Appendix 7 for the questionnaire and the results). The oral and written feedback from the participants were reviewed thematically to identify the advantages and disadvantages of the prototype.

The device was given to the participants as unassembled, and they were asked to try realising how to use it. All the participants successfully inserted the units inside the wraps and understood how to fix the textile wrap on foot. They also managed to switch the device on; however, they did not discover that the product has more than one vibration mode. The feature was explained to them subsequently.

All the participants confirmed the wearability of the product. However, as they did not have the experience of using or seeing a similar device, it was not possible for them to compare the outcome of this research with similar products. The characteristics of the product the participants highlighted as the advantages included **lightness, comfort, safety, being washable** (the textile wrap) and **cleanable** (the vibration units), **adaptability to different foot sizes** and **having a beautiful and modern look**. A fascinated participant described the product as “futuristic” and believed the vibration unit looked like a “spaceship”!

As a disadvantage, most of the expert participants preferred the vibration unit material to be more flexible and to fit better to the curvature of the foot. Moreover, the experts mentioned using smaller vibration motors that can make the product slimmer (something to put on like a sock or to put inside the shoe like shoe insoles) would be more desirable. With the current Myovolt vibration technology, this is not feasible, but future technical advancements may help better address these issues.

One of the participants doubted if people with weak hands (such as people with osteoarthritis or rheumatoid arthritis in their hands) could easily fasten the Velcro. Due to the restrictions of not being able to include participants with plantar fasciitis in this study, it was not possible to have the prototype tested by such people. Myovolt will perform prototype testing later on the real patients to assess its clinical efficacy, and if needed, the necessary changes will be made to make the wrap more convenient to use.

Furthermore, participants were interested to know about the functional features of the product such as how to charge its battery, how long it can work when fully charged, the duration of each therapy cycle, etc. This information would need to be included in a product manual or user’s guide.

[26] Likert Scale Questionnaire are usually used to evaluate how participants feel or think about a special topic by rating a number of statements by marking (for example circling around) them or choosing the closest score number (for example, 1 2 3 4 5) .

4.3 How to use the product

Figure 61 displays the product fixed around the foot. As vibration waves penetrate deeply into the tissues, there is no need to use it only on a barefoot. The user needs to remove their shoes (if already worn) and apply the device either directly on foot or the foot covered by socks.

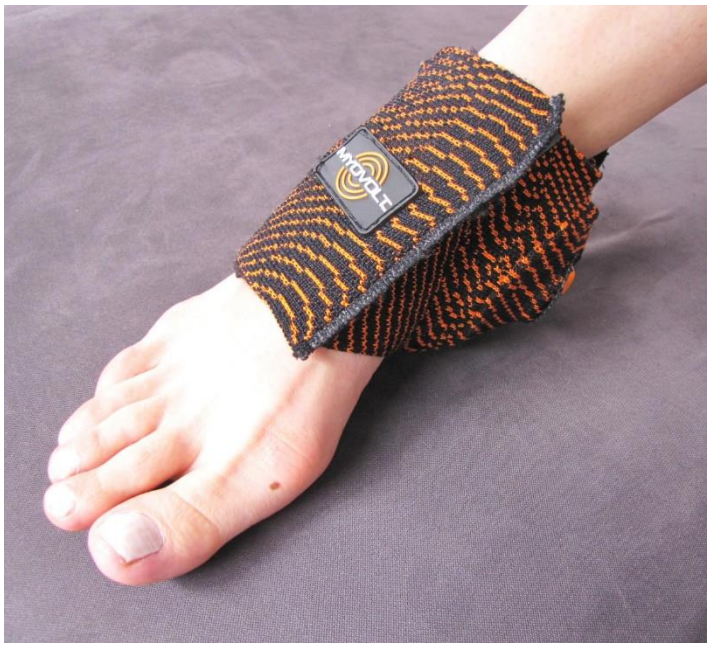


Figure 61 The device attached to the foot

To use the product, the user has to follow these steps:

1. Insert the vibration unit inside the slot prepared on the side of the wrap without the Myovolt logo badge (right or left side, depending on the foot affected by plantar fasciitis) (Figure 62).

Figure 62 Insert the vibration unit inside the textile wrap.

2. Place the wrap (with vibration unit inserted inside) under the foot, so the flat surface of the vibration unit is facing towards the foot sole (Figure 63).

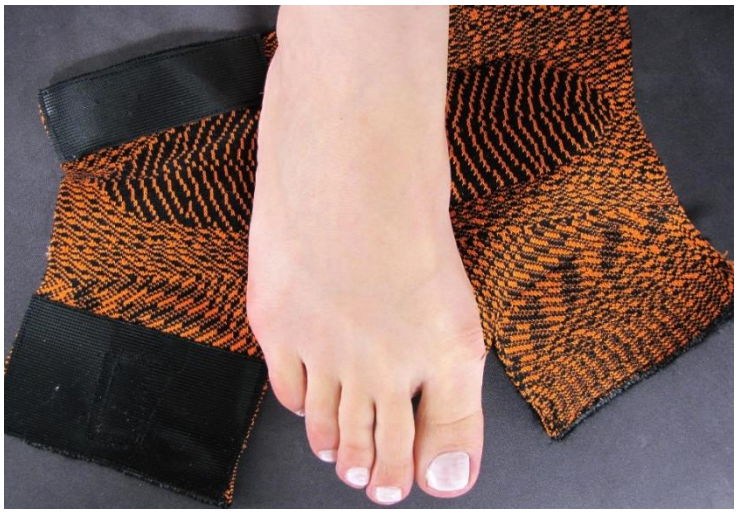


Figure 63 Place the vibration unit inserted in the wrap under the foot.

3. Fix the Velcro at the back of the foot (Figure 64).

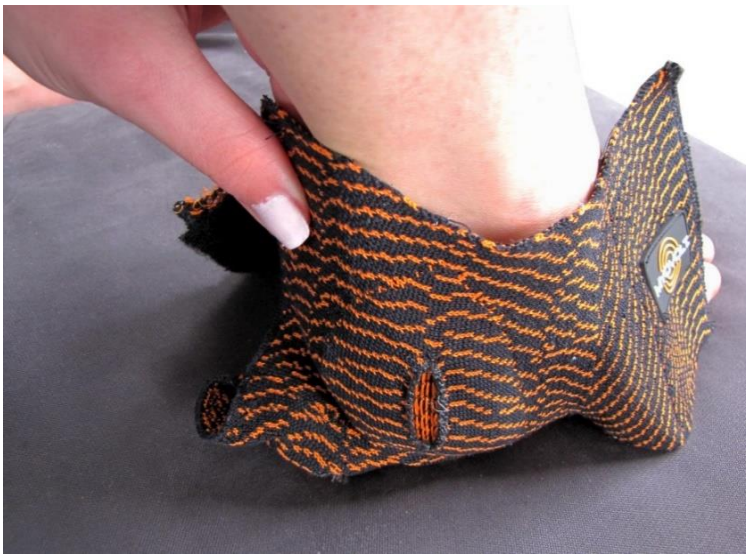


Figure 64 Fix the textile wrap at the back of the foot.

4. Fix the Velcro pieces at the front of the wrap and adjust them, so it is firmly yet comfortably encloses the foot (Figure 65).

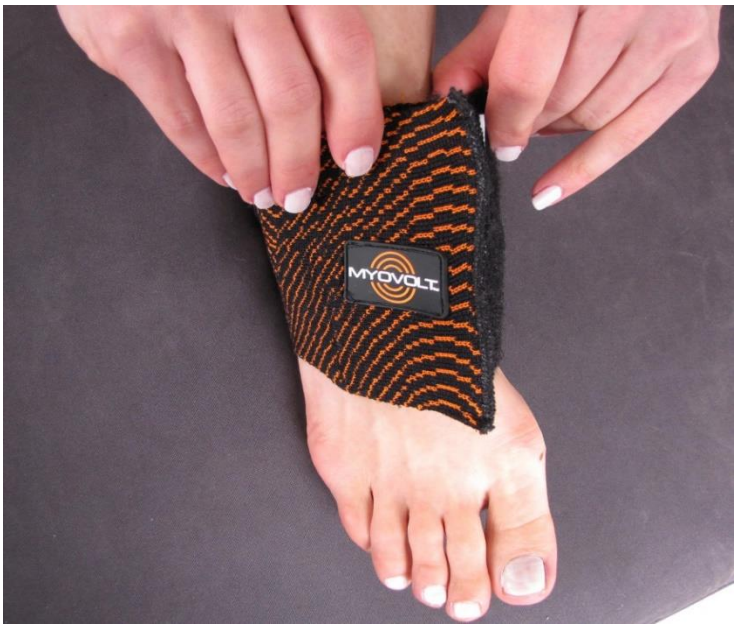


Figure 65 Fix the textile wrap at the front.

5. Push the power button; then hold it for 3 seconds until the unit starts vibrating (Figure 66).

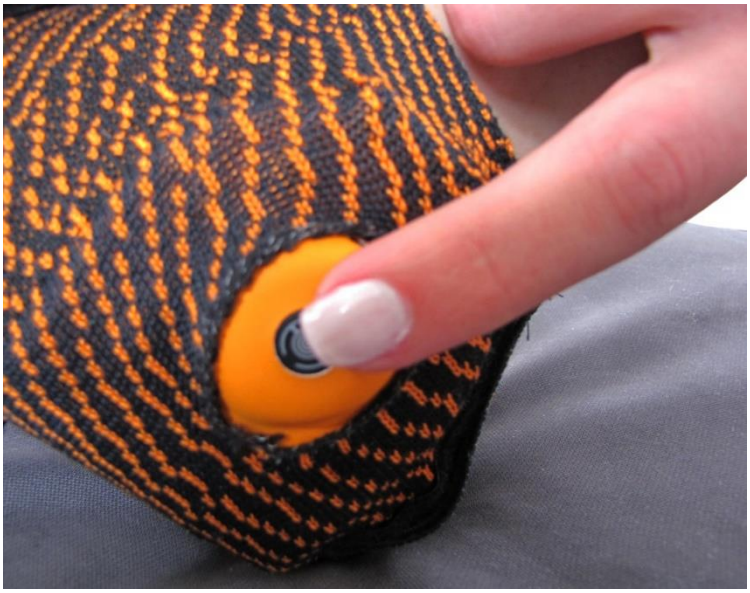


Figure 66 Push the power button and hold it for three seconds. Then use it to change the vibration mode.

6. Pushing the power button quickly, the user can choose one of the three predefined programmes.

4.4 Product features

The key features of the prototype include:

1. **Adaptability to different foot sizes:** The product comes in two versions (Figure 48 Figure 48Figure 49). The double unit fits the small-medium size, and the Triple unit fits medium-large size feet.

2. **Wearability:** Using a textile wrap that feels soft and comfortable enables hands-free use of the device. Furthermore, the adjustable textile wrap fixes the vibration unit securely to the foot sole; therefore, it allows applying vibration more deeply.

3. **Flexibility:** Using EVA as the material for the vibration units encloses the technology and allows the placement of some creasing lines on them. The units are flexible and can fit the foot's curved form.

4. **Lightness:** The double unit enclosed in the textile wrap weighs about 130gr, and the weight of the triple unit plus the textile wrap is approximately 200gr.

5. **Ease of use:** According to the experts who participated in the second round of the interviews, this product is straightforward and easy to use. The user needs to insert the vibration units inside the textile wrap first (Figure 67 and Figure 68) and then fix the textile wrap on foot.

Figure 67 The double unit inside the textile wrap

Figure 68 The triple unit inside the textile wrap

6. **USB-chargeable battery:** Using a conventional USB (Type C) cable, users can easily attach the Li-Polymer battery of the device to a computer USB port or a USB wall adapter and charge the vibration units (Figure 69). When fully charged, the battery runs up to 80 minutes. The operation voltage of the battery is 3.7V.

Figure 69 USB-chargeable vibration units

7. **Three modes:** The device comes with three predefined vibration programmes (two pulsing and one continuous vibration programmes), each lasting for 10 minutes.

8. **Frequency range:** Vibration motors of the device can create a vibration frequency of 0 – 170Hz.

9. **Integrated multicolour touch control (power button):** This button shows the different possible modes including ‘switched on/off’, ‘low charge’ and ‘full charge’.

10. **Easily cleanable:** The vibration units’ enclosures are easy to clean using wipes, and disinfectant liquid cleaners (or wet wipes) and the textile wrap is washable (hand washing is recommended).

11. **Wireless control:** Users can also control the vibration intensity and duration using a mobile application according to their needs and desires.

4.5 Sponsor company feedback

Once prototyping and the second round of interviews finished, the researcher reported the sponsor company about the outcome and asked them to give feedback on the project progress. The following is the comment given by the Myovolt managers.

"Farshid worked with Myovolt throughout his research project covering several phases of development for a new foot-based device. Initially he created an extensive range of designs which were evaluated for suitability and engineering merit. Farshid worked well collaboratively with Myovolt, and the other departments to develop and fine-tune the direction for innovative designs to work towards a final working prototype. At several points, he had to pivot the design to suit technical and functional suitability for the foot device and we think the final result will be used in the Myovolt medical range.

Overall, the project with Farshid has been a success and his talents have resulted in a fast-tracked development project."

5. Discussion

5.1 The outcome of the research

The data gathered through the study was principally qualitative and can help define a pathway for future work. The aim of collecting this data was to address the following research question:

1. What are the most critical considerations including users' needs, technical requirements, market and financial restrictions in the design of a wearable vibration therapy device for domestic users to improve plantar fasciitis, using Myovolt's existing technology?

2. How can the design process and specific design methods be employed to answer users' needs and design requirements in the form of an easy-to-use product for the purpose of the project?

Expert interviews and the theoretical inquiry identified the requirements to consider in the design process. In particular, interviewing clinical experts provided greater insight into what end users may expect from a device (in the first round), and how they might experience the designed product (in the second round). Experts' motivation and interest in the research in both stages of the interviews, especially the second stage when seeing, testing and giving feedback on the prototype, was very promising and helpful to the researcher.

At the end of the project, the positive feedback from experts and the sponsor company, Myovolt on the prototype (and their intention to add the product to their current product portfolio) confirmed that the researcher has successfully responded to research questions despite the limitations of the study.

The project also gave the researcher an opportunity to develop theoretical and practical knowledge, explore new disciplines and technologies (physiotherapy and podiatry as well as textile knitting), and work with people from other fields and backgrounds. Moreover, doing research and reflecting the entire design process stages under the supervision of academic supervisors was an opportunity for the researcher to learn and apply new research methods and research writing in a professional way.

5.2 Significance

This investigation has produced valuable insights into the design and development process of a user-centred wearable vibration therapy device. It also forms a sound basis for understanding and satisfying the requirements to consider in the design of wearable products for home rehabilitation. It has introduced a new material and manufacturing process (knit-to-shape process as an alternative for cut-and-sew with neoprene) to the company, a technique that enables excellent conformability and fit as well as manufacturing advantages.

Additionally, the multidisciplinary approach taken in this study helped to achieve the goal of using design thinking and modern technology to create a user-friendly product addressing an old human problem in a novel way.

The project not only helped the researcher employ his previously gained knowledge of industrial design to create a new user-centred product for an industrial company, but also can be used as a guideline for further academic and professional design studies related to medical/therapeutic products. It can help future researchers/students realize how to deal with designing a new medical product to achieve the best possible results regardless of all the limitations they may face in the project, whether it is not clearly defined requests of the third parties (such as industrial partners), time and budget restrictions, ethical limitations, etc.

The design requirements concluded from the background research and experts' interviews, such as secure and comfortable attachment to the foot, applicable to different foot sizes, etc. were addressed through the design solution created through the project. In relation to the initial request of the industry partner, the final design is a wearable product that uses Myovolt's existing vibration technology to help domestic users manage plantar fasciitis independently at home.

5.3 Limitations of the study

As with most research, this project was also subject to some limitations. The first restriction was the lack of previously conducted investigations both into clinical trials of the efficacy of the focal vibration for reducing the pain caused by plantar fasciitis and into other design projects that aimed to design a user-centred therapy device for treating this condition.

The other limitation of this study was the lack of user participants due to the difficulty of obtaining ethics approval (See 3.1.2 Field study). Moreover, due to time restrictions, it was possible to invite only a limited number of expert subjects to attend the interviews. A more significant number of participants to share their experiences and perceptions in the interview sessions might improve understanding of the end users' needs and evaluating the degree to which these requirements may have been satisfied. However, the group of experts interviewed for this study provided valuable insights that informed the design development and product evaluation.

Finally, due to the strict one-year timeframe for the masters' project, and the complexity and expertise required in setting up medical testing, it was not possible to test the therapeutic efficacy of the device. Myovolt will complete this process outside the scope of this master's research project.

5.4 Need for future work

This research project has highlighted a number of opportunities for future work. First, this investigation provided one final design solution (attaching the vibration unit to the foot with a textile wrap, as selected by the sponsor company) for enabling domestic users to manage the pain caused by plantar fasciitis. Other alternatives, proposed in the initial concept stage of this project, such as concepts based on using double-sided adhesive tapes, could also be explored.

Furthermore, in the next stage (the clinical trial) to be conducted by the company, the built prototype needs to be tested on actual patients with plantar fasciitis to evaluate its medical efficacy and usability in a variety of real-world situations.

As discussed in the section The use of vibration therapy for musculoskeletal disorders: a review of the current research, there is further need for clinical studies on the efficacy of using focal vibration therapy devices (either handheld or wearable) to relieve plantar fasciitis pain.

This research also can provide an example for future studies to merge design thinking, wearable technology development and health science (notably physiotherapy, podiatry and rehabilitation) to create new user-centric medical products.

Finally, any product design can be reviewed in a suitable time to find out how to improve or even redesign it to answer the ever-changing desires or trends of the customers or to benefit from new advancement in technology, manufacturing processes or materials. For future development of this product, the design of smaller vibration motors and the creation of slimmer, lighter and more flexible vibration modules that would correspond better to the foot's complex shape would enable refinement of the design.

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Appendices

Appendix 1: HDEC Scope of Review form

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

HDEC – Scope of Review Form

Introduction:

This form will help determine whether HDEC review is required, and if not, will result in an 'out of scope' letter from HDEC. This letter will not include an HDEC reference number but can be used as evidence of HDEC review not being required. This form is not considered a full HDEC application and can only determine whether a potential application should be submitted to HDEC for review. Please note this application form is oriented towards observational research. For a table of features of studies and their corresponding HDEC review level, see appendix 3.

Please note, your locality may have additional ethical review policies, please check with your locality. If your study involves a DHB, you must contact the DHB's research office before you begin. If your study involves a university or polytechnic, you must contact its institutional ethics committee before you begin.

Submission Process:

Once you have completed the form please email it to HDECS@moh.govt.nz

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Before you begin:

What is health and disability research?

Health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes. Consider whether your study is health research, or some other kind of research. Only health research is reviewed by HDECs.

Application Form

Study title	Design of a wearable vibration therapy device for foot and ankle
First Name	Farshid
Last Name	Sarmast
Address	2/8-Scotland Place-Hillcrest-Hamilton
Organisation	Auckland University of Technology (AUT)
Email	Farshid.sarmast@gmail.com
Phone	0223117291

Q1 Summary of study – briefly explain your study using lay language. This explanation should include:

- your participant population
- study aims
- study question(s)
- any procedures,
- benefits to individuals or future people and
- and anticipated risks for participants.

This study is part of a Master of Creative Technologies thesis. The purpose of the full Master of Creative Technologies study is to research and design a wearable device to relieve plantar fasciitis pain using vibration as the therapeutic method for domestic use. This ethics application is concerned with user-centred research to help understand experts' (physiotherapists or podiatrists with experience in treating plantar fasciitis) feedback that will be used to inform the design process. Data will be collected through experts' questionnaires, up to 3 experts' interviews. The minimum number of participants will be 5, and the maximum number will be 10.

The design process will be informed by the feedback from experts in foot/ankle rehabilitation (podiatry or physiotherapy practitioners) and experts in product design. The research findings will contribute to developing a device to enable people with plantar fasciitis to manage their condition, anywhere and anytime, independently, in a simple and convenient way, using vibration therapy.

The intended output of the Master of Creative Technologies research is a prototype device which will be shown later to clinicians to get feedback only about usability, comfort and convenience. In this step, the participants will be observed, photographed or video-recorded (if needed) to understand how they might feel about the prototype and whether the design prototype is understandable, easy to use and comfortable or not. If the participants find aspects of the prototype unsatisfactory, the design process would be revised to make the necessary changes and improve the design.

The industry partner of this project, which is funded by Callaghan Innovation, is Myovolt Ltd, based in Christchurch. Myovolt already manufactures and markets a vibration therapy device consisting of a vibrating module which is wrapped around different body parts (including leg, neck, arm, etc.) using a fabric band. They aim to redesign their product to fit the foot properly and comfortably and in an appealing shape.
The entire research project seeks to address three research questions:

1. What are the most important considerations in the design of a wearable vibration therapy device for domestic users to improve plantar fasciitis?
2. What design and technical approaches can help to integrate vibration technology into an easy-to-use wearable rehabilitation device?
3. What are the most suitable materials and manufacturing processes that help create this product?

The benefits of the research are as follow:

- For the clinicians (experts), an opportunity to collaborate in the research and design process for a new wearable device for relief of plantar fasciitis pain.

- For the researcher, an opportunity to gain feedback from clinicians and health experts and consider the needs of the final users in the design process. This research will contribute towards completion of a Master of Creative Technologies.
- For people with the disease: Plantar fasciitis is commonly experienced pain. Therefore, developing a convenient wearable device to help self-management of this condition is advantageous.
- For Myovolt, the research may inform the development of a new product to manufacture and commercialize.
- For Callaghan, this is an opportunity to support an R&D project for a Kiwi company and an academic thesis.

Health information:

Is there any identifiable health information involved in your study, at any point in time? (E.g. identifiable when the information is accessed, recorded, stored).

Please explain what information is accessed for the project, and comment on its identifiability at each stage of the study.

Participants' real names will not be used anywhere in the research. Instead, identities will be anonymised, by referring to expert 1, 2, … Identifiable information (participant information sheets, contact details) will be stored separately from data collected for analysis. Any discussions of data with supervisors or industry partners will use the anonymised identities.

No, go to Q4

Q2 Has consent for accessing records for the purpose of **this** project been sought from patients? Please explain your answer.

Not applicable.

Q3 Is the access and use of health information directly related to the purpose it was collected for?

Not applicable.

Q4 Is your study an observational study or an audit and related activity?

Please review Appendix 1 of this application, select a type of study and **justify your answer.**

An observational study.

Q5 Is this project conducted at the applicant's own institution or does it involve multiple health agencies?

At the applicant's own institution.

Q6 Does this project have a hypothesis? Will the study produce any generalisable information? (the extent to which the findings of a clinical study can be reliably extrapolated from the subjects who participated in the study to a broader patient population and a broader range of clinical settings.)

The data collected from the interviewing and observation of the experts and participants will be used in the design process of a product that is aimed to be commercialised and presented to a larger population.

Human tissue:

Q5 Will your study use human tissue? Yes / No ✓

If yes, please note that HDEC review is required for **most** health research studies that involve human tissue.

For research involving tissue, HDEC review is not required if tissue is **both** anonymous **and** already consented for use. For example, when working with de-identified tissue that is provided to researchers from a tissue bank, where consent for future research is already provided for storage and future use.

An audit or related activity requires HDEC review only if it involves the use, collection or storage of human tissue without consent, other than in accordance with a statutory exception (set out at section 20(f) of the Human Tissue Act 2008 and Right 7(10)(c) of the Code of Health and Disability Services Consumers' Rights 1996).

Please provide information on the use of tissue in this study.

- For research, explain the consent and identifiability of the tissue.
- For audit please explain how your study meets a statutory exception.

Risks to participants:

Q6 If you have human participants they must be recruited in their capacity as consumers of health and disability services, relatives of consumers, or volunteers in early-phase clinical trials (for instance, health professionals or members of the general public)

According to Appendix 2, are any of your participants vulnerable? Please explain your answer below.

No, the research will not involve vulnerable people.

Supporting Documents:

1. Please list here any supporting documents that may assist in HDECs scope of review assessment.

Appendix 1 – HDEC Scope from SOP

When does a study require HDEC review?

Main criteria

1. Health and disability research requires HDEC review only if it involves one or more of the following:

    1.1. **human participants** recruited in their capacity as:

        1.1.1. consumers of health or disability support services, or

        1.1.2. relatives or caregivers of consumers of health or disability support services, or

        1.1.3. volunteers in clinical trials (including, for the avoidance of doubt, bioequivalence and bioavailability studies)

    1.2. the use, collection or storage of **human tissue** (as defined by the Human Tissue Act 2008), unless:

        1.2.1. informed consent (which may include informed consent to future unspecified research) has been obtained for such use, and tissue will not be made available to researchers in a form that could reasonably be expected to identify the individual(s) concerned, or

        1.2.2. one or more of the statutory exceptions to the need to gain informed consent set out at section 20(f) of the Human Tissue Act 2008 (or Right 7(10)(c) of the Code of Health and Disability Services Consumers' Rights 1996) applies

    1.3. the use or disclosure of **health information** (as defined by the Health Information Privacy Code 1994), unless:

        1.3.1. this use or disclosure has been authorised by the individual(s) concerned, or

        1.3.2. health information will not be disclosed to researchers in a form that:

            1.3.3. could identify, or could reasonably be expected to identify, the individual(s) concerned, or

            1.3.4. would allow for the information to be matched with other data sets (for example, through the use of non-encrypted identifiers such as National Health Index numbers).

Exemptions to main criteria

2. **Studies on low-risk devices:** A study involving a medical device does not require HDEC review if the device is (or would be) classified as a low-risk (class I) medical device by Australia's Therapeutic Goods Administration (TGA).[1]

3. **Minimal-risk observational studies:** An observational study requires HDEC review only if the study involves more than minimal risk (that is, potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study).

4. For the avoidance of doubt, an observational study always involves more than minimal risk if it involves one or more of the following:

    4.1. one or more participants who will not have given informed consent to participate, or

    4.2. one or more participants who are vulnerable (that is, who have restricted capability to make independent decisions about their participation in the study),[2] or

    4.3. standard treatment being withheld from one or more participants, or

    4.4. the storage, preservation or use of human tissue without consent, or

    4.5. the disclosure of health information without authorisation.

5. **Audits and related activities:** An audit or related activity requires HDEC review only if it involves the use, collection or storage of human tissue without consent, other than in accordance with a statutory exception (set out at section 20(f) of the Human Tissue Act 2008 and Right 7(10)(c) of the Code of Health and Disability Services Consumers' Rights 1996).

6. **Student-led research:** From 1 January 2013, a study conducted wholly or principally for the purposes of an educational qualification requires HDEC review only if it:

    6.1. is an intervention study, or

    6.2. is not conducted at or below Master's level.

Inclusions

7. Regardless of the exemptions to the main criteria outlined above, a study requires HDEC review if it:

    7.1. involves the use of human tissue samples taken as part of New Zealand's Newborn Metabolic Screening Programme (known as 'Guthrie cards'), or

    7.2. is funded by the Health Research Council of New Zealand (HRC) and is not able to be reviewed by an institutional ethics committee approved by the HRC's Ethics Committee (HRCEC).

    7.3. involves the establishment or maintenance of a tissue bank (see section 13).

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[1] The TGA's guidance on device classification can be found from page 77 of the Therapeutic Goods Administration's 2011 *Australian regulatory guidelines for medical devices*, available from the TGA's website at http://tga.gov.au/pdf/devices-argmd.pdf.

[2] This term is defined more fully in the *Ethical Guidelines for Intervention Studies*.

Appendix 2 – Definitions of observational research

For more information please see http://ethics.health.govt.nz/ethical-standards-health-and-disability-research

Observational research:

The primary purpose or justification for observational research is to add to generalisable knowledge about a health or disability issue. The six main types of observational research are summarised below.

A note from the HDEC Secretariat: Generally speaking if health information is being accessed for research and the research is not directly related to the purpose for which the information was originally collected (e.g. quality audit) then it falls into the category of observational research.

Case control studies examine the relationship between an attribute and a disease by comparing those with and without the disease with respect to the presence of the attribute or level of exposure to it.

Cohort studies examine the relationship between exposure to a factor or factors and the probability of the occurrence of a disease (or other outcome) by observing large numbers of people over a period of time and comparing incidence rates of the disease (or outcome) in relation to exposure levels. A cohort study may be a clinical cohort study (for example, where a group of patients with a given disease is followed to examine the prognosis).

Cross-sectional studies examine the relationship between diseases (or other health-related characteristics) and other variables of interest in a defined population at one particular point in time, by collecting health and other information concerning members of the population. These include questionnaires or surveys done for research purposes.

Case reports are reports of cases from health or disability services or research settings.

Case series describe a set of cases of a disease (or similar problem). For example, a clinician may assemble a case series on a topic of interest, such as an unexpected adverse effect experienced by patients taking a particular medication.

Descriptive studies examine the existing distribution of variables in populations, for example, analyses of cancer registry data or emergency department data by person, place or time.

Audit or related activity:

The primary purpose or justification for an audit or related activity is to improve delivery of the particular health or disability support service being studied or to control a threat to public health. (The results of audits and related activities should be disseminated at least to those able to take necessary action. Wider dissemination, including through publication in scientific journals, may sometimes be appropriate.) The 10 main types of audit and related activities are summarised below.

A note from the HDEC Secretariat: For the sake of clarity, the purpose of accessing identifiable health information for audit or related activity must be **closely connected** to the purpose for which the information was originally connected and can reasonably be assumed to be within the expectations of the person from whom it was collected.

Audits involve the systematic evaluation of aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality.

Programme evaluation is a type of audit where a whole programme is evaluated, rather than specific interventions.

Evaluation studies aim to determine the relevance, effectiveness and impact of activities in the light of their objectives. Several types of evaluation are distinguished, including evaluation of the structure, process and outcome of an activity.

Quality assurance activities aim to improve health and disability support services by assessing the adequacy of existing practice against a standard.

Outcome analyses involve the assessment of health and disability support service quality by reviewing health care information to evaluate outcomes without comparing them against a standard. For example, clinicians may retrospectively examine health care notes and perform descriptive analyses to determine the outcome of medical treatment or course of a particular illness.

Benchmarking aims to improve practice through the comparison of two or more health and disability support services.

Public health investigations explore possible risks to public health, are often of an immediate or urgent nature, and are often required by legislation. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions.

Public health surveillance involves the monitoring of risks to health by methods that include the systematic collection, analysis and dissemination of information about disease rates.

Pharmacovigilance (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population, by such methods as the spontaneous reporting of adverse events and the monitoring of all adverse events for a restricted group of medicines (prescription event monitoring).

Resource utilisation reviews evaluate the use of resources in a particular health or disability service activity, for example, by reviewing health records to determine health care inputs such as chest X-rays for patients with a particular diagnosis.

Appendix 2 – Vulnerable populations

For more information please see http://ethics.health.govt.nz/ethical-standards-health-and-disability-research

A study poses more than minimal risk where one or more participants are potentially vulnerable.

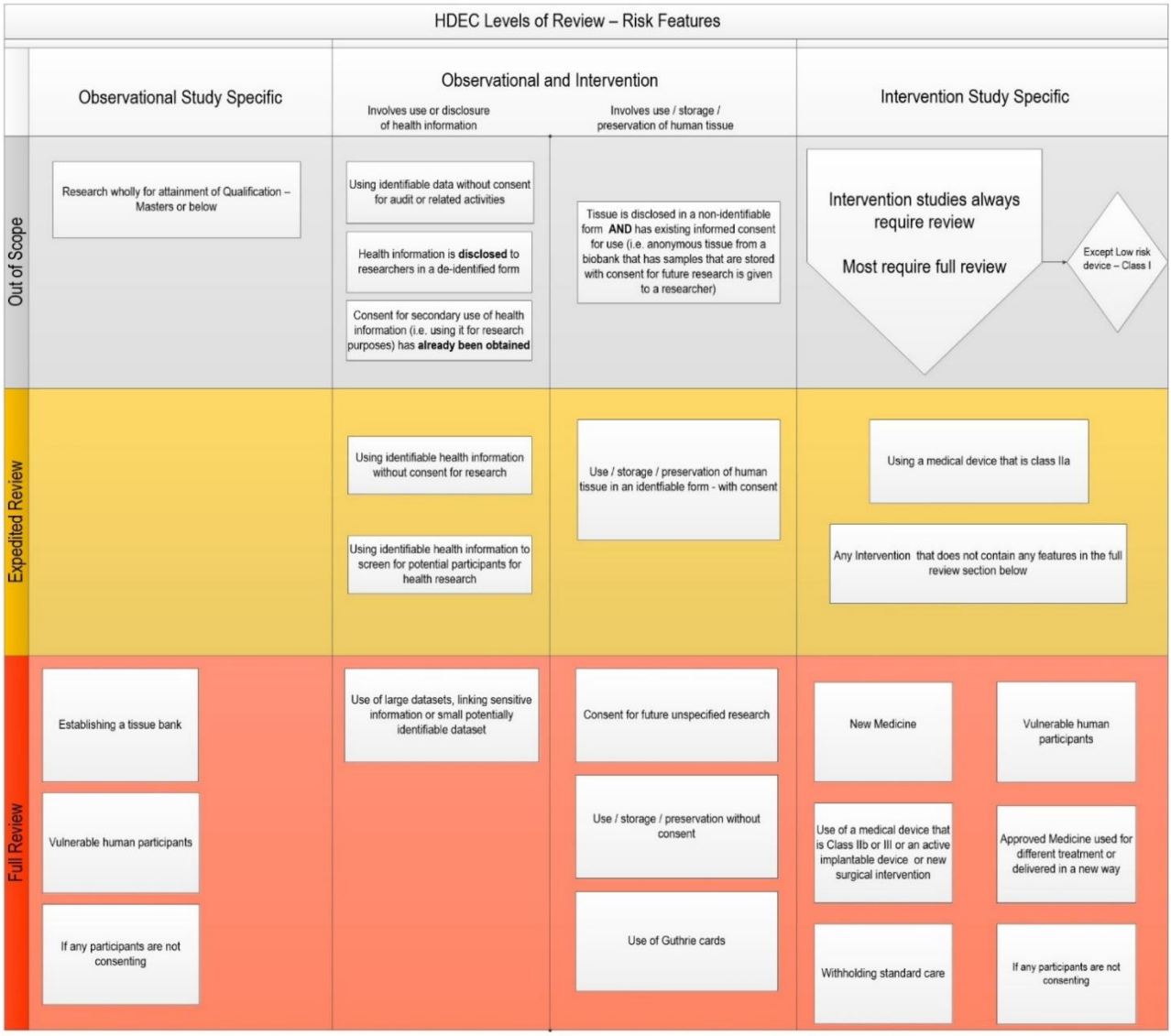
Vulnerability is a broad category. It includes people who have restricted capability to make independent decisions about their participation in the study (ie, who might traditionally be regarded as lacking the capacity to consent to participate). It also encompasses people who may lack the ability to consent freely or may be particularly susceptible to harm either because of their health status, physical or mental capacity or employment status, or as a result of imprisonment. Non-exhaustive examples of potentially vulnerable people include:

- children and young people
- people with mental illness
- people with serious intellectual disability
- people with English as a second language and/or a different cultural background to the investigators (for studies whose details are primarily, or only, stated in English)
- people whose freedom to make independent choices is restricted (eg, prisoners, employees or students of a researcher or sponsoring company).

It is important to remember that even if a group is identified as being likely to be vulnerable, the label may not apply to all individuals in such groups, and even where it does apply, it may do so only intermittently.

A note from the HDEC Secretariat: This may include the context of recruitment.

Appendix 3 – Features of Health Research



Appendix 2: Ethics Application Form Submitted to AUTEC

Please do not staple your application

Auckland University of Technology Ethics Committee (AUTEC)

AUT
TE WĀNANGA ARONUI O TĀMAKI MAKAU RAU

EA1

APPLICATION FOR ETHICS APPROVAL BY AUTEC

For AUTEC Secretariat Use only

_____/_____

Please print this application single sided in greyscale and do not staple. Once this application has been completed and signed, please read the notes at the end of the form for information about submission of the application for review.

NOTES ABOUT COMPLETION

- Ethics review is a community review of the ethical aspects of a research proposal. Responses should use clear everyday language with appropriate definitions being provided should the use of technical or academic jargon be necessary.
- The AUTEC Secretariat and your AUTEC Faculty Representative are able to provide you with assistance and guidance with the completion of this application which may help expedite the granting of ethics approval.
- The information in this application needs to be clearly stated and to contain sufficient details to enable AUTEC to make an informed decision about the ethical quality of the research. Responses that do not provide sufficient information may delay approval because further information will be sought. Overly long responses may also delay approval when unnecessary information hinders clarity. In general, each response should be around 100 words.
- AUTEC reserves the right not to consider applications that are incomplete or inadequate. Please do not alter the formatting or numbering of the form in any way or remove any of the help text.
- Comprehensive information about ethics approval and what may be required is available online at http://aut.ac.nz/researchethics
- The information provided in this application will be used for the purposes of granting ethics approval. It may also be provided to the Graduate Research School, the Research and Innovation Office, or the University's insurers for purposes relating to AUT's interests.
- The Form is focussed around AUTEC's ethical principles, which are in accordance with the *Guidelines for the approval of ethics committees* in New Zealand.

To respond to a question, please place your cursor in the space following the question and its notes and begin typing.

A. *Project Information*

A.1. What is the title of the research?

If you will be using a different title in documents to that being used as your working title, please provide both, clearly indicating which title will be used for what purpose.

Experts' opinions research to inform the design of a wearable vibration therapy device

A.2. Is this application for research that is being undertaken in stages? ☐ Yes ☒ No

If the answer is 'Yes' please answer A.2.1 and the following sections, otherwise please answer A.3 and continue from there.

A.2.1. Does this application cover all the stages of the research? ☐ Yes ☒ No

If the answer is 'No' please provide details here of which stages are being covered by this application, otherwise please answer A.3 and continue from there.

No. This application is to cover data gathering including experts' opinions study that will be used to inform a design research project. The full Master of Creative Technologies project also includes a literature review, current products review, material and technology review, as well as research through design that will result in the development of design prototypes. These other aspects of the project do not require ethics approval. No user testing or clinical testing will be conducted as part of this Master of Creative Technologies research project. The participants will only provide information to assist design development and give initial feedback on the usability, comfort, and ergonomic aspects of the initial product prototypes.

A.3. Who is the applicant?

When the research is part of the requirements for a qualification at AUT, then the applicant is always the primary supervisor. Otherwise, the applicant is the researcher primarily responsible for the research, to whom all enquiries and correspondence relating to this application will be addressed.

Frances Joseph (Primary supervisor)

A.4. Further information about the applicant.

A.4.1. In which faculty, directorate, or research centre is the applicant located?

AUT, Colab

A.4.2. What are the applicant's qualifications?

MFA, Visual Arts, University of New South Wales

PhD, Design, AUT

A.4.3. What is the applicant's email address?

An email address at which the applicant can be contacted is essential.

frances.joseph@aut.ac.nz

A.4.4. At which telephone numbers can the applicant be contacted during the day?

021 370 780

A.5. Research Instruments

A.5.1. Which of the following does the research use:

☒ a written or electronic questionnaire or survey ***☐ focus groups*** ***☒ interviews***
☐ observation ***☒ participant observation*** ***☐ ethnography*** ***☒ photographs***
☒ videos ***☐ other visual recordings*** ***☒ a creative, artistic, or design process***
☐ performance tests
☐ some other research instrument (please specify)

Please attach to this application form all the relevant research protocols. These may include: Indicative questions (for interviews or focus groups); a copy of the finalised questionnaire or survey in the format that it will be presented to participants (for a written or electronic questionnaire or survey); a protocol indicating how the data will be recorded (e.g. audiotape, videotape, note-taking) for focus groups or interviews (Note: when focus groups are being recorded, you will need to make sure there is provision for explicit consent on the Consent Form and attach to this Application Form examples of indicative questions or the full focus group schedule. Please note that there are specific confidentiality issues associated with focus groups that need to be addressed); a copy of the observation protocol that will be used (for observations); full information about the use of visual recordings of any sort, including appropriate protocols and consent processes; protocols for any creative, artistic, or design process; a copy of the protocols for the instruments and the instruments that will be used to record results if you will use some other research instrument.

A.5.2. Who will be transcribing or recording the data?

If someone other than the applicant or primary researcher will be transcribing the interview or focus group records or taking the notes, you will need to provide a confidentiality agreement with this Application Form.

AUT Master of Creative Technologies student, Farshid Sarmast.

A.6. Please provide a brief plain English summary of the research (300 words maximum).

The purpose of the full Master of Creative Technologies project, is to research and design a wearable device to relieve plantar fasciitis pain using vibration as the therapeutic method. This ethics application is concerned with gathering of experts' (physiotherapists or podiatrists with experience in treating plantar fasciitis) feedback that will be used to inform the design process. Data will be collected through experts' questionnaires and two interviews and observations sessions.

The design process will be iterative, informed by the feedback from experts in foot/ankle rehabilitation (podiatry or physiotherapy practitioners) and experts in product design. The design process is a non-linear sequence of stages consisting of **identifying the problem** from the practitioner's perspectives, **idea generation**, **prototyping**, and **evaluation**. The research findings will contribute to developing a device to enable the people with plantar fasciitis to manage their condition, anywhere and anytime, independently, in a simple and convenient way, using vibration therapy.

The intended output of the Master of Creative Technologies research is a prototype device which will be shown to clinicians to get feedback about usability, comfort and convenience. In this step, the subjects will be interviewed, observed, photographed or video-recorded to understand how they might think about the prototype and whether they find the design prototype understandable, easy to use and comfortable for users or not. If they find any aspect of the prototype unsatisfactory, the design process would be revised to make the necessary changes and improve the design.

A.7. Additional Research Information

A.7.1. Is this research an intervention study? ☐ Yes ☒ No

For research in general, what is the difference between intervention, interaction, and observation? Intervention includes both physical procedures by which data are gathered and manipulations of the participant or participant's environment that are

performed for research purposes. Interaction includes communication or interpersonal contact between the investigator and participant that are performed for research purposes. Observation is neither an intervention nor an interaction. (cf https://www.gvsu.edu/hrrc/faq-definitions-35.htm).

Within health and disability research, 'intervention study' has the meaning given to it by the National Ethics Advisory Council's Ethical Guidelines for Intervention Studies; namely, a study in which the investigator controls and studies the intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). The term 'intervention study' is often used interchangeably with the terms 'experimental study' and 'clinical trial' (s.24 Standard Operating Procedures for Health and Disability Ethics Committees).

No. The research will gather data on the qualities required for a user-centred therapy device through questionnaires, interviews, and observations, and will not involve any intervention, experimental study, or clinical trials. Input and feedback will be sought only from experts in the fields of rehabilitation and product design.

A.7.2. Is this Health and Disability Research? ☐ Yes ☒ No

Health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes (s.21 Standard Operating Procedures for Health and Disability Ethics Committees).

A.7.3. Does this research involve people in their capacity as consumers of health or disability support services, or in their capacity as relatives or caregivers of consumers of health or disability support services, or as volunteers in clinical trials (including, for the avoidance of doubt, bioequivalence and bioavailability studies)? ☐ Yes ☒ No

B. *The Ethical Principle of Research Adequacy*

AUTEC recognises that different research paradigms may inform the conception and design of projects. It adopts the following minimal criteria of adequacy: the project must have clear research goals; its design must make it possible to meet those goals; and the project should not be trivial but should potentially contribute to the advancement of knowledge to an extent that warrants any cost or risk to participants.

B.1. Is the applicant the person doing most of the research (the primary researcher)? ☐ Yes ☒ No

If the answer is 'No' please answer B.1.1 and the following sections, otherwise please answer B.2 and continue from there.

B.1.1. What is the name of the primary researcher if it is someone other than the applicant?

Farshid Sarmast

B.1.2. What are the primary researcher's completed qualifications?

B.A in industrial design, University of Art, Tehran, 2002

B.1.3. What is the primary researcher's email address?

An email address at which the primary researcher can be contacted is essential.

farshid.sarmast@gmail.com

B.1.4. At which telephone numbers can the primary researcher be contacted during the day?

022 311 72 91

B.2. Is the primary researcher

☐ an AUT staff member ***☒ an AUT student***

If the primary researcher is an AUT staff member, please answer B.2.1 and the following sections, otherwise please answer B.3 and continue from there.

B.2.1. In which faculty, directorate, or research centre is the primary researcher employed?

If the response to this section is the same as that already given to section A.4.1 above, please skip this section and go to section B.2.2.

B.2.2. In which school or department is the primary researcher employed?

B.3. When the primary researcher is a student:

B.3.1. What is their Student ID Number?

16922289

B.3.2. In which faculty are they enrolled?

Design and Creative Technologies

B.3.3. In which school, department, or Research Centre are they enrolled?

Colab

B.4. What is the primary researcher's experience or expertise in this area of research?

Where the primary researcher is a student at AUT, please identify the applicant's experience or expertise in this area of research as well.

Farshid Sarmast has about 14 years' experience in user research for product design (home appliances, furniture, tableware, etc.), however, not in designing medical products and wearable technology. He has completed postgraduate papers in research methods and the theory underpinning the research process. To ensure safety and rigour, the supervisors (one from the faculty of Design and Creative Technologies and one from the faculty of Health and Environmental Sciences) will provide content knowledge and advice.

The primary supervisor, Dr Frances Joseph, has a long experience in design and supervising academic design projects, particularly e-textiles, wearables, and innovation through design and new technologies.

The secondary supervisor, Dr Lynne Taylor, is a physiotherapy lecturer with good experience focused on evaluation and promotion of physical activity especially in older people and using wearable sensors technology.

B.5. Who is in charge of data collection?

Primary researcher

B.6. Who will interact with the participants?

Primary researcher

B.7. Is this research being undertaken as part of a qualification? ☒ Yes ☐ No

If the answer is 'Yes' please answer B.7.1 and the following sections, otherwise please answer B.8 and continue from there.

B.7.1. What is the name of the qualification?

Master of Creative Technologies

B.7.2. In which institution will the qualification be undertaken?

Colab

B.8. Details of Other Researchers or Investigators

B.8.1. Will any other people be involved as researchers, co- investigators, or supervisors? ☒ Yes ☐ No

If the answer is 'Yes' please answer B.8.1.1 and the following sections, otherwise please answer B.8.2 and continue from there.

B.8.1.1 What are the names of any other people involved as researchers, investigators, or supervisors?

- Dr Lynne Taylor
- Dr Craig Baguley

B.8.1.2 Where do they work?

- Department of Physiotherapy
- School of Engineering, Computer and Mathematical Sciences

B.8.1.3 What will their roles be in the research?

- Secondary supervisor
- Third supervisor (Mentor)

B.8.1.4 What are their completed qualifications?

- PhD Auck, MBA Auck, MSc (Physiology) Auck, Advanced Dip Physio Auck IT
- PhD, ME, BE, NZCE

B.8.2. Will any research organisation or other organisation be involved in the research? ☒ Yes ☐ No

If the answer is 'Yes' please answer B.8.2.1 and the following sections, otherwise please answer B.9 and continue from there.

B.8.2.1 What are the names of the organisations?

Myovolt Ltd. & Callaghan Innovation

B.8.2.2 Where are they located?

Christchurch

B.8.2.3 What will their roles be in the research?

Farshid Sarmast, Master's student, contacts experts and invites them to participate in the research, collects and transcribes data, and interprets and analyses the data.

Supervisors oversee and support research progress

Myovolt as the industry partner and applicant for the Callaghan R&D Fellowship will define the overall direction of the whole project (including functional, brand and manufacturing aspects and borders) in consultation with supervisors and AUT's Research Office.

Callaghan will financially support the researcher and the project

B.9. Why are you doing this research and what is its aim and background?

Please provide the key outcomes or research questions and an academic rationale with sufficient information, including relevant references, to place the project in perspective and to allow the project's significance to be assessed.

Plantar fasciitis is a common foot condition resulting in foot pain, which occurs in active working people, either athletes or non-athletes.

Vibration therapy is a novel method that may be useful for relieving the pain caused by plantar fasciitis (Usuki & Tohyama, 2011). However, a primary literature review and market analysis show that most of the previous studies have used plate vibrators for whole body vibration (Albasini, Krause, & Rembitzki, 2010; Aminian-Far, Hadian, Olyaei, Talebian, & Bakhtiary, 2011; Cardinale, Wakeling, & Viru, 2005; Lohman, Petrofsky, Maloney-Hinds, Betts-Schwab, & Thorpe, 2007), and the majority of vibration therapy devices in the market deliver this type of vibration. This research aims to design a wearable vibration therapy device to apply local vibration to the foot to relieve the pain caused by plantar fasciitis. The object of this investigation is to seek experts' feedback and input in regards to design of a new wearable vibration therapy device that can be applied anywhere by end users to reduce their conditions.

The industry partner of this project, which is funded by Callaghan Innovation, is Myovolt Ltd, based in Christchurch. Myovolt already manufactures and markets a vibration therapy device consisting of a vibrating module which is wrapped around different body parts (including leg, neck, arm, etc.) using a fabric band. They aim to redesign their product to fit the foot properly and comfortably and in an appealing shape.

The entire research project seeks to address three research questions:

1. What are the most important considerations in the design of a wearable vibration therapy device for domestic users to improve plantar fasciitis?

2. What design and technical approaches can help to integrate vibration technology into an easy-to-use wearable rehabilitation device?

3. What are the most suitable materials and manufacturing processes that help create this product?

B.10. What are the potential benefits of this research to the participants, the researcher, and the wider community?

For the clinicians (experts), an opportunity to collaborate in the research and design process for a new wearable device for relief of plantar fasciitis.

For the researcher, an opportunity to gain feedback from clinicians and health experts and consider the needs of the final users in the design process. This research will contribute towards completion of a Master of Creative Technologies.

For Myovolt, the research may inform the development of a new product to manufacture and commercialize.

For Callaghan, this is an opportunity to support an R&D project for a Kiwi company and an academic thesis.

B.11. What are the theoretical frameworks or methodological approaches being used?

Crouch and Pearce (2012), recognise that an interpretivist research philosophy takes into account human behaviours, actions, and life experiences, and may help study users, so is recognised as the most suitable way of framing this research. Moreover, an abductive approach is taken in this study. Kolko (2009) explains abduction as "the argument to the best explanation" (para, 26). In other words, after collecting data (through the study of foot/ankle problems, vibration therapy applications for foot/ankle problems, existing products analysis, and participants study, etc.), the most likely hypothesis related to research questions will be formed.

More specifically the research investigation takes a phenomenological approach. Creswell (1994) states that it is "a strategy of inquiry in which the researcher identifies the essence of human experiences about a phenomenon as described by participants" (p. 13). As Cohen, Manion, Morrison, and Library (2007) also argue, phenomenology

"advocates the study of direct experience taken at face value, and one which sees behaviour as determined by the phenomena of experience rather than by external, objective and physically described reality" (p. 22). In this method, the researcher asks subjects to talk or write about their own experiences. The researcher should consider participants' beliefs and feelings and put aside his or her own ideas to really understand people's world (Hycner, 1985). As experts' knowledge and experience of treating foot and ankle problems are important, this method will be useful for this study. Moreover, this project will try to answer the research questions, through a qualitative research that will consist of a study of previous work (including published scientific and clinical trials or market analysis), and clinicians' study. The design process in this project is a non-linear sequence of stages including Problem Identification, Idea generation, Realisation (prototyping), and Evaluation, and will involve several iterations. In other words, at any stage, it will be possible to go back and repeat previous steps. Design process phases, altogether, work as a means of addressing the research questions and assessing the hypothesis.

B.12. How will data be gathered and processed?

In the first session, data gathering will involve a 30-minute semi-structured interview using the questions listed in a questionnaire. In the second session (the session of prototype feedback), the clinicians will be interviewed and photographed when using the prototype to observe and to understand if they find the prototype understandable and easy to use. If the participants find the prototype unsatisfactory, the design process should be revised to make the necessary changes and improve the design. Both interviews will be audio recorded and comments transcribed. Recording and transcription data will be stored on password protected (closed access) files on secure AUT servers, on secure AUT premises.

B.13. How will the data be analysed?

Please provide the statistical (for quantitative research) or methodological (for qualitative or other research) justification for analysing the data in this way.

The research will include qualitative and informal interviews, conducted after participants have answered a short questionnaire, to let them freely talk about their experiences and ideas. This may help the researcher receive honest and unbiased information from participants. The collected data will be then assessed, categorized, and arranged to define parameters for the design process. Data collected will include responses to some initial questions to provide demographic information and feedback and comments from unstructured interviews. This information will be analysed from a designer's perspective, to identify insights that can inform the design of the device. In particular, this will include comments about usability, comfort, mobility and other human factors. The photos taken while the participants try using the prototype will be analysed to help identify design features that require improvement.

B.14. Has any peer review taken place? ☒ Yes ☐ No

If your answer is 'Yes', please specify and provide evidence e.g. a letter of confirmation.

☐ ***AUT Competitive Grant*** ☒ ***External Competitive Research Grant***

☒ ***PGR1*** ☐ ***PGR2*** ☐ ***PGR9*** ☐ ***Independent Peer Review****

Optional exemplars for evidencing peer review are available from the Ministry of Health (HDEC) website (http://ethics.health.govt.nz/) or from the Forms section of the Research Ethics website (http://aut.ac.nz/researchethics)

C. *General Project Details*

C.1. Likely Research Output

C.1.1. What are the likely outputs of this research?

☒ ***a thesis*** ☐ ***a dissertation*** ☐ ***a research paper*** ☒ ***a journal article***

☐ ***a book*** ☒ ***conference paper*** ☐ ***a documentary*** ☐ ***an exhibition***

☐ ***a film*** ☐ ***some other artwork*** ☐ ***other academic publications or presentations***

☒ ***Some other output, please specify= Design prototype***

C.2. Research Location and Duration

C.2.1. In which countries and cities/localities will the data collection occur?

New Zealand: Auckland or Hamilton

C.2.1.1 Exactly where will any face to face data collection occur?

If face to face data collection will occur in participants' homes or similarly private spaces, then a Researcher Safety Protocol needs to be provided with this application.

Interviews will be held at experts' work locations (i.e physiotherapy or podiatry clinics or departments of hospitals where their work).

C.2.2. In which countries and cities/localities will the data analysis occur?

New Zealand/ Auckland and/or Hamilton

C.2.3. When is the data collection scheduled to commence?

As soon as Ethics approval is obtained.

C.3. Research Participants

C.3.1. Who are the participants?

Physiotherapists or podiatrists with at least 3 years' experience in the management of foot/ankle problems

C.3.2. How many participants are being recruited for this research?

If you are unsure, please provide an indicative range.

5 to 10 experts.

C.3.3. What criteria will be used to choose who to invite as participants?

Physiotherapists and podiatrists with a minimum of 3 years' experience in the management of foot/ankle problems, based in Auckland or Hamilton, who are willing to participate in two interviews.

C.3.3.1 How will you select participants from those recruited if more people than you need for the study agree to participate?

The criteria to choose among the experts will be availability and the length of their experience in the treatment of people with plantar fasciitis (at least 3 years). Experts with longer experiences in treating plantar fasciitis who can be available to attend two interviews will be chosen.

C.3.4. Will any people be excluded from participating in the study?

☐ Yes ☒ No

Exclusion criteria apply only to potential participants who meet the inclusion criteria. An exclusion criterion is any characteristic that ought to disqualify any potential participant from recruitment into the study. Consider exclusion criteria when there are heightened risks due to power differences in the relationship, recent injury, or other characteristics that might place potential participants at unreasonable risk of harms.

If the answer to this question is 'Yes' please answer C.3.4.1 and the following sections, otherwise please answer C.3.5 and continue from there.

C.3.4.1 What criteria will be used to exclude people from the study?

C.3.4.2 Why is this exclusion necessary for this study?

C.3.5. Recruitment of participants.

Please describe in detail the recruitment processes that will be used. If you will be recruiting by advertisement or email, please attach a copy to this Application Form

C.3.5.1 How will the initial contact with potential participants occur?

Experts' contact details will be collected from internet. They will be contacted via email or telephone to ask if they will be happy to participate in the research.

C.3.5.2 How will the contact details of potential participants be collected and by whom?

The primary researcher will collect all the potential participants' contact details. All contact details will be stored on a password protected (closed access) file, on secure AUT servers.

C.3.5.3 How much time will potential participants have to consider the invitation?

Following contact made with participants and providing them with the Information Sheet, the primary researcher will follow up with them after 7 days to answer any questions and confirm if they will participate in the research.

C.3.5.4 How will potential participants respond to the invitation?

By receiving the first email from a potential participant, they will be replied via an email containing more details about the research, asking them for their interest in participation, and an information sheet and the consent form as the attachments.

C.3.5.5 How will potential participants give consent?

Following confirmation of participation in the research, participants will be asked to sign a written consent form.

C.3.5.6 How and when will the inclusion criteria and exclusion criteria given in sections C.3.2 and C.3.3 be applied?

Inclusion criteria will be clearly outlined on the recruitment poster, during initial contact with potential volunteers, and on the Information Sheet. Participants will be screened for eligibility following their expression of interest.

C.3.5.7 Will there be any follow up invitations for potential participants?

If after 7 days from the initial contact less than or 5 experts have answered with the signed consent form, then potential participants will be contacted to ask if they are still interested to participate.
As well, there will be an invitation for participants to view the design prototype and evaluate it for understandability, comfort and usability issues, at the end stages of the research.

D. *Partnership, Participation and Protection*

D.1. How does the design and practice of this research implement the principle of Partnership in the interaction between the researcher and other participants?

How will your research design and practice encourage a mutual respect and benefit and participant autonomy and ownership? How will you ensure that participants and researchers will act honourably and with good faith towards each other? Are the outcomes designed to benefit the participants and/or their social or cultural group? How will the information and knowledge provided by the participants be acknowledged?

The researcher will work with the participants in an equal and honest relationship to encourage an effective mutual partnership. Data collection (interviews) will be face to face, at a time and location that is mutually agreed upon.

The participants will be assured of the confidentiality of their information. Participants' feedback and perspectives will be respected at all times during the research. Participants will have control over the information they wish to share and will not be pressured to answer questions if they do not wish to do so. Participants are able to stop or withdraw from the research at any given time without reason, in which their contributions to the study will be omitted, and recordings and transcripts will be destroyed. Participant input will be acknowledged in the thesis, any resulting academic papers and presentations arising from the study, without disclosing the participant's identity. All the information provided by the participants will be used with no bias, misinterpretation or alteration to prevent any bad feeling, shame or embarrassment to the participant.

After the interview stage, a "Thank you" email will be sent to each participant individually with the general findings of the interviews, to acknowledge their participation in the research.

D.2. How does the design and practice of this research implement the principle of Participation in the interaction between the researcher and other participants?

What is the actual role of participants in your research project? Will participants be asked to inform or influence the nature of the research, its aims, or its methodology? Will participants be involved in conducting the research or is their principal involvement one of sharing information or data? Do participants have a formal role as stakeholders e.g. as the funders and/or beneficiaries of the research? What role will participants have in the research outputs (e.g. will they be asked to approve transcripts or drafts)?

Participants will help the researcher learn about their knowledge and experiences to inform the design of a device that relieves the pain arising from plantar fasciitis. The information they provide can be used to develop design parameters for a user-friendly product. Analysing the information collected and using it in the design process will fall within the researcher's role.

D.3. How does the design and practice of this research implement the principle of Protection in the interaction between the researcher and other participants?

How will you actively protect participants from deceit, harm and coercion through the design and practice of your research? How will the privacy of participants and researchers be protected? How will any power imbalances inherent in the relationships between the participants and researchers be managed? How will any cultural or other diversity be respected?

Before starting the interview, the researcher will try to make sure that participants feel safe, comfortable and equal to the researcher. They will be asked to answer questions freely and with no restriction. The researcher will also give them enough time to think and prepare a suitable response. In brief, the interviews will be open discussions with the participants, focussing on topics and issues pertinent to their condition rather than formal structured questions and answers. Participants will have the right to refuse to answer any question or discuss any topics they do not like.

E. *Social and Cultural Sensitivity (including the obligations of the Treaty of Waitangi)*

E.1. What familiarity does the researcher have with the social and cultural context of the participants?

The researcher has lived for more than 3 years in New Zealand and has been in touch with people of various cultural backgrounds in work and education contexts. The researcher has personal experience of chronic conditions that

have required physiotherapy treatment in New Zealand and has had informal discussions with professionals including clinicians and physiotherapists in developing an understanding of the project context.

E.2. What consultation has occurred?

Research procedures should be appropriate to the participants. Researchers have a responsibility to inform themselves of, and take the steps necessary to respect the values, practices, and beliefs of the cultures and social groups of all participants. This usually requires consultation or discussion with appropriate people or groups to ensure that the language and research approaches being used are relevant and effective. Consultation should begin as early as possible when designing the project and should continue throughout its duration.

All researchers are encouraged to make themselves familiar with Te Ara Tika: Guidelines for Maori Research Ethics: A framework for researchers and ethics committee members which is able to be accessed through the Research Ethics website. Researchers may also find Te Kaahui Maangai a directory of Iwi and Maaori organisations to be helpful. This may be accessed via the Te Puni Kookiri website (http://www.tkm.govt.nz/). As well as these documents, the Health Research Council has published Pacific Health Research Guidelines, and Guidelines on research involving children. (see http://www.hrc.govt.nz). There are also guidelines by various organisations about researching with other populations that researchers will find helpful.

Before choosing the topic and starting the research, the researcher has conducted a literature review on past studies and a search for existing products, and also wearable technologies, materials and trends. This has given an insight to the researcher. The industry partner has also given the researcher some information about the technology and market of the product. Some initial informal discussions with clinicians and physiotherapists (in Auckland and Hamilton) to ascertain areas of interest/need for product development in the broader area of foot and ankle pain were instigated in 2017, however, these were not formal consultations.

E.2.1. With whom has the consultation occurred?

Please provide written evidence that the consultation has occurred.

With Myovolt's contact person, Dianne Jones

Elly Tobias (Elly's Physio & Healing Centre)

E.2.2. How has this consultation affected the design and practice of this research?

The consultation has given the researcher primary insights from both client''s and expert's perspective and helped to understand the problem and find the potential directions towards generating user-centred design ideas.

E.3. Does this research target Māori participants? ☐ Yes ☒ No

All researchers are encouraged to make themselves familiar with Te Ara Tika: Guidelines for Maori Research Ethics: A framework for researchers and ethics committee members

If your answer is 'No', please go to section E.4 and continue from there. If you answered 'Yes', please answer the next question.

E.3.1. Which iwi or hapu are involved?

E.4. Does this research target participants of particular cultures or social groups? ☒ Yes ☐ No

AUTEC defines the phrase 'specific cultures or social groups' broadly. In section 2.5 of Applying for Ethics Approval: Guidelines and Procedures it uses the examples of Chinese mothers and paraplegics. This is to identify their distinctiveness, the first as a cultural group, the second as a social group. Other examples of cultural groups may be Korean students, Samoan husbands, Cook Islanders etc., while other examples of social groups may be nurse aides, accountants, rugby players, rough sleepers (homeless people who sleep in public places) etc. Please refer to Section 2.5 of AUTEC's Applying for Ethics Approval: Guidelines and Procedures (accessible in the Ethics Knowledge Base online via http://www.aut.ac.nz/about/ethics) and to the relevant Frequently Asked Questions section in the Ethics Knowledge Base.

If your answer is 'No', please go to section E.5 and continue from there. If you answered 'Yes', please answer the next question.

E.4.1. Which cultures or social groups are involved?

Practitioners who work with patients with plantar fasciitis

E.5. Does this research focus on an area of research that involves Treaty obligations? ☐ Yes ☒ No

All researchers are encouraged to make themselves familiar with Te Ara Tika: Guidelines for Maori Research Ethics: A framework for researchers and ethics committee members.

If your answer is 'No', please go to section E.6 and continue from there. If you answered 'Yes', please answer the next question.

E.5.1. Which treaty obligations are involved?

E.6. Will the findings of this study be of particular interest to specific cultures or social groups? ☒ Yes ☐ No

If the answer is 'Yes' please answer E.6.1 and the following sections, otherwise please answer F.1 and continue from there.

E.6.1. To which iwi, hapū, culture or social groups will the findings be of interest?

People with chronic or acute plantar fasciitis, aged 18-80 either athletes or non-athletes

E.6.2. How will the findings be made available to these groups?

The findings of the research will be used to inform the design process of a device that will help the participants improve their conditions.

F. *Respect for the Vulnerability of Some Participants*

"Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable." (Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organisation).

F.1. Will your research involve any of the following groups of participants? ☐ Yes ☒ No

If your research involves any of these groups of participants, please clearly indicate which ones and then answer F.2 and the following section, otherwise please answer G.1 and continue from there.

☐ ***people unable to give informed consent?*** ☐ ***your (or your supervisor's) own students?***
☐ ***preschool children?*** ☐ ***children aged between five and sixteen years?***
☐ ***legal minors aged between sixteen and twenty years?***
☐ ***People lacking the mental capacity for consent?***
☐ ***people in a dependent situation (e.g. people with a disability, or residents of a hospital, nursing home or prison or patients highly dependent on medical care)?***
people who are vulnerable for some other reason (e.g. the elderly, persons who have suffered abuse, persons who are not competent in English, new immigrants)? – please specify

F.2. How is respect for the vulnerability of these participants reflected in the design and practice of your research?

F.3. What consultation has occurred to ensure that this will be effective?

Please provide evidence of the consultation that has occurred.

G. *Informed and Voluntary Consent*

G.1. How will information about the project be given to potential participants?

A copy of all information that will be given to prospective participants is to be attached to this Application Form. If written information is to be provided to participants, you are advised to use the Information Sheet exemplar. The language in which the information is provided is to be appropriate to the potential participants and translations need to be provided when necessary.

An information sheet containing some basic information about the purpose and scope of research will be emailed to the potential participants once they answered to the invitation.

G.2. How will the consent of participants be obtained and evidenced?

AUTEC requires consent to be obtained and usually evidenced in writing. A copy of the Consent Form which will be used is to be attached to this application. If this will not be the case, please provide a justification for the alternative approach and details of the alternative consent process. Please note that consent must be obtained from any participant aged 16 years or older. Participants under 16 years of age are unable to give consent, which needs to be given by their parent or legal guardian. AUTEC requires that participants under the age of 16 assent to their participation. When the nature of the research requires it, AUTEC may also require that consent be sought from parents or legal guardians for participants aged between 16 and twenty years. For further information please refer to AUTEC's Applying for Ethics Approval: Guidelines and Procedures.

Participants will be asked to fill and sign a consent form sent to them via email after they answered to the invitation, and send it back to the researcher.

G.3. Will any of the participants have difficulty giving informed consent on their own behalf? ☐ Yes ☒ No

Please consider physical or mental condition, age, language, legal status, or other barriers.

If the answer is 'Yes' please answer G.3.1 and the following sections, otherwise please answer G.4 and continue from there.

G.3.1. If participants are not competent to give fully informed consent, who will consent on their behalf?

Researchers are advised that the circumstances in which consent is legally able to be given by a person on behalf of another are very constrained. Generally speaking, only parents or legal guardians may give consent on behalf of a legal minor and only a person with an enduring power of attorney may give consent on behalf of an adult who lacks capacity.

G.3.2. How will these participants be asked to provide assent to participation?

Whenever consent by another person is possible and legally acceptable, it is still necessary to take the wishes of the participant into account, taking into consideration any limitations they may have in understanding or communicating them.

G.4. Is there a need for translation or interpreting? ☐ Yes ☒ No

If your answer is 'Yes', please provide copies of any translations with this application and any Confidentiality Agreement required for translators or interpreters.

H. *Respect for Rights of Privacy and Confidentiality*

H.1. How will the privacy and confidentiality of participants be protected?

Please note that anonymity and confidentiality are different. For AUTEC's purposes, 'Anonymity' means that the researcher is unable to identify who the participant is in any given case. If the participants will be anonymous, please state how, otherwise, if the researcher will know who the participants are, please describe how the participants' privacy issues and the confidentiality of their information will be managed.

Participants' real names will not be used anywhere in the thesis. Instead, identities will be anonymised, by referring to expert 1, 2, ... All the identity and information collected will be kept as confidential by the researcher. Any discussions of data with supervisors or industry partners will use the anonymised identities.

H.2. How will individuals or groups be identified in the final report?

If participants or groups will be identified, please state how this will happen, why, and how the participants will give consent.

Individuals will only be identified using numbers e.g. expert 1, 2,3 etc.

H.3. What information on the participants will be obtained from third parties?

This includes use of third parties, such as employers or professional organisations, in recruitment.

Experts contact details will be obtained from the internet or Yellow Pages.

H.4. How will potential participants' contact details be obtained for the purposes of recruitment?

Through public information (such as the internet or Yellow Pages, or referral via supervisors).

H.5. What identifiable information on the participants will be given to third parties?

No information.

H.6. Who will have access to the data during the data collection and analysis stages?

Primary researcher (Farshid Sarmast) and research supervisors (Frances Joseph and Lynne Taylor) will have access to the data, which is to be stored on a USB or hard drive in a locked filing cabinet in the office of Lynne Taylor (**Department of Physiotherapy, A-11, School of Clinical Sciences, Faculty of Health and Environmental Sciences**). The consent forms are stored in a separate locked file cabinet from the data, which contains no information that will lead to the participant identification

H.7. Who will have access to the data after the findings have been produced?

Primary researcher (Farshid Sarmast) and research supervisors (Frances Joseph and Lynne Taylor) will have access to the collected data during the design process and until finishing the writing of exegesis.

H.8. Are there any plans for the future use of the data beyond those already described? ☐ Yes ☒ No

The applicant's attention is drawn to the requirements of the Privacy Act 1993 (see Appendix I of AUTEC's Applying for Ethics Approval: Guidelines and Procedures). Information may only be used for the purpose for which it was collected so if there are plans for the future use of the data, then this needs to be explained in the Information Sheets for participants. If you have answered 'Yes' to this question, please answer section H.8.1.1 and continue from there. If you answered 'No' to this question, please go to section H.9 and proceed from there.

H.8.1.1 If data will be stored in a database, who will have access to that information, how will it be used, for what will it be used, and how have participants consented to this?

H.8.1.2 Will any contact details be stored for future use and if so, who will have access to them, how will they be used, for what will they be used, and how have participants consented to this?

H.9. Where will the data be stored once the analysis is complete?

Please provide the exact storage location. AUTEC normally requires that the data be stored securely on AUT premises in a location separate from the consent forms. Electronic data should be downloaded to an external storage device (e.g. an external hard drive, a memory stick etc.) and securely stored. If you are proposing an alternative arrangement, please explain why.

During the research process, electronic data will be stored on a password protected file system, which is only accessed by the researcher (Farshid Sarmast) and supervisors (Frances Joseph and Lynne Taylor) while employed by AUT on secure AUT servers.

Paper files with no information identifying individual participant identities will be stored in locked file cabinets in the office of Lynne Taylor (**Department of Physiotherapy, A-11, School of Clinical Sciences, Faculty of Health and Environmental Sciences**), which is key locked accessible only by her. Any other paper forms will be shredded at the completion of the research.

H.9.1. For how long will the data be stored after completion of analysis?

AUTEC normally requires that the data be stored securely for a minimum of six years, or ten years for health data. If you are proposing an alternative arrangement, please explain why.

For six years.

H.9.2. How will the data be destroyed?

If the data will not be destroyed, please explain why, identify how it will be safely maintained, and provide appropriate informed consent protocols.

Paper-based data will be destroyed by shredding, audio data will be manually destroyed and all the electronic data will be deleted. Data and information concerning a participant who has withdrawn from the study will also be destroyed, with the exception of their consent form which will be marked as a withdrawal, until such time when all other data is destroyed.

H.10. Who will have access to the Consent Forms?

The researcher (Farshid Sarmast) and supervisors (Frances Joseph and Lynne Taylor).

H.11. Where will the completed Consent Forms be stored?

Please provide the exact storage location. AUTEC normally requires that the Consent Forms be stored securely on AUT premises in a location separate from the data. If you are proposing an alternative arrangement, please explain why.

The completed Consent Forms will be stored in the secondary supervisor's office (**Department of Physiotherapy, A-11, School of Clinical Sciences, Faculty of Health and Environmental Sciences**).

H.11.1. For how long will the completed Consent Forms be stored?

AUTEC normally requires that the Consent Forms be stored securely for a minimum of six years, or ten years in the case of research involving health data. If you are proposing an alternative arrangement, please explain why.

For six years.

H.11.2. How will the Consent Forms be destroyed?

If the Consent Forms will not be destroyed, please explain why.

If after the six-year period, the data is not needed and will be completely removed from the researcher's external hard drive. Any paper forms will be shredded.

H.12. Does your research involve the collection of personally identifiable and sensitive data? ☐ Yes ☒ No

Sensitive data can be used to identify an individual, object or location and has a risk of discrimination, harm or unwanted attention. Sensitive data potentially poses a substantial threat to those who are or who have been involved in it, especially if it is shared inappropriately, or if it falls into the wrong hands. If you have answered 'Yes' please identify what data is being collected and how it is sensitive and provide a Data Safety Management Protocol (see the Forms section of the Research Ethics website for a guide to drafting one). If the answer is 'No', please answer H.13 and continue from there.

H.13. Does your project involve the use of previously collected information or biological samples for which there was no explicit consent for this research? ☐ Yes ☒ No

If the answer is 'Yes' please answer H.13.1 and the following sections, otherwise please answer H.14 and continue from there.

H.13.1. What previously collected data will be involved?

H.13.2. Who collected the data originally?

H.13.2.1 Why was the information originally collected?

H.13.2.2 For what purposes was consent originally given when the information was collected?

H.13.3. How will the data be accessed?

H.14. Does your project involve any research about organisational practices where information of a personal or sensitive nature may be collected and / or where participants may be identified? ☐ Yes ☒ No

If the answer is 'Yes' please answer H.14.1 and the following sections, otherwise please answer I.1 and continue from there.

H.14.1. How will organisational permission be obtained and recorded?

H.14.2. Will the organisation know who the participants are?

H.14.3. How will the identity of the participants be kept confidential?

I. *Minimisation of risk*

I.1. Risks to Participants

Please consider the possibility of moral, physical, psychological or emotional risks to participants, including issues of confidentiality and privacy, from the perspective of the participants, and not only from the perspective of someone familiar with the subject matter and research practices involved. Please clearly state what is likely to be an issue, how probable it is, and how this will be minimised or mitigated (e.g. participants do not need to answer a question that they find embarrassing, or they may terminate an interview, or there may be a qualified counsellor present in the interview, or the findings will be reported in a way that ensures that participants cannot be individually identified, etc.) Possible risks and their mitigation should be fully described in the Information Sheets for participants.

I.1.1. How much time will participants be required to give to the project?

Two sessions, including 10-15 minutes for answering the questionnaire and 20 minutes for the interview. The interviews will be conducted on the days mutually convenient for the researcher and the participants.

I.1.2. What level of discomfort or embarrassment may participants be likely to experience?

It is unlikely that participants will feel any discomfort or embarrassment. Data collection (interviews) will be face to face, at a time and location that is mutually agreed upon. Participants will not be pressured to answer a question if they do not wish to do so and can stop the interview at any time. Interviews can also be stopped at any time by the researcher if they are concerned about the participant. Questions are not intended to be embarrassing or discomforting to the participant in any way.

I.1.3. In what ways might participants be at risk in this research?

They will not be at physical risk. In the case of any mental discomfort, they will be immediately encouraged to stop.

I.1.4. In what ways are the participants likely to experience risk or discomfort as a result of cultural, employment, financial or similar pressures?

There are no costs associated with participating in this study apart from the time required to complete the interview. Data collection (interviews) will be face to face, at a time and location that is mutually agreed upon.

I.1.5. Will your project involve processes that are potentially disadvantageous to a person or group, such as the collection of information, images etc. which may expose that person/group to discrimination, criticism, or loss of privacy? ☐ Yes ☒ No

If your answer is 'Yes', please detail how these risks will be managed and how participants will be informed about them.

I.1.6. Will your research involve collection of information about illegal behaviour(s) which could place the participants at current or future risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships? ☐ Yes ☒ No

If your answer is 'Yes', please detail how these risks will be managed and how participants will be informed about them.

I.1.7. If the participants are likely to experience any significant discomfort, embarrassment, incapacity, or psychological disturbance, please state what consideration you have given to the provision of counselling or post-interview support, at no cost to the participants, should it be required.

Adult research participants in Auckland are able to utilise counselling support from the AUT Counselling Team, otherwise you may have to consider local providers for participants who are located nationwide, or in some particular geographical area or who are children. You may discuss the potential for participant psychological impact or harm with the Head of AUT Counselling, if you require. Please check the relevant Frequently Asked Question on the research ethics website as well and ensure the appropriate wording in included in the Information Sheet when counselling opportunities need to be offered.

I.1.8. Will any use of human remains, tissue or body fluids which does not require submission to a Health and Disability Ethics Committee occur in the research? ☐ Yes ☒ No

e.g. finger pricks, urine samples, etc. (please refer to section 13 of AUTEC's Applying for Ethics Approval: Guidelines and Procedures). If your answer is yes, please provide full details of all arrangements, including details of agreements for treatment, how participants will be able to request return of their samples in accordance with right 7 (9) of the Code of Health and Disability Services Consumers' Rights, etc.

I.1.9. Will this research involve potentially hazardous substances? ☐ Yes ☒ No

e.g. radioactive material, biological substances (please refer to section 15 of AUTEC's Applying for Ethics Approval: Guidelines and Procedures and the Hazardous Substances and New Organisms Act 1996).

If the answer is 'Yes', please provide full details, including hazardous substance management plan.

I.2. Risks to Researchers

If this project will involve interviewing participants in private homes, undertaking research overseas, in unfamiliar cultural contexts, or going into similarly vulnerable situations, then a Researcher Safety protocol should be designed and appended to this application. This should identify simple and effective processes for keeping someone informed of the researcher's whereabouts and provide for appropriate levels of assistance.

I.2.1. Are the researchers likely to be at risk? ☐ Yes ☒ No

If the answer is 'Yes' please answer I.2.1.1 and then continue, otherwise please answer I.3 and continue from there.

I.2.1.1 In what ways might the researchers be at risk and how will this be managed?

I.3. Risks to AUT

I.3.1. Is AUT or its reputation likely to be at risk because of this research? ☐ Yes ☒ No

If the answer is 'Yes' please answer I.3.1.1 and then continue, otherwise please answer I.3.2 and continue from there.

I.3.1.1 In what ways might AUT be at risk in this research?

Please identify how and detail the processes that will be put in place to minimise any harm.

I.3.2. Are AUT staff and/or students likely to encounter physical hazards during this project? ☐ Yes ☒ No

If yes, please provide a hazard management protocol identifying how harm from these hazards will be eliminated or minimised.

J. *Truthfulness and limitation of deception*

J.1. How will feedback on or a summary of the research findings be disseminated to participants (individuals or groups)?

Please ensure that this information is included in the Information Sheet.

The final design prototype will be presented participants individually, and the design features will be explained.

J.2. Does your research include any deception of the participants, such as non-disclosure of aims or use of control groups, concealment, or covert observations?

☐ Yes ☒ No

Deception of participants in research may involve deception, concealment or covert observation. Deception of participants conflicts with the principle of informed consent, but in some areas of research it may sometimes be justified to withhold information about the purposes and procedures of the research. Researchers must make clear the precise nature and extent of any deception and why it is thought necessary. Emphasis on the need for consent does not mean that covert research can never be approved. Any departure from the standard of properly informed consent must be acceptable when measured against possible benefit to the participants and the importance of the knowledge to be gained as a result of the project or teaching session. This must be addressed in all applications. Please refer to Section 2.4 of AUTEC's Applying for Ethics Approval: Guidelines and Procedures when considering this question.

If the answer is 'Yes' please answer J.2.1 and the following sections, otherwise please answer J.3 and continue from there.

J.2.1. Is deception involved?

J.2.2. Why is this deception necessary?

J.2.3. How will disclosure and informed consent be managed?

J.3. Will this research involve use of a control group?

☐ Yes ☒ No

If the answer is 'Yes' please answer J.3.1 and the following sections, otherwise please answer K.1 and continue from there.

J.3.1. How will the Control Group be managed?

J.3.2. What percentage of participants will be involved in the control group?

J.3.3. What information about the use of a control group will be given to the participants and when?

K. *Avoidance of Conflict of Interest*

Researchers have a responsibility to ensure that any conflict between their responsibilities as a researcher and other duties or responsibilities they have towards participants or others is adequately managed. For example, academic staff members who propose to involve their students as participants in research need to ensure that no conflict arises between their roles as teacher and researcher, particularly in view of the dependent relationship between student and teacher, and of the need to preserve integrity in assessment processes. Likewise researchers have a responsibility to ensure that any conflict of interest between participants is adequately managed for example, managers participating in the same research as their staff.

K.1. What conflicts of interest are likely to arise as a consequence of the researchers' professional, social, financial, or cultural relationships?

As Myovolt, the industry partner of the project will intend to commercialize the outcome of the project, they will be informed about the findings of the research. So, the researcher will do his best to keep the participants' information confidential and use it in the design process and also in his dissertation without revealing participants' names or personal information.

K.2. What possibly coercive influences or power imbalances are there in the professional, social, financial, or cultural relationships between the researchers and the participants or between participants (e.g. dependent relationships such as teacher/student; parent/child; employer/employee; pastor/congregation etc.)?

As participants are voluntary and independent, there will not be any power imbalance.

K.3. How will these conflicts of interest, coercive influences or power imbalances be managed through the research's design and practice and how will any adverse effects that may arise from them be mitigated?

K.4. Does your project involve payments or other financial inducements (including koha, reasonable contribution towards travel expenses or time, or entry into a modest prize draw) to participants? ☐ Yes ☒ No

If the answer is 'Yes' please answer K.4.1 and the following sections, otherwise please answer K.5 and continue from there.

K.4.1. What form will the payment, inducement, or koha take?

K.4.2. Of what value will any payment, gift or koha be?

K.4.3. Will potential participants be informed about any payment, gift or koha as part of the recruitment process, and if so, why and how?

K.5. Have any applications for financial support for this project been (or will be) made to a source external to ☒ Yes ☐ No

If the answer is 'Yes' please answer K.5.1 and the following sections, otherwise please answer K.6 and continue from there.

K.5.1. What financial support for this project is being provided (or will be provided) by a source external to AUT?

The full Master of Creative Technologies thesis project has been awarded a Callaghan Innovation R&D Fellowship Grant.

K.5.2. Who is the external funder?

Callaghan Innovation

K.5.3. What is the amount of financial support involved?

20,000 NZD

K.5.4. How is/are the funder/s involved in the design and management of the research?

Myovolt as the industry partner has defined the design brief and will give guidelines and feedback and technically support the project.

Callaghan pays the researcher stipend and travel costs.

K.6. Have any applications been (or will be) submitted to an AUT Faculty Research Grants Committee or other AUT funding entity? ☐ Yes ☒ No

If the answer is 'Yes' please answer K.6.1 and the following sections, otherwise please answer K.7 and continue from there.

K.6.1. What financial support for this project is being provided (or will be provided) by an AUT Faculty Research Grants Committee or other AUT funding entity?

K.6.2. What is the amount of financial support involved?

K.6.3. How is/are the funder/s involved in the design and management of the research?

K.7. Is funding already available, or is it awaiting decision?

K.8. Do the applicant or the researchers, investigators or research organisations mentioned in Part B of this application have any financial interests in the outcome of this project? ☒ Yes ☐ No

If the response is 'Yes', please provide full details about the financial interests and how any conflicts of interest are being managed, otherwise, please respond to section K.9 and continue from there.

Myovolt as the industry partner will intend to commercialize the designed product.

K.9. Are the participants expected to pay in any way for any services associated with this research? ☐ Yes ☒ No

If the response is 'Yes', please provide full details about the charges and describe how any benefits will balance the burdens involved as well as how any conflicts of interest are being managed. Otherwise please respond to section L.1 and continue from there.

L. *Respect for Property*

Researchers must ensure that processes do not violate or infringe legal or culturally determined property rights. These may include factors such as land and goods, works of art and craft, spiritual treasures and information.

L.1. Will this research impact upon property owned by someone other than the researcher? ☐ Yes ☒ No

If the answer is 'Yes' please answer L.1.1 and the following sections, otherwise please answer L.2 and continue from there.

L.1.1. How will this be managed?

L.2. How do contexts to which copyright or Intellectual Property apply (e.g. research instruments, social media, virtual worlds etc.) affect this research and how will this be managed?

Particular attention should be paid to the legal and ethical dimensions of intellectual property. Care must be taken to acknowledge and reference the ideas of all contributors and others and to obtain any necessary permissions to use the intellectual property of others. Teachers and researchers are referred to AUT's Intellectual Property Policy for further guidance.

The researcher and the industry partner will have an intellectual property agreement, based on the Callaghan Innovation Fellowship contract. The Callaghan contract and associated agreements are managed through the university Research Office. A PGR16 form with 36 months' embargo request has been submitted to the faculty.

M. *References*

Please include any references relating to your responses in this application in the standard format used in your discipline.

Albasini, A., Krause, M., & Rembitzki, I. V. (2010). *Using Whole Body Vibration in Physical Therapy and Sport E-Book: Clinical practice and treatment exercises* (1st edition). Churchill Livingstone.

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Cohen, L., Manion, L., Morrison, K. R. B., & Library, E. (2007). *Research methods in education* (6th ed). London ; New York : Routledge. Retrieved from https://trove.nla.gov.au/work/6502360

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Usuki, F., & Tohyama, S. (2011). Vibration therapy of the plantar fascia improves spasticity of the lower limbs of a patient with fetal-type Minamata disease in the chronic stage. *BMJ Case Reports*, *2011*, bcr0820114695. https://doi.org/10.1136/bcr.08.2011.4695

World population projected to reach 9.7 billion by 2050 | UN DESA | United Nations Department of Economic and Social Affairs. (n.d.). Retrieved May 16, 2018, from 2015-report.html

N. Checklist

Please ensure all applicable sections of this form have been completed and all appropriate documentation is attached as incomplete applications will not be considered by AUTEC.

Have you discussed this application with your AUTEC Faculty Representative, the Executive Secretary, or the Ethics Coordinator?	☒ Yes ☐ No
Is this application related to an earlier ethics application? If yes, please provide the application number of the earlier application.	☒ Yes ☐ No
Are you seeking ethics approval from another ethics committee for this research? If yes, please identify the other committee.	☒ Yes ☐ No

HDEC

Section A	*Project information provided*	☒
Section B	*Research Adequacy information provided*	☒
Section C	*Project details provided*	☒
Section D	*Three Principles information provided*	☒
Section E	*Social and Cultural Sensitivity information provided*	☒
Section F	*Vulnerability information provided*	☒
Section G	*Consent information provided*	☒
Section H	*Privacy information provided*	☒
Section I	*Risk information provided*	☒
Section J	*Truthfulness information provided*	☒
Section K	*Conflict of Interest information provided*	☒
Section L	*Respect for Property information provided*	☒
Section M	*References provided*	☒
Section N	*Checklists completed*	☒
Section O.1 and 2	*Applicant and student declarations signed and dated*	☒
Section O.3	*Authorising signature provided*	☒

Spelling and Grammar Check (please note that a high standard of spelling and grammar is required in documents that are issued with AUTEC approval)

Attached Documents (where applicable)

Participant Information Sheet(s)	☒
Consent Form(s)	☒
Questionnaire(s)	☒
Indicative Questions for Interviews or Focus Groups	☒
Observation Protocols	☐
Recording Protocols for Tests	☐
Advertisement(s)	☐
Researcher Safety Protocol	☐
Hazardous Substance Management Plan	☐
Any Confidentiality Agreement(s)	☒
Any translations that are needed	☐
Other Documentation	☒

O. Declarations

O.1. Declaration by Applicant

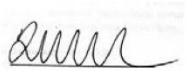
Please tick the boxes below.

☒ *The information in this application is complete and accurate to the best of my knowledge and belief. I take full responsibility for it.*

☒ *In conducting this study, I agree to abide by all applicable laws and regulations, and established ethical standards contained in AUTEC's Applying for Ethics Approval: Guidelines and Procedures and internationally recognised codes of ethics.*

☒ *I will continue to comply with AUTEC's Applying for Ethics Approval: Guidelines and Procedures, including its requirements for the submission of annual progress reports, amendments to the research protocols before they are used, and completion reports.*

☒ *I understand that brief details of this application may be made publicly available and may also be provided to the Graduate Research School, the Research and Innovation Office, or the University's insurers for purposes relating to AUT's interests.*



12/07/18

Signature *Date*

O.2. Declaration by Student Researcher

Please tick the boxes below.

☒ *The information in this application is complete and accurate to the best of my knowledge and belief.*

☒ *In conducting this study, I agree to abide by all applicable laws and regulations, and established ethical standards contained in AUTEC's Applying for Ethics Approval: Guidelines and Procedures and internationally recognised codes of ethics.*

☒ *I will continue to comply with AUTEC's Applying for Ethics Approval: Guidelines and Procedures, including its requirements for the submission of annual progress reports, amendments to the research protocols before they are used, and completion reports.*

☒ *I understand that brief details of this application may be made publicly available and may also be provided to the Graduate Research School, the Research and Innovation Office, or the University's insurers for purposes relating to AUT's interests.*

12/07/2018

Signature *Date*

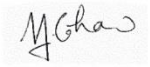
O.3. Authorisation by Head of Faculty/School/Programme/Centre

Please tick the boxes below.

☒ *The information in this application is complete and accurate to the best of my knowledge and belief.*

☒ *In authorising this study, I declare that the applicant is adequately qualified to undertake or supervise this research and that to the best of my knowledge and belief adequate resources are available for this research and all appropriate local research governance issues have been addressed.*

☒ *I understand that brief details of this application may be made publicly available and may also be provided to the Graduate Research School, the Research and Innovation Office, or the University's insurers for purposes relating to AUT's interests.*



12.07.2018

Signature *Date*

Notes for submitting the completed application for review by AUTEC

- Please ensure that you are using the current version of this form before submitting your application.
- Please ensure that all questions on the form have been answered and that no part of the form has been deleted.
- Please provide ***one*** printed, single sided, A4, and signed copy of the application and all related documents.
- Please deliver or post to the AUTEC Secretariat, room WU406, fourth floor, WU Building, City Campus. The internal mail code is D-88. The courier address is 46 Wakefield Street, Auckland 1010. Alternatively, please hand the application to the Research Ethics Advisor in person at one of the Drop In sessions at any of the four campuses (http://www.aut.ac.nz/researchethics/resources/workshops-and-drop-inns).
- Applications should be submitted once they have been finalised. For a particular meeting it needs to have been received in the AUTEC Secretariat by midday on the relevant agenda closing day [AUTEC's meeting dates are listed in the website at http://www.aut.ac.nz/researchethics]
- If sending applications by internal mail, please post them at least two days earlier to allow for any delay that may occur.
- Late applications will be placed on the agenda for the following meeting.

MINIMAL RISK CHECKLIST

Your application may be appropriate for an expedited review if it poses no more than minimal risk of harm to participants. To assist AUTEC's Secretariat to screen the application for assignment to the correct review pathway, please complete the following checklist:

Does the research involve any of the following?

ANONYMOUS SURVEY ASSESSMENT

		Yes	No
1	The collection of anonymous and non-sensitive survey/questionnaire data only. *(If YES is checked, the application may receive an expedited review if the data is from adults and poses no foreseeable risks to participants OR where any foreseeable risk is no more than inconvenience – no further questions on this checklist need be answered.)*	☒	☐

MINIMAL RISK ASSESSMENT[1]

		Yes	No
2	Participants who are unable to give informed consent (including children under 16 years old), or who are particularly vulnerable or in a dependent situation, (e.g. people with learning difficulties, over-researched groups, people in care facilities, or patients highly dependent on medical care)?	☐	☒
3	A reasonable expectation of causing participants physical pain beyond mild discomfort, or that experienced by the participants on an every-day basis, or any emotional discomfort, embarrassment, or psychological or spiritual harm, (e.g. asking participants to recall upsetting events)?	☐	☒
4	Research processes which may elicit information about any participant's involvement in illegal activities, or activities that represent a risk to themselves or others, (e.g. drug use or professional misconduct)?	☐	☒
5	Collection of any human tissue, blood or other samples, or invasive or intrusive physical examination or testing?	☐	☒
6	The administration of any drugs, medicines, supplements, placebo or non-food substances?	☐	☒
7	An intervention of any form of exercise, or other physical regime that is different to the participants' normal activities (e.g. dietary, sleep)?	☐	☒
8	Participants who are being asked to give information of a personal nature about their colleagues, employers, teachers, or coaches (or any other person who is in a power relationship with them), and where the identity of participants or their organisation may be inferred?	☐	☒
9	Any situation which may put the researcher at risk of harm? (E.g. gathering data in private homes)?	☐	☒
10	The use of previously collected biological samples or identifiable personal information for which there was no explicit consent for this research?	☐	☒
11	Any matters of commercially sensitive information?	☐	☒
12	Any financial interest in the outcome of the research by any member(s) of the research team?	☒	☐
13	People who are not giving consent to be part of the study, or the use of any deception, concealment or covert observations in non-public places, including social media?	☐	☒
14	Participants who are in a dependent or unequal relationship with any member(s) of the research team (e.g. where the researcher is a lecturer/ teacher/ health care provider/ coach/ employer/ manager/ or relative etc.) of any of the participants?	☐	☒

[1] If "No" is checked to all items 2-14, the application's status as Minimal Risk will be checked by the Secretariat, and may be forwarded to expedited review. Applications with more than Minimal Risk (any one "yes" to questions 2-14 above), and applications where the checklist is not completed will appear on AUTEC's next agenda.

Appendix 3: AUTEC Approval Letter

Auckland University of Technology Ethics Committee (AUTEC)

Auckland University of Technology
D-88, Private Bag 92006, Auckland 1142, NZ
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

18 July 2018

Frances Joseph
Faculty of Design and Creative Technologies

Dear Frances

Ethics Application: **18/278 Experts' opinions research to inform the design of a wearable vibration therapy device**

Thank you for submitting your application for ethical review. I am pleased to advise that a subcommittee of the Auckland University of Technology Ethics Committee (AUTEC) approved your ethics application, subject to the following conditions:

1. Clarify why no modest koha is being offered to participants in consideration of their time and efforts; please note that if the 2 interview sessions are not at the participants place of work, their travel expenses should at least be covered;
2. Provide a procedures and interview questions for the second study visit;
3. Amendment of the Information Sheet as follows:
    a. In the benefits section, state that the company may derive commercial benefit from the design, and that participants have no share of this;
    b. Explain in more detail about the photographs i.e. that photographs will only be taken of the foot, and no identifiable images will be published;
    c. Include more detail about the interview sessions. For example, where and when they will occur;
    d. Detail the total costs of time in the 'costs' section;
    e. Clarify if transcripts of the interviews will be offered for member checking.

Please provide me with a response to the points raised in these conditions, indicating either how you have satisfied these points or proposing an alternative approach. AUTEC also requires copies of any altered documents, such as Information Sheets, surveys etc. You are not required to resubmit the application form again. Any changes to responses in the form required by the committee in their conditions may be included in a supporting memorandum.

Please note that the Committee is always willing to discuss with applicants the points that have been made. There may be information that has not been made available to the Committee, or aspects of the research may not have been fully understood.

Once your response is received and confirmed as satisfying the Committee's points, you will be notified of the full approval of your ethics application. Full approval is not effective until all the conditions have been met. Data collection may not commence until full approval has been confirmed. If these conditions are not met within six months, your application may be closed and a new application will be required if you wish to continue with this research.

To enable us to provide you with efficient service, we ask that you use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

I look forward to hearing from you,

Yours sincerely

Kate O'Connor
Executive Manager
Auckland University of Technology Ethics Committee

Cc: farshid.sarmast@gmail.com; Lynne Taylor; Craig Baguley

Appendix 4: Consent Form

Consent Form

For use when interviews are involved.

Project title: ***Design of a wearable vibration therapy device for foot and ankle***

Project Supervisor: ***Frances Joseph***

Researcher: ***Farshid Sarmast***

- ☐ I have read and understood the information provided about this research project in the Information Sheet dated 02/07/2018.
- ☐ I have had an opportunity to ask questions and to have them answered.
- ☐ I understand that notes will be taken during the interviews and that they also will be audio-taped and transcribed.
- ☐ I understand that I may be photographed or videoed during the interviews.
- ☐ I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without being disadvantaged in any way.
- ☐ I understand that if I withdraw from the study then I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible. Remove data ○ Allowed to keep data ○
- ☐ I understand that there is no plan for the future use of the data beyond those already described.
- ☐ I agree to take part in this research.
- ☐ I wish to receive a summary of the research findings (please tick one): Yes○ No○

The findings of this research, which is granted by Callaghan Innovation, will be used in the design process of a wearable vibration therapy device to relieve plantar fasciitis for Myovolt Ltd, and in the researcher's dissertation without revealing the names of the participants.

Participant's signature: .....

Participant's name: .....

Participant's Contact Details (if appropriate):

.....

.....

.....

.....

Date:

Approved by the Auckland University of Technology Ethics Committee on type the date on which the final approval was granted AUTEC Reference number type the AUTEC reference number

Note: The Participant should retain a copy of this form.

Appendix 5: Information Sheet

Expert Information Sheet

Date Information Sheet Produced:

12/07/2018

Ethics Application No.: 18/278

Project Title

Design of a wearable vibration therapy device for foot and ankle

An Invitation

Hello,

My name is Farshid Sarmast and I'm conducting this research as a part of my master's thesis at AUT/Colab. The findings of this research, which is funded by Callaghan Innovation, will be used in the design development process for a wearable vibration therapy device to help relieve plantar fasciitis for Myovolt Ltd. The research findings will also form part of my Master of Creative Technologies dissertation, without revealing the names or details of participants. I am hoping to gather your comments and experience in treating plantar fasciitis to help inform the design process in the development of a wearable vibration therapy device to assist people with plantar fasciitis to relieve their condition at home. This is a design research and will not involve patient testing. Your insights will help develop design strategies. Your participation in this research and the time you spend answering my questions are highly appreciated. This information sheet has been created to help you decide about participating in this research. Please don't hesitate to ask me any question before making your decision.

What is the purpose of this research?

This aim of this study is to gather experts' knowledge and opinions in regards to the design of a wearable vibration therapy device that could be used at home by the end user to help relieve plantar fasciitis and the pain arising from this condition.

How was I identified and why am I being invited to participate in this research?

You have been invited to participate in this research due to your experience in the treatment of plantar fasciitis. Your contact details have been found on the internet, through the recommendation of my supervisors or in the Yellow Pages.

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used respecting participant anonymity. However, once the findings have been produced, removal of your data may not be possible.

What will happen in this research?

In the first session, data gathering will involve a 30-minute semi-structured interview using the questions listed in a questionnaire. In the second session (the session on prototype feedback), the clinicians will be interviewed and photographed when using the prototype to observe and to understand if they find the prototype understandable and easy to use. Photos will only be taken of the hand and foot when trying the prototype on the foot, and no identifiable images will be published. If the participants find the prototype unsatisfactory, the design process should be revised to make the necessary changes and improve the design.

Both interview sessions will occur in participants' places of work, in the days and times mutually agreed, to keep time commitment to a minimum. Both interviews will be audio recorded and comments transcribed by the researcher. This data will be labelled using a participant numbering system so it remains anonymous Recording and transcription data will be stored on password protected (closed access) files on secure AUT servers, on secure AUT

premises. Only if the audios recorded were hard to understand, would the researcher check them with the participants.

What are the discomforts and risks?

There will be no discomfort or risk involved with this study. There will be no activity that can induce discomfort or risk.

How will these discomforts and risks be alleviated?

In the case you feel any discomfort, you are more than welcome to decline to answer the questions and withdraw from the research.

What are the benefits?

Your participation not only will help me in doing my master's degree research, it will also be of great help in developing a new user-centred device to help relieve plantar fasciitis. The outcome will be research and prototypes for a wearable device for home users to relieve their pain caused by plantar fasciitis. Myovolt Ltd, as the industry partner in this project will solely own the intellectual property and intends to further develop and commercialize the designed product. The participants will not have any share of the project IP.

How will my privacy be protected?

The information gathered from the interviews will be incorporated as broad statements, not assigned to you as a person. No real participant name will be revealed and used in the dissertation. I will use numerical identifiers (expert one, expert two etc.) once the questionnaire and interview are processed.

What are the costs of participating in this research?

The only cost for the participants will be the time they spend answering questions (two 30-minute interview sessions).

What opportunity do I have to consider this invitation?

You will have one week from the sending date of this email to consider the invitation.

Will I receive feedback on the results of this research?

After making a prototype as the final stage of the design process you will be contacted to see the outcome and comment on it.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, *Dr Frances Joseph,* frances.joseph@aut.ac.nz*, and a* 021 370 780.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, Kate O'Connor, *ethics@aut.ac.nz*, 921 9999 ext 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researcher Contact Details:

Farshid Sarmast

farshid.sarmast@gmail.com

Ph. no.: 022 311 72 91

Project Supervisor Contact Details:

Dr Frances Joseph

frances.joseph@aut.ac.nz

Ph. no.: 021 370 780

Approved by the Auckland University of Technology Ethics Committee on *type the date final ethics approval was granted*, AUTEC Reference number *type the reference number*.

Appendix 6: The First Interview Questionnaire

Hi,

Thanks for taking the time on helping me in my research. Please answer the following questions.

1. Which group(s) make(s) up the majority of your patients with plantar fasciitis?
   Athletes, of any age ☐ Non-athletes 18-50 ☐ Non-athletes over 50 ☐ Other groups ☐

2. 1. Do you use/have you used or known of patients using vibration to relieve pain for any condition you treat (including Plantar Fasciitis)? Please explain.

3. What are your views on vibration therapy?

4. In your opinion, what features does a foot/ankle vibration therapy device need to have so that patients can easily use on their own?

5. Any other comments or suggestions?

Appendix 7: The Second Interview Questionnaire

Hi,

Thanks for taking the time to help me with my research. Please answer the following questions about the device prototype presented to you.

			Strongly agree			Strongly disagree			NA
1	My typical clients will easily understand how to use the device.		○ 100%	○ 0%	○ 0%	○ 0%	○ 0%		○ 0%
2	The device easily fits the form of the foot.		○ 87%	○ 13%	○ 0%	○ 0%	○ 0%		○ 0%
3	The device can be wrapped in a tight and secure way.		○ 87%	○ 13%	○ 0%	○ 0%	○ 0%		○ 0%
4	The device has a more attractive overall design than similar products I have seen.		○ 100%	○ 0%	○ 0%	○ 0%	○ 0%		○ 0%
5	The prototype is light and comfortable.		○ 100%	○ 0%	○ 0%	○ 0%	○ 0%		○ 0%
6	Overall, I find the design of the device satisfactory.		○ 87%	○ 13%	○ 0%	○ 0%	○ 0%		○ 0%
7	Are there any product features you do not find suitable?	N0							
8	If you were to design this product, what would you change?	Choose a more flexible material for vibration units Make vibration motors smaller (if possible)							
9	Which product features could the users use the device without?	None							
10	In your opinion, what are the advantages or disadvantages of this product over other similar devices?	Advantages: lightness, comfort, safety, being washable (the textile wrap) and cleanable (the vibration units), adaptability to different foot sizes and having a beautiful and modern look Disadvantages: vibration motors sizes							
11	Is there anything else you want to share or comment on?	No							

Appendix 8: Foot Sizes

Figure 70 displays the dimensions related to foot. Among these dimensions, the ones more important to this research have been explained in more detail.

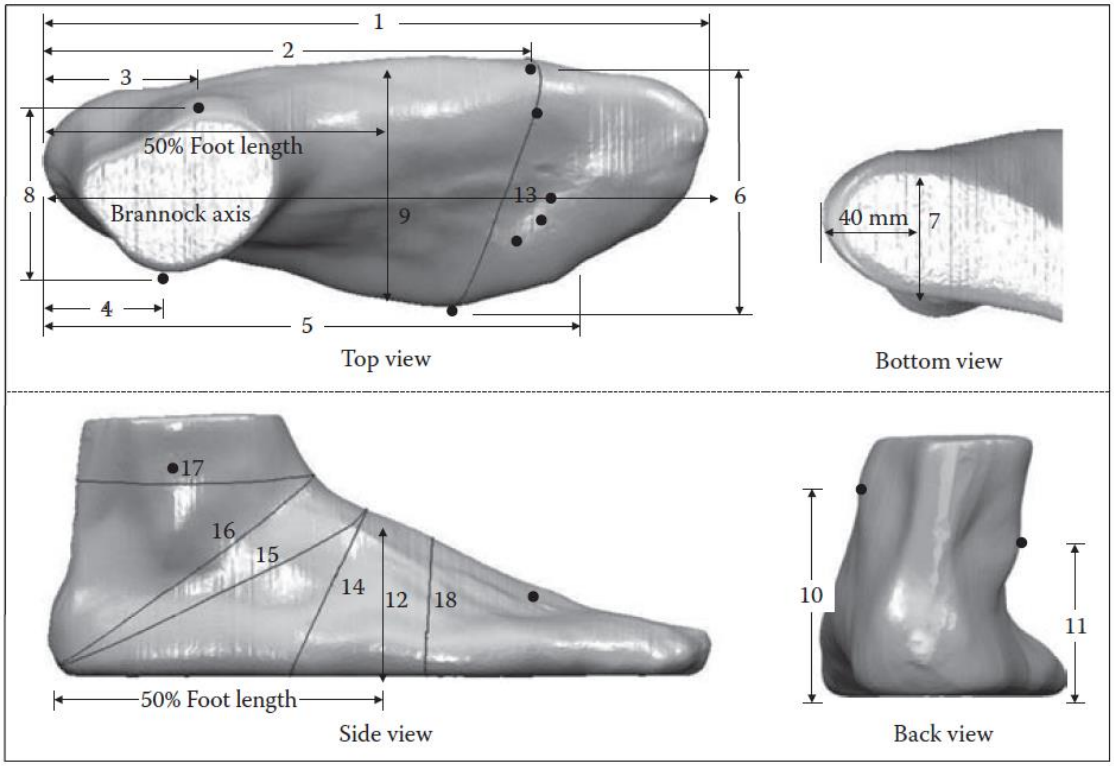


Figure 70 Foot dimensions Reprinted with permission from (Goonetilleke, 2013)

"1. Foot length: The distance along the Brannock axis from pternion[27] to the tip of the longest toe.

2. Arch length: The distance along the Brannock axis from pternion to the most medially prominent point on the first metatarsal head.

3. Heel-to-medial malleolus: Length from pternion to the most medially protruding point of the medial malleolus measured along the Brannock axis.

4. Heel-to-lateral malleolus: Length from pternion to the most laterally protruding point of the lateral malleolus measured along the Brannock axis.

5. Heel-to-fifth toe: The distance along the Brannock axis from pternion to the anterior fifth toe tip.

6. Foot width: Maximum horizontal breadth (Y-direction), across the foot perpendicular to the Brannock axis in the region in front of the most laterally prominent point on the fifth metatarsal head.

7. Heel width: Breadth of the heel 40 mm forward of the pternion.

8. Bimalleolar width: Distance between the most medially protruding point on the medial malleolus and the most laterally protruding point on the lateral malleolus measured along a line perpendicular to the Brannock axis.

9. Mid-foot width: Maximum horizontal breadth, across the foot perpendicular to the Brannock axis at 50% of foot length from the pternion.

[27] "An anatomical landmark at the most posterior point of the heel of the foot when the subject is standing erect." (Kent, 2007)

10. Medial malleolus height: Vertical (Z-direction) distance from the floor to the most prominent point on the medial malleolus.

11. Lateral malleolus height: Vertical (Z-direction) distance from the floor to the most prominent point on the lateral malleolus.

12. Height at 50% of foot length: Maximum height of the vertical cross-section at 50% of foot length from the pternion.

13. Ball girth: Circumference of the foot, measured with a tape touching the medial margin of the head of the first metatarsal bone, top of the first metatarsal bone, and the lateral margin of the head of the fifth metatarsal bone.

14. Instep girth: Smallest girth over middle cuneiform prominence.

15. Long heel girth: The girth from instep point around back heel point.

16. Short heel girth: Minimum girth around back heel point and dorsal foot surface.

17. Ankle girth: Horizontal girth at the foot and leg intersection.

18. Waist girth: Circumference at the approximate centre of the metatarsal, measured in a vertical plane, perpendicular to the Brannock axis." (Goonetilleke, 2013, pp. 163–164)

- **Foot length**

Table *3* displays foot dimensions (length and width) for people of different ages, races, and body sizes. Moreover, to make sure of covering the broadest possible range of foot sizes in this study, a more extensive search was done to find different foot measurements in the research papers. Table 4 displays the findings.

Table 3 Male and Female Anthropometric Foot Measurements, in cm (Weinger, Wiklund, & Gardner-Bonneau, 2010, p. 108)

		Percentile (Male)			Percentile (Female)		
		5th	50th	95th	5th	50th	95th
Foot length	U.S. adults, aged 19–60	24.9	27.0	**29.2**	22.4	24.4	26.5
	British adults, aged 19–35	24.0	26.5	28.5	**21.5**	23.5	25.5
	East German adults, aged 18–59	24.3	26.4	28.5	22.2	24.1	26.0
	Japanese adults, aged 18–30	23.4	25.1	26.9	21.7	23.2	24.6
Foot breadth (width)	U.S. adults, aged 19–60	9.2	10.1	11.0	8.2	9.0	9.8
	British adults, aged 19–35	8.5	9.5	11.0	8.0	9.0	10.0
	East German adults, aged 18–59	9.1	10.2	11.3	8.3	9.3	10.4
	Japanese adults, aged 18–30	9.7	10.4	11.1	8.9	9.6	10.3

Table 4 Foot measurements obtained from research papers

Research	Population	Measurement	Data (min, mean, max)
Cheng & Perng, 2000	Taiwanese, 2486 male adults	Foot length	22.2 (min), 28.6 (max)
Baxter & Baxter, 2011	807 NZ Army personnel	Foot length	18.2, 26.28,34.0
Sarghie, Mihai, Costea, & Rezuş, 2017	92 female from Romania	Foot length Instep circumference	24.4 (average for the elderly) 24.25 (average for general female population) 24.2 (average for the elderly) 23.4 (average for general female population)
Kanaani et al., 2010	160 Iranian men	Foot length Heel breadth	24.3, 26.5, 28.7 (5^{th}, 50^{th}, and 95^{th} percentiles) 6.5, 7.2, 8
Witana, Xiong, Zhao, & Goonetilleke, 2006	20 Hongkonger university students	Foot length Instep girth	22.6(min), 27.4 (max) 20.2 (min), 27.7 (max)
Tu, 2014	122 males and 96 females (Taiwanese)	Foot length Instep girth	20.8 (min), 24.6 (max) 19.8 (min), 25 (max)
Chaiwanichsiri, Tantisiriwat, & Janchai, 2008	Healthy older people: 108 men, 105 women, aged 60–80 years	Foot length Instep girth	20.6 (min), 28.2 (max) 19.8 (min), 29.15 (max)
De Mits et al., 2010	5 healthy men, 5 healthy women	Foot Length Instep Circumference Heel Breadth	25.5 (av mean) 23.7 (av mean) 6.3 (av mean)
LEE, KOUCHI, MOCHIMARU, & WANG, 2015	One hundred Taiwanese and 100 Japanese female	Foot length Instep girth	23.5 (mean for Japanese) 23.4 (mean for Taiwanese) 22.1 (mean for Taiwanese) 21.8 (mean for Taiwanese)
Maneesh Kumar & Brabiaux, 2017	100 French people, 50 males and 50 females	Foot length Instep circumference Heel breadth	20 (min), 32 (max) 22.9 (min), 26.5 (max) 6.1 (min), 7.4 (max)
NASA-STD-3000, the Man-System Integration Standards (https://msis.jsc.nasa.gov/)	Body Size of the 40-Year-Old Japanese Female for the	Foot length	21.3, 229, 24.4 7 (5^{th}, 50^{th}, and 95^{th} percentiles)

	Year 2000 in One Gravity Conditions Body Size of the 40-Year-Old American Male for the Year 2000 in One Gravity Conditions	Foot length	25.4, 27.3, 29.3 (5^{th}, 50^{th}, and 95^{th} percentiles)
Hong, Wang, Xu, & Li, 2011	1,236 Chinese young adult men and 1,085 Chinese young adult women	Foot length Midfoot girth	23.3-25.2 22.4-24.6
Karmegam et al., 2011	150 males and 150 females, 18 to 24 years 3 ethnicities: Malays, Chinese, Indians	**Foot length** Male Malays: Female Malays: ------ Male Chinese: Female Chinese ------ Male Indian Female Indian	 25 (min), 25.37, 27.05, 28.69 (5^{th}, 50^{th}, and 95^{th} percentiles), 29.7 (max) 18.80 (min) 20.11, 22.45, 25 (5^{th}, 50^{th}, and 95^{th} percentiles), 26.30 (max) 20.4 (min) 21.53, 25.45, 28.3 (5^{th}, 50^{th}, and 95^{th} percentiles), 29.5 (max) 20.3 (min), 20.42, 23.3, 25.28 (5^{th}, 50^{th}, and 95^{th} percentiles), 25.4 (max) 22.7 (min), 23.02, 25.8, 28.55 (5^{th}, 50^{th}, and 95^{th} percentiles), 28.7 (max) 20.2 (min), 21.36, 23.3, 26.04 (5^{th}, 50^{th}, and 95^{th} percentiles), 26.40 (max)
Del Prado-Lu, 2007	1805 Filipino workers in 31 manufacturing industries	Foot length	Male: 25.42 (mean), 23 (5^{th}), 25.5 (median), 28.00 (95^{th}) Female: 22.63 (mean), 20 (5^{th}), 23 (median), 25 (max)
Kejonen, Kauranen, & Vanharanta, 2003	100 randomly selected Finnish subjects (50 men, 50 women; aged 31–80y)	Foot length Heel width	24-26.5 6.1-6.8

Abd Rahman, Md Dawal, Yusoff, & Mohd Kamil, 2018	146 male and 168 female participants (18–45 years old, Malaysian), compared to the data from Indonesian, Filipino and Thai population	Foot length	22.6-25.4
Salami, 2009	500 students 18 to 29 years	Foot Length	Male: 24.8, 26.4, 27.5 (5^{th}, 50^{th}, and 95^{th} percentiles) Female: 23, 25, 27 (5^{th}, 50^{th}, and 95^{th} percentiles)
Onuoha, Okafor, & Oduma, 2013		Foot Length	25.7 (mean male), 25.1 (mean female)
Blanchonette, 2017	Australian civilian males 18-30 years old	Foot length	26.6 (mean), 24.3 (5^{th}), 28.7 (95^{th})
Hanson, Sperling, Gard, Ipsen, & Olivares Vergara, 2009	105 Swedish males and 262 females, aged 18–65	Foot length, right Foot length, left	19.4 (min), 24.5, 26.6, 28.6 (5^{th}, 50^{th}, and 95^{th} percentiles), 30.6 (max) 22.9 (min), 24.8, 26.6, 28.9 (5^{th}, 50^{th}, and 95^{th} percentiles), 30.8 (max)

As previously stated in Chapter 2 and illustrated in Figure 4 and Figure 5, plantar fasciitis affects an area from the midfoot to the hindfoot, hence vibration should be applied to this area. Therefore, comparing the data from all the above studies, the length that the device has to cover is approximately 18.2/2=9.1≈9cm for the shortest foot, and 34/2=17cm for the longest foot. Therefore, a difference of 8cm exists between the length of the area to apply vibration for the shortest and longest feet.

To cover the 8cm length difference, two approaches were adopted in idea generation phase: an extendable product with changeable length, and a product with fixed length in two lengths, small-medium foot sizes (18-26cm) and medium-large foot sizes (26.5-34cm). The latter was the base of the design concept selected to develop.

Foot length does not differ between healthy, overweight and obese people, but the obese adults have larger dimensions for the foot's ball height, and widths (heel, ball and foot) and circumferences (heel and ball) (Price & Nester, 2016).

In order for the product to be adaptable to various foot widths, the approach taken was to make the textile wrap (that fixes the vibration unit on the foot) flexible and stretchy and make it open on the front and back sides. This is the rationale behind designing an open panel that can be fastened and adjusted using Velcro pieces on both front and back.

There were other dimensions to consider in the textile wrap (as follow), which are of less importance. Using the shoe last as a base for measuring dimensions helped the designer and the technician to make the wrap with suitable sizes.

- **Heel width:** 6-8mm. The maximum amount (8mm) was considered.
- **Mid-foot width:** 22.4-24.6cm. An amount of 25cm seemed suitable, but as these measurements belong to Chinese adults, and there may be larger amounts in some

other communities, 5%≈1.5cm was added to comply with those mid-foot widths. Therefore, the amount of 26.5cm was considered as the mid-foot width.

- **Lateral malleolus height:** Table 5 below displays this dimension reported in some studies. For the textile wrap, the maximum amount, 8.3≈8cm needed to be used.

Table 5 Lateral malleolus height

Research	Population	Data (min, mean, max)
Defense Technical Information Center, 1982	10,852 US Air Force (UASF) personnel	5.3-8.3
Emamgholizadeh Minaei, Hajaghazadeh, Allahyari, Khalkhali, & Keramat, 2016	580 Iranian university students	5.2-8.1
Mickle, Munro, Lord, Menz, & Steele, 2010	312 community-dwelling older men and women	7.1-7.7
Tu, 2014	122 male and 96 female Taiwanese	6.3-6.4
Witana et al., 2006	11 men and 9 women, Hong Konger	5.1-7.5

- **Instep girth:** as Table 4 shows, this amount ranges from 19.8≈20cm to 29.15≈29cm. For this project, the maximum amount was taken into consideration.

- **Waist girth:** Waist girth (dimension #18 in Table 6) is the circumference at the approximate centre of the metatarsal, measured in a vertical plane, perpendicular to the Brannock[28] axis (Goonetilleke, 2013). The maximum amount of 28cm was used (Table 6).

Table 6 Waist girth measurements

Research	Population	Data (min, mean, max)
Chaiwanichsiri et al., 2008	108 Thai men, 105 Thai women, aged 60–80 years	18.8-26
Emamgholizadeh Minaei et al., 2016	580 Iranian university students	19.6-28
Witana et al., 2006	11 men and 9 women, Hong Konger	20.1-27.1

[28] A very popular measuring tool in the footwear industry (https://brannock.com)