DESIGNING COMPRESSION GARMENTS WITH INTEGRATED SENSORS FOR ENHANCED MONITORING & TREATMENT

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Designing compression garments with integrated sensors for enhanced monitoring & treatment

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I wish Kaspar and Marie Josee every success with the further development of the product. It will have a great impact on the well-being of many.

ABSTRACT

Cardiovascular disease is one of the leading causes of death, representing 32% of all global deaths (World Health Organization, 2021). The mainstay treatments are medical compression stockings (MCS) and physical activity. Although MCS has been shown to positively affect treatment and support disorder control (e.g. leg swelling), research shows incredibly low therapy compliance (Raju et al., 2007).

Throughout history, the involvement of digital technologies has greatly enhanced healthcare.
Nonetheless, developments are not embraced by the medical compression stockings industry yet. For instance, since the invention of medical compression stockings (with a graduated compression) in 1960, the design of medical compression stockings (MCS) has hardly changed (Sarı & Oğlakcıoğlu, 2016).

This thesis explores the integration of sensors into medical compression stockings and aims to innovate current compression stockings by including wearable technology. The feasibility and viability of smart stockings are examined, and barriers are defined through a combination of interviews, literature and user observations. Findings are translated into design requirements.

Throughout the research, multiple problems have been identified, ranging from user dissatisfaction to product shortcomings.

For instance, MCS only have an expected lifespan of half a year. Yet, MCS are yearly reimbursed by health insurance companies. Also, wearing, product care, and health complications can even shorten the lifespan of MCS.
For the successful treatment of disorders, it is essential that MCS exert the correct amount of compression.

The presented smart stockings with the app address these shortcomings.
The smart stocking is able to monitor the exerted compression of MCS. By constantly validating the product, users gain ownership over the quality of their compression therapy.

Aside from product validation, compression monitoring is translated into the level of fitness of the user. Increased compression (outside of the walking range) indicates an expanding circumference of the ankle. Together with a vascular surgeon, guidelines are discussed. The combination of the smart stocking and the app has the potential to give medical recommendations to users.

With the app, users can be rewarded for their therapy adherence and goals tailored to the specific user and their physical capabilities. Lastly, not every healthcare complication is immediately measurable through compression change. Therefore, the app can ask additional questions based on visible signs, this way it also coaches users to monitor their health.

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DAILY

1 MOTIVATION

In this chapter, the project and its importance are introduced. To understand the motives and the project flow, the used approach is explained.
Lastly, an overview of the report with its deliverables is presented.

1.1 INTRODUCTION

With ageing populations, the demand for care will increase tremendously (World Health Organization, 2022). But, the perceived workload of (district) nurses is already strikingly high and is only expected to increase (CBS, 2019). A transformation towards healthier ageing is not only a desired transformation but also a necessary transformation.

Cardiovascular disease is one of the leading causes of death, representing 32% of all global deaths (World Health Organization, 2021). The mainstay treatments are medical compression stockings (MCS) and physical activity. Although MCS has been shown to positively affect treatment and support disorder control (e.g. leg swelling), research shows incredibly low therapy compliance (Raju et al., 2007).

Throughout history, the involvement of digital technologies has greatly enhanced healthcare. The innovation of medical equipment, in particular, has led to significant advancements in medical care, including the replacement of multiple analogue medical gadgets with more accurate and smaller digital devices (Esfahani, 2021). For example, in hospital settings, stethoscopes for measuring heart rate are replaced by more advanced digital products. Heart rate and certain blood values can even be measured by everyday objects such as watches.

Nowadays, the advances furthermore offer the possibility of small instruments (e.g., sensors) incorporated directly into garments, also referred to as wearables. For example, in the Emerging Materials group at Technical University Delft, recently a new technology has been developed to weft-knit soft and stretchable sensors which can measure movements and strains in clothing in an unobtrusive way. In the fabric, a silver-coated wire is knitted.

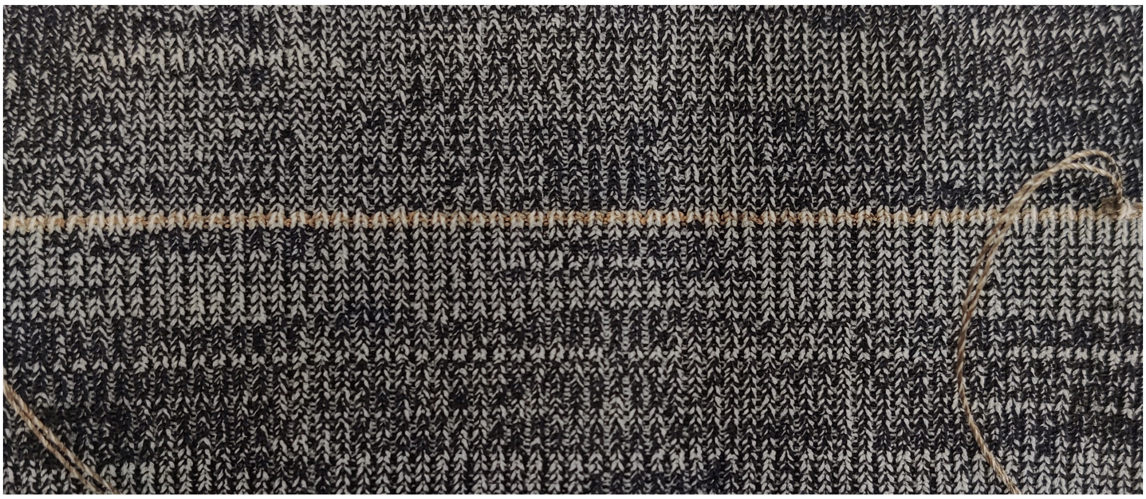


figure 1.1.1 weft knitted sensor by the TU Delft

These wearables provide a wide range of functions, from monitoring physiological parameters (such as respiratory and heart rate) to physical movements (pedometer and fall detection). Besides supporting healthcare professionals,

these monitoring developments also allow non-clinicians to gain insights into their health at any given time of the day.
If utilized, such data even has the potential to provide users with preventive advice to enable them with healthier lifestyle choices. Such innovations empower society and future healthcare in the necessary transformation from a curative healthcare system towards a preventive healthcare system.

Nonetheless, developments are not embraced by the medical compression stockings industry yet. For instance, since the invention of medical compression stockings (with a graduated compression) in 1960, the design of medical compression stockings (MCS) has hardly changed (Sarı & Oğlakcıoğlu, 2016). Today, stockings are also offered in bright colours and recently a new market, sports gear, is slowly embracing compression garments with more sleek designs (Baan, 2020). Yet, they completely lack any kind of incorporated technology.

figure 1.1.2 Ordinary medical compression stockings

With sensors integrated into medical stockings, it will be possible to continuously monitor the compression of limbs and transfer this information back to the wearer. Such insights can empower users to make more preventive health decisions and actively improve their health.

Yet, technologies come with additional challenges. For example, vulnerable users need to be capable enough to operate devices correctly. Otherwise, self-operated wearables could be dangerous if healthcare decisions are made on incorrect data. Designers face challenges in making new technologies as user-friendly as possible while ensuring the quality of the medical measurements.

This thesis explores the integration of sensors into medical compression stockings and aims to innovate current compression stockings by including wearable technology. The feasibility and viability of smart stockings are examined, and barriers are defined through a combination of interviews, literature and user observations. Findings are translated into design requirements.

1.2 APPROACH

There is low adherence to conventional compression stockings. Although patients are informed about the importance of wearing MCS they choose to not adhere to their MCS. To find the reasons behind this low adherence and to improve the adherence it is important to understand the user needs and capabilities.

Throughout the project, research directions are user-centred driven.The approach of the project is inspired by the double diamond model, which consists of four phases: discover, define, develop, and deliver. The framework and phases are used as guidelines. Yet, extensive research and intermediate reflection created a going back and forward through the phases.

Extensive time is taken in setting up research questions, which are the pillars of the project. Although they are not often explicitly addressed throughout the report, the themes serve as a driving force throughout the entire project. Consequently, the distinct presence of the research questions remains evident in the focus and outcomes of this project. The themes manifest themselves in the research directions, findings, product requirements, and presented prototypes.

A combination of literature research, interviews, user observations, and sensor tests are combined to answer the research questions and to determine design requirements for MCS. To develop products understandable and usable for all end users, designs are subsequently combined with evaluation through interview sessions with a specific focus on the predetermined strengths.

Answers and evaluation criteria are generated throughout the process. Newly gained information is applied in the project and used as a guideline for the next steps and/or argumentation behind design decisions.

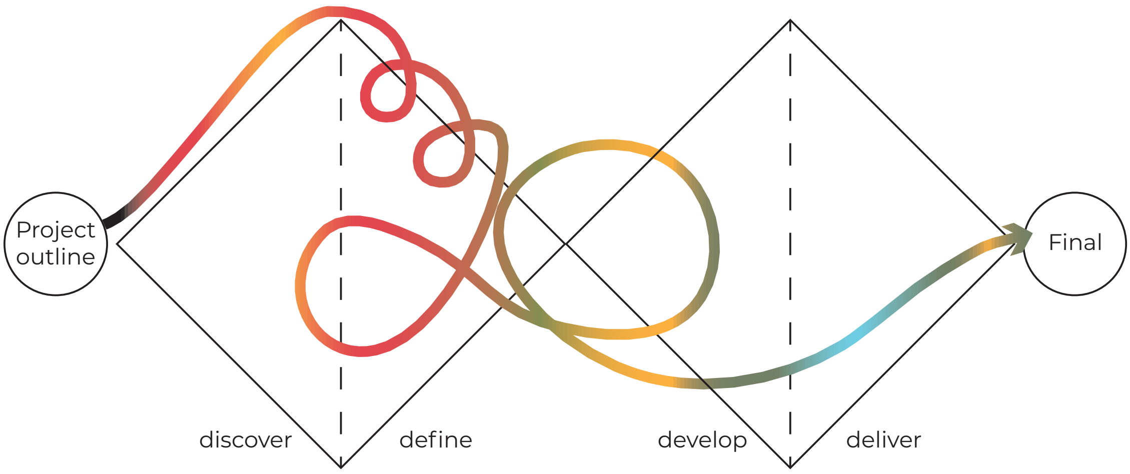


figure 1.2.1 Process

1.3 PROJECT

Adherence to MCS is very important for the health of MCS patients. The lack of patient adherence suggests a negative patient experience and MCS are in desperate need of innovation to help patients get into or maintain a healthier life by adhering to MCS.

This thesis investigates what such innovation may entail and composes the following product vision for subsequent design and testing:

*An innovative compression stocking with **integrated sensors**. Besides applying the right amount of compression they can track user activity and **measure their level of fitness.** This information is **directly linked back** to the user (and vascular surgeon) in an understandable manner. The state-of-the-art sensor stocking will motivate users to exercise through positive feedback and is an **improvement in patient experience**.*

Within the assignment, there are several highlighted elements, which indicate how the designed compression stockings differ from the current compression stockings through the integration of technical advances. Since the right amount of compression is already essential for compression stockings to properly function, it has not been highlighted, but it remains a requirement in future products as well.
These elements help define the scope of the project and are further translated into three main research questions that are used as the driving force throughout the project:

RQ1. To what conditions do the stockings and sensors need to comply to collect 'workable' data about the stretch and compression within the compression stockings?
RQ2. How can we utilise the data to improve health outcomes?
RQ3. How can the data facilitate an improved user experience and more user compliance?

The research questions specifically focus on investigating three main aspects, i.e, technical, user motivation, and therapy adherence, respectively. Some additional information is needed to provide further clarification.

In particular, the technical focus of RQ1 is primarily on the sensor. Often sensors are able to translate a phenomenon into measured data (input). Although they provide this input, this has to be checked for sensitivity, outliers, and noise and might need to be adapted before conclusions can be drawn. The raw data needs to be transmitted into information that shows consistency and matches reality. Apart from the data, the performance of the sensor in real-life situations must be evaluated. Only if the data can show consistency and is compliant with reality, the sensor can be considered capable enough to collect 'workable' data.

RQ2 focuses on the user (motivation). Particularly, the reasons behind a user's motivation of users to either start wearing or avoid wairing compression stockings more. Also, what are the user's capabilities, needs and desires?

And lastly, RQ3 focuses on therapy adherence and communication. Once we motivate patients to start wearing their compression stockings, we need them to keep wearing their compression stockings. Therefore users will need to understand the benefits of compression therapy for their health.

To help answer the main research questions, additional sub-questions are composed, which have a wider and more detailed focus to help improve the stockings, generate knowledge, and generate assessment criteria:

1. What are the problems (e.g., low patient adherence) with the current stockings? What are the reasons and consequences?
2. What are the user needs? How would smart stockings (eg, data collection?) address some of these problems and meet user needs?
3. What kind of sensors are currently applied in the field of compression stockings? What kind of data can we collect from using the sensors/smart stockings? How are they already used in different settings/scenarios?
4. What are patients' attitudes toward smart stockings and their acceptance towards data collection?
5. How should the sensors be used to collect what type of data from users? In what way should the generated data be presented to the user for them to understand the data?
6. What would users like the smart compressions stockings to look like?

The research questions support the investigation and inform the subsequent design of the compression stocking.

1.4 DELIVERABLES

To summarise, the focus of the project is threefold: technical, user (motivation), and therapy adherence. By integrating sensors into MCS, the aim is to enhance compression monitoring and treatment.

Throughout the project, both users and healthcare providers are involved through interviews and validation moments.
This thesis discusses:

1. The importance of MCS and user behaviour determinants
2. Requirements for Smart Stockings with integrated sensors
3. Sensor evaluations
4. Prototypes
5. Design strategies and implications
6. Smart Stockings which incorporated the generated knowledge
7. A proposed app design with suggested interactions and healthcare recommendations
8. Future recommendations

The outcomes of this project will generate knowledge for future projects, and supposedly provide the resources to others to continue working on smart compression garments.

2 LITERATURE REVIEW STATUS QUO

Compression therapy is a widely used treatment option for a variety of lower limb conditions. This chapter provides the basics of the anatomy and physiology of the lower limb, as well as an in-depth analysis of specific disease characteristics that are effectively treated with compression therapy.

Additionally, we explore the concept of compression therapy and its various forms, including both stockings and bandaging. Finally, we examine the importance of patient compliance for effective treatment in compression therapy and explore reasons for non compliance. This chapter will introduce limitations and user needs within compression therapy.

By delving into these key topics, this chapter aims to provide a comprehensive understanding of the use of MCS in medical practice.

2.1 ANATOMY AND PHYSIOLOGY LOWER LIMB

Medical compression stockings (MCS) are commonly prescribed for the treatment of various vascular disorders affecting the lower limb, examples are deep vein thrombosis, varicose veins, and lymphedema. To understand the role of MCS in treating these disorders and diseases, it is important to understand the anatomy and physiology of the lower limb.

After understanding the structure and function of the lower limb, one can understand the current interventions for vascular disorders and how MCS can help alleviate symptoms and prevent further complications. This subchapter provides an overview of the basics of the anatomy and physiology of the lower limb.

The lower limb serves as the foundation for movement and support of the body. Composed of bones, muscles, blood vessels, and nerves, the lower limb is responsible for weight-bearing activities, such as standing, walking, and running (Marieb et al., 2015). Typically MCS cover the area from the foot to the knee, from this moment on this area is referred to as the leg (so excluding the knee, upper leg, and hips).

Besides serving as the foundation for movement and support of the body, the muscles in the lower limb serve as the motive force for returning venous blood from the lower part of the body back to the heart (Recek, 2013). This force is called the calf muscle pump and can be explained by the physiology of muscles.

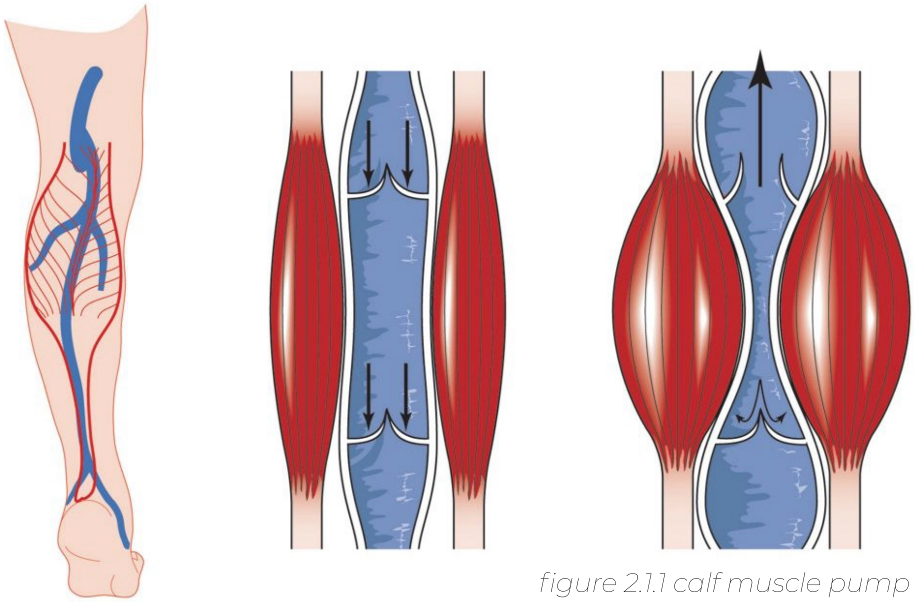


figure 2.1.1 calf muscle pump

The muscles in the leg are skeletal muscles, meaning that they only attach to bones, tendons or to skin (other muscle types are excluded from the explanation). Muscles consist of many small fibres. During muscle contraction, the contraction is activated through the hydrolysis of ATP, this causes all the fibres to shorten. The way a muscle's shape changes determines its function and direction (Wakeling et al., 2020). As the muscle fibres shorten, they expand in girth to maintain the volume, making the fibres press onto each other in a transverse (outwards) direction. This transverse expansion during muscle contraction puts pressure on everything inside the leg. This pressure causes the radius of veins to diminish and due to the incompressibility of blood, a flow is created. To prevent reflux (blood flowing backwards), veins consist of one-directional valves. This mechanism of supporting the venous system is called the calf muscle pump.

Movement of the foot is controlled through muscles that are connected to tendons proximal (above) of the ankle (Marieb et al., 2015). Inside the foot there is barely space for muscles, so the feet primarily consist of tendons. To assure that all the tendons stay in place and the feet can move, the tendons are kept in place and guided from the calve to the footbone by the retinacula. A special band on the ankle is connected to the bone on both sides and has very limited stretch abilities. Therefore it is a firm place with relatively few shape changes caused by muscle contractions.

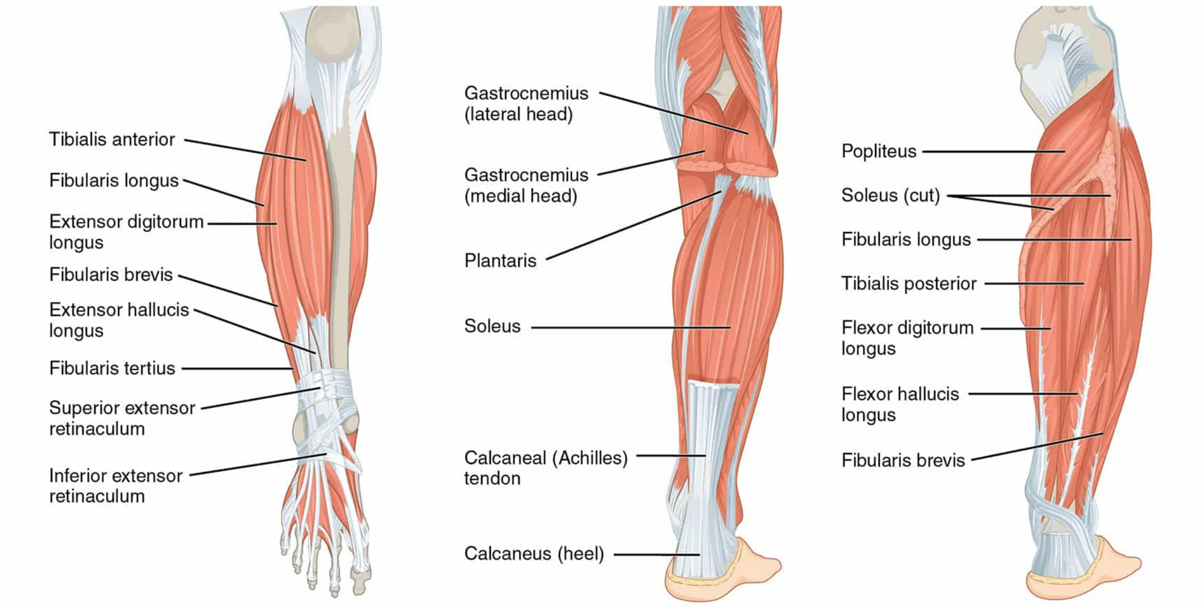


figure 2.1.2 anatomy lower leg

2.2 DISEASES

Unfortunately, diseases affecting the venous and lymphatic systems of the leg are prevalent and can lead to morbidity and impairment in daily activities. In the previous subchapter, the anatomy and physiology of the legs are discussed, which helps to understand the pathogenesis of these diseases.
In this subchapter, the focus shifts to various disorders that can affect the venous and lymphatic systems of the legs. Literature helped dividing them into 3 categories (rabe et al., 2018):

1. Chronic venous disease
2. Acute venous disorders
3. Lymphatic disorders

The disorders are discussed and by understanding the nuances of conditions, the prevalent role of MCS in compression care will be understood, as also why MCS are one of the mainstays of therapy for these conditions. Infographics with additional characteristics are provided per category.

Chronic venous disease

Chronic venous disease (CVD) refer to vascular pathologies occurring in the lower extremities of the body (Ligi et al., 2018). CVD represents the sequelae of general venous insufficiency. To classify CVD, the CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classification system is used (Lim & Davies, 2014; Lurie et al., 2020). The CEAP is created in 1994 to create a uniform diagnosis and comparison of chronic venous disease. Before the CEAP classification, there was a lacking precision in diagnosis, leading to reporting errors in studies and venous problems management. In 1995, the CEAP is incorporated into the 'Reporting Standards in Venous Disease' and worldwide adopted. Depending on the patient's conditions and treatment aims the type of compression therapy can be prescribed.

The 'C' in CEAP, clinical, focuses on signs and symptoms related to CVD. The classification scheme goes from C0 to C6, and are based on increasing severity (Carman & Al-Omari, 2019). Patients classified as C0 show no signs of venous disorders, where C6 describes the most severe skin changes associated with venous disease. Figure 2.2.1 shows an overview of CVD with stages and accompanying characteristics.

CVD spans a wide spectrum of conditions, per class one disorder is described. The early stages of CVD are C1 and C2.

Spider veins

Telangiectasias (spider veins) result from damaged small superficial blood vessels in the skin (Sandean & Winters, 2023). Spider veins rarely cause health problems, but can be treated for cosmetic reasons.

Varicose veins

Incompetent valves, weak vascular walls, and increased intravenous pressure can lead to varicose veins (Raetz et al., 2019). Veins work against gravity to return blood to the heart, supported by the calf muscle pump. The valves prevent reflux, but with damaged or weakened valves blood can flow backwards and pool in the veins, causing veins to stretch or twist.

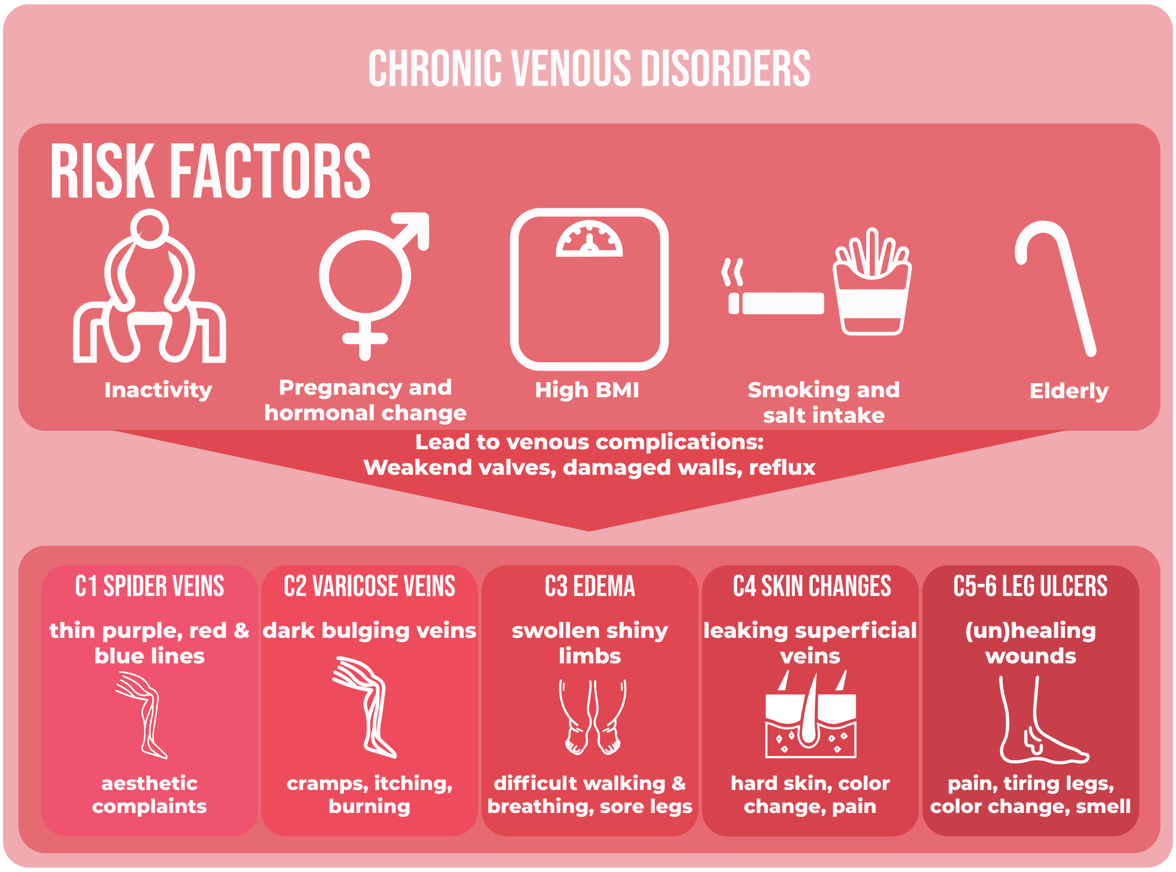


figure 2.2.1 overview CVD

The late stages of CVD (C3 to C6), primarily identified as chronic venous insufficiency (CVI) is the development of venous hypertension from shear stress and reflux of incompetent valves (Ligi et al., 2018). This can lead to edema, venous dilatation, worsening valve insufficiency, and a repetitive cycle of increasing pressures and further dilatation. These changes in blood flow create further complications on microlevel, causing a series of conditions, resulting in:

Edema

Edema is the build-up of fluid in body tissues (Gasparis, et al., 2020). It occurs when (tiny) veins leak fluid. The fluid builds up in nearby tissue, often causing swelling.

Lipodermatosclerosis

Lipodermatosclerosis is caused by chronic venous hypotension, which causes the smallest veins (capillaries) in the skin to leak liquids, fibrin (a protein), and blood cells (Mekkes, 2022). The chemical properties of blood make cells oxidize and the degradation of fibrine causes inflammations. After constant exposure (months to years) to these processes, the skin starts to feel hard.

Leg ulcers

A leg ulcer is a breakage in the skin on the leg which is exposed for at least six weeks (Chapman, 2017). This breakage allows air and bacteria to infiltrate the underlying tissue and cause infections.

For this thesis the clinical manifestation is the most important element of the CEAP. Nonetheless, the other classes in the CEAP classification system are shortly explained. Etiology (E) focuses on the cause of the CVD, this can be classified as congenital, primary, secondary, and no obvious venous cause (Carman & Al-Omari, 2019). The anatomy (A) is used for the location of the veins in which the disease is located. They are classified as deep veins, superficial veins, and perforator veins. Lastly, the pathophysiology (P) stands for the changes in the veins. They are classified as venous reflux, obstruction, combined reflux and obstruction, and no discernable venous changes nor reflux or obstruction.

Acute venous disorder

Different from chronic venous disorders, which develop gradually over time, acute venous disorders can arise rapidly with an onset of symptoms and potentially serious complications. Acute venous disorders include among others (Meissner et al., 2007):

Venous thrombosis

Deep venous thrombosis (DVT) is clot formation (thrombosis) which is (typically) in a deep calf vein, which spreads upwards in the body (proximally) (stubbs et al., 2018). The cause of this clot formation can be wall damage of veins, stasis or low blood flow, and hypercoagulability (the tendency for blood to form clots, which can be genetics or lifestyle habits) (Line, 2001). Pulmonary embolism (PE) is an acute complication of DVT, which is a clot that 'breaks off' and travels to an artery in the lung, where it forms a blockage to blood flow. Similar to DVT, superficial vein thrombosis is a blood clot in a vein, only this being near the skin's surface (Cosmi, 2015). It shares the same risk factors as DVT.

Post-thrombotic syndrome

After DVT, 20%-50% of the patients develop post-thrombotic syndrome (PTS) (Kahn, 2016). PTS is a consequence of chronic damage to the venous outflow, which damaged the valves in the veins (Engeseth et al., 2021).

Lymphatic disorder

Lymphedema

The lymphatic system is a network of tissues, vessels, and channels throughout the body that assist in fluid balance and immunologic function (Zurcher, 2022). A chronic condition (and the only one further discussed) of the lymphatic system is lymphedema. Lymphedema is a localized form of soft tissue swelling caused by impaired lymphatic drainage (Grada & Phillips, 2017). There are two classifications for lymphedema; primary (caused by vascular anomalies), and secondary (caused by injury, non-accidental injury, or treatments (e.g. radiotherapy or surgery)).

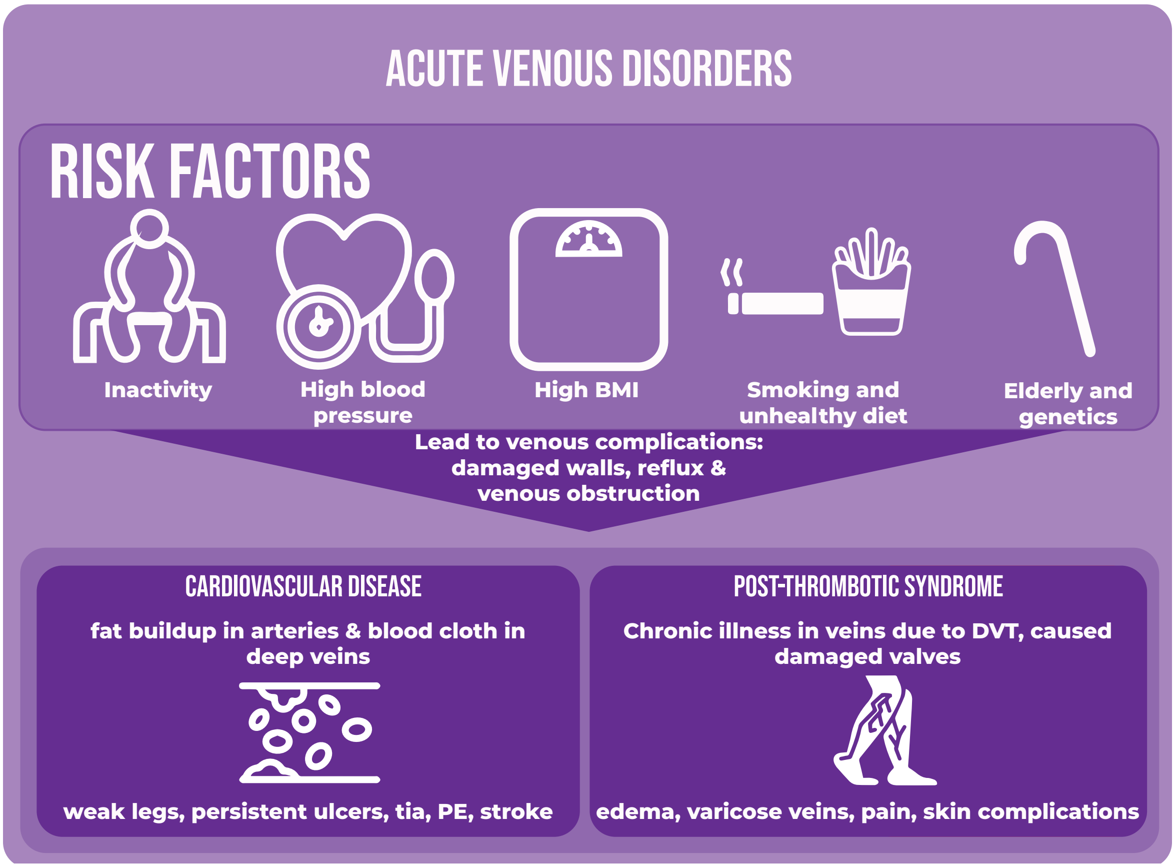


figure 2.2.2 overview acute venous disorders

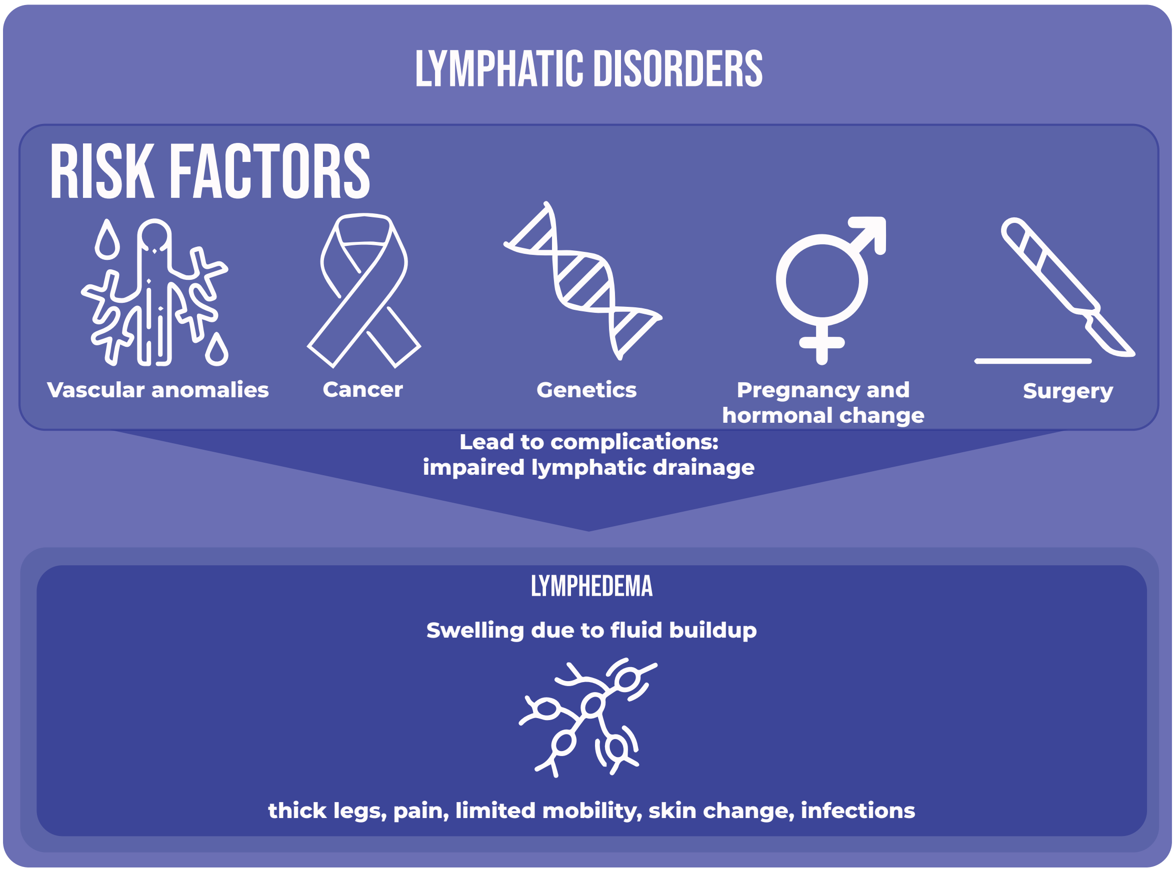


figure 2.2.3 overview lymphatic disorders

2.3 COMPRESSION THERAPY

Compression therapy is a combination of compression garments, such as stockings, and/or bandages with flexible structures. These are applied to enclose specific body parts with a defined pressure pattern (Rotsch et al., 2011). Through this pressure, there is less space for liquids to swerve within the tissue and the diameter of major veins is reduced in the compressed body part (Lim & Davies, 2014). Due to the incompressibility of liquids, the compression increases the velocity and volume of blood flow (Motykie et al., 1999). Compression therapy can be used for cosmetic, medical and sporting purposes.
For medical purposes, they are typically used to support blood circulation and/or for post-surgery recovery (Wang, 2017; Livermore et al., 2021). Depending on the patient's situation different types of compression therapy methods and materials are used.
This subchapter reviews the working mechanism of compression garments and the beneficial value of applying compression stockings in the treatment of venous and lymphatic disorders.

Compression stockings

Medically prescribed compression stockings (MCS), are fabric garments covering a specified limb (Rotsch et al., 2011). The amount of compression differs over the length of the stocking. In the case of lower limb MCS, the greatest degree of compression is at the ankle and gradually decreases up the stocking.

A wide range of compression stockings exist. Depending on the outcomes of the classified disease a specific type of compression stocking is prescribed (Rotsch et al., 2011). There are four compression classes.

figure 2.3.1 compression stockings

Class	I	II	III	IV
Compression intensity	Light	Medium	Strong	Very strong
Pressure on the ankle (mmHg)	15-21	23-32	34-46	>49

Table 2.3.1 compression classes

Patient parameters play an important role in the fitting and selection process. Selection criteria include medical indications, side, compression class, which limbs, the ankle-brachial index, and the recommended production technique.

There are two production techniques, flat knitted and circular knitted, that have their own specifications and characteristics for the final product. The difference between characteristics of flat knitted and circular knitted are summarized in the table below (2.3.2):

Flat knitted	Circular knitted
Flat seam	Seamless
Slightly stiffer because the elastic yarn is knitted without stretch abilities	More stretchable because the elastic yarn is knitted with some stretch abilities
More suitable for very specific tailormade MCS	Less suitable for large size differences within MCS
Little stretch in length orientation, easier to put on	More stretch in length orientation, harder to put on

Table 2.3.2 differences flat & circular knitted MCS

figure 2.3.2 flat knitting machine

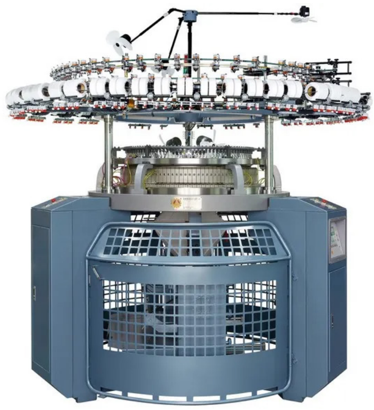


figure 2.3.3 circular knitting machine

The dimensions of patients make if they qualify for confection or tailormade stockings. Based on the previous factors the best type of compression stockings is selected per patient.

The most important feature of compression garments is the elastic property that put pressure on the enclosed body parts. To accomplish this, fibres and yarns with strong extensibility and elastic recovery are required (Xiong & Tao, 2018). The synthetic elastic fibres that are used in compression garments have an extension break over 200% and a quick recovery after tension is released.

MCS are supposed to exert the intended compression for 6 months (Rabe et al., 2021). Depending on the use of the stockings, this may be longer or shorter. Wear and tear, product care, and/or shape changes in a user's leg can strongly diminish this time.

Bandages

Compression bandages are used in the treatment and prevention of the diseases discussed in the previous subchapter (Rajendran et al., 2016). They are designed to exert a predefined amount of compression on the leg if applied at a constant tension. Differences in production techniques and materials decide the amount of compression they can exert. Similar to MCS there are different classes of compression shown in table 2.3.3 below.

Class	Bandage type	Function
1	Lightweight conforming	Apply low levels of sub-bandage pressure and used to hold dressings in place
2	Lightweight support	Apply moderate sub-bandage pressure and used to prevent edema
3a	Lightweight compression	Exert a pressure range of 14 - 17 mmHg at the ankle
3b	Moderate compression	Exert a pressure range of 18 - 24 mmHg at the ankle
3c	High compression	Exert a pressure range of 25 - 35 mmHg at the ankle
3d	Extra-high compression	Exert a pressure of up to 60 mmHg at the ankle

Table 2.3.3 bandage classes

The construction, the tensile force of the fibres, and the application of the bandages determine the provided compression. Therefore, the right application is crucial because incorrect pressure could be counter-productive (Ochoa et al., 2014). A perfect applied bandage (Rajendran et al, 2016):

1. Provides the appropriate compression for the individual
2. Provides evenly distributed pressure over the body contour
3. Provides a gradient pressure diminishing from the ankle upwards
4. Maintains pressure until the next application
5. Covers from the toes to the tibial tuberosity (just underneath the knee) without gaps
6. Does not interfere with dressings
7. Does not irritate/cause allergies

figure 2.3.4 bandage application

2.4 EFFECTIVENESS COMPRESSION THERAPY

Although often prescribed, it is important to know what amount of compression is required for treatment. Also, the effectiveness of MCS per disorder is discussed and the possible preventive nature MCS may have.

Chronic venous disease

Venous symptoms, quality of life, and edema formation in patients with early stage CVD can significantly be improved by low-pressure compression stockings compared with placebo stockings (Rabe, 2018). For individuals in professions that require standing for long time periods (e.g. hairdressing), and who experience venous symptoms, wearing leg compression stockings of 15-20 mmHg can alleviate these symptoms.

Varicose veins

Compression stockings are typically the first line of treatment for patients with varicose veins without healed or active ulceration (Shingler et al., 2021). However, there is insufficient high-certainty evidence proves wheter MCS are effective as the initial treatment of varicose veins in people without healed or active ulceration.

MCS did show to reduce post-operative side effects in venous interventions (Rabe, 2018), such as pain and improve physical functioning during the first week after treatment (for a specific treatment; endovenous great saphenous vein ablation. A heat-induced treatment in the longest vein of the leg) (Bakker et al., 2013). Also, Reich-Schupke et al. (2014) reported that 23-32 mmHg MCS are superior to 18-21 mmHg MCS in the first week after varicose vein surgery, by reducing edema and discomfort in the first week after surgery. The benefits did not sustain for the longer post-surgical period of six weeks.

Edema

Long-distance travellers benefit from the usage of stockings (Rabe, 2018). Low-ankle pressure graduated compression thighs reduce flight-induced ankle edema and (subjectively rated) travel symptoms of leg pain, discomfort and swelling, and improve energy levels.

Already low-pressure MCS (10-20 mmHg) are able to reduce edema symptoms. But, the pressure level should be tailored to the severity of the disease. Nonetheless, the exerted pressure should be limited to the lowest pressure possible to maintain patient compliance.

Skin change

Wearing MCS significantly reduces the area of lipodermatosclerosis compared to patients not wearing MCS (Vandongen & Stacy, 2000). The stockings provided 35-45 mmHg pressure t the ankle with a graduated reduction covering the calf.

Leg ulcers

Wearing MCS reduces the recurrence rates of ulcers significantly (Rabe et al., 2018). Within MCS, higher compression (25-35 mmHg) showed a lower recurrence rate than moderate compression (18-24 mmHg) (Nelson et al., 2006). However, compliance with MCS was lower in user groups wearing ‘high compression’, compared with the ‘moderate’ groups (Rabe et al., 2018).

Acute venous disorder

Venous thrombosis

There is a paucity of evidence from randomized controlled trials on the benefits of MCS for acute DVT (Rabe et al., 2018; Sachdeva et al., 2018). Nonetheless, compression therapy showed superiority for pain reduction compared to bedrest without compression and showed that in the first 9 days edema was significantly reduced (Blätter & Partsch, 2003). Also, with compression, less thrombus progression is reported, compared to no compression.
Also, prolonged wearing of MCS after DVT reduces the incidence of PTS (Musani, 2010). MCS in combination with different blood clot prevention medications have shown to have beneficial effects on the treatment of superficial vein thrombosis (Di Nisio et al., 2013).

Post-thrombotic syndrome

MCS are sometimes prescribed to patients with DVT to help prevent PTS. However, some randomized controlled trials both show evidence favoring MCS, while other trials fail to show benefit of MCS (Burgstaller et al., 2016). Therefore, it is hard to justifiably determine the preventive effects of MCS for PTS.
Patients having PTS get prescribed wearing MCS, these help with symptoms related to PTS (edema, heavines, and aching legs) (Kahn, 2009). Preferably >30 mmHg compression garments are prescribed, only if these are to constricting to apply lower compression of 20-30 mmHg can be considered.

Lymphatic disorder

Lymphedema

Compression is the most important component of lymphedema maintenance therapy (Rabe, 2018). High-compression stockings have shown to be effective (30-40 mmHg), but typically the highest level of compression that a patient tolerates (20-60 mmHg) is most beneficial.

2.5 TREATMENT COMPLIANCE

For MCS to properly function, they are required to exert the correct amount of compression to the calves and ankles. To assure this, they are fitted by a bandagist. Patients are required to wear MCS for treatment or to avoid (further) increased risk of developing the previously mentioned diseases. However, the discomfort and often preventive reason of wearing MCS cause long-term patient adherence to MCS with the recommended interventions to be an unmet need. Determinants that drive individual-level behavioral choices need to be identified.

To treat chronic venous diseases, the first choice of treatment is often compressive stockings. Yet, out of research by Raju et al. (2007), who used data from 3144 new CVD patients seen from 1998 to 2006, only 21% of the patients reported using their stockings on a daily basis. 12% used them most days and 4% used them less often. The remaining 63% abandoned the stockings after a trial period or have not used the stockings at all.
When researching the reasons for the non-compliance most people indicated:

not a specific reason	30%
it was not prescribed by the primary physician	25%
did not help	14%
binding/'cutting off'of circulation	13%
'too hot' to wear	8%
limb soreness	2%
poor cosmetic appearance	2%
unable to apply without help	2%
contact dermatitis or itching	2%
other reasons	2%

There was no difference in compliance between genders (39% man vs. 38% woman), nor different decile age groups.

A good reason for non-compliance may be inadequate patient education. For patients, it is important to understand why they need to wear stockings. Because the use of compression stockings is quite dependent on the individual behaviour of the user, the individuality of the treatment may cause patients to become negligent. Yet, even under direct physician supervision non-compliance still ranges from 21-67% (Raju, 2007; Erickson et al., 1995).

Another reason behind the noncompliance of wearing compression stockings may be because of the lack of knowledge about healthcare. However, research shows that even clinicians themselves just have slightly better adherence to medical recommendations than non-clinicians (Frakes et al., 2021). This suggests that adhering to treatment is not dependent on the knowledge of users. Therefore the lack of knowledge is not solely the problem of the lack of adherence, and another solution has to be found.

Yet, another undiscussed item is that most studies rely on self-reported data. But the research of Prince et al. (2020) about sedentary behaviour shows that self-report measures can lead to a very underestimated sedentary time when compared to device measures. Depending on the self-reporting measures; single-item vs. multi-items and tools that employ shorter vs. longer recall periods can improve the accuracy, especially when compared to device data. However, there remains a high degree of variability within and between studies, which leads to poor precision and can have great consequences for the interpretation and use of measures. It is suggested that researchers should be cautious when comparing self-reported studies and device measures with health outcomes.

To avoid relying on self-reported data, Uhl et al. (2016) tested their intervention for compression stocking compliance with a thermal probe that was inserted in the stocking. This sensor recorded the temperature every 20 minutes to check whether the stocking was worn at the moment of measurement.
In order to achieve better patient compliance in using compression stockings they designed a study of two groups, a control group and a test group, in which the test group received in-depth recommendations from a physician and additional recommendations through SMS. The recommendations were sent to the user once a week over a time period of four weeks.
After the trial, the patient group receiving recommendation messages showed better compliance of wearing the compression stockings. But more interestingly, they concluded that the improvement in wearing time is achieved by the increase of wearing days and not the average wearing time per day. Because they did not find a significant difference between the hours on days when the compression stockings were worn by patients in each group. When comparing the compliance by wearing days only, the compliance is 33% higher for the test group that received recommendations over the time period of four weeks compared to the control group.

Lastly, to create more adherence, Rotsch et al. (2011) suggest that besides medical function designers of compression stockings should also look beyond medical function. Customers expect fashionable textile constructions that innovate. Expansion of properties of textiles through insertion of agents, and/or colours, partial colouration, and massaging effects through patterned compression are given examples to improve the compression stockings to assure a wider acceptance in the future.

TAKE AWAYS - CHAPTER 2 LITERATURE RESEARCH

Lower leg

Muscles consist of many small fibres that shorten during muscle contraction. By expanding in grid, they put pressure on everything around. Inside the leg this stimulates blood flow. The muscles in the leg serve as the motive force for returning venous blood back to the heart through the "calf muscle pump". Movement of the foot is controlled through muscles connected to tendons proximal of the ankle, while tendons in the foot are kept in place by retinacula.

Diseases

Diseases affecting the venous and lymphatic systems of the legs can lead to significant morbidity and impairment in daily activities. The three main categories affecting these systems are: chronic venous disorders, acute venous disorders, and lymphatic disorders. Understanding these disorders is crucial for healthcare professionals & designers to better support patients with venous and lymphatic disorders of the leg.

Treatments

Compression therapy is one of the mainstays of therapy for the diseases. It is a combination of compression garments, such as stockings, and/or bandages with flexible structures. These are applied to enclose specific body parts with a defined pressure pattern. The pressure supports blood circulation. Although the therapy has shown effectiveness there is enormous noncompliance among patients.

Design strategies

Compression therapy showed to be an effective form of treatment. The amount of compression exerted by the garments is crucial, so future interventions are required to keep the correct compression. The expected lifespan of MCS is half a year but this can decrease due to wear and tear, product care, and/or shape changes in a user's leg.

The large noncompliance indicates a patient dissatisfaction; user needs have to be taken into account during the design process of a new product. It is also suggested to take aesthetics of the product into account.

Designer takeaway

Within compression therapy the excerted pressure by the garments is crucial for effective treatment. Indicate patient needs to create more patient compliance.

Healthcare takeaway

Compression therapy is a largely applied way to treat patients with vascular and lymphatic disorders. Noncompliance has major impact on the (negative) development of diseases.

Researcher takeaway

If trying to improve compliance, measure in the increased amount of days that MCS are worn, rather than focussing on the amount of wearing hours.

Next steps

Although evidence shows clear effectiveness of compression therapy for vascular and lymphatic disorders there is a low user motivation. Literature identified some answers, but a deeper understanding is required to better understand user needs.

Therefore, the next step is performing interviews. Beside interviewing users (like the literature), a wider focus should be considered. So, also healthcare providers are interviewed to gain insights into their understanding of patient needs.

3 USER RESEARCH HEALTHCARE PROVIDERS & USER

Literature provided some arguments about user behavior and the importance of compression stockings.

But, to find a better understanding of the user's motives, experts and a user are interviewed. These interviews are also used to understand the pain points of current designs and the impact MCS has on the interviewee to research potential interventions.

3.1 PURPOSE

Literature provided some reasons for noncompliance, the biggest response was 'not a specific reason' with 30%. Also not being prescribed by the GP or having the feeling that the products do not help were mentioned. These answers sound deflecting and are not informative enough to help with generating an understanding of how patients may become more motivated to stay compliant with compression treatment. So a lack of understanding of underlying needs remains.

To gain this understanding, a more holistic approach is taken. Interviews are set up, to get insights into compression stockings from people with first-hand experiences. With their personalized view and experiences with compression therapy, potential struggles and motives people have aim to be explored.
To collect a wide range of information, four people with different relations to compression stockings have been recruited for an interview.

First, an interview with the manager of a medical compression stockings provider company was interviewed. Followed by a user, a district nurse and lastly a bandagist.

The interviews were semi-structured with a predefined flow. Each interview had phases in the following order: a general start, expert knowledge, and desires. Prior to the meeting, for each phase of the interview, open questions were prepared. Based on the answers given additional questions were asked for more in-depth information.

In the general start, questions about the relation between the interviewee and compression garments was the focus. Depending on the provided answers,

MANAGER MEDICAL COMPRESSION STOCKINGS PROVIDER

Prior to working as the manager at the medical compression stocking provider, **Jeroen** was in finance. Later he joined a company that creates tools to support users in donning and doffing, nearly 16 years ago. Eight years ago he followed the training to become an authorized bandagist. For two years he is the manager of the company.

USER

The first time **Jody** started wearing MCS was roughly 8 years ago when she was 54. After her surgery for varicose veins (developed during pregnancy) in her right leg she wore stockings that covered her feet up to her thigh. Past the recovery period, she was allowed to stop wearing the stockings.
A year later she got thrombosis in her left leg, which was treated with medicine. But when she redeveloped thrombosis a year later again, the GP told her that it would be best to start wearing MCS on a regular basis.

the overall tone of the interview could be estimated. In the knowledge phase the focus was more on expert questions to collect information. Specific questions for the researcher to understand compression garments were asked. Also opportunities and essential qualities of compression garments were explored. Lastly, the desires are explored, through questions about needs, pains, and opportunities the user needs and attitude are explored.

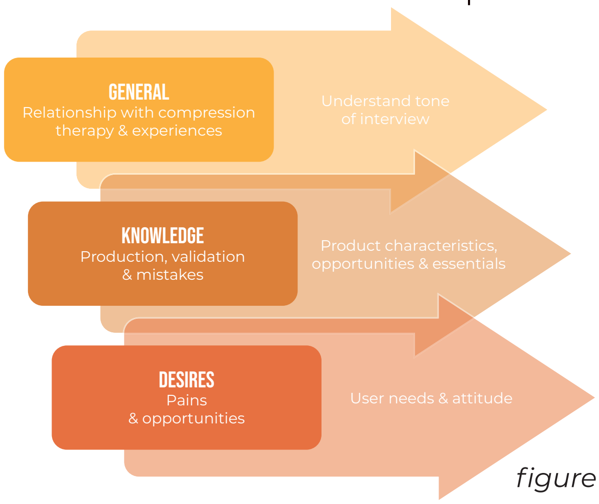


figure 3.1.1: setup & intentions

Based on the interviewee's profile (related to their interaction with compression garments) the questions were tailored to their relation. Overall, there was overlap in the questions and the information that was gathered in one interview was applied in the next interviews. During the interviews, the phases guided the conversation to make sure desired topics were covered, but it was not mandatory to ask prepared questions in a specific order as long as every phase was discussed.

DISTRICT NURSE

Jeanet is a district nurse, aged end of 50. Originally schooled as a graphic designer she decided to make a career shift roughly 5 years ago. Besides being a district nurse she followed additional education, which makes that she is certified to apply bandages. Since not a lot of district nurses are able to apply bandages, most of the patients in her district who need such treatment are assigned to her.

BANDAGIST

Monica, early fifties, used to work at a homecare shop before becoming a bandagist. This trajectory makes that she is an expert in advising people to remain independent for as long as possible. Beside fitting MCS she knows to which experts she needs to refer patients if different care is needed beside prescribed MCS. Monica is a colleague of Jeroen, but also works for a cancer care centre. Especially within cancer patients she sees a large diversity of patients who require compression therapy. Monica aims to keep life as bearable as possible for her patients, so she tries to think along with her patients to see if additional compression products could improve the quality of life.

3.2 THEMATIC ANALYSIS

Every interviewee shared their knowledge and insights on compression stockings. Afterward, the collected data is structured using a thematic analysis-inspired approach. With a thematic analysis of data, patterns, themes, and trends can be identified.

Several themes were identified; the fitting process, donning and doffing, compliance, and aesthetics. By presenting these themes, a better understanding of compression garments perceived by users and healthcare providers will be understood. This understanding support in the process of necessary product innovations and promotes health outcomes.

Fitting process

There are a lot of stockings manufacturers, and every manufacturer has slightly different properties. The cardiovascular surgeon writes a prescription after which it is the task of the bandagist to find the perfect fit.

To fit the correct compression MCS, five measuring points on the leg are used. By wrapping a measuring tape around the leg with legs up, the circumference is measured. This is tougher for patients with edema because the bandagist needs to measure through the edema. To do so, the measuring tape is pulled tightly to push away the fluid buildup. Although uncomfortable, this is very important. Otherwise, the stockings are misfitting and provide too little compression.

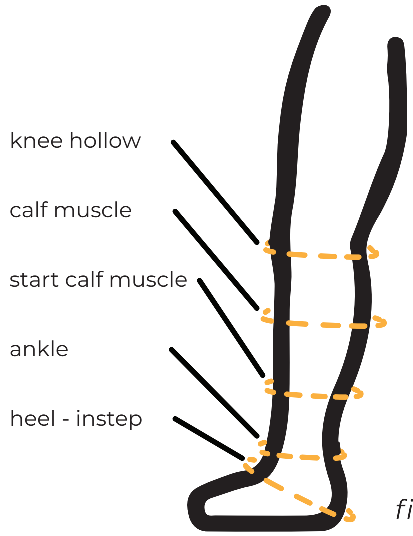


figure 3.2.1: measuring points

When ordering stockings, the bandagist takes all the requirements into account and finally based on the patient's dimensions, a decision between a confection or a tailormade product is made.

"If my stockings would look like a panty, then it would be acceptable. Now you clearly see that I am wearing stockings." - User

During the fitting process, the patient's needs and capabilities should be taken into account. Within products and manufacturers are small differences. E.g. MCS are produced in white fabric and dyed to desired colours, this causes darker-coloured MCS to be stiffer than light-coloured due to the number of colouring treatments. This stiffness affects the donning and doffing ease, for 'weaker' users this is crucial information. Also, the fashion styles of users may affect their adherence to MCS later.

"I notice a difference in the amount of compression, the stiffer the harder." - District nurse

Although there is a numerous availability of colours, on estimation 95% of the users stick to black and skin-coloured stockings. Because they need to wear the stockings for an entire year patients fear bright colours becoming too eye-catching. Mainly men pick black stockings, whereas women more often pick skin-coloured stockings. Besides a more inclusive colour pallet, MCS has not innovated or changed much over the last years.

MCS are offered as medical devices, therefore they need to adhere to the European Medical Device Regulations (MDR). In the Netherlands there is a register (de lijst van Bernink) with all companies that comply with all MCS requirements. Healthcare providers only order MCS of companies that are on this list. Throughout the product lifespan, the compression of MCS is never validated whether it (still) provides the correct amount of compression. Possibly users are exposed to too little or too much compression. Another reason why healthcare providers work with this list is that the Dutch healthcare insurance system reimburses MCS from companies that are on this list. Each year, users are entitled to a new pair.

Donning & doffing

The most compression of MCS is on the ankle (100%), offering very little stretch possibility. Unfortunately, the ankle is right above the instep/heel, which is very wide. The difference in circumference makes donning (and doffing) hard. Some tools exist to support donning and doffing.
Often younger patients are able to donn and doff themselves. But with age this becomes harder. Diminishing muscle strength and flexibility cause elderly to require a (district) nurse to donn and doff. Most of the patients that district nurses visit, wear MCS and require help with it. It is physically demanding work, that becomes increasingly heavy with edema patients.

"I think 80% of my patients wear MCS, and I need to help all these patients to donn and doff. So it would be amazing if something changes the dependency. Ideally, patients can do this themselves and district nurses are not required to help with this anymore."- District nurse

A major inconvenience experienced by elderly MCS patients is the dependency on district nurses. They need to wait for the district nurse to help them. For patients, it is 'hard' to start or finish the day before the district nurse visits.

“Often people do have the strength and mobility to put on ‘hemakousjes’, compression socks with a limited amount of compression. “I wish something like this could also be possible for compression stockings because then we can focus more on providing care and spend more time with patients and patients who don’t need us don’t have to wait for us anymore.”” - District nurse

Within compression therapy the ultimate intervention would give users their indepence back, by making it easy to donn and doff. An attempt is with velcro stocking (figure 3.2.2). However, this product is very little prescribed for multiple reasons. The amount of compression is inconsistent (depending on how well it is closed) and the design looks like a bulky harness, so much bigger than stockings. Also, elderly don’t have the finger strength to open and close the velcro, so they remain dependent on district nurses.

figure 3.2.2: velcro stocking

(Non) adherence

The small circumference of the ankle that needs to be pulled over the heel makes donning (and doffing) very hard and for some people this is such an inconvenience that they do not put on their MCS at all. Especially because the support of the stockings is for within the leg, sometimes no visible changes may occur, thus the urgency can seem less obvious.

“Not everybody can be helped. But there is a difference between people who can’t be helped and people who don’t want to be helped. For instance from people with dementia you cannot expect them to adhere to therapy. But some people are simply too stubborn and don’t want to.” - Stockings provider

Also aesthetics play an important role in adherence. Patients want to be able to look nice, especially in the summer when wearing dresses or shorts. According to the interviewees MCS are not part of an aesthetic appearance. Nonetheless, also putting on MCS should be part of a routine, because even when stockings are not visible they are not worn consistently.

“In the winter I can actually wear my stockings, I don’t wear dresses in the winter. It is just a matter of laziness. It should be part of my routine.” - User

“We often experience that people appreciate wearing their stockings.” - Stockings provider

This is especially interesting because every interviewee indicates that nearly everybody does appreciate the feeling and support in the legs that the stockings provide when they are worn.

Actually, one group who is exceptionally well adhering to MCS are the patients that receive daily visits by district nurses. They simply don’t have the choice to be non-compliant and have nurses putting them on for them.

Unfortunately, sometimes family members don and doff, and patients claim that they have worn their stockings, but the sudden increase of fluid buildup shows differently. The same holds for patients that healthcare providers run into during spontaneous encounters. So even to healthcare providers patients are (often) not honest.

Beside the adherence to wearing stockings, people are also rather reluctant to remain physically active. They expect the stockings to take over the treatment aims of their CVD. So all the healthcare providers remain repeating to all their patients that they need to keep wearing their stockings and undertake physical activity. Nonetheless, both pieces of advice remain often unmet.

Mistakes

Even though healthcare providers try to provide users with all the necessary information, users sometimes just forget or may not know everything. For example, it is recommended to wear ordinary socks over MCS to avoid product wear. Yet, this is often either forgotten or ignored.

Another struggle is that people don’t dispose old MCS when they receive new ones. Yet, the looks are the same so it is hard to distinguish old and new MCS but the compression quality goes down over time. Because the amount of compression is very important in MCS, there is a need to distinguish new models from the old ones (or patients just need to throw out old models). Also, a common mistake is the washing temperature, when MCS is washed at too high temperatures the amount of compression quickly deteriorates.

“Coincidentally, even today a patient asked me if he is actually supposed to wear socks with his stockings because he always gets holes in his stockings.” - District nurse

It is a common misconception that MCS going over the knee provides more support. This is only prescribed if patients have major edema and possibly lymphatic problems. MCS that go over the knees often sag which causes irritation. More importantly, MCS support the calve muscle pump. This is only located in the calves, therefore having higher MCS does not (necessarily) resolve in better health results.

The mistakes users make, make it extra important for users to get new stockings. Each year they are reimbursed, but it is a patient’s responsibility to make sure they actually get new ones. It is not uncommon that they forget this.

Bandaging

Besides MCS also bandages can be applied in compression therapy. Applying bandages is a physically demanding and time-consuming task, and health-care providers need to be trained to do this. Not every district nurse is licenced to do this, which causes qualified nurses often to apply bandages to multiple patients a day. Besides bandaging, for these patients the girth of the legs needs to be measured 1 to 3+ times a week (based on doctors' prescriptions). The measurements (or prescription) decide whether a patient needs to receive new bandages. Unfortunately not every district nurse is as careful with measuring, so errors may occur due to measuring on slightly different spots, or because not everybody uses the measuring tape correctly. Lastly, values are rounded off per 0.5 cm, therefore there is quite a large range.

"Currently we follow prescriptions of measuring the circumference 1 to 3 times a week. Sometimes we don't need to reapply the bandages for a week, but patients also really dislike this as well." - District nurse

Before visiting a patient, district nurses don't know if it will be necessary to apply bandages, which can be very inconvenient. Besides applying bandages being physically heavy, it is also very time-consuming. This eventually is inconvenient for other patients, since they need to wait longer before the district nurse visits them. Often they call because they are scared that the nurse forgot about them.

There is a huge efficiency opportunity if the girth of patients' ankles and compression would be measured automatically without nurses being required to visit. Another opportunity within bandaging therapy is for healthcare providers to have more insights when applying bandages, providers don't know what amount of compression they actually apply. They perform a step-by-step procedure, but the actual applied pressure is never validated. Therefore, it is possible that the garments provide patients have too much, or too little compression.

TAKE AWAYS - CHAPTER 3 USER RESEARCH

Main insights

MCS are physically very demanding for district nurses to put on and take off. The dexterity of users can improve this, but it remains tough.

For users wearing MCS it is important that aside from the user's needs and capabilities, also the stockings need to comply with the user's lifestyle.

For some patients, nurses need to measure the circumference of the patient's legs 1-3 times (or more) a week. Depending on the measurements, nurses may need to reapply bandages, both measuring and reapplying are very time-consuming and make schedules very inconsistent. This increases the waiting time of later patients, both the dependency and waiting for district nurses is considered a major inconvenience for patients.

When applying bandages, nurses have no idea of the amount of pressure they actually apply.

Old and new stockings are hard to distinguish by physical appearance, yet for successful therapy, it is important patients use their newest stockings.

Design strategies

With more information about the compression, both patients and healthcare providers can benefit. This assures that the correct garments are worn with enough compression.

All users of MCS would benefit if MCS are easier to put on and taken off.

Dependency and waiting time are big struggles. Diminishing this would have major impact.

Designer takeaway

Apart from wearing stockings, patients need to keep moving and stimulate the calf muscle pump. They often don't know, or simply don't do it enough. Most ordered stockings are black or 'skin colored'. Aesthetics is often an excuse for not wearing MCS, but even when not visible (some) patients remain not noncompliant.

Healthcare takeaway

The inconvenience of putting MCS on and off seems an important reason for patients not to wear. District nurses are a driving force in compliance of elderly patients. If patients are required to put them on themselves (with the help of family) they often become noncompliant.

Researcher takeaway

Because MCS are medical devices they need to comply with medical regulations. In the Netherlands there is a list of certified companies for which MCS get reimbursed. Therefore, experts trust that the provided products meet the ordered requirements and are not further validated.

Next steps

MCS are worn by a wide age group and all age groups needs are equally important. Lifestyle is an indicated need, and needs to be further explored.

Lack of motivation to move is indicated and should be taken into account.

Putting MCS on and off is often mentioned, and may be the most important problem for users. To create mainingful impact, this needs to be further explored.

To assure that patients have the correct amount of compression, a validation tool should be considered within garments.

4 LITERATURE REVIEW SENSORS

To ensure that MCS effectively fulfil their treatment objectives, it is crucial they exert the appropriate level of compression. Also, the inconveniences of Ill-fitting MCS often lead to non-compliance among users.

To address these challenges and enhance the quality assurance of MCS, this chapter delves into the exploration of sensor integration within compression stockings.
By integrating sensors into MCS, sensors could offer users real-time monitoring and measurement of compression levels, offering the potential for improved fit, comfort, and treatment outcomes.

Emerging technologies that may be implemented compression therapy are discussed and based on future sensors, a literature review is used to estimate the acceptance of (elderly) users of such technology. Finally, the insights are bundled into criteria for a suitable sensor.

4.1 SENSOR POTENTIAL

Venous and lymphatic disorders in the leg can lead to significant morbidity and impairment in daily activities, highly impacting the quality of life for patients. Compression therapy is the preeminent treatment for these disorders. Depending on the disorder a choice between (primarily) bandages or MCS is made. For successful treatment of the disorders, it is essential that a correct amount of compression is exerted by the products, and that patients adhere to their compression therapy.

Remarkably, MCS has undergone very little innovational development. This is especially interesting since there is awfully low patient adherence to the use of MCS. In the interview with the home care nurse, she indicated that some patients get daily visits, and some patients only get visited a couple of days because family members also provide care. Patients who have family members helping are required to don and doff their MCS themselves (or the family member).

If MCS are repeatedly worn, (most) patients do not show large increasing edema and often have their legs become slimmer over time. This makes it easier to put on the compression stockings in the morning because the legs are less expanded. Patients say to be wearing their MCS as prescribed. Yet, if not daily visited, many patients have swollen legs, due to edema. So district nurses immediately know whether patients have been compliant with their treatment. Not only do swollen legs make putting MCS on a lot harder (and physically demanding) for district nurses, but often it also requires (additional) bandaging treatment. Furthermore, it causes annoying discussions between nurses and patients about their non-compliance.

Data insights are a valid argument to support nursing staff in their persuasion to patients about the importance of compliance with compression therapy. But it can also create patient empowerment, if patients are truly compliant but still develop problems, data insights can show that the chosen type of intervention may not be suitable for this patient.

Another large frustration of the elderly is the dependency on district nurses to help them put their stockings on and take them off. Patients can be waiting for a long time and are often anxious that the district nurse forgot about them. While MCS are lagging behind in getting innovative, materials and healthcare advances are developing and healthcare is transforming towards a more tailor-made healthcare system (Li et al., 2019). In such a system, individuals are better monitored with wearable technology. This additional monitoring provides both healthcare providers and users with a better understanding of physical developments. The insights can help with preventive care and early detection of diseases, this empowers users with healthier lifestyles and empowers healthcare providers with better and easier decision-making.

This chapter is going to discuss the current existing sensors for compression therapy and innovative advances that can help improve experiences within compression therapy. In the end, (emerging) sensors may trigger an attitude shift towards MCS and its appearance. And with sensors, users can gain insight into their health and gain more ownership of their compression treatment.

Validation of compression garments

For successful compression therapy, both compliance and the correct amount of exerted interface pressure are key. Commercial pressure sensors for compression therapy exist but are not regularly used.

The exerted pressure stimulates blood flow and helps diminish fluid retention. Valves close better, which diminishes reflux, and the incompressibility of liquids causes the fluid to be transmitted back into the body. Arm compression garments are expected to deliver the highest degree of compression on the wrist and gradually decrease along the arm toward the shoulder. Unfortunately, there is a lack of consistency in these gradients for commercial compression sleeves (Ng et al., 2017) . This is especially distressing because the healthcare providers who have been interviewed or involved in this thesis admitted to not validating the compression of their prescribed compression garments. Luckily, in the Netherlands the list of Bernink safeguards the quality of provided compression garments. Yet, the inconsistency of graduated pressure in compression garments on the market shows the need for additional validation.

Also, the district nurse explained that MCS are yearly reimburse by insurance companies. This is important because in the first place MCS have an expected lifespan of 6 months (Rabe et al., 2021). Depending on the use of the stockings, this may be longer or shorter. But, overtime compression garments start to wear and the amount of compression deteriorates (Lim & Davies, 2014). Although users are advised to discontinue using older compression stockings (and are advised to throw old stockings away) they typically keep the stockings. Over time new and old stockings get mixed during laundry cycles. Especially if users receive stockings with the same visual appearance as their previous model, new and old models are hard to distinguish. This causes users to wear old stockings that provide too little compression for their proposed treatment.

Commercially available pressure sensors

There are compression sensors on the market that help monitor and evaluate the effectiveness of compression garments for patients. A well-established device is the PicoPress (Ning et al., 2019). The device has a circular transducer that is placed on the desired spot underneath the compression garment. In research by Ning et al. (2019), the PicoPress performed better than similar monitoring devices (Smart Sleeve Pressure Monitor and the Juzo Pressure Monitor) compared to a sphygmomanometer.

As can be seen in figure 4.1.1, the PicoPress is a handheld device. Although it can be used for dynamic measuring, the device is not suitable for wireless and continuous monitoring. So it is impossible to use for everyday monitoring of compression in a normal life setting.

figure 4.1.1 Picopress used in bandaging

A widely available and affordable sensor is a force sensing resistor (FSR). They produce a decrease in electrical resistance as more pressure (physical force) is applied to the sensing area (Interlink Electronics, Inc., n.d). Typically FSR sensors exists out of two conductive halves printed on the same substrate. They are not connected with each other. On the substrate a spacer is placed, a thin material that separates the bottom substrate to new layers above. On the spacer a new substrate layer is placed with conductive ink. When the sensor is exposed to pressure, the conductive ink closes an electrical circuit between the two conductive halves of the bottom substrate. As more pressure causes more contact between the conductive halves, the magnitude of the electrical output corresponds to the exerted pressure applied.

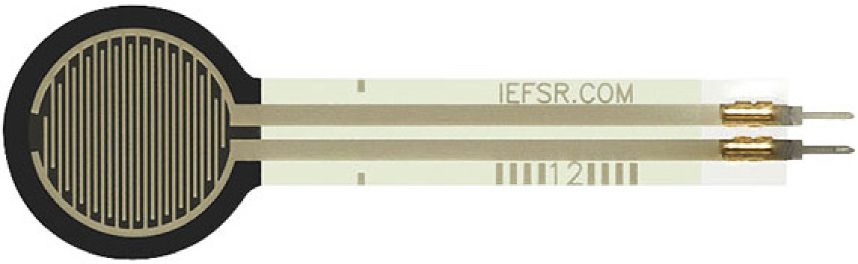


figure 4.1.2 FSR sensor

4.2 EMERGING SENSORS

Pressure sensors

Among others, Farooq et al. (2020) developed a thin-film flexible wireless pressure sensor made for continuous pressure monitoring. The sensor can be created through low-cost production techniques and works through an inductor-capacitor (LC) resonant circuit. In this sensor, the resonance frequency (oscillations of a system in unforced resonance) is proportional to the applied pressure. By placing multiple of these wireless sensors under compression garments the sensors can give a personalized output of the interface pressure. The sensors developed in the research showed good sensitivity in lab research. Future tests will include human subjects to validate the true effectiveness.

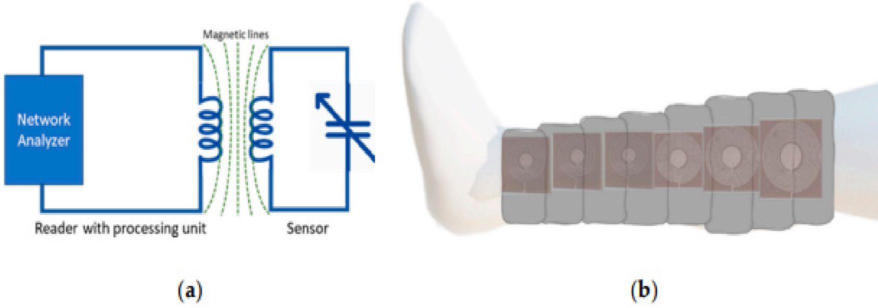


figure 4.2.1 (A) Schematic diagram of sensor with network analyzer (B) Application using sensors under bandage, both by Farooq et al. (2020)

A flexible, lightweight, wireless platform developed by Park, et al. (2020) monitors pressure and skin temperature between compressive garments and the skin. The visual appearance is a band-aid-like white silicon strip that consists of a coin cell battery, a three-dimensional pressure sensor, a temperature sensor, and electronics. On a thin, flexible copper-clad polyimide film substrate a Bluetooth system is integrated and the sensors are connected through a Wheatstone bridge circuit configuration. The studies and trials on human subjects show accurate, stable performance which makes this product an interesting technology to be implemented into compression garments.

Stretch sensors

A different approach to interface pressure measurement is through the expansion of fabrics. In the emerging materials lab of the Technical University Delft, new types of sensors and materials are developed and embraced. Beyza et al. (2022) have been working on the development of a low hysteresis, linear weft-knitted strain sensor for smart textile applications. Often knitted strain sensors come along with high hysteresis and low gauge factor values, making the sensors unreliable. Yet, their research found that with the correct parameters, it is possible to produce low hysteresis linear sensors with a working range of up to 40%.

figure 4.2.2 a weft-knitted stretch sensor

An example of a previous graduation project with a weft-knitted sensor is a breathing sensor (Valk, 2020). The sensor measures resistance (change) which was displayed on an external device. Based on the output, the breathing frequency can be determined by looking at the period of the waves.

Another application of knitted sensors is in motion recognition in a walking cycle (Li et al., 2019). They placed 10 sensing areas in high elastic knit sweat-pants. Different body moments are reflected through the strain deformation of the fabric structure and consequently the electrical signal. Each of the 10 sensors gave different sensing performances for motion. They suggest this is mainly related to the different placement around the knee. This different displacement is differently affected by the motion of joints and the response of resistance to the recovery of deformation. Through differences in the peak value of resistance, valley value, and time ratio of peak point in the gait period, the four tested kinds of gait could be recognized and distinguished from each other.

For compression therapy, the correct interface pressure is essential. Hutchison (2017), published a paper that describes integrating a similar sensor in a smart bandage for bandage application to show whether a healthcare provider is applying the bandage with the intended pressure. Yet, Hutchison published while developing the bandage, so no results of the outcomes are presented.

To calculate the interface pressure on circular objects, one can use the Laplace equation (Schuren & Mohr, 2008):

$$P=T/R$$

In which 'P' is pressure in Pascal, 'T' is the Tension of the bandage in Newton per meter, and 'R' is the radius of the curvature in meters. However, the units are not commonly used in medical practice (Thomas, 2014). Furthermore, the human leg is not circular, therefore working with the radius would offer little practical value in a clinical setting. Thus, a modified version is proposed:

$$P=(T\ n * 4620)/\ C\ W$$

In this formula the pressure is in mmHg, a unit commonly used in compression therapy. The 'T' is the bandage tension in Kgf, 'n' stands for the number of layers applied, 'C' is the circumference of the limb in cm, and 'W' the width of the bandage in cm. The 4620 is from the conversion of units.

Yet, the theoretical approach of using calculations to estimate the interface pressure comes with deficiencies (Thomas, 2003). The formula holds for a circular cross-section. However, since the human limb is not circular, most likely any attempt to correlate the average pressure to a single point measurement on a limb will be unsuccessful, as can be seen by multiple publications (e.g. Barhoumi et al., 2018; Schuren & Mohr, 2008). Thomas (2014) indicates more difficulties when working with the modified Laplace equation and validation tests. However, Thomas also shows that, when compression bandages are correctly applied to a cylinder with known bandage tension and circumference, the modified Laplace equation can predict the average interface pressure correctly. But, it remains hard.

Application of sensors

All-day monitoring and the accessibility to this data collection is especially intriguing when being used in a wireless body area network (WBAN) (Esfahani, 2021). In a WBAN, multiple vital signs are collected by different sensors on the body, that can be integrated into different wearables. Combined, these sensors provide an overview of the entire health. This overview of real-time monitoring is an exciting expansion of healthcare when these WBANs can transfer health-related information to healthcare providers in real-time for safekeeping, analysis or action. Such e-health services that keep users connected to medical professionals and caregivers are a huge advancement for preventive and home-based healthcare because it has the potential to reduce the workload of district nurses and cuts back the back-and-forth travel costs for users (Murnane et al., 2016).

Current challenges

However, some technological limitations make the immediate integration of many sensors for a WBAN slightly farfetched. Below three current challenges are summarized (Chen, et al. 2021).

1. *Signal deterioration during motion or long use*
   For reliable signal recording, most sensors are required to be in close contact with the skin. However, during motion, the mismatch between the stretch of the skin and the device (Young's modulus differences) leads to sliding and detachment. This can be tackled with self-adherent sensors using Van der Waals' force or chemical adherence, but wet conditions remain challenging. Also, long-wear sensors and skin irritation need to be evaluated.

2. *Power supply and data transmission*
   Real-time wireless monitoring requires communication between the sensor and another device. The current low-power miniaturized Bluetooth technology consumes power of at least 1 mW, but most of the current thin-film batteries only have less than 1 mW power capabilities. Thus, requiring additional power sources. And other techniques often have shorter connectivity distances or limited sampling rates. Moreover, data transmission units usually rely on commercial bigger chips, which makes the sensing units bulkier again.

3. *Limited deep learning medical diagnosis*
   Although more data is coming available, the diagnostic abilities through big data and deep learning are still underdeveloped. The one-sidedness of one sensor's output is limited and to become informative for users and external healthcare providers, multiple profound parameters are required. If successfully combined, vital signs can potentially be monitored and detected by integrated AI algorithms.

4.3 SENSOR ACCEPTANCE OF ELDERLY

Although there are great advancements in sensor development being made, we already established that greater risks for cardiovascular diseases and lymphatic diseases arise with advanced age. Therefore, this subchapter focuses on technology characteristics that help older adults embrace technology.

Despite advancements made in the field of wearables, a low-level acceptance of health technology by older adults (60+ years old) is frequently reported (Li et al., 2019). Therefore, Li et al., (2019) investigated user acceptance of smart wearables to enable technology to serve older adults better. They focused on unique features of smart wearables, such as: compatibility, perceived social and performance risk, and health status. In their study they found that the majority of the participants (n= 146) expressed willingness to accept smart wearables now or in the future. The major antecedent of intention to use is perceived usefulness (reflection on the benefits that a participant gains from using smart wearables). Other key findings, relevant to this project, are summarized below.

Elderly with poorer health conditions are significantly more positive about the intention to use smart wearables and their perceived usefulness.

Elderly surrounded by others who use or speak fondly of smart wearables significantly perceive smart wearables as useful compared to those who do not have this supportive ecosystem. Similar results have been seen in the past for mobile phone usage, elderly were significantly affected by the opinion of their (grand)children (Mallenius et al., 2007).

To clarify the usefulness of smart wearables, healthcare providers should emphasize the pragmatic functions and benefits of smart wearables. Such emphasis through additional messages by the healthcare provider also enhanced the adherence to compression stockings in the previously mentioned research by Uhl et al. (2016).

Performance risks, such as low measuring accuracy, quality, and privacy concerns can significantly decrease the perceived usefulness of smart wearables. The survey showed that 34.9% of the participants were concerned about the reliability and measuring accuracy of smart wearables. Therefore, it is suggested that measuring the accuracy of the physical signs is clearly shown to users through e.g. certificates that products meet industry standards and regulatory requirements of the target market.
A customized setting for transmitting physical signs to caregivers would effectively mitigate privacy concerns the elderly have.

Smart wearables should be compatible with current technologies (e.g. tablets and smartphones) and be age-friendly (with a proper interface design). In addition, facilitating training, technical support (and financial aid) by practitioners or family, supported by (well-designed) technology training can help elderly overcome concerns about using innovation technologies. Which will enhance technology acceptance.

The smart wearables should comply with and improve the lifestyle of elderly. Therefore, they are expected to be light and small, elegant, water-proof, and easy to put on and take off.

Designers should take the aesthetic preference (color, style, and fashion appeal) of end-users into account because this has a significantly positive effect on attitudinal factors.

4.4 SENSOR CRITERIA

The limitations of current devices show the need for advancements to enable daily monitoring. It is essential to understand what future sensors should comply with to design for future devices. Literature helped list requirements for sensors.

To create the next-generation sensors for continuous compression monitoring, some challenges and parameters require careful consideration in the design process to assure successful compression care. Important criteria discussed and additional criteria that sensors need to comply with are listed below.

Requirements

1. *Placement*
   The placement of the sensor is crucial since there can be a significant difference in outcome over the length of the compressed limb because compression garments provide a graduate distributed compression. Current measuring devices generally rely on individual probes that measure pressure at a specific point of contact. This is especially limiting if sensors are used for validation of the gradient of pressure (Hageman, et al. 2018). Preferably sensors are embedded into compression garments/intertwined as part of the fabric.

2. *Body posture*
   Currently, when conducting compression garment measurements, the position of the limb must be in upright position. Physiologic changes affect the morphology of the limb and cause deformation of the compression garment, thus the overall pressure balance (Hageman, et al. 2018). For continuous monitoring, redefined pressure needs should be considered. While working in both dynamic and relaxing use cases the sensor is required to be highly sensitive, since it needs to monitor pressures ranging from zero mmHg to at least 50 mmHg (0-8 kPa).

3. *Device size*
   Although existing sensors used in clinical practice are accurate and robust, they are mostly tethered, rigid, large, and connected to additional power sources (Farooq, et al. 2020). New sensors should be small-scale, thin, flexible, lightweight, and have the ability to connect wireless (Li et al. 2019). This also means that the sensor should be compatible with the current technology that users already have.

4. *Accessible*
   The sensor should be affordable to ensure accessibility to a wide range of users. For the sensor to be age-friendly, small details such as tiny buttons, text, or connectors should be avoided in the final design. Preferably everything is waterproof. This way it can be washed with other clothing garments.

TAKE AWAYS - CHAPTER 4 LITERATURE RESEARCH

Main insights

There is a need for additional validation of compression garments. Research showed inconsistencies in graduated compression patterns. Also, MCS are only yearly reimbursed, while products have an expected lifespan of half a year, but this may fluctuate depending on the care.

There are two different sensor approaches towards compression monitoring presented. One approach is through knitted stretch sensors, the other approach is by directly monitoring the interface pressure.

E-health services including continuous monitoring have the potential to reduce the workload of nurses and safekeeping the patient at the same time. It may even the relationship between patients and healthcare providers. But, there are three challenges to be solved yet; long-wearing sensors are challenging on the skin, power supply and data transmission are often big, and deep learning analysis is still underdeveloped.

Design strategies

To enhance acceptance among seniors, the design and service should be age-friendly, as well as match their lifestyle and aesthetic.

Data insights have various potentials: better understanding of physical development, support of preventive care and healthier lifestyle choices, early detection of symptoms, empowers healthcare providers with decision-making.

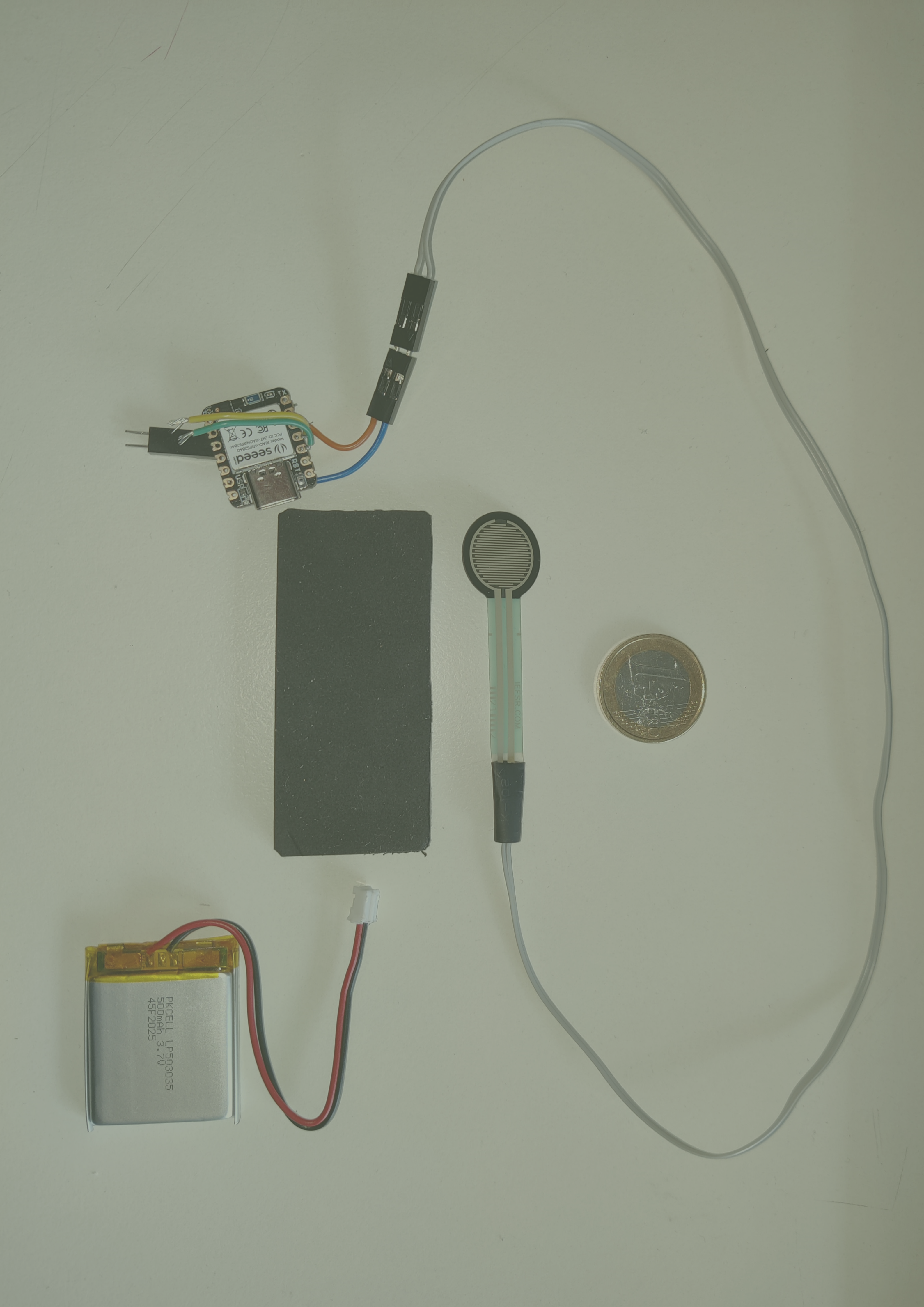
When implementing new sensors into MCS there are certain requirements that need to be taken into account: Placement, ability to measure dynamic and relaxing use cases, high sensitivity, small, integrated, and accessible.

Designer takeaway

Generally speaking, the elderly are not fond of new technology, but they can be positively influenced by their social surroundings, adding customized settings to address privacy concerns, and making design age-friendly.

Next steps

For the research process, the introduced sensors need to be tested to find the best possible sensor. By implementing them into prototypes the acceptance and liability in the given context can be examined.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5 EMBODIMENT PROVISIONAL DESIGN

This chapter presents the embodiment of the generated knowledge up until this point. Prototypes are created throughout the process of designing a smart compression stocking system.

The user-centered approach (with interviews, observations, and brainstorming) combined with literature made the design process comprehensive with the user at the heart of the design and development process.

Two provisional prototypes have been developed and are presented in this chapter.

5.1 APPROACHES

Two provisional prototypes have been developed to test potential approaches to compression monitoring. The designs are discussed and evaluated based on the requirements and wishes, as well as the strengths, weaknesses, and future potentials per prototype are discussed.

The first prototype works with a weft-knitted stretch sensor, the second prototype works with a wired FSR sensor. Both sensors operate with the same microcontroller. The microcontroller needs to be powered by an external battery source to measure the electrical signal of the sensor. The microcontroller can connect to a computer or phone via Bluetooth and transmit measured data to a webpage. Here, the collected data can be stored from this page by downloading it to an Excel file. The webpage discards unsaved data.

By understanding the design rationales, encountered challenges, and improvements, this chapter helps understand elements that need to be taken into account when developing pressure-monitoring compression garments.

Comparison

To monitor the exerted pressure of compression garments to provide interesting insights for users and healthcare providers, two approaches are previously described.

The first approach is to measure and monitor the circumference of the ankle. This can directly be transformed into a visual representation, and this data can show the exerted compression through recalculation. The visualized data represents development throughout the day and can easily be linked to the effect (and importance) of physical activity.

The second approach is by directly measuring the amount of compression provided by the compression garment with a sensor between the limb and the garment. When the ankle expands, the pressure exerted by compression garments will also increase. Monitoring the provided pressure is a compelling approach because it adds constant validation of MCS, and it can be used in bandage applications.

Both approaches are applied in provisional prototypes. For the stretch measurement, the weft-knitted stretch sensor is picked. For direct pressure measurement, the FSR sensor is used. Both sensors are small-scale, lightweight, and compatible. Differences are described and highlighted in this chapter.

5.2 WEFT-KNITTED SENSOR STRETCH BAND

Integration of a weft-knitted stretch sensor is especially intriguing for its embodiment opportunities into MCS. The knitted sensor can be fully integrated into clothing garments during the knitting process. This seamless integration makes the sensor unobtrusive and users don't feel the sensor in their stocking while wearing it. Also, by embedding the sensor into a garment, user mistakes of misplacing the sensor are avoided.

figure 5.2.1 preliminary mockup of runner with knitted sensors

To test the potential of the weft-knitted stretch sensor, first, a band with the sensor included is developed. Rather than developing an entire stocking, the important elements and working mechanisms can be tested with this band. This functional prototype is a replica of the weft-knitted stretch sensor by Beyza et al. (2021). It has a 1 x 1 rib knitting structure, using Nylon-Lycra as non-conductive material and 235 dtex Silver-Nylon, 600 Ω/m as the conductive material. The sensing area is enclosed with non-stretch denim fabric and a closing mechanism similar to a bra fastener. With this closing mechanism, the band can easily be wrapped around the ankle. Both sides of the band have conductive wires with pins that can connect to a microcontroller. Since the sensor is free from irritating materials it is safe for every user to wear.

figure 5.2.2 weft-knitted sensor stretch band

Through strain deformation of fabric structure, the change in electrical signal is measured. The length of the band is 24 cm, similar to the average circumference of a human ankle (Karakaş & Bozkir, 2007). The sensing area is 7 cm long and the only stretching material in the band. The denim fabric around the sensing area functions as a pocket for the microcontroller and battery. As explained, through calculation, the stretch can be used to calculate (an approximation of) the interface pressure.

By having a flat knit band, rather than a tube, the prototype is easier to put on and avoids the sensor being overstretched. Pulling a tube over the heel of the foot requires extensive stretching which is preferably avoided since the sensor performs well if the sensor is not further stretched than 40%. To avoid this from happening in a final product the sensing area can be elongated until it is nearly around the entire ankle.

By having the sensor integrated into the product it also ensures that every time when wearing, the sensing area is located on the same place. This filters out a user error of misplacing the sensor, and allows the data to be compared for trend differences.

Unfortunately, current fabric sensors are (still) sensitive to laundry cycles. Published papers show that textiles with integrated conductive yarns are still heavily affected by washing detergent and laundry washes (Gaubert et al., 2020). Through washing, the deterioration of silver causes wires to become less conductive, thus increasing the resistance output. This change of resistance is a problem for the prototype, since the resistance is calibrated and used to estimate the stretch (which is used to approximate the interface pressure). Before such wires can be integrated into large-scale production, the industry needs to tackle this concern. Also, the performance of the sensor needs to be validated in combination with different environments and skin products.
For instance, whether the sensor starts to behave differently when exposed to sweat or moisturizing cremes.

figure 5.2.3 computer generated sketch with stretch sensor in MCS

The reliable knitting structure of Beyza et al. (2021) makes the weft-knitted sensor an appealing contender for compression therapy integration. Especially since the sensor can easily be knit into MCS during the production process.
In the presented use cases, knitted sensors are only applied in dynamic integrations. Monitoring the pressure/circumference of the ankles of users is a combination of dynamic and inactive user scenarios and therefore it is important that the sensor performs well in both use cases.

5.3 FSR WIRED SENSOR

The FSR wired sensor is an FSR sensor packed into a foam, connected to the microcontroller through a thin wire. The strength of this solution is the direct measurement of the compression of MCS. The sensor does not give a calculation based on assumptions. This monitoring directly validates the quality of the stockings.

Another convenience of this application is that it is easy to produce, and does not require any changes to the existing MCS. Therefore, this solution is an easy innovation to add to the current compression therapy. Having a small wired FSR sensor can also be easily applied to bandages. This way healthcare providers have immediate feedback on the amount of compression their applied bandages exert on the leg.

The used sensor is the Interlink Electronics FSR® 402 13 mm Circle x 56mm. The sensor is optimized for human touch control of electronic devices such as medical systems. For the sensor to measure compression it requires a thickened foam surface for even pressure distribution. Therefore, the sensor is packed into 2 mm neoprene slices. Neoprene is a rubber material that is water resistant and flexible, due to its elastic properties it will return to its original shape after deformation (Navodya et al., 2020). To avoid sharp soldering ends also the tail is included.
For this provisional prototype, the length of the researcher's leg is chosen as a minimal wire length (28 cm).

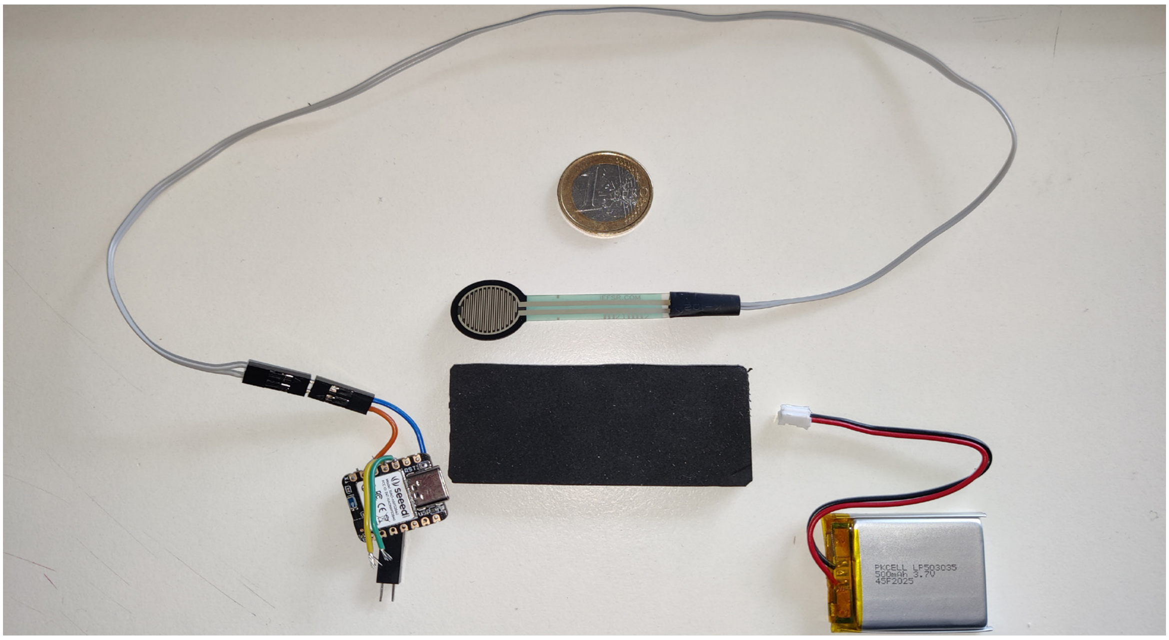


figure 5.3.1 Wired FSR sensor

This approach directly monitors compression. A challenge for this approach is that the exerted compression of MCS deteriorates over time, if this deterioration goes simultaneous with a swelling leg, the monitored compression value could remain the same. Therefore, with the integration of this approach, it is important for users to remain cautious about their own health.

Also, this sensor is sensitive to touch and force. The most exerted compression is at the ankle and often the beginning of fluid buildup. Therefore it is also the most reliable place to measure compression. Yet, if users wear shoes/boots that cover the ankle, this will directly touch the sensor and is likely to cause disruption of the measurements.

Placing the sensor in the correct place (consistently) may be hard for users, especially for users with high compression class MCS. During observational sessions with the bandagist, it became clear that users put their MCS on in various ways, but often it involves a lot of pulling. A loose sensor can easily move during such actions. The organic shape of the ankle makes that exerted pressure on some places on the ankle will be less than in other places. In order to detect gradual changes in compression, it is crucial that data can be compared. A difference in placement would disrupt this.

figure 5.3.2 computer generated sketch with FSR sensor under MCS

Also, MCS can be validated with previously described products such as the Picopress. During MCS validation, the leg is required to be in an upright position, and the compression is measured when the user is inactive. However, when continues monitoring, daily activity needs to be taken into account. So the sensor also needs to perform well in dynamic use cases and the monitored data needs to be evaluated before haphazardly warning the user about measured values.

Although the described characteristics of neoprene make it a very suitable material for insulating the sensor in this design application. Skin contact with neoprene may cause two dermatological risks: allergic reaction and miliaria rubra (Stern et al., 1998). Luckily neoprene sensitivity is rare, but its application for a developed sensor may require reconsidering.

Lastly, during a preliminary wear test, it was found that the sensor in this proposed design caused a pressure pattern on the leg. After wearing the wired FSR sensor for 20 minutes the images on the right was taken. Clearly, the shape of the sensor pad and wire can be seen, so if this approach is taken, some changes are required to minimize the pressure points.

figure 5.3.3 pressure patterns left on the leg after wearing proposed FSR sensor for 20 minutes

TAKE AWAYS - CHAPTER 5 EMBODIMENT

Main insights

Two different sensor approaches for compression monitoring are explored. Both sensors are small-scale, lightweight, and compatible. Both are able to use the same microcontroller. The microcontroller is powered by an external battery and can connect to other devices via Bluetooth for data transmission to a webpage.

Approach one: Weft- knitted sensor

The sensor measures the change in electrical signal and can translate this to the circumference of the ankle. The interface pressure can be calculated

The strengths are that this sensor is easy to fully embed into MCS during production, which allows proper data analysis since the sensor is always placed in the same place. Also, users won't feel this sensor while wearing the stocking.
The weakness is that the wires are still sensitive to laundry cycles, this may damage the conductivity and change the resistance output, which is used for the interface calculation.

Approach two: Wired FSR sensor

The sensor measures the electrical signal and can translate this to the amount of compression. It is packed into a neoprene material for even pressure distribution and connected to the microcontroller through a thin wire.

The strengths are that it is easy to produce and can immediately be used. Besides MCS it can also be used for bandages.
The weaknesses of the sensor may be that swelling and MCS deterioration may go simultaneously, causing the monitored values to remain the same. The sensor is also sensitive to touch and force, clothing garments may disrupt proper monitoring. Besides that, the sensor is not in a fixed position and may move, which makes data incomparable. Also, neoprene may cause dermatological risks, and the current prototype leaves pressure marks on the skin.

Designer takeaway

Weft knitted sensor:
Potential for a future design: the sensing area can be elongated until it is nearly around the entire ankle.

Wired FSR sensor:
Explore if the neoprene pocket can be smaller and overall thinner.

Researcher takeaway

Weft knitted sensor:
Only investigated in the dynamic use cases, but for the intended integration inactive use cases are equally important. So the performance needs to be validated in different activities and exposed to different environments.

Wired FSR sensor:
FSR sensors are usually measured in inactive conditions and used for touch and force, compression monitoring needs to be tested.

Next steps

Since the weft-knitted prototype shows stronger advantages than the FSR sensor, it will be used for further exploration. When validating the innovative aim of this project, the weft-knitted sensor will be shown to healthcare providers and users to get their feedback on it for further development and iteration.

6 USER RESEARCH OBSERVATIONS & INTERVIEWS

This chapter addresses the user acceptance validation of the chosen prototype with the weft-knitted stretch sensor.
It seeks to enrich the perspective of users and the daily challenges they encounter when with MCS. A wider user group is considered, a field trip with a district nurse is arranged, and interviews with users ranging from mid-20 to mid-50 are set up.

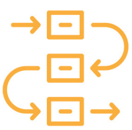
Furthermore, it looks into data collection and possible privacy issues. It does this by presenting the user attitude, perceived aesthetic and comfort, as well as discussing data collection. Thus, the chapter is based on user studies of users who wear MCS dependently and independently and aims to provide insights from different stakeholders.

6.1 FIELD TRIP WITH DISTRICT NURSE

Compression garments are a widely used tool for elderly. Despite recognising the importance of the products, so far, literature and interviews have been the primary form of information gathering. To avoid possible bias and confirm (or discredit) assumptions, a field trip with a district nurse is arranged. In this observation session, the physicality of the job becomes clearer and the challenges district nurses and MCS patients face when using stockings become clear. Also, it helps validate the proposed intervention of the weft-knitted stretch sensor. At the end of the observations, small interviews with the elderly patients are performed to gain firsthand insights into their experiences. Additionally, the weft-knitted stretch sensor is introduced to them. In this subchapter, the findings of the user observations and interviews conducted during the field trip are presented.

The field trip was approximately 2 hours in the morning. To arrange the observations, patients beforehand gave consent and were helped to get dressed by another district nurse prior to our visit. Therefore our focus of the visit was primarily on the patient's well-being and donning of compression garments. Aside from donning, there was space to ask short questions about the proposed prototype. The patients visited (n=4) were over 80 years old. The observational study and questions afterwards provide valuable information for the development of smart compression garments. The insights provide an understanding and requirements of future product characteristics that promote better health outcomes for users.

Insights observation



The schedule of district nurses is created by planners. Depending on the severity of the patient's fluid buildup the schedule of district nurses gets adjusted by these planners. For example, one patient first needs to be put on the MCS before starting the day. If this patient wakes up and starts walking, their legs immediately expand tremendously. Therefore the schedule is adapted and the district nurses always start each day by visiting this patient.

As mentioned before in this report, stimulating the calf muscle pump through undertaking physical activity is extremely important for compression patients to help alleviate disorder symptoms. However, this observation trip showed that this is not always possible. During the interview with one patient with major edema, it was asked whether she was supposed to walk more. Yet, due to joint fractures, walking is very painful, which makes it impossible for this patient to undertake a lot of physical activities.

With advanced age, overall mobility deteriorates. Over time it becomes harder to bend over and it can become (nearly) impossible for some elderly to touch their own feet. Aside from mobility, the deterioration of muscle strength must be considered when designing for elderly patients. For elderly that are able to touch their feet, they are (often) able to put on ordinary socks and light compression socks, referred to as 'hemakousjes'. But the combination of limited mobility and muscle strength makes elderly unable to put on MCS themselves.

A Covid-19 accelerated trend is that most elderly possess a tablet device that is connected to the internet. Primarily the tablet is to stay connected with family members. With some basic training from family members elderly know how to work with the tablet and use it for news, television and as a communication tool.

The work for district nurses is very demanding. Work is physically heavy when donning and doffing, which is especially a concern when they get older. But also, they constantly have to stay connected and answer calls. Throughout their shift they get called pretty often, these calls are a combination of additional requests and concerned patients whether the district nurse is still going to visit (and to check that they have not been forgotten). Therefore, planning can fluctuate and both nurses and patients have to deal with this.

Prototype band validation

When showing the prototype stretch band, the band was closed at the Achilles heel. The district nurse immediately responded to this by emphasising that the likelihood of elderly being able to close anything on the backside of the leg is very small. If the product is supposed to be worn independently from help, the closing (if the product has a closing mechanism) should be in the front of the leg.

Also, the current closing mechanism was, as expected, too small for users to properly use. As the strength and mobility in elderly's hand becomes less, a simpler closing has to be considered. Velcro was suggested.

If the stretch sensor is to be integrated into compression care, it is important that the sensor can be individually put on. New technology should aim to relieve the intense workload of district nurses, rather than adding additional tasks to the work of district nurses. Especially because additional tasks will create even longer waiting moments for other patients.

The elderly were presented with the prototype and the working mechanism was explained. Although they were aware that personal information could potentially be shared with district nurses, none of them shared concerns about sharing data or privacy-sensitive information.

Although mobile monitoring devices have the potential to improve the health of patients, nurses are hoping for future integrations to also support them in their job.

6.2 INTERVIEWS WITH YOUNGER USER

As previously concluded, most discussed disorders come with advanced age. Although elderly patients are wearers of MCS, they primarily just undergo treatment because district nurses put them on and therefore are the leading force in treatment adherence.
Nonetheless, MCS is worn by a much wider range of people that are responsible themselves to adhere to their compression therapy. Therefore a more diverse panel of people are interviewed for richer insights and validation of the sensor band.

The interviews are set up with two initial focuses. The first focus is the initial use, understanding the reason of wearing MCS, but also the thought process when users put on their MCS. The second focus is how to sustain wearing MCS. What are the motives for these users that after a (long) time of wearing they still comply or discontinued their therapy?
To gain this understanding, interview questions are prepared prior to the interview. Depending on the therapy compliance and motives different questions were prepared. A predefined flow chart guiding through the questions made sure that all desired topics are discussed. Although different setups for interviews are prepared, still the interviews went through different stages.

First, the background of the user is asked, in this stage users are asked to describe their morning routine. Depending on whether interviewees mention putting on their MCS or not, a corresponding set of follow-up questions is picked. Secondly, a deeper reasoning behind their motives is searched; moments in their routine are highlighted and their thinking process is discussed. Thirdly, desires and alternatives are discussed, both style options and product options are explored.

JAAP

Jaap started wearing medical compression stockings in his early fifties, primarily due to the effects of thrombosis. Currently, he is mid-fifties. He notices that the MCS support the blood flow in the legs, typically Jaap wears his MCS on a daily basis. Jaaps hobbies are going on hikes and cycling.

EMMA

Recently graduated Emma, mid-twenty, started wearing MCS post-surgery. She lives in a student house with other students. On estimation, she wears her MCS around 90% of the time. Her hobbies are playing volleyball and yoga.

Lastly, the focus shifts more towards technology driven solutions followed by their interpretation and whether they think technology has the potential to fulfil their needs.

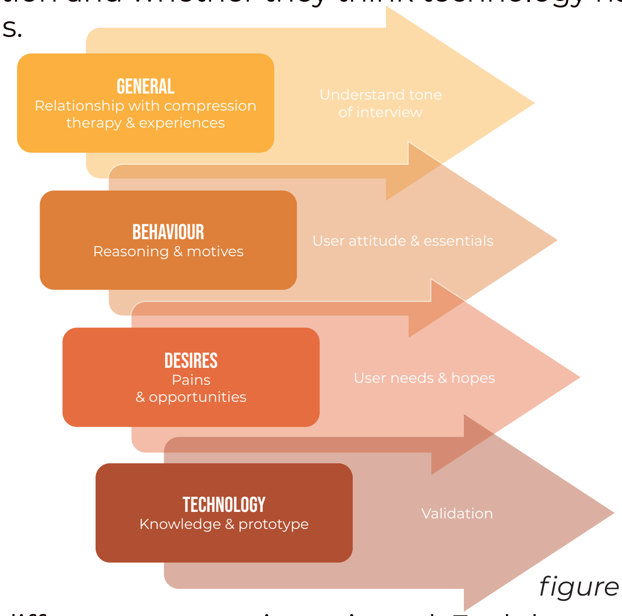


figure 6.2.1: setup & intentions

Four people of different ages are interviewed. Each have different reasons for wearing MCS. Combined with Jody from chapter two, the 'younger' users interviewed have the ages (and identified gender) of; mid twenty (female), early-thirty (female), early forty (male), mid-fifty (male), and early sixty (female). Representing a wide range of ages and possibly different attitudes.

The collected data is structured using a thematic analysis-inspired approach. With a thematic analysis of data, patterns, themes, and trends can be identified.

STIJN

Stijn is in his final thirty and recently started to wear MCS because of May-Thurner syndrome. His stockings are on the dresser and putting them on is the first activity he undertakes. He is a father and besides his full-time job he likes to play hockey.

JOANNA

Different from the other interviewees, Joanna started to wear stockings without them being medically prescribed or for medical reasons. Joanna is early 30 and saw compression stockings appear on social media, the beneficial effects of them made her interested. She wears stockings during travel and on days where she'll stand a lot.

6.3 THEMATIC ANALYSIS

Every interviewee shared their experiences on compression stockings. Afterward, the collected data is structured using a thematic analysis-inspired approach. Several themes were identified; Attitude, Aesthetics, Comfort, and Data collection. By presenting these themes, a better understanding of user needs and desires becomes clear. The presented data will support design decisions and shine light on user thoughts.

User attitude

There is an interesting difference in user attitude towards compression garments that is age dependent. The elderly (80+) just undergo treatment because district nurses donn and doff for them. With the help of a district nurse they accept that they need to wear MCS. However, 'middle-aged' people (50 to 65 years old), are rather reluctant. Typically they refer to MCS or colours as 'grandmother products' or 'old fashioned colours'. There is some embarrassment when they (need to) wear their stockings. Wearing MCS give them a feeling of being much older than they actually are.

"It is not something you tell, something your proud of. But when you sit down and your ankle becomes visible friends see something they don't expect, not your leg; that is a stocking. So they ask about it, even if you don't particularly show it. Well, this does give a feeling, not to sound depressed, but you feel old. Just slightly, and sometimes you think; it is what it is. But just sometimes you think; 'Jesus, I am not that old, and yet I am already wearing stockings.' But after that you just order another round of beers and continue with your day." - Jaap

However, the younger interviewed users (25 to final 30) understand the medical importance to wear MCS. They have open conversations about it with friends and care less if their MCS are visibly worn. Yet, if possible they pick their stocking in a colour that matches an everyday outfit.

"When I told my colleagues that I needed to wear MCS they already started to make jokes about how if I'd also wear them during my vacation on Mallorca." - Stijn

Younger users also search for additional stockings to wear during exercise and have a sense of ownership of their therapy. Based on the activities that they will have that day, they decide what stockings they will wear and may decide to pick a different compression class.

"It also depends on the activities of the day, on the other hand, I try to be like; oh well. Cause that is also what it is! But, in the summer I have more pain complaints in my leg, so I wear them more in the summer than in the winter. Although I also have more summer outfits which I don't want to wear them. Oh well. It's also part of the deal." - Emma

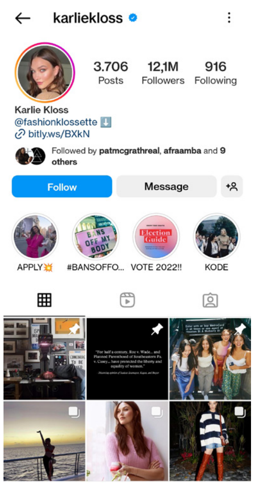


Figure 6.3.1: instagram page of Karlie Kloss with 12.1 million followers

"For hockey, I switch to a class 1 compression stocking, and I put my sports socks over them." - Stijn

Young people are even starting to wear compression garments as lifestyle products. By seeing compression garments worn by influencers, the usage of compression garments is normalized. People start to learn about the benefits it may have during travel or how it can improve workouts.

"I actually started wearing my stockings because, I don't know if you know her, but I saw a picture of Karlie Kloss wearing them on Instagram." - Joanna

Aesthetics

There is a unanimous agreement that the current MCS are not pretty and clearly look like MCS regardless of the skin colour appearance. Although there have been (some) colour improvements over time, the appearance is not desired.

"It would be nice if more colours are possible. But it improved over the last few years. My first pair were some grandmother's brown stockings. So it improved, but I have a pale skin tone, I have no idea how it is for people with darker skin tones than I have." - Emma

Because of the current aesthetics, everybody has some slight aversion to wearing their stockings. A change of appearance that would enable them into becoming more like an ordinary garment would motivate everybody to wear their MCS with less hesitation. Here as well there is a difference between the young users and the middle-aged user.

"If a compression stocking looks like a panty, then it will just be perceived as a panty by others, or a sock, whatever. And I notice of myself, I need to wear one. The other is for preventive reasons. But I wear the preventive less often, I think that, once stockings are part of the outfit I'd rather wear them both. Because now it still feels like a mental threshold to wear them both, others say that they don't notice it, but for me, it is a confirmation of me really having something." - Emma

"During my holiday, when I am wearing shorts, I won't wear my stockings because I think it is embarrassing. The reason why I am saying this is, if your stockings don't look like MCS but just like happy socks then people won't associate it with MCS. So I would probably wear my MCS more if they look like part of an outfit. It's actually a win-win because you wear your stockings because you have to, and you don't feel embarrassed by it." - Jaap

Every interviewee that wears their MCS because they are prescribed agreed by this. Brands like Stox Energy socks are appealing because it diminishes the focus on MCS being a medical device.

"Yes I have heard of them [Stox], they look like running socks. I'd be open to it and when I started my compression therapy I also discussed it with my doctor. Unfortunately, my doctor said to me: 'you have the sturdiest compression stockings possible, so there are no alternatives for you.' But with those the medical element isn't there anymore, I think that can be really valuable for users." - Emma

"I really like happy socks, but now I am bound to these blue stockings. So give them more colours if you are going to redesign them!" - Stijn

Only Joanna (the interviewee that did not have her stockings prescribed) was less outspoken about the aesthetics.

"It was my choice to wear them, therefore the function is more important to me than the style because I can also easily decide to not wear them." - Joanna

Comfort

Every interviewee had a different opinion about the comfort of its stocking. Ranging from positive feelings to acknowledging multiple elements of discomfort. Each perspective will be highlighted with quotes.

Jaap mentioned that in warm climates his limbs can swell up a little bit, also during hikes he notices that his feet expand a bit. This causes increasing compression, which can lead to pain. The discomforts make that during a hike Jaap always takes off his MCS within an hour of walking (if he decided to wear them in the first place). But, he feels like this is a moment where he can permit himself to do this because it is during physical activity so the blood flow is already stimulated.

"Your legs expand during warm weather but your stockings remain the same size. So they become more and more uncomfortable to wear because your compression increases. It should have a cooling element." ... "Also, the top curls in your knee pit, this causes irritation. And lastly, my skin gets very dry, so I do apply my Nivea creme, but it is annoying because it is an extra demotivating side effect." - Jaap

Stijn has the most neutral attitude about his MCS of all. He mentioned that the doctor told him that if the MCS would bother him too much he is allowed to take them off. However, since the MCS don't give him any complications he is very compliant.

"I have absolutely no problems with them [MCS], so why would I not wear them? Especially because it is important for my blood flow, so why wouldn't I wear them?" - Stijn

For Emma there are some situations where she absolutely swears by wearing her MCS and other moments when she on purpose takes them off.

"I play volleyball, then I always wear them, with jumping I notice that without MCS my legs get tired much faster. However, with yoga I never wear them, otherwise, I can't sit on my knees and make certain poses. But when I am wearing heels, I always wear them as well. Otherwise, my legs really start to hurt. So I can not not wear them in combination with heels, I'll get problems midway through the day. Besides that, when I know that I will be sitting the entire day, then I am also wearing them." - Emma

For Joanna comfort is more related to the effects of the MCS on her legs. So she likes the feeling of support and that her legs are not getting tired. But when asked whether she likes to wear her stockings, her reply is merely focused on aesthetics.

"Well, they are not pretty yet." - Joanna

Data collection

Interviewees were asked about the potential of integrating the weft-knitted stretch sensors and sensor integration into MCS and their opinion. Differences were typically driven by personal interests and the relationship they have with their stockings.

Jaap for instance does not immediately understand why sensors would be needed within compression therapy. In the first case, it seems to him like a gadget rather than a medical tool. Monitoring your ankle is just another source of information, just like smartwatches are monitoring heart rate. Also, if the sensor would alarm users about fluid buildup during the occurrence that sounds scary to Jaap.

"I would be scared if my watch would tell me; 'You need to move now.' Because then it would be too late! It should make forecasts like; 'If you remain seated, that would not good. So time to move!' So preventive manners would be a really nice addition to the band. Maybe it is different for every person, but that the band is able to perform forecasts based on statistics. The band would collect data, and with that data the band might be able to perform predictions and inform users that they need to move. If the band would like that, than I would actually like it. Cause it becomes more useful!" - Jaap

Emma has a completely different opinion than Jaap. For Emma, constant monitoring her legs through sensor integration may provide more knowledge about her health. She experiences accidental pain and really wants to know what could possibly trigger this. She is also interested to see if there are changes in her leg during those painful moments. Data may offer her insights into small lifestyle changes that help prevent pain in the future.

"I experience accidental moments of pain, but through the years I have never been able to find out what could be triggers that I feel better or worse. So I think it is very cool to know when I feel worse, something is also happening. For instance, the moment my legs expand, that I am able to connect it to something because now it is completely blanc and I just have 'bad moments'. I think I would like to be able to connect more." - Emma

Stijn has a technical background, so he also acknowledges that emerging technologies excite him in general. Therefore he seems most excited about the sensor.

"As much information as possible! This is super cool to track how your legs are developing throughout the day." - Stijn

Lastly, Joanna, who wears her stockings for general support thinks it is a cool feature but confesses probably not using it.

"To me, there is not really added value to having such information. Maybe during travelling, but I actually don't know if I would use it." - Joanna

Apart from collecting data, it is asked whether their healthcare provider is allowed to have access to this data. Also, if healthcare providers can see such data, are they allowed to send out reminders to increase adherence, similar to the research by Uhl (chapter 2)? Jaap is slightly hesitant in sharing his data, but turns actively against it when healthcare providers would use it to send reminders.

"That almost feels like a violation of my privacy and is very pedantic. Like big brother is watching you. So no, I am my own boss." - Jaap

Different from Jaap, Emma is fine if her data would be shared with her healthcare provider to discuss trends during consults. But Emma also does not want to receive reminders about the importance of wearing her stockings. She considers this a patient's own responsibility and the doctors do not need to know everything that is going on in your life.

"I am also not waiting for my dentist to remind me that I need to brush my teeth." - Emma

Stijn on the other hand is very flexible about his data. Even becoming more excited about the possibilities that his data has to offer. Since he wears his MCS on a daily basis he finds it hard to have an opinion about the reminders. Nonetheless, the potential of creating a large database to improve healthcare really excites him.

"Share everything! Of course, with the guarantee of safety of privacy, but in general I think it is good to share patient information with other clinicians. We need to help each other, so I think others can benefit from sharing my results with other researchers and doctors. So even start comparing my data to others! If my data is anonymized then it is all for the better if such data is shared with everyone." - Stijn

TAKE AWAYS - CHAPTER 6 USER RESEARCH

Main insights

Undertaking physical activity to avoid disorder symptoms is not always possible due to the user's age or other painful symptoms. Also, muscle deterioration due to ageing makes physical mobility and stretching a major limitation to put on MCS individually.
Elderly are commonly introduced to tablet devices by family members and understand the benefits!

Young users have various reasons to wear MCS, which range from post-surgery, and other health syndromes to improved blood flow conditions.

There is a clear difference in age groups' user attitudes towards MCS. Elderly undergo treatment while youngsters understand and accept the medical advantages, and may even choose to wear MCS voluntarily. Middle-aged people are more reluctant due to the stereotype of ageing.
The current skin toned appearance is not desired. The appearance is associated with a medical and elderly purpose, which provides an extra burden to wear.
Overall, the support is appreciated, most comfort dissatisfaction is more related to aesthetics.
Data collection is well perceived if it provides additional value (e.g. more knowledge or improved behaviour) to the users with prescribed MCS.
However, reminders to wear MCS are less welcomed as they provoke a feeling of surveillance.

Design strategies

Handling of hardware and the product should be on the front side or the lateral side of the leg, otherwise, it may form a burden for users. Also, tiny mechanisms should be avoided.
Users must be able to work with the product without help from others.
Data sharing should be optional to offer ownership and security to the user.
The product should not have a skin-toned colour.

Designer takeaway

Skin tones make MCS perceived as medical products.
Improved promotion for the middle-aged target group is necessary to dissolve the stereotype.

Researcher takeaway

Further investigation is recommended for compression adjustment/flexibility when dealing with warm climates and increased swelling that lead to increased compression and pain.

Next steps

Translate the user insights into specific design requirements.

Obtaining additional information from healthcare professionals to improve the overall design quality and feasibility regarding medical recommendations

7 REQUIREMENTS & WISHES

This chapter encompasses expert views on further product development with regard to medical recommendations based on collected data.

Also, previously gained insights are translated into specific product requirements presented in a visual overview.

Both the newly generated knowledge, as well as the requirements are the base for further design steps.

7.1 EXPERT INPUT - VASCULAR SURGEON

Ultimately, MCS provide a constant amount of compression throughout the entire lifespan. Unfortunately, product wear and washing cycles diminish the MCS performance. To avoid users wearing worn-out products, embedded sensors can monitor the compression.
Previously two approaches are discussed to monitor this compression, a knitted stretch sensor directly produced into the garment and an embedded FSR sensor. Regardless of the used technique to monitor the compression of the garment, this measured compression can also be interpreted into the well-being of the patient. To provide users with healthcare recommendations the expertise of healthcare professionals is required.

To develop a product that supports users and gives healthcare recommendations, a collaborative requirement-gathering session with vascular surgeon Dr. M.J.E. van Rijn is held. Her expertise and input are highly valued since the product recommendations and data gathering have the potential to directly affect patient decision-making and her way of working. Also, it ensures effectiveness and alignment with clinical needs. During the session, she shared her knowledge of how the product can add value to user treatment.

With a compression-measuring smart stocking three use cases are discussed:
1. *Compression decreases*
2. *Compression increases*
3. *Compression remains constant*

For each case, user interactions and recommendations are thought out.

Compression decreases

Monitored compression decrease is probably the most straightforward case. MCS are individually prescribed products, meaning that they are often tailored to the patient. Also, the amount of compression of the MCS is essential for that specific treatment aims. Therefore, products that are too worn out to provide the correct amount of compression need to be replaced. The product should warn the user that it is time to replace the MCS since the compression does not comply with the treatment aims anymore.

Compression increases

The only case that compression increase is possible is when the leg expands. With a concerning increase in compression, the MCS should warn the user. There is a variety of medical reasons that the legs can expand. Therefore it is hard to pinpoint the actual cause for the compression increase and the severity of the cause.The first question that needs to be presented to users is whether they had been consistently wearing their MCS. Since not wearing MCS is a logical cause for slight swollen legs, and not a reason for concern.

In case of consistent wearing (or exceptional increase), the product can inform the patient with a list of possibilities. E.g. an inflammation, a new thrombosis or the lack of physical movement. Some causes have additional visible indications, these could be presented to the user combined with questions to help the user indicate the cause of the leg increase.
In most cases, with a major compression increase the product needs to advise patients to visit a healthcare professional. This does introduce a chal-

lenge that needs to be researched in future research. The threshold point to visit a healthcare provider needs to be determined because it is undesired if clinics get overflowed with stressed patients who got the advice to visit their healthcare provider if they have no healthcare risks. On the other hand, if the product wrongly advises patients that there is no need for concern in a hazardous situation, this can have much more detrimental results for the patient.

A pressure increase throughout the day does necessarily have to be alarming. It is possible for the leg to increase (a little) due to everyday life activities. However, if the exerted compression is increased in the morning when a patient has been sleeping, this is more concerning. After sleeping (in a lying position; supine) the legs are supposed to be slim. So the product should be able to compare new data to old data to recognize such abnormalities.

Compression remains constant

Therapy-wise, the ideal situation is that patients remain compliant with wearing their MCS and their compression also remains constant. However, when looking at the previously presented numbers of noncompliance this is a rather rare scenario. Therefore, it is important to celebrate users who manage to remain compliant.

Physical activity is equally important when wearing MCS, and probably patients with consistent compression undertake this physical activity already. Still, the stockings may help stimulate this with personalized goals. Interviews (chapter 2) showed that patients can be very reluctant with moving, therefore setting personalized walking goals with a predefined amount of steps tailored to the physical capabilities of the users may help the users motivate to walk. This goal can be set together with the healthcare provider, and it can be discussed if a daily goal or a weekly goal matches the user's preferences. Apart from step goals, even wearing stockings can be a daily goal and putting it on and off may be used as criteria to reward patients. Most important is that the additional element can be personalized to the specific user. Future stages may even bring users with similar goals together in (online) communities to create social interactions as well.

To the knowledge of the researcher, there is no (found) prior data/publications that recommend which compression changes require patient interventions while continiously monitoring compression. During the session, the assumption is made that the difference of one compression class is a considerable change, big enough for the user to seek help from a healthcare professional. It is recommended for future projects to collect patient data and/or more expert input to validate this. The compression classes are not linearly scaled, so a change of 9 mmHg is picked, similar to the range of class II.
Also, although MCS are a rather uniform solution to multiple disorders, the way how disorders manifest themselves differs. So triggers for one disorder, may be beneficial for another. The product's recommendations regarding the user's health should be closely assessed by professional healthcare providers.

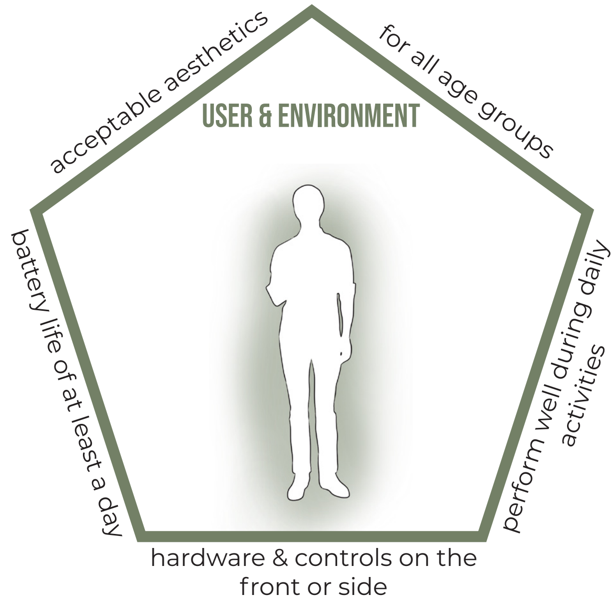
7.2 PRODUCT REQUIREMENTS

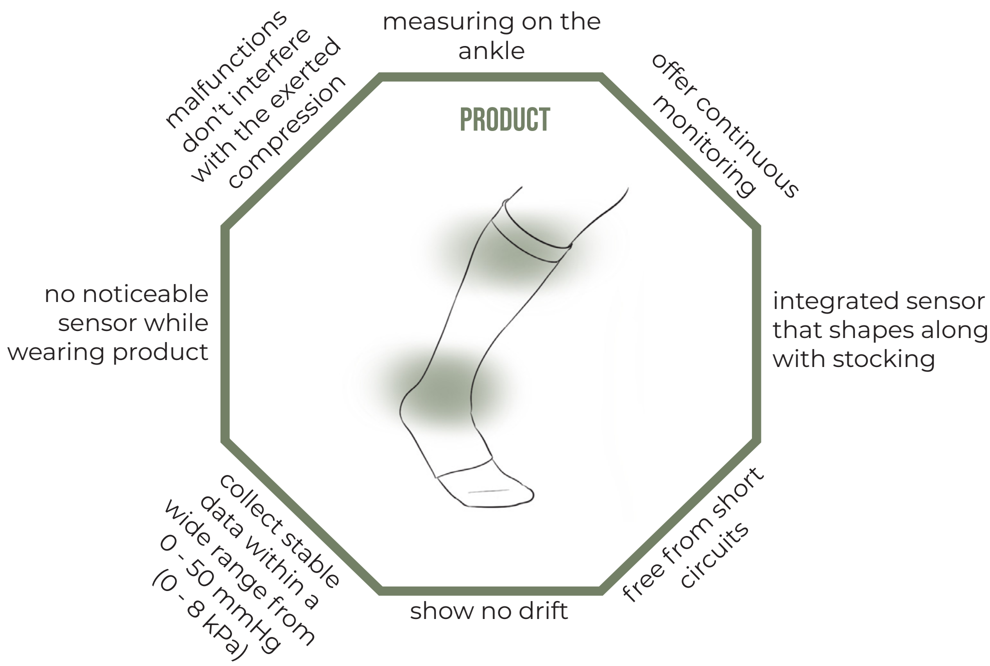
At the start of the project, three research questions are formulated to serve as guiding principles throughout the project. They played a crucial role in structuring the project and research. In this chapter, the generated knowledge of these pillars is converged into the product requirements that will be implemented into the final product. Apart from these items, some wishes about future MCS products are documented.

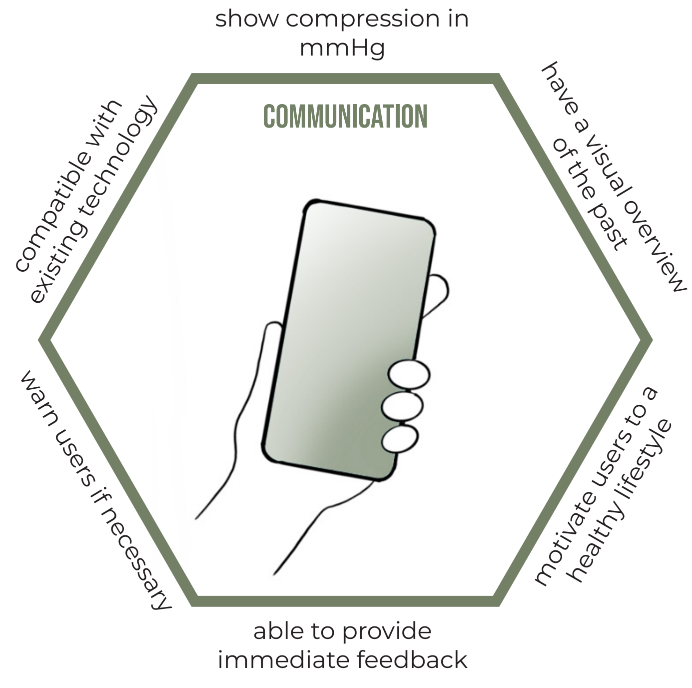
The essential requirements for this project are separated into three layers: product, user & environment, and communication. Additional requirements can be found in a list in the appendix. Each requirement is something the product *should* comply with. The requirements are visualized in the figure on the right.

Additionally, there are 5 wishes that the project strives to comply with.

1. A major painpoint for especially elderly who are dependent or district nurses is the actual dependency. Since schedules of district nurses are fluent they sometimes need to wait longer than expected. This causes a lot of stress, preferably future interventions can help provide additional information.
2. It is very hard to pull MCS over the heel, preferably future products make this easier. This may empower users to put on their own stockings (again), and makes it less physically demanding for district nurses to put on all the MCS.
3. Apart from wearing compression garments, users often need to move more. Preferably future products stimulate users in doing so. Still keeping in mind the physical capabilities of users, some users might be unable to go for (long) walks.
4. Future MCS should help users disguise old from new products.
5. For ease, preferably the sensor is embedded into the product rather than being integrated.


USER & ENVIRONMENT
acceptable aesthetics
for all age groups
perform well during daily activities
hardware & controls on the front or side
battery life of at least a day


PRODUCT
measuring on the ankle
offer continuous monitoring
integrated sensor that shapes along with stocking
free from short circuits
show no drift
collect stable data within a wide range from 0 - 50 mmHg (0 - 8 kPa)
no noticeable sensor while wearing product
malfunctions don't interfere with the exerted compression


COMMUNICATION
show compression in mmHg
have a visual overview of the past
motivate users to a healthy lifestyle
able to provide immediate feedback
warn users if necessary
compatible with existing technology

TAKE AWAYS - CHAPTER 7 REQUIREMENTS & WISHES

Main insights

Requirements for the final product are set up, they are separated into three layers; product, user & environment, and communication. The final product should comply with the visualized requirements.
Product primarily focuses on the sensor and performance, User & environment on the user lifestyle and user scenarios, and communication focuses on the interaction between the user and the product.

There are three monitoring scenarios for the final prototype. The product responses are discussed and can roughly be summarized into the following:
Compression decreases: MCS are too worn out, replace
Compression remains constant: Good, engage with the user to keep wearing MCS
Compression increases: first ask whether the user has been wearing MCS, and follow up with more specific questions to determine the correct recommendation.

Data collected over an extended time period should also be compared to detect abnormalities.

Designer takeaway

Strategies to maintain the user's motivation need to be further investigated and prioritized. Possible behaviour change strategies to further look into are:

- Rewarding the user for constantly wearing their MCS.
- Setting personal goals for physical activity
- Creating a community feeling with like-minded people

Healthcare takeaway

Proper decision-making models need to be defined to determine the urgency of a healthcare professional intervention, and it needs to be adapted to each disorder to fulfil valid recommendations.

Researcher takeaway

Further investigation is needed on compression changes and the required patient interventions.

Next steps

Incorporate the requirements into a final prototype to showcase opportunities and possibilities of future MCS.

8 SENSOR EXPERIMENTS

In this chapter, three tests designed to evaluate the feasibility of the weft-knitted stretch sensor in the medical application of a sensor band are presented. To assess its performance, we conducted a strain hold test, a wearing test, and a calibration test.

In the first test, we tested the performance of the sensor under a constant stretch for a long duration. The second test involved wearing the sensor during various activities to assess its performance under a normal life setting. Finally, the calibration test aimed to determine a relationship between the sensor's measured resistance and the applied stretch, and whether a different sensor might perform better.

Together, these tests provide a comprehensive evaluation of the weft-knitted stretch sensor's potential as a reliable and accurate appliance for monitoring strain and deformation in a sensor band.

8.1 STRAIN HOLD TEST

In the documented use cases of knitted sensors, they are only used in a dynamic manner. The sensors are exposed to increasing strain and afterward released, often relatively short tests with only repetitive movements. Yet, in the application of the sensor in the sensor band, the sensor is meant for constant monitoring and can also be exposed to a constant strain (e.g. if users are not moving). Therefore it is equally important for the sensor to perform well under constant strain. Especially since such data collection can provide insights into the fluid buildup. This is a slow process and may not occur at all, so the sensor has to show consistent data when it is exposed to a constant environment (such as a stretch hold). The lack of strain hold tests makes this the first performed test with this sensor band.
This test is performed shortly after producing the weft-knitted sensor, and prior to integrating it into the sensor band.

Goal

To test the sensor performance under a constant stretch for a long time duration.

Material

The weft knitted stretch sensor has a 1 x 1 rib structure, using Nylon-Lycra as non-conductive material and 235 dtex Silver-Nylon, 600 Ω/m as the conductive material. The sensor connects to a microcontroller through wires on both sides of the sensor that are knitted with (the same) conductive wire.

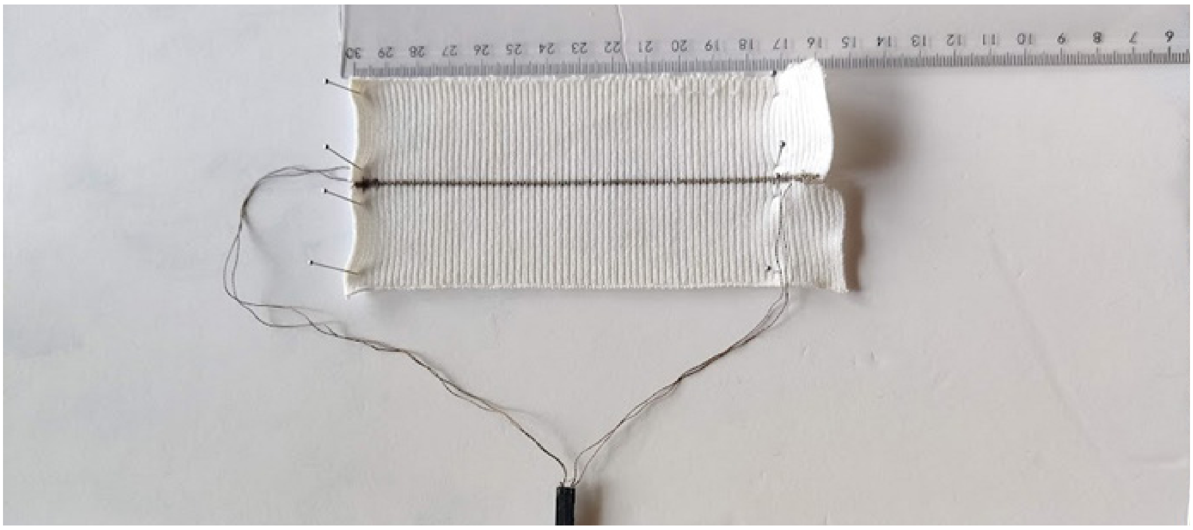


figure 8.1.1 sensor hold at stretch

Method

To test the sensor performance, the sensor is fixated on a (flat) foamboard with 4 bobby pins per side. The sensor is connected to an Arduino 33 BLE, using the same conductive wires that are also knitted into the sensor. A firmware is uploaded on the Arduino to read out the digital signal of the sensor.

Prior to the test, the following steps are taking in the following order:

1. The sensor is checked for ruffling at the edges, and fixation points on both sides are picked, making sure the sensor is not ruffling.
2. The length between the fixation points is called the working range and from this moment on these points are used as reference points. The length of the working range is measured with a ruler.
3. A desired length increase within 40% stretch is chosen (in our case the sensor is stretched from 11 cm to 13 cm).
4. One side is fixated using 4 bobby pins. During pinning, the knitting structure is followed to assure that all pins are placed at the same height.
5. The sensor is connected to the Arduino.
6. The Arduino is connected to the computer for power.
7. Set the settings for data collection to the average measured value per second.
8. The Arduino is connected to the computer via Bluetooth connection and data collection is started.
9. The sensor is stretched to the chosen length increase (of step 3). During the stretch, it is important that the sensor is evenly stretched, so over the entire width. The velocity at which the sensor is stretched is not taken into consideration during this test.
10. The stretched side is also fixated with 4 bobby pins, again the knitting structure is followed to assure that all pins are placed at the same height.
11. Let the data be collected for an extensive amount of time (in our case a time span of 5 hours).
12. Take out the bobby pins on the stretched side of the stretch.
13. Wait for another 30 minutes while data is collected.
14. Export the collected data to an Excel for data analysis.

Results

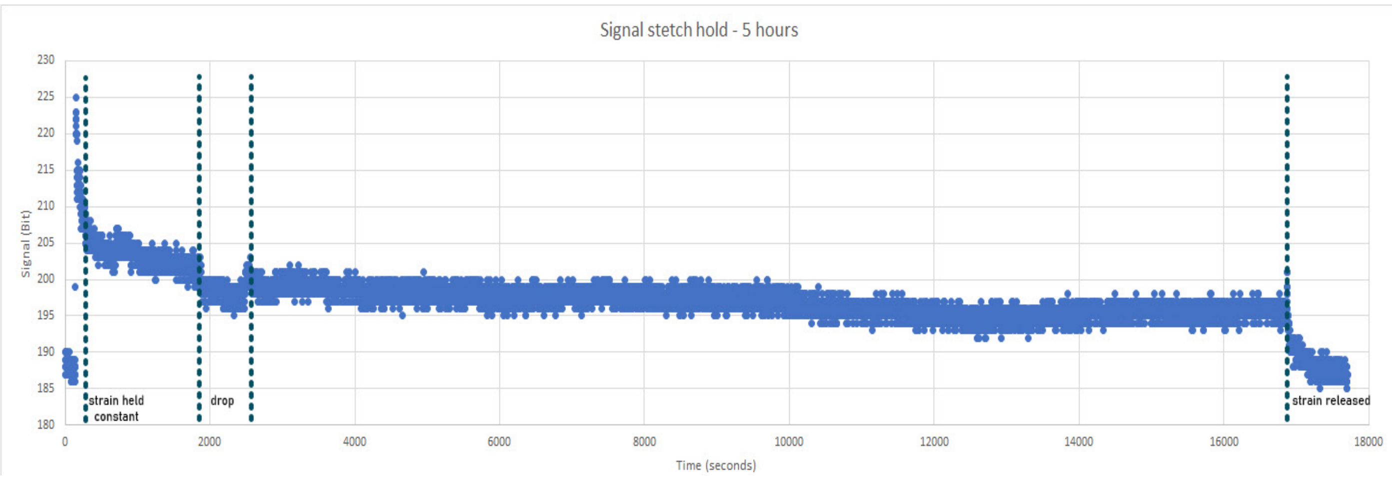
The Arduino has a 10 bit resolution, giving it a measurement range from 0 to 1023 bits. The sensor measures resistance, low values correspond to little measured resistance, and high values correspond to high measured resistance. In this test, the values are not calibrated to the amount of resistance.

Graph 6.1 ‘Signal stretch hold – 5 hours’ displays the signal versus time measured by the sensor (large graph can be found in the appendix). The x-axis represents the time in seconds, while the y-axis represents the signal of the sensor in bits. Each point in the graph represents the average value of one second. At the start of the test, the sensor is not stretched and the values fluctuate between 186 and 190 bits, with an average value of 188 bits. Noise is around 2 bits.

Once the sensor is stretched and fixated, a high peak appears. Fixating the sensor takes 15 seconds. The measured values during fixation fluctuate between 220 and 225 bits. When the sensor is fixed it is remained untouched until the sensor is released after approximately 5 hours. The moment the sensor is in its stretched position, the resistance moves towards an equilibrium in an exponential decline curve, after 45 seconds the value is 211 and the signal starts to decline in a more linear fashion. In this phase, the noise is around 3 bits.

Around 1700 seconds (~28 minutes), when the signal is between 199 and 204 bits, the signal has a drop in value where it starts to range between 195 and 199 bits for a duration of around 500 seconds (~8 minutes). After the drop of 500 seconds, the signal rises again between 199 and 203 bits. Now it continues to slowly decline. Around 12000 seconds (~3 hours and 20 minutes) the signal stops declining and remains at an average value of 195 bits, with a noise value of 2 bits, until the sensor is released from its stretch.

After 17000 seconds (~4 hours and 45 minutes) the sensor is released on one side, this is clearly visible in the graph as the signal drops down in an exponential declining curve again. After 45 seconds the value is 191 which in the following 773 (~13 minutes) seconds decreases to an average value of 188.



graph 8.1.1 signal stretch hold

Conclusion

When the sensor is stretched and held into a stretched position, there is a clear change of signal. First, the signal shows a peak, this is followed by an exponential decline and the signal moves toward an equilibrium. The noise of the sensor is between 2 and 3 bits.

Most likely the elastic properties of the Nylon-Lycra knitted in the sensor cause the stress relaxation curve. Stress relaxation is a time-dependent decrease in stress under constant strain (Ashter, 2013). When the band is strained, a tensile deformation finds its place, once the desired length is reached the strain is held constant. During the stretch the contact points of the conductive wires become less, causing more resistance. After the strain is held constant, the viscoelastic behavior of the band restructures which makes the conductive threats start to have more touching surfaces again, thus causing a decrease in resistance.

Lastly, the graph shows that the equilibrium of the signal of the stretched sensor is higher than the signal of the unstretched sensor. So, the sensor is able to monitor when it is held under in a constant stretch.

8.2 WEARING SENSOR BAND TEST

After the strain hold test, we understand how the sensor behaves under fixed stress. During the strain hold test, the sensor was sensitive to noise.
Because the intended use of the sensor is to be worn throughout the day it is important to know how the sensor behaves in an ordinary life setting. So, to find out how the sensor responds to daily activities the band is worn during the morning to monitor activities starting from putting on the sensor until noon.

Goal

To test the sensor performance during different activities of a normal life setting.

Material

For this test, the sensor band consisting of the (previously introduced) weft-knitted sensor is worn over a hockey sock. The band is worn by the researcher himself, a 25-year-old male with no cardiovascular diseases. The test is started in the following order:

1. The Arduino is placed in the pocket of the band and both wires of the sensor are connected to the Arduino.
2. The Arduino is connected to an external battery source.
3. The band is placed around the ankle and checked that there is not a short circuit.
4. The battery is placed in the sock on top, on the lateral side of the calf.
5. The Bluetooth connection between Arduino and the laptop is made for data collection.

The settings for the data input are set to the average of the last 20 seconds.
After getting dressed and the sensor is put on, a 'normal' morning ritual is started, consisting of breakfast, coffee, and working behind a desk. In the last half hour, the circumference is increased. In three steps of 1 cm each, the circumference is increased from 25,5 cm to 28,5 cm with the help of Copic markers. The increased steps are approximately 10 minutes after each other. The increase was introduced while being in a sedentary position behind a desk.

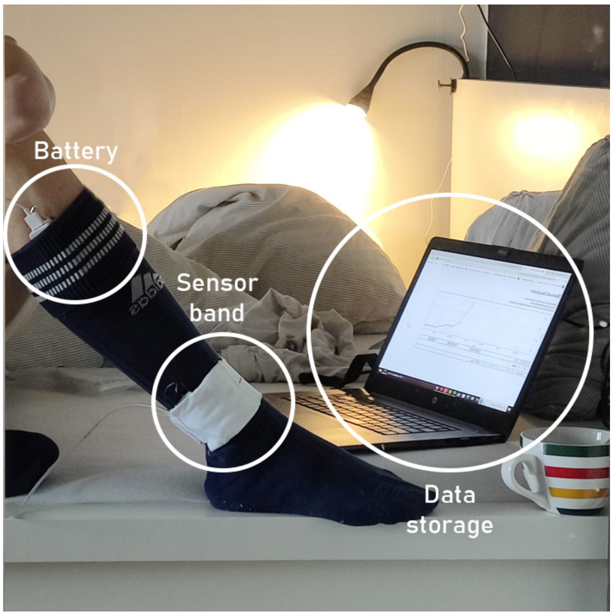
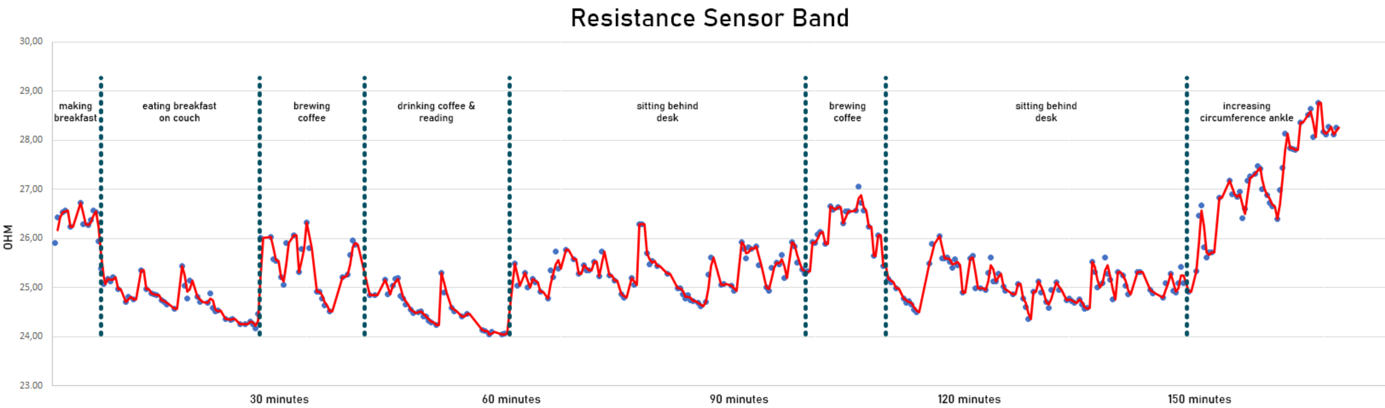


figure 6.2.1 materials wearing test

The activities are noted in a notebook with timestamps.The data is collected and transferred to an Excel in which short circuit values are filtered. The remaining data is plotted in a scatter graph and a trendline of a moving average with a period of 2 is added to the scatter graph. The performed activities are added to the graph based on the notes with timestamps.

Results

The graph below displays the resistance versus time measured by the sensor band. The x-axis represents time in minutes, while the y-axis represents the resistance of the band in ohms. The red line in the graph is the moving average with a period of 2 and represents the resistance of the circuit changing over time. At the start of the graph the sensor is activated and the values fluctuate between 26 and 27 ohms. Noise is around 0.5 ohms. During the first 5 minutes, breakfast is prepared. After approximately 5 minutes the resistance drops between (just over) 24 and 25 ohms. In the following 25 minutes, breakfast is eaten while sitting on the couch. Similar to the strain hold test the resistance decreases in an exponential curve. The equilibrium seems to be around 24 ohms. There are two peaks present.



graph 6.2.1 resistance sensor band wearing test

After breakfast, the resistance rises up. There are local high peaks of 26,3 ohms and local minimums of 25,0 ohms with one clear distinct minimum near 24 ohms. This minimum is immediately followed by another peak. The values during drinking coffee and reading show similar results as eating breakfast on the couch.

Once sitting the behind desk, 60 minutes after the start, the measured resistance is approximately between 25 and 26 ohms. Clearly remaining higher than when sitting on the couch. In this period there is a less exponential decline curve in the measured resistance.
The second time brewing coffee, the resistance values are higher than the first time. Typically being between 26 and 27, similar to making breakfast. The break is also shorter, so possibly there was more movement. The second time sitting behind a desk shows comparable results to the first time sitting behind a desk.

In the last half hour, after 150 minutes, the circumference of the ankle is increased while remaining sitting behind the desk. The first circumference increase (25,5 cm to 26,5 cm) is very clear with a resistance increase of 1,5 ohms to 26,8 ohms but is immediately followed with lower values of 25,9 because the Copic marker skewed. After readjustment, the value goes to 26,9 ohms. Once the second Copic marker is placed underneath the band and the circumference is 27,5 cm the measured resistance is only slightly increased to 27,3. Again the value eventually drops. With the last circumference increase to 28,5 cm the resistance immediately peaks at 28,2 ohms and even goes up to 28,8 ohms but stabilizes for the last values around 28,3 ohms.

Conclusion

When wearing the sensor band there is a clear difference in measured resistance between sitting and standing activities. The higher resistance when sitting behind the desk suggests there is more foot movement or the ankle is more expended than during sitting on the couch. Noise levels change between 0,5 ohms to 1 ohms. The results show no noticeable signal drift during the experiment.

Based on the results it can be concluded that the sensor distinguishes differences in the circumference of the ankle during different activities of a normal life setting.

8.3 CALIBRATION TEST

Based on the results of the ‘wearing sensor band test’ we can conclude that the sensor distinguishes differences in the circumference of the ankle during activities in a normal life setting. Also, the sensor monitored a change in resistance during the circumference increase (of 1 cm steps) while wearing. Which, if properly calibrated can be used to calculate the applied compression of the MCS (see chapter 5.X, for more details).
Besides the weft-knitted stretch sensor, also Force Sensing Resistors (FSR) meet a lot of the design requirements and therefore are an interesting contender to be included in compression therapy. For sensors to be applied in healthcare monitoring devices, it is essential to calibrate the sensor. So, a calibration test to calibrate measured resistance to circumference and pressure is conducted.

Goal

To calibrate the weft knitted stretch sensor and the FSR sensor to pressure and circumference increase.

Material

Sensor band

Contains the weft knitted stretch sensor with a 1 x 1 rib structure, using Nylon-Lycra as non-conductive material and 235 dtex Silver-Nylon, 600 Ω/m as the conductive material. The sensor connects to a microcontroller through wires on both sides of the sensor that are knitted with (the same) conductive wire. The sensor is turned into a band by closing it between two white denim sides (with no stretchability) and closed with a bra fastener (also with no stretchability).

figure 8.3.1 sensor band

Force Sensing Resistor

The sensor used is the Interlink Electronics FSR® 402 13 mm Circle x 56mm. The sensor is optimized for human touch control of electronic devices such as medical systems (see datasheet in appendix).

figure 8.3.2 FSR sensor

Method

To calibrate the two sensors, an expanding object is created. For the test setup, a PVC tube is placed on a four-jaw chuck. A four-jaw chuck is a device used to hold and rotate cylindrical shaped objects in milling and lathe machines. By rotating a chuck key, the four jaws can move inwards and outwards to grip a workpiece. Our PVC tube is 15 cm long, cut once lengthwise, and has a wall thickness of 3 mm. The circumference of the PVC tube is 26 cm. The length-ways cut allows the tube to expand when the jaws of the chuck move outwards.

Prior to the test, the following steps are taken in the following order:

1. The PVC tube is placed on the four-jaw chuck and the cut is placed in between two jaws, to avoid the tube to make abrupt movements during the test.
2. When the PVC tube is expanded, it has a tendency to expand into a cone shape. Therefore the sensor band is placed as close to the chuck as possible. In the middle of the band is the sensing area of the band. It is checked how many rotations the chuck key needs to make for even 3 mm circumference increase steps (in our case a 360-degree spin corresponds with a 3 mm increase of circumference for the PVC tube).
3. Both wires of the sensor band are connected to the Arduino BLE. Make sure that a short circuit (between the chuck and the wires or between the conductive wires themselves) is avoided, if necessary place something between the chuck and the wires. The Arduino is connected to the laptop for power supply.
4. The Bluetooth connection between Arduino BLE and the laptop is made for data collection.
5. As the results of the strain hold test showed, the sensor band first displays a resistance peak and after that moves to an equilibrium in an exponential decline curve. The waiting time until the resistance hits this equilibrium is determined (in our case a waiting time of 45 seconds after the expansion is used).
6. To create an even pressure distribution on the FSR sensor, it is placed between two 3 mm thick PE foam pieces.
7. The FSR sensor (between foam pieces) is put underneath the sensing area of the sensor band. The FSR sensor is connected to a (different) Arduino Uno with a 1 kOhm reference resistor. Make sure that a short circuit (between the chuck and the wires) is avoided, if necessary place something between the chuck and the wires.
8. The Arduino uno is wired to a computer that stores the measured sensor output in bits.
9. A sensor of a picopress is also placed underneath the sensor band sensing area.
10. The picopress is calibrated (according to instructions of the picopress).
11. A notebook and pen are used to document the measured pressure of the Picopress.
12. The laptop screen is split, such that both the measured resistance of the sensor band and the measured bits of the FSR sensor are displayed.

After all these steps are performed, the calibration test can start.

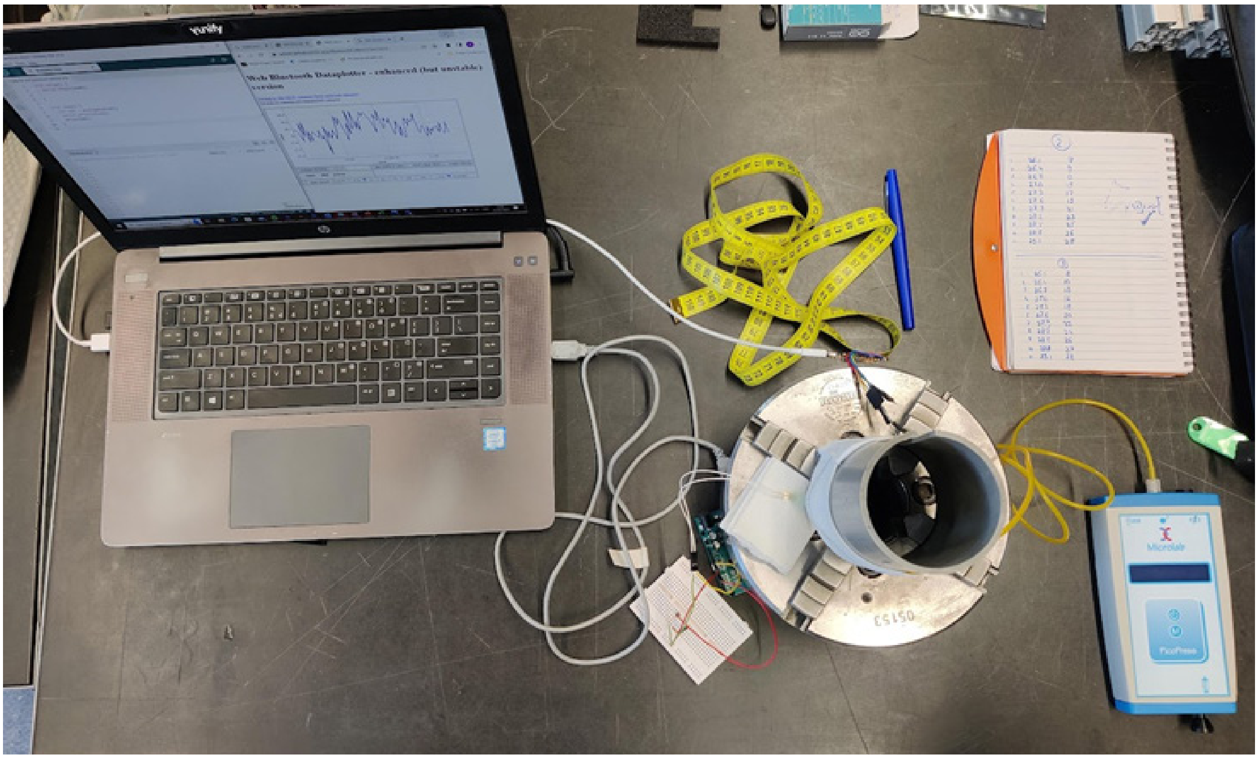


figure 8.3.3 test setup

First, the starting circumference is measured with a measuring tape and the compression of the band is read out via the Picopress and noted in a note-book. Besides that, a screenshot is taken of the laptop screen with both the sensor screens displayed. The screenshot is automatically saved into a local folder on the computer. Now a repetitive process is started until the PVC tube is increased by 3 cm in total.

1. The circumference of the PVC is expanded by 3 mm.
2. A timer of 45 seconds is started
3. Once the timer goes off, a screenshot of the computer screen is made (which is saved into a local folder)
4. During the screenshot, the applied pressure of the sensor band is read out on the screen of the Picopress.
5. The measured pressure when the timer went off is documented in the note-book.
6. The circumference (increase) is checked.
7. Exactly 60 seconds after the screenshot is taken the circumference is increased again until a circumference increase of 3 cm is achieved.

After the test, the four-jaw chunk is spun back, until the PVC tube hits the starting circumference. All the collected data is collectively stored in one Excel file. The test is repeated four times to ensure consistency. The collected data is analysed to check the correlation between each sensor and the circum-ference/pressure increase. The data is also plotted to visualize the relationship between the resistance change and the circumference/pressure change.

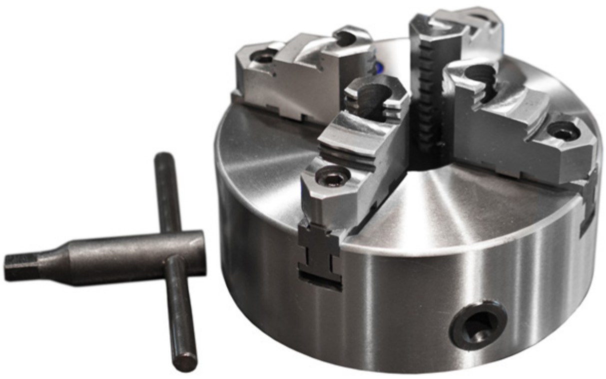


figure 8.3.4 fourclaw chunk

Results

Graph 6.3.1 ‘Compression Picopress’ shows the measured compression in millimeter Mercery per circumference. The x-axis represents the circumference of the PVC tube, the y-axis shows the compression. For each test, a trendline is drawn in a dotted format with the equation in the figure. As can be seen in the graph, the measured compression increases in a very linear fashion. The slopes of the four trendlines amount to 6.7879 (test 1), 7.0303 (test 2), 6.8788 (test 3), and 6.0000 (test 4). The corresponding R-squared values are per test: 0.99, 0.99, 0.98, and 0.99, respectively. Combined there is an average trendline y=6,6743x – 164.185

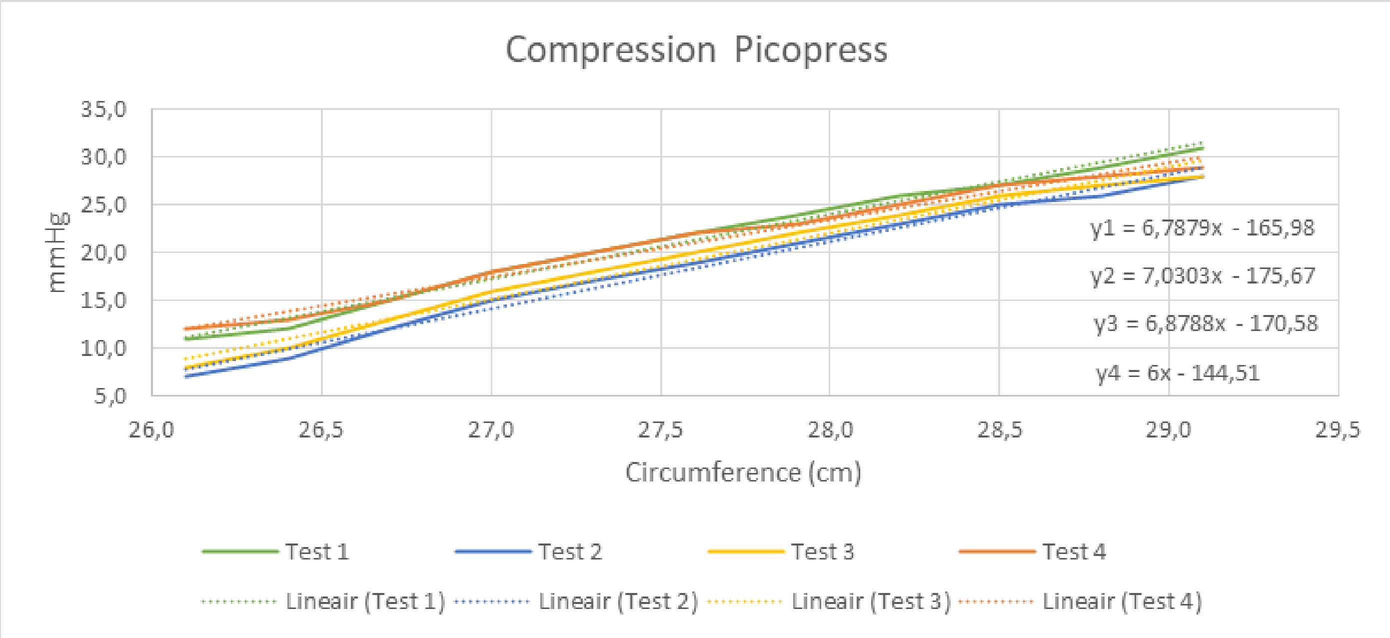
Graph 6.3.2 ‘Signal FSR sensor’ below shows the measured signal (in bits) of the FSR sensor. On the horizontal axis is the circumference of the PVC tube, and on the vertical axis is the voltage output in bits. The Arduino Uno microcontroller with a 10-bit input, so a range between 0 to 1023 bits (for 0 to 5V). For each test, a trendline is drawn in a dotted format with the equation in the figure, especially in the range from 26,1 to 27 cm in circumference the measured value differs from the trendlines. But from approximately 27 cm all the lines start to increase in a more linear fashion. The slopes of the four trendlines amount to 91.606 (test 1), 73.152 (test 2), 81.939 (test 3), and 61.152 (test 4). corresponding R-squared values are per test: 0.93, 0.89, 0.87, 0.97, respectively. Combined there is an average trendline y = 76.962x – 1875.2.

Lastly, graph 6.3.3, ‘resistance sensor band’ shows the measured resistance of the sensor band. On the horizontal axis is the circumference of the PVC tube, and on the vertical axis is the measured resistance of the sensor band. The measured resistance change differs per test. In every test ,a clear decline moment is present, whereas the circumference keeps increasing. None of the tests seem to generate similar results, nor detect similar behavior for the sensor. The corresponding R-squared values are per test: 0.71 (test 1), 0.51 (test 2), 0.46 (test 3), and 0.09 (test 4). The signal change is not proportional to the circumference increase and the small change in signal remains probably within the order of magnitude of the noise level of the sensor.

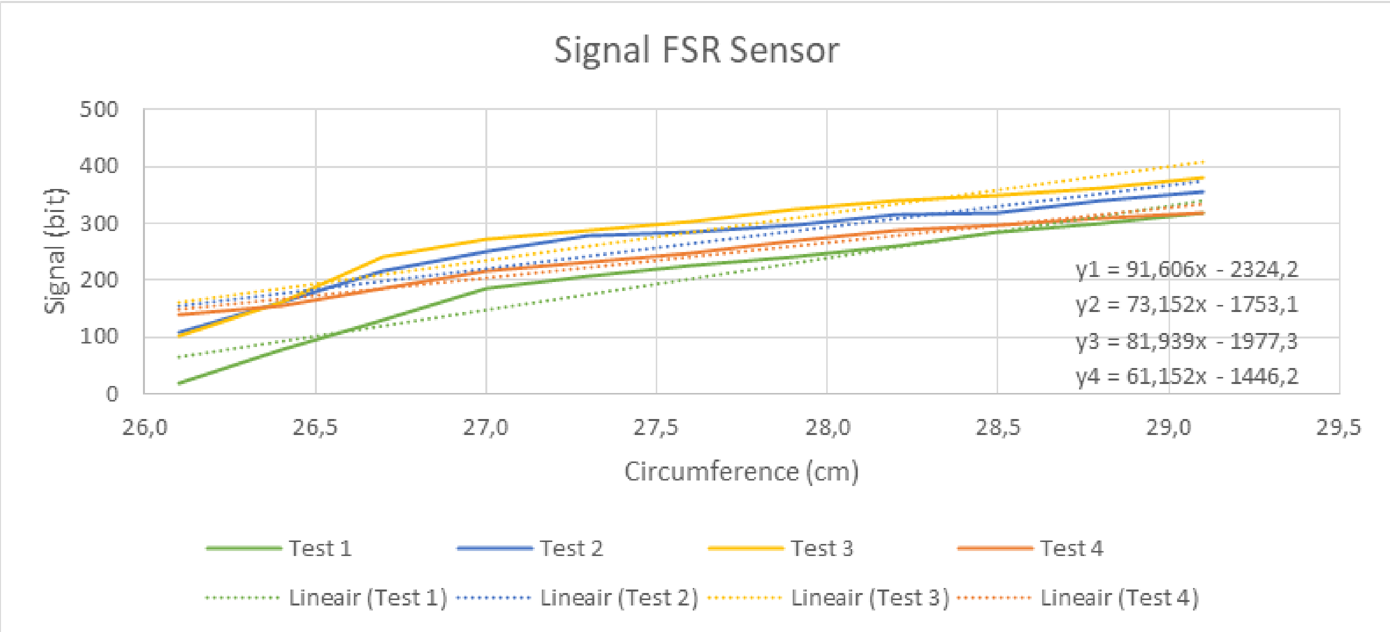
After the results were collected (which were slightly unexpected), it is recalculated whether the sensor was stretched within the working range of 40% stretch. The exposed sensor is 9.5 cm prior to the test, once placed around the PVC tube the sensor is stretched to 10.6 cm, a stretch of 11.6%. In the last circumference, the sensor is stretched up to 13.6 cm, a stretch of 43%, which goes over the 40% working range. The vertically dotted black line in the graph (at a circumference of 28,8 cm), corresponds to a 40% stretch of the sensor.

Conclusion

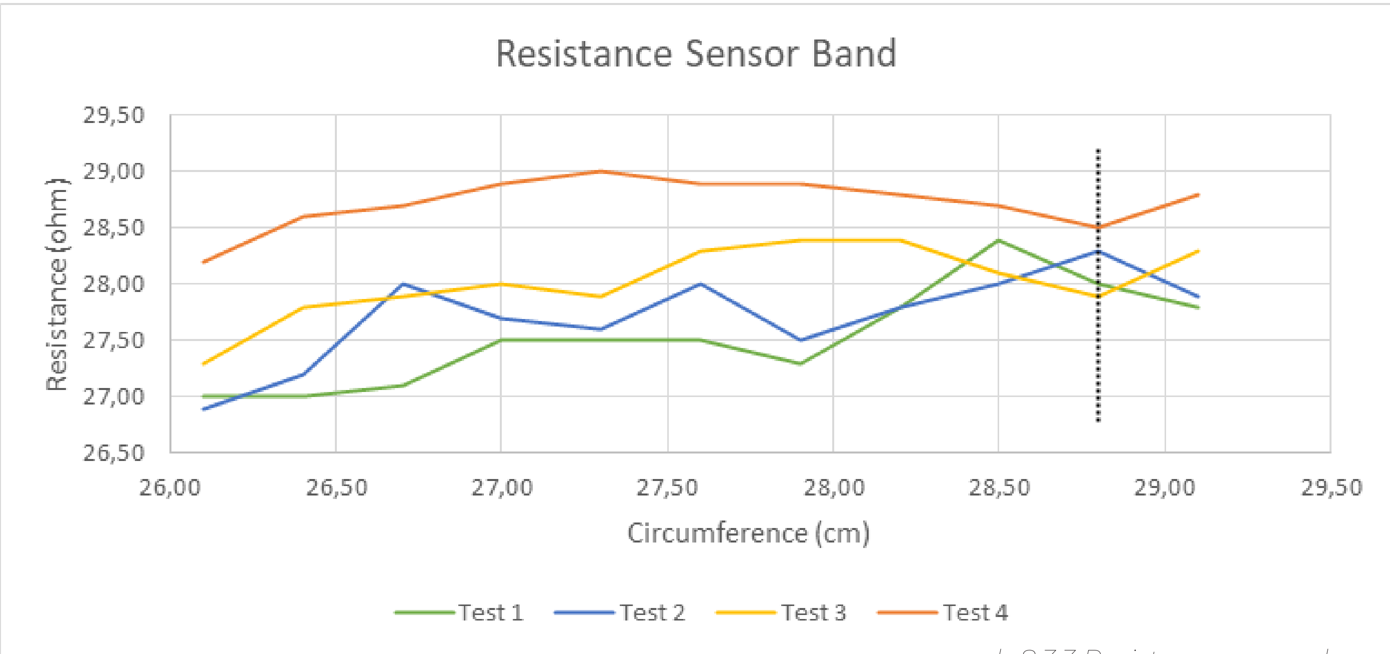
As graph 6.3.1 showed, with an increasing circumference the compression in the test increased linearly with an average trendline of y = 6,6743x – 164.185. The FSR sensor also showed a linear increase in values with increasing circumference, though having some differences during smaller circumferences (thus compression values) The average trendline for the FSR sensor is y = 76.962x – 1875.2. In this test, the measured data of the sensor band showed no clear response to an increasing circumference while remaining in the working range of 40% stretch. Hence it is concluded that the band is not suitable for calibration and this may not be a suitable appliance for the sensor band. So, for the remainder of this project, we will continue working with the FSR sensor.



graph 8.3.1 compression picopress



graph 8.3.2 Signal FSR sensor



graph 8.3.3 Resistance sensor band

TAKE AWAYS - CHAPTER 8 SENSOR TESTS

Test 1

When the sensor is stretched and held into this stretched position, there is a clear change of signal. First, the signal shows a peak, this is followed by an exponential decline and the signal moves toward an equilibrium. The equilibrium of the signal of the stretched sensor is higher than the signal of the unstretched sensor. So, the sensor is able to monitor when it is held under in a constant stretch. The noise of the sensor is between 2 and 3 bits.

Test 2

When wearing the sensor band there is a clear difference in measured resistance between sitting and standing activities. Noise levels change between 0,5 to 1 ohms. The results show no noticeable signal drift during the experiment.

Based on the results it can be concluded that the sensor distinguishes differences in the circumference of the ankle during different activities of a normal life setting.

Test 3

With an increasing circumference the compression in the test increased linearly. The FSR sensor also showed a linear increase in values with increasing circumference. In this test, the measured data of the sensor band showed no clear response to an increasing circumference while remaining in the working range of 40% stretch. Hence it is concluded that the band is not suitable for calibration and this may not be a suitable appliance for the sensor band.

Design strategies

Although results from test 1 and 2 seemed promising, the weft knitted stretch sensors did not show reliable results in test 3. Therefore, the prototype designed for compression care in this thesis, will not include the weft knitted stretch sensor. For the remainder of this project, we will continue working with the FSR sensor.

Designer takeaway

When working with emerging technologies, first make sure the technology is suitable for the intended application before designing.

Healthcare take-away

The weft knitted stretch sensor did not show applicable for compression therapy appliances yet.

Researcher take-away

Do more research into the weft knitted stretch sensor to find out why the sensor failed in test 3 while it seemed promising in tests 1 and 2.

Next steps

Integrate these insights into a new prototype that complies with the design requirements from chapter 5, including a FSR sensor.


DAILY

9 FINAL DESIGN

The research questions guided throughout the project to generate knowledge of three pillars; users, therapy adherence, and technology. This knowledge is converged in requirements. The sensor tests and the strengths of both provisional designs are applied in the embodiment of the final prototype.

In this chapter, the final prototype of the smart compression stockings is presented. Followed by a user test, the discussion and future recommendations.

9.1 SMART STOCKING

The final prototype is a marine blue compression stocking, with an integrated FSR sensor on the inside of the stocking. Flexible conductive wires (treated with a coating to expand the lifespan) are connected to the FSR sensor and knitted to the top of the stocking to connect with a microcontroller. The microcontroller can be fitted into a small pocket while wearing the stocking.

The FSR sensor is placed on the ankle for the following reasons:

1. MCS are expected to exert the most compression on the ankle. Therefore, this point can be used to indicate if the compression stockings overall comply.
2. Fluid buildup starts in the ankle and feet, shape change would be detected here first.
3. By placing the sensor on the retinacula this place is least exposed to shape changes caused by muscle contractions.
4. The sensor is placed on the lateral side of the ankle, to assure being exposed to compression.

The used sensor is the Interlink Electronics FSR® 402 13 mm Circle x 56mm. The manufacturer claims that the sensor is optimized for human touch control of electronic devices such as medical systems.

figure 9.1.1 Smart stocking

The sensor is embedded to assure that data is always collected from the same spot. This makes data comparable and allows abnormalities to be detected. To avoid creating pressure points on the user's leg, instead of wires, stretchable conductive yarn is sewn onto the stocking to connect the sensor to the microcontroller.

For the FSR sensor to properly function the sensing area is required to be covered by a foam piece. Several shapes and sizes have been explored. To avoid neoprene skin contact and to make the sensor as small as possible, only the sensing area (diameter of 13 mm) is covered with a laser-cut 2 mm thick neoprene circle. This is held in its place by carefully knitting a pocket around it.

figure 9.1.2 sensor cover explorations

The sensor is positioned in the stocking by pricking the soldering pins through the stocking. On the outside, the pins are soldered to the conductive flexible yarn. The pins are insulated to avoid short circuits and sharp edges. On the inside, the sensor is fixed to the stocking by knitting a stretchable lycra fabric cover over it.

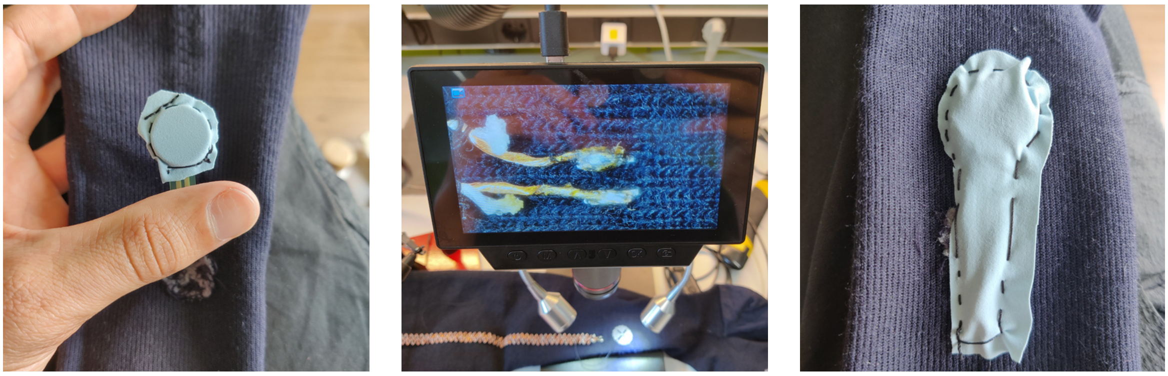


figure 9.1.3 series of sensor integration

The sensor is connected to the microcontroller by Seeed Studio XIAO nRF52840, which is able to connect wirelessly via Bluetooth. The dimensions of the controller are 2.2 cm by 1.8 cm. It is packed in heat shrink tubing to avoid any rough edges. Combined with the soldered connections it weighs 3 grams. The microcontroller is powered by a 500 mAh, 3.7 V lithium battery. The dimensions of the controller are 3.0 cm by 3.5 cm. It is packed into a laser-cut neoprene pocket and combined weighs 11 grams. Both can be placed into a fabric pocket on top of the stocking.

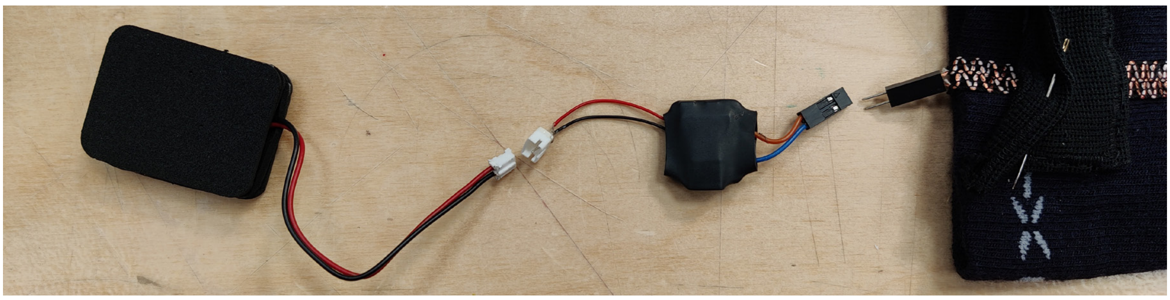


figure 9.1.4 Battery with microcontroller and smart stocking

The marine blue stocking is by the brand ‘Stox’. The stocking is a circular knit made of merino wool, which claims to be temperature regulating. It has a compression class II and is clinically validated.

9.2 APP DESIGN

The smart stocking is required to support users in multiple ways. When the stocking measures an abnormality it must alert the user, but also ask additional questions to support and coach the user. Because the smart stockings are supposed to inform users on multiple layers, it is decided to come up with a mockup app design.

The first visible element on the homepage is a timeline of the day with the current compression. In the graph, the compression is mapped in mmHg and classes vs the time. Since compression stockings are only worn during the daytime, the timeline starts at 7 o'clock and finishes at 23 o'clock. This, of course, can be tailored to user preferences.
Major changes in compression increase/decrease need to be detected. In case data shows such abnormalities the app sends out a push notification to the user to inform about this observation.

Compression increases when standing up and decreases when sitting. Therefore, the compression graph indirectly monitors activity. Over time this can be used to predict behaviour. For instance, if data consistently shows that a fixed time period of inactivity causes increased compression, the app should preventively coach users to undertake physical activities (that activate the legs). Through physical activity the calf muscle pump is stimulated and blood circulation is supported.

Another important use case is for gradual change over an extended time period. E.g. if users start each day with slightly more compression. In the morning, after sleeping, the legs are supposed to be slim. If an increase in morning compression is measured this shows healthcare signs that need to be checked by a healthcare professional.

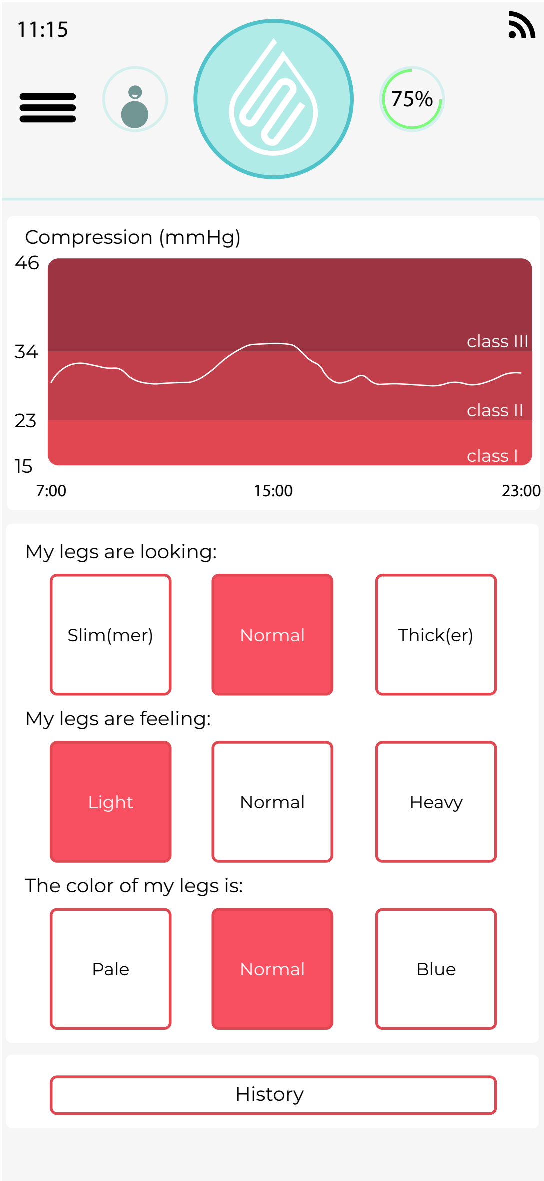


figure 9.2.1 App interface

Before the app starts stressing out the user the app should check whether the user has been consistently wearing its compression stockings. In case no data is collected, it can ask the user. Especially for users that have been constantly wearing compression stockings it is important to undertake actions. This may range from replacing stockings to receiving medical help.

Underneath the compression graph are additional questions, to help the user monitor their leg based on visible signs. Since not every complication has a circumference change, the questions can still help users log physical signs of their leg. Based on the provided answers users give, the app may provide recommendations. If the answers show troublesome signs, it could advise users to contact their healthcare provider.

It can even be considered that the app directly exchanges collected data with healthcare providers. Such exchange enables healthcare providers to support their patients. However, the interviews showed that such a feature may be perceived as pedantic and requires careful consideration before implementation. Another concern is about who has access to the data, this data should only be used to provide improved care and not be used to penalize users. Nonetheless, through the direct sharing of user data, this app could contribute to improved patient outcomes and supports the collaborative interaction between patient and healthcare provider.

Lastly, the app can be used for information about the smart stocking, such as the battery life of the microcontroller. To keep engagement with compliant users, the app could provide personalized settings and goals. For elderly users a lower step goal and independently putting on the stockings could be motivating to wear, whereas younger users may want a high step goal and quick idle alerts. Different personalized settings can be explored and added to stimulate user engagement and therapy compliance.

9.3 USER TEST

To validate the performance of the smart stocking, a user test is set up. During the user test, the participant will wear the smart stockings for a couple of hours on a workday. The smart stocking is exposed to everyday activities and worn from noon to late afternoon.

Materials

For this test, the smart stocking is worn over a time period of four hours and 15 minutes. Starting at noon until late afternoon. Previously introduced Stijn (participant in the interviews of chapter 6) participated in the user test. During the user test, Stijn was working from home. He performs his work behind a computer. Stijn (further referred to as user) is late thirty and wears his stockings on a daily basis.

The test started in the following order:

1. The user is provided with the smart stockings, and the user test and product are explained again.
2. The user is provided with a user guide (which can be found in the appendix), in the guide the user can read back the roadmap of the test, the explanation of the product, how to connect the stockings to the webpage, a logbook, the proposed app design, and a feedback page.
3. After everything is clearly explained again, it is emphasized that participation in this test is voluntary and the user may stop at any given moment for no apparent reason.
4. The battery is connected to the microcontroller, and the microcontroller is connected to the stocking.
5. The microcontroller and battery are placed into the designated pocket.
6. The smart stocking is connected through Bluetooth to the webpage for data collection.
7. The smart stocking is put on and small tests such as touching the sensor, sitting and standing are performed.
8. The settings for the data input are set to one data point per second.

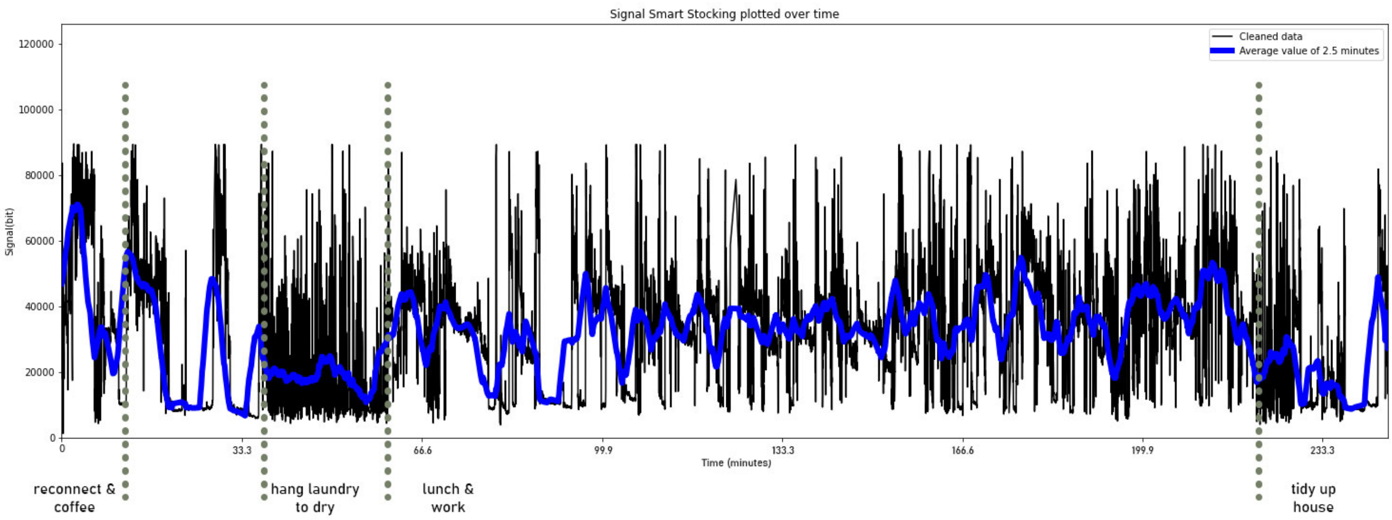
While setting up the user test and explaining the product, responses about the product are observed and documented. Once everything is set up and data collection is started, the values of sitting and standing are noted. These documented values help pick a threshold value during data filtering.

The user continues its workday and the researcher leaves. In order to understand the collected data better, the user is asked to log his activities in the logbook. Throughout the test, the user and researcher communicate via WhatsApp. After wearing the smart stocking for a couple of hours, the data is saved into a CSV file. The data file is sent to the researcher via mail. The collected data is visualized and cleaned using Python. Error measurements, such as value points in which the sensor was unable to detect pressure, are filtered by using the threshold. In this case, the threshold to exclude values is anything above 90000 bits. A graph is made containing the cleaned data with an average line of the past 2,5 minutes. The performed activities (logged in the user guide) are added to the graph.

Results

Sensor collected

Graph 9.3.1 shows the signal of the smart stocking versus time measured by the integrated FSR sensor. The x-axis represents time in minutes, while the y-axis represents the signal of the sensor in bits measured by the microcontroller (Seeed Studio XIAO nRF52840). The data collection started at 12 o'clock.



graph 9.3.1 Signal Smart Stocking plotted over time

The black line is cleaned data excluded from points above the threshold, and the blue line is the average value of the past 2,5 minutes. From all 14728 data points, 424 are filtered by the threshold.

FSR sensors measure resistance, by applying force on the sensor the resistance becomes less. So, in the graph, high measured values correspond with much resistance thus 'little' exerted compression by the smart stocking. Low values, in the graph, correspond with less measured resistance meaning more compression provided by the smart stocking.
The average values range approximately from 9000 to 70000 bits. Noise is around 10000 bits. The measurements start with the user connecting the stocking to the webpage, the average value rises up to approximately 70000. During this moment the user was probably sitting, this is followed by dropping measured values which likely corresponds to the activity of grabbing a cup of coffee.

Until doing the laundry no activity is logged in the logbook, but it can be expected that the higher values correspond to drinking the coffee while sitting. After approximately 35 minutes the user started hanging the laundry to dry. During this activity, the measured data is approximately between 1800 and 2200 bits.
From approximately 100 to 160 minutes the data collection is relatively stable. The average values remain (roughly) between 30000 and 45000 bits. Once the user starts to tidy up the house (around 215 minutes) the measured value clearly lowers to a range between 10000 and 20000 bits, indicating that the user is standing and walking around.

Observations

When the smart stockings were given to the user, he showed clear excitement. The user told about a conversation with a friend (a nurse), they talked about the smart stockings and how it was about time that MCS started to innovate. Bandages improved over time, but MCS did not. Therefore, new advances applied to MCS are likely to be embraced with open arms!

The product was set up together. However, a problem occurred when trying to establish a Bluetooth connection between the microcontroller and the webpage. On the devices of the user the popup, used to show available microcontrollers for data collection, was blocked. On both phones of the user (IOS and Android software), the pop-up was blocked. Eventually, the microcontroller was connected to the webpage on a computer. This limited the mobility of the user since a connection is lost from around 15 meters.

When putting on the smart stocking the sensor was exactly on the intended spot on the ankle. The user was able to indicate this because the sensor, even though it was covered, felt a little bit colder against the leg. Only the perceived temperature difference made the sensor noticeable, overall the smart stocking felt nice.

The pocket on the calf, intended for storing the microcontroller and battery while wearing, was too small. The microcontroller was hanging slightly above the pocket. Because of the sturdiness of the cables it remained in a 'fixed' position. Future prototypes can have shorter conductive wires to connect to the microcontroller.

The user did not provide feedback on the possible interface. When showing it he remained neutral and he did not leave comments in the guide.
After the user test, when the smart stocking was collected from the user again, he mentioned that with his disorder, he does not have (noticeable) circumference changes. Since the product focuses on monitoring the compression, he questioned whether the smart stocking has added value for him personally. Nonetheless, he did recognize the convenience of monitoring the quality of MCS, and he sees the potential impact of the product for people that experience fluid buildup. Especially if the product also coaches users to remain physically active.

Conclusion

The results show a difference in resistance during standing and walking activities from work (sitting) activities. The lower resistance typically occurred during walking activities and higher resistances were measured during work activities. While working, the sensor average line showed a lot of local peaks. The noise level was around 10000 bits. The results show no noticeable signal drift during the experiment.

Based on the measured signal it can be concluded that the sensor is able to distinguish differences in interface pressure between the ankle and the compression stocking during a workday in a home setting.

Connecting the stocking with the webpage showed some difficulties, future products should tackle this. Also, the pocket for the microcontroller and battery should be slightly bigger to better fit the hardware.
For this user, the perceived usefulness was not totally clear. However, the user understood the potential impact on other users (that may experience circumference changes) when the product is combined with data analysis and coaching.
He only felt the sensor because of a perceived temperature difference, although this did not bother the user, another fabric may be considered to cover the sensor.

Overall it can be concluded that the smart stocking performed well in this user test and that the integrated FSR sensor was well-embedded. It is important to emphasize the strengths of the product because it may improve the immediately perceived usefulness.

9.4 DISCUSSION & FUTURE RECOMMENDATIONS

The project has clearly shown the need for advances in medical compression stockings. Throughout the research, multiple problems have been identified, ranging from user dissatisfaction to product shortcomings. For instance, MCS only have an expected lifespan of half a year. Yet, MCS are yearly reimbursed by health insurance companies. Also, wearing, product care, and health complications can even shorten the lifespan of MCS.
For the successful treatment of disorders, it is essential that MCS exert the correct amount of compression.

The presented smart stockings with the app are able to monitor the exerted compression. By constantly validating the product, users gain ownership over the quality of their compression therapy.

Aside from product validation, compression monitoring can be translated into the level of fitness of the user. Increased compression (outside of the walking range) indicates an expanding circumference of the ankle. Together with a vascular surgeon, guidelines are discussed. The combination of the smart stocking and the app has the potential to give medical recommendations to users.

With the app, users can be rewarded for their therapy adherence and goals tailored to the specific user and their physical capabilities. Lastly, not every healthcare complication is immediately measurable through compression change. Therefore, the app can ask additional questions based on visible signs, this way it also coaches users to monitor their health.

Evaluate

The product is evaluated based on the setup criteria, requirements, and wishes. These help list future recommendations.

User & Environment

The proposed smart stocking is a combination of a fashionable compression stocking with integrated technology. During interviews, people mentioned to like products by this brand since they look different from current MCS. During the user test, the microcontroller worked for 4 hours straight. The exact battery life has not been tested, but after the user test the smart stocking was collected 4 hours later and the microcontroller was still working. Future projects may explore this further.

The pocket for the hardware is placed on the side of the stocking. This makes the control easier and more accessible for different age groups. Nonetheless, this prototype worked with small connectors. Future products must change this to avoid small and hard-to-handle items. For example, pogo pins could offer a solution to make a quick connection between the stocking and the microcontroller.


figure 9.4.1 pogo pins

For now, the battery and microcontroller were separate units, these can easily be combined in one pocket. The reason for this project to not do this was the ability to charge and size increase.

Product

One of the most essential elements for collecting reliable data is that every time the same spot is used while monitoring. By integrating the sensor into the smart stocking this is assured. By fixating the sensor with lycra (a fabric with some stretch abilities) the sensor area shapes with the stocking. However, there was a small perceived temperature difference between the sensor (cover) and the stockings. So the sensor was a little bit noticeable when putting the product on.
Tests showed that the sensor and microcontroller are capable of continuous monitoring with no noticeable drift. Unexposed metal wires that may cause short circuits have been insulated.

The sensors showed quite some noise, future studies should examine whether the amount of noise is acceptable. Since there was still a clear distinction between standing/walking and sitting now it was decided that the noise was within acceptable ranges. Also, the sensor showed linear results in the calibration tests and therefore showed reliability. Still, the sensor showed some difficulties to show constant results underneath ~20 mmHg. Especially for lower-class compression garments the specific sensor may be reconsidered. Nonetheless, the sensor and compression remained separate elements in the product, if future projects start to combine compression monitoring with self-regulating compression garments, acceptable noise levels should be reconsidered.

Communication

The current product works with the webpage that displays the digitally measured output. This value is not converted to mmHg yet. Future researchers should test whether each FSR sensor responds similarly and the impact of the length of the flexible conductive wires. This is important before the sensor can be calibrated to mmHg. Nonetheless, all tests have shown that the sensor is able to provide immediate feedback on the measured values. The microcontroller connects to the webpage through Bluetooth, which makes the microcontroller highly compatible. However, user settings may block the pop-up to connect with the microcontroller. This project only suggests an app interface, future project can develop this further, once an app (or other communication mechanism) is developed, other requirements such as warnings, motivation, and visual overviews of the past can be incorporated.

Wishes

For the elderly the dependency on district nurses to help them put the stocking on and off is a major pain point. Although this would be a major product improvement, the focus of this project has been on enhanced monitoring and treatment. Future students are highly recommended to combine my insights with a product that makes it easier for people to put their stockings on and off.

The suggested app combines the needs of all users. There is no distinction between young and old users. When further developed, such distinctions could be considered. For elderly patients, it may be interesting to keep track of whether they individually put on their stockings. While for younger users the impact of walking may be more interesting to learn. Personalized goals and settings may even promote therapy adherence.

Additional future recommendations

Production was not part of the requirements. To integrate this sensor, flat knitted stockings are more convenient since all the materials can easily be sown in before both sides of the stocking are merged with a seam. In circular knitted stockings (like the prototype), the sensors have to be hand sown. This is a hard and time-consuming additional task in production.

Future projects may want to research the weft-knitted stretch sensor again. We were very surprised by the results of the calibration test, especially since the sensor is heavily tested by the faculty of Industrial Design Engineering. It could be that the sensor was only locally distorted during the calibration test and therefore behaved 'weird'. If the knitted sensor could work, it is especially intriguing since the sensor is very easy to embed into products, by adding it in the knitting process. That would strongly diminish the production difficulties the current prototype will have, and existing design patterns may be explored.

The current design has a clearly visible connection from the sensor to the microcontroller with stretchable conductive wires. This is to emphasize that the stocking is an exciting new product. However, it should be validated with users whether this visibility and emphasis are actually appreciated.
Lastly, although users have been involved throughout the entire project, the final prototype is only discussed with one user. A larger interview and test group would increase insights and may provide additional insights.

GLOSSARY

Throughout the thesis I became my own expert on the topic of medical compression stockings and user understanding. Unfortunately, like every expert in their own field, I became a victim of jargon. To support readers through the material I have made this small glossary!

MCS/stockings	Medically prescribed compression stockings
Compression therapy	Wearing compression garments, in the thesis focused on MCS
District nurse	Nurse that visits patients at home
Donning	Putting on MCS
Doffing	Taking off MCS
Compliance	Following the doctor's orders of wearing MCS
Adherence	Remain wearing MCS from own initiative rather than a doctor's order/loyal to the therapy
Fluid buildup	A consequence of limited blood flow and lymphatic system, limbs swell up because the body is unable to properly stow this away

REFERENCES

Ashter, S. A. (2013). Thermoforming of Single and Multilayer Laminates: Plastic Films Technologies, Testing, and Applications. William Andrew.

Baan, E. de. (2020, June 20). Kousen die doen wat ze beloven. Trouw. https://www.trouw.nl/wetenschap/kousen-die-doen-wat-ze-beloven~b8dc282a/?referrer=https%3A%2F%2Fwww.google.com%2F

Bakker, N., Schieven, L. W., Bruins, R., Van Den Berg, M., & Hissink, R. (2013). Compression Stockings after Endovenous Laser Ablation of the Great Saphenous Vein: A Prospective Randomized Controlled Trial. European Journal of Vascular and Endovascular Surgery, 46(5), 588–592. https://doi.org/10.1016/j.ejvs.2013.08.001

Barhoumi, H., Abdessalem, S. B., & Marzougui, S. (2018). Assessment of the accuracy of Laplace's law in predicting interface pressure generated by compressive garment used for medical applications. Middle East Conference on Biomedical Engineering. https://doi.org/10.1109/mecbme.2018.8402418

Blättler, W., & Partsch, H. (2003, December 1). Leg compression and ambulation is better than bed rest for the treatment of acute deep venous thrombosis. PubMed. https://pubmed.ncbi.nlm.nih.gov/15153824/

Burgstaller, J. M., Steurer, J., Held, U., & Amann-Vesti, B. (2016). Efficacy of compression stockings in preventing post-thrombotic syndrome in patients with deep venous thrombosis: a systematic review and metaanalysis. VASA, 45(2), 141–147. https://doi.org/10.1024/0301-1526/a000508

Carman, T. L., & Al-Omari, A. (2019). Evaluation and Management of Chronic Venous Disease Using the Foundation of CEAP. Current Cardiology Reports, 21(10). https://doi.org/10.1007/s11886-019-1201-1

Centraal Bureau voor de Statistiek. (2019, May 9). Aantal verpleegkundigen toegenomen. Centraal Bureau Voor De Statistiek. https://www.cbs.nl/nl-nl/nieuws/2019/19/aantal-verpleegkundigen-toegenomen

Chapman, S. (2017). Venous leg ulcers: An evidence review. British Journal of Community Nursing. https://doi.org/10.12968/bjcn.2017.22.sup9.s6

Chen, S., Qi, J., Fan, S., Qiao, Z., Yeo, J. C., & Lim, C. T. (2021). Flexible Wearable Sensors for Cardiovascular Health Monitoring. Advanced Healthcare Materials, 10(17), 2100116. https://doi.org/10.1002/adhm.202100116

Cosmi, B. (2015). Management of superficial vein thrombosis. Journal of Thrombosis and Haemostasis, 13(7), 1175–1183. https://doi.org/10.1111/jth.12986

Di Nisio, M., Wichers, I. M., & Middeldorp, S. (2013). Treatment for superficial thrombophlebitis of the leg. The Cochrane Library. https://doi.org/10.1002/14651858.cd004982.pub5

Engeseth, M., Enden, T., Sandset, P. M., & Wik, H. S. (2021). Predictors of long-term post-thrombotic syndrome following high proximal deep vein thrombosis: a cross-sectional study. Thrombosis Journal, 19(1). https://doi.org/10.1186/s12959-020-00253-8

Erickson, C. A., Lanza, D. J., Karp, D. L., Edwards, J. W., Seabrook, G. R., Cambria, R. A., Freischlag, J. A., & Towne, J. B. (1995). Healing of venous ulcers in an ambulatory care program: The roles of chronic venous insufficiency and patient compliance. Journal of Vascular Surgery, 22(5), 629–636. https://doi.org/10.1016/s0741-5214(95)70051-x

Esfahani, M. I. M. (2021). Smart textiles in healthcare: a summary of history, types, applications, challenges, and future trends. Nanosensors and Nanodevices for Smart Multifunctional Textiles, 93–107. https://doi.org/10.1016/b978-0-12-820777-2.00006-6

Farooq, M., Iqbal, T., Vazquez, P., Farid, N., Thampi, S., Wijns, W., & Shahzad, A. (2020). Thin-Film Flexible Wireless Pressure Sensor for Continuous Pressure Monitoring in Medical Applications. Sensors, 20(22), 6653. https://doi.org/10.3390/s20226653

Frakes, M., Gruber, J., & Jena, A. (2021). Is great information good enough? Evidence from physicians as patients. Journal of Health Economics, 75, 102406. https://doi.org/10.1016/j.jhealeco.2020.102406

Gaubert, V., Gidik, H., Bodart, N., & Koncar, V. (2020). Investigating the Impact of Washing Cycles on Silver-Plated Textile Electrodes: A Complete Study. Sensors, 20(6), 1739. https://doi.org/10.3390/s20061739

Gasparis, A. P., Kim, P. S., Dean, S. M., Khilnani, N. M., & Labropoulos, N. (2020). Diagnostic approach to lower limb edema. Phlebology, 35(9), 650–655. https://doi.org/10.1177/0268355520938283

Grada, A., & Phillips, T. J. (2017). Lymphedema. Journal of the American Academy of Dermatology, 77(6), 1009–1020. https://doi.org/10.1016/j.jaad.2017.03.022

Hageman, D. J., Wu, S., Kilbreath, S., Rockson, S. G., Wang, C., & Knothe Tate, M. L. (2018). Biotechnologies toward Mitigating, Curing, and Ultimately Preventing Edema through Compression Therapy. Trends in Biotechnology, 36(5), 537–548. https://doi.org/10.1016/j.tibtech.2018.02.013

Hutchinson, J. (2017). Innovation in compression: smart bandage technology to improve bandage application and monitoring. Veins and Lymphatics. https://doi.org/10.4081/vl.2017.6631

Interlink Electronics, Inc. (n.d.). FSR Sensor, Force Sensing Resistor | Interlink Electronics. https://www.interlinkelectronics.com/force-sensing-resistor

Kahn, S. R. (2009). How I treat postthrombotic syndrome. Blood, 114(21), 4624–4631. https://doi.org/10.1182/blood-2009-07-199174

Kahn, S. R. (2016). The post-thrombotic syndrome. Hematology, 2016(1), 413–418. https://doi.org/10.1182/asheducation-2016.1.413

Karakaş, P., & Bozkir, M. G. (2007). Determination of Normal Calf and Ankle Values Among Medical Students. Aesthetic Plastic Surgery, 31(2), 179–182. https://doi.org/10.1007/s00266-006-0132-6

Li, J., Ma, Q., Chan, A. H., & Man, S. (2019). Health monitoring through wearable technologies for older adults: Smart wearables acceptance model. Applied Ergonomics, 75, 162–169. https://doi.org/10.1016/j.apergo.2018.10.006

Li, Y., Miao, X., Niu, L., Jiang, G., & Ma, P. (2019). Human Motion Recognition of Knitted Flexible Sensor in Walking Cycle. Sensors, 20(1), 35. https://doi.org/10.3390/s20010035

Ligi, D., Croce, L., & Mannello, F. (2018). Chronic Venous Disorders: The Dangerous, the Good, and the Diverse. International Journal of Molecular Sciences, 19(9), 2544. https://doi.org/10.3390/ijms19092544

Lim, C. S., & Davies, A. H. (2014). Graduated compression stockings. Canadian Medical Association Journal, 186(10), E391–E398. https://doi.org/10.1503/cmaj.131281

Line, B. R. (2001). Pathophysiology and diagnosis of deep venous thrombosis. Seminars in Nuclear Medicine, 31(2), 90–101. https://doi.org/10.1053/snuc.2001.21406

Livermore, N. R., Schoenbrunner, A. R., & Janis, J. E. (2021). A Critical Examination of the Science and Role of Compression Garments in Aesthetic Surgery. Plastic &Amp; Reconstructive Surgery, 148(4), 682e–685e. https://doi.org/10.1097/prs.0000000000008373

Lurie, F., Passman, M., Meisner, M., Dalsing, M., Masuda, E., Welch, H., Bush, R. L., Blebea, J., Carpentier, P. H., De Maeseneer, M., Gasparis, A., Labropoulos, N., Marston, W. A., Rafetto, J., Santiago, F., Shortell, C., Uhl, J. F., Urbanek, T., van Rij, A., . . . Wakefield, T. (2020). The 2020 update of the CEAP classification system and reporting standards. Journal of Vascular Surgery: Venous and Lymphatic Disorders, 8(3), 342–352. https://doi.org/10.1016/j.jvsv.2019.12.075

Mallenius, S., Rossi, M., Tuunainen, V.K. (2007) Factors affecting the adoption and use of mobile devices and services by elderly people - results from a pilot study. Proceeding of 6th Annual Global Mobility Roundtable, Los Angeles

Marieb, E. N., Hoehn, K., & Pearson. (2015). Human Anatomy and Physiology, Global Edition. Pearson Education, Limited.
Mekkes, J.R. (2022, March). Lipodermatosclerosis en hypodermitis. huidziekten.nl. https://www.huidziekten.nl/zakboek/dermatosen/ltxt/lipodermatosclerosis.htm

Meissner, M. H., Wakefield, T. W., Ascher, E., Caprini, J. A., Comerota, A. J., Eklof, B., Gillespie, D., Greenfield, L. J., He, A. R., Henke, P. K., Hingorani, A., Hull, R. D., Kessler, C. M., McBane, R. D., & McLafferty, R. B. (2007). Acute venous disease: Venous thrombosis and venous trauma. Journal of Vascular Surgery, 46(6), S25–S53. https://doi.org/10.1016/j.jvs.2007.08.037

Miller, J. A. (2011). Use and wear of anti-embolism stockings: a clinical audit of surgical patients. International Wound Journal, 8(1), 74–83. https://doi.org/10.1111/j.1742-481x.2010.00751.x

Motykie, G. D., Caprini, J. A., Arcelus, J. I., Reyna, J. J., Overom, E., & Mokhtee, D. (1999). Evaluation of Therapeutic Compression Stockings in the Treatment of Chronic Venous Insufficiency. Dermatologic Surgery, 25(2), 116–120. https://doi.org/10.1046/j.1524-4725.1999.08095.x

Musani, M., Matta, F., Yaekoub, A. Y., Liang, J. W., Hull, R. D., & Stein, P. D. (2010). Venous Compression for Prevention of Postthrombotic Syndrome: A Meta-analysis. The American Journal of Medicine, 123(8), 735–740. https://doi.org/10.1016/j.amjmed.2010.01.027

Murnane, E. L., Cosley, D., Chang, P., Guha, S., Frank, E., Gay, G., & Matthews, M. (2016). Self-monitoring practices, attitudes, and needs of individuals with bipolar disorder: implications for the design of technologies to manage mental health. Journal of the American Medical Informatics Association, 23(3), 477–484. https://doi.org/10.1093/jamia/ocv165

Navodya, U. K., Keenawinna, G., & Gunasekera, U. (2020). The Development of Sustainable Alternative to Neoprene Wetsuit Fabric. https://doi.org/10.1109/mercon50084.2020.9185195

Nelson, E.A., Adderley U. (2016, Jan 15) Venous leg ulcers. BMJ Clin Evid. PMID: 26771825; PMCID: PMC4714578.

Nelson, E. a. S., Harper, D., Prescott, R. J., Gibson, B. E., Brown, D. C., & Ruckley, C. (2006). Prevention of recurrence of venous ulceration: Randomized controlled trial of class 2 and class 3 elastic compression. Journal of Vascular Surgery, 44(4), 803–808. https://doi.org/10.1016/j.jvs.2006.05.051

Ng, J. L., Collins, C. E., & Knothe Tate, M. L. (2017). Engineering mechanical gradients in next generation biomaterials – Lessons learned from medical textile design. Acta Biomaterialia, 56, 14–24. https://doi.org/10.1016/j.actbio.2017.03.004

Ning, J., Fish, J. H., Trinh, F., Abbas, J., Seiwert, A. J., & Lurie, F. (2020). Comparison of three pressure monitors used to measure interface pressure under compression bandages. Phlebology, 35(4), 262–267. https://doi.org/10.1177/0268355519862178

Ochoa, M., Rahimi, R., & Ziaie, B. (2014). Flexible Sensors for Chronic Wound Management. IEEE Reviews in Biomedical Engineering, 7, 73–86. https://doi.org/10.1109/rbme.2013.2295817

Park, Y., Kwon, K., Kwak, S. S., Yang, D. S., Kwak, J. W., Luan, H., Chung, T. S., Chun, K. S., Kim, J. U., Jang, H., Ryu, H., Jeong, H., Won, S. M., Kang, Y. J., Zhang, M., Pontes, D., Kampmeier, B. R., Seo, S. H., Zhao, J., . . . Rogers, J. A. (2020). Wireless, skin-interfaced sensors for compression therapy. Science Advances, 6(49). https://doi.org/10.1126/sciadv.abe1655

Prince, S. A., Cardilli, L., Reed, J. L., Saunders, T. J., Kite, C., Douillette, K., Fournier, K., & Buckley, J. P. (2020). A comparison of self-reported and device measured sedentary behaviour in adults: a systematic review and meta-analysis. International Journal of Behavioral Nutrition and Physical Activity, 17(1). https://doi.org/10.1186/s12966-020-00938-3

Rabe, E., Partsch, H., Hafner, J., Lattimer, C. R., Mosti, G., Neumann, M., Urbanek, T., Huebner, M., Gaillard, S., & Carpentier, P. H. (2018). Indications for medical compression stockings in venous and lymphatic disorders: An evidence-based consensus statement. Phlebology, 33(3), 163–184. https://doi.org/10.1177/0268355516689631

Rabe, E., Földi, E., Gerlach, H., Jünger, M., Lulay, G., Miller, A. A., Protz, K., Reich-Schupke, S., Schwarz, T., Stücker, M., Valesky, E. M., & Pannier, F. (2021). Medical compression therapy of the extremities with medical compression stockings (MCS), phlebological compression bandages (PCB), and medical adaptive compression systems (MAC). Hautarzt, 72(S2), 37–50. https://doi.org/10.1007/s00105-020-04706-z

Rajendran, S., Anand, S. C., & Rigby, A. J. (2016). Textiles for healthcare and medical applications. Elsevier EBooks, 135–168. https://doi.org/10.1016/b978-1-78242-465-9.00005-7

Raju, S., Hollis, K., & Neglen, P. (2007). Use of Compression Stockings in Chronic Venous Disease: Patient Compliance and Efficacy. Annals of Vascular Surgery, 21(6), 790–795. https://doi.org/10.1016/j.avsg.2007.07.014

Raetz, J., Wilson, M., & Collins, K. (2019, June 1). Varicose Veins: Diagnosis and Treatment. PubMed. https://pubmed.ncbi.nlm.nih.gov/31150188/
Recek, C. (2013). Calf Pump Activity Influencing Venous Hemodynamics in the Lower Extremity. International Journal of Angiology, 22(01), 023–030. https://doi.org/10.1055/s-0033-1334092

Reich-Schupke, S., Feldhaus, F., Altmeyer, P., Mumme, A., & Stücker, M. (2014). Efficacy and comfort of medical compression stockings with low and moderate pressure six weeks after vein surgery. Phlebology, 29(6), 358–366. https://doi.org/10.1177/0268355513484142

Ringer M, Lappin SL. (2022, May 25) Orthostatic Hypotension. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan–. PMID: 28846238.

Rotsch, C., Oschatz, H., Schwabe, D., Weiser, M., & Möhring, U. (2011). Medical bandages and stockings with enhanced patient acceptance. Handbook of Medical Textiles, 481–504. https://doi.org/10.1533/9780857093691.4.481

Sachdeva, A., Dalton, M., & Lees, T. (2018). Graduated compression stockings for prevention of deep vein thrombosis. The Cochrane Library, 2019(4). https://doi.org/10.1002/14651858.cd001484.pub4

Sandean, D. P., & R Winters, R. (2023, January 3). Spider Veins. StatPearls - NCBI Bookshelf. https://www.ncbi.nlm.nih.gov/books/NBK563218/

Sarı, B., & Oğlakcıoğlu, N. (2016). Analysis of the parameters affecting pressure characteristics of medical stockings. Journal of Industrial Textiles, 47(6), 1083–1096. https://doi.org/10.1177/1528083716662587

Schuren, J., & Mohr, K. (2008). The efficacy of Laplace's equation in calculating bandage pressure in venous leg ulcers. Wounds UK, 4(2), 38–47. https://www.wounds-uk.com/journals/issue/14/article-details/the-efficacy-of-laplaces-equation-in-calculating-bandage-pressure-in-venous-leg-ulcers-1

Shingler, S. L., Robertson, L., & Stewart, M. C. W. (2021). Graduated compression stockings for the initial treatment of varicose veins in people without venous ulceration. The Cochrane Library, 2021(7). https://doi.org/10.1002/14651858.cd008819.pub4

Stern, E. B., Callinan, N. J., Hank, M., Lewis, E. J., Schousboe, J. T., & Ytterberg, S. R. (1998). Neoprene Splinting: Dermatological Issues. American Journal of Occupational Therapy. https://doi.org/10.5014/ajot.52.7.573

Stubbs, M., Mouyis, M., & Thomas, M. (2018). Deep vein thrombosis. BMJ, k351. https://doi.org/10.1136/bmj.k351

Thomas, S. (2003). The use of the Laplace equation in the calculation of sub-bandage pressure. EWMA Journal, 3(1), 21–23. http://www.worldwidewounds.com/2003/june/Thomas/Laplace-Bandages.html

Thomas, S. (2014). The production and measurement of sub-bandage pressure: Laplace’s Law revisited. Journal of Wound Care, 23(5), 234–246. https://doi.org/10.12968/jowc.2014.23.5.234

Uhl, J. F., Benigni, J. P., Chahim, M., & Fréderic, D. (2016). Prospective randomized controlled study of patient compliance in using a compression stocking: Importance of recommendations of the practitioner as a factor for better compliance. Phlebology: The Journal of Venous Disease, 33(1), 36–43. https://doi.org/10.1177/0268355516682886

Vandongen, Y., & Stacey, M. (2000). Graduated Compression Elastic Stockings Reduce Lipodermatosclerosis and Ulcer Recurrence. Phlebology, 15(1), 33–37. https://doi.org/10.1177/026835550001500106

Valk, D. van der. (2020). Knitted Smart Textile Sensors: Integrating technlogy into garments by using knitting [MsC]. Delft University of Technology.

Wakeling, J. M., Ross, S. A., Ryan, D. S., Bolsterlee, B., Konno, R., Domínguez, S., & Nigam, N. (2020). The Energy of Muscle Contraction. I. Tissue Force and Deformation During Fixed-End Contractions. Frontiers in Physiology, 11. https://doi.org/10.3389/fphys.2020.00813

Wang, Y. R. (2017). Manikins for evaluation of pressure performance. Manikins for Textile Evaluation, 241–258. https://doi.org/10.1016/b978-0-08-100909-3.00011-x

World Health Organization: WHO. (2021). Cardiovascular diseases (CVDs). www.who.int. https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)

World Health Organization: WHO. (2022). Ageing and health. www.who.int. https://www.who.int/news-room/fact-sheets/detail/ageing-and-health

Xiong, Y., & Tao, X. (2018). Compression Garments for Medical Therapy and Sports. Polymers, 10(6), 663. https://doi.org/10.3390/polym10060663

Zurcher, K. S., Huynh, K. N., Khurana, A., Majdalany, B. S., Toskich, B., Kriegshauser, J. S., Patel, I., Naidu, S., Oklu, R., & Alzubaidi, S. (2022). Interventional Management of Acquired Lymphatic Disorders. Radiographics, 42(6), 1621–1637. https://doi.org/10.1148/rg.220032

Sourcelist images

Front page Chapter 2:
Amazon (n.d.). Compression Socks, 20-30 mmHg Graduated Knee-Hi Compression Stockings for Unisex, Open Toe, Opaque, Support Hose for DVT, Pregnancy, Varicose Veins, Relief Shin Splints, Edema, Beige Large [image]. Amazon. https://www.amazon.com/Compression-Graduated-Stockings-Pregnancy-Varicose/dp/B07C2SS7P4

2.1.1:
Venosan (n.d.), Calf Muscle pump [image]. Venosan. https://venosan.us/content/the-calf-muscle-pump-compression/

2.1.2:
Belleza, M.R.N., (2023). Muscular System Anatomy and Physiology [image]. Nurselabs. https://nurseslabs.com/muscular-system-anatomy-physiology/

2.3.1:
Compression Socks Shop (n.d.). Medical compression stockings, class 3, beige [image]. Compression Sockshop https://compressionsockshop.co.uk/shop/157-compression-stockings/1915-medical-compression-stockings-class-3-beige/

2.3.2:
Fibre2fashion (n.d.). Single Flat bed Knitting Machine Buyer [image]. Fibre2fashion
https://www.fibre2fashion.com/machines/single-flat-knitting-machine-buyers-19159512

2.3.3:
Kiron, M. I. (2021). Four Truck Single Jersey Circular Knitting Machine [image]. Textile learner
https://textilelearner.net/four-truck-single-jersey-circular-machine/

2.3.4:
Lohmann-rauscher (n.d.). Compression bandages [image]. Lohmann-rauscher https://lohmann-rauscher.co.uk/products/bandages-and-support

Front page 3:
Chestnut Square (2021). The Health Benefits of Wearing Compression Socks [image] Chestnut Square https://www.chestnutsquare.info/the-health-benefits-of-wearing-compression-socks

3.2.2:
Brightlife (n.d.). FarrowWrap 4000 Beenstuk [image]. BrightLife direct https://www.brightlifedirect.com/blogs/news/alternatives-to-wearing-compression-socks-and-stockings

4.1.1 Medis (n.d.). Microlab Picopress [image]. Medis https://www.medismedical.com/?product=picopress

4.2.1
Farooq, M., Iqbal, T., Vazquez, P., Farid, N., Thampi, S., Wijns, W., & Shahzad, A. (2020). Thin-Film Flexible Wireless Pressure Sensor for Continuous Pressure Monitoring in Medical Applications. Sensors, 20(22), 6653. https://doi.org/10.3390/s20226653

4.1.2
Interlink (n.d.) Interlink Electronics Membrane Pressure sensor - 18mm Round [image]. Tiny Tronics https://www.tinytronics.nl/shop/en/sensors/weight-pressure-force/membrane/interlink-electronics-membrane-pressure-sensor-18mm-round

5.2.1 drawing on
Healthline (n.d.). Can Wearing Compression Socks Be Harmful? [image]. healthline https://www.healthline.com/health/can-wearing-compression-socks-be-harmful

5.2.3 & 5.3.2 drawing on
Podobrace (n.d.). Novamed Steunkousen - Gesloten teen (beige) (Per paar) [image] Podobrace https://www.podobrace.nl/shop/product/novamed-steunkousen-drukklasse-1/

8.3.2
Interlink (n.d.) Interlink Electronics Membrane Pressure sensor - 18mm Round [image]. Tiny Tronics https://www.tinytronics.nl/shop/en/sensors/weight-pressure-force/membrane/interlink-electronics-membrane-pressure-sensor-18mm-round

8.3.4
MT industry (n.d.) K12-125 Zelfcentrerende 4-klauwplaat [image]. MT industry https://mtindustry.nl/product/k12-125-zelfcentrerende-4-klauwplaat/?gad=1&gclid=CjwKCAjw-IWkBhBTEiwA2exyO1HxV3-XrxxGKqy0z_NSIyN8iswY6lVHLQPbod4ChJK3gOA5TrTu7RoCzfkQAvD_BwE