BSc Creative Technology

Designing a low-cost monitoring system for lymphedema: Empowering life after cancer

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ABSTRACT

More people are at risk of getting Lymphedema, due to an increase in occurrence of cancer. Lymphedema is an implication of cancer treatment and is the result of damaged lymph nodes due to surgery or radiation. This on its turn, results in swelling which can be experienced as uncomfortable. Treatment is delayed due to late diagnosis and the costs of more intense face to face follow-up are too high. This research developed a patient friendly and low-cost self-monitoring tool to overcome these issues. This was done by following the Creative Technology Design Process. The prototype resulting from this process, was evaluated through a use evaluation consisting of two phases with 8 healthy participants and one Lymphedema patient. This evaluation was focused on usability, reliability and speed of measurements. The usability was tested through the use of the System Usability Scale. The average score was 78,75, therefore it can be said that the usability of the tool is good. The method to test the reliability turned out to be not suitable and it is advised to test the usability of the developed tool in future research. The speed of measurement had an average of 8 minutes and 16 seconds to measure both arms. Therefore it can be said that the product has potential to be a great low-cost contribution to the monitoring of Lymphedema at home. Future research should focus on testing the reliability and researching the possibilities of different sizes.

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1 INTRODUCTION

1.1 Introduction

Cancer is a decease that is growing in its occurrence. When patients are done with their treatment, they are not yet done with the implications of this decease. Lymphedema is one of these implications that can occur up to three years after the patient has recovered from cancer. Lymphedema occurs when the lymph nodes are damaged. Surgery or radiation as treatment for cancer can be the reason for this damage. When the lymphatic fluids accumulate and the lymph nodes are not capable of properly draining this fluid, swelling will occur. After breast cancer this happens in the arms due to damage to the lymph nodes in the arm pits. This swelling can cause pain and discomfort and even result in limited mobility. Lymphedema is a progressive disease and when not treated properly and timely, it can cause permanent damage. Next to that, almost half of patients who undergo surgery for breast cancer develop lymphedema, but are not monitored regularly. Because of this and the progressive nature of the disease, early detection is needed. [1] [2]
Currently the two methods that are used the most to diagnose Lymphedema in the arm are the circumference method and taking the whole-arm volume. The first technique is done by taking the circumference of the arm in multiple places and comparing it to the other arm. Here the difference between each measured location is checked, as well as the total difference between the two arms [3][4]. The second technique is taking the volume of the arm by submerging it in a water basin and comparing it to the volume of the other arm. If the difference is big enough, 3-10%, Lymphedema is diagnosed [4]. These techniques are mostly used in clinical settings and since cancer checkups are commonly only once or twice a year, this results in possible late detection of the disease.
As it is not feasible to provide more intensive face to face follow-up due to overload of the healthcare sector, at home monitoring is needed to avoid late detection. But at this point there are only a few tools suitable for at home measurement. The down-side of these tools is the fact that they are too expensive to take into production. Since these tools are used to monitor lymphedema and are therefore a prevention method, they are often too expensive to be cost-effective. Next to that, these tools are still underdeveloped or require technical knowledge and will therefore not be implemented in the near-future [5].
Thus, the goal of this research is to design a tool that can be used to monitor lymphedema to allow for early detection of lymphedema. This tool should be usable in the home setting. Next to that it should be reliable and patient friendly to ensure that people do in fact use it. Lastly, it is important that the tool is inexpensive, to make sure that it will be cost-effective and production is possible.

1.2 Research questions

The main research question is:
How can you design a reliable, patient friendly and low-cost self-monitoring tool to monitor lymphedema after cancer?

To answer this research question, the following sub-questions are formed:

1. **What tools can be used for monitoring Lymphedema?**
2. **What characteristics of lymphedema are measurable?**
3. **What requirements should this tool address?**
4. **To what extend is the designed tool reliable to monitor lymphedema after cancer in a patient friendly way?**

In Chapter 2 background research will be conducted. It starts with a literature research where Lymphedema will be explained. Next the state of the art is analysed, which will answer sub-question 1. Chapter 3 describes the methods used throughout the thesis to develop this monitoring tool. Sub-question 2 will be answered in Chapter 4 by means of an interview with an expert in the field of Lymphedema. Chapter 4 also includes user research, where after sub-question 3 can be answered, and ends with a set of preliminary requirements which are specified in Chapter 5. Chapter 5 ends with an explanation about the final concept. Chapter 6 then continues with describing the realisation of the final prototype. The use evaluation of this prototype is explained in Chapter 7, thereby the last sub-question is answered. Chapter 8 discusses and reflects on the findings in Chapter 7 and on the process of the study. The thesis is concluded in Chapter 9.

2 BACKGROUND RESEARCH

2.1 Literature research

To get a better understanding of what the current status of monitoring tools for Lymphedema is, a literature research and state of the art analysis was conducted. To start it is of importance to know what Lymphedema is. Lymphedema is an accumulation of extracellular fluid in the tissue. This occurs due to malfunction of the lymphatic system. The lymphatic system is unable to regulate the fluid balance in the tissue which can lead to swelling of the affected region [6]. There are two types of Lymphedema, primary and secondary [2]. In this paper we will only look at secondary lymphedema in the arm, which refers to Lymphedema caused by external damage to the lymphatic system, in this case due to treatment for breast cancer.
As shortly explained before. Lymphedema occurs when the lymphatic load exceeds the transport capacity of the lymphatic circulatory system. Once this occurs, the buildup of protein-rich fluids will keep increasing. The already present extracellular fluid will pull more fluid out of the lymphatic vessels. This results in a progressive disease. Lymphedema can be categorised in 4 different stages, which can be seen in figure 2.1 [2].
The first stage that will be explained is stage 0. In this stage the lymph transport capacity is reduced. There is approximately 30% more fluid in the extracellular space than normal. This may result in discomfort, aching and heaviness in the affected extremity. At this stage there is no measurable increase in volume and therefor this stage is very hard to detect.
Stage 0 goes over in stage I. In stage I a difference in volume is measurable. This difference is caused by protein-rich fluid built-up. The tissue will feel soft and an indent will remain for a few minutes after pressure is applied to a small spot. After rest and elevation the edema may be hardly noticeable but at the end of a day it will be visible. Lymphedema in this stage is reversible an therefor diagnosis before progression to the next stage is necessary.
In stage II, Lymphedema is irreversible. Some of the protein-rich fluid will be replaced by tissue fibrosis (scarring). The skin will become more fragile and start to thicken or break down. The tissue is stiffer than in stage I and therefore pitting is more difficult to induce. When diagnosis is done at this stage, chronic treatment is needed since the disease is irreversible.
The last stage is stage III. At this stage is spoken of lymphedema elephantiasis. This refers to the severe swelling and skin alterations of the affected extremity. Diagnosis should occur way before this stage and proper treatment needs to be started. [2]
Because of these symptoms, Lymphedema can have high impact on the quality of life. The swelling and scarring may result in limited mobility and pain [5]. Fatigue is another symptom, this is a result of inflammation due to the prolonged presence of swelling and proteins [1]. This interferes with activities of daily living and therefore it also has impact on the mental health of patients.

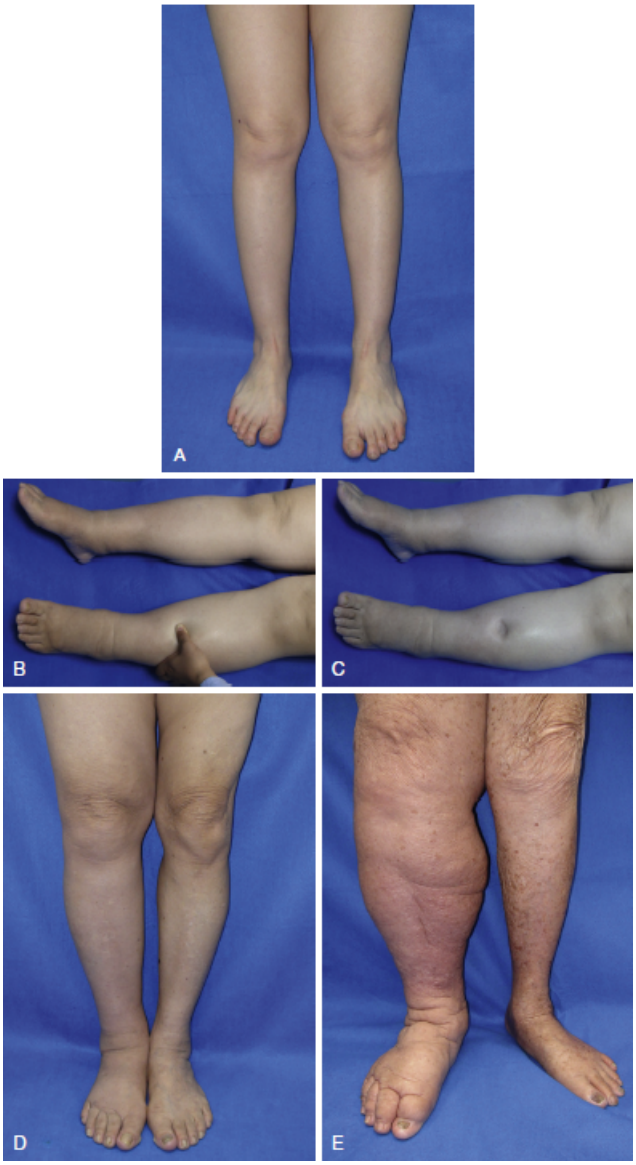

Figure 2.1: Stages of lymphedema as defined by the International Society of Lymphology. **(A)** Stage 0: normal-looking leg. **(B,C)** Stage I: spontaneously reversible lymphedema; left leg showing pitting edema after 1 minute of continuous pressure. **(D)** Stage II: spontaneously irreversible lymphedema. **(E)** Stage III: lymphostatic elephantiasis with severe fibroadipose deposition and skin changes.

Source: [1]

2.2 State of the art

As for the state of the art of lymphedema monitoring methods there are already some techniques and tools on the market. In this section these techniques and tools will be discussed with regard to the tools used in a clinical setting and in an at-home setting.

2.2.1 Monitoring in a clinical setting

There are many different methods to monitor Lymphedema, but three of them are mentioned in many papers. These three will be discussed more elaborate, followed by a short mentioning of the methods that were less present in the literature.

Circumference method

The first one that is often talked about is the circumference method. For this method the circumference of the arm or leg is taken at multiple spots at a certain interval. Both Dylke [4] and Hayes et al. [3] talk about the advantages and disadvantages of this method. At this moment, the circumference method is the most used method because of its simplicity. The only thing needed is a tape measure and therefore the costs are very low. Another welcome advantage is the possibility to determine the swelling more specifically. Since the circumference is taken on different spots on the arm, the spots with the biggest difference can be determined. On the other side there is a big disadvantage. There is a lack of agreement over the used measuring protocols. There are different advises about how many measurements need to be taken and what the interval between these measurements needs to be. This results in difficulties with comparing measurements between clinicians, since a different interval may be chosen. Next to that there is a disagreement about the inter-limb difference to determine when the limb is abnormal or not. A last disadvantage may be that the conversion from the circumference to a volume measure, done by calculating the volume of each segment of the arm, can be burdensome. So, although this method is often used as the reference method for research, this does not necessarily mean that it is an user-friendly method.

Whole limb volume method

The second method is the whole limb volume method. Here the whole arm or leg is submerged in a basin of water. The water displacement is measured to determine the volume of the limb. According to Dylke [4] this method is very reliable, but is not interchangeable with other methods. There is also a higher risk at infection of the limb. Next to that there are health and safety concerns for the clinician due to the need to carry large containers with water. Lastly, also with this method, there is a wide range of measurement protocol which leads to the unfeasibility to compare results between clinicians. Next to these disadvantages, there are also a few promising aspects. This method is very quick to use and no conversions are needed. Besides, the ability to easily measure the volume of irregular shapes is a big advantage. It appears that the disadvantages of this method outweigh the advantages and therefore it is not widely used anymore.

Bioimpedance spectroscopy

The third method that will be discussed is bioimpedance spectroscopy (BIS). A lot of research has been done into this method. With this method the extracellular fluid can be measured to detect lymphedema. Dylke [4] states that BIS had a greater sensitivity than alternative techniques and that it is especially useful for early detection. But on the other hand, it cannot be used on people that are pregnant or have a pacemaker. Hayes et al. [3], Ward et al. [7] and Shah et al. [8][9] mentioned BIS and its advantages. They state that BIS is rapid to perform but it still has a high degree of reliability. Most important of all it is a non-invasive technique and therefor it can be performed often without causing any harm. But BIS does also have some disadvantages. It is a more expensive technique than the circumference method and the whole limb volume method. The output of a measurement with BIS is a voltage, which most clinicians find hard to interpret correctly. The conversion of this value to a volume is based on a lot of assumptions and might therefore be not reliable. Lastly, moderate exercise up to 2 hours before measuring can negatively influence the measurements done, due to reduced impedance [10]. But, because of all the promising results of new research, this technique is growing in popularity.

Methods in research

There are numerous other techniques that are not yet developed enough to take into practise. These techniques will be mentioned shortly to highlight their existence, but because of their early stages in research they will not be discussed elaborately. Firstly, [6],[11] and [9] mention the use of an infrared camera. This is used in both perometry and the Kinect system of Lu et al. [6], which estimates the arm volume by making a 3D image with the use of the infrared camera. The second technique that will be mentioned is ultrasound. [12] and [13] talk about ultrasound in their research. Next to that [14] mentioned Ultrasound as well as MRI in her letter as a response to the article by Kim et al. [15], that is about the use of MRI to diagnose lymphedema. Lastly a few papers mention tonometry, which measures the resistance of the skin to pressure, but this is only tested on changes in the breast and not on any extremities [3][16]. So, these techniques are not yet developed enough to discuss them elaborately, but they are worth mentioning to enhance further research.

2.2.2 Monitoring in the home environment

Next to monitoring methods in the clinical setting, there is also some research done in home monitoring methods for Lymphedema. In the next sections these methods will be discussed.

Mobilymph

Ibrahim et al. [17] published an elaborate study in a mobile-based bioimpedance diagnosis and monitoring system for lymphedema (Mobilymph). It makes use of the bioimpedance spectroscopy technique, which is also used in a clinical setting and has therefore the same advantages and disadvantages as mentioned earlier. Nevertheless, a good thing to mention is the fact that this study developed, tested and validated this method and therefore it can be used in practise. The downside, however, it still makes use of the same assumptions to make a conversion to a volume as mentioned at section 2.2.1 and is therefore not as reliable as wished for.

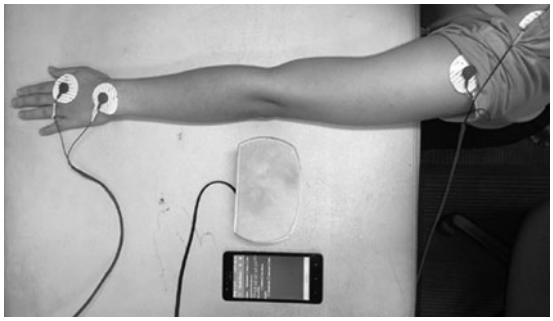

Figure 2.2: Mobilymph monitoring device.
Source: [17]

Wearable devices

Mobilymph is not the only device that is developed for self-monitoring. Rajab et al. [5] discussed six different at-home measurement devices in their paper, from which three are wearable devices. Two of the wearable devices developed a sleeve that measures the circumference of the arm using an elastic sensor. A sleeve like this should be worn the whole day and may lead to discomfort. On the other hand, because it is worn the whole day, it collects continuous

data. Another wearable device uses dielectric and strain sensors to detect volume and hydration changes. An advantage of this device is the fact that it is only a small patch of sensors that is placed at the upper arm. Another advantage that also holds for the devices in sleeve form, is that these wearable devices are less prone to user generated variability. But, because they are placed on the skin for longer times there may arise some measurement fluctuations due sweat created by the skin contact. That the sensors are quite expensive can be seen as another disadvantage and lastly, these devices are still in research and are not yet validated.

Stationary devices

Next to these three wearable devices, Rajab et al. [5] reviews three non-wearable devices that use an IR or 3D camera setup. These sensors are all more accurate than the wearable sensors, but they require more technical knowledge to set up the monitoring structures. Next to that, these set ups output only non continuous measurements. This also asks for accountability of the patients to monitor on set times and days to give the best results. Although there are some disadvantages, these devices all use of the shelve sensors and therefore their implementation in practise is more likely. In contradiction to the bioimpedance method of Ibrahim et al. [17], which is also a stationary device, these six devices are not tested on patients with severe swelling or distortions in the skin which is a great loss.

2.3 Reflection on background research

From the literature, it is found that there exist a lot of different measuring methods for lymphedema in many different stages of research. There are some already in use in a clinical setting, like the circumference method, the whole limb volume method and the bioimpedance method. There are also many methods still in research and not yet implemented into practice. A few methods are developed for measuring Lymphedema in a home environment, like Mobilymph and IR sensor setups, who all use sensors.
So, it can be said that there are some monitoring methods but there are also some gaps in this field of research. Especially in the direction of self-monitoring devices, there is plenty of room for more research. These self-monitoring devices are especially helpful in early diagnostication of Lymphedema, which is in demand, but lack of technical knowledge of the patient should be considered. While there were a few studies about at-home monitoring, these were not validated or suitable to implement due to complexity or costs and therefore not possible to implement in home-based use.

3 METHODS AND TECHNIQUES

In this chapter the design process will be explained. From the previous chapter it is clear that there is a need for a low-cost, at-home monitoring device for Lymphedema. The first step in the design process is conducting a stakeholder analysis. Next the methods used will be explained. The Creative technology design process was used as a guideline [18]. The steps of this process will be elaborated on.

3.1 Stakeholder analysis

A stakeholder analysis is performed to show who to take into account when designing the monitoring tool. Next to that it shows who's needs are most important. Here the patient is the most important stakeholder. It should be a product that they are willing to use and what would help them (see figure 3.1).

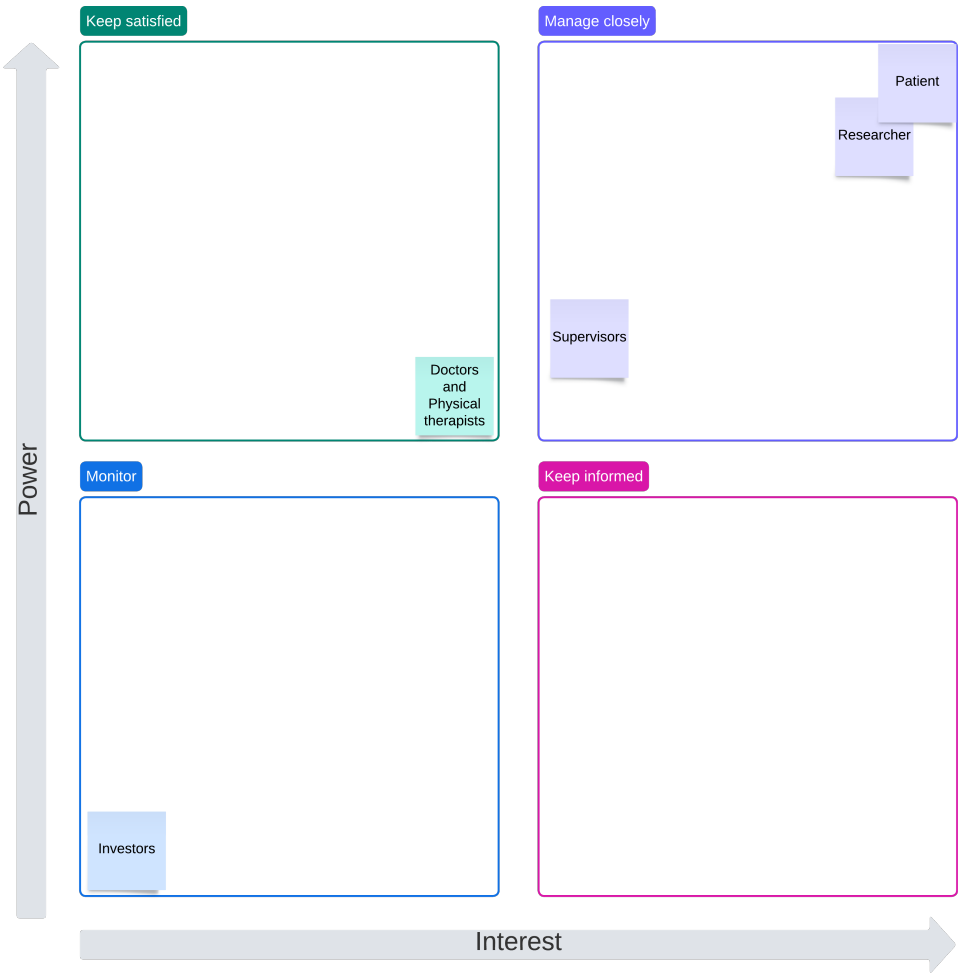

Figure 3.1: Stakeholder analysis.

The patient

The patient will be the end-user of the product and therefore they should be kept in mind in every decision that is made when designing the product. They decide if they want to use the tool, so their opinion is very important. If the tool is designed correctly with the patient in mind, it will be more likely that the tool will be used.

Researcher

As the conductor of this research, the researcher has a lot of power but also a lot of interest. Although they have a lot of power, they should always keep the wishes of the patient at their first place.

Supervisors

The supervisors of this project have some saying in what happens and have quite some interest in the outcomes, but the decisions will be made by the researcher at the end.

Doctors and physical therapists

The doctors and physical therapists have little direct influence on the product. They do however give their expertise and are at the end the people who advise the patient to use the tool. Therefore they do have some power.

Investors

In this research the investors are less important to keep in mind, since it will only be in a early stage of designing. Therefore they will have little interest and little power, yet.

3.2 Creative technology design process

The creative technolgy design process is developed by Mader and Eggink [18] and serves as a guideline for the process of this design process. It consist of four phases: ideation, specification, realization and evaluation as can be seen in figure 3.2. Each phase will be explained in more depth in this section and the different steps in each phase will be highlighted. Moreover, each phase aligns with its own chapter in this report.

3.2.1 Ideation

The ideation phase follows a spiral form, incorporating the problem definition, acquisition of relevant information and idea generation. A creative idea can have many sources, like a flash of inspiration, thinking techniques and related work. To form these ideas, a good understanding of the user and the interaction with the to be designed tool is required. So after extensive literature research, the ideation phase starts with a PACA analysis followed by an interview with an physiotherapist who is specialized in the treatment of Lymphedema. This results in a broader understanding for who and how the designing needs to happen. Now some convergence need to happen to decide upon a monitoring technique to focus on. This is done by collecting the information and forming this into a list of preliminary requirements. With this list, a broad first concept can be generated and can be used in the next phase.

3.2.2 Specification

In the specification phase, the starting point is the outcomes of the ideation phase. With the initial concept and the preliminary requirements an ordered list of requirements is made. This is done by making a distinction between functional and non-functional requirements first. The functional requirements are focused on the technical functionalities and what the product needs to do. The non-functional requirements are more focused on the looks of the product, but also how it feels. Next to that, it says something about how the product needs to function.
Then, these distinctive requirements are prioritised using the MoSCoW method. The MoSCoW method, as explained in Chapter 10 of the DSDM agile project framework handbook [19], is a method to prioritise requirements. The requirements are divided into four categories: Must have, Should have, Could have and Won't have. In the Must have category are all the requirements that are needed to adhere to the Minimun Usable SubseT (MUST), i.e. without these requirements the product is not usable. In the Should have category are the requirements that are important but not vital. It may be very nice to have them in the project but without these requirements the product can still be used. In the Could have category are the requirements that are desirable, but less important. These requirements will only be implemented in the product in a best case scenario. Lastly, in the Won't have category are the requirements that will not be implemented in the product this time. There might be a future research where these can be implemented but the choice is made to leave them out to clarify the scope of the project.
With these prioritised requirements, a prototype can be made. This prototype is made with an iterative approach. A first version of the prototype is build and tested by the researcher. In this case it is tested by the researcher on themselves. This prototype is evaluated to identify missing and malfunctioning functions and requirements. These are then added and/or improved and it is tested again. This process continues until the final design is reached. This design is the basis for the next phase, the realisation.

3.2.3 Realisation

In the realisation phase the final design is realised into a working prototype. Here the choices for certain components, like the kind of fabric, will be discussed and the steps of constructing the prototype are tracked. At the end of the realisation a prototype is ready that can be used in the evaluation phase.

3.2.4 Evaluation

In the last phase the prototype is tested to evaluate the previously set requirements. This is done by the use of user tests. There are 8 user tests with healthy participants of ages between 20 and 70 years old. These participants are asked to perform a measurement with the developed tool on one of their arms. The main goal of these user tests are to evaluate the user experience. The participants are asked to give a score for using the prototype, using the System Usability Scale [20]. Also, the measurement with the developed tool is verified using the circumference method with a measurement every 10 cm starting at the wrist [21]. These circumference measurements are then used to calculate the volume of the arm, using the truncated cone model [22][4].
To test the reliability and the use by Lymphedema patients, another user test is done with one Lymphedema patient of 80 years old. The participant is again asked to perform a measurement, this time on both their arms. The difference measured between the arms by the developed tool is compared to the difference between the measurements with the circumference method. Again the volume is calculated using the truncated cone model. Also this participant is asked about their experience with the developed tool. At the end of the evaluation phase, a conclusion can be drawn about the use of the prototype and this is the basis for the conclusion chapter.

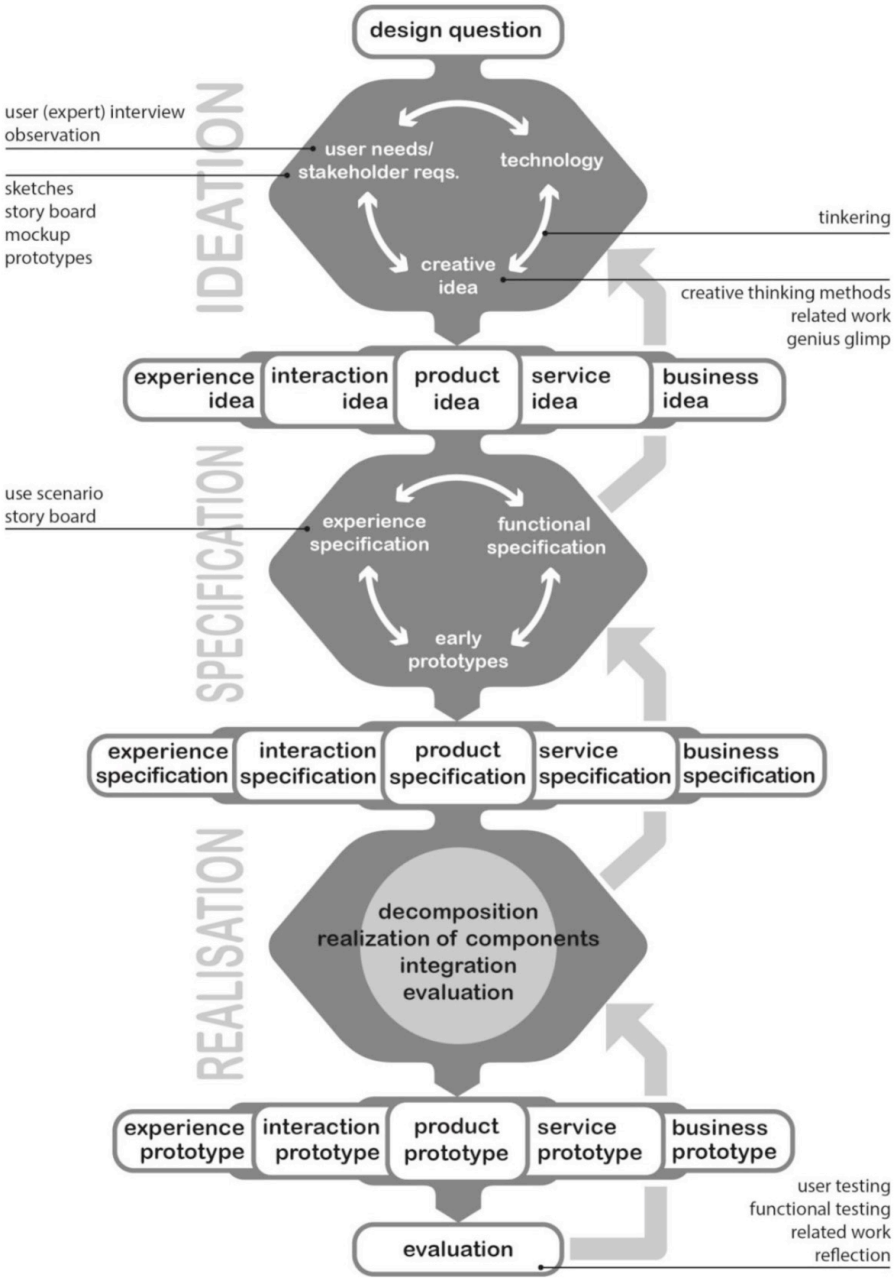

Figure 3.2: Create Design Process Phases.
Source: [18]

4 IDEATION

The aim of the ideation phase is the get a better insight in the user and get wide variety of ideas. This phase starts with doing user research. Next to that an expert in the field of Lymphedema was interviewed to get a better understanding of their point of view and to get information about the medical side of the device.

4.1 User research

To get a better understanding of the user, a PACA analysis is conducted. The PACA analysis follows the user centered design guidelines. PACA stands for: People - Activities - Context - Artefacts. [23]

4.1.1 People

First, the users will be discussed. The users of the device are patients that have recovered from cancer. As mentioned in chapter 1, these people have a higher risk at developing lymphedema and therefore need to monitor closely if they develop any symptoms. The focus in this research is on lymphedema development in the arms, so the target users are people that have had treatment in the area of their arms, like breast cancer patients. While eventually the device is meant to be used by these patients, the functionality of the device can be tested by anyone with two arms. Furthermore these people already went through a lengthy process of cancer recovery. This often means many hospital visits and a lot of uncertainties. To avoid many more hospital visits and give some form of comfort an at home monitoring tool is needed.

4.1.2 Activities

Next, the focus will be on how the users will use the prototype. This device is intended to use on a regular basis. The frequency of use will be answered by the interview with the expert. The time of one measurement is really dependent on the skills of the user but should not be too long. The whole measurement, start to finish, should be doable within 20 min. Next to that it should not be too complicated, so everyone can perform the measurement. Lastly, the measurements should give a reliable reading to make sure that tracking of the development of lymphedema is done right.

4.1.3 Context

The device is intended to use in an at home setting. The use of the device is highly dependent on the responsibility of the user and is completely voluntary. When the measurement is done, the results need to be tracked to be able to monitor the lymphedema. This is another responsibility for the user. It is also important to consider that the device might need to be used by the user on their own, without any help. This illustrates the context wherein the device will be used.

4.1.4 Artefacts

Lastly, the opportunities and the constraints of artefacts present are considered. The price of the device can be a constraint. This is especially of importance when considering if the bigger picture can be profitable when using the device. If the device is too expensive, the money saved by early diagnosis does not outweigh the price of the production of the device. Making the device a portable size gives the user the opportunity to take it with them and therefore does not limit the freedom of the user.

4.2 Expert interviews

An expert with a background in treating Lymphedema was interviewed. It was a semi-structured interview with six question to start off the conversation. The questions and their accompanying answers can be found in appendix A. The goal of the interview was to get a better understanding about what characteristics of Lymphedema can be used to monitor it and what requirements for the monitoring tool need to be fulfilled. Next to that it was important what the view of the expert was with regard to the monitoring of Lymphedema in an at home setting.
The interview made clear that the reliability is a very important aspect. The measured difference between both arms should be the same if the arm does not develop Lymphedema. It is less important if the measurement is accurate. As long as it is reliable, the necessary information can be retrieved. The expert also mentioned that a platform to save the measurements can be of added value. Depending on the used monitoring technique, drawing a conclusion about the measurement can involve complicate calculations. To ensure that the right conclusion is made about the measurement, an online platform to enter the measurements is useful.
Lastly the interview gave valuable information about the characteristics of Lymphedema. The most distinct characteristic is the thickening of the limb. Sometimes this thickening happens in the whole arm, but this is not always the case. It also happens that the thickening is very local, this can best be detected with a method that also measures locally, like the measuring tape. Another characteristics is the speed at which the Lymphedema can develop. Right after the surgery it might be quicker than after some time. Right after the surgery it is advised to measure weekly. Later this might by less frequent but still at least once a month.

4.3 Conclusion of ideation

Given the information from the user research and the expert interviews, a list of preliminary requirements can be made (see table 4.1).

No.	Requirements	Source
1	Non-invasive	Expert interview
2	Solo measurable	User research
3	Inexpensively	User research
4	Reliable	Expert interview
5	Compact	User research
6	Quick to use	User research
7	Easy tracking of the measurements	User research and expert interview

Table 4.1: Preliminary requirements.

With these requirements multiple ideas were produced and a first concept was generated. The first concept would be a sleeve with which the circumference of the arm can be measured at multiple locations. Some ideas about the method of measuring were thought of. The classical

way by using a measuring tape was one of the ideas. This ideas would need to be adapted to work with the sleeve to ensure easy measuring. Another idea was to have a string with two markers where each arm would have its own marker and the difference between the two markers needed to be measured. With this concept and the preliminary requirements, specification about the device can be set up.

5 SPECIFICATION

With the first concept and the preliminary requirements the global approach that the device is taking, is set. The decision was made to make a sleeve to measure the circumference. In this chapter the preliminary requirements will be more specified by setting up functional and non-functional requirements. Next to that, the requirements will be prioritised using the MoSCoW method [24]. With these prioritized requirements, iteration can be made and a final concept can be decided upon.

5.1 Functional and non-functional requirements

A division is made between functional and non-functional requirements. Where the functional requirements say something about the technical functionalities and what the product does, the non functional requirements say something about the looks and feeling of the device and how the product does it. The latter addresses more of the emotional side of the product. For clarity, the requirements are put into a table (see table 5.1 and 5.2) accompanied with an elaboration on the reasoning behind the requirement.

Requirement	Reasoning
A measurement should be doable within 20 minutes	If a measurement takes too long to do, the chances are higher that people will not perform the measurements frequently. If the time it takes to use the device is short then people are more eager to stick to using it.
Should have a portable size	Since the measurements need to be done regularly (about once a week) for a very long time (at least up to two years), it is important that the device is easy to take with you. People might need to take it on a holiday, so it should not be too heavy and big.
Give reliable measurements	To be able to compare measurements with each other, the measurements need to be reliable. The device can measure a different value as the golden standard, but as long as the difference is always the same, this is not a problem. For this a correction can be implemented.
Measurements can be saved in an online platform	To keep track of their measurements over time, it is convenient to have an online platform where patient can put in their measurements. Next to that, if their doctor has insight into this platform, they can keep an eye on the data.
Calculating tool to transform circumference measurements into volume	Not only the circumference says something about the progression of the lymphedema, but also the volume gives valuable information. There are calculating methods to transform the circumference measures into a volume measure. This calculating tool should preferably be implemented in the same online platform as mentioned above.

Table 5.1: Functional requirements.

Requirement	Reasoning
Comfortable to use	People should not be withhold of using the tool, because of discomfort. Next to that it should not harm the person using it by scratching the arm.
Usable with one hand	People might be home alone and have nobody to help them. Therefore they should be able to use the device on their own. Asking for help should not be the limiting factor in the use of this device.
Easy and quick to learn	An explanation by the doctor, the first time using it, should be sufficient to learn to use it. The accompanying online platform can assist with common questions about the use of the tool.
Made out of inexpensive materials	If the device is cheap to make, there is a higher chance that it will be produced and used. Therefore the materials should be cheap and easily accessible.
Usable by every patient	Everyone can be a potential user since no one is excluded of potentially getting cancer. Therefore the device should be usable by everyone in any condition.

Table 5.2: Non-functional requirements.

5.2 MoSCoW

The MoSCoW method is used to prioritise the functional and non-functional requirements. This results in a list of requirements that will and will not be included in the prototype.

Must have

- Give reliable measurements
- Comfortable to use
- Made out of inexpensive materials
- Usable with one hand

Should have

- Easy and quick to learn
- Portable size
- Measurement is doable within 20 min

Could have

- Measurements can be saved in an online platform
- Calculating tool to transform circumference measurements

Won't have

- Usable by every person

  Note: The user group will be too broad to make it feasible. The choice had to be made to exclude some people, therefore only people with a risk at getting lymphedema in their arms, with two arms and without mental impairments are included.

5.3 Final concept

The final concept was developed using the prioritized specifications in this chapter. First more iterations were made on the first concept. It started of with the idea of a sleeve that could measure the circumference. Along the way of the designing process multiple decisions had to be made. These decisions will be explained and reasoning will be given.

5.3.1 Circumference measurement

The first decision made was about how the circumference would be measured. Multiple options were possible like measuring the tension on a elastic and converting this into a length measure, using a piece of string to measure the circumference or using a measuring tape directly. The latter was chosen as this was an inexpensive method with as little as possible steps. If a string would be used, more steps were needed to get a length measure and every step would give an opportunity to get measuring errors. A drawing of the execution of the measuring tape can be seen in figure 5.1

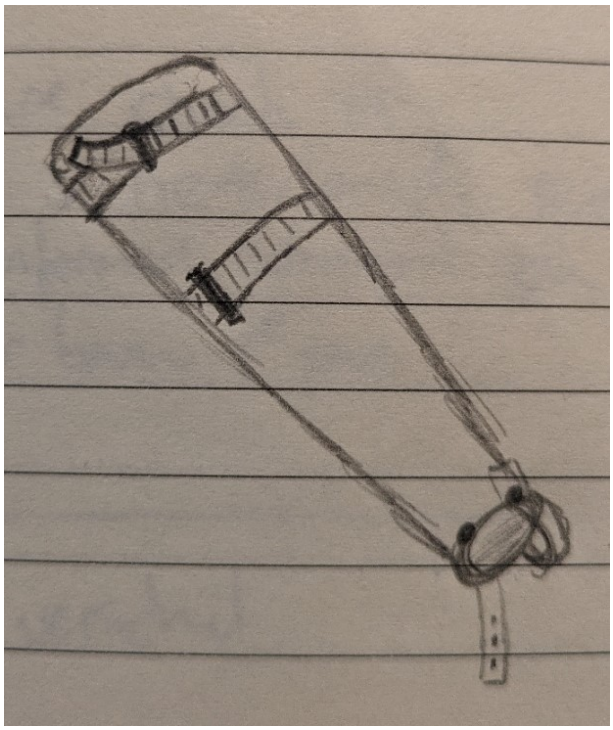

Figure 5.1: Drawing of the measuring tape on sleeve.

Secondly, the sleeve needed to be elastic and the measuring tape should not be the limiting factor in the elasticity of the sleeve. To solve this problem, a tunnel was made of the stretch fabric. The measuring tape could slip in this tunnel so it would not limit the stretch of the fabric (see figure 5.2).The measuring tapes were spaced 10 cm apart and the first tape is located at the styloid process (wrist), this is one of the standards used when using the circumference method [21]. With this prototype, tests could be performed.

Figure 5.2: First testable prototype with measuring tape in a tunnel of stretch fabric.

5.3.2 Fixating measurement

A very important part that needed to be figured out was how the measurements would be fixed on the measuring tape so it can be read when the sleeve is taken off. First of all the start of the

measuring tape needed to be fixed to the sleeve. When this was done, the start could not move anymore and pulling on the other end would result in tightening the measuring tape around the arm and the circumference could be read on the measuring tape at the point where the tape would overlap (see figure 5.3 and figure 5.4).

Figure 5.3: Prototype with loose measuring tape.

Figure 5.4: Prototype where the top 3 measuring tapes are tightened.

Now a way of fixating the measured length needed to be though of. Multiple options were explored. Since the start of the measuring tape is made out of an metal, a magnet was used to put on the measuring tape. Although the magnet did stick at first, when loosening the sleeve to take it off, the magnet would fall off and the measuring was lost. A second iteration was done by sticking magnetic tape to the underside of the measuring tape, but this compromised the flexibility of the measuring tape and therefor was not a good solution. The best solution turned out to be a simple paperclip that can be moved to the desired place. The paperclip placement can be seen in figure 5.5.

Figure 5.5: Paperclip on the measuring tape.

5.3.3 Marker placement

The next problem that needed to be solved was to find a way to make sure that the paperclip was placed at the right spot and that the right measurement will be read. The first thing was solved by placing an arrow on the sleeve itself at the starting point of the measuring tape and also placing an arrow on the paperclip. The right measurement is taken when these arrows line up. This can be seen in figure 5.6. The marker on the sleeve was place in such a way that, when the markers would align, the measurement could be read above the arrow. This needed to be indicated to minimise the chance of reading the wrong measurement. A white line was drawn at the side of the arrow on the measuring tape. Next to that an arrow was drawn that pointed at the side where the reading needs to be taken. This can be seen in figure 5.7.

Figure 5.6: Marker placement on paperclip.

Figure 5.7: Indication for right measurement reading.

5.3.4 Tightening indicators

When testing another inconvenience was encountered. It was not clear where to pull to tighten and loosen the measuring tape. Some indication needed to be added to solve this inconvenience. Where to pull to tighten was already more clear but for continuity also this was indicated. A label was stick at the end of the measuring tape that said ”vast ->”, this indicated what way to pull to tighten the measuring tape. Since the place on the measuring tape to loosen would vary per user, this indicator was placed on the sleeve itself. A label with the text ”<- los” was placed at the end where the user would need to tug. The placement of these labels can be seen in figure 5.8.

Figure 5.8: Labels for loosening and tightening the measuring tape.

5.3.5 Online platform

Due to time constraints, no online platform was developed. There are however, already simple excel sheets available to turn the circumference measurements into a volume [22], but these do not indicate if the patient needs to contact the specialist. They do also not take the amount of local swelling into account, they only look at the total volume change. There are also some solutions to the tracking of the measurements and the integration of sharing the results with the specialist. Vivica is one of them [25]. They have a platform to enter your health data and communicate with the specialist. To incorporate the function to calculate the volume of the arm, the function of the excel sheet can be integrated in such a system like Vivica.

6 REALISATION

In this chapter the realisation of the final concept is described. First a list with the used materials is given. Next the construction of the product is described from the start, the plain fabric, to the end product. Lastly the use of the final prototype is explained. This is done through the use of a scenario to illustrate how the product can be implemented into the real world.

6.1 Materials

In this section the materials used to make the product will be listed.

Stretch fabric: To make sure the sleeve ”grows” with the circumference of the arm, stretch fabric is used. A soft and very stretchy fabric would be suitable as a basis for the sleeve.

Thread: Black thread is used to construct the sleeve

Measuring tape: Five measuring tapes were used to implement the measuring function

Paperclip: Five normal paperclips are used as set-point for the measured length

Paper: Black paper is used to make the markers. Ten arrows are cut from it.

White marker: A white marker is used to indicate the places where the measurements can be read. The marker is white so it was clearly visible on the black paper of the markers.

6.2 Construction

The fabric was cut to shape. A sleeve of a large sized shirt was used as a template and the seam allowance was added to the shape before cutting it out. This size was chosen to make sure that a variety of people was able to use the prototype. In production it would be better to make different sizes to accompany the different sizes of the patients.
The tunnels for the measuring tape were cut to be 1.5 cm wider than the measuring tape itself, to allow room for easy adjustment of the tightness. These tunnels were sown on the piece of fabric for the sleeve. They were spaced with an interval of 10 cm, starting at the wrist and stopping at the top of the upper arm. This was chosen over 4 or 5 cm intervals since it has been shown that 10 cm intervals provide comparable estimates of the limb volume compared to 4 or 5 cm intervals, but fewer intervals leads to less time per full measurement [4]. The measuring tape is guided through the tunnel of fabric twice. So the measuring tape goes once through the tunnel to make the tape go around the whole arm and then the tape goes through again to make sure that the measuring tape can be tightened by pulling at the loose end. The start of the measuring tape is secured to the sleeve by needle and thread in a way that it lines up with the seam in the sleeve. The seam acts as a guideline for the start of the tape. These steps are repeated with all 5 measuring tapes. Next, the excess op the tapes is cut off. In the prototype there is a bigger remainder to accommodate a diverse group of testers, but in the real product this can be cut to fit the patient.

Lastly the mechanism to set the measurement needs to be constructed. For this a paperclip is placed on the measuring tape. To make sure that it does not slip off, the front of the paperclip is tied to the back with a piece of string (see figure 6.1). For better grip of the paperclip, to move it to the right spot, a piece of tape was added to the end to elongate the grip(see figure 6.2). Next, a piece of black paper in the form of an arrow is stuck to the top of the paperclip. On this arrow a white line and arrow were drawn on the side closes to the start of the measuring tape. Then the paperclip was placed so the marked side of the arrow would align with the start of the measuring tape. Now the paperclip is placed correctly to read the measurement, so at this position, the arrows should align. Therefore the second paper arrow is now places across the paper arrow on the paperclip and the points of the arrows are aligned. The final touch is done by adding the labels ”vast ->” and ”<- los” at the right spot, at the end of the measuring tape and on the tunnel for the measuring tape closest to the start of the measuring tape respectively. The complete prototype can be seen in figure 6.3

Figure 6.1: Attachment of paperclip to measuring tape.

Figure 6.2: Complete attachment of the paperclip to the measuring tape.

Figure 6.3: The complete prototype.

6.3 Use of final prototype

In this section the scenario is explained and a walk through of the use of the product will we done. This scenario is summarized in the diagram in the sequence diagram in figure 6.4.

6.3.1 Scenario

When a patient is treated for cancer, this person will see their oncologist for regular check ups. This doctor will tell the patient that it is important to monitor for Lymphedema since it is a common effect of cancer treatment. The doctor will then show them the sleeve and tell them that they will need to monitor this them self. The doctor will tell them that they need to measure every week on the same day and at about the same time every time to minimize fluctuations in the measurements and ensure correct tracking over time. The doctor will show them how to use the sleeve and do the first base line measurement together with the patient. The patient will loosen the measuring tapes in the sleeve. Next they will put on the sleeve on one of their arms. Then they will slowly pull on the lose ends one at a time, to close the loops of measuring tape around their arm. When the measuring tapes are tightened, but without putting a lot of force on the loose ends, the paperclips can be moved. The arrow on the paperclip should line up with the arrow on the sleeve to ensure a correct measurement. Then the sleeve can be removed. This will be done by loosening the measuring tapes, but making sure that the paperclips do not move. When all the measuring tapes are loosened, the sleeve can be removed from the arm and the measurements can be read on the measuring tape at the highlighted spot, above the white line. These measurements need to be written down, preferably on an online platform, mentioning if these are the measurements of the affected side or the non affected side. If the measurement are uploaded to an online platform, the doctor can also monitor the measurements and calculations can be done about the volume of the arm. Now, the other arm needs to be measured the same way as the first one and these measurement also need to be written down. Also here it is important to clearly mention if the measurements are done on the affected or non affected arm.

6.3.2 Risk criteria

The next step is preferably done through the online platform, since the comparison can be difficult. There are three possible ways how measurements can be classified as abnormal[4]. First every measurement on the affected arm needs to be compared to its accompanying measurement of the non affected arm. If there is a difference of 2 or more cm, the measurement is classified as abnormal and it should be checked by a qualified doctor or therapist. The second way is if the sum of differences is more than 5 cm, also in this case, a doctor needs to take a look at it. Lastly if the measurements of two adjacent points on one arm have a difference of 2 cm or more, the measurement is again classified as abnormal and a doctor or therapist needs to take a look at it. Another method is to calculate the volume of the arm, using the truncated cone volume and take the difference between both arm in a percentage. An increase of 10% in arm volume is seen as a indicator of abnormal swelling [26]. These comparisons can be done by the patient but they are prone to error, therefore an online platform or tool is preferred.

6.3.3 Sequence diagram

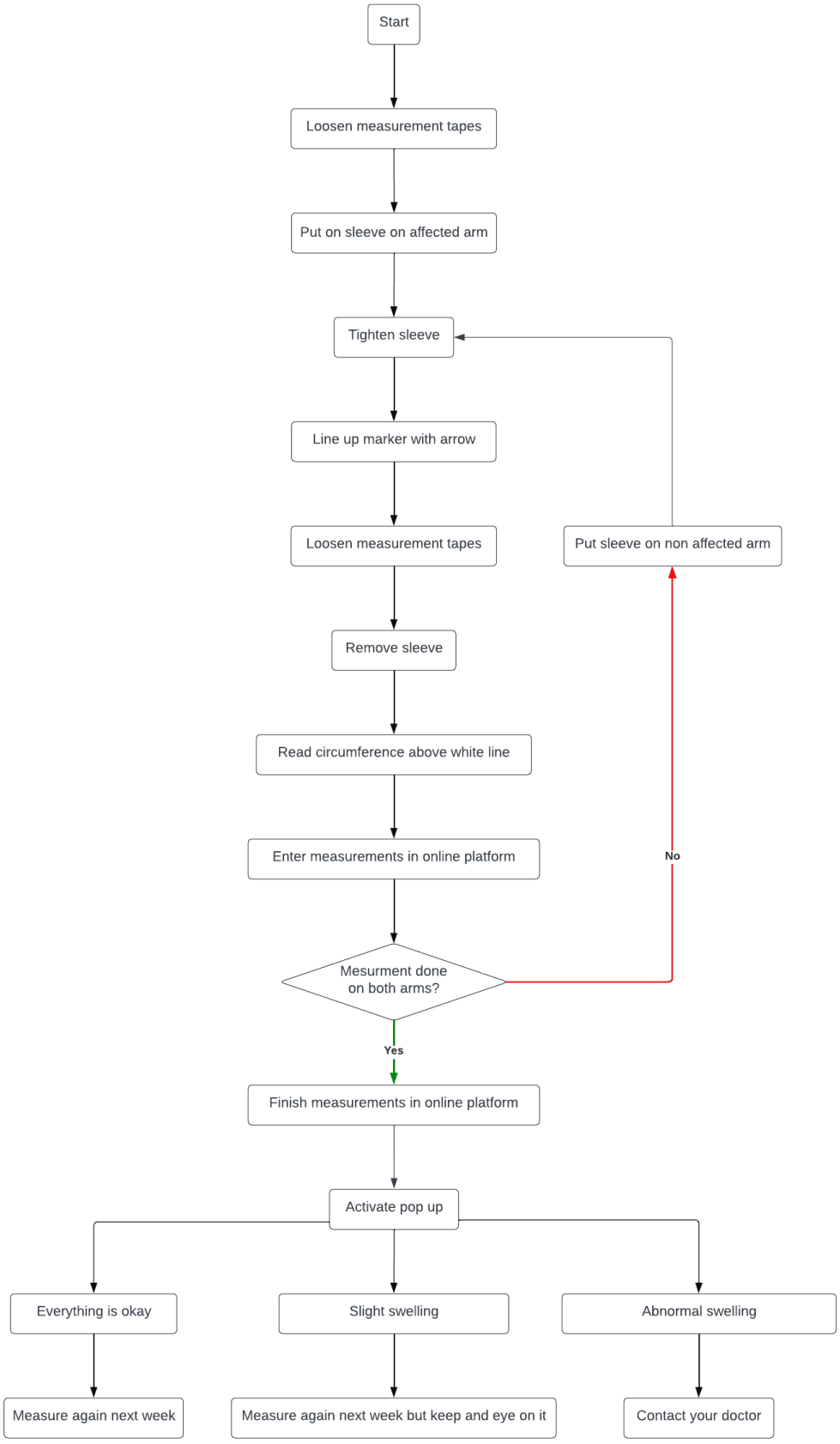

Figure 6.4: Sequence diagram of the use of the monitoring tool.

7 EVALUATION

With the final prototype, an user evaluation is performed to see if the requirements set in chapter 5 are met. First the focus of this evaluation is made clear. A recap of the goals of this research is done and focus points for the user evaluation are formed. Next, for each of the focus points a description is made how these focus points will be evaluated. Lastly the results of the user evaluation described.

7.1 Evaluation focus

Before focus points are formed, it is important to look at the goal of the whole research. The research question of this research was: ”How can you design an reliable, patient friendly and low-cost self-monitoring tool to monitor lymphedema after cancer?”. So, with the user evaluation should check if the tool is patient friendly and to what extend people think the product is comfortable to use. Next to that it needs to check if the tool is easy and quick to learn and the length it takes to do a measurement needs to be checked. This is all needed to check that the tool is indeed patient friendly. To check if it suffices the self-monitoring part, tests need to be done to confirm if the tool can be used, using one hand. And lastly the evaluation should contain a test to check the reliability of the tool. To give a clear overview, the focus point are listed below:

1. To what extend is the tool patient friendly and comfortable to use?
2. Is the tool easy and quick to learn?
3. How long does it take to do a measurement?
4. Is it possible to do a measurement as a solo user?
5. Does the tool give reliable measurements?

7.2 Evaluation approach and methods

Every focus point needs to be addressed in the evaluation, therefore for every focus point the approach needs to be described. Since some focus point can be addressed in the same tests, first the recruitment process will be described. Next, the tests itself will be described and then the focus point that are addressed by that test are matched.

7.2.1 Recruitment process

For the first phase eight participant were recruited. These participants were selected to be above eighteen years old, healthy and fluent in English or Dutch. Any participant with an impairment on one of their arms or a mental impairment was excluded from the research. The recruitment took place through the network of the researcher.

For the second phase one participant with Lymphedema in one of their arms was recruited. This participant was selected to be above eighteen years old. This participant was recruited through the network of a physiotherapist specialised in the treatment of Lymphedema. Unfortunately this participant was not fluent in English or Dutch but the physiotherapist acted as an interpreter.

7.2.2 User tests

The user tests are split into two phases. The first phase will be done with eight healthy participants. The second phase will be done with a Lymphedema patient. **here will come a better intro**

First phase: healthy participants

The first test that will be done is the usability test with eight healthy participants. This includes a test to measure the time it takes the participant to do the measurement with the prototype, the feasibility of executing the self-measurement with one hand as a solo user and the reliability. This phase will end with an interview to collect the opinions about the user experience. First the participant will be handed over the information brochure and the informed consent will be started. A verbal explanation about the research is given next to the information brochure. After consent, the setting wherein the prototype is meant to use is explained. Next to that the use of the prototype is explained. This explanation will only consist of the basics, what is expected to be told by the doctor in a real case. They will be asked to measure their arm with the prototype and pay attention to their experience with the prototype. The time it takes to complete the measurement will be measured and with this focus point 3 will be addressed. During the interaction with the prototype, the participant was observed how they were using the prototype. At the end of the measurement with the prototype, the circumference of their arm will be measured using a measuring tape. These measurements will be compared to each other and the difference will be calculated. This difference is then compared to the difference of the other participants. This is used to address focus point 5. Then, they will be asked to answer the questions of the System Usability Scale (SUS) [20], which can be found in appendix C. Next a few questions are asked to explain their experience with the prototype. These question can be found in appendix B. They will also be asked about their opinion of the difficulty of using the prototype. Next to that they will be asked if they would change things and why. With this information, focus point 1,2 and 4 are addressed.

Second phase: Lymphedema patient

The third test will be done with a participant that is diagnosed with lymphedema on only one of their arms. Here the reliability will be measured again, but this time there will not be a comparison between participants but an inter-limb difference is taken. This means that the circumference of the affected arm will be compared to the non-affected side. Also in this test the circumference is measured again using a measuring tape to verify the measurements done with the prototype. This test will also end with an set of questions like in test one. This is to ensure that the experience is still sufficient with a more swollen arm.

7.3 Results of evaluation

To start off, the measured results will be discussed. This includes the time measurements, the SUS-score and the measured circumference and calculated volume of the arm. Next, the observations during the user tests are discussed and the findings are explained. Lastly, an overview is given of the requirements and which requirements were met.

7.3.1 Time measurements

During the user tests in the first phase, the time it took to do a measurement of one arm with the developed tool was noted. The times of 8 participants were recorded. The time was started when the participant picked up the sleeve and the time was stopped when the last circumference measurement was written down. The times are written down in table 7.1.
As can be seen in figure 7.1, the average time of a measurement is 4 minutes and 8 seconds. Since the margin set in chapter 5 was for a full measurement, so two arms, the time needs to be doubled to include the measuring of both arms. So the average time for a full measurement is 8 minutes and 16 seconds. This is well within the margin for 20 minutes. The fastest time was 3 minutes and 10 seconds and the slowest time was 6 minutes and 11 second, so almost doubled. Although this might seem like a big variation in time, this is still all within the margin of 20 minutes. Since this time was also for one arm, we can double the time to get the time for a full measurement. The slowest time for a full measurement will then be 12 minutes and 22 second, which is still within the margin of 20 minutes.

Participant	Time (mm:ss)
1	04:00
2	03:14
3	03:36
4	03:10
5	04:29
6	04:53
7	06:11
8	03:31

Table 7.1: Time it took to measure one arm. Time started at the moment the sleeve was picked up. Time stopped at the moment the last circumference value was written down.

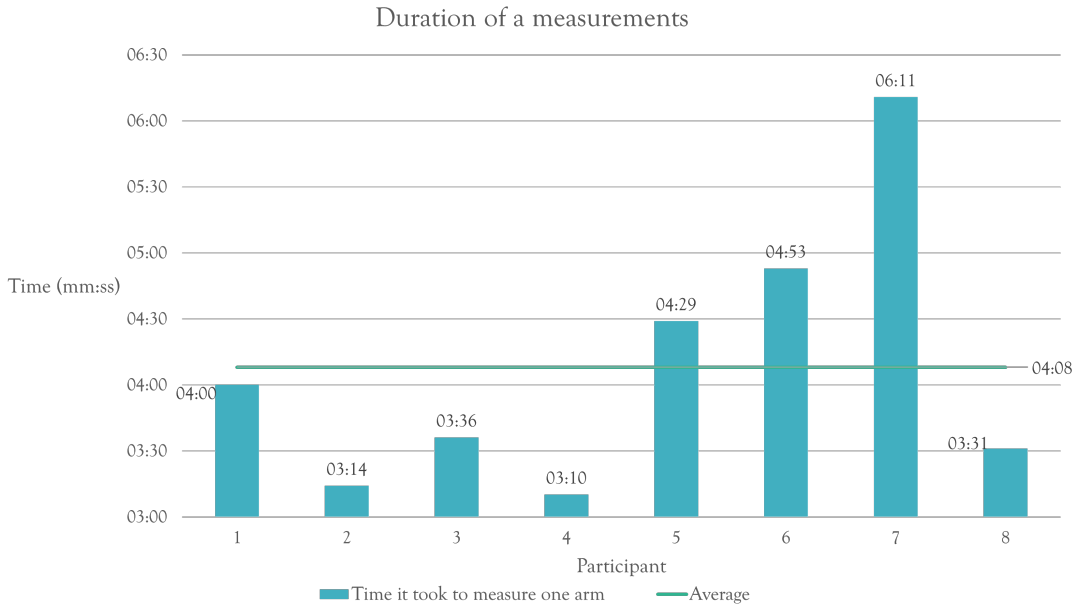

Figure 7.1: Graph of the time it took to do one measurement on one arm and the average time (green line).

7.3.2 SUS

At the end of the measuring time, the 8 participants in the first round were asked to fill in the System Usability Scale questionnaire (see appendix C). Since this questionnaire is not specifically made for product testing but rather for website testing, participants 2 to 8 were asked to interpret the questions to best fit the situation. They were asked to imaging the use of the product as if they were a patient themselves. Before participant 1 filled in the questionnaire this comment was not made and this resulted in some confusion.
The results can be seen in table 7.2. The score is calculated the following way: for questions 1,3,5,7 and 9 it is the assigned score (1-5) minus 1. For questions 2,4,6,8 and 10 it is 5 minus the assigned score. All these scores are added and then multiplied with 2.5.
All participants thought that they did not need the support of a technical person to use the tool, as became clear from the answers to question 4. Also question 7 is almost answered unanimously, therefore it can be said that the participants thought that most people would learn to use the tool very quickly. To visualize the results a graph was made, as can be seen in figure 7.2. Here it can be clearly seen that the first participant scored significantly lower than the average of 78.75. This might be explained by the confusion about the questionnaire.

Participant	q1	q2	q3	q4	q5	q6	q7	q8	q9	q10	SUS-Score
1	1	4	2	1	2	3	3	4	3	2	42.5
2	4	1	4	1	4	2	5	2	5	2	85
3	4	2	3	1	5	2	5	2	3	1	80
4	4	2	5	1	4	2	5	1	5	1	90
5	4	1	4	1	5	1	5	2	4	1	90
6	5	1	5	1	4	3	5	1	4	1	90
7	4	2	4	1	4	1	5	3	4	3	77.5
8	5	2	4	1	4	3	5	1	1	2	75

Table 7.2: SUS-score per participant.

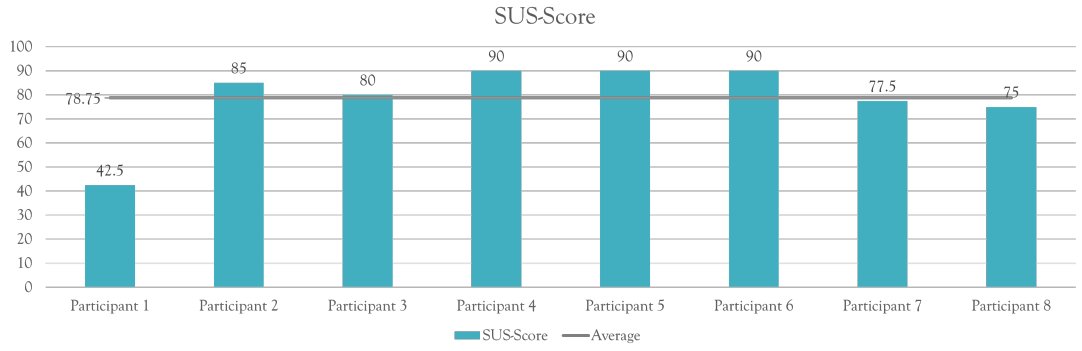

Figure 7.2: Graph of the SUS-score and the average (grey line).

Part of the SUS-score is the placement on the scale. The scale is divided into sections. These sections include two forms of interpretation. One is split in three sections and indicates if the score is acceptable or not acceptable or just marginal. The other interpretation splits the scale into 6 parts to specify the score even more. This scale with its interpretation can be seen in figure 7.2. As can be seen the average falls into the acceptable region and it can be said that the system usability of the developed tool is good.

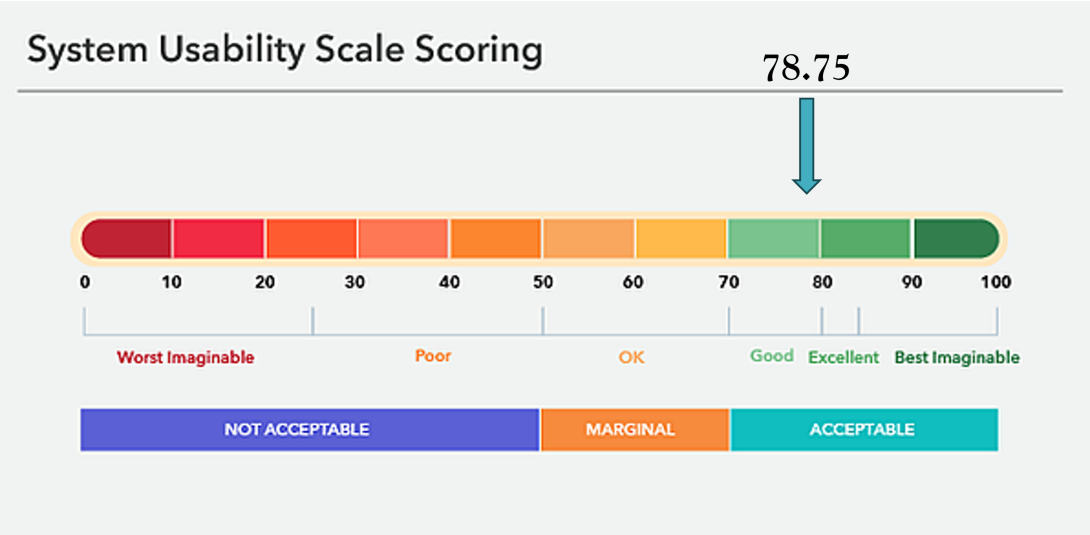

Figure 7.3: SUS scale and the location of the average of 78.75 on the scale.

7.3.3 Volume calculations

The circumference of the arm is measured of 9 participants, whereof 8 in the first round. These 8 have only done measurements on one of their arms. Participant 9 (patient participant) did measure it on both arms. These measurements were done to test the reliability of the developed tool. The full measurements can be seen in appendix D. To convert these circumference measurements into a volume measurement, some calculations are needed. The truncated cone model is used for this, figure 7.4 shows an example of an truncated cone.

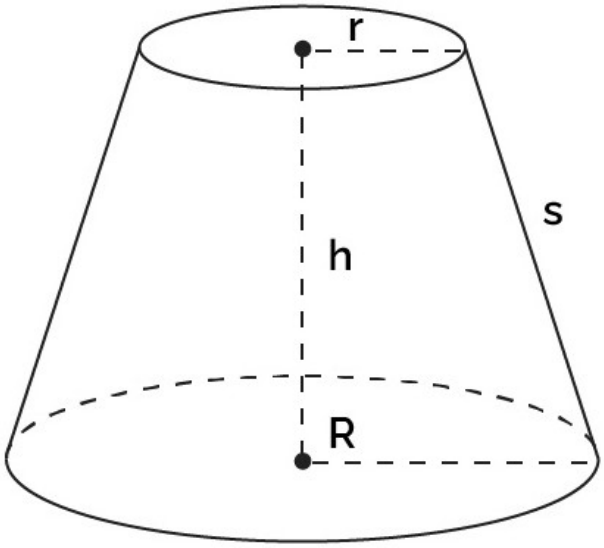

Figure 7.4: Truncated cone with R being the bigger radius, r the smaller radius, h the height perpendicular to the surface of the circles and s the slanted height.

Formula 7.1 is the formula for calculating the volume of a truncated cone. Where V is the volume of the truncated cone, h is the height of the cone perpendicular to the surface of the circle, r is the smaller radius and R is the bigger radius.

$$V = \frac{1}{3} * \pi * h * (r^2 + r * R + R^2) \tag{7.1}$$

The measuring tapes were spaced 10 cm apart. This is however not the height, but the slanted height s. To convert the slanted height to the height of the cone formula 7.2 is used. This formula is based on Pythagoras' theorem.

$$h = \sqrt{s^2 - (R - r)^2} \tag{7.2}$$

To complete the calculations, the circumference needs to be converted into a radius. This can be done using formula 7.3. Where r is the radius and c the circumference. This formula can be used for both r and R in formula 7.1 and 7.2 with c and C respectively.

$$r = \frac{c}{2\pi} \tag{7.3}$$

These calculations are done for all the participants for both the measurement with the tool and with the tape and the results can be seen in table 7.3. It was expected that the volume measured with the tool would be greater than the volume measured with the measuring tape, therefore the difference in volume is calculated by subtracting the measuring tape volume from the tool volume. The variety of volume differences is broad. One of them even found a smaller volume with the tool than with the measuring tape, which is in contrast with the expectations. This variety might be explained by the differences in tightness of the tool between the participants. These observations will be elaborated on in the next section. But for now we can say that there is no clear conclusion about the reliability of the developed tool.

Participant	Volume measured with developed tool(L)	Volume measured with measuring tape(L)	Volume difference(L)
1	2.14	2.06	0.08
2	2.34	2.20	0.14
3	2.16	2.06	0.10
4	2.01	1.95	0.06
5	2.23	2.18	0.05
6	2.37	2.51	-0.14
7	2.40	2.17	0.23
8	2.18	1.92	0.26
patient participant left arm	2.02	1.75	0.27
patient participant right arm	1.95	1.71	0.24

Table 7.3: The calculated volume of the measurements done with the developed tool and with the measuring tape. And the volume difference of these two measuring methods.

7.3.4 Observations

During the user test the participants were also observed while they were doing the measurement. During the explanation of the use of tool they were asked if they had any questions about the use. If it was clear for them they could start the test. If any questions came up during the testing, they were allowed to ask questions but they were encouraged to try to figure it out themselves to mimic the at home setting without an expert next to them. Most participants worked it out themselves, 2 participants asked one question and after that was answered they could continue. Overall the participants were able to figure out how it worked although they were a bit insecure sometimes.
A second observation was that there was a lot of variation in how tight the participants would set the measuring tapes. Some could pull it completely tight without any troubles and some pulled on the tape and it would not move smoothly. This might be a result of the friction between the two layers of measuring tape inside the tube of fabric. Another explanation might be that

not all participants pulled the tape in the same direction. The participants that pulled the tape along the curve of the arm had clearly less trouble with the friction than the participants that pulled straight down. These differences in tightness of the tool also resulted in differences in the volume difference between the tool and the tape measurement. The tape measurement was done by the researcher and was tried to be the same tension everytime. This results in less room for variation in the tape measurements. This might explain the inconclusiveness of the test results for the reliability.
Lastly, most participants were surprised by the simplicity of the developed tool. They thought it looked more complex than the measurement in fact was. They also mentioned that it was quick to learn, especially when it would be used often. Another positive thing was the portability. They could imagine that people would want to take it with them if they would need to measure every week and they though it was easy to put in your bag. But also at home it would be easily stored away. An improvement that was mentioned was the use of multiple sizes. At this moment the prototype was made in one size and would not accommodate everyone. One participant mentioned using sizing like in clothes to make sure that there is a fit for everyone.
Overall the tool was well received by the participants and they could imagine using it if they would need to do so. The overall opinion was that after some practice it would be really fast to use and they would be confident in doing so.

7.3.5 conclusion

The previously mentioned results can be used to evaluate the implementation of the requirements set in the specification phase (see chapter 5). Table 7.4 gives an overview whether the requirements were met.

Requirement	Priority	Requirement met?
Give reliable measurements	Must have	Inconclusive
Comfortable to use	Must have	Yes
Made out of inexpensive materials	Must have	Yes
Usable with one hand	Must have	Yes
Easy and quick to learn	Should have	Yes
Portable size	Should have	Yes
Measurement is doable within 20 min	Should have	Yes
Measurements can be saved in an online platform	Could have	No
Calculating tool to transform circumference measurements	Could have	No
Usable by every person	Won't have	No

Table 7.4: Evaluation of implementation of the set requirements.

8 DISCUSSION & FUTURE WORK

During the developing process it turned out that the developed tool seems to be a promising concept, however, strengths and limitations were identified during the process. In this chapter these will be discussed. First a brief summary of the results is given, then the strengths and limitations of this research will be reviewed, lastly recommendations for future work are given.

8.1 Summary of the findings

The goal of this project was to design a reliable, patient friendly and inexpensive self-monitoring tool to monitoring lymphedema after cancer. As more people are at risk of getting Lymphedema due to cancer treatment, it is of increasing importance that early detection methods are developed.
The literature revealed that frequent measuring is needed to enable early detection. However, currently there are no suitable tools on the market yet. This is because of the high costs of used sensors and the complexity of available methods.
The creative technology design process described by Mader and Eggink [18] was applied to design and evaluate this at home monitoring tool. In the ideation phase the user was analysed and an expert was interviewed. This resulted in a list of seven preliminary requirements and a first concept. After specifications of these requirements and prioritising them, an ordered list of requirements was available. With this list iterations on the product were made and final concept in the form of a sleeve with measuring tapes was made.
In the realisation phase the final prototype was constructed that could be used in the evaluation phase. In this last phase the prototype was evaluated with eight healthy participants and one lymphedema patient. The evaluation focused on usability, reliability and speed of measurements. The evaluation showed that the participants thought the prototype had a good usability and it was quick to use, which can be seen in the average SUS-score of 78,75 and time of use of 8 minutes and 16 seconds. While there were still some improvements and recommendations, the prototype was experienced as simple and after some practice as easy to use.

8.2 Strengths and limitations

Nevertheless, the conducted research does come with its limitations, but there are also strengths. These strengths and limitations will be described in two parts, the process and the prototype.

8.2.1 Process

There was a narrow ideation focus. In the ideation phase there was only one concept developed and this was taken to the specification. When there is a too narrow focus on a concept, this may limit creativity. A result might be that alternative solutions that could be more effective are overlooked.

During the evaluation, user tests were done. During these tests, no demographic information was asked. If this information, like age, would have been asked, it might have given some insight about the differences in preferences of the different age groups.
Another aspect of the user tests that could have been improved was the way the reliability was checked. Now, the measurement of the participant with the tool was compared with the measurements of the researcher with the measuring tape. The results of this comparison, the volume difference, was then compared between subjects. But, because there was a too big variability in the measurements done by the participants, this gave no good results about the reliability. In a real life case the measurements of the same patient need to be reliable so a test within subject would have been better. A comment can be made about the reliability of the testing with the patient participant. Here, both arms were measured and therefore the comparison between the volume differences can be done within subject. But, because this was only one participant, no conclusions can be drawn.
A last limitation of the process was the fact that the existing questions for the System Usability Scale, do not all suit the application in user testing with a product. For example, the first question of the SUS is : ”I think that I would like to use this system frequently”. This question was a bit strange in the context of the project, since the tool is not intended to be a ”fun” thing to use but rather practical. It would have been better if these questions would have been reviewed before they were used in the user testing.
Although there were some limitations, there were also some strengths. One of the strengths was the fact that a clear decision was made about the scope of the research. From the beginning it was clear that it was not feasible to include every possible patient, therefore the choice was made to exclude the requirement that it needed to be usable by everyone.
Next, a decision was made about the evaluation. The main testing would be done with only healthy participant due to ethical reasons. Next to that, it was easier to gather healthy participants then patients who recovered from breast cancer and were at risk of Lymphedema. The results would not be influenced due to this choice since the capabilities of healthy people would be the same as those of cancer survivors. Therefore this can be seen as a strength since this ensure a bigger sample size for the user tests.

8.2.2 Prototype

Also the prototype had its limitations and its strengths.The biggest limitation had to do with the friction of the measuring tape on itself. As already explained in section 7.3.4, there was friction between the two layers of measuring tape in the tube of fabric. Because of this friction some participants were not able to pull the measuring tape as tight as they would have liked. The result of this was that the reliability could not be tested this way. This limited the outcomes of the research.
Although the next limitation did not directly limited the research, it is still something that should be mentioned. While the prototype did fit all the participants, the sizing could have been a problem. The prototype was made in one size that would accommodate most average sized participants. This did however exclude people that would fall outside of this category to be a participant. Using different sizes for the sleeve might give valuable insights.
On the other hand there were also some strengths that are worth mentioning. Although the prototype was made in one size, scaling it to multiple sizes can be an easy process. Only the sleeve itself needs to be made bigger and the measuring tapes can be kept longer. Fortunately all the other aspects stay the same.
Another strength is the fact that the reading of the measurement does not need to happen while the tool is still worn. The user can set the measuring while wearing the tool, but when that is done the tool can be taken off and the measurements can be read while the sleeve lies in front of them. This makes it easy to read and the user does not need to move in uncomfortable

positions to read the measurements.
Lastly, the costs of the materials for the tool were taken in consideration along the whole design process. A clear decision was made to not use any sensors to keep the costs low and to make sure that delay of production due to chip shortage is avoided. If the costs are low, the point at which this solution becomes economically viable will arrive earlier.

8.3 Recommendations

In this section recommendations for future research are described. These recommendations are based on the use evaluation and the limitations that are discussed.
First and foremost, this research would benefit from more user testing. The main point of improvement is the form of reliability testing. It would be best to test the reliability within subject. A participant can be asked to test both arms multiple times to check if the outcomes are reliable. Another point of improvement is recording the age of the participant. When the age of participants is asked, a conclusion can be drawn if there is any difference between age groups and if an adaptation of the monitoring tool is needed to accommodate to these differences. A third point where improvement is possible, is in the way the usability is tested. Although a conclusion could be drawn, it is best to have a better understanding of the questions asked within the System Usability Scale and it might be better to change them to better fit the application within product testing. A last improvement regarding the user testing is to test over a longer period. In this research the participants only used the tool once. Their opinion about the tool might change if they would have to use the tool every week for and extended period. Also their measurements might change because they will have had more practice in using the tool. Therefore it is recommended to test the tool for a longer period, like 2 months.
Next it is recommended to apply improvements to the prototype. If this product were to be developed further, it is recommended to look in to different sizing options. It might also be interesting to research if this tool can be tailor-made and if this is still low-cost enough to be produced. Also the way the measurements are set, now still with a paperclip, can be greatly improved. The paperclip is not secure enough to avoid shifting during the process of taking off the sleeve, unless being very careful. For this research it did suffice since this was mentioned to the participants, but for frequently use this would not be the case. Lastly, the friction between the two layers of measuring tape influenced the measurements. This should be resolved in future research. A solution might be to cut a slit at the beginning of the fabric tunnel, so the top layer of measuring tape can leave the fabric tunnel and avoid the friction at all. This should be tested however, since the friction also made sure that the measuring tape would stay tight after pulling. So a balance needs to be found between friction, that is sufficient to keep the measuring tape in place, but limited enough to not obstruct the tightening process.
Lastly, the production of the product is a big aspect of realizing the at home monitoring of Lymphedema. Therefore it is advised to research the possibilities and constraints of producing this tool. When research is done in the production, new iterations on the prototype can be made to accommodate for the changes needed to produce the tool on a bigger scale.

9 CONCLUSION

This research aimed to answer the following research question:

How can you design an reliable, patient friendly and low-cost self-monitoring tool to monitor lymphedema after cancer?

First a literature review was conducted. Existing monitoring and measuring methods were analysed. Multiple methods that could be adapted to use in a remote setting were found. From the expert interview it became clear that a method that also measures locally would be the best to detect local swelling. Next to that the PACA analysis revealed that it is important to consider low-cost options, this resulted in the choice to implement the circumference measurement in to a tool for at home monitoring.
Based on the requirements from the specification phase, a product was developed. The usability, reliability and the speed of this product was evaluated with the use of user tests. This led to overall positive responses about the usability and speed of the tool. However, the wrong choice was made about the method to test the reliability. So to answer the research question, a self-monitoring tool to monitor lymphedema after cancer should implement inexpensive and easy accessible materials. Furthermore, it should be comfortable to use and should be usable with one hand. Additionally, the outcomes of the measurements need to be reliable. This, except the reliability, is implemented in the developed monitoring tool and it is checked by means of user tests. So, to conclude, the product has potential to be a great contribution to the monitoring of Lymphedema at home. Due to the low-costs, it can be a great solution to an economically viable tool. But, more research is needed to further improve the product and discover all of its possibilities. The most relevant next step would be to conduct more user testing with a focus on testing the reliability and research the possibilities of different sizes.

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A EXPERT INTERVIEW

The person that was interviewed was dutch, therefore the original questions are in Dutch. An translation of the questions and the answers is given below.

A.1 Questions(Dutch)

1. Wat zijn volgens u belangrijke kenmerken van Lymfoedeem?

   1.1 In hoeverre denkt u dat deze meetbaar zijn? Waarom?

   1.2 In hoeverre denkt u dat deze thuis meetbaar zijn? Waarom?

2. Stel, er wordt een ”meetinstrument” ontwikkeld om thuis deze kenmerken te meten. Zou u dit uw patienten aanraden om te gebruiken? Waarom wel/niet?

   2.1 Puur clinisch, waaraan moet dit meetinstrument voldoen om betrouwbaar te zijn?

   2.2 Hoe vaak zou dit gemeten moeten worden?

   2.3 Zijn er nog andere dingen die u kwijt wilt met betrekking tot dit meetinstrument?

A.2 Answers(Dutch)

1. Hetgeen dat het meeste opvalt is het zwellen van de arm. Dit gebeurd niet altijd over de hele arm maar soms ook op een specifieke plek. Er is dus een toename van het volume van de arm. Een ander kenmerk is dat de textuur van de huid kan gaan veranderen, dit gebeurd niet in elk geval even sterk en is dus iets lastiger als duidelijk kenmerk te nemen.

   1.1 De toename in volume is op meerdere manieren te meten. Je kan het opmeten met een meetlint op meerdere plekken in het aangedane gebied. Bij een arm kan je dit bijvoorbeeld op 10 plekken doen, anderen meten het op 5 plekken. Hier is niet echt een eenduidig protocol voor. Met deze metingen kan je dan het volume uitrekenen, maar je kan ook per plek specifiek zijn of daar zwelling is ontstaan.

   Een andere manier is in een waterbak, hiermee kan je de waterverplaatsing gebruiken om het volume te meten. Het nadeel is wel dat dit dus alleen een totaal volume geeft en niet kan meten of er een specieke plek er bovenuit steekt qua zwelling.

   1.2 Beide zijn opzich wel thuis meetbaar maar beide zullen hun eigen complicaties hebben. Ik denk dat bij beide het lastig is om tegelijkertijd je eigen arm te meten en af te lezen. Bij de waterbak kan je dan verschuiven en dan meet je mogelijk net meer of minder ver op de arm. En het lijkt me ook geen comfortable positie. Met een meetlint is het lastig om dit elke keer precies op dezelfde plek te meten en om dit met een hand te doen als je je eigen arm meet.

   Ik denk dus dat ze op het moment wel thuis te gebruiken zijn maar wel altijd met iemand anders erbij en er is wellicht wat training voor nodig. Ik ben nu vooral bang dat de patient niet de expertise heeft om elke keer een juiste meting uit te voeren

en dan krijg je misschien te veel diversiteit in de metingen om het daadwerkelijk te kunnen gebruiken.

2. Dat ligt er heel erg aan hoe dit in zijn werk gaat. Het zou erg fijn zijn als mensen thuis de meting kunnen doen want dan kan er ten eerste vaker een meting worden gedaan en ten tweede hoeven ze dan niet naar het ziekenhuis te komen voor een meting. Maar het is wel belangrijk dat variatie in de metingen zo veel mogelijk wordt beperkt. Als je gaat kijken naar de metingen met een meetlint, dan is het voor een therapeut af en toe al lastig om altijd op dezelfde plek en even strak te meten. Ik kan me voorstellen dat dit voor een patient alleen nog maar lastiger is en dit kan de hele meting juist sterk beinvloeden. Als dit allemaal goed doordacht is zou ik zeker achter zoiets staan!

    2.1 De meting moet elke keer ”hetzelfde” gedaan worden. Wat ik hier mee bedoel is dat het niet uitmaakt of wat je meet het daadwerkelijke volume is of omtrek, maar het verschil tussen de werkelijke waarde en de gemeten waarde moet wel altijd hetzelfde zijn. Uiteindelijk kijk je naar een verschil tussen links en rechts. Het is zeg maar zo: als ik een omtrek van 37 en 39 meet op een plek met dit instrument maar het is daadwerkelijk 32 en 34, dan is het verschil tussen die twee in beide gevallen 2 en dat is wat ik wil weten. Verder moet het niet iets zijn dat de omtrek zou kunnen verkleinen, vooral omdat het weefsel van een arm met Lymfoedeem anders reageert op druk dan een arm zonder Lymfoedeem. Het moet dus niet een steunkous achtig iets zijn dat strak zit.

    2.2 Zeker in het begin na een opertatie zou ik zeggen dat er toch wel wekelijks gemeten moet worden. Naar mate je verder van de operatie af komt zou je dit minder vaak kunnen doen maar minimaal 1 keer per maand.

    2.3 Het is ook wel handig om dan rekening te houden met hoe deze metingen worden bijgehouden. Als dit apparaat niet automatisch aangeeft of er sprake is van mogelijk Lymfoedeem, dan moet de patient dit zelf doen. Hier kunnen ingewikkelde berekeningen aan vast zitten, afhankelijk van hoe dit gemeten wordt natuurlijk. Het zou nog fijner zijn als het ergens online kan komen zodat de arts of therapeut dit ook kan monitoren en als het nodig is aan de bel kan trekken.

    Daarnaast spreekt het denk ik wel voor zich dat het beter is als het een non-invasief meetinstrument wordt, zeker als mensen het thuis moeten gaan gebruiken. Dit kan een hoop complicaties voorkomen, denk ik.

A.3 Questions(English)

1. What are important characteristics of Lymphedema?

    1.1 To what extend do you think these can be measured? Why?

    1.2 To what extend do you think these can be measured at home? Why?

2. Suppose a measuring intrument is developed to measure these characteristics at home. Would you recommend the use of this instrument to your patients? Why yes/no?

    2.1 Looking at the clinical aspects, what requirements must this instrument meet to be reliable?

    2.2 How often should a measurement be done?

    2.3 Are there any other things you would like to say regarding this measuring instrument?

A.4 Answers(English)

1. The thing that stands out most is the swelling of the arm. This does not always happen over the entire arm, but sometimes in a specific spot. So there is an increase in the volume of the arm. Another characteristic is that the texture of the skin can change, but this does not happen to the same extent and is therefore somewhat more difficult to take as a clear characteristic.

    1.1 The increase in volume can be measured in several ways. You can measure it with a measuring tape in several places in the affected area. For example, with an arm you can do this in 10 places, others measure it in 5 places. There isn't really a clear protocol for this. With these measurements you can calculate the volume, but you can also be specific per location as to whether swelling has occurred there.

    Another way is in a water container, where you can use the water displacement to measure the volume. The disadvantage is that this only gives a total volume and cannot measure whether a specific spot stands out in terms of swelling.

    1.2 Both can be measured at home, but both will have their own complications. I think that with both it is difficult to measure and read your own arm at the same time. For the water displacement, you can move your arm and you may then measure slightly more or less far on the arm. And it doesn't seem like a comfortable position to me either. With a measuring tape it is difficult to measure this exactly in the same place every time and to do this with one hand when you measure your own arm.

    So I think they can currently be used at home, but always with someone else present and it may require some training. My main concern now is that the patient does not have the expertise to perform the correct measurement every time and then you might end up with too much diversity in the measurements to actually use it.

2. That very much depends on how this would work. It would be very nice if people could take the measurement at home because, firstly, measurements can be taken more often and secondly, they do not have to come to the hospital for a measurement. But it is important that variation in measurements is limited as much as possible. If you look at the measurements with a measuring tape, it is sometimes difficult for a therapist to always measure in the same place and equally tight. I can imagine that this is even more difficult for a patient and this can strongly influence the entire measurement. If this is all well thought out, I would definitely support something like this!

    2.1 The measurement must be done ”the same” every time. What I mean by this is that it doesn't matter whether what you measure is the actual volume or circumference, but the difference between the actual value and the measured value should always be the same. Ultimately you are looking at a difference between left and right. It's like this: if I measure a circumference of 37 and 39 in a spot with this instrument but it is actually 32 and 34, then the difference between the two is 2 in both cases and that is what I want to know. Furthermore, it should not be something that could reduce the circumference, especially since the tissue of an arm with Lymphedema responds differently to pressure than an arm without Lymphedema. So it should not be a compression stocking like something that is tight.

    2.2 Especially in the beginning after an operation, I would say that measurements should be taken weekly. As you get further away from the operation, you could do this less often, but at least once a month.

    2.3 It is also useful to take into account how these measurements are saved. If this device does not automatically indicate whether there is possible lymphedema, the patient must do this themself. This can involve complicated calculations, depending

on how this is measured, of course. It would be even better if it could be posted online somewhere so that the doctor or therapist can also monitor this and contact the patient if necessary.

In addition, I think it goes without saying that it would be better if it became a non-invasive measuring instrument, especially if people have to use it at home. This could prevent a lot of complications, I think.

B USER TEST QUESTIONS

Participant number:
Amount of questions during testing:
Time it took to measure:
Can you describe in words your opinion about the tool?
Is there anything you would like to change to the tool?

C SYSTEM USABILITY SCALE

System Usability Scale

Participant number:

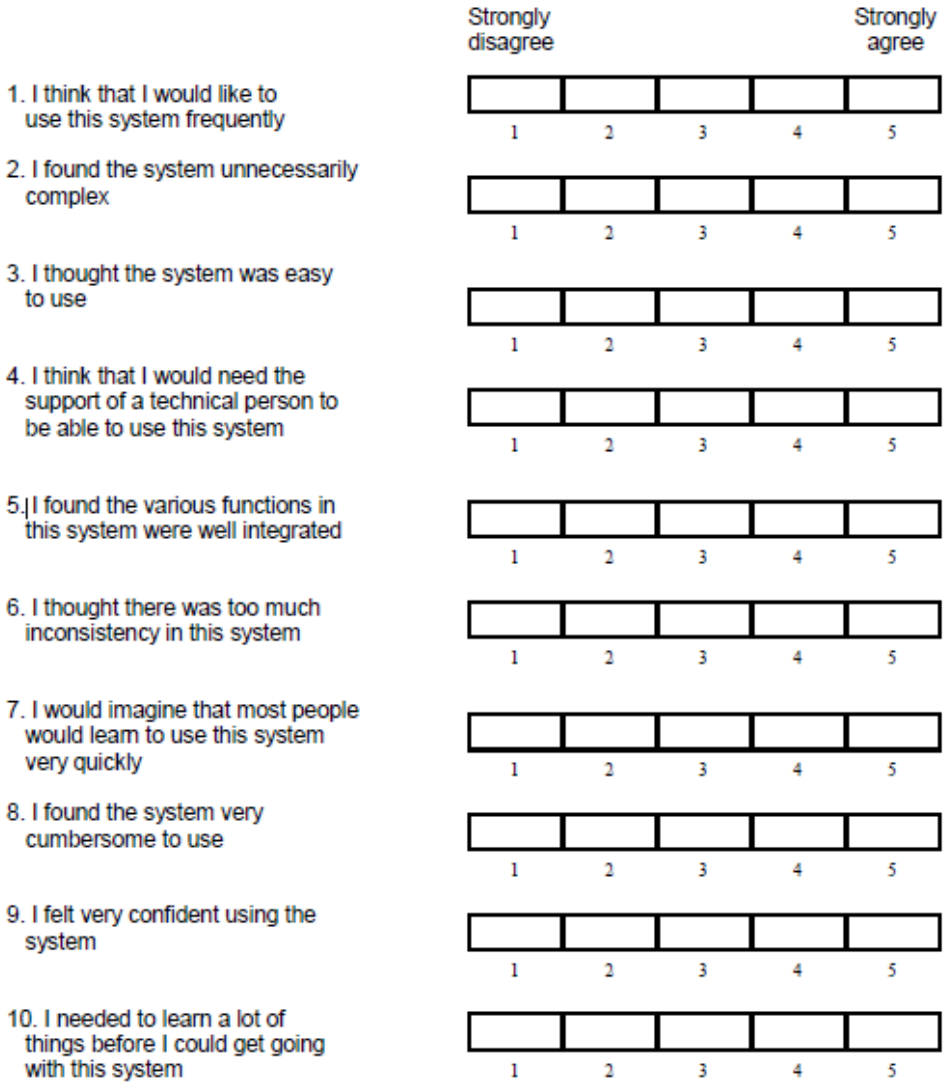
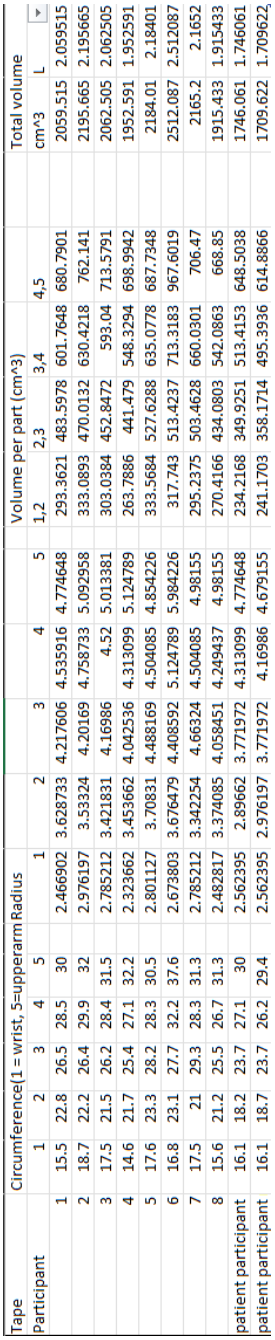


Figure C.1: System Usability Score

D CIRCUMFERENCE TO VOLUME CALCULATIONS



Tape	Circumference(1 = wrist, 5=upperarm					Radius					Volume per part (cm^3)				Total volume	
Participant	1	2	3	4	5	1	2	3	4	5	1,2	2,3	3,4	4,5	cm^3	L
1	15.5	22.8	26.5	28.5	30	2.466902	3.628733	4.217606	4.535916	4.774648	293.3621	483.5978	601.7648	680.7901	2059.515	2.059515
2	18.7	22.2	26.4	29.9	32	2.976197	3.53324	4.20169	4.758733	5.092958	333.0893	470.0132	630.4218	762.141	2195.665	2.195665
3	17.5	21.5	26.2	28.4	31.5	2.785212	3.421831	4.16986	4.52	5.013381	303.0384	452.8472	593.04	713.5791	2062.505	2.062505
4	14.6	21.7	25.4	27.1	32.2	2.323662	3.453662	4.042536	4.313099	5.124789	263.7886	441.479	548.3294	698.9942	1952.591	1.952591
5	17.6	23.3	28.2	28.3	30.5	2.801127	3.70831	4.488169	4.504085	4.854226	333.5684	527.6288	635.0778	687.7348	2184.01	2.18401
6	16.8	23.1	27.7	32.2	37.6	2.673803	3.676479	4.408592	5.124789	5.984226	317.743	513.4237	713.3183	967.6019	2512.087	2.512087
7	17.5	21	29.3	28.3	31.3	2.785212	3.342254	4.66324	4.504085	4.98155	295.2375	503.4628	660.0301	706.47	2165.2	2.1652
8	15.6	21.2	25.5	26.7	31.3	2.482817	3.374085	4.058451	4.249437	4.98155	270.4166	434.0803	542.0863	668.85	1915.433	1.915433
patient participant	16.1	18.2	23.7	27.1	30	2.562395	2.89662	3.771972	4.313099	4.774648	234.2168	349.9251	513.4153	648.5038	1746.061	1.746061
patient participant	16.1	18.7	23.7	26.2	29.4	2.562395	2.976197	3.771972	4.16986	4.679155	241.1703	358.1714	495.3936	614.8866	1709.622	1.709622

Figure D.1: Measured circumference with the tape measure. Transformed into a radius and then then volume per part is calculated.

Tool	Circumference(1 = wrist, 5=upperarm)					Radius					Volume per part (cm^3)				Total volume	
Participant	1	2	3	4	5	1	2	3	4	5	1,2	2,3	3,4	4,5	cm^3	L
1	19.5	23.5	26	28.8	30	3.103521	3.740141	4.138029	4.583662	4.774648	368.1596	487.4899	597.3617	687.8059	2140.817	2.140816994
2	20.5	23.7	27.9	30.1	31.4	3.262676	3.771972	4.440423	4.790564	4.997465	388.8381	529.6819	669.1569	752.4057	2340.083	2.340082664
3	22.6	22.7	26.2	28.1	30.9	3.596902	3.612817	4.16986	4.472254	4.917888	408.2505	475.7886	586.5545	692.3544	2162.948	2.162947883
4	17.5	22.7	26.2	27.4	29.5	2.785212	3.612817	4.16986	4.360845	4.695071	322.185	475.7886	571.5485	644.0345	2013.557	2.013556517
5	19.5	24.1	27.5	28.3	31.1	3.103521	3.835634	4.376761	4.504085	4.949719	378.5686	529.6889	619.4312	701.767	2229.456	2.2294556
6	18.7	23.7	27	30.2	35.2	2.976197	3.771972	4.297183	4.806479	5.602254	358.1714	511.3981	650.7453	849.868	2370.183	2.370182844
7	20.5	22.6	30.4	29.1	33	3.262676	3.596902	4.83831	4.631409	5.252113	369.6456	558.5134	704.2716	766.7357	2399.166	2.399166332
8	18.4	22.5	27	28.5	32.8	2.928451	3.580986	4.297183	4.535916	5.220282	333.1981	487.5494	612.7708	747.0393	2180.557	2.180557476
patient participant left	19.2	22.2	25.9	27.7	29.3	3.055775	3.53324	4.122113	4.408592	4.66324	341.1888	460.3856	571.5374	646.3281	2019.44	2.019439903
patient participant right	19.7	21.7	25.7	26.7	29	3.135352	3.453662	4.090282	4.249437	4.615493	341.0738	447.1309	546.2487	617.1577	1951.611	1.951611126

Figure D.2: Measured circumference with the developed tool. Transformed into a radius and then then volume per part is calculated.