Evaluating Leg Length Discrepancy during Total Hip Arthroplasty

Enhancing Conventional Surgical Workflows

Master Thesis
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December, 2020

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Acknowledgements

Writing a thesis is a challenging time in itself, doing so during a global pandemic requires an exceptional support network. I would like to thank the supervisory team for their guidance, in navigating this project with me. A big thank you to the external partners that made it possible to continue this graduation project despite the global uncertainty. A special thanks to all the medical staff at the two hospitals, who allowed me into their workspace, contributed to research, the process and ultimately the end result. Not to forget, a warm thank you to the brave participants of the online co-creation sessions, who offered their free time and allowed me to pick their brains, thereby shaping the process and improving the quality of the project tremendously.

Last but should have been first, thank you to my personal support network. My family, girlfriend and friends ... my environment.

Abstract

The human body, although seemingly symmetrical, can in fact be highly asymmetrical. Our bodies are predetermined by our DNA and co-shaped by our environment. This leads to most of the world's population having a discrepancy in leg length either from birth or developed during their life time. It is completely natural and goes unnoticed, as changes are incremental and people get used to it. On the contrary, when undergoing total hip replacement surgery and waking up with one leg longer than the other, the change is almost instantaneous and immediately noticeable. Current surgical solutions do not address this issue in a practical manner within the operating theatre, leading to surgical teams developing their own methods and procedures to evaluate the change in patient's leg length.

Introducing new workflows to medical professionals often entails neglecting the protocols they spent years practicing. This thesis identified this bottleneck and instead of introducing new methods and procedures, it was decided to build on existing ones. This was done by exploring common surgical workflows in respect to total hip replacement and determining an approach to enhance surgical team's capabilities in evaluating leg length discrepancy.. Important in achieving this goal it to make any given design solution effortless, reliable and undisruptive to various workflows

In order to do so, user research was performed by joining multiple surgical teams within the OR, thereby observing and evaluating their methods. One method in particular stood out, which is best described as the 'loaded assessment'. During this assessment the surgeon or circulating nurse will centre the patient's feet, apply pressure to the heels and try to evaluate the discrepancy. Although this method being seemingly simple, its execution is difficult to perform by a single person and varying pressure differences may confuse the assessment.

Following the initial research phase, co-creation sessions with technical experts were organised, after which various concepts were developed and tested on the basis of feasibility, desirability and viability. Finally, a functional prototype based on the loaded assessment principle was developed and tested for its functionality and conceptual expectation.

Reading Guide

Chapter Highlights

A concise summary of each chapter's key insights or highlights is presented on the last page of each chapter. These summaries can be found in a green rectangle (Fig. 1).

Throughout the text, primary insights are highlighted in the same shade of green, like such.

Relevant quotes from throughout the process can be recognised by this format.

Lastly, a list of abbreviations is provided on page 11. Not to worry, each term will be spelled out once when mentioned for the first time, so this is just for the case that one slips the mind.

The basics are covered, let's get started!

Key Insights

- Key insight #1
- Key insight #2
- Key insight #3
- Key insight #4
- Key insight #5
- ...

Fig. 1 - *Example of the 'Key Insights rectangle'*

Chapter Overview

Each chapter features the same structure, even if the naming of individual sections may vary:

Background - a brief introduction to the background of the chapter
Methods & Procedure - a description of research and design activities performed
Findings - a presentation of the resulting insights
Discussion - a brief discussion on these findings

Chapter 1 - General Introduction
This chapter provides a general overview of the topic's most relevant aspects, such as problem statement, research questions, assignment approach and solution space.

Chapter 2 - Literature Review
This chapter starts the Discovery Phase and explores academic literature related to the topic and beyond. A summary of all topics relevant for the scope of this thesis is provided.

Chapter 3 - User, Context & Market Analysis
This chapter explores first hand insights into orthopaedic clinics, by means of a survey and observations. The findings are translated into personas, a surgical timeline, market matrix mapping and more.

Chapter 4 - Problem Definition
This chapter starts and concludes the Define Phase by the means of presenting the most relevant key findings, opportunity areas (chapters 2 & 3) and finalising them by means of a list of requirements.

Chapter 5 - Co-Creation Sessions
This chapter starts the Develop Phase and describes the setup and execution of the performed Co-creation sessions, as well as illustrates the ideation process, morphological chart and ideation sketches.

Chapter 6 - Prototyping
This chapter uses the previous morphological chart as basis for testing proof-of-concepts (Pocs). These tech / non-tech PoCs allow to evaluate the feasibility of any given concept direction.

Chapter 7 - Final Concept
This chapter is the start of the Deliver Phase and introduces the final concept. First a general overview is provided by means of sketches and later more detail by means of renders and technical details.

Chapter 8 - Final Prototype
This chapter introduces the components, processes and methods used for creation of the final prototype. Detail on technical challenges and deviations from the final prototype are provided briefly.

Chapter 9 - Testing and Evaluation
This chapter is concerned with the testing and evaluation of the final prototype, by technical experts as well as medical experts in a non-clinical setting.

Chapter 10 - General Discussion
The final chapter will present the final discussion about this project and draw conclusions about the main research questions and their answers, future continuation and general limitations.

Table of Contents

Abbreviations

ASIS	Anterior Superior Iliac Spline
CAS	Computer Assisted Surgery
CoR	Centre of Rotation
CT	Computerised Tomography
FOD	Femoral Offset Discrepancy
FoV	Field of View
FLLD	Functional Leg Length Discrepancy
GT	Greater Trochanter
IMU	Inertial Measurement Unit
IR	Infrared
LiDAR	Light Detection and Ranging
LLD	Leg Length Discrepancy
LLI	Limb Length Inequality
MM	Medial Malleolus
MRI	Magnetic Resonance Imaging
NPS	Net Promoter Score
OA	Osteoarthritis
ON	Osteonecrosis
OR	Operating Room
PoC	Proof of Concept
PPE	Personal Protective Equipment
PRO	Patient Reported Outcome
PT	Pelvic Tilt
RAS	Robotic Assisted Surgery
RDGG	Reinier de Graaf Gasthuis
RHOC	Reinier Haga Orthopaedic Centre
THA	Total Hip Arthroplasty
THR	Total Hip Replacement
TLLD	True Leg Length Discrepancy
UHMWPE	Ultra High Molecular Weight Polyethylene
UWB	Ultra wide Band
VCSEL	Vertical Cavity Surface Emitting Laser

Chapter 1

General Introduction

General Introduction

1.1 Background

Hip replacement surgery is often named among the most successful surgical procedures of the 20th century (Knight et al., 2011, p. 16), due to its almost immediate pain relief and high success rate. Considering that the median age for hip replacement is 67 years (American Joint Replacement Registry & American Academy of Orthopaedic Surgeons, 2018), having the ability to maintain full control of your body and lifestyle becomes increasingly important in ageing societies, such as the ones found in Europe and North America (Cooper et al., 1992, p. 287). High quality implants have a life expectancy of 15 - 20 years (Zimmer Biomet, 2020b), which if put into perspective, is time that a patient is freed of pain and walking aids, allowing them to lead a more active lifestyle. Some studies even suggest that there is a positive correlation between Total Hip Arthroplasty (Cnudde et al., 2018, p. 1172) and the patient's life expectancy.

1.1.1 Total Hip Arthroplasty (THA)

With the first metallic hip replacement surgery performed 80 years ago(Manzi et al., 2016, p. 57), modern medicine has come a long way in improving the techniques and tools used in order to facilitate and improve the outcome of THAs in terms of longevity of the implants themselves, functional biomechanics and most importantly patient well-being and quality of life. 80 years of research and development overcame a multitude of obstacles, however, some remained, such as (but not limited to): Irreversible tissue damage, implant dislocation, Leg Length Discrepancy (LLD), Femoral Offset Discrepancy (FOD) and the associated effects on other parts of the body by any of these complications. Nonetheless, before diving deeper into any unintended consequences and what causes the challenges associated with preventing them, it is important to first explain why and how THAs are carried out.

According to the Dutch Arthroplasty Register (LROI, 2019) the majority of THAs is performed in patients suffering from Osteoarthritis (OA), which causes tremendous chronic pain and inhibits the affected to lead an active lifestyle, with many patients requiring walking aids, such as canes, rollators or wheelchairs. During THA or Total Hip Replacement (THR) the deceased ball and socket joint are removed from the patient's pelvis and replaced with artificial components (Fig. 2). The surgeon will repair

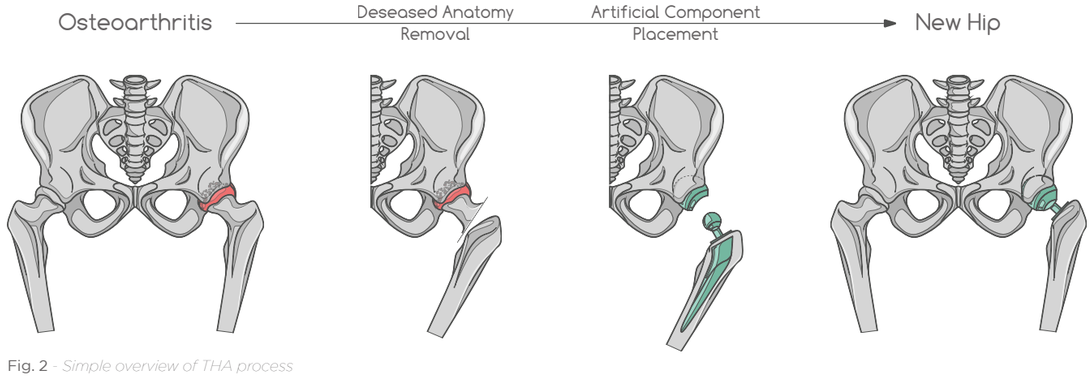


Fig. 2 - *Simple overview of THA process*

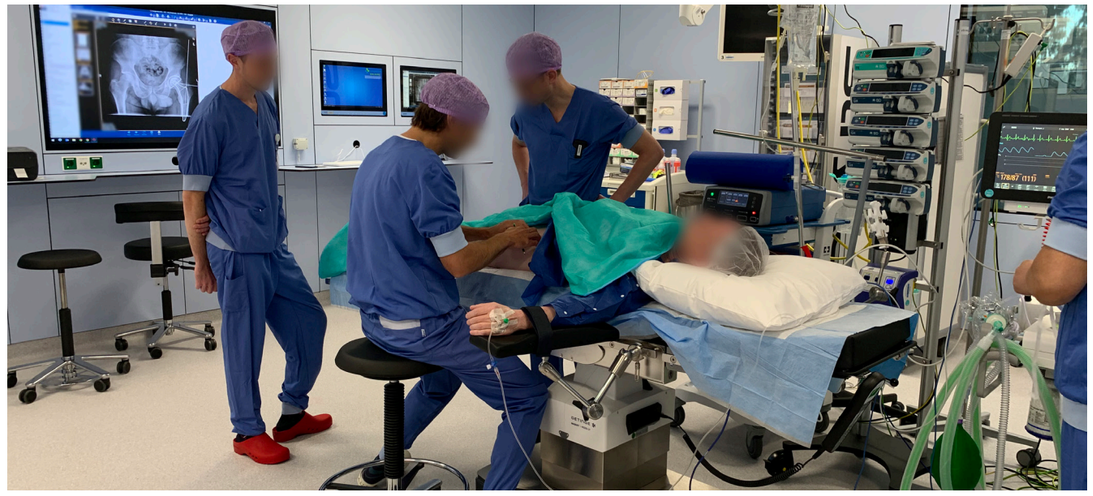


Fig. 3 - *Patient being marked-up before THA*

fractures (if necessary), remove any damaged cartilage within the Acetabulum (pelvic socket) and place a cup inside of it. Afterwards, with the head of the Femur already removed, in its place a stem and head to complete the ball-socket joint are positioned.

Disregarding the effects of surgical intervention, this means that the pain relief for patients suffering from OA is instant (Varacallo et al., 2020, pp. 1–3). Depending on the surgical approach, patients may be released from the hospital and back on their feet within a week. In particular, the Anterior approach allows for fast recovery, as it is the least invasive option causing the least amount of tissue damage (Mayr et al., 2009, p. 813). Regardless which approach is favoured by the surgeon, the core objectives of the THA remains the same, yet techniques vary with the implant systems used and therefore deserve a closer look (see Chapter 2). For this thesis, Zimmer Biomet's cementless Taperloc® Complete Hip Implant System is at the centre of attention (Zimmer Biomet, 2020c).

1.1.2 Leg Length Discrepancy (LLD) and Femoral Offset Discrepancy (FOD)

Every human body is unique in anatomy, biomechanics and anomalies. This does not exclude individual leg length or femoral offset and means that differences in dimensions can exist. These differences, or discrepancies, have a multitude of causes, from being present at birth to being acquired over time as the result of trauma or abnormal biomechanics. In fact, one study suggests that up to 90% of the world's population has some form of LLD or FOD (Khamis & Carmeli, 2017, p. 279). Many people may not even be aware of it or have complaints that are caused by these conditions without being aware of the root cause. For example, LLD can cause pain or functional impairment in other parts of the body, such as the neck, back, hip or foot (Knutson, 2005, p. 11). This can be compared to a biomechanical / anatomical chain reaction, caused by gravity and static or dynamic loads. Needless to say, when an individual is aware of their LLD / FOD, they will notice it frequently while walking or simply standing (Austin et al., 2019, p. 185). Arguably, the only moments when they will not notice it, is while lying down or differently formulated, when no loads are applied to the system.

1.1.3 LLD and FOD after Total Hip Arthroplasty

As explained, already previous to a THA, a patient can suffer from LLD or FOD as a result of their condition, also known as preoperative LLD or FOD. This can and should be mitigated during THA, even though not being the primary focus of the procedure. Not correcting

preoperative LLD and FOD during surgery may lead to unintended problems postoperatively (Hozack & Parvizi, 2004, p. 1829). These problems not only concern pain or functional impairment as mentioned before, but also lead to rapid degeneration and dislocation of the implants. Such instances would then require the surgeon to perform a revision surgery, which everyone involved (patient, surgeon & hospital) would like to avoid.

Nonetheless, if a patient with or without preoperative LLD or FOD wakes up after a THA with a disproportionally large LLD or FOD, it is in many cases immediately noticeable for them (Fig. 4). Just like the pain relief, also the lengthening or shortening of dimensions is immediately noticeable. Understandably, the patient's anatomy and biomechanics are not able to adjust within such a short timeframe, which in turn will have psychological impacts. It goes without saying that patients are quick to sue their hospital and surgeon for malpractice, making LLD one of the top causes for litigation (Upadhyay et al., 2007, p. 6).

In order to avoid this, surgeons will apply various methods in order to reference, assess and reconstruct leg length and offset. These range from self-developed methods, to mechanical devices like callipers and digital software analysis, but ultimately a surgeon and their team will develop and customise their own workflow, shaped by years of experience and influenced by hospital and health system regulations. More detail on different methods and procedures will be provided in chapter 2 and 3.

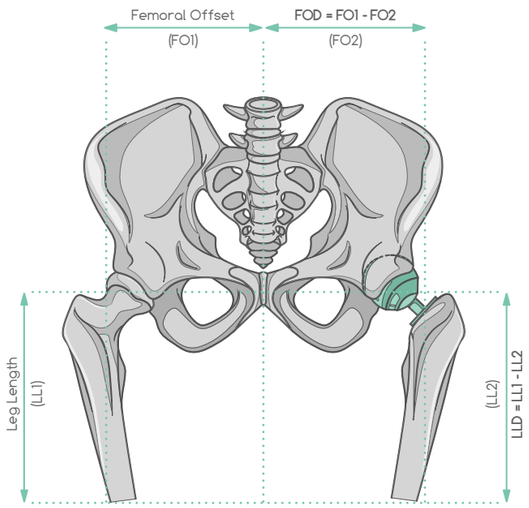


Fig. 4 - *Simple definition of leg length and femoral offset*

1.2 Problem Statement

1.2.1 Scope

The Human Body is a complex arrangement of bony anatomy and soft tissues. Unlike solid objects, it is a complex biological system, therefore referencing and dimensioning it requires consideration of its complexity in anomalies. Considering those anomalies, the complex nature of this topic requires a narrow scope in order to make the project feasible within the given time constraint. Therefore, this thesis will be focussing on the most relevant context and definition of LLD, with the potential for broader applications outside of primary THA.

Currently, within the biomedical industry focussing on orthopaedic surgery solutions does not offer tailored approaches for evaluation of LLD and FOD. Solutions that allow for evaluation of LLD and / or FOD range from methods that surgeons developed themselves, over traditional mechanical devices, up until high-tech robotic systems (Loughenbury et al., 2018, p. 107). Computer-assisted surgery (CAS) and Robotic assistive surgery (RAS) focus mainly on surgeon navigation, by tracking surgical instruments and the patient's position during the procedure (Ogawa et al., 2014, p. 153). Such real-time analysis navigation and tracking systems merely offer LLD and FOD evaluation as a feature, rather than a focussed solution. Interestingly enough, many systems do not take symmetric referencing of the lower limbs as a starting point but instead only reference bony landmarks on the operative side of the patient, in an attempt to reproduce these dimensions after implant placement. Furthermore, many of these systems are accused of not fitting into conventional surgical workflows and require specialised training (Lin et al., 2011, p. 601). By replacing the surgeon's traditional training experience, procedures tend to become less time and cost effective (Kong et al., 2020, p. 178).

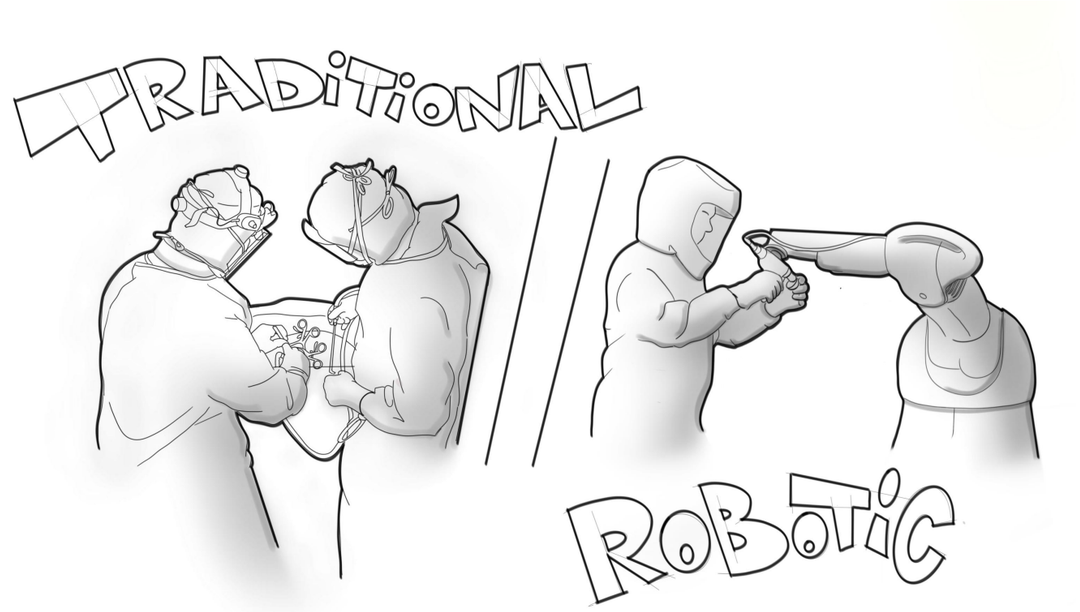


Fig. 5 - *Comparison between conventional and robotic surgery*

Arguably the biggest problem with many of these systems is that they have a very high financial entry barrier for hospitals or private clinics to overcome. Robotic or even purely digital (software) solutions will financially set back a hospital substantially and are in essence luxury products or services.

"Several methods described for the measurement of LLD and several devices manufactured to overcome LLD are either too complicated or too expensive to be practical for routine use" (Desai et al., 2013, p. 337)

1.2.2 Solution Space

The design solution, envisioned as a passive but modern tool for validation of LLD and potentially FOD, will be focussing on enhancing conventional surgical workflows and thereby empowering surgeons and their teams. This is in contrast to current industry trends that aim for semi-automation of surgery. Nonetheless, it is not excluded that the solution may in the future become a subsystem of robotic solutions, however this will not be the end-goal of this thesis. Whereas the primary use case of the product will be within an intraoperative context, widening the application area to pre- and postoperative evaluations enables the tool to create a measurement standard. Through this, measurements become reliable and reproducible, therefore allowing for comparison of different evaluation results taken during different stages of the process (Fig. 6). These comparable figures will then give data-driven insight into the success of THA in respect to LLD and FOD.

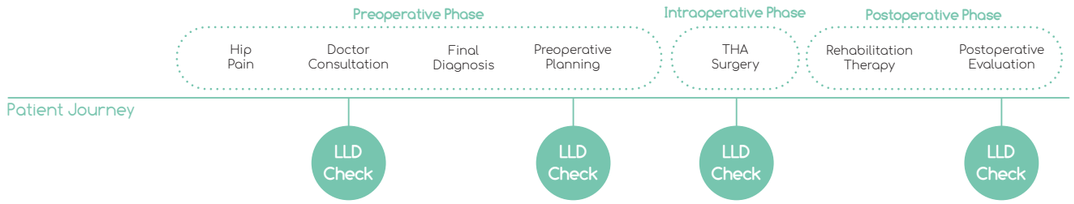


Fig. 6 - *Overview of phase dependent LLD checks*

1.2.3 Research Questions

In order to generate a better understanding of the problems, three main research questions and two sub-questions are posed with the purpose of making the research process more specific.

1. How to more accurately reference, assess and dimension lower limbs while considering a patient's individual anatomical differences?
    a. How can symmetry be evaluated and created in an asymmetric biomechanical system?
    b. What role does the patient's position play during repeated LLD assessments?
2. How can post-operative LLD be prevented during THA, without disrupting conventional surgical workflows?
3. How can high-tech solutions be empowering to the user and provide a sense of control?

These questions cover a broad area of knowledge spanning from established medical methods, technological trends up until user - product interactions.

1.3 Assignment & Approach

1.3.1 Assignment

Considering the limitations, requirements and opportunities of the scope, solution space and research questions, the following design assignment was created in order to prevent post-operative LLD and FOD.

"Develop a concept and functional prototype for evaluation of LLD and/or FOD, fitting most conventional surgical workflows for primary THA using the Anterior approach, which empowers the user by providing data-based feedback in real-time."

1.3.2 Project Approach

The project approach will be carried out following the double diamond process (British Design Council, 2019), established in four phases - Discover, Define, Develop and Deliver (Fig. 7). The following paragraphs will outline each phase briefly, in terms of methodology and expected outcome.

Discover

During the Discover phase, the goal is to broaden the horizon and establish a comprehensive understanding of the topic. Research is primarily focussed on how THAs are performed, what differences exist in execution, what methods and tools are used most commonly and during which points during a patient's journey does leg length or femoral offset and the evaluation of LLD or FOD play a role. This will help to uncover opportunity areas, based on key findings, which in turn will enable the formulation of concrete goals for any potential solution. The selection of methods deployed for the Discover phase can be found in chapter 2 and 3.

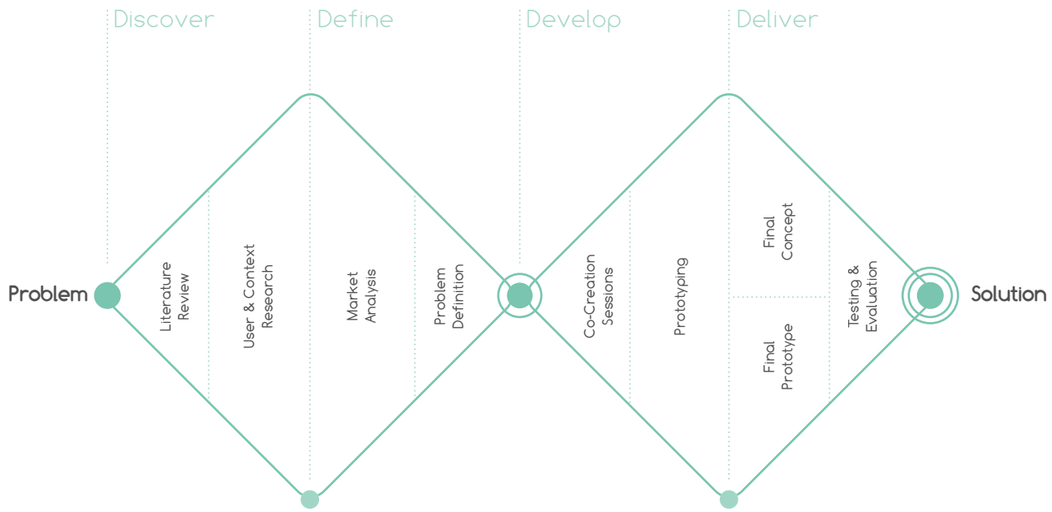


Fig. 7 - *Double Diamond process overview*

Define

During the define phase, divergence of knowledge is stopped and convergence is started. All gathered insights get formulated into definitions that allow for evidence-based development of ideas. The primary goal for this phase is to define the relevant problems and the scope of this project. An important method that is deployed in this phase is the 'List of Requirements', which will not only define the desired functionality, benchmarks and features of the desired solution, but additionally acts as a final checklist when evaluating any given concept at the end of the process. Further methods utilised during this phase can be found in chapter 4.

Develop

For this project, the develop phase is split into two sub-phases - Ideate and Conceptualise. During both phases key insights and ideas will result from co-creation sessions, held with medical experts, designers and engineers. Co-Creation sessions generate a multitude of ideas and inputs, broadening the solution space and enabling classification of solution directions. Promising ideas are clustered and processed by evaluating desirability, feasibility and viability. Finally, proof of concepts are devised, tested and evaluated and will form the basis of the final concept. For more details on which methods are used during the co-creation sessions, please consult chapter 5.

Deliver

During the deliver phase (convergence) everything comes together. The final prototype is assembled, tested and evaluated, all results and findings are documented, and the entire project converges towards one point. Last tweaks and adjustments will be made before all deliverables are submitted. More detail on this phase can be found in chapters 6-9.

Key Insights

- One study suggests that up to 90% of the world's population has some form of LLD or FOD.
- Many surgical systems are accused of not fitting conventional surgical wor flows and require specialised training.
- By replacing the surgeon's traditional training experience, procedures tend to become less time and cost effective.

Chapter 2

Literature Review

Literature Review

2.1 Background

LLD and FOD are well documented topics in the scientific literature, from medical studies, over expert testimonies to patient reported outcomes (PROs). There is a magnitude of causes in particular for LLD, all of which will be explored in this chapter. Not only can LLD be a result of surgical intervention after fractures or degenerative joint conditions, such as Osteoarthritis (OA) of the hip or knee joints, but it can also be a result of anatomical anomalies, such as acquired and abnormal gait patterns caused by unusual flexion or abduction by surrounding muscles (Austin et al., 2019, p. 184). Moreover, LLD can also be congential, or in other words present from birth, meaning that many people's anatomy simply adjusted during adolescent growth spurt, thereby becoming used to one leg being slightly longer than the other without ever being aware of the 'condition' (Khamis & Carmeli, 2017, p. 277). In fact, literature suggests that an estimated 70 - 90% of the world's population has some form of LLD (Khamis & Carmeli, 2017, p. 279). The following section will explore what makes a relevant LLD, in consideration of the scope of this research and how relevant cases can be tackled, in addition to why it is even necessary to do so, given that so many people live with LLD without being aware of it in the first place.

2.2 Methods & Procedure

During the process of finding relevant studies and papers, various combinations of keywords were entered into different search engines, such as the TU Delft online Library and Google Scholar. An inventory was created by clustering relevant topics and reading each paper carefully. Suitable information was highlighted and extracted into a separate document, creating a condensed collection of knowledge. The most relevant clusters of knowledge are presented and reviewed in the next section '2.3 Findings'.

2.2.1 Keywords & Literature Map

For this literature review, a selection of keywords has been made in order to filter relevant research out of a vast selection of academic papers. For explorative reasons, keywords beyond the scope of this project have been included in order to create a comprehensive understanding of the topic and potential relevant secondary knowledge. Additionally, literature on potentially supportive technologies has been included, so that the solution space is further defined, alongside core knowledge acquisition. Keywords and phrases used for this literature review can be obtained from the literature Map (Fig. 8). This literature map also visualises the presumable scope and the literature review boundary.

2.3 Findings

2.3.1 Types of LLD and OD

As mentioned, LLD and FOD are commonly congential and are not necessarily noticeable to the patient (Khamis & Carmeli, 2017, p. 277). Human bodies, just like the ones of other living beings do not grow in a symmetrical fashion, rather they are predetermined by DNA and co-shaped by their environment. These typically are small incremental changes over longer periods of time and therefore barely noticeable by the affected patients. This is in contrast to a sudden change in the body's biomechanics, which is why a distinction is made between preoperative LLD or FOD and postoperative LLD or FOD.

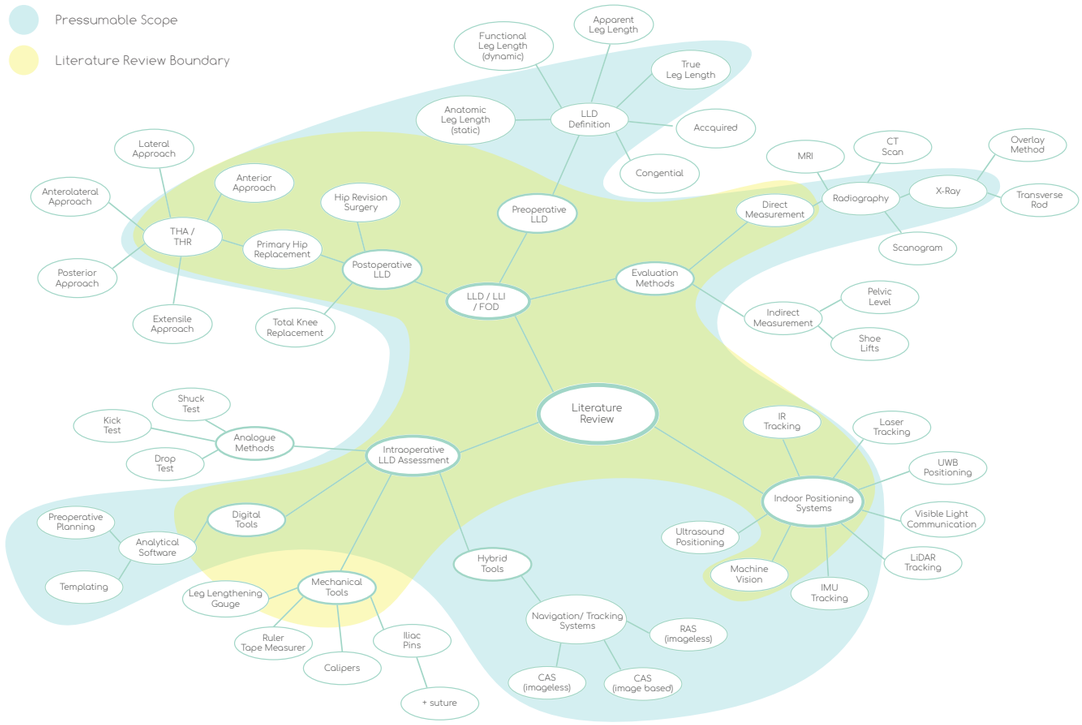


Fig. 8 - *Literature map and keywords*

It is entirely possible for a patient's preoperative LLD to be the cause for their condition, for example Osteoarthritis (Murray & Azari, 2015, p. 231). Even a FOD may degrade the pelvic joint in various ways, by shifting the Centre of Rotation (CoR) of the patients femoral head away from the acetabular CoR. Intraoperative medial changes of FOD are a common reason for dislocation of the hip joint, caused by the lack of tension in surrounding muscles and ligaments (Forde et al., 2018, p. 131). This same concept applies to LLD, too much tension in the surrounding structures reduces mobility of the joint, whereas too little tension will lead to dislocation. In some cases, surgeons will slightly exaggerate leg length and femoral offset in order to achieve the desired tension, which is determined by a technique called telescoping (Zahar et al., 2013, p. 351).

2.3.2 LLD and FOD Assessment

When evaluating a patient's LLD, one needs to consider a variety of factors (Fig. 9). Firstly, the context needs to be considered. A patient's LLD and FOD can be evaluated during three phases of their hospital journey: Preoperative, intraoperative and postoperative. Most surgeons will perform an LLD and FOD evaluation during each of these phases, but depending on how they have been trained and where they work, it will lead them to use different tools, methods and protocols to establish these evaluations. For example, an orthopaedic surgeon may use various forms of medical imaging techniques (weight-bearing radiograph, computed radiograph, scanogram, fluoroscopy, CT scan, MRI scan etc.)* to determine LLD and FOD during each of the three phases (Sabharwal & Kumar, 2008, p. 2920). Nonetheless, not all orthopaedic surgeons will use the same evaluation methods during each of these phases, establishing no baseline for interphase comparison. To complicate things even further, pre- and postoperative evaluations may not even be performed by the orthopaedic surgeon, but by an orthopaedic practitioner, who may use entirely different

tools or methods (Fig. 10). Regardless of who is performing the evaluation, depending on the phase and method, patients will find themselves in various positions for their assessment, which in turn influences the assessment result. During pre- and postoperative assessments, an orthostatic or supine positions may be more common, but ultimately depends on the methodical preference of the orthopaedist. During intraoperative assessments, the position of the patient will be determined by the surgical approach. For posterior, direct lateral and anterolateral approach, the patient is in lateral position, whereas during the anterior approach, the patient is in supine position (see section '2.3.3 Surgical Approaches').

Secondly, a precise definition and method of leg length and its evaluation has to be chosen. Determining landmarks on the patient's anatomy will enable a more reproducible and consistent way of measuring. Throughout literature one can find a variety of landmarks and their relationships to each other (Desai et al., 2013, p. 337), some deemed reliable like the relationship between the Anterior Superior Iliac Spine (ASIS) and Medial Malleolus (MM), others not, like the relation between ASIS and the Greater Trochanter (GT). If the measurement is taken between two anatomical points, then we are talking about a direct clinical method (Khamis & Carmeli, 2017, p. 278). An example of this would be, measuring from the Anterior Superior Iliac Spine (ASIS) to the Medial Malleolus (outside ankle - see Fig. 12), of which the discrepancy between sides is considered True Leg Length Discrepancy (TLLD). Important aspects to consider during the use of direct clinical methods is the allocation of a landmark below soft tissues through palpation, the straightness of the measurement (e.g. deflected by soft tissue) and the squareness of the pelvis or Pelvic Tilt (PT). For example, a slight PT, in relation to the lower limbs, may extend one of the legs and therefore render the measurement inaccurate. This is one of the main reasons why once landmarks have been chosen, repeated measurements have to be taken and averaged. Studies have shown that physicians (Sabharwal & Kumar, 2008, p. 2912) fail to reliably diagnose and determine LLD. Another important aspect to consider is the positioning of the patient before measurements. Multiple Studies have shown that slight changes in the patient's position may vary measurements by multiple millimetres (Khamis & Carmeli, 2017, p. 278).

Alternatively, an orthopaedic practitioner / shoemaker would most likely use an indirect

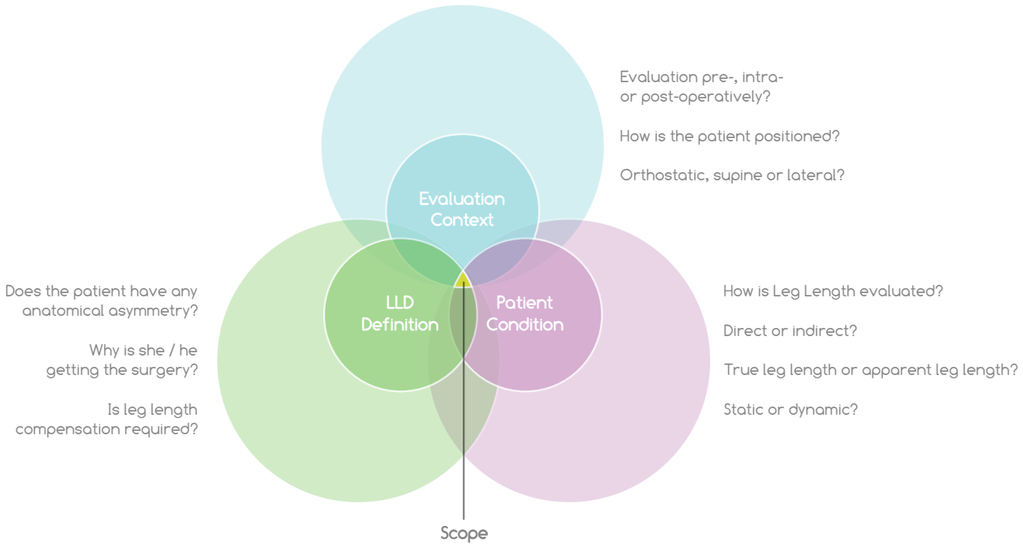


Fig. 9 - *Overview of dependencies that define the scope*

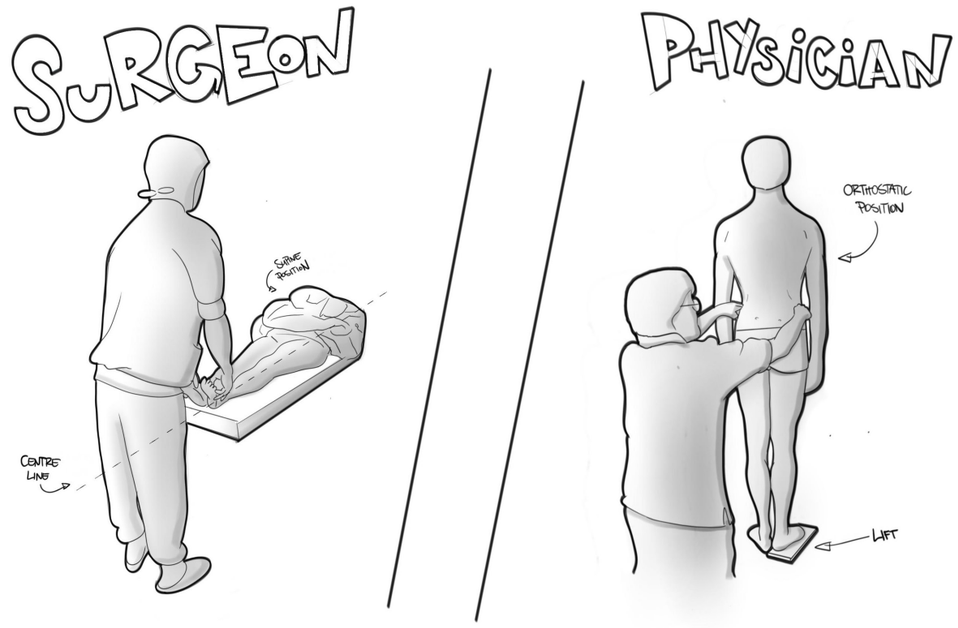


Fig. 10 - *Comparison between surgeon and physician evaluation of LLD and the assosciated patient position*

clinical method. These methods utilise wedge shaped shoe lifts, which are being placed under the patient's heels (Sabharwal & Kumar, 2008, p. 2912). Then through radiographic imaging, a pelvic level (Fig. 11) or more commonly simple palpation, the squareness of the pelvis is evaluated. With both examples, the practitioner will pay attention to the Iliac Crest on both sides of the pelvis and evaluate whether they are horizontal to each other. If not, a different sized lift is chosen and the process repeated, until a satisfactory result is reached. The height of the final lift ultimately determines the final LLD. Indirect methods are prone to false positives caused by asymmetric loading or inconsistent compensation as some studies suggest (Khamis & Carmeli, 2017, p. 277).

Thirdly the patient's condition needs to be established by thorough inspection of the patient's anatomy. Not only may the orthopaedist find that through osteoarthritis, the patient's operative leg has become shorter than before, the patient may have other anatomical conditions that need to be considered. Such conditions include anatomical bony asymmetries / anomalies / deformities on ASIS or Malleoli, excess soft tissue or biomechanical deviations, such as joint contractures, static structural malalignment or dynamic deviations (e.g. abnormal hip adduction or knee flection). Some of these conditions may result in false measurements depending on what method is used and in which context the evaluation is taking place.

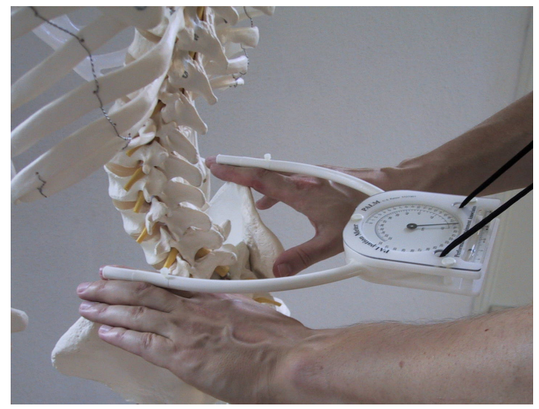


Fig. 11 - *PALM device for palpation of LLD*

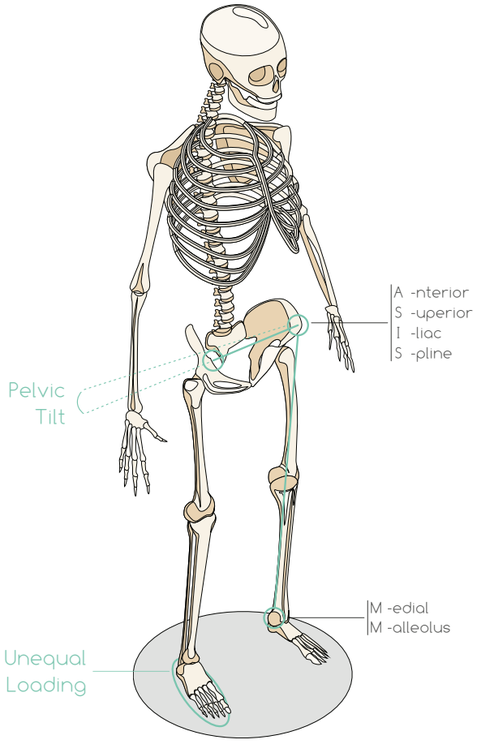


Fig. 12 - *Overview of landmarks and contributing LLD factors*

Many orthopaedic surgeons reportedly avoid to rely on a single assessment method during intraoperative assessment. One study suggests that a majority of practitioners uses at least two methods, thereby decreasing the risk of incorrect measurements and increasing reliability of the diagnosis (Loughenbury et al., 2018, p. 104).

"The fact that more than one technique is used suggests that no one technique is completely accurate and that surgeons feel that employing a combination of techniques gives better results than just using one."
(Loughenbury et al., 2018, p. 104)

2.3.3 THA - Surgical Approaches

As briefly mentioned before, a surgeon will perform THA or THR in case a patient is suffering from hip osteonecrosis (ON), a fracture or various forms of arthritis, most commonly OA (Dutch Arthroplasty Register (LROI), 2019). In either case the core of the surgical procedure is of the same nature, yet the way to the joint in question may differ, which is referred to as the surgical approach. When talking about THAs there are four approaches that have predominately been practiced for the past decades:

Direct Lateral Approach

This approach, as the name suggests, takes a lateral approach towards the patient's hip joint (Fig. 13). The patient may lie in lateral or supine position, depending on the surgeon's preference. It came to popularity due to the low dislocation risk associated with this approach (Karadsheh, 2020b). It's decrease in popularity can be attributed to higher risk of postoperative abductor dysfunction, which is extremely difficult to treat (Petis et al., 2015, p. 138). Additional structures at risk include the femoral nerve and the superior gluteal nerve, which can cause Trendelenburg gait pattern if damaged (McKean et al., 2020).

Anterolateral Approach

This approach is usually performed with the patient in lateral position, or lying on their side (Fig. 13). Muscles and hip capsule are released from the greater trochanter and reattached with heavy suture after the joint replacement, making it one of the more invasive approaches (Patel, 2015). Structures at risk are the femoral nerve, artery and vein. Unintended consequences include postoperative abductor limb and even femoral shaft fractures (Karadsheh, 2020b).

Posterior Approach

This approach requires for the patient to be in lateral position, or lying on their side, as the approach is posterior (Fig. 13). It provides excellent access to acetabulum and femur, while preserving the hip abductors, which in turn minimises the risk of abductor dysfunction (Karadsheh, 2020b). Some surgeons favour this approach, as it can be made more extensile if needed. Opponents of this approach cite a higher dislocation rate and risk for nerve damage associated with this approach (Karadsheh, 2017). Through adjusted techniques and larger implant heads of the ball and socket joint, the dislocation rate has been decreased in recent years (Maratt et al., 2016, p. 128).

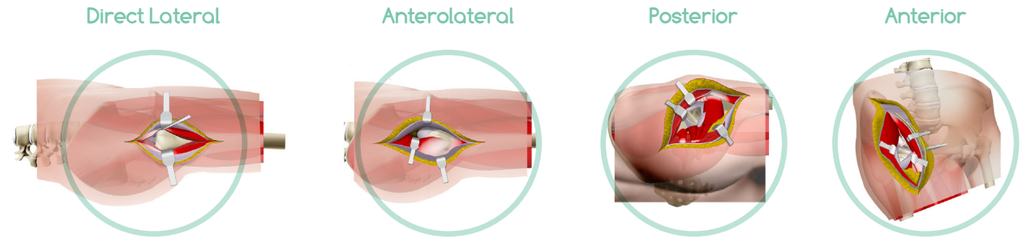


Fig. 13 - *Overview of the most practiced surgical approaches*

Anterior Approach

This approach is usually performed with the patient in supine position (Karadsheh, 2020a), or lying on their back (Fig. 13). This approach, when used with implant systems using small diameter heads, decreases dislocation rates in comparison to the posterior approach(Karadsheh, 2020b). With modern hip implant systems, dislocation rates between the anterior and the posterior approach are similar (Maratt et al., 2016, p. 128). One major advantage the anterior approach has to offer is that it is associated with early functional recovery, making it popular with both surgeons and patients (Christensen & Jacobs, 2015, p. 96). Nonetheless, early revision is commonly seen due to the femoral component loosening (Meneghini et al., 2017, p. 100).

According to the Dutch Arthroplasty Register (LROI) Annual Report 2019 (see Appendix B), the majority of procedures performed in the Netherlands today use the Posterior approach. Yet a significant positive trend for the Anterior approach can be noticed since 2013. The Anterior approach is by no means a new technique, but due to the recent developments in implant systems, minimal tissue damage and early functional recovery time, it is increasingly favoured by patients as well as surgeons. More interestingly though for this thesis, is that it allows or rather requires for the patient to remain in supine position, which may offer opportunities that other approaches do not.

2.3.4 Implant Systems

When it comes to the design of implants, there is many variations or systems surgeons can choose from. There is a selection between cemented and uncemented, one-piece or modular cups, single or dual mobility sockets, small or big heads, all metal or ceramic coated balls and many more (Zimmer Biomet, 2020a). Although there may be a lot of detail variation in each implant system, typically the individual components are the same. The most basic system breakdown will consist of three functional components:

Acetabular Cup

The Acetabular cup is the component of each system, that will be placed into the hip socket, the acetabulum (Fig. 14). It usually consists of two parts, the metal cup itself, which anchors into the pelvic bone and a cup liner, made from a highly corrosion resistant polyethylene with a low friction coefficient (Ultra-high-molecular-weight polyethylene - UHMWPE). Older systems come as monobloc (one-piece) shells with a machined articular surface and do not require a liner.

Fig. 14 - *Components of an implant system*

Femoral Component

The Femoral component, as the name suggests, is the implant that is placed in the Femur or thigh bone (Fig. 14). It has a complex, tapered shape and is inserted into the bone, after osteotomy (bone preparation). Moreover, the femoral component can come as monolithic or modular system, with the latter splitting up into a stem and a neck. The modular femoral component is not to be confused with the modular 'trial implants', used intraoperatively for trial fitting (Fig. 15). The last part of the femoral component is a size variable head, which is always modular and only placed, once all other components have been placed.

Articular Interface

The articular interface does not belong to either of the components but is the literal area between the Acetabular cup and the Femoral component - ball socket joint. The interface size (measured in diameter) can be configured to the patient's needs and will determine factors such as stability, range of motion, friction (wear and tear), inertia and dislocation probability. A larger articular interface seems beneficial when performing the posterior approach, whereas a smaller interface is preferred for the anterior approach, as mentioned in the previous section '2.3.3 THA Approaches'.

2.3.5 Trial Implants

As laid out, implants and their components come in a range of different shapes and sizes, with a suitable configuration selected depending on needs of the patient and the availability in any given hospital or clinic. These configurations can be determined preoperatively, but ultimately the final decision is made intraoperatively. In order to make that decision and prepare the patients anatomy for receival of their implant, surgeons will use a set of trial implants.

Trial implants or more commonly referred to as broaches, are tools with a jagged or grater like surface, that act as reamers and are used for sizing templates (Fig. 15), enabling the surgeon to adjust leg length, offset and version in an iterative process during the procedure. These trial implants only concern the femoral component and consists of 3 parts:

Trial Stem

The trial stem is a wedge or taper shaped part, that doubles as a broach for shaping the femur internally (Fig. 15 and 17). A typical Zimmer Biomet trial implant system will have 14 trial stems (Zimmer Biomet, 2020d), each one incrementally increasing in size. After initial preparation of the soft bone, an appropriate size is chosen and hammered into the femur, checked for fit,

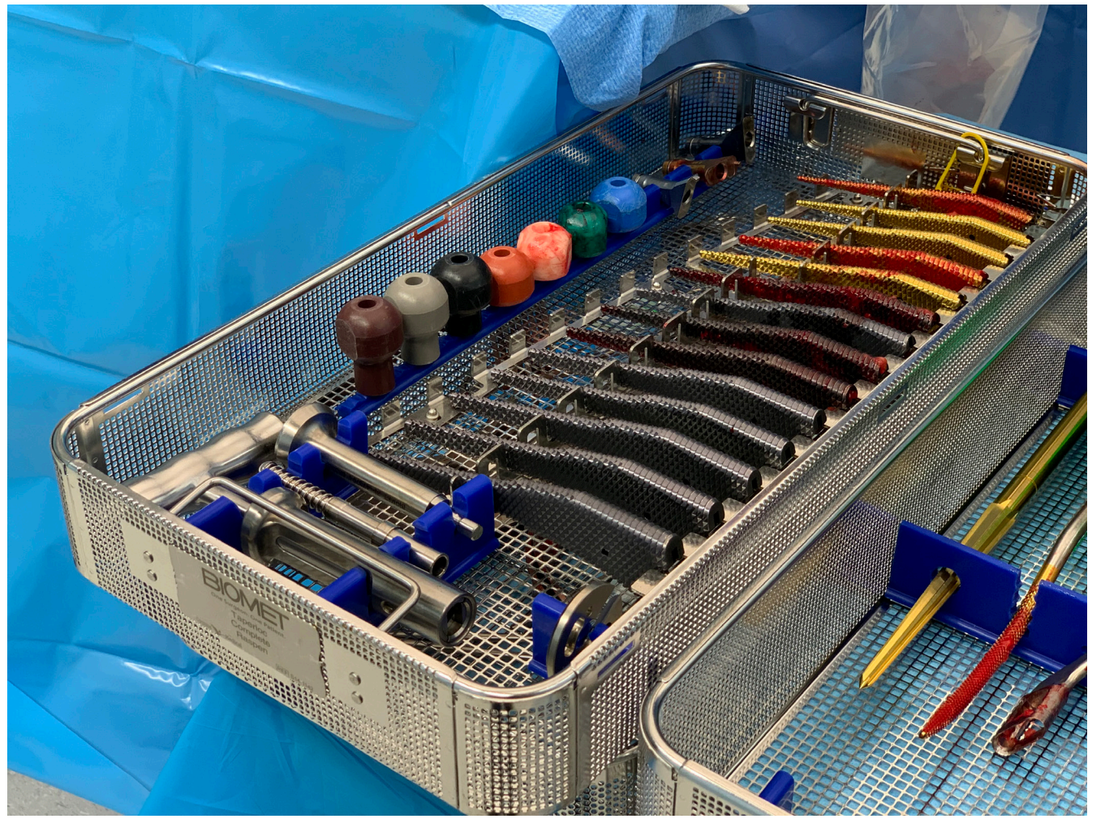


Fig. 15 - *Zimmer Biomet Taperloc trial implant set*

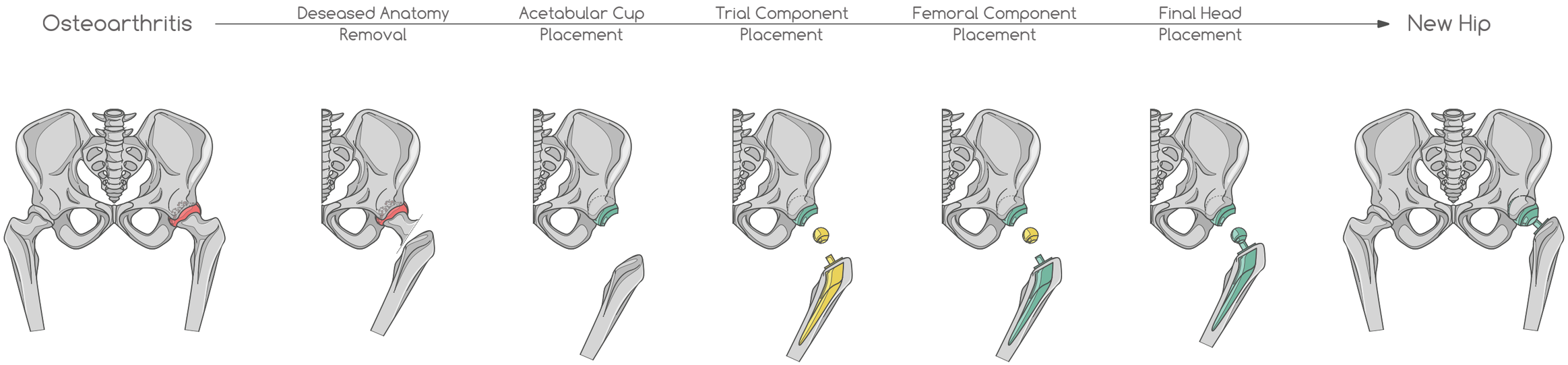


Fig. 16 - *Simple overview of the trial implant use and iteration process*

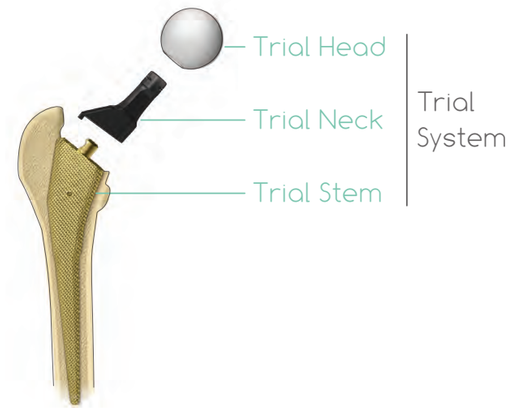


Fig. 17 - *Overview of trial implant components*

removed and the next sequential size is hammered in. This process continues until the appropriate size is found, which will be slightly smaller than the final implant (Fig. 16). This so called 'underreaming' will ensure compression hoop stresses around the implant, also called a 'press-fit' (Mirza et al., 2010, p. 171).

Trial Neck

The trial neck is the part that goes in-between the stem and the head (Fig. 15 and 17). In Zimmer Biomet's trial implant system it comes in 3 variations (Zimmer Biomet, 2020d) of angles and allows the surgeon to adjust femoral offset and leg length. These two values have an important impact on biomechanics, as the muscles and ligaments around the hip joint have developed with functional performance based on the original anatomy. Fine tuning these parameters will have an enormous effect on the patient's well-being as well as the longevity of the implant itself.

Trial Head

The trial heads (Fig. 15 and 17), unlike the final head, are made from UHMWPE and come in seven different sizes, from 26 - 44 mm (Zimmer Biomet, 2020d). The diameters increase in 3 mm incremental steps and can be placed on the neck interchangeably. The head is the last part of the implant placed inside the patient, therefore the trial head is the last part with which leg length and femoral offset can be adjusted (Fig. 16).

Needless to say, trial implants are essential to a successful THA and provide the surgeon with an iterative workflow (Fig. 16), that allows for exploration and evaluation supported by their years of experience.

2.3.6 Stakeholder Map

Based on the insights from the literature review, a stakeholder map (Fig. 18) has been created, in order to visualise how information flows between stakeholders and how stakeholders influence each other. The most relevant stakeholders are placed along the map, which is divided along two scales: influence and interest. These scales form four quadrants: Context Setters, Key Players, Concerned Citizens and Bystanders. The most relevant stakeholders to a THAs are placed within these quadrants and arrows between them symbolise connections as well as information flow directions.

Healthcare Authorities

These authorities set the regional boundary conditions within healthcare. They are in close contact with Hospitals and the private industry, in this case Zimmer Biomet. Healthcare authorities set the rules and regulation around practices and medical equipment by engaging in talks and reviewing research and new findings from relevant advisors.

Hospital

Hospitals are the closest stakeholder that can be considered an authority, without being a government body. A hospital, in this case Reinier de Graaf Gasthuis (RDGG) and Reinier Haga Orthopaedic Centre (RHOC), will set the boundary conditions for their staff within their clinics. They do operate within the rules and regulations imposed on them but at the same time engage in talks over policy advise.

Zimmer Biomet

The private industry is a key player as well as a context setter in the way that they determine what they supply hospitals in terms of their services and product portfolio. In this case implant systems and the required tools, knowledge and training is provided by them. They will listen to feedback from surgeons as well as patients and actively participate in academia by publishing research findings frequently. In terms of manufacturing and maintenance (sterilisation and repair), Zimmer Biomet is required to operate within the context set by health authorities, but has the potential to influence the policies that shape it.

Orthopaedic Surgeon

Orthopaedic surgeons are the key players with the most interest and influence during a THA. The end responsibility and liability about the outcome of the procedure lies with them. Orthopaedic surgeons are required to adjust their protocols, procedures and methods to the policies set by any given clinic. They actively participate in shaping these policies by providing feedback to hospital management and staying informed through academia, in some cases even actively participating in conducting studies and publishing papers.

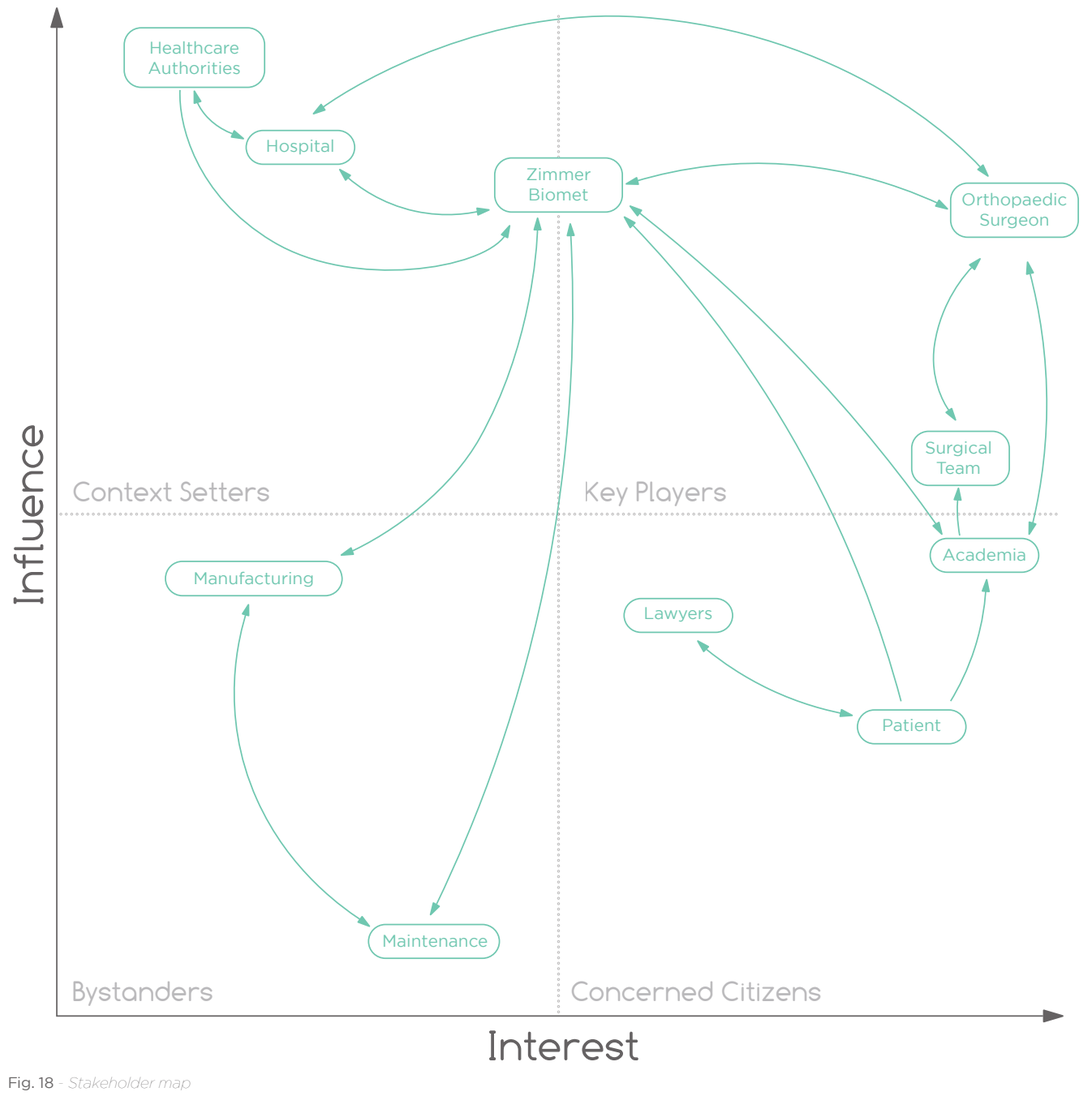


Fig. 18 - *Stakeholder map*

Surgical Team
Surgical teams are under direct command of the operating orthopaedic surgeon during a procedure. While performing their roles and functions within the OR they assist the surgeon as well as the hospital by making sure that all protocols within the OR are executed correctly. Just like in team sports, a surgical team within the OR is only as good as its weakest player, therefore interest in keeping procedures run smoothly is very high. Surgical teams too will stay up to date with academia and constantly exchange methods to improve each other's work (Fig. 19).

Academia
Medical research is constantly evolving and new insight are created on a frequent basis. Many parties participate in this creation of knowledge: universities, hospitals, companies as well as individual surgeons and their peers will team up to discover new methods and techniques or weigh various hypothesis against each other.

Fig. 19 - *Circulating Nurse explaining how to reposition patient's legs*

Patient
The patient is the main beneficiary and subject of this ecosystem. They do not only gain from years of medical collaboration across many fields, but in turn every other stakeholder gains from them. Patients will actively participate in research studies and stay in close touch with their surgeons to provide feedback and insights. That is when things go the way they should. If that is not the case patients are quick to get in touch with a lawyer in order to raise red flags.

Lawyers
Concerned citizens such as lawyers will defend the patient's rights to adequate care and lawful practices. They too have an influence on the shaping of rules and regulations, even if this may be more of a side effect. Their primary concern is to make sure that their clients are compensated accordingly if rules and regulations are skirted to the disadvantage of the patient.

Manufacturing
Manufacturing facilities underly the same rules and regulations set by health authorities and are ultimately part and controlled by the private industry. Their influence is on the quality of the finished product and therefore the long-term performance and outcome of a THA partially depends on them. By informing what levels of manufacturing are achievable, they too can influence policies through industry partners. Within the medical industry these so-called manufacturing standards are more often than not the state of the art.

Maintenance
Maintenance providers, as far as it is not the manufacturer themselves, not only repair and replace equipment and components but are also responsible for sterilisation services. In the context of THA, this means that all reusable instruments from during the procedure get shipped to them, where they will be cleaned and sterilised before being thoroughly inspected and sent to Zimmer Biomet and ultimately back to the hospital.

2.4 Discussion

2.4.1 General
In this chapter a dense amount of information has been collected in order to gain an adequate understanding of the context required to operate in. Not all information will ultimately be relevant to the scope of the project, yet having a comprehensive understanding beyond it seldom does harm. In order to focus the knowledge on what is relevant, current insights will be applied to the research questions in the following section.

2.4.2 Research Questions

How to more accurately reference, assess and dimension lower limbs while considering a patient's individual anatomical differences?

It is standard practice to evaluate LLD via palpation of anatomical bony landmarks, in particular when it comes to interphase evaluation. Referencing the same landmarks across multiple phases will highlight anatomical differences and uncover anomalies as well as context specific dimensional changes. It can be argued that various imaging techniques may be more accurate for the referencing of these landmarks. In particular weight-bearing x-rays or CT scans offer insights on how the patients anatomy and biomechanics behave in a use case scenario.

How can symmetry be evaluated and created in an asymmetric biomechanical system?

As mentioned, bodies of living beings have a certain degree of asymmetry built in by nature and rather one needs to consider what functions are required to be symmetrical. For example, biomechanically it does not make sense to make the femur on each side of a patient the exact same length, if that means that the overall length of the legs will be different. Thereby, focussing on the functional requirements, such as leg length during standing and walking are of primary importance. Otherwise formulated, creating symmetry in a loaded static condition or dynamic loaded condition is the goal. The latter, being more complex than the former, will be neglected for this work.

What role does the patient's position play during repeated LLD assessments?

According to research, patient reposition in between assessments can greatly distort the result of each measurement. Thinking of the human body of a series of chained links with various degrees of freedom may illustrate the problem better. Simplifying the human lower body system (excluding the complexity of the foot) would make it consist of seven members (pelvis, upper legs, lower legs, feet) connected by four ball-socket joints (hips, ankles) and two hinges (knees). Imagining to move this system around and trying to reposition it into the exact same way repeatedly proves to be a challenge. Therefore the patient's position plays an immense role during repeated LLD assessments, unless one knows the exact position and orientation of each link and member within the system.

How can post-operative LLD be prevented during THA, without disrupting conventional surgical workflows?

The only logical intermediate answer to this question is to use conventional surgical workflows as the basis for developing an LLD assessment method. Therefore it becomes important in the following phases of this project to pay close attention to these workflows and uncover which steps and protocols throughout the process can be improved. It will be unlikely to introduce an improvement to a currently used method, especially across multiple workflows, without changing the execution of a particular action. Nonetheless, this approach will ensure minimal disturbance of the daily routine of surgical teams.

How can high-tech solutions be empowering to the user and provide a sense of control?

The intermediate answer to this question is similar to the previous one: by building upon the actions and routines of users and providing quantified feedback. To explain in more detail, when it comes to LLD or FOD assessment many techniques and methods are skill based. The result of one's palpation assessment is only as good as their palpation skills and even when using an x-ray to assess two situations, the resulting analysis is dependent on estimation and interpretation of distances, positions and orientations of landmarks. Therefore, to properly empower the user through technology while at the same time retain their sense of control over the action, is to digitalise these actions and provide haptic, auditory or visual feedback on what they are doing.

2.4.3 Limitations

The obvious limitation of this literature review stems from the vast amount of literature available as well as the time constraint of this project. For good reason, studies and research into medical issues generally take their time. This has to do with the inherent complexity of these issues as well as stringent rules and regulations required to adhere to while researching.

Key Insights

- A patient's LLD and FOD can be evaluated during three phases of their hospital journey: Preoperative, intraoperative and postoperative.

- According to research, patient reposition in between assessments can greatly distort the result of each measurement.

- Not all orthopaedic surgeons will use the same evaluation methods during each of these phases, establishing no baseline for interphase comparison.

Chapter 3

User, Context & Market Analysis

User, Context & Market Analysis

3.1 Background

Based on the previously described literature review (Chapter 2) a more detailed understanding of user, context, market and available technologies has to be gained. For this phase a selection of design research methods has been made, which are described in the following paragraphs. The previously introduced research questions (Chapter 1) are leading in this exploration and need to be kept in mind during the process.

3.2 Method & Procedure

3.2.1 Observations

For first-hand insights into the surgical procedures and environment of a Total Hip Arthroplasty, multiple Operating Room (OR) visits have been planned. These visits took place at the Reinier de Graaf Gasthuis (RDGG) in Delft and the Reinier Haga Orthopaedic Centre (RHOC) in Zoetermeer. Eight days were spent in the OR, observing and following around four surgeons and their teams. During these seven days a total of 21 primary THAs have been observed, together with one hip revision in order to evaluate whether the latter may be of interest to the scope of this project. During the observed surgeries, various steps and procedures have been documented by pictures, videos and notes, all of which have been used for defining and visualising primary insights and secondary information.

3.2.2 Expert Survey

An online survey was created in collaboration with the supervisory team and surgeons at RDGG and RHOC. This survey combines qualitative with quantitative questions and was distributed with the surgical teams performing THAs at RDGG and RHOC. In most cases, members of the surgical teams, who evaluated LLD intraoperatively were asked to fill out the survey in between surgeries, others did so in their off time. Depending on their function within the OR and their level of OR experience, participants are presented with varying questions. The resulting paths were visualised and can be found in closer detail in Appendix C. An overview of all questions (neglecting paths) can be found on the next page.

Questions

1. *Would you like to participate in this study?*
2. *How many years of OR experience do you have?*
3. *What is your function in the OR?*
4. *What surgical approach do you perform?*
5. *Have you ever used radiographic fluoroscopy as assessment / navigation method?*
6. *How comfortable do you feel using radiographic fluoroscopy as assessment / navigation method?*
7. *Have you ever used computer-assisted (imageless) assessment / navigation methods?*
8. *How comfortable do you feel using computer-assisted assessment / navigation methods?*
9. *How comfortable do you feel using computer-assisted assessment / navigation methods?*
10. *How comfortable do you feel using imageless computer-assisted assessment / navigation methods?*
11. *Do you assess Leg Length Discrepancy (LLD) and Offset Discrepancy (OD) preoperatively?*
12. *Through which tool or method?*
13. *Do you compensate for preoperative LLD and OD during surgery?*
14. *Through which method?*
15. *Do you assess LLD and OD intraoperatively yourself?*
16. *Do you assess Leg Length Discrepancy (LLD) and Offset Discrepancy (OD) preoperatively?*
17. *Through which tool or method?*
18. *How do you assess Leg Length Discrepancy (LLD) intraoperatively?*
19. *How do you assess Offset Discrepancy (OD) intraoperatively?*
20. *What factors may confuse your assessment of LLD or OD?*
21. *How often do you feel unsure about the assessment?*
22. *Are there specific situations in which you feel unsure?*
23. *Can you give examples?*
24. *How could more certainty be provided?*
25. *Despite your confidence, how could even more certainty be provided?*
26. *Do you assess Leg Length Discrepancy (LLD) and Offset Discrepancy (OD) postoperatively?*
27. *Through which tool or method?*
28. *What is acceptable LLD to you?*
29. *What is acceptable OD to you?*
30. *Would you like to participate in an online Brainstorm / Co-creation Session or follow-up survey?*
31. *Please provide your phone number or email address.*
32. *Is there any final comment you would like to make?*

3.2.3 Technology and Market Analysis

During this analysis, an inventory of current market solutions that allow for evaluation of leg length or femoral offset has been created. Afterwards, three matrixes were made using relevant descriptions on each scale. These matrixes are similar to two analytical methods from the Delft Design Guide - the Perceptual Map and the Ansoff Growth Matrix (Delft University of Technology, Faculty of Industrial Design Engineering, 2014). The matrixes presented can be considered a remix or combination of these methods, but vary in their execution. Instead of mapping brand perceptions onto the scales of the matrix, features and functionalities are mapped. This allows for mapping of current solutions into the various quadrants. In that way, potential opportunity areas and market gaps can be identified, similar to results of an Ansoff Growth Matrix. The different scale attributes chosen and their definitions are listed in Fig.21.

Particular attention has been given to the technologies featured in these solutions, which are represented by indoor positioning, spatial referencing and tracking systems. These systems were evaluated on the basis of desirability, feasibility and viability, in order to determine whether they are suitable for the desired solution space.

Analog	solutions without electronics
Digital	solutions containing electronics
Validation (passive)	solutions that do not navigate the surgeon
Navigation (active)	solutions that navigate the surgeon
Imageless	solutions that do not utilise any medical imaging technology
Image based	solutions that utilise medical imaging technology
Invasive	solutions that require component positioning within the patient's body
Non-invasive	solutions that do not require component positioning within the patient's body
Symmetric referencing	both leg lengths are considered during the assessment
Asymmetric referencing	only the operative leg length is considered during the assessment

Fig. 21 - *Scale attributes for Market Matrix Mapping*

Fig. 22 - *Fluoroscopy OR setup with x-ray*

Fig. 23 - *Surgeon comparing pre- & intraoperative x-ray*

Fig. 24 - *Templating OR setup*

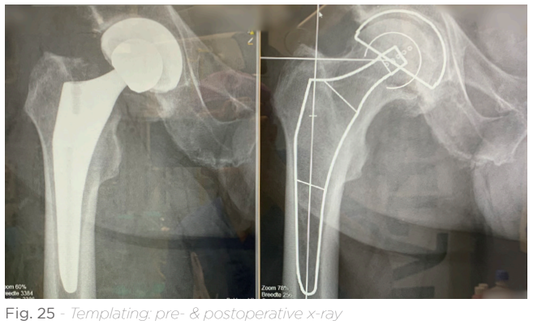


Fig. 25 - *Templating: pre- & postoperative x-ray*

3.3 Findings

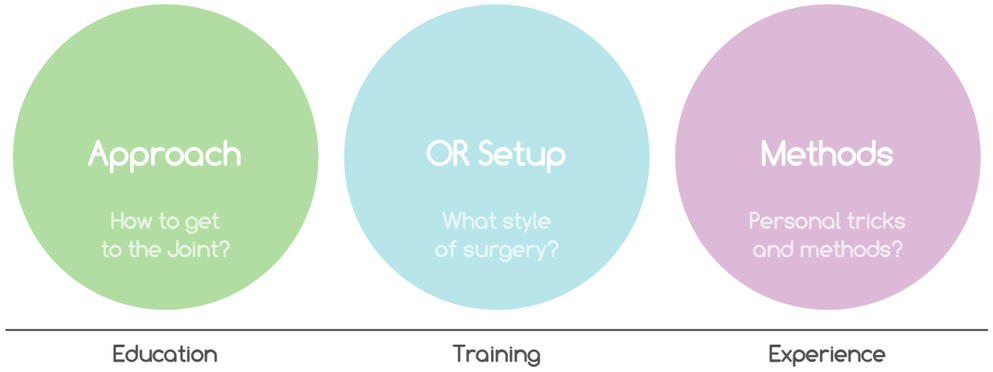


Fig. 26 - *Three pillars of surgical workflow customisation*

3.3.1 Surgical Workflow Customisation

Every surgeon customises their workflow to a certain degree, which is why it is important to point out how each surgeon chooses their workflow. To a certain extent these workflows will be created by circumstances, which can be best described as the three pillars of surgical workflow customisation: Approach, OR Setup and Methods (Fig. 26).

The approach describes the surgical approach a surgeon chooses to perform, which is informed by years of education and practice. A professor at medical school may put forth a paper or hold a lecture about any given surgical approach, that eventually will make an impact on the next generation of surgeons and inform their decision to practice a particular or even multiple approaches given the circumstances. In a similar situation, hospital management, informed by their staff or academia, may dictate which approaches are to be performed in any given hospital or clinic.

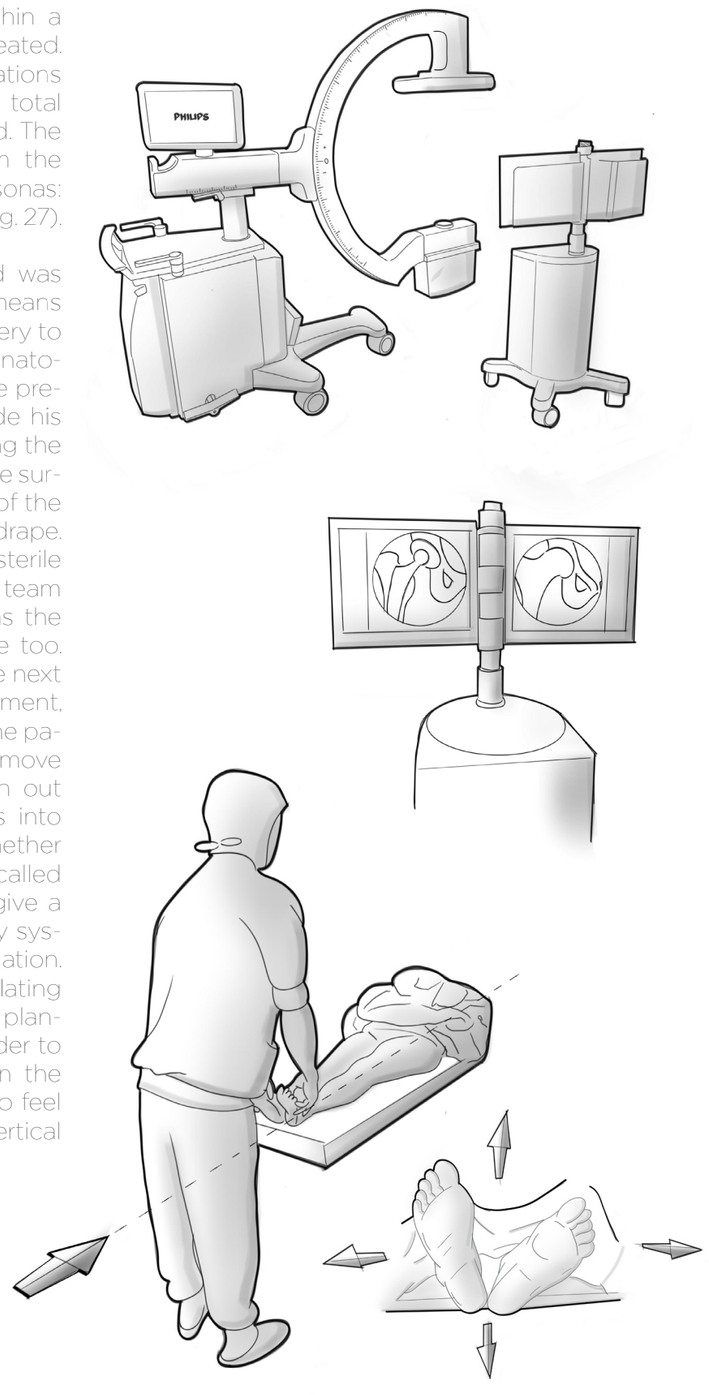
The OR setup on the other hand is determined by the surgeons training. Two surgery styles were observed during the research phase: Fluoroscopy, which utilises a X-ray in order to verify fit, position and orientation of implants; and Templating, which estimates implant sizes preoperatively but ultimately relies on visible landmark orientation, once inside the patient. Two of the surgeons during the observations performed fluoroscopy style surgery and two performed templating style surgery. All surgeons observed confirmed that their OR setup and therefore surgery style was primarily influenced by their mentor who trained them. This is one of the many cultural aspects that need to be considered when wanting to design for surgeons.

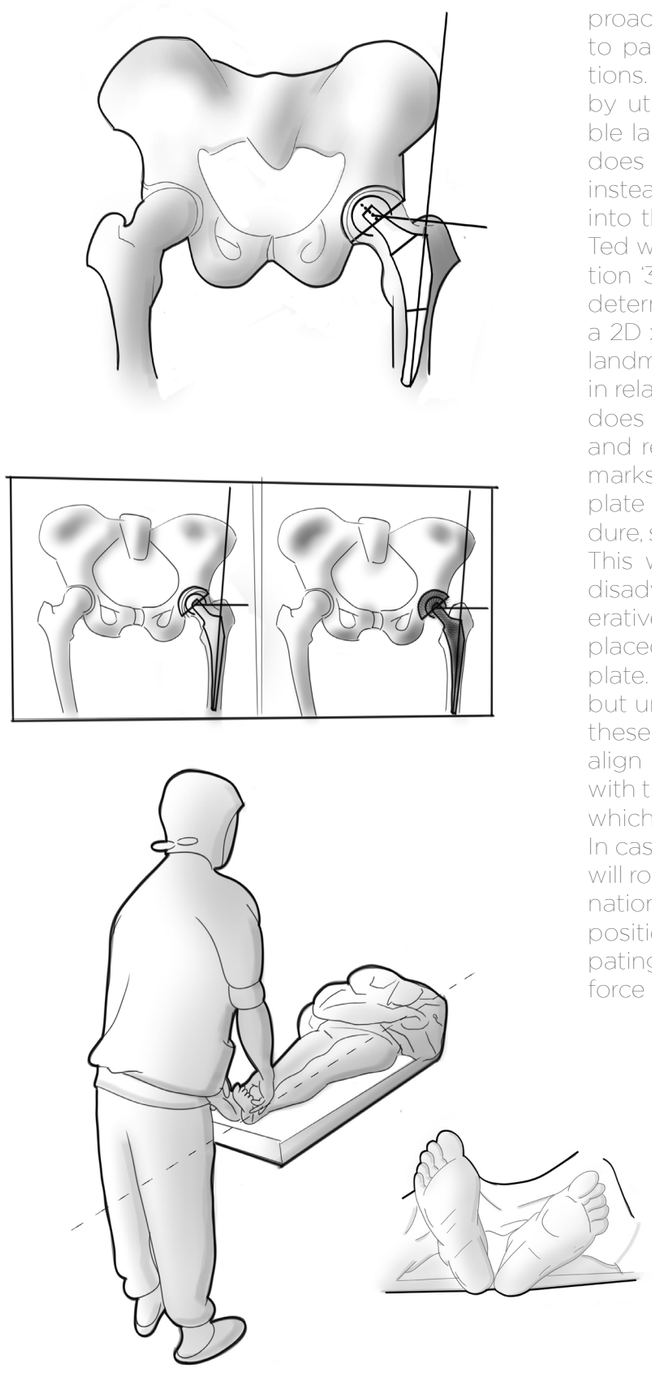
The final methods pillar is primarily formed by years of experience and practice. Every surgeon will develop small methods or tricks for different stages of a THA, which they were informed by through peers or academia. Eventually every surgeon will hand down these methods to their trainees, who in turn may adapt these methods or alter them slightly to their liking.

3.3.2 Personas

To visualise the different workflows within a THA better, two personas have been created. These personas are based on observations carried out at both hospitals, where in total four surgeons were followed and studied. The previously mentioned three pillars form the basis of understanding for the two personas: Fluoroscopy Flyn and Templating Ted (Fig. 27).

Flyn prefers the anterior approach and was trained to perform Fluoroscopy. This means that Flyn utilises an X-ray during the surgery to periodically check the patient's internal anatomy and compares the x-rays taken to the preoperative one in real time. Flyn will divide his OR into sterile and non-sterile zones along the length of the OR table. This means that the surgical site will be separated from the rest of the patient's body by a transparent vertical drape. This allows for the x-ray to be in the non-sterile zone and allows for secondary surgical team members to assess the patient's LLD, as the patient's feet are in the non-sterile zone too. For more detail on the OR Layout see the next section and Fig. 28. During a LLD assessment, the circulating nurse will bring together the patient's feet along their bodies centreline, move them in various directions to straighten out the pelvis and then press their thumbs into the patient's heels in order to evaluate whether they can feel a difference. This is what is called a loaded-assessment and is meant to give a better impression of how the lower body system performs during a 'standing' simulation. Sometimes Flyn will try to help the circulating nurse by pressing the patient's feet into a plantigrade position (90 degree angle), in order to simulate more realistic conditions. When the circulating nurse is unsure, Flyn will try to feel the difference through the transparent vertical drape, which can be challenging.





Ted sometimes performs the Posterior approach, yet prefers the Anterior approach due to patient recovery time and recent publications. Ted has been trained to perform THA by utilising templating and orienting via visible landmarks within the patient, therefore he does not use a transparent vertical screen, but instead places the patient's entire lower body into the sterile zone. Days before the surgery, Ted will utilise a templating software (see section '3.3.6 Market Matrix Mapping'), in order to determine the right component sizes based on a 2D x-ray image. Ted will pick out anatomical landmarks on the x-ray and place the implants in relation to these points. This means that Ted does not use an x-ray during his procedures and relies solely on his identification of landmarks and preoperative templating. His template is visible on a screen during the procedure, so that he can verify the implant position. This way of performing the surgery has the disadvantage that only after taking a postoperative x-ray Ted will be able to see how well he placed the implants in comparison to his template. Ted too will periodically check for LLD, but unlike in Flyn's case, he primarily performs these assessments himself. He will collect and align the patient's feet along their centreline, with the feet in pronation at a 30-degree angle, which allows him to observe the patient's heels. In case a surgical drape is blocking his view he will rotate the feet to normal (straight not supination), potentially force them into plantigrade position and try to feel the difference by palpating the patient's heels. Ted will not exert any force or simulate any load conditions.

Fig. 27 - *Personas: Fluoroscopy Flyn (left) and Templating Ted (right)*

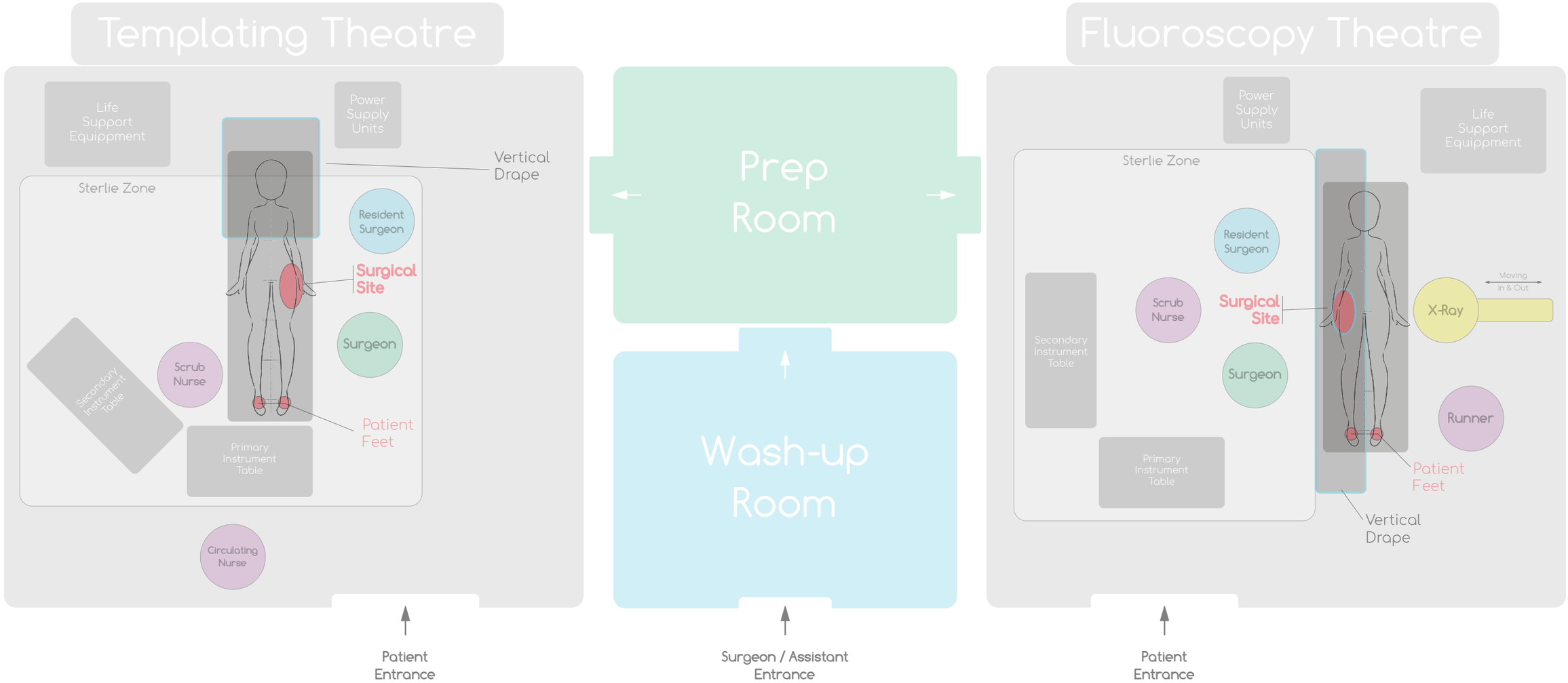


Fig. 28 - *Overview of templating versus fluoroscopy OR layout*

3.3.3 OR Layout

In order to get a better understanding of the spatial context of an OR and the roles of each actor withing it, a top-view schematic has been created for the Fluoroscopy style setup, as well as the templating style setup (Fig. 28). As can be seen from this schematic, each OR has two adjacent rooms next to it: the wash-up and the prep-room. These two rooms are only entered by the Surgeon, Resident Surgeon, Scrub Nurse and preparation personnel. After a few procedural preparations, the Surgeon, Resident Surgeon and Scrub Nurse, will leave the operating theatre through the patient entrance and start cleaning in the wash-up room. From here they will enter the prep-room, where they will be dressed in sterile personal protective equipment (PPE). From the prep-room, where also all instruments and equipment get prepared, they will enter the operating theatre and walk straight into the sterile zone, without touching anything on their way to avoid contaminations. As soon as they are within the sterile zone, they will be dressed in a second layer of PPE, to raise the safety level.

On the fluoroscopy schematic can be seen that the vertical drape is hung between the patient and the sterile zone, allowing for the patient's feet to be in the non-sterile zone (also see Fig. 29). This allows for the Circulating Nurse to perform LLD checks during the procedure, without requiring any PPE other than a surgical mask and gloves. At this point it is important to mention that this set-up is not standard procedure even when performing fluoroscopy, but illustrates well that there really are immense variations in workflows between surgeons. As mentioned previously, every surgeon and their surgical team develop their own methods and procedures, therefore customising their unique workflow and OR setup. The most striking difference between the two setups is the x-ray machine, or rather the lack thereof. For orthopaedic surgeries, the x-ray will have a C shaped arm that is retractable (Fig. 22), the x-ray detector hovering above the OR table and the x-ray generator beneath. After being referenced with the patient and OR table, its position in the room is locked and the arm is retracted away from the surgical site. When OD assessment is required during the surgery, the radiological assistant will extend the arm, take an x-ray and retract the arm again.

The majority of surgeons will have their patient's feet within the sterile zone, so that they can evaluate LLD with a minimal amount of surgical drapes in the way, as is the case in the templating setup. On the templating schematic can be seen that the general room setup is comparable to the previous setup, but varies around the OR table. The first difference is that the sterile zone encompasses the lower part of the OR table and therefore places the patient's feet within it too. Additionally, the instrument tables are differently distributed, as well as the surgical team. In particular the position of the scrub nurse on the other side of the OR table is noticeable. This is made possible due to the lack of an x-ray machine.

Fig. 29 - *Patient outside terile zone separated by transparent surgical drape (fluoroscopy)*

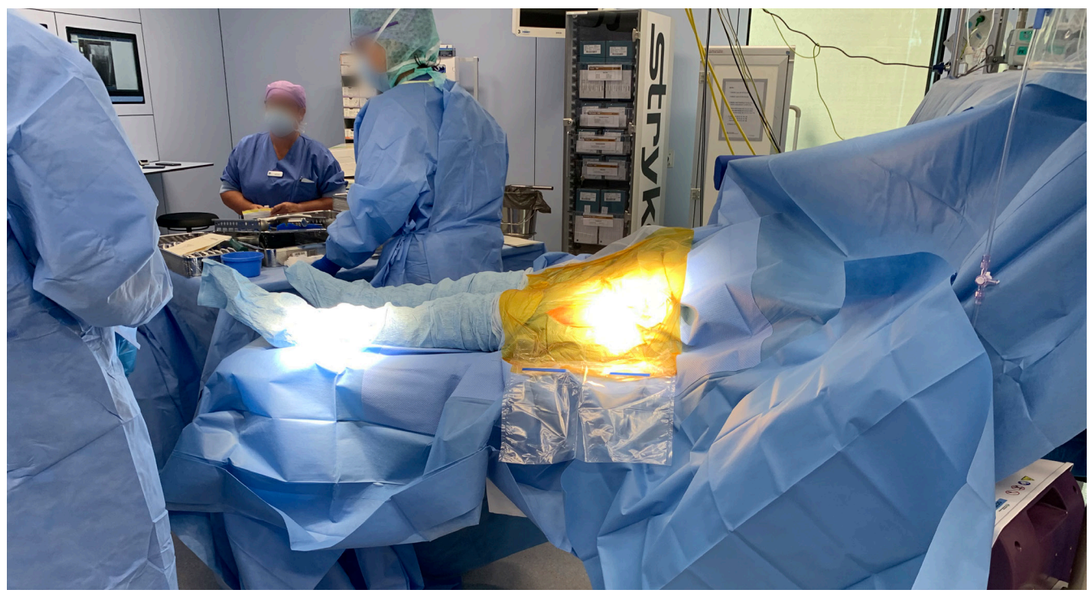


Fig. 30 - *Patient inside sterile zone covered in surgical drapes*

3.3.4 Surgical Timeline

For creation of the surgical timeline, resulting insights and information from observations was condensed into a timeline (Fig. 33). This timeline visualises the different steps taken during a THA, including detailed descriptions, the stakeholders involved in each step, the time taken for each step (averaged over multiple procedures) and iterative processes with the corresponding time required for each iteration (to be multiplied by the amount of iterations). The two previously observed workflows and their overlaps have been visualised on the timeline, blue being fluoroscopy and green being templating. Additionally, relevant but difficult to verbally describe steps were visualised in pictures. Furthermore, colour coding has been applied to steps which are of high importance to the scope of this project. There have been three high importance moments identified: LLD assessment, OD assessment and Patient repositioning.

As can be seen from the timeline, the average THA will take 80 minutes on average, including OR preparation and clean up. Once the final acetabular component is placed inside the patient, the 'Iterative Space' starts (step 21). This space describes the timeframe during which the surgeon and his team try to find the appropriate femoral component configuration for the patient, which may take multiple iterations. If all steps succeed on first try, the steps in this space will be concluded within 11 minutes (on average). On the contrary, if the surgeon needs to make multiple iterations, these steps will take up to 26 minutes, which is an increase by 19% over the entire timeline. It is noticeable, that with every iterative cluster for fluoroscopy all three high importance moments take place in this order: Patient Leg Repositioning, OD Assessment and LLD assessment. In case of templating, the OD assessment can be neglected due to the described lack of an x-ray.

Fig. 31 - *Circulating nurses repositioning patient's legs*

Fig. 32 - *Circulating nurses performing LLD check*

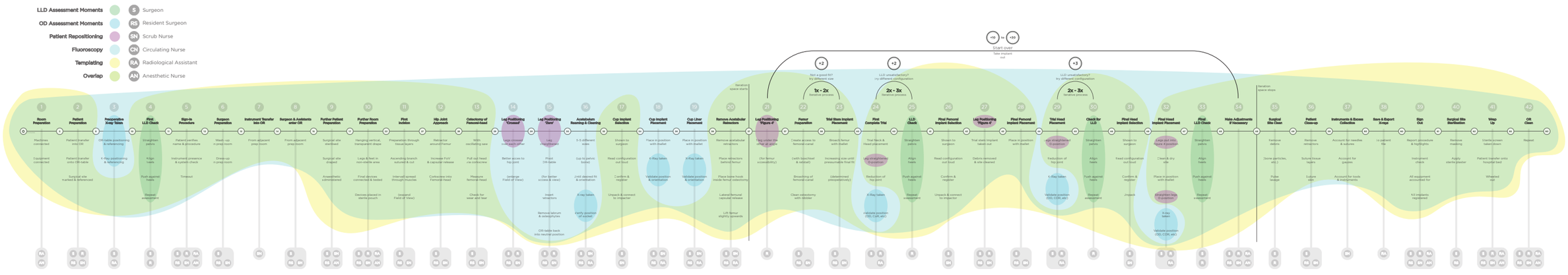


Fig. 33 - *Surgical timeline (small)*

Fig. 34 - *Figure 4 position*

Each of these consecutive moments builds on top of the previous one and therefore needs to be carried out correctly. For example: if the patient's legs are not positioned in exactly the same way before every assessment, the result of different evaluations may differ. If the OD assessment indicates incorrect positioning, the result from the LLD assessment may be non-admissible. Likewise, if during the 'First Complete Trial' (step 24 - 25) the LLD assessment is unsatisfactory, then the configuration may be incorrect and leading to unsatisfactory results during the 'Second Trial' (step 29 - 30) and the 'Final LLD Check' (step 33). Lastly, if during the 'Final LLD Check' the result is unsatisfactory, the surgeon will have to remove the entire femoral component and start again from the beginning of the iterative space (step 21).

This will not only increase the length of the procedure but will also render the used femoral component unusable, which therefore will be discarded.

This shows that more accurate and reliable evaluations of OD and LLD will result in faster assessment and iterations. More reliable measurements may even result in less iterations overall and reduced risk for incorrect placement of the femoral component. Considering that each evaluation moment takes up around one minute during the procedure and with respect to the findings of the literature review (chapter 2), it is of importance not to add any time or effort to the assessment. This solution criteria counts for the evaluation moments themselves, but also for the OR preparation time (see step 1).

Fig. 35 - *Crossed legs position*

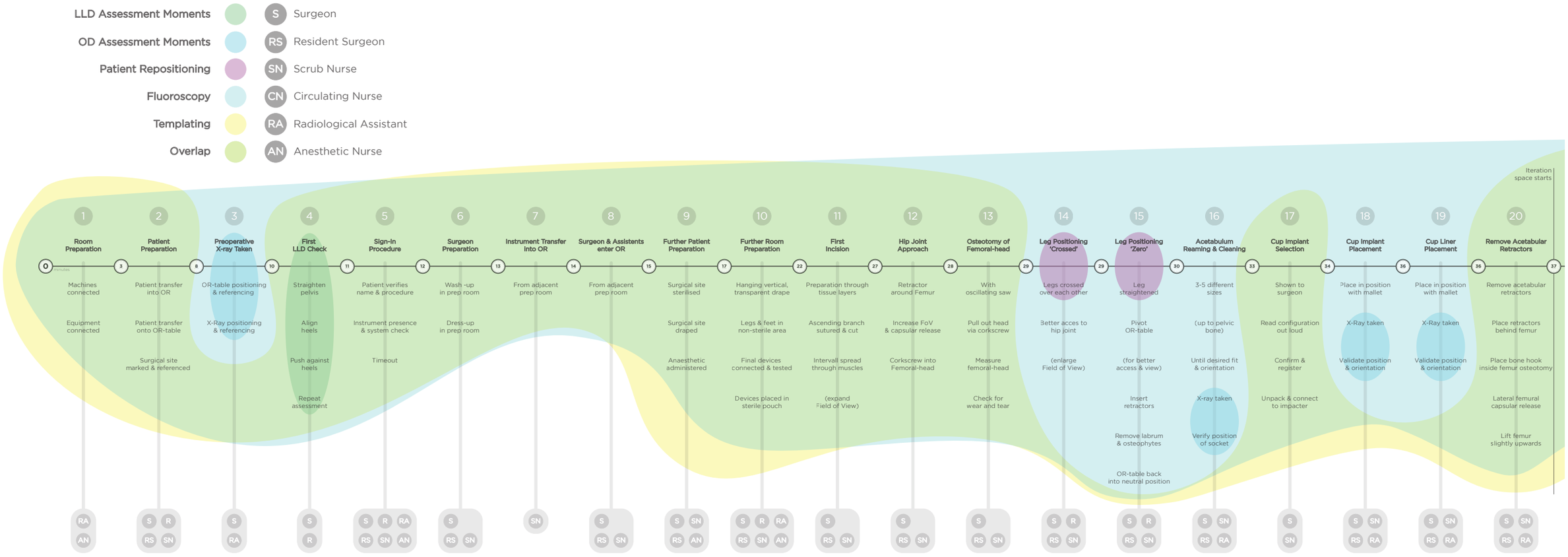


Fig. 36.1 - *Close-up of surgical timeline (part 1)*

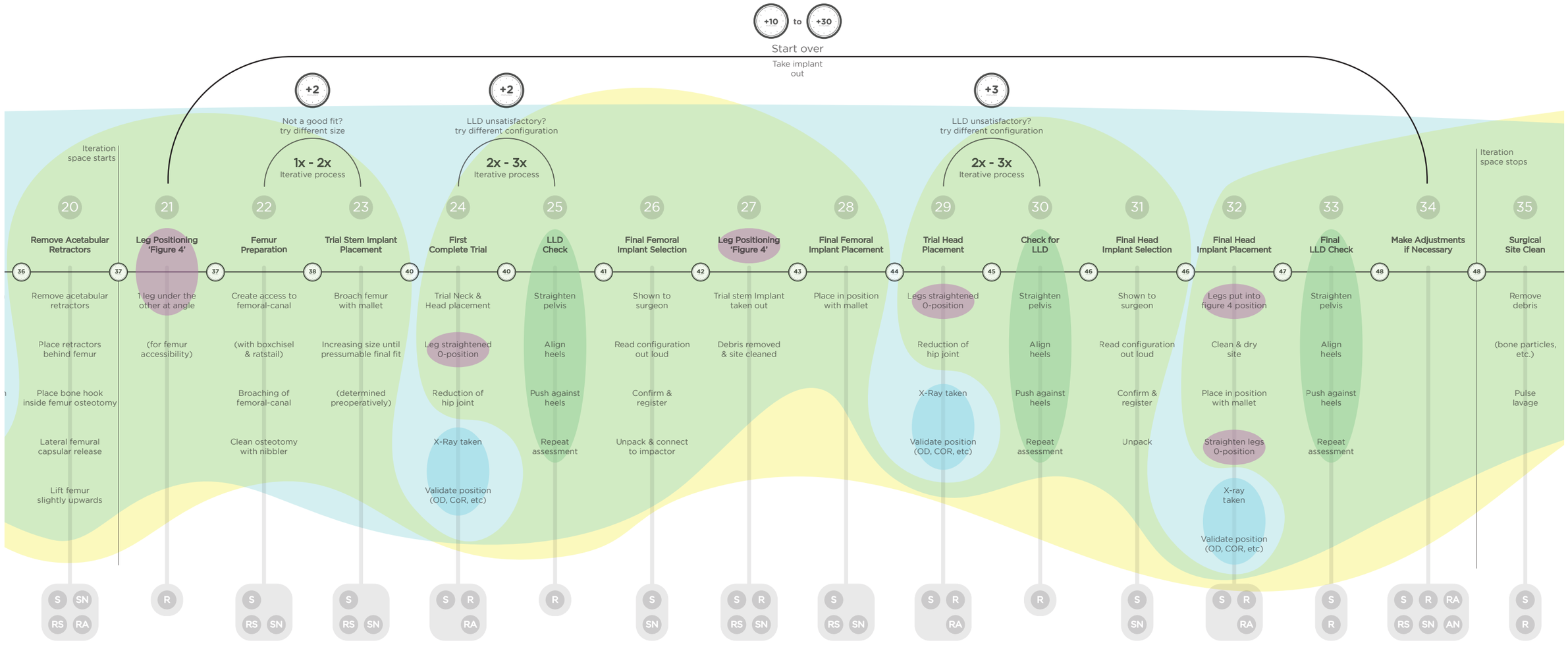


Fig. 36.2 - *Close-up of surgical timeline (part 2)*

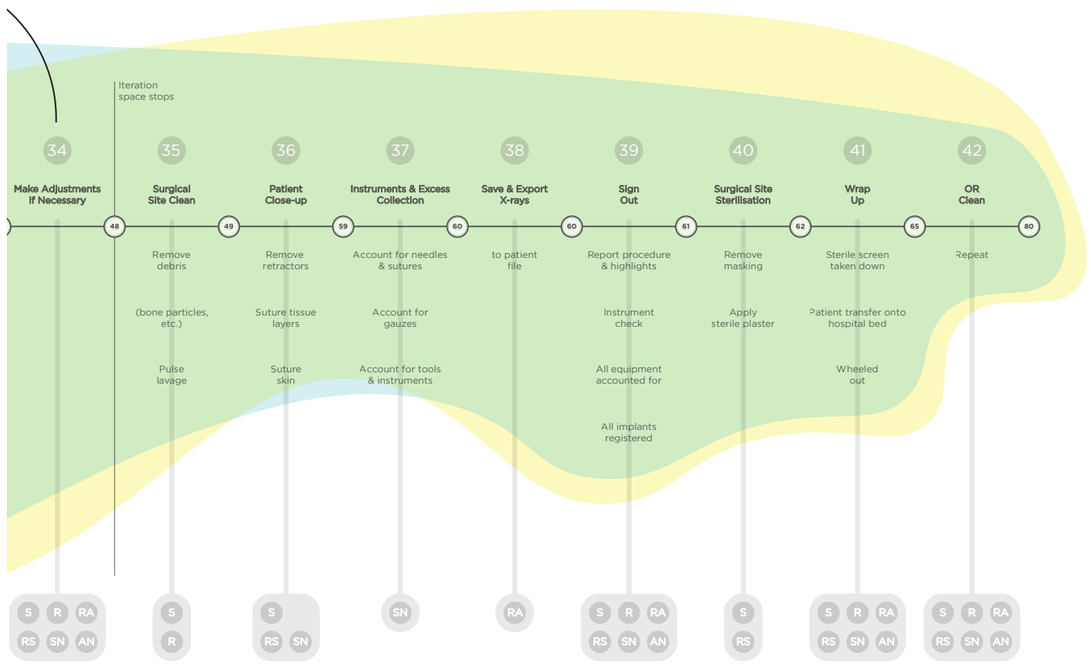


Fig. 36.3 - *Close-up of surgical timeline (part 3)*

3.3.5 Survey Results

The survey distributed among staff of RDGG and RHOC offered some conclusive insights into the cognitive thought processes of surgical team members. Six surgeons, three resident surgeons and two circulating / scrub nurses participated and offered many insights of which the most relevant are mentioned below. For more detailed insight on survey results see Appendix C.

The anterior approach is to be the most frequently performed approach, followed by the direct lateral and posterior approach, making the focus of this work suitable. Five out of nine surgeons have used fluoroscopy as assessment / navigation method to perform any of these approaches and a Net Promoter Score (NPS) of 20 seems to indicate that they feel comfortable doing so. When being asked whether the participating surgeons have ever performed surgery using computer-assisted (imageless) assessment / navigation methods, seven replied that they have not, whereas two have used image-based computer-assisted methods. The surgeons that have used such methods provide a NPS of -50 when asked how comfortable they felt using these methods. These insights indicate that advanced solutions like image-based assessment / navigation methods are not commonly seen and do not provide the desired ease of use expected of such a system in the given context.

When being asked about LLD and FOD assessment, all participants report performing an assessment preoperatively. The methods mentioned by surgeons range from physical examination of landmarks such as heels, knees, ankles and iliac crest height (when standing) to X-Ray images (lesser trochanter, acetabular teardrop and other landmarks). Circulating nurses also rely on palpation of heels, medial malleoli and analysis of x-rays. When asked whether surgeons compensate for preoperative LLD intraoperatively, seven replied that they do, whereas two do not. When asked about the method of compensation used the answers range from fluoroscopy, preoperative templating and sizing the prosthetic components (anatomical landmark orientation) - head size (offset head) and neck angle. When surgeons were asked whether they assess LLD and FOD intraoperatively themselves, six said that they do so, whereas two said no and one surgeon saying that circulating nurses performs these checks in his OR.

Regarding intraoperative assessment of LLD, eight out of ten participants say that they perform their assessment by examining the patient's heels, two also use the knees, two the ankles. Additionally, two also mention telescoping (testing tissue and ligament laxity) and one takes the tip of the trochanter and centre of rotation (CoR) of the ball and socket joint as their evaluation reference. Interestingly, four participants choose to deploy multiple methods to make their assessment, validating findings from chapter 2. For intraoperative assessment of FOD, seven out of ten participants reference orientation via landmarks made visible through fluoroscopy, whereas the remaining three rely on templating and non-radiographical identification of visible landmarks within the patient.

When asked about which factors may confuse their assessment of LLD and FOD intraoperatively, seven out of ten mention the position of the patient (that may change throughout the procedure), of which four specifically reference pelvic tilt (PT). Additional factors include the x-ray settings, dysplasia of the non-operative hip, instability of the hip and cup position.

When asked about performance of postoperative assessment of LLD and FOD, nine out of eleven participants answered this question positively, whereas two say that they do not perform any assessment postoperatively. When asked once again what methods are used for the assessment, five out of nine mention physical examination and seven mention (weight bearing) x-rays. Interestingly, in total five participant mention multiple assessment methods. When asked what acceptable LLD is in their opinion, eight out of ten answered 10 mm or less, of which four believe 5mm or less is acceptable. When asked the same question about FOD, seven replied with 5mm or less.

Overall, the above mentioned insights are satisfactory to the expected outcome and inform the desirable direction of this project sufficiently.

3.3.6 Market Matrix Mapping

Current solutions within the field of Orthopaedic surgery range on a wide spectrum. From manual or analogue measuring tools up until robotic arm navigation systems. All solutions have their own unique application field and value proposition, usually rooted in their technological makeup. Yet all of them require different procedural steps or assist the surgeon during different parts of the surgery.

In order to get a sense of the market saturation and visualise primary market gaps, the first matrix was chosen to be general, with one scale trading off between analogue / digital solutions and the other scale trading off navigation (active) / validation (passive) solutions (Fig. 37). Unsurprisingly, it was found that all manual instruments collect themselves in the analogue / validation (passive) quadrant of the matrix, whereas more modern and high-tech solutions find themselves in the digital / navigation (active) quadrant. This visualises that both the analogue / navigation (active) and the digital / validation (passive) quadrants are entirely empty. In the case of the first, it should come as no surprise, as analogue / navigation (active) solutions would be rather cumbersome, potentially expensive and time consuming to operate. On the other hand, digital / validation (passive) solutions that do not attempt to navigate the surgeon but intend to enhance the surgeons conventional workflow may be of interest. Due to their passive nature, solutions within this space would require a minimal learning curve, while maximising the potential to fit various surgical workflows.

Diving more into detail and creating potential to utilise medical imaging techniques, the scales of the second matrix display invasive / non-invasive on one scale and imageless / image-based on the other scale (Fig. 38). All modern solutions will use some form of medical imaging technology as a primary input for analysis of the patient's anatomy. Navigation solutions will typically use CT scans and Pre- and intraoperative templating software solutions will use x-ray images. As can be seen after plotting the solutions, not much changes in terms of distribution of the solutions. All analogue tools are still separated from the digital solutions. The only outliers are software based templating solutions, which fall into the image-based / non-invasive quadrant.

Given that only templating solutions are found in this space, it can be argued that there may be room for solutions that do or do not rely on 2D templating but fall into the same quadrant (e.g. 3D templating as opposed to 2D templating). The primary opportunity area of this matrix however are imageless / non-invasive solutions, due to their passive potential (aligned with the first matrix), lower cost and simply lack of invasiveness to the patient. It should be stated that non-invasive solutions are the future aspiration of medical assessment technology, yet are also harder to realise. Nonetheless, reduced production costs, lower regulation requirements and faster patient recovery are all benefits that make this direction worth exploring.

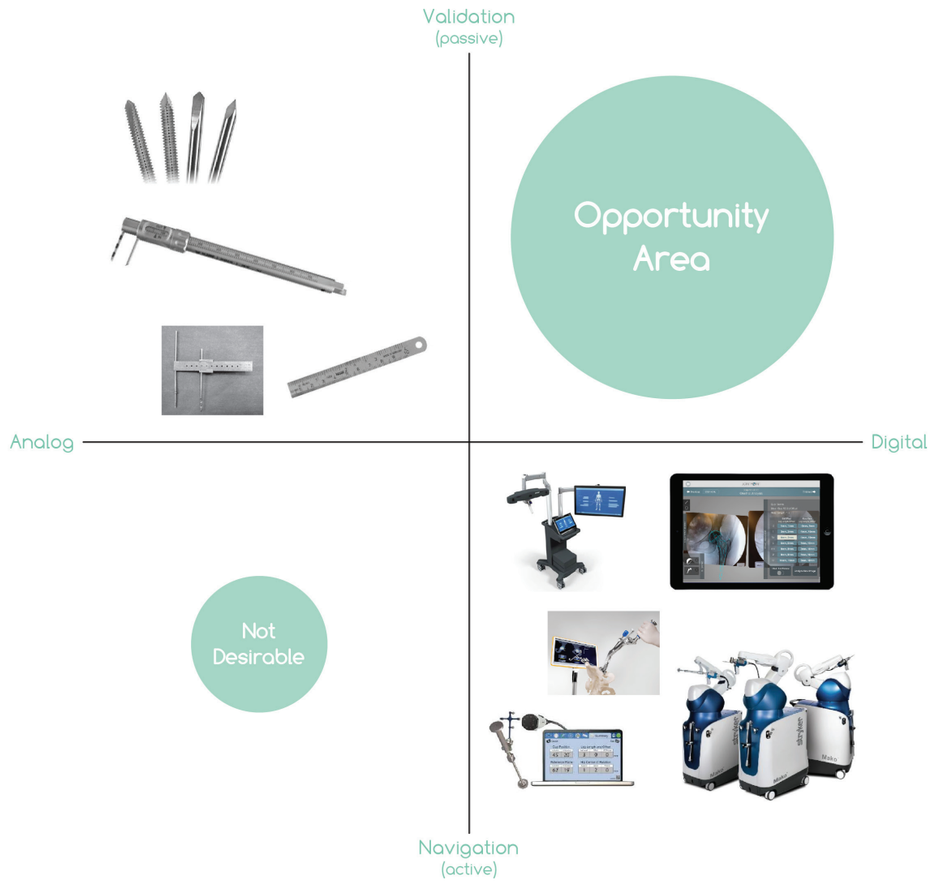


Fig. 37 - *Market matrix showing opportunity for passive, digital solutions*

Fig. 38 - *Market matrix showing opportunity for imageless, non-invasive solutions*

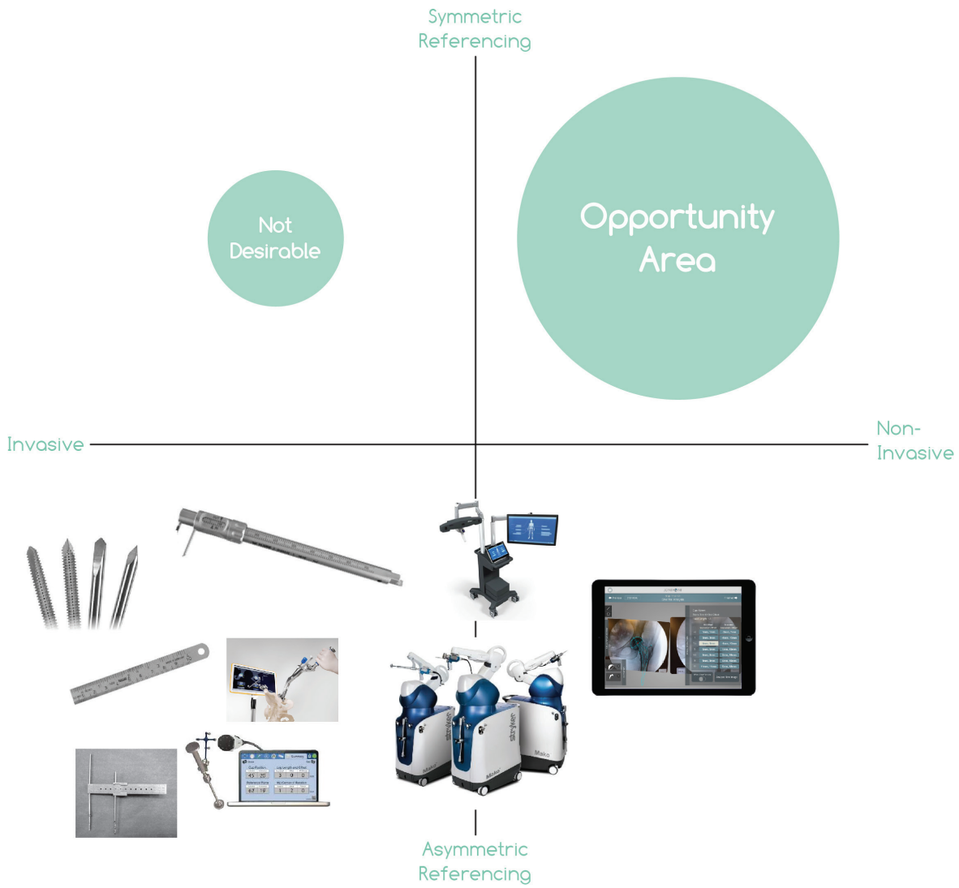


Fig. 39 - *Market matrix showing opportunity for symmetric referencing, non-invasive solutions*

The final matrix retains the invasive / non-invasive scale and combines it with symmetric referencing at one end and asymmetric referencing on the other end of the second scale (Fig. 39). Now the image shifts drastically, digital and analogue solutions start to mix and distribute themselves along the invasive / non-invasive scale, while mostly staying within the asymmetric referencing space. The only solutions that manage to break through to the symmetric referencing quadrant are the ones that make use of CT scans as primary analysis input. As previously mentioned, CT scans can provide information about both legs and are cheaper to carry out than their more sophisticated and comprehensive counterpart, MRIs. Be that as it may, there is a financial entry barrier and most hospitals will rely on simple 2D x-ray imagery to establish preoperative plans.

Nonetheless, all of the solutions utilising CT scans still rely on invasive components in order to track the position of instruments and patient. This makes it the main argument against that direction, as unnecessary damage to the patient would like to be avoided making the invasive / symmetric-referencing quadrant undesirable. On the other spectrum however, creating a non-invasive / symmetric referencing solutions makes a lot of sense. Not only would it be less invasive to the patient, but it would allow for assessment of the entire lower body system, potentially creating the most desirable result. Another advantage, under the aspect of the anterior approach, a solution within this category would allow for simulations of loads on both of the patient's lower limbs, allowing for observations of how different load cases affect the patient's LLD and FOD.

3.4 Discussion

3.4.1 General

In this chapter, the final chapter of the Discover Phase, first hand insights into the daily workings of surgical teams and their cognitive processes was gained and summarised. It becomes important to cross reference these insights against the research questions and evaluate which parts are relevant for the continuation of this work.

3.4.2 Research Questions

How to more accurately reference, assess and dimension lower limbs while considering a patient's individual anatomical differences?

After analysing various workflows, OR layouts and observation insights, it seems that the most promising direction forward is the adoption of a protocol that ensures accurate patient repositioning and evaluation of lower limb functionality. Technologically, various approaches are possible, yet few are sensible. Many non-invasive high-tech solutions are still in their exploration and research phases, from an OR point of view. For example, using Augmented Reality (AR) glasses in combination with machine vision in order to reference, assess and dimension a patient's lower limbs (with input from MRI or CT scans) is by today's standards not accurate enough for surgical application. Although likely feasible in the future, today's implementation of such technologies would require the use of physical trackers, which when attached to the patient's skin are prone to great error margins. It is to be considered whether a digital but low-tech approach may be more desirable to achieve a functional assessment of the lower body system.

How can symmetry be evaluated and created in an asymmetric biomechanical system?

Considering current technologies, it is feasible to analyse the patient's lower body anatomy via MRI or CT scans, assign functional priority in respect to symmetry and simulate it in different use conditions in order to evaluate what results formulate positively in respect to various implant configurations. Software solutions are extremely suitable and capable of producing virtual simulations with reasonable accuracy today. Yet one challenge still remains in translating these virtual ambitions into practice. Currently, the private sector is heavily investing in robotic technologies to bridge that gap, which is a costly and research intensive undergoing. This high financial entry barrier is likely to hinder these technologies from wide spread adaptation, making it accessible to only selected hospitals and surgical teams. Reverting to the earlier mentioned digital and low-tech approach, this entry barrier is diminished. Instead of deploying advanced machinery into increasingly complex ORs, one ought to consider what is possible with less or already existing resources.

What role does the patient's position play during repeated LLD assessments?

The answer to this question has not changed much since the last chapter and was partially answered with the first research question. The survey in particular validates that patient repositioning in between assessment can greatly confuse the assessment of LLD and FOD. Observations in the OR showed that users will try to mitigate the risk of a tilted pelvic (for example) by lifting the patient's feet up high or moving them from side to side. This observation brings about the question whether such a 'limb movement protocol' would be advisable to implement into any potential solution. With the importance of the patient's position during repeated assessments established, this aspect will remain under close consideration.

How can post-operative LLD be prevented during THA, without disrupting conventional surgical workflows?

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As addressed at the end of chapter 2, enhancing current protocols and methods seems to be the least disruptive approach. In particular the surgical timeline offers great insight into overlapping areas between workflows and

therefore moments of opportunity. It is noticeable that FOD assessments do not take place with templating style surgery, meaning that it may be difficult to include it into the solution scope. Instead the focus will primarily lie on LLD assessments and how they are performed by the different surgical teams. Any device developed needs to accommodate the evaluation methods described for each persona.

How can high-tech solutions be empowering to the user and provide a sense of control?

The only way for high-tech solutions to be empowering to the user is to include them in the process. During the development of technological solutions, it is necessary to build the human aspect into a system, if one wishes its users retain a sense of control. In particular within an OR the human aspect is extremely important. An arguably small amount of people like the idea of being operated on by an completely autonomous robot, neither the patient nor the surgical team. Healthcare has always been and hopefully will always be based on the evaluating party to have an understanding of what it is like to be human, therefore it is advisable to allow the user to become part of the solution. The human, does not fall short of skills and abilities and if these skills and abilities were to be enhanced in an intuitive and user friendly manner that is quantifiable and therefore repeatable, we would not need to take the human aspect out of any OR solution.

3.4.3 Limitations

Overall the outcomes of this phase are satisfactory, considering the contextual requirements in 2020. It would have been beneficial to carry out more observations and in-depth interviews with experts, yet unfortunately moments of direct contact were scarce and it is an understatement to claim surgical teams are busy, even in normal working conditions. Moreover, the survey participation turned out to be rather low, as it was primarily focussed on the two hospitals (RDGG & RHOC). An attempt was made to distribute the survey among the Dutch Hip Association to increase participation numbers, without success.

Key Insights

- Surgical workflows are created by circumstances, which can be best described as the three pillars of surgical workflow customisation: Approach, OR Setup and Methods.

- Every surgeon will develop small methods or tricks for different stages of a THA, which they were informed by through peers or academia

- A loaded-assessment and is meant to give a better impression of how the lower body system performs during a 'standing' simulation.

Chapter 4

Problem Definition

Problem Definition

4.1 Background

In the first three chapters (Discover phase) a vast amount of insights has been gathered. Some of which link directly to the scope, while others fall outside of it. Chapter 1 gave a holistic overview of the topic, recent and past developments and hinted at underlying issues with the main objective. Chapter 2 provided a comprehensive overview of the academic literature, associated with the topic's identified key focus areas. In Chapter 3, detailed insights into the OR and biomedical industry were gained from first hand reports, observations and through analytical methods. In this chapter, which marks the start of the Define Phase, all of these insights are translated and defined into concrete problems. These problems and other results obtained during the Define phase, form the basis for ideation, particularly playing a significant role during co-creation sessions (chapter 5).

4.2 Method & Procedure

The method 'Problem Definition' from the Delft Design Guide was leading in finding appropriate means to formulate the problems associated to the topic and scope.

"A problem always has to do with the dissatisfaction about a certain situation. Because satisfaction is a relative concept, problems are also of relative nature. They are defined from the perspective of a problem owner."
(Delft University of Technology, Faculty of Industrial Design Engineering, 2014)

Considering the complex nature of this topic, it must be realised that in a clinical context there is a multitude of problem owners to a single problem. Nonetheless, in a bid to simplify our focus the problems in this section are formulated from the primary problem owner's perspective. In this case, our problem owners are surgeons, as they carry the end responsibility and ultimate liability for the outcome of every surgery. Secondary problem owners include circulating nurses, as a surgeon sometimes relies on their LLD assessment in a fluoroscopy style surgery setting. Leaning on the research from Chapter 3, the following sections will illustrate the key findings and opportunity areas before defining the problem focus and deriving solution requirements.

4.3 Findings

4.3.1 Key Findings

The most relevant insight uncovered during the Discover phase, have been formulated into six findings, that will be leading during the Develop Phase.

1. No standard intraoperative method or tool for LLD / OD assessment due to varying workflows

Surgeons customise their workflows, which are a result of their education, training and experience level. Every surgeon will modify their workflow from time to time, based on new insights from academia or peers. This leads to the variety in methods that surgeons deploy in order to assess LLD.

2. Complex Biomechanics of the foot

Regardless of how a LLD assessment on the heels of the patient is carried out during a THA, there always seems to be the problem of the inherent complexity of the foot and its biomechanics. The foot has varying degrees of freedom along three axes, allowing it to go into abduction, adduction, eversion, inversion, dorsiflexion and plantarflexion. When the user wants to assess the length of the leg by pressing against the heels of the patient, both feet acts like levers, making it impossible to be put into a 90 degree position without an extra hand. That in combination of trying to apply equal pressure on both heels makes it difficult to hold them in a symmetric position. Overall, it takes skill to carry out this assessment by a single person which hinders a qualitative assessment.

3. Limited support of conventional workflows in surgical navigation solutions

Current industry trends are pointing unanimously towards Robotics Assisted Surgery (RAS) and navigation of the surgeon. This development aims to semi-automate certain aspects of a THA and ultimately support the surgeon. Unfortunately, the implementation looks different, as little consideration is given for varying conventional workflows. Rather the focus lies on creating entirely new workflows, reducing the adaptability of any given technology.

4. High entry barrier (cost + training) for high-tech digital solutions

State-of-the-art technologies, such as RAS systems, cannot be afforded by every hospital or orthopaedic clinic. Even if so, THAs are prolonged by the extra steps required to operate the system and therefore increase the infection risk for the patient. Most importantly, however, is the fact that surgeons need to be trained in order to be navigated by the system. This requires a significant investment by the clinic.

5. Symmetric intraoperative leg referencing available only in advanced solutions.

If a surgeon wants to quantify their LLD assessment intraoperatively, in respect to the non-operative leg, they need to use advanced systems. These systems will analyse CT or MRI scans and track the patient's position throughout the surgery. This may happen by means of invasive markers placed on bony landmarks and / or tracking of surgical instruments. Although these systems are becoming more common, they are not going to be available in every clinic due to the required investment in specialised equipment and the training of elaborative workflows that comes with it.

6. No interphase method or tool for LLD assessment

Currently there is no device that lets you compare pre-, intra- and postoperative measurements. All measurements utilise different tools and methods during different stages, making independent measuring results incomparable across different phases of the patient journey.

4.3.2 Opportunity Areas

The three most desirable opportunity areas have been created from the insights of previous chapters and were afterwards formulated in an opportunity statement that was combined with the initial design assignment - the design vision.

1. Low-tech and non-invasive solution approach

Nowadays, it is difficult to argue against digital solutions, nonetheless ORs are extremely crowded and notoriously busy with state-of-the-art technologies. It is tempting to look towards technologically advanced solutions like AR, machine vision or robotics and add it to the abundance of technologies already available in the OR. Yet contrary to current trends, a more low-tech approach may be favourable at times. Not only would a low-tech approach flatten the learning curve and increase adaptation potential, but such an approach would also most likely require a non-invasive approach. Ultimately non-invasive solutions are more favourable to surgeons and patients, due to decreased infection risk and faster recovery time.

2. Non obstrusive solution approach

An operating room is sometimes referred to as an operating theatre, due to the routine and practice required to perform within it. Even the slightest changes in protocols and procedures can disrupt routines and workflows ultimately leading to irritations and potential errors. In order to support and enhance existing surgical workflows it is important to formulate a solution that is purely validatory in nature. It is not only desirable but crucial not to disrupt the surgical team's workflow and let them validate the effect of their work (in relation to LLD) periodically when required. This allows for adaptation of the solution by multiple teams with differing workflows, as in any workflow it can be used as a validation tool.

3. Symmetric Simulations of loads

Although it seems counter intuitive to simulate an orthostatic (standing) position on a patient in supine position, it makes perfect sense when taking functional requirements into account. As argued before, a patient is unlikely to pick up on LLD while lying down and would rather experience discomfort while standing or walking. Taking this into consideration, it seems an interesting approach to simulate loads onto the lower body system of the patient, to see what effect these loads have on their leg length. It only seems suitable to provide quantified feedback on whether these loads are being applied equally and therefore improve the quality of the assessment. One does need to consider that not every surgical team will perform these loaded assessments, nonetheless the symmetrical aspect of this approach stays equally important. Ultimately, the exact length of each limb is irrelevant, rather the focus should lie on the relative leg length in relation to the other leg.

Considering the described key findings and opportunity areas, a newly informed design vision was formulated.

"Develop a concept that allows for imageless, non-invasive and symmetric evaluation and validation of LLD, which provides digital, data-based feedback in real-time, while complementing conventional surgical workflows for primary THA."

4.3.3 List of Requirements

In order to summarise the most important solution requirements gathered during the Discover Phase, a list of technical requirements was formulated. These requirements form the basis for the start of the Develop Phase and ultimately serves as a validation tool for the Deliver Phase.

Main Requirements

- The product should be specifically designed for use by surgeons or circulating nurses;
- The product should improve the current quality of assessment;
- The product should provide quantified assessment of LLD;
- The product should provide real-time feedback to the user (visual and haptic);
- The usability of the product should empower the surgical team and support their workflow;
- The look and feel of the product should improve confidence in the performed assessment;
- The product is to be used non-invasively.

Context Requirements - Surgical & Patient

- The product is to be used during primary THA;
- The product is to be used inside and outside of the sterile field;
- The patient is lying in supine position;
- The patient's pelvis is perpendicular to the lower limbs;
- The patient's medial malleoli are centrally aligned with the sagittal plane;
- The patient's feet sustain a 90-degree angle during assessment (plantigrade);
- The patient's feet may get loaded with a simulating force / load case.

Context Requirements - Usage & Interaction

- The product should depict intuitive use cues;
- The user should be able to operate the product after 1 training session;
- Preoperative set-up should take less than 1 minute;
- The product must not interfere with intraoperative repositioning of patient's legs;
- Intraoperative assessment must take less than 1 minute;
- The communication of an assessment should be clear and leave no room for interpretation;
- All other communications should be clear and leave no room for interpretation (e.g. pressure difference).

Embodiment Requirements - Component

- The product should have millimetric accuracy;
- The product should have its own power supply or battery;
- All components should be replaceable.
- The weight and shape of the product should allow for portability within the hospital by one person.

Embodiment Requirements - Architecture

- The product architecture should diminish the stresses on secondary internal components during assessment;
- The product architecture should allow for maintenance or repair of internal components;
- The housing should allow for external cleaning with chemical agents;
- The housing should protect internal components from dust and liquids.

4.4 Discussion

4.4.1 General

Considering the complexity of the topic, the problem definition was never going to be an easy task. A lot of issues have to be taken into account in order to have a basis from which to start developing suitable ideas. The key findings as well as the opportunity areas have been chosen based on research but also reflect the directions that are most desirable, feasible and viable for this particular work.

4.4.2 Limitations

It could be argued that the key findings as well as the opportunity areas have a lack of limitation. The List of requirements on the other hand limits itself in the sense that it is meant for primary prototype development. In normal conditions, this list would be much more extensive, including comprehensive manufacturing, maintenance and potentially sustainability requirement. As these aspects fall outside of the scope for this thesis, they are not included.

Chapter 5

Co-Creation Sessions

Co-Creation Session

5.1 Background

This chapter marks the start of the Development Phase, which is based on the two previous phases: Discover and Define. In order to dive more into detail on potential solutions for technical sub-problems, a series of Co-creation sessions was organised including industry professionals as well as informal validatory talks and sessions with medical experts. The goal of these sessions was not only to creatively diverge (second half of the double diamond process) and generate quantities of ideas, but also to validate thought processes and trends. The co-creation sessions, given the circumstances in the year 2020, were held online.

5.2 Method & Procedure

5.2.1 Technical Expert Sessions

Six co-creation sessions were organised with a total of 26 participants ranging from recent graduates of medical and engineering related fields to industry professionals in medical as well as general product development. The methodology used during the sessions was a cross-method approach from the delft design guide, namely Brain writing / drawing and How To's (Delft University of Technology, Faculty of Industrial Design Engineering, 2014).

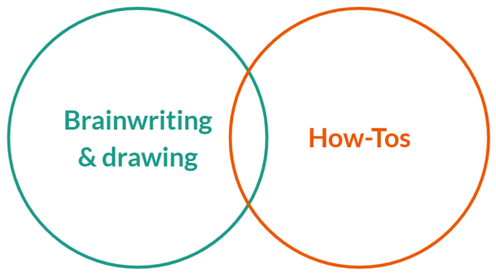


Fig. 40 - *Delft Design Guide methods fusion*

Problem statements were formulated in How To's and participants were asked to generate ideas to any given problem statement within a time limit (2-3 minutes). The How To's were formulated as follows:

1. How to measure Leg Length Discrepancy? (non-invasively)
2. How to simulate loads on the patient's legs? (during a measurement)
3. How to measure pelvic tilt? (non-invasively)
4. How to make a non-obtrusive device? (only present when needed / never in the way)
5. How to measure leg offset discrepancy? (non-invasively)
6. How to give the user a sense of empowerment and control? (during a measurement)
7. How to straighten the pelvis? (before a measurement)

Previous to the actual rounds, participants received an introduction to the topic and problem statements with varying amounts of contextual information. After each session, the process was slightly adjusted in order to improve the quality of results for the consecutive session. All session slides and the equivalent ideas can be found in Appendix D for closer inspection and analysis.

5.2.2 Riddle

In order to abstract the problem statements addressed during the session, a riddle was created and sent to every participant a few days prior to the session. The riddle summarises the various micro-level problems a potential solution might face (identified during the Discover phase) and incentivises the participant to think creatively. This abstraction includes principles of tracking and validating patient position and orientation by creating an analogy to geometric principles in form of a fishing boat and net (Fig. 41). The aim was to mentally prepare participants for the complexity of the topic and playfully get them into the specific problem solving mindset.

5.2.3 Medical Expert Sessions

After the technical expert sessions, all resulting ideas were analysed and sorted into clusters. Each cluster represents either a function or a category for any given solution. This overview formed the basis for primary concept sketches, which in turn were used during two informal validation sessions with the medical expert of the supervisory team. The expert was presented the process of how and why these ideas were formed, before presenting the sketches and giving a brief but detailed explanation about each of them. This opened up a dialogue and allowed for the collection of critical feedback, wishes and considerations. The sketches can be found in section '5.3.2 Concept Sketches' and the equivalent slides (used throughout the medical expert sessions) can be found in Appendix E.

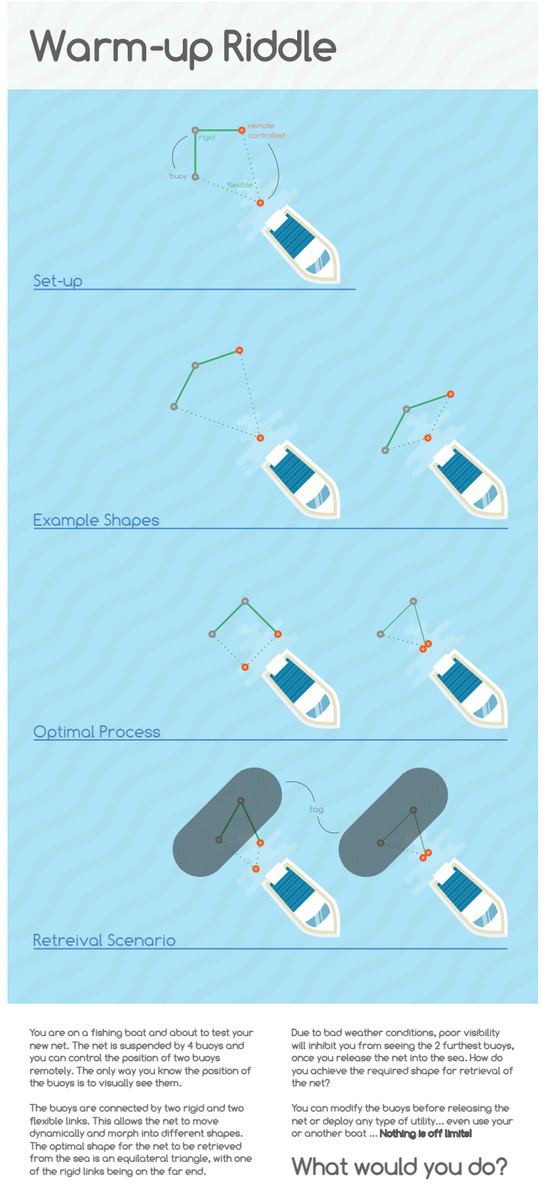


Fig. 41 - *Co-creation session warm-up riddle*

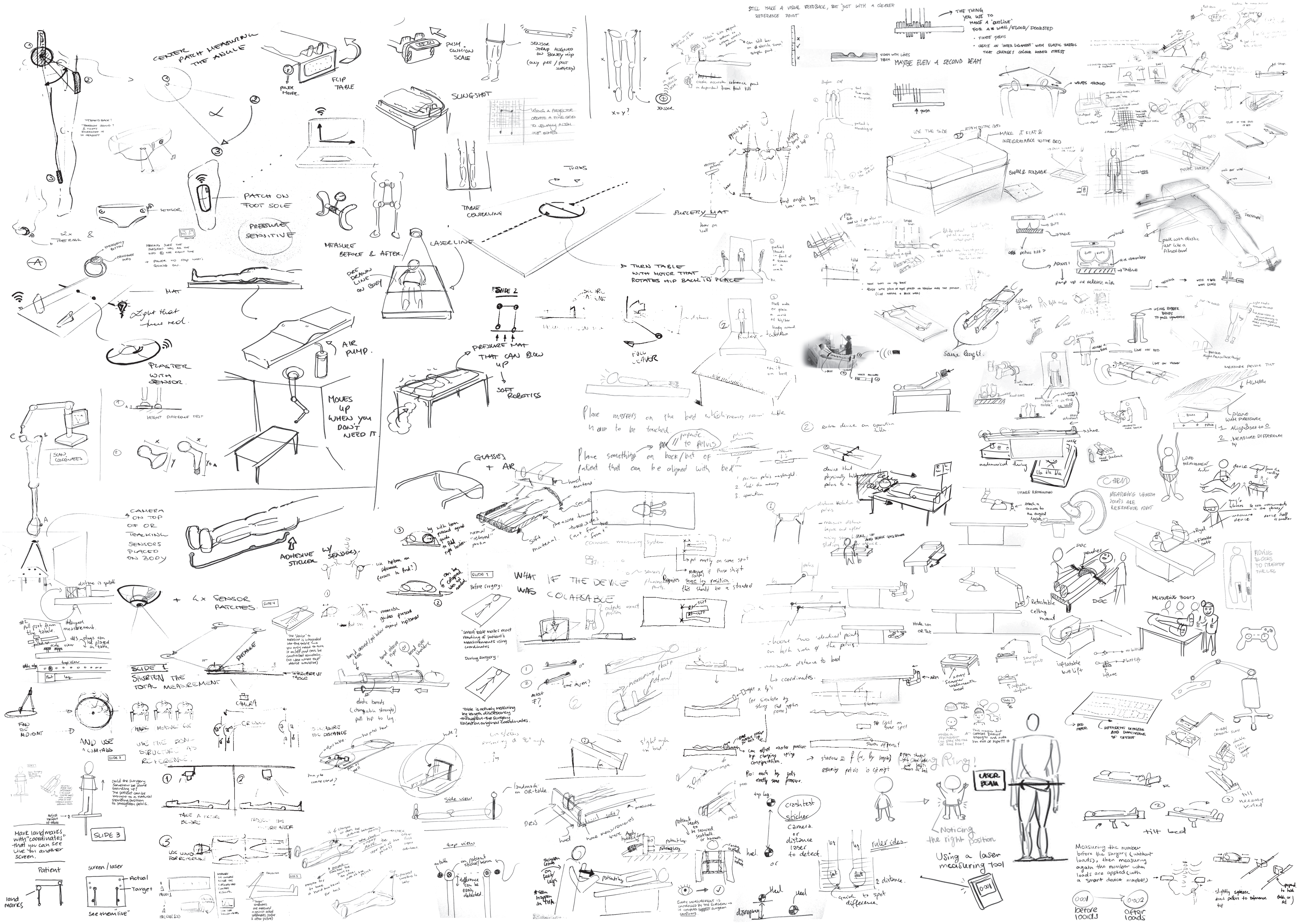


Fig. 42 - Co-creation session sketches

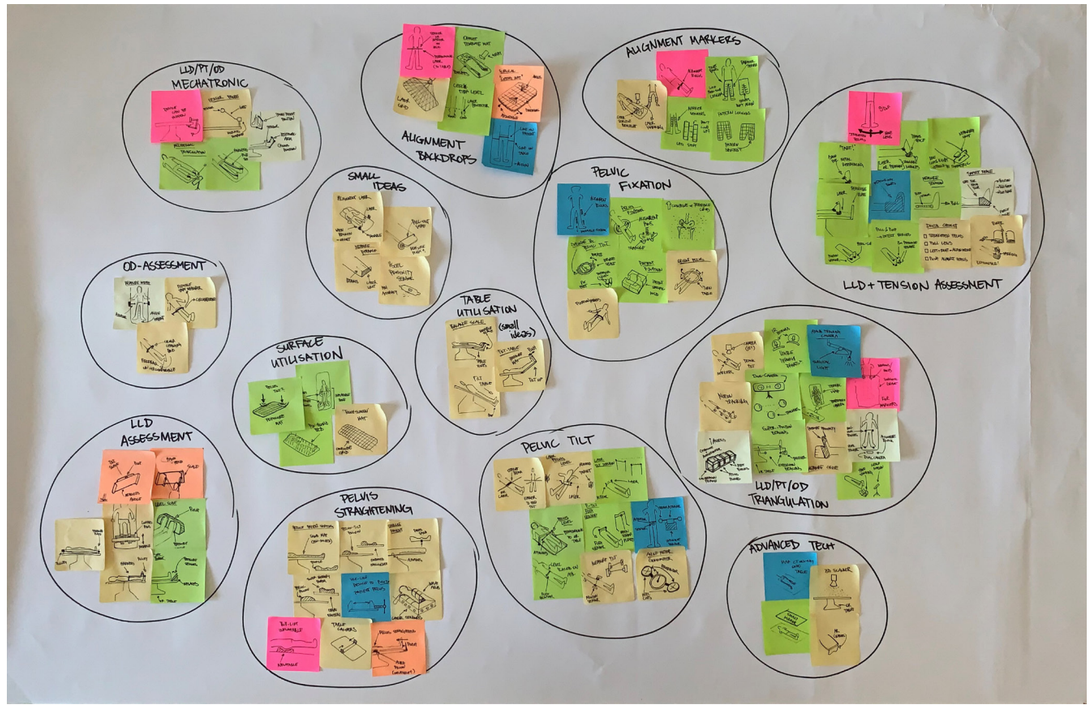
5.3 Findings

5.3.1 Ideation

During ideation, a Post-it chart was created. This Post-it chart is a precursor to the morphological chart in the sense that it is still more abstract than concrete. The Post-it chart started out as a simple collection of ideas, some gathered throughout the research process and some resulting from the co-creation sessions. As a result of the sessions, more than 200 ideas were gathered, however it is important to note that some of the ideas fell outside the scope of this research and were therefore not included. Furthermore, doubled ideas or ideas similar in nature were discarded and only the ones with the highest quality and value, in respect to scope and research goals, were selected for continuance.

The collection in Fig. 43 represents the 90 most original and promising ideas that were selected for the next stages of the project. These 90 ideas were broken off into different clusters which represent the primary function / direction of those ideas.

In Fig. 43 the clusters are visible and it is noticeable that although many ideas were generated throughout the process, only a hand full of semi-valuable ideas for non-invasive OD assessment were generated. This development led to the discontinuance of this direction with the primary focus being LLD assessment from this point forth.



1. LLD assessment solutions
2. FOD assessment solutions
3. PT assessment solutions
4. Pelvis straightening solutions
5. Pelvis fixation solutions
6. Mechatronic solutions (LLD / FOD / PT)
7. Triangulation solutions (LLD / FOD / PT)
8. Alignment markers / backdrop solutions
9. Advanced tech solutions
10. Small independent ideas

Fig. 43 - *Post-it chart clusters (unfiltered)*

6.2.1 Morphological Chart

A morphological chart was created in order to facilitate concept creation. The functions of the chart are based on the problem statements from the co-creation sessions and list potential solutions to each sub-problem, which were collected during ideation. This allows for a visual overview of all potential function combinations or configurations, which in turn enables visual concept creation. Here the ultimate goal, enhancing conventional surgical workflows, was the basis for choosing the most desirable and feasible configurations from the morphological chart. The configurations chosen for exploration and further development are highlighted in Fig. 44. Close attention should be paid to the colour coding that will be used in the following sections.

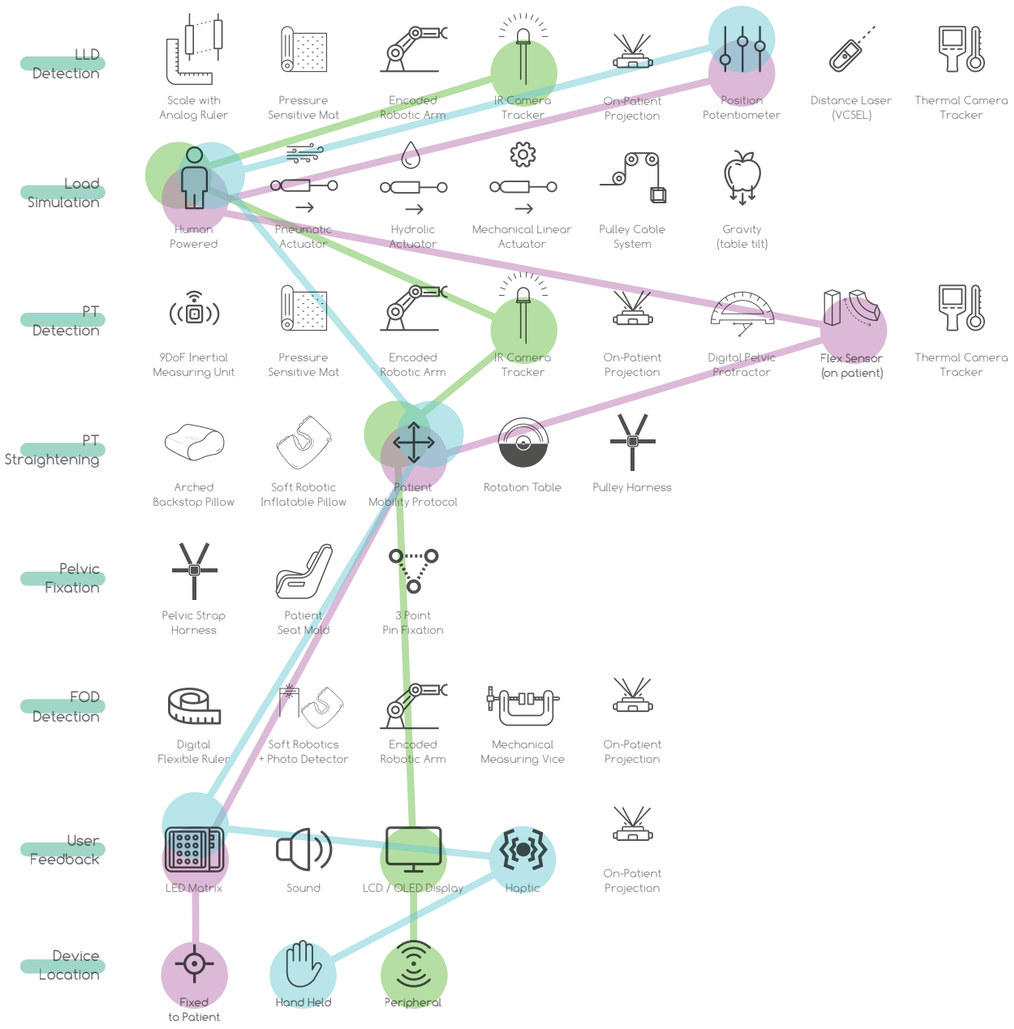


Fig. 44 - *Morphological Chart*

5.3.2 Ideation & Concept Sketches

In this section various sketches of cluster combinations, as well as singular clusters can be seen, explored and studied. The aim was to visualise the most promising ideas from each cluster and in some cases combine them with complementary ideas from other clusters. The colour coding from the morphological chart corresponds with the coding of the sketches. These sketches were used as visual aids during the medical expert sessions in order to discuss desirability, feasibility and viability.

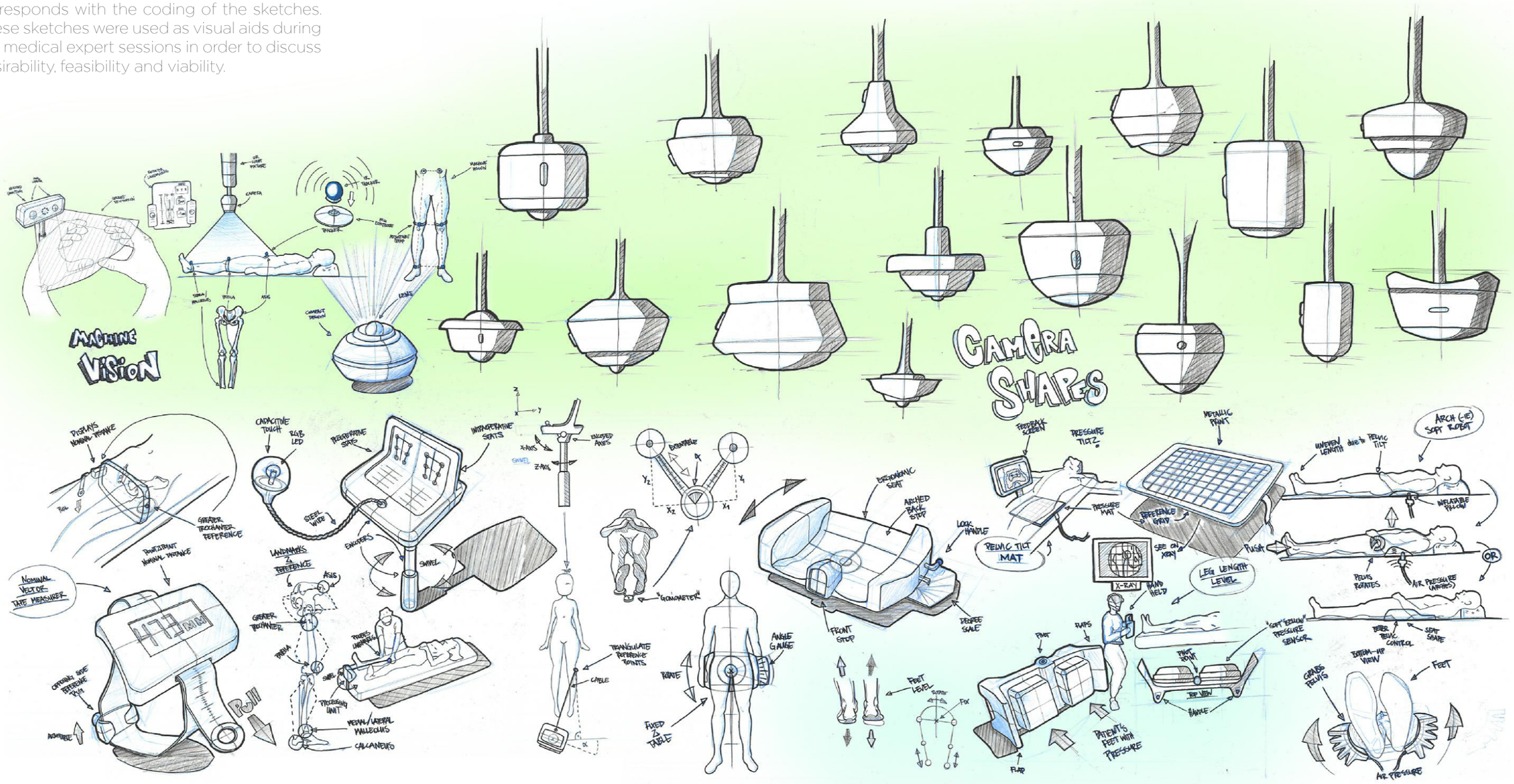


Fig. 45 - *Ideation & concept sketches (part 1)*

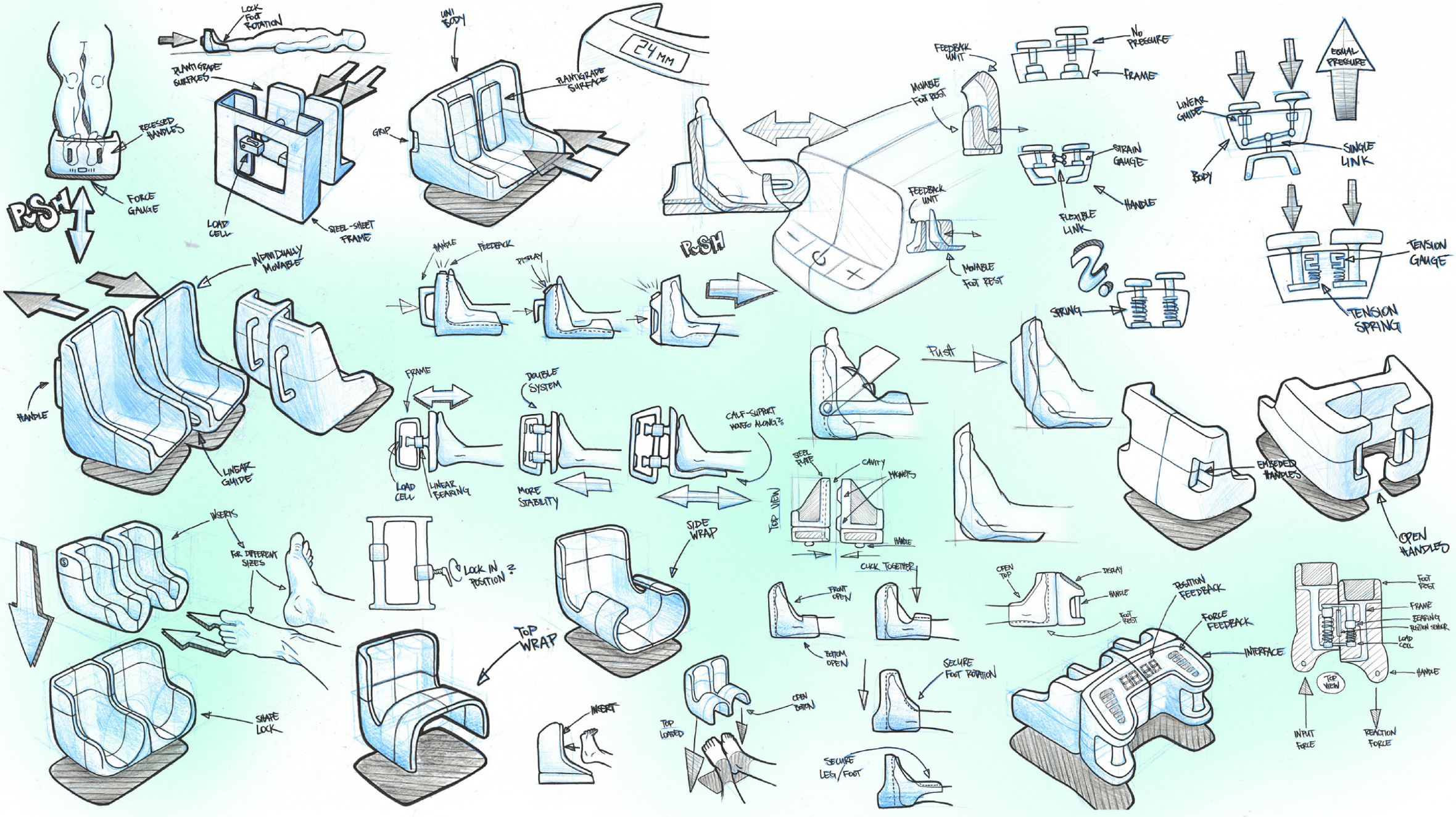


Fig. 46 - *Ideation & concept sketches (part 2)*

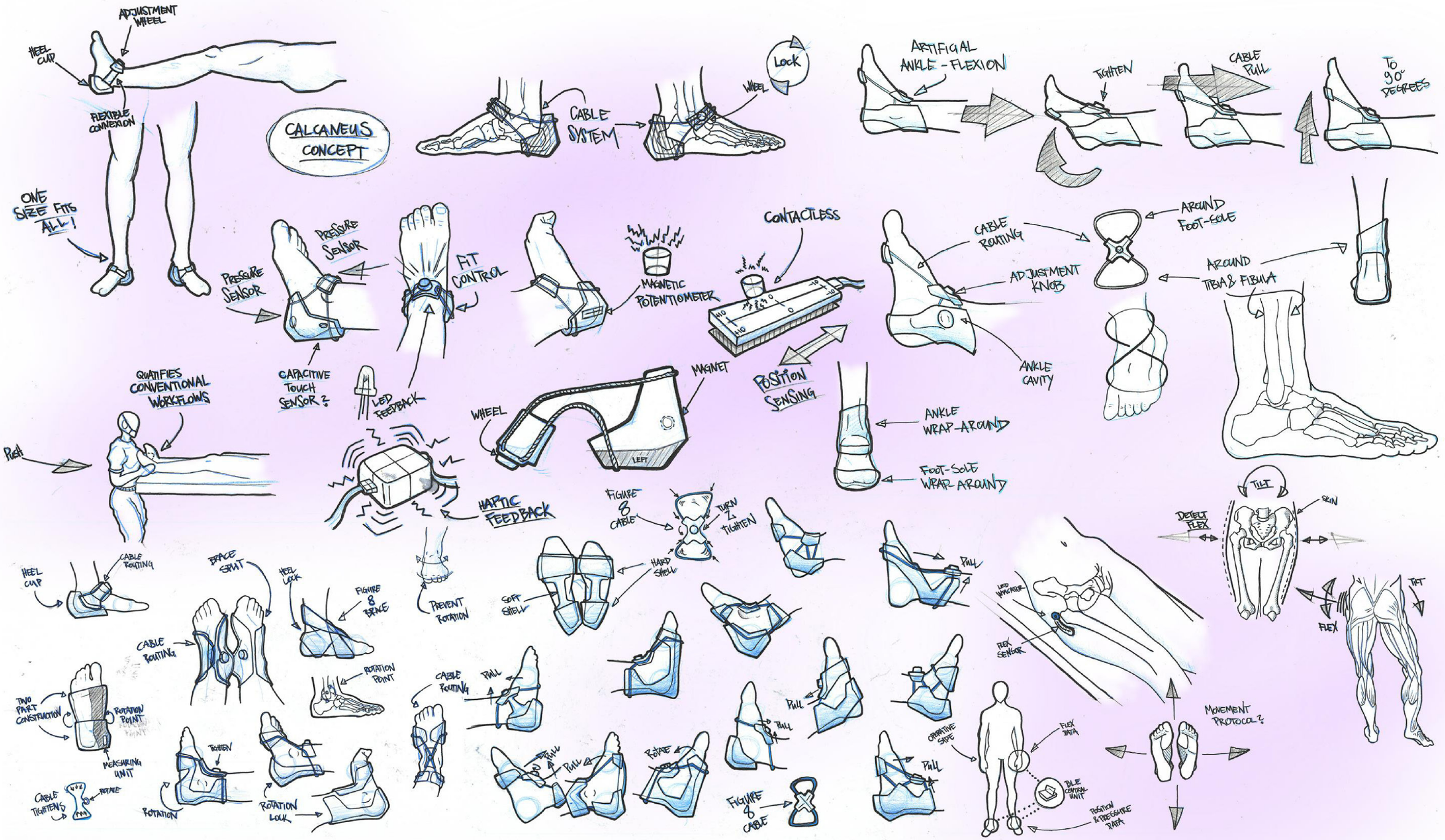


Fig. 47 - *Ideation & concept sketches (part 3)*

5.4 Discussion

5.4.1 General

Judging by the quantity of resulting ideas, one can conclude that the co-creations were a success, despite being held online. Updating the procedure and slides after each session also immensely increased the quality of ideas with each new session. The sessions were each 1,5 hours long, which was a limiting timeframe, however as these sessions were held in the evenings after people's workday, it was the maximum time that seemed reasonable to request. Surprisingly the online aspect of the co-creations made it easier to facilitate the sessions than expected. As an example, after the first ideation round, all participants were asked to click a picture of their sketches and send them in a dedicated WhatsApp group, so that while the second round started it was possible to place the sketches on the corresponding slides. This keeps the facilitator of the sessions busy instead of awkwardly looking over participants shoulders, as would be the case when all physically in the same room. In fact, it seemed like participants were more relaxed to sketch freely, especially the ones that are not used to sketching frequently. Some participants even mentioned that these sessions felt more comfortable in their home without any external pressure other than the time limit.

5.4.2 Limitations

As expected, having held the co-creation sessions online put certain limitations on their execution as well. The ability to give more in depth explanations by the means of models or props was not possible. Additionally, it proved difficult to have the same creative exchange as one would in a physical setting, due to the nature of human interaction. It was noticed that from time to time miscommunications occurred that were solely caused by digital interaction as opposed to physically showing biomechanical principles on a participant or sketching out explanations on a whiteboard (for example). Nonetheless, this approach was required and executed to a satisfactory level and resulted in qualitative input from the sessions.

Later in the process, potential concept directions were discussed during informal sessions with the four orthopaedic surgeons (RDGG and RHOC) and the supervisory team separately due to availability. The experts as well as the supervisory team agreed with the chosen direction, although more diverse input could have been generated by having a formal collaborative session. An open exchange between medical experts may have led to more critical exchanges and in-depth insights. Also involving more experts from other hospitals could have contributed positively to this exchange. The reasons for not being able to engage more experts in these sessions was primarily due to the social restrictions imposed in the year 2020 but was also due to time constraints and the nature of the research partnership of the project.

Key Insights

- The functions of the morphological chart are based on the problem statements from the co-creation sessions and list potential solutions to each sub-problem, which were collected during ideation.

- Only a hand full of semi-valuable ideas for non-invasive OD assessment were generated. This development led to the discontinuance of this direction with the primary focus being LLD assessment from this point forth.

Chapter 6

Prototyping

Prototyping

6.1 Background

For validation of potential concept directions, a series of Proof-of-Concepts (PoCs) has been created. These PoCs have been chosen based on the morphological chart from Chapter 5, which maps technical solutions to the various sub-problems. Each PoC features a core technology or working principle thereof in order to simulate a given technical function and evaluate its performance. These chosen PoCs focus on:

1. Near-infrared gesture tracking of the user's hands
2. Vertical cavity surface emitting Laser (VCSEL) measurement of LLD
3. Magnetic potentiometer (MagnetoPot) for heel relative position sensing
4. Flex sensors for pelvic tilt (PT) detection
5. Machine vision tracking of patient's lower limbs

Additionally two non-technology based PoCs were performed in order to explore product-user interactions and ergonomics of cable-brace systems and hand-held devices.

In order to physically test and evaluate the entire system later in the process, the selected PoCs form the basis for prototyping a complete and functional system. To also make the final prototype as aesthetically pleasing a possible, a balance between prototyping form and function is desired but cannot always be achieved. Therefore, priority lies on fulfilling the spatial anticipations of the final concept during this process. Furthermore, no custom components are used in this phase (except for 3d printed parts) and as many off-the-shelf parts were utilised in order to keep cost low and iterability high.

6.2 Method & Procedure

6.2.1 Arduino

Arduino is a user-friendly electronics prototyping platform that is utilised during the PoC phase, which will also serve as the final prototyping platform. All codes used for the PoC experiments are modified versions of the Arduino library codes, which can be found in Appendix F. It was decided to use the Arduino Nano 33 BLE (Bluetooth Low Energy) Series, due to their low power consumption and small form factor. This will allow for compact and wireless characteristics required for most of the potential concepts. An Arduino Nano 33 BLE Sense, which has a superior chip for faster data processing was selected to act as the central processing device.

6.2.2 OpenMV

OpenMV is a user-friendly machine vision development platform and similar to Arduino in its ease of use. This platform was used in order to explore the potential, the limitations and the opportunities of the machine vision concept. The OpenMV Cam H7 was equipped with an infrared (IR) lens and a polarising filter, anticipating the bright lighting conditions of an OR.

6.2.3 FDM 3D printing

Fused deposition modelling (FDM) is one of the many 3D printing technologies particularly suitable for rapid prototyping. This method was chosen for functional shape exploration of enclosures and housing of various concepts, due to its reasonably fast printing time and minimal post-processing effort. This allows for custom form factors, embedded shape intelligence and a faster iteration speed. Primarily the machine used for 3D printing was a Creality CR20 Pro in combination with Colorfabb PETG and TPU filaments.

6.2.4 Dined 3D Anthropometry

Dinded on an online anthroprometric database hosted and developed at TU Delft. The datasets are based on manual measurements as well as 3D scanning data. In order to ensure ergonomic fit of any given concept, 3D Anthropometry input on various foot sizes and shapes was retrieved from Dined (TU Delft, 2020). As starting point the CEASAR (NL) population dataset has been chosen. Within this population male and females of the age group 51 - 66 years was selected, as this is the oldest segment available and the closest range in relation to the age of the target demographic. Due to limited information on feet within this dataset rather general demographic factors have been chosen: Stature and Bodymass (Fig. 48). For Stature, the measures of 1540 - 1860 mm (P5 - P95) and for Bodymass 56 - 109 kg (P5 - P95) have been chosen. The resulting mannequin was downloaded and post-processed in Rhinoceros, MeshLab and Solidworks in order to extract the relevant surface information of the right foot.

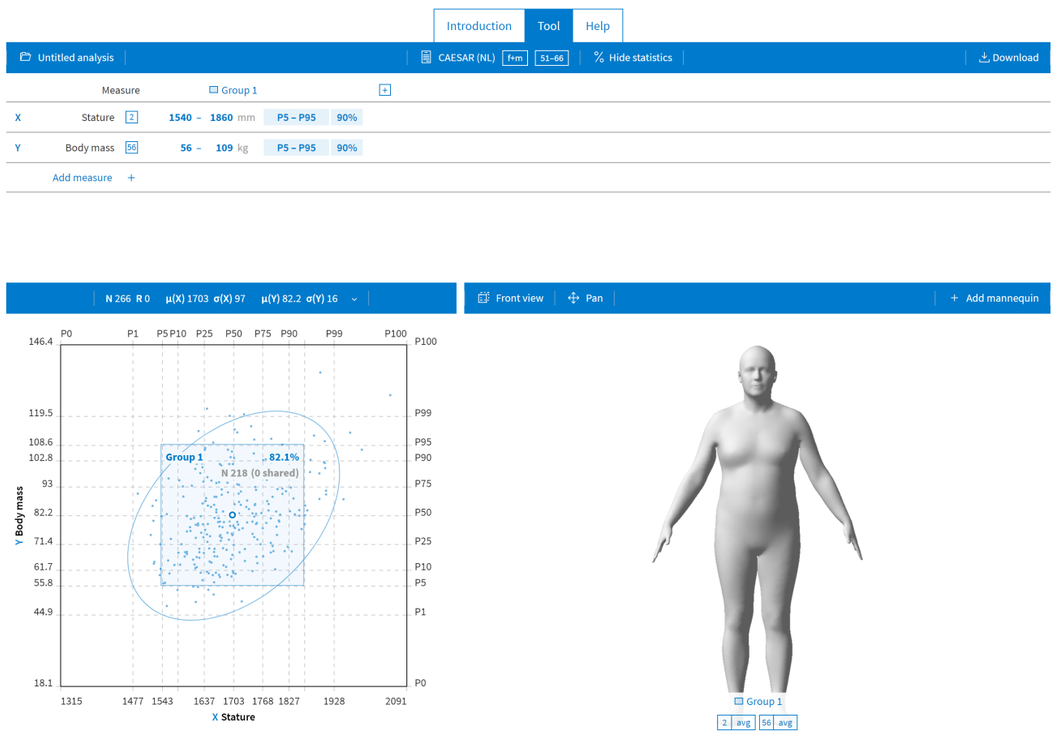


Fig. 48 - *DINED population sample*

6.3 Findings

6.3.1 PoC #1 - Dual IR Camera Gesture Tracking

Setup

The first PoC is based on a dual infrared camera set-up in combination with infrared emitting diodes, as can be found in a Leap Motion Controller (Fig. 50). In this experiment the goal is to only facilitate the user's hands as input for landmark referencing. This would allow for a near unobtrusive experience where only the camera / LED assembly would need to be positioned during set-up and feedback given on a screen during each assessment.

A test has been devised based on a gesture observed during the research phase. This gesture simulates the hand positions during a loaded LLD assessment, the thumbs press against the heels while the index fingers rest on the lateral malleoli. By launching the Leap Motion Diagnostic screen, toggling to top view and enabling tracking information of limb coordinates, it is possible to check the accuracy of each finger's virtual position in relation to its physical position (Fig. 50).

Considering the physical location of each thumb to be at x/y = 0 would mean that the position of the left and right index would be at x = -5, y = 15 and x = 5, y = 15 respectively. As the executed gesture is symmetrical, it is expected for the virtual position to reflect this symmetry in equivalent magnitude to its coordinates.

Result

As can be seen in Fig. 49, the highlighted coordinates represent the determined virtual positions of each thumb and index. The individual error tolerance was significant, ranging from 0,329 - 7,679 mm. The average error margin was calculated by determining the position discrepancy between left and right finger positions for all three coordinates across all three tests. Across three tests, including intermediate sensor calibration, the average error margin was 3,098mm. Considering the millimetric accuracy desired and required for the solution makes these findings unsatisfactory. More pictures of the test results can be found in Appendix G).

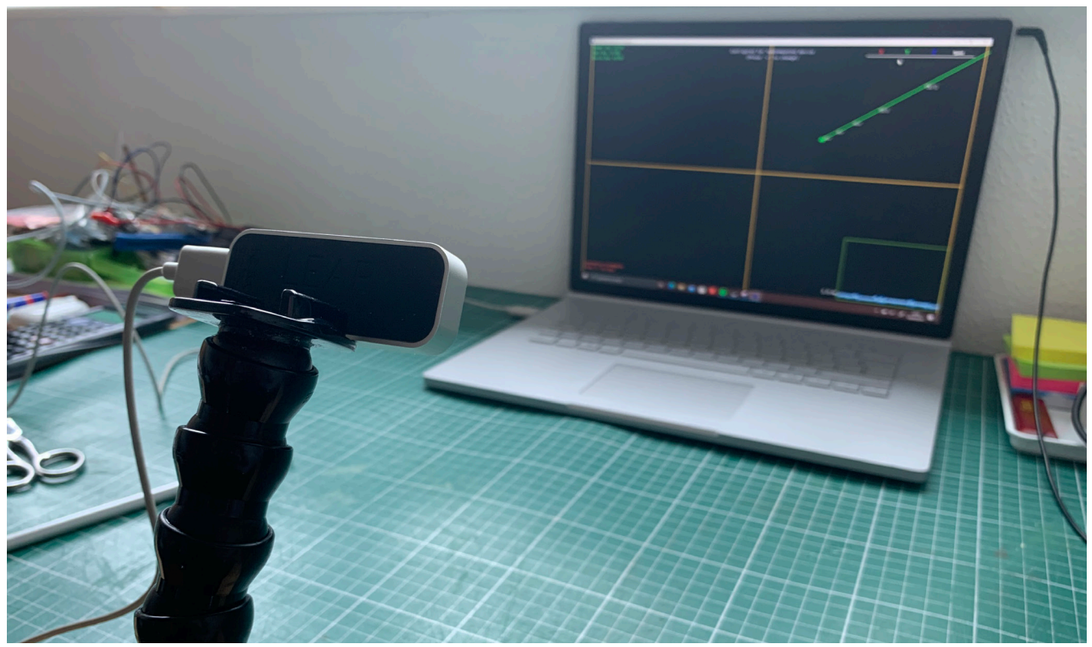


Fig. 49 - *Test setup: LeapMotion pointing at cutting mat*

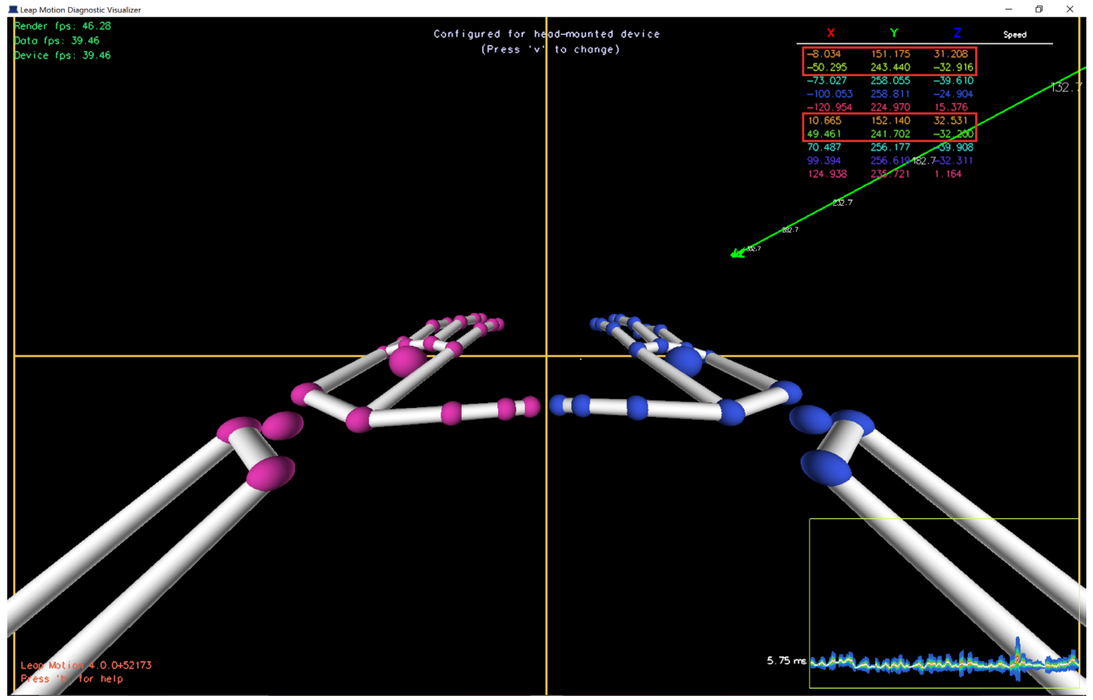


Fig. 50 - *Finger position tracking with highlighted coordinates*

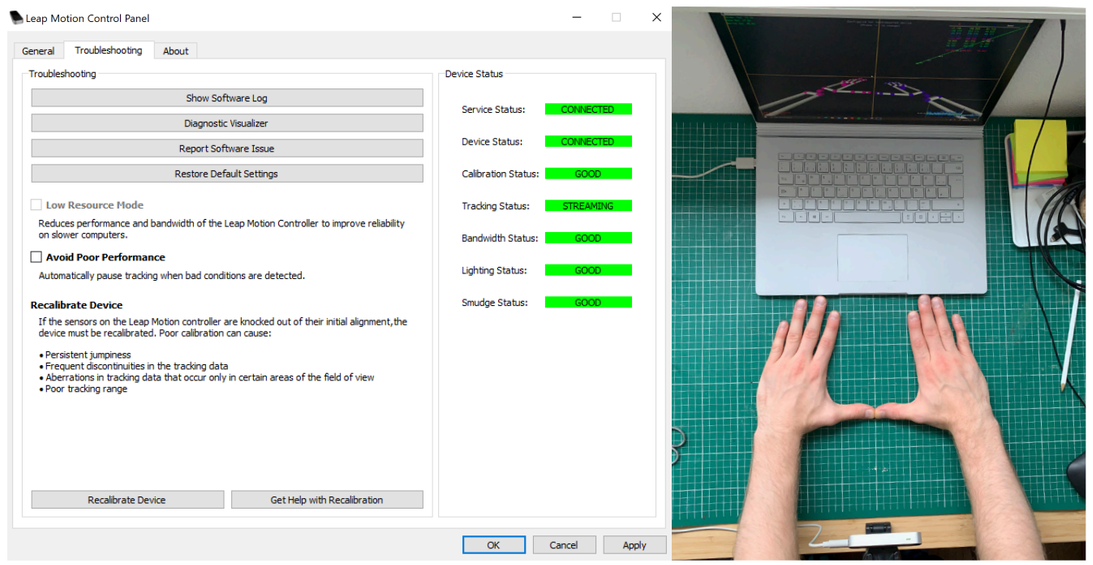


Fig. 51 - *LeapMotion Diagnostic window (middle), Hand gesture on cutting mat (right)*

6.3.2 PoC #2 - VCSEL LLD Measuring

Setup

The second PoC is based on a Vertical Cavity Surface Emitting Laser (VCSEL) in order to determine its potential to detect LLD with reasonable error tolerance. For this an experiment was devised where the VCSEL sensor was attached vertically to the centre of rotation of a protractor. The protractor's degrees of angle can be set in 5-degree increments and pointed onto a target surface. This target surface is simulating the patient's heels that may also be measured through an augmented surface (fig. 53). The idea being that the VCSEL sensor is attached to the OR table in a perpendicular manner, determining the distance discrepancy between each target surface. Alternatively, this concept could be mirrored with one VCSEL sensor placed on each heel, measuring the distance to a vertical surface, perpendicular to the length of the OR table.

Result

With this set-up, it was decided to first take a straight measurement from a distance of 150mm. Afterwards the sensor is rotated 10 degrees to the left and 10 degrees to the right, for which a distance of 152 mm is expected. For each rotation the distance discrepancy of the last 15 readings have been averaged (fig. 52). For the straight measurement individual error margins ranged from 0 - 4 mm, with the average calculated to be 1,687 mm. For the 10 degrees right measurement, individual error margins ranged from 0 - 7 mm, with the average calculated to be 1,533 mm. For the 10 degrees left measurement, individual error margins ranged from 0 - 4 mm, with the average calculated to be 1,467 mm. The results show that it is possible to get reliable measurement readings with a VCSEL sensor, that are close to millimetric accuracy, making these test results satisfactory.

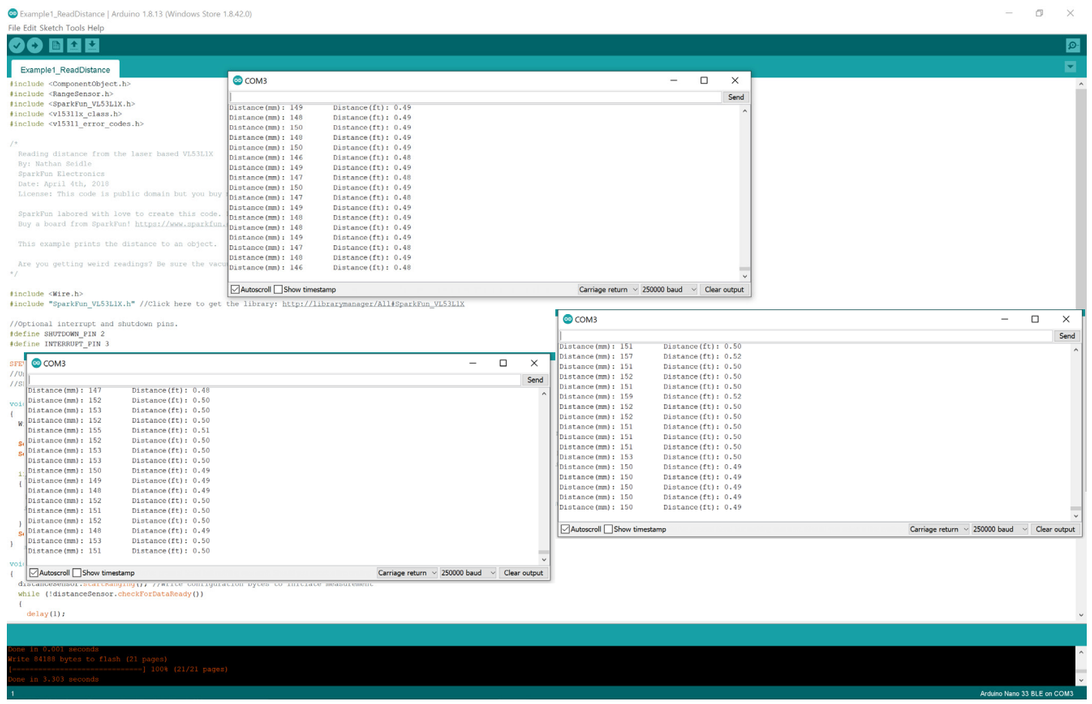


Fig. 52 - *Measurements and Arduino code*

Fig. 53 - *Test setup: Target surface with 5 degree left orientation*

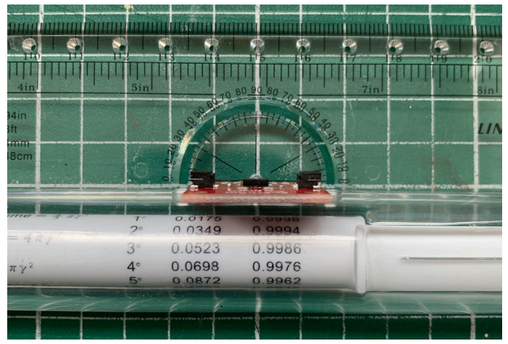


Fig. 54 - *Straight orientation*

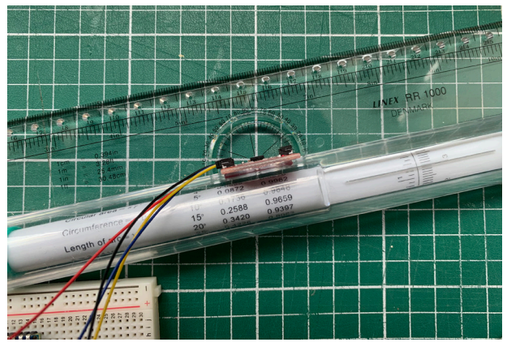


Fig. 55 - *Test setup: 5 degree left orientation*

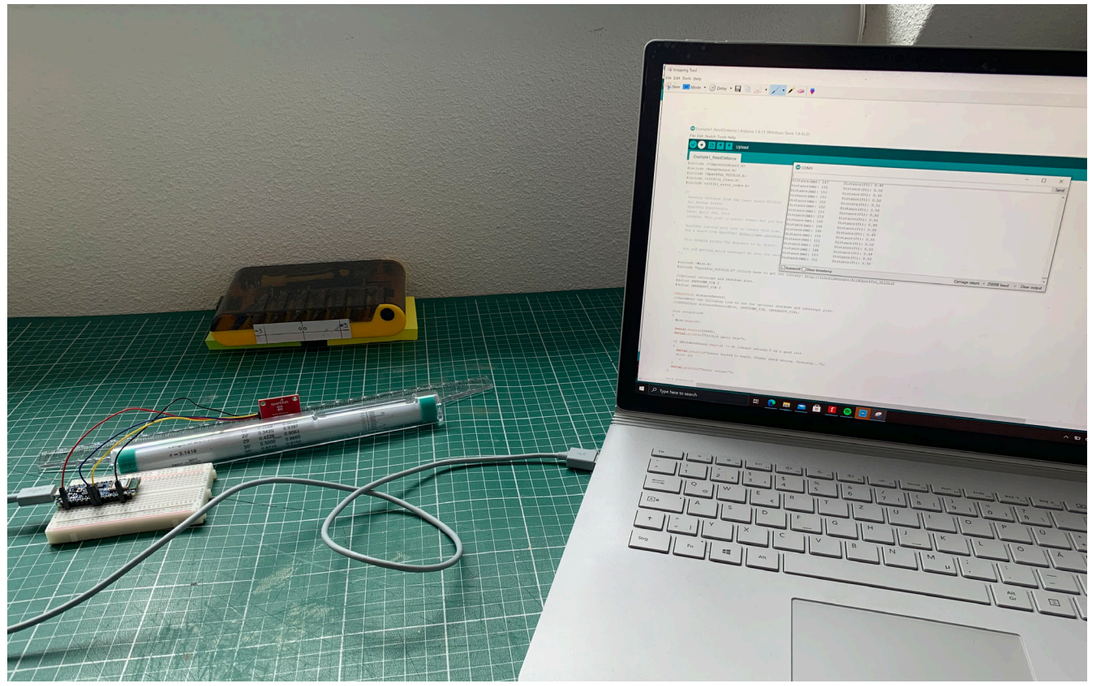


Fig. 56 - *Test setup: VCSEL sensor attached to protractor*

6.3.3 PoC #3 - Magnetic Potentiometer LLD Measuring

Setup

The third PoC is based on a magnetic potentiometer which acts as a position sensor for relative position sensing. The assembly of the MagnetoPot houses a small disc magnet that pushes against a linear force sensitive resistor, when activated by an external magnet. In theory this allows accurate and stable sensor readings, while enabling a completely enclosed design. The aim is to determine whether the sensor can provide repeatable and accurate sensor reading down to the millimetre. The potentiometer is mounted in a transparent casing which in turn is setup in a fixed position (fig. 57). From the other side of the casing a cubic magnet is attached to which the end of a metric calliper is attached. The calliper is elevated and moved in parallel to the MagnetoPot in 1 mm increments back and forth.

Result

The sensor reading is extremely stable due to the characteristics of magnets and quite accurate as well. However, it was noticeable that whenever a direction change occurred it would take approximately 0,5mm of calliper movement until the MagnetoPot's internal magnet would start moving. This of course has to do with the characteristics of the magnetic field and the friction required to overcome by the internal magnet. This effect caused an average error margin of 0,5mm, which on the upside was extremely consistent. Nevertheless, these results are extremely encouraging and prove that this concept direction has potential for an accurate and stable position readout.

Finally, the configuration of the setup was changed. A second MagnetoPot was introduced and mounted facing the opposite way of the first Sensor. This was done in order to evaluate whether it is feasible to have two sensors within a central device and only a magnet placed on each heel. Additionally, a 1 mm steel plate was placed between the sensors in order to increase the magnetic forces acting on them. This would have the added benefit of locking the patient's heels together allowing for more liberated manipulation of the patient's feet. Although feasible in theory, due to the opposing polarity of the internal magnets, the concern here was that the opposing magnetic fields may disturb the sensors performance. The conclusion was that there was no interference between the sensors and no interference caused by the opposing magnet. In fact, due to the steel plate, the bond between magnets and the 'sensor unit' was increased significantly. Unfortunately, no force gage was present to quantify the results, nonetheless this direction seems promising to go forward with.

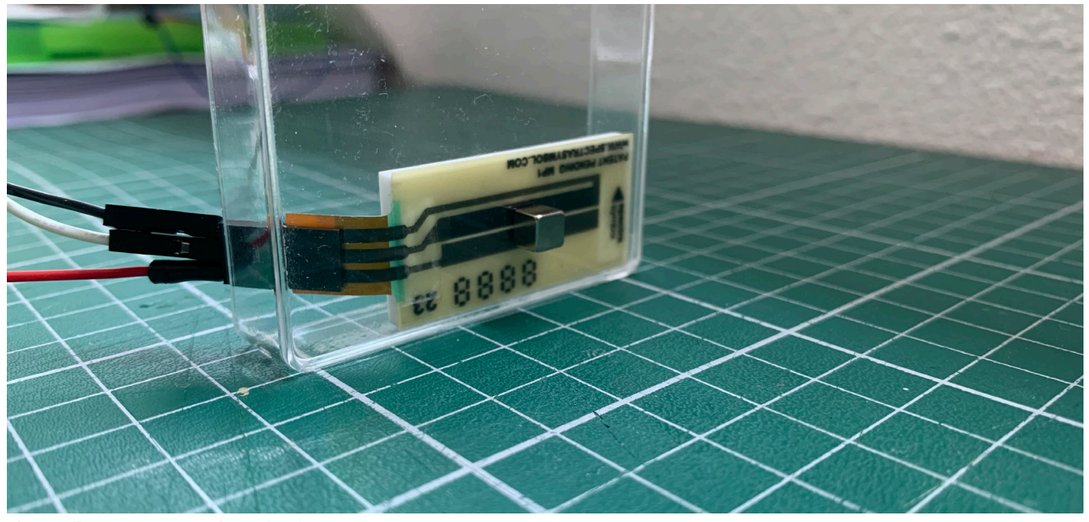


Fig. 57 - *Test setup: MagnetoPot with cubic magnet*

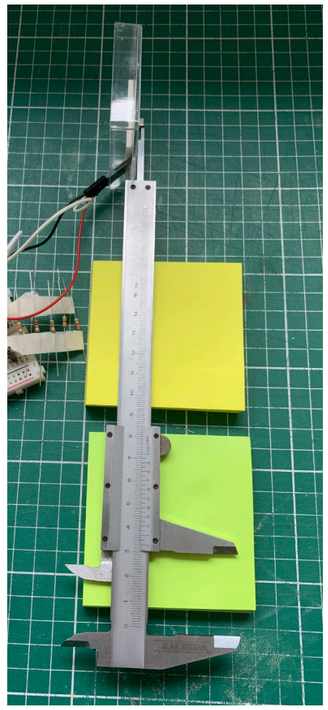


Fig. 58 - *Test setup: Calliper*

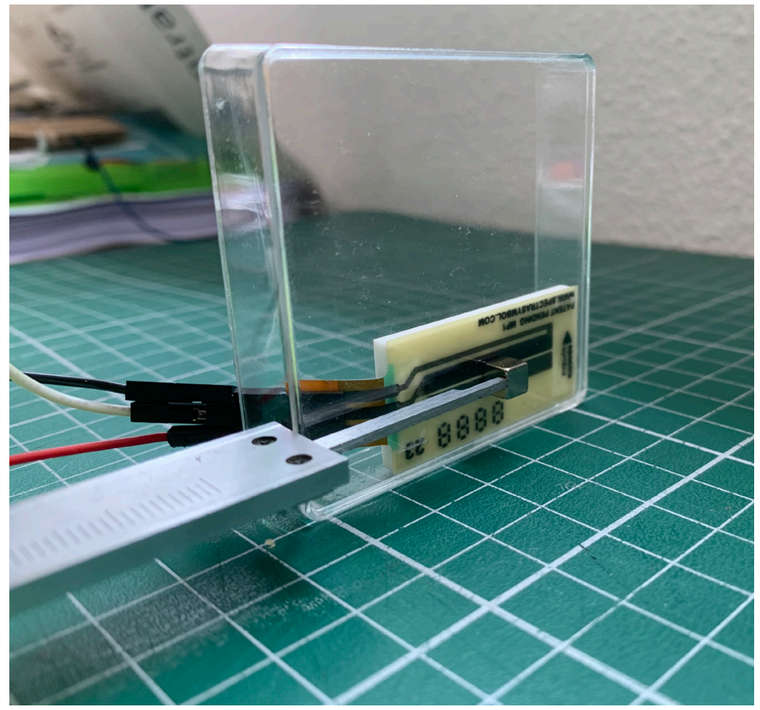


Fig. 59 - *Test setup: Calliper attached to cubic magnet and MagnetoPot*

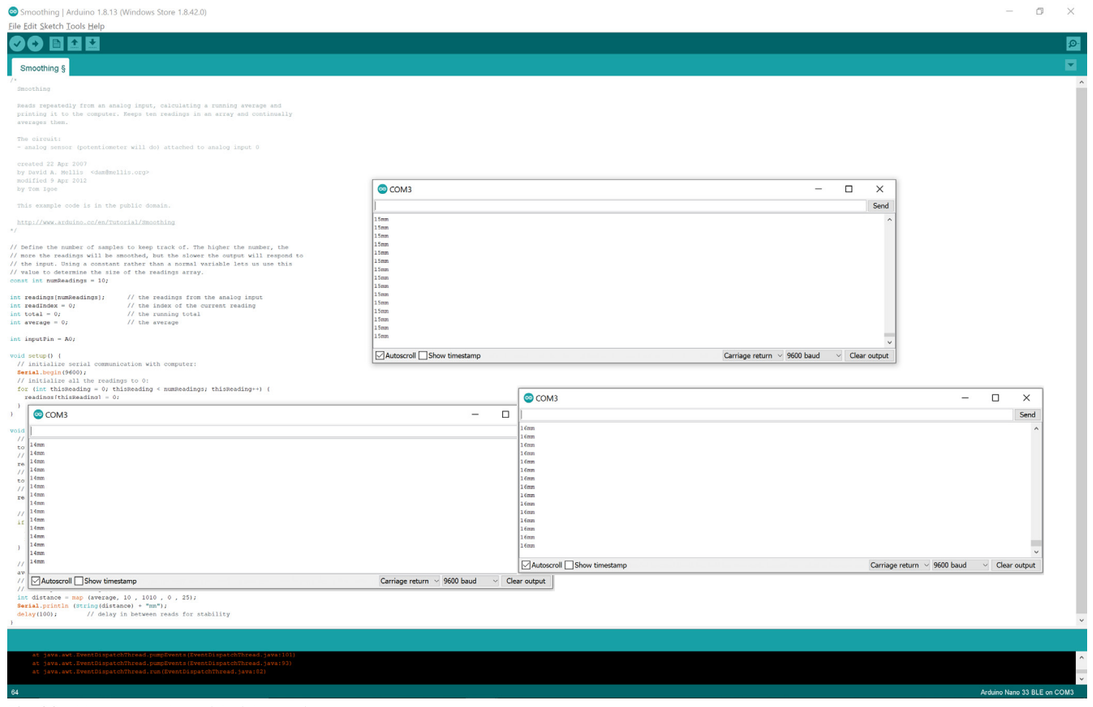


Fig. 60 - *Measurements and Arduino code*

6.3.4 PoC #4 - Flex Sensor PT detection

Setup

The fourth PoC is based on a flex sensor for detection of pelvic tilt. The theory being that if you rotate the pelvis in the perpendicular axis to the coronal plane, the greater trochanter on either given side is going to protrude or recess. This state change in theory is detectable by a flex sensor. In a use case scenario, the user locates the greater trochanter on the non-operative side, applies the flex sensor to the patient's skin and calibrates it. Once the surface of the skin changes into a more convex or concave shape a state change is detected by the sensor and communicated to the user.

For this test setup, a flex sensor was applied with double-sided tape to the right side of a test subject's pelvis. The sensor was calibrated and wired in such a way that an LED would trigger if a state change was detected. As no literature or resource could be found as to how much PT is induced during a THA, a test in order to establish a benchmark was devised. The participant's heels were aligned and then pressed against with varying pressures, in order to artificially induce pelvic tilt. Through this it was determined how much the pelvis could be shift by applying varying pressures on each heel and the participant was asked to remember each position. It is to be mentioned that these tests were carried out on a laminated floor which has a low friction coefficient compared to the cushioning of an OR table. This naturally induces a greater PT than would result during the surgery, which for preliminary testing is acceptable.

Result

Afterwards, the actual test was performed under the same conditions, only this time the participant was asked to shift their pelvis into the previously induced positions. First the participant was asked to shift the left side of their pelvis towards their torso (clockwise rotation - participant's perspective), which makes the greater trochanter on the right side of their body recess. Then they were asked to shift their right side in the same manner but in the opposite direction (anti-clockwise - participant's perspective), which makes the greater trochanter on the right side protrude.

After applying the sensor to the participant, one benchmark measurement was taken (analogue value between 0 - 1023 and averaged over 10 readings). When the participant was lying still without any PT induced the read-out value was at 853 (benchmark value). When being asked to shift their pelvis clockwise, the sensor value read 847 and when asked to shift anti-clockwise the value read 860. It is noticeable that a greater state change was detected when the greater trochanter was brought into a protruding position than when brought into a recessing position. Nonetheless, these state changes are rather minimal, yet can be amplified by fine tuning of the electronic circuit with different resistor values. Altogether, this concept direction seems promising but will require much more extensive research and experimentation in order to make feasible. If looked into, it is advisable to explore how the physical deformation of the flex sensor can be intensified, for example by suspending it between two ECG electrodes while placing one on a 'stable' skin area and the second one on top of the greater trochanter.

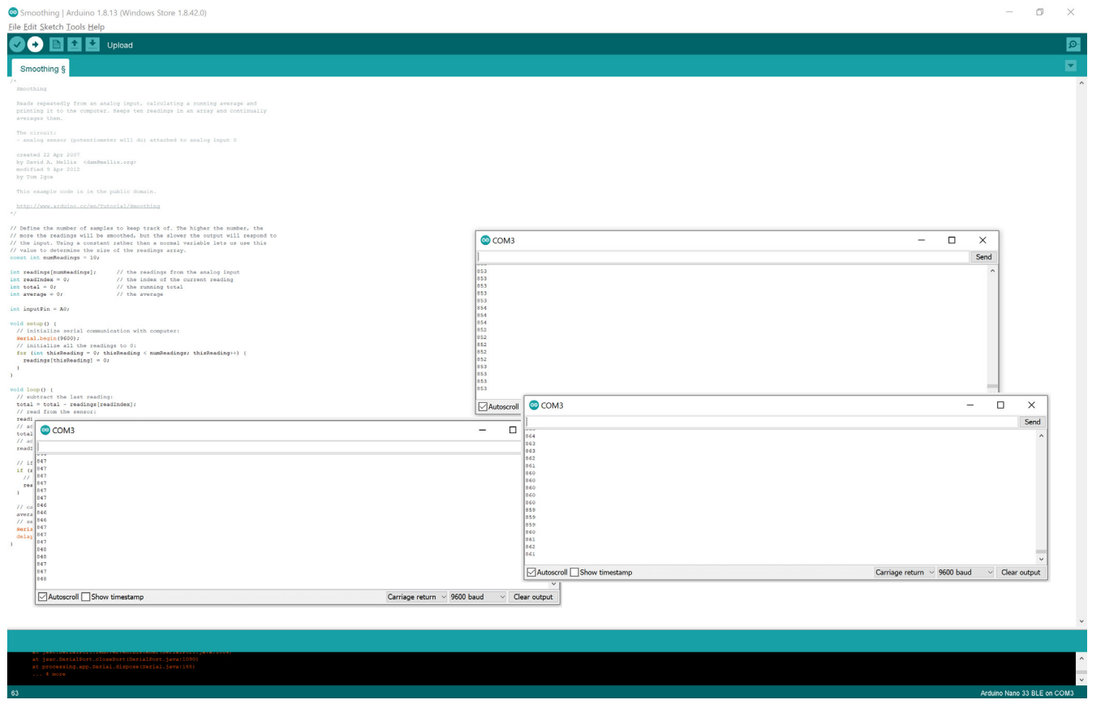


Fig. 61 - *Test results and Arduino code*

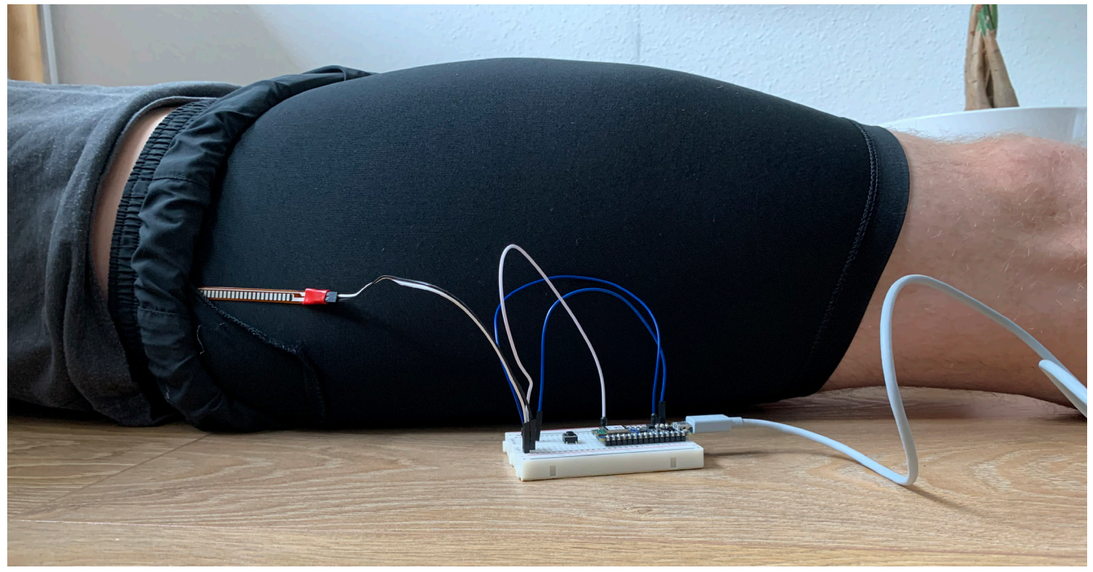


Fig. 62 - *Test setup: Flex sensor attached to participant and test circuit*

6.3.5 PoC #5 - Machine Vision Lower-Limb Tracking

Setup

The fifth PoC utilises machine vision, technologically similar to PoC #1 but different in its execution. Here a OpenMV Cam H7 Pro with an IR lens and polarising filter is combined with tree IR emitting trackers. This time instead of illuminating the scene with IR diodes, the aim is to track the individual IR emitters. The reason for not choosing retroreflective trackers (that simply reflect IR light), is the goal to track the markers from behind surgical drapes, for which a high light density is required. This was done in order to simulate a situation where the visual line-of-sight to one of the markers is compromised, due to placement of surgical drapes on a landmark, ultimately obscuring it.

To evaluate whether the OpenMV Cam H7 Pro is able to track the position of IR trackers accurately without the interference of surgical drapes, a simple test setup has been created (fig. 65). The camera was suspended, facing downwards and pointing towards a ca. 1000 x 750 mm surface. Translating the resolution of the camera (2592x1944 px), to this flat surface means that each pixel represents a square of ca. 0,385 x 0,385 mm (neglecting lens distortion). The IR emitting trackers are positioned on randomly chosen coordinates in order to form a triangle. The code used for this PoC is an altered version of the OpenMV 'IR Beacon Grayscale Tracking' library code, which can be found in Appendix F). The code would draw rectangles around each IR source and determine each centre point before providing the coordinates via the Serial Terminal (fig. 63). In three tests, each tracker was displaced in 1 mm increments, by bending the diode (along y-axis). In order to observe whether the machine vision program would accurately track its position, screenshots were taken and coordinate positions compared.

Result

The results of this PoC were rather encouraging, with the program being able to pick up minimal displacement of the diodes. The diodes were placed in such a way that when bent, they would displace in the y-coordinate. Before starting the experiment, one benchmark screenshot was taken, which placed the first diode (D1) at x: 1347, y: 878; the second diode (D2) at x: 748, y: 1177 and the third diode (D3) at x: 1202, y: 1333. After referencing their position, each diode was bent 1mm to the left, resulting in D1 (x: 748, y: 1183), D2 (x: 1202, y: 1336), D3 (x: 1347, y: 879). This process was repeated two more times, with similar results. Displacement discrepancies ranged from 0 - 6 pixel points, which translates into ca. 0 - 2,4mm. On average, when displaced by one millimetre, pixel coordinates changed by 2,1 pixel points, which is the equivalent of ca. 0,8mm. Given that the accuracy of the displacement was performed by hand, there is expected to be an error margin. Nonetheless, the OpenMV camera proved to be able to register minimal displacement with surprising accuracy, making this direction interesting for future exploration.

Considering the results from the first test, the surgical drape test was attempted. In order to evaluate whether trackers obscured by surgical drapes, are accurately trackable, the same test setup was facilitated and two types of surgical drapes were used. Firstly a drape that consists of a single fabric. The second one a bi-material drape, which consists out of fabric reinforced by a solid thermoplastic layer. Both drapes were loosely placed on top of the trackers (Fig. 67). The results were rather discouraging as the surgical drapes acted as diffusers for the emitter. It resulted in a homogeneous IR light source when trackers were placed too close to each other or too far from the drape, ultimately combining their centre points. In Fig. 65 is visible how the light from one IR emitter was accurately registered, which can be attributed to the minimal distance between IR diode and drape (Fig. 68). It could be argued that decreasing the light intensity could counteract the diffusion and have a similar effect, in which case the coordinate of each diode could be accurately registered through surgical drapes.

Although being an extremely interesting direction, this concept would require extensive research and experimentation and will not be explored any further.

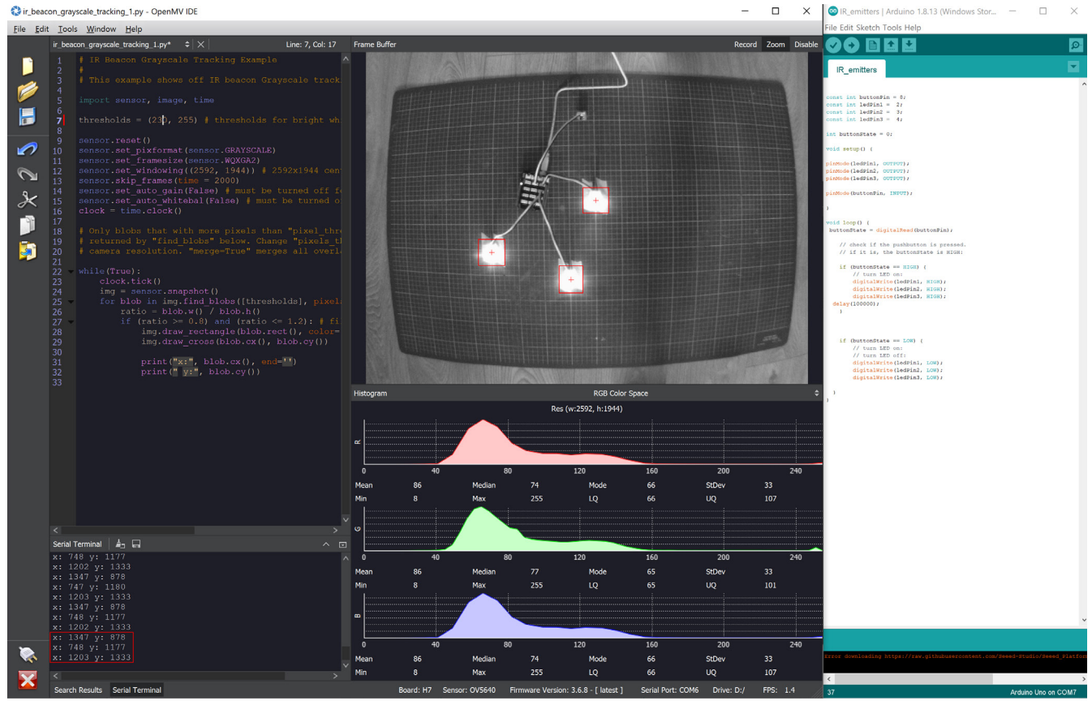


Fig. 63 - *Benchmark coordinates with OpenMV and Arduino code + three displacement results*

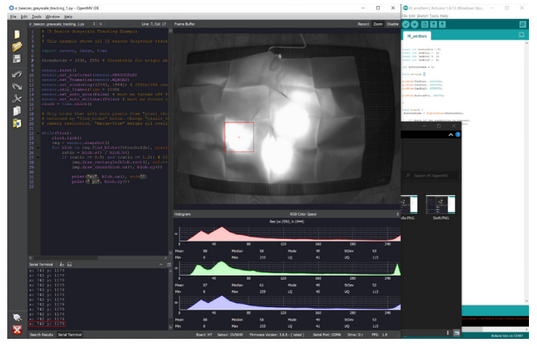


Fig. 64 - *Succsessful surgical drape test*

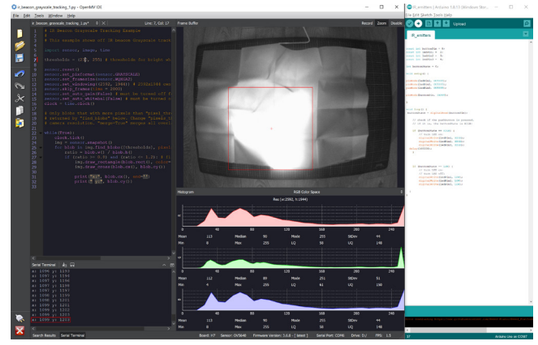


Fig. 65 - *Failed surgical drape test*

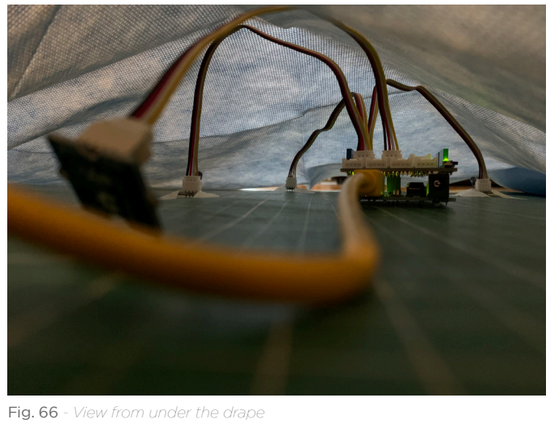


Fig. 66 - *View from under the drape*

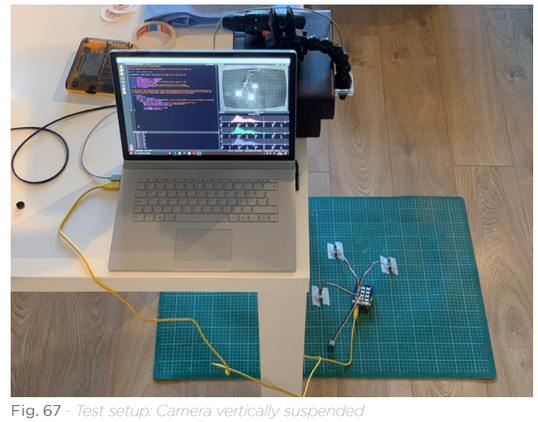


Fig. 67 - *Test setup: Camera vertically suspended*

6.3.6 Non-tech PoC #1 - Cable fixation

Setup

This non-tech PoC was created in order to determine whether the fixation of a heel cup would allow for repeatable and reliable LLD assessment. As covered during the Discover Phase, the patient's position during an LLD assessment needs to be kept consistent across multiple evaluations in order to make the results comparable. Making the measuring device wearable naturally mitigates that risk, on top of being unobtrusive to workflow, OR setup and allowing for repositioning of the patient's feet during the procedure. On the other hand, the importance of correct initial placement is increased alongside other challenges such as potential slippage of the device during patient repositioning.

Result

A series of heel cups with cable systems has been prototyped. Heel cups were printed in PETG and cushioned with PE foam in order to ensure an appropriate fit and grip. The cup embraces the Calcaneus (heel bone) as the intended point of reference. Initial prototypes (Fig. 68) did not meet the desired position stability required for this concept. The heel cup, although being tightened firmly, was prone to slippage when collisions occurred, due to the pull directions of the rope as well as the foam used inside the cup. It was also found that the extending element of the cup, which was meant to act as a lever for easier foot manoeuvrability was almost completely unusable. This was in part due to faulty surface information from the DINED model, which misrepresents the underside of the foot. This incorrect surface information may be the result from 3D scanning participants in a standing position, which does not allow for collection of accurate data points from the underside of the foot.

Considering these preliminary findings the cup design was altered slightly. Areas on the underside of the foot that were deemed unreliable were excluded, which decreased print time. The rope guides were increased in size to alter the direction of the pulling forces and finally the inside cushioning was printed in shore A95 TPU with foaming capabilities (Colorfabb, 2019). This improved the fit and grip of the brace significantly, in particular the TPU was not too elastic to distort the fit accuracy and not too firm avoiding discomfort. Altogether, this direction seemed promising, yet after presenting it to experts and the supervisory team (see Appendix H), concerns about the practicality of this direction arose. In particular, not allowing for fixation of ankle rotations lead to concerns that although technically feasible, this direction would be undesirable within the OR. In light of the expert feedback and the struggles with the DINED model, it was decided to abandon this direction.

Fig. 68 - *First iteration (3D printed)*

Fig. 69 - *Third iteration (3D printed)*

Fig. 70 - *3D printed heel cup and cable system iterations*

6.3.7 Non-tech PoC #2 - Ergonomics Mock-ups

Setup

This non-tech PoC was created in order to determine whether a hand held device should consist out of a unibody or two split-bodies, as sketched out during the ideation phase. Additionally, it was to be determined which surfaces would be required in order to orientate and retain the patient's feet within the device, which was tested on a participant. Lastly, it was of interest to investigate how either device would be handled by the user in terms of ergonomic grip. In order to explore these aspects and interactions, a series of 'quick and dirty' mock-ups have been created from cardboard and thermoplastic containers. This technique is also sometimes referred to as 'makeshift or frankenstein prototyping'.

Result

The first result were two unibody mock-ups, one top-loaded, meaning that it would be placed over the patient's feet and one bottom-loaded, meaning that the patient's feet are lifted into the device. Although the interaction of the top-loaded mock-up was much more desirable in terms of handling while interacting with the participant's feet, the device did not sit securely enough. With the bottom-loaded device on the other hand, it was noticeable that the weight of the patient's feet would allow for the device to self-orientate (due to the flat bottom surface) and secure the device, even though being tested on a cushioned couch. One aspect that both unibody mock-ups had in common was that it proved difficult to get the participant's feet into them. One would first need to lift one leg before twisting the device and trying to slide the equivalent side underneath the participant's foot. Once the first foot was in, the second one proved much easier to position. Nonetheless, there is an awkward interaction moment that should be considered and possibly avoided.

Moving on to the split body mock-ups, three variants were created for testing. The first was bottom-loaded with a large flat surface on the underside, the second was a bottom-loaded one with a round(-ish) bottom surface and the third one was a side loaded one with a cavity

Fig. 71 - *Unibody mock-up pressed against feet*

to lock the heel into. The first version worked most intuitively, due to the split-body design it was easy to lift each foot into their half and then guide them together. The flat underside and inner surface made it extremely easy to align the two halves and slide them parallel to each other. The second version behaved the exact same way as the first one, except for the alignment and orientation of both halves. The rounded underside would make it difficult to handle the feet and slide them in parallel. However one needs to consider that no magnets pull the halved together in this mock-up, thereby this still remains an option. The third version had the same problem and the side-loading aspect of it made getting the feet into position difficult. On the upside, having the heel lock into position was a feature that gave great control over the orientation of the foot and should be considered in terms of form factor.

When applying pressure on either version, it seemed most ergonomic to grab each body from the outside, embracing it in a natural grip position (Fig. 71). In an attempt to introduce some variety, two modified luggage scales were used as grips, while also measuring the pressure applied to each foot.
In this particular instance, having a protruding grip proved to decrease the control over each half, yet on the plus-side it did verify that one tends to apply differing pressures to each foot. Over five tests the average difference in force was 3N (or 0,3 kg).

Fig. 72 - *Unibody and split-body cardbord / plastic mock-ups*

Fig. 73 - *Modified luggage scale*

Fig. 74 - *3D printed mechanism modification*

6.4 Discussion

6.4.1 General

It is safe to conclude that some of the PoCs can be categorised as insightful but not feasible and can therefore be excluded for final concept selection.

PoC #1 had the worst performance results, with inaccurate measurements and an overall unreliable interaction factor. This approach fails to provide precise enough feedback on the user's hands and therefore landmarks on the patient's body, which leads to its exclusion from further development.

PoC #2 certainly had promising results in terms of accuracy, but would require a more complex set-up in order to implement. The necessity of a target surface to compare the measurement against (in either direction), requires a precise setup of a reference structure, potentially attached to the OR table itself. This increases the risk for human error during set-up of the target surface. Additionally, it is counterproductive to add installations into already crowded OR rooms. As a more flexible solution is desired that has the potential to work in multiple OR setups, leads to the exclusion of this concept direction too.

PoC#3 has been proven to be quite reliable as a relative positioning method. This concept direction allows for the flexible approach described earlier, as either part of this sensor can be easily embedded and enclosed in any type of system. This would allow for devices that are entirely sealed and can be exposed to chemical cleaning agents, which would fulfil the sterilisation requirements mentioned in Chapter 4. This concept direction, in combination with pressure sensors would allow for evaluation of how much force is applied to either foot, ensuring that equal pressure is applied to the patient's lower body system during a loaded assessment. Having precise feedback on the relative position of the heels to each other at any given force input is valuable insight. However, this interaction is optional as the magnetic potentiometer also provides feedback for an unloaded assessment, as long as the feet are aligned along the centre line of the patient and the device is perpendicular to that line.

as this can be very context specific. No doubt, with a more finely calibrated system and more precise sensors, high levels of accuracy on pelvic shift state change can be provided and in particular the embodiment and placement of the sensor should be investigated further. As pelvic tilt frequently being mentioned as a factor for LLD assessment confusion, it would have been chosen for continuation in a less time constraint setting. Unfortunately, since this is not the case with this project, it was decided to leave this development open for future explorations. Instead it was decided to make use of an already proven alternative, which is a movement protocol in order to straighten the patient's pelvis (Chapter 3).

PoC #5 has been proven to be surprisingly accurate and should be considered for application towards future robotic systems. The main drawback of this concept is that line-of-sight towards the trackers can be interrupted, which in a present scenario may very well be anything from gauzes, instruments or drapes. Additionally, it should be considered that these markers are being attached to the patient's skin which, as soft tissue, has the potential to shift throughout the surgery. Therefore, for implementation of this concept, two main boundary conditions have to be fulfilled: 1. Procedures have to be as minimally invasive as possible to minimise skin shifts. 2. A tidy environment is required, minimising the risk of an obstacle interrupting the line-of-sight between markers and camera. Additionally, one is to consider whether in a robotics context multiple cameras may be used in order to increase the field of view and the angles of view, which would ensure the visibility of all landmarks (e.g. heels) and mitigate the risk of visual line of sight corruption.

Non-tech PoC#1 was considered a promising direction at first, yet after listening to expert feedback it was decided that too many challenges and risks remained with this direction. Although this concept allows for maximum flexibility in terms of workflow adaptation and OR set-up, it also allows for maximum human error during usage, therefore not enhancing or improving current methods.

Non-tech PoC#2 showed that a split body approach would provide better user-product-patient interaction, which was contrary to the initial assumption. Additionally, it was assumed that having a protruding handle would improve ergonomics, which it does not. In conclusion, the final concept should be based on a split body approach and facilitate shape integrated ergonomics, that allow the user maximum control over the device.

6.4.2 Limitations

The primary limitation to the PoC phase was that it was carried out at home and not in a laboratory. Certainly, test results could have been improved by using more precise set-ups, machinery and evaluation methods that are only available in laboratory conditions. Additionally, many more concepts could have been tested and the ones that were chosen could have been tested more in depth and involving more participants in order to increase the quality of results. Unfortunately the time frame of the project and social distancing measures did not allow for it. Particularly the machine vision concept is an interesting direction to explore in more depth, considering current industry trends. Moreover, there were other directions identified during ideation that were not tested due to lack of time, such as the metallic print reference grid (Chapter 5) for fluoroscopy. Overall, the results are informative but can only be treated as preliminary results from a professional research and development perspective.

Key Insights

- PoC#3 featuring the Magnetopot position sensing performed reliably and has been chosen for continuance.

- PoC#4 featuring the flex sensor proved to be an interesting direction but fell outside the scope of the project due to time limitations.

- PoC#5 featuring machine vision also proved to be an interesting direction, in particular for more futuristic and advanced scenarios. Potentially a great supplement for RAS.

Chapter 7

Final Concept

Final Concept

7.1 Background

After having performed the tech and non-tech PoCs (Chapter 6), all gathered insights were translated into digital concept sketches (Fig. 75) in order to communicate the envisioned development direction. These sketches, alongside the findings were presented to the main expert and the rest of the supervisory team in order to open a discussion on features, details, expectations and execution of the final concept. Following these discussions, the conclusions were translated into a 3D CAD model, for which Solidworks 2019 was used, before presenting intermediate results to the supervisory team for further feedback. Finally after having gathered all final remarks and discussion points, the final model, which also forms the basis for the final prototype (Chapter 8), was created and rendered in Keyshot 9. These renders are presented in the following sections in order to explain the concept in more detail. For more information on which components were used for the final prototype, see Chapter 8, Section 8.2.

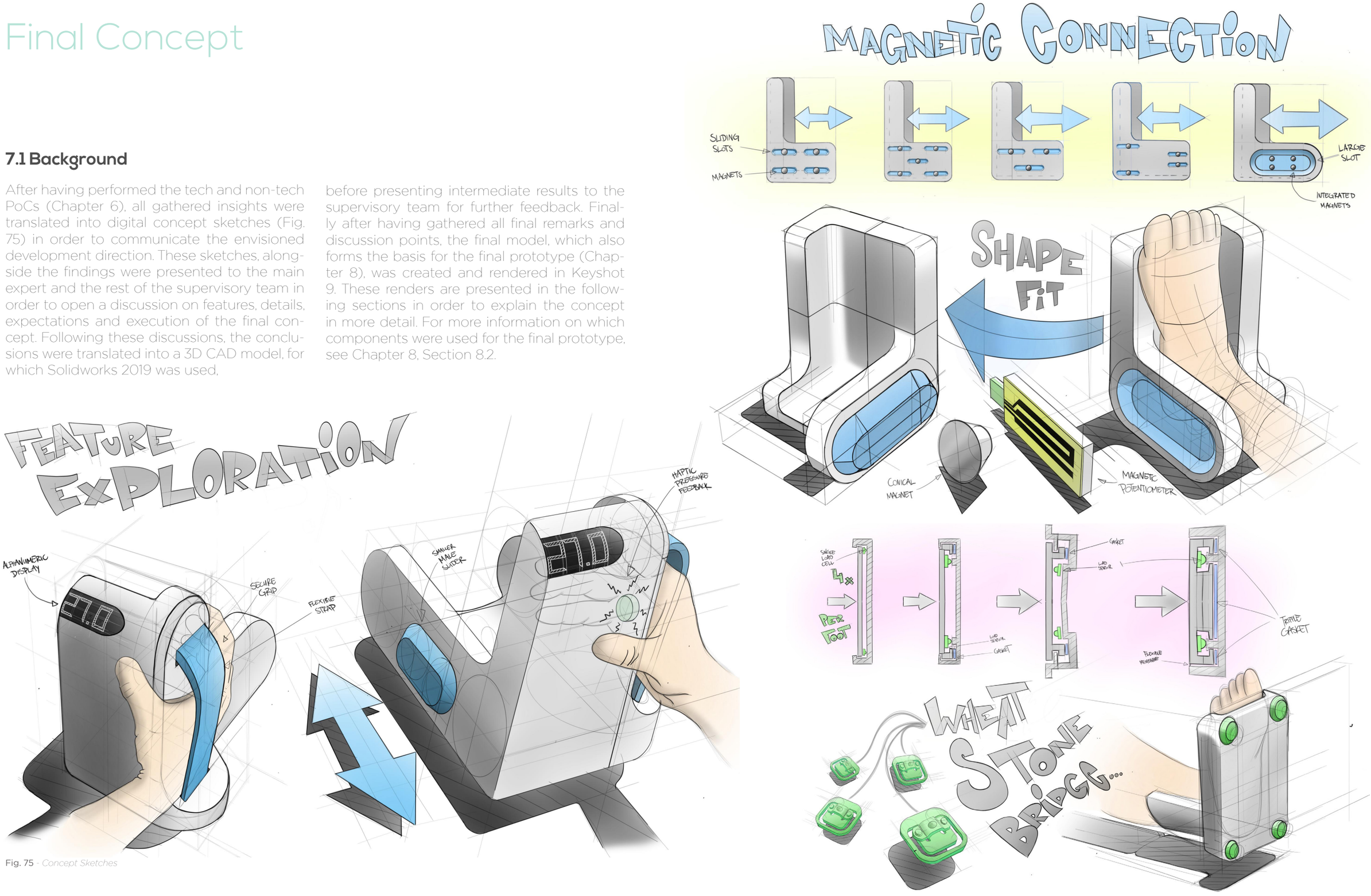


Fig. 75 - *Concept Sketches*

7.2 Concept Overview

7.2.1 PlusMinus

PlusMinus is a hand held device, similar in topology to a defibrillator. The device consisting of two units and a charging station. The two units are magnetically connected when in use, clicking together while conveniently switching the device on. The same magnetic features are used for suspending the unit onto the charging station, aligning the wireless charging coils precisely. The meaning of the name PlusMinus is manyfold. Primarily originating from the role that magnets play in this concept, creating a playful analogy to the attraction of opposite polarity. Nonetheless, the meaning extends further to the primary function of the device, constantly evaluating relative position of the units to one another.

Fig. 76 - *Concept Renders*

7.2.2 Working Principle

Core Technologies

Breaking down the concept, it is based on two core technologies:

1. Magnetopot
   - for relative position sensing

2. Wheatstone bridge
   - for reaction force sensing

The Magnetopot being discussed and reviewed in Chapter 6, now closer attention is paid to the Wheatstone bridge. The technological principle of the latter is what enables precise weight, mass or force sensing and is found in many household items, such as kitchens or body-weight scales. A more descriptive analogy and example product for this instance would be the Wii Balance board, which is a gaming / fitness console controller that measures the users weight distribution across the device. For this concept the same principle of a Wii balance board is used in order to evaluate whether the user of the device is applying equal forces to the feet of the patient. To get an extremely precise and reliable measurement, each contact surface is equipped with four load sensors, forming a Wheatstone bridge configuration. In order to overcome the discrepancy in length between both legs, the body is split into two halves and a movable, magnetic link is introduced. Therefore, by placing a Magnetopot in one unit of this split body design, the relative position of both units to each other can be determined (Fig. 78).

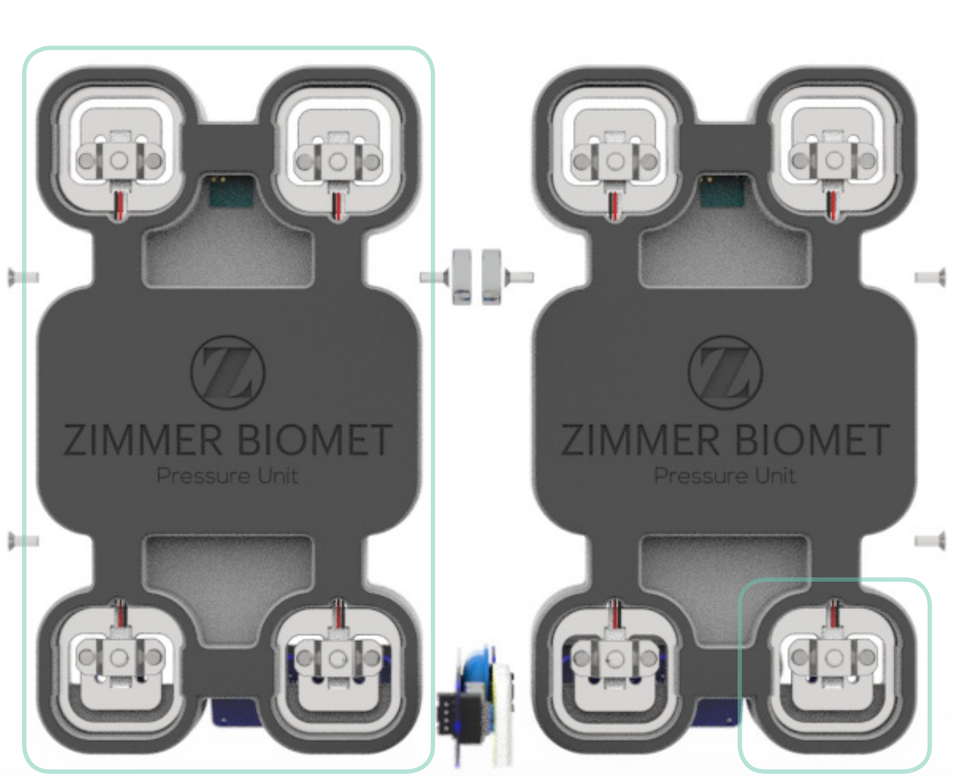
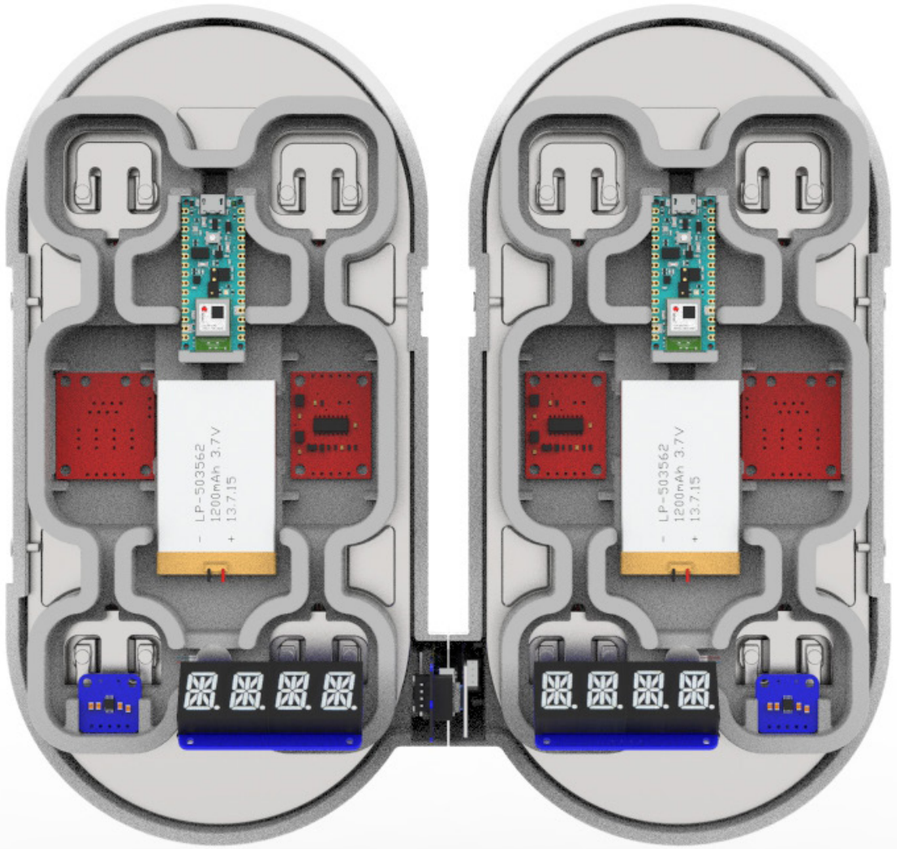


Fig. 77 - *Pressure unit (load cell) composed of four load sensors*

Fig. 78 - *MagnetoPot inside of sliding element*



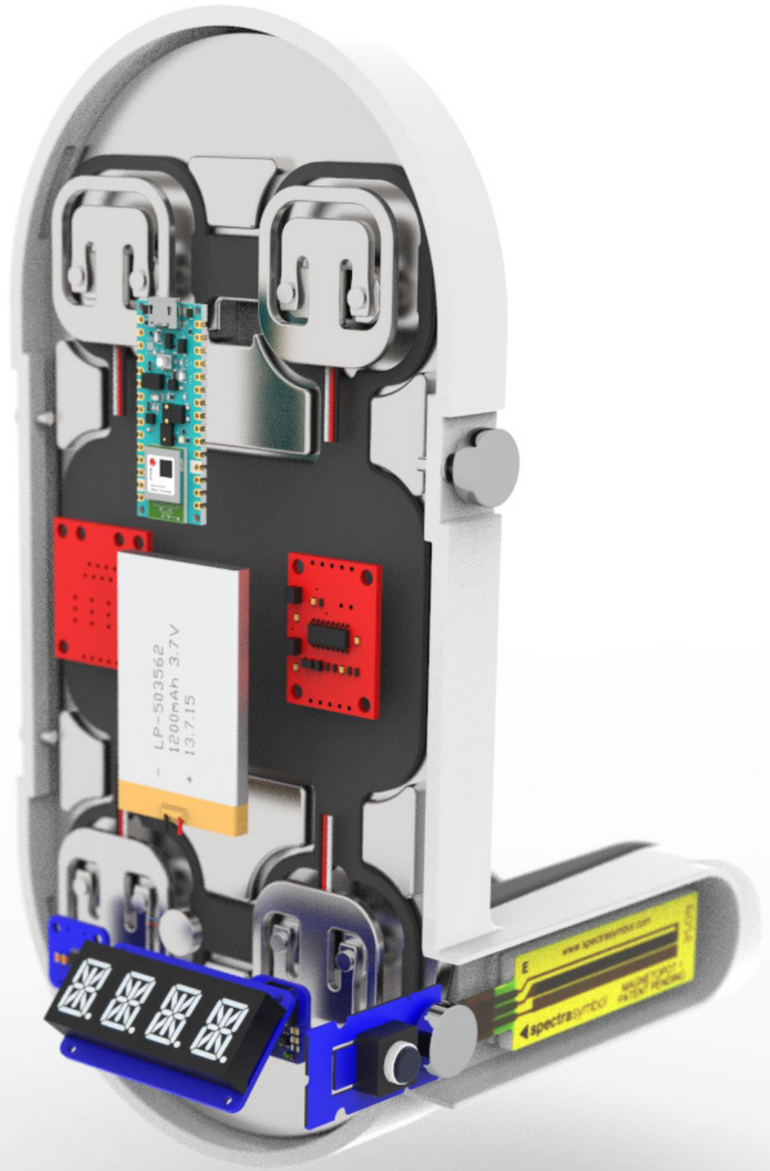


Fig. 79 - *Inner workings: component view*

User Communication

In order to communicate position and reaction forces to the user effectively, two principles have been chosen:

1. Alphanumeric display
   - for position communication

2. Haptic motor
   - for excess force communication

Alphanumeric displays are found in many household appliances, such as alarm clocks, microwaves or ovens. They are affordable and versatile, as they are able to display numbers as well as letters and consume little electricity. One display is used to communicate the negative discrepancy of the shorter leg in millimetres, whereas the longer leg stays at '+0.00', leading to an alternation effect, depending on which leg is longer. For the second principle, providing reaction force feedback, one haptic motor per unit is used. These motors will provide haptic feedback in case of unequal force application and vibrate the unit that has too much pressure applied to it. This way two separate communication channels for position and force sensing are created, reducing the risk of misinterpretation of any device feedback.

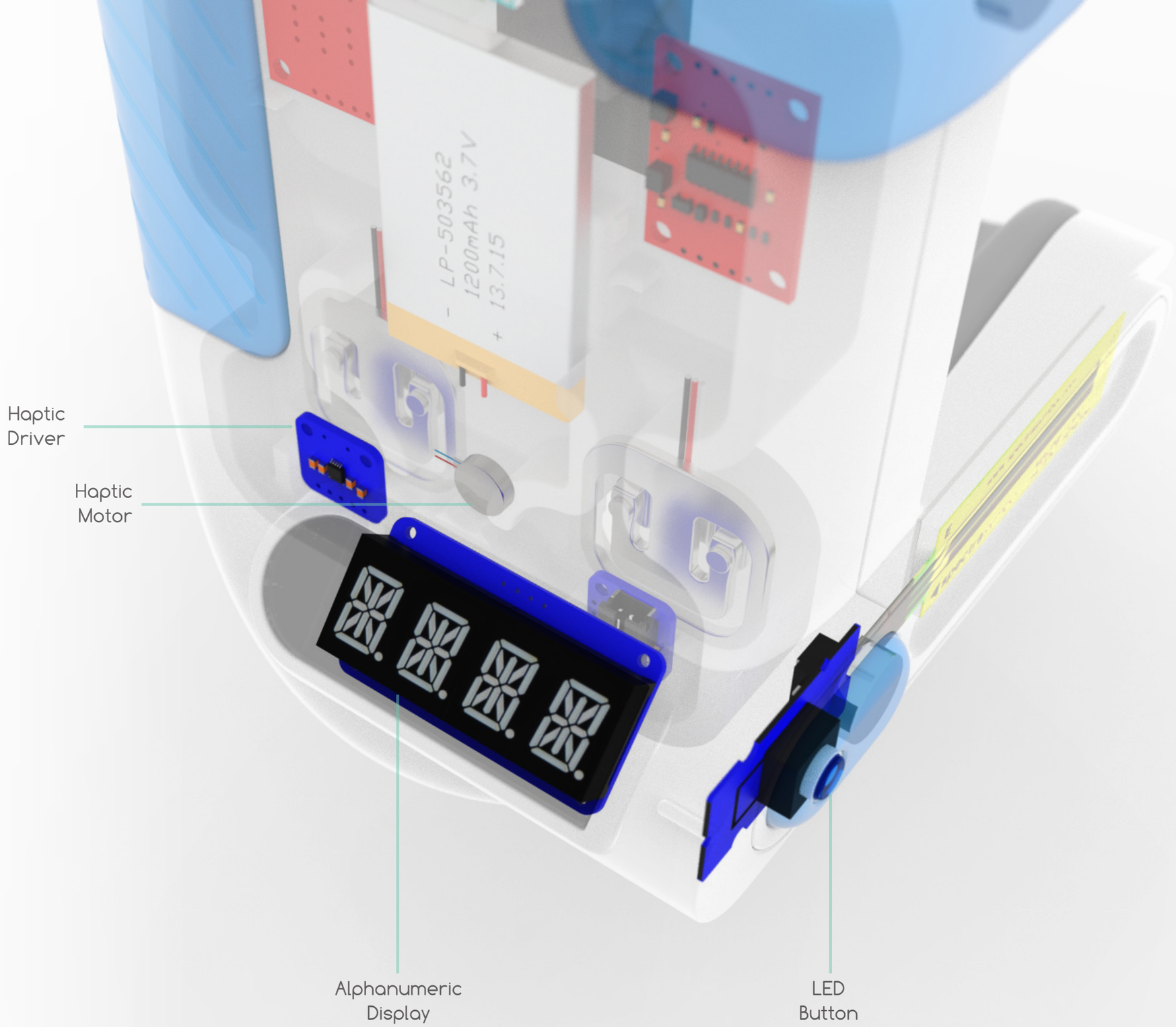


Fig. 80 - *User communication components*

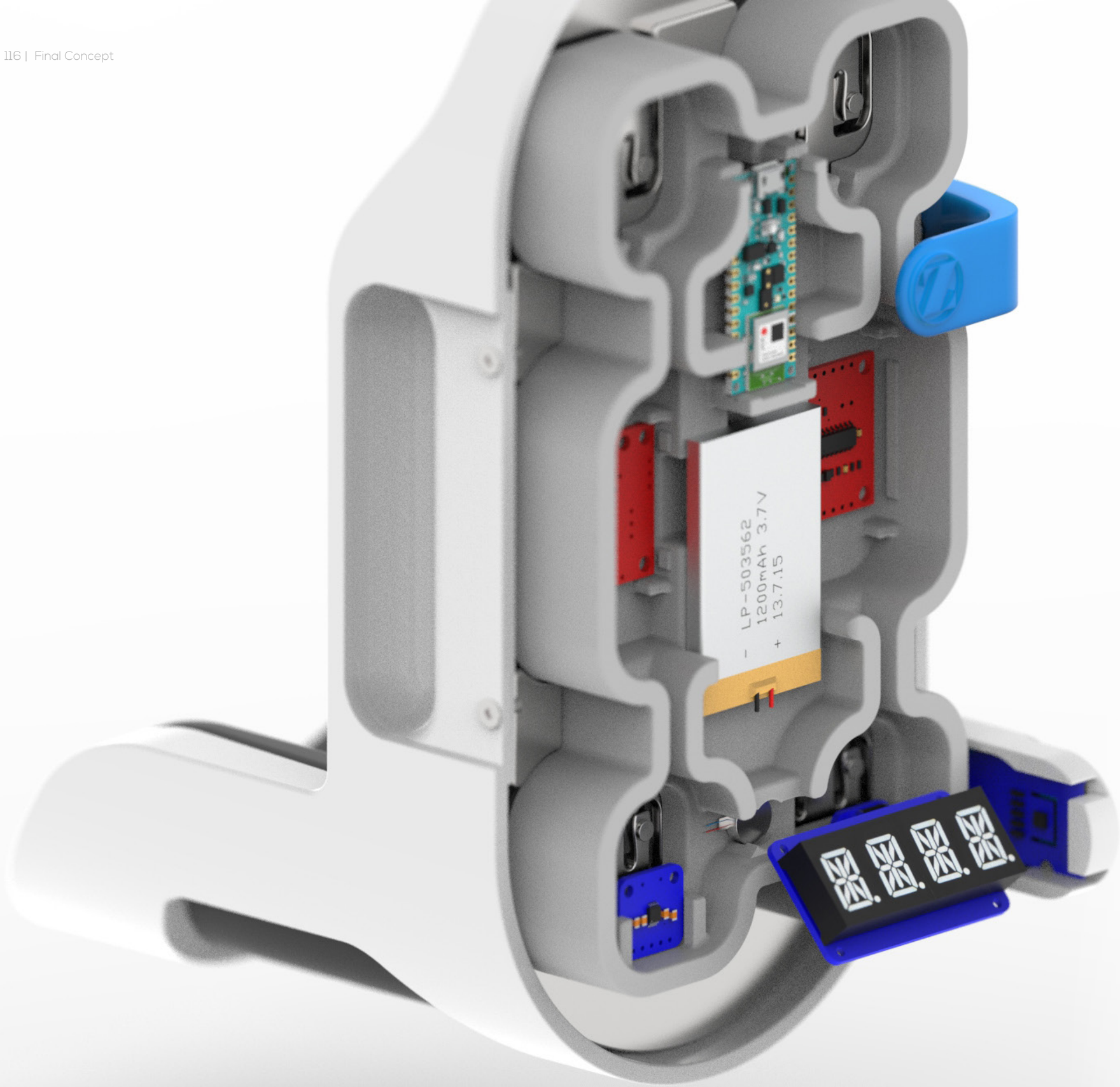


Fig. 81 - *Component frame close-up*

Power Supply, Charging & Storage

Each device's power button is located on the slider inside the protruding magnet housing, and features a blue LED. This means that the device switches on by itself, as soon as the two units connect. This effect is amplified by the blue LED illuminating the sliders and the alphanumeric displays switching on. This means that if the device does not switch on when connected, either the alignment is incorrect or the batteries are low. In order to prevent the latter scenario an 1200mAh battery is featured within the device, which given the low power consumption of all components will allow for all-day usage (based on a 10 hour work day + buffer). Nonetheless, this battery can be charged wirelessly on the accompanied charging stand. Here too the magnets and shape of the stand allow for perfect alignment of both the receiver and transmitter coils. This charging stand also doubles as a storage device in between LLD assessment moments or between surgeries.

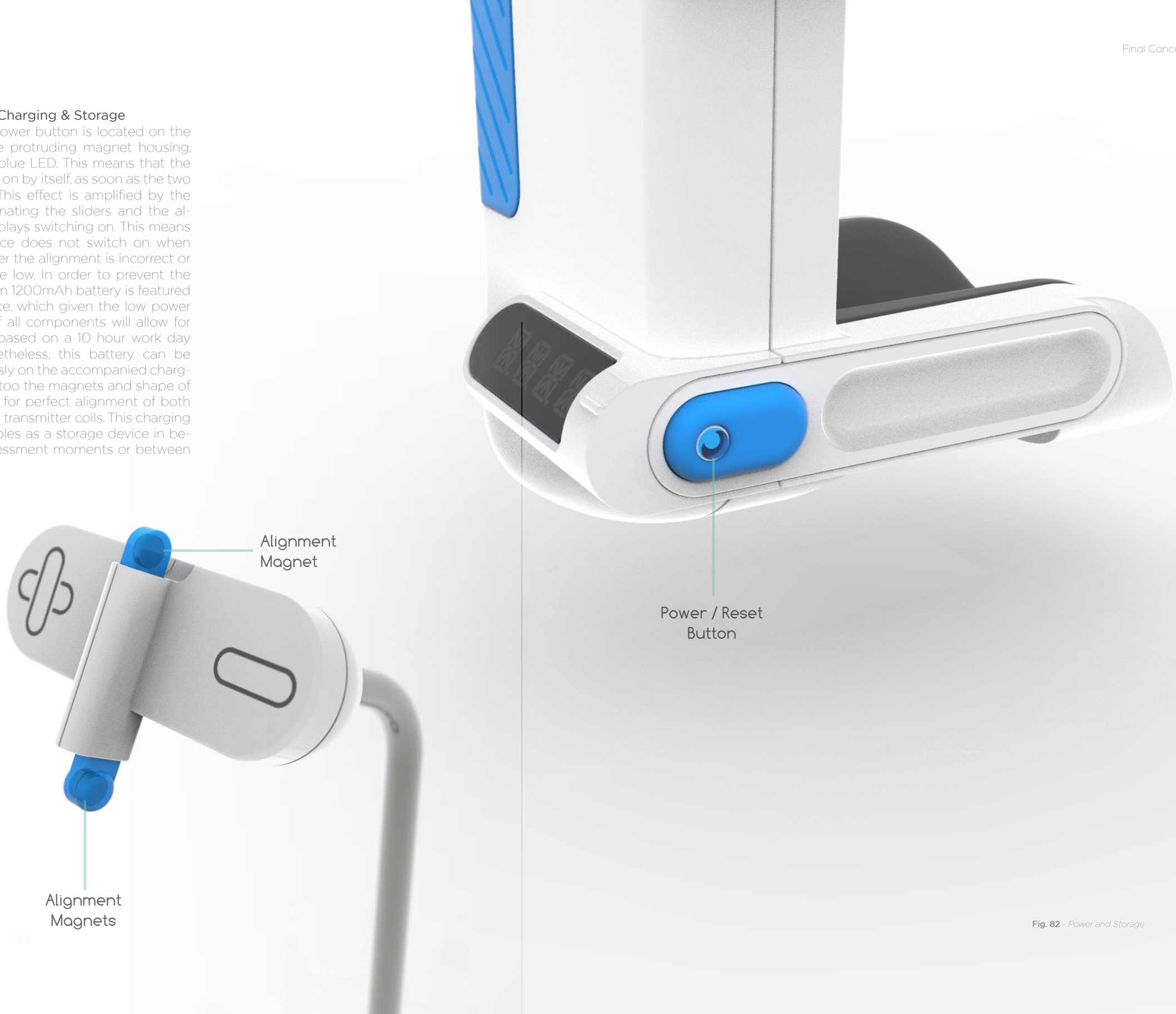


Fig. 82 - *Power and Storage*

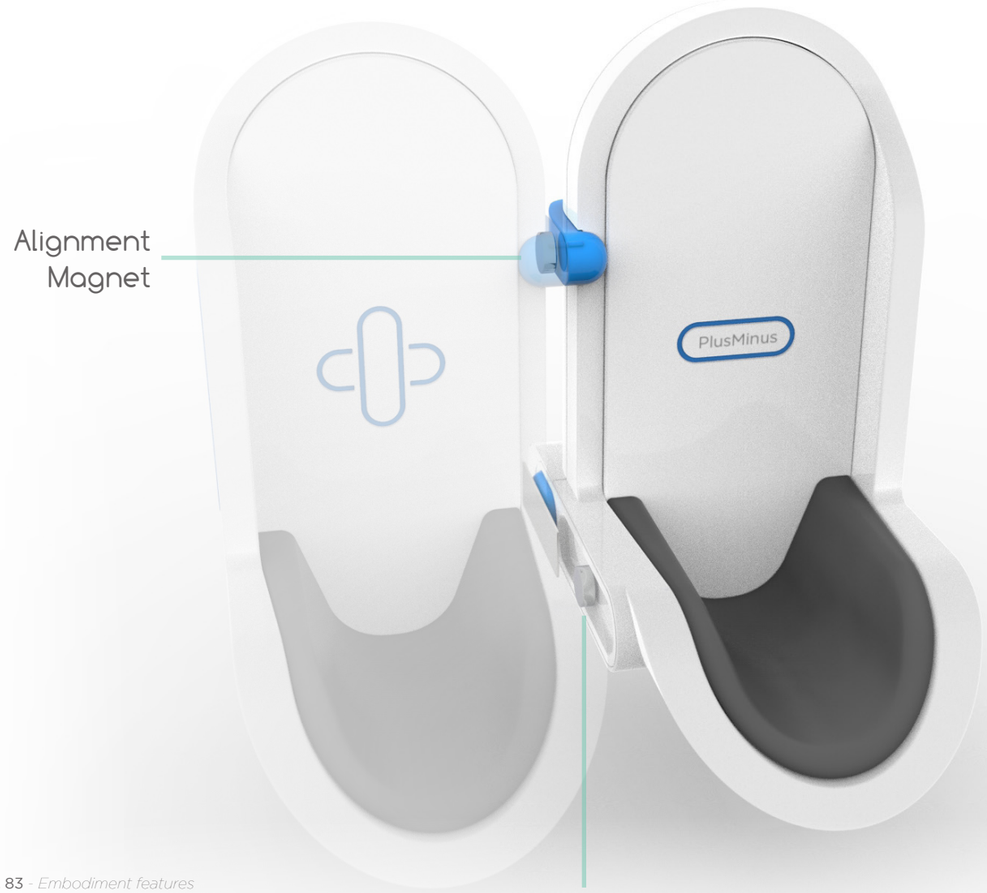
Stand

Wireless
Charging Coil

Embodiment Features

The first noticeable embodiment feature is the colour and texture differentiation of the handle portion compared to the rest of the device. The differentiation in look and feel create a use cue for intuitive user-product interaction. The next noticeable feature is the semi-soft insert, which restrains the patient's foot while providing stability and comfort. The insert is modular and comes in three different sizes (S, M and L) and can therefore be customised to each patient's foot size. The next feature, an alignment magnet placed on the top of either unit, provides additional stability during small discrepancy assessments. Furthermore, with these magnets the position calibration of the device can be checked, as when engaged neutrally the unit would display +00.0.

In case the entire system malfunctions due to component failure or low batteries, additional features have been incorporated in the embodiment of the device, that allow for 'offline' LLD assessments. For visual as well as haptic assessment, an embossed line has been placed on either side of the device. These embossed lines allow for relatively precise evaluation of leg length equality by eye, as well as touch. The placement of these alignment lines, next to the alphanumeric display (facing the primary user) and on the blue alignment magnet housing (facing the secondary user) also allows for two people to evaluate the device's position from opposing sides (e.g. surgeon and circulating nurse).



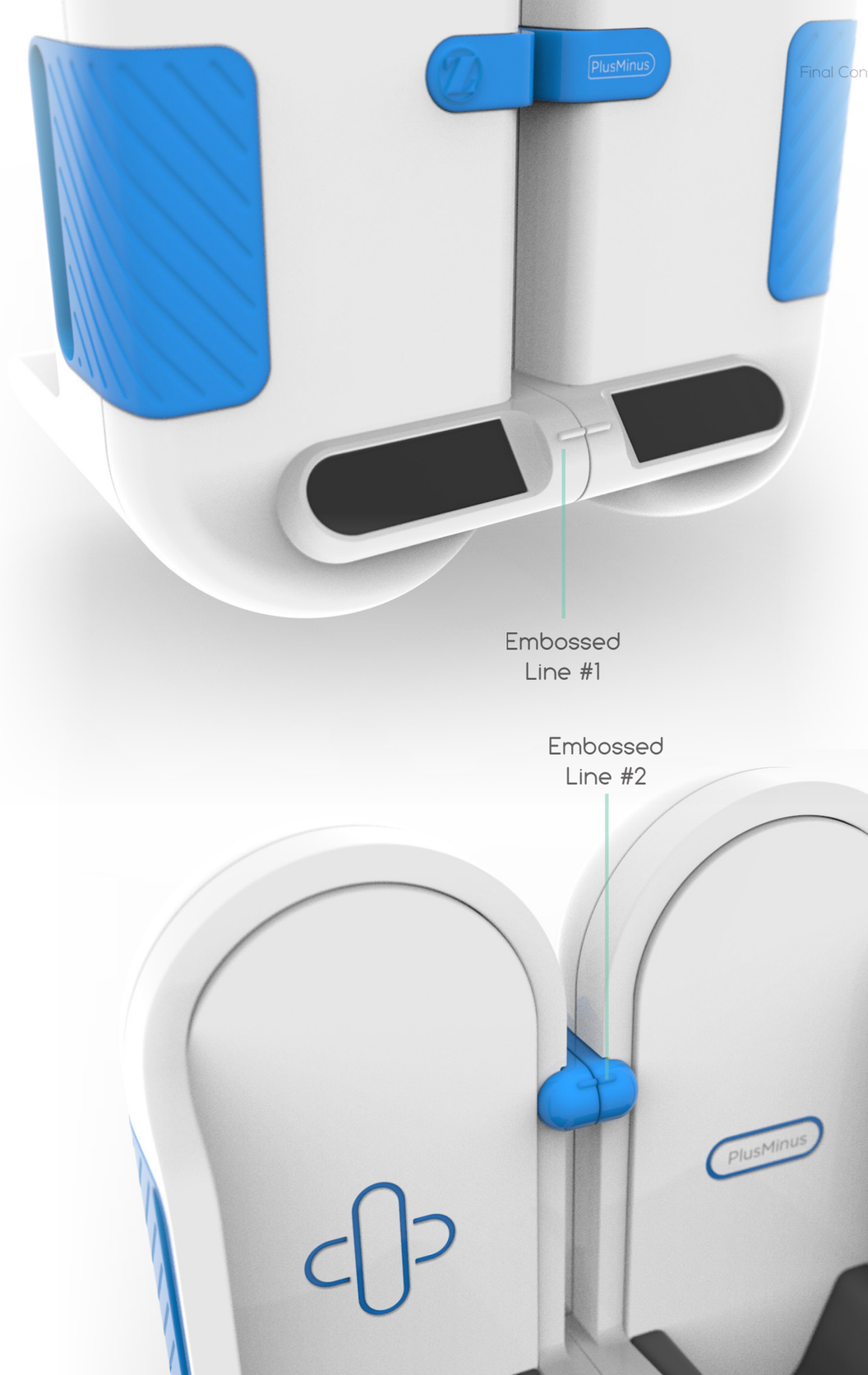


Fig. 83 - *Embodiment features*

For rough offline evaluation of larger discrepancies the earlier mentioned alignment magnets can be facilitated. The diameter of 15mm means that as soon as these magnets start to engage noticeably, the discrepancy is within 10mm. Otherwise, if the magnets are out of each other's range, it indicates a discrepancy of at least 10mm. Although an 'offline' assessment falls short in applying equal pressure to the patient's feet, it still improves the current way of assessing a patient's LLD by putting the patient's feet into plantigrade position as well as requiring only one person to perform the assessment.

Lastly, frequent rotation within the OR may not allow for traditional sterilisation methods between THAs. Although the product is entirely sealed and therefore able to undergo sterilisation by various cleaning agents, a custom sterile plastic cover has been created, which can be discarded after each surgery. This not being the sustainable design choice, it should be considered that in a non-surgical setting (pre- or postoperative) the device can be sterilised quickly between patients.

Fig. 84 - *Modular Inserts (size M)*

Data Logging
As the device uses Bluetooth to communicate, all data can be directly logged into the electronic patient's file. This would allow for pre-, intra-, and post-operative assessments to become more easily comparable, therefore creating a measurement standard. Ultimately in a patient journey this would mean that the patient is assessed preoperatively, and any preoperative LLD is registered. Intraoperatively, surgeons can make informed decisions on whether they want to replicate that discrepancy or align legs equally, based on each patient's history, context and condition. Postoperatively additional assessments will reveal long-term effects of THA on postoperative LLD. This may allow for algorithmic pattern recognition ultimately creating data-driven insights into the relation between pre-operative LLD, postoperative LLD and surgical workflows.

7.3 Discussion

7.3.1 General

This concept, being the first of its kind, will most likely turn out to be flawed in many ways that are unidentified at this point. In a product development context, many more proof of concepts and experiments would be performed at this point. Due to the time frame of this project, these steps are skipped and an attempt at a complete and integrated functional prototype of this version is created.

7.3.2 Limitations

The primary limitation of this concept is probably ergonomics. For example, very little time was spent on investigating what the most ergonomic grip for this device would be, or even if the proposed product-user interaction makes sense from a cognitive ergonomics standpoint. Especially in regard of the latter, many assumptions made may turn out to be biased. These types of insights can only be gained through user testing, which context and time wise did not fit into the development scope.

Key Insights

- The concept, is based on two technologies:

1. Magnetopot - for relative position sensing
2. Wheatstone bridge - for reaction force sensing

- Two communication principles were chosen:

1. Alphanumeric display - for position communication
2. Haptic motor - for excess force communication

Chapter 8

Final Prototype

Final Prototype

8.1 Background

After having constructed the entire concept in CAD software (Chapter 7), it was time to start fabricating it. Keeping the prototyping methods in mind, the individual parts of the concept were modelled accordingly. This means fit tolerances and wall thicknesses appropriate for FMD 3D printing using PETG and TPU filament. In order to ensure the fit of all electronic components listed in the next section, a series of test prints were performed in order to dial in tolerances to 'press fit' levels (Fig. 85) and minimal dead space. As slicing software, Simplify3D (Version 4.1.2) was used with custom designed print profiles (see Appendix I) and the machine used remained the Creality CR20 Pro.

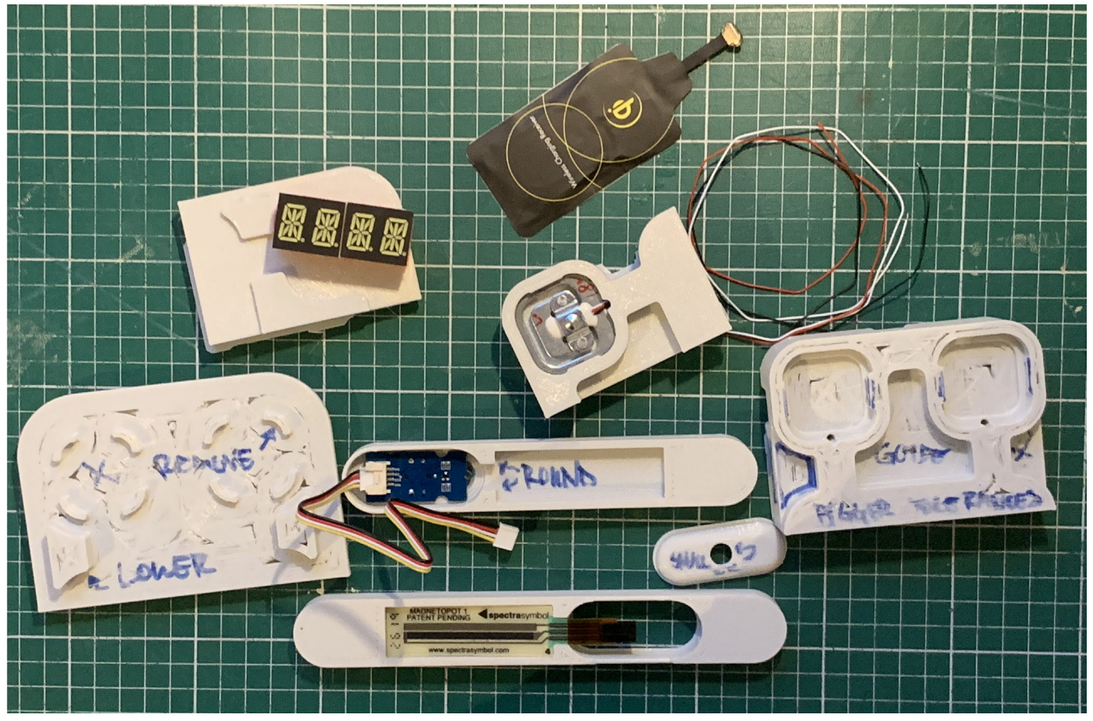
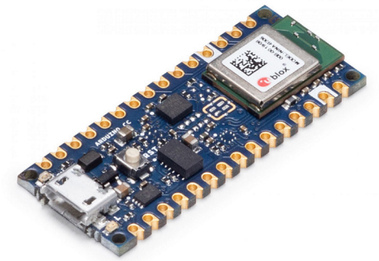


Fig. 85 - *Component fit test prints*

8.2 Component Overview

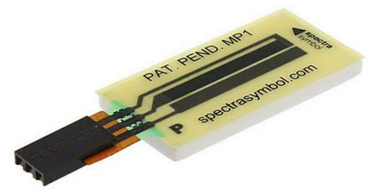
Nano 33 BLE

The Nano 33 BLE is the latest small factor microcontroller from Arduino (Arduino, 2019), released in 2019. This board runs off 3.3 Volt logic and is able to communicate wirelessly over Bluetooth Low Energy to a host of peripheral devices. One Nano 33 BLE board per unit is used, one acting as the central device and the other as the peripheral device.



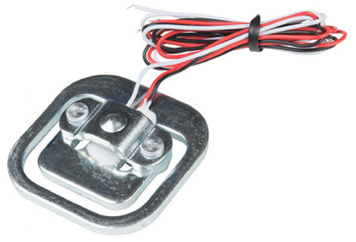
Magnetopot (50mm)

The Magnetopot by Spectrasymbol (Spectra Symbol, 2019) is similar to their linear potentiometer technology (see Appendix J). The Magnetopot houses an internal magnet, which pushes against a force sensitive resistor, when activated by an external magnet. This allows for precise and stable position sensing. One Magnetopot with a linear sensing distance of 50mm is housed in the left unit (from the primary user's view), next to the right heel and patients right medial malleolus. This allows for relative position sensing of 25mm in either direction, which was deemed sufficient based on the survey results in Chapter 3.



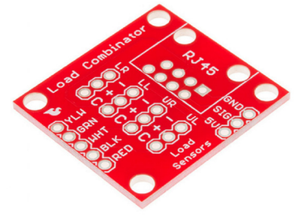
Load Sensor (50kg)

Four load sensors (or strain gauges) by SparkFun (SparkFun Electronics, 2019) are used per unit. Usually load sensors of this type are found in body-weight scales and are not to be confused with load cells (see next paragraph). This particular strain gauge can measure forces up to 500N and can be amplified for better data resolution.



Load Sensor Combinator

The load sensor combinator by Sparkfun (SparkFun Electronics, 2017) does exactly what is says: it combines load sensors and configures them into a wheatstone bridge, thereby forming a load cell. This allows for much more accurate measurements of force or pressure. One combinator is placed in either unit and has the four load sensors connected to it.



Vibrating Mini Motor Disc
The vibrating mini motor disc by Adafruit (Adafruit Industries, 2020e) is a haptic motor with a small footprint of 2.7 x 10mm (diameter) running on 2-5 volts. One motor per unit will provide the user with haptic feedback on excessive applied force on either patient's foot.

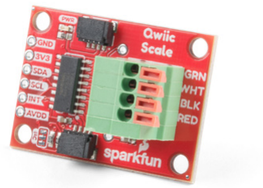
Haptic Motor Controller (DRV2605L)
The haptic motor controller by Adafruit (Adafruit Industries, 2020a) allows for simple programming of vibration patterns, is placed in either unit for individual motor control and sits between the motor and the Nano 33 BLE.

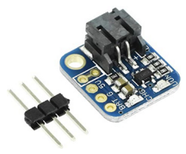
Quad Alphanumeric Display
The quad alphanumeric display by Adafruit (Adafruit Industries, 2020d) is a 60 segment LED matrix (14 segments per character excl. dots), that allows for displaying letters as well as numbers. Each display, placed in either unit, can visualise up to four characters, therefore allowing for numeric feedback on position discrepancy or error messages.

Grove LED Button (blue)
The blue Grove LED button by Seeed Studio (Seeed Studio, 2020), combines a button and LED in one unit and places it on top of a compact breakout board, with quick connect cable adaptors. This LED button also uses 3.3V logic and can therefore easily be combined with the Nano 33 BLE. One LED button is placed in either unit, right next to the primary magnets, acting as the power button of the system and communicating power status via the LED to the user.

Lithium Ion Polymer Battery (3,7V 1200mAh)
The LiPo battery by Adafruit (Adafruit Industries, 2020c) is intended to last for a whole working day. One battery per unit will allow for continuous LLD evaluations, even without intermediary charges.

LiPo Battery Backpack
The LiPo battery backpack by Adafruit (Adafruit Industries, 2020b) allows for 500mA charging cycles and ensures quick recharging of both units. The LiPo battery backpack is connected to the battery, Nano 33BLE and the LED button.





Qi Receiver Coil
The Qi Wireless receiver by a no-name brand is placed right underneath the patient contact surface or the pressure plate. This receiver coil allows for the device to be recharged when placed onto the charging station.

8.3 Results

8.3.1 System Overview
A circuit diagram was created in order to make a visual overview that will be used as template for soldering and coding logic. On the left hand side, there are the four load sensors, followed by the combinator and the Qwicc Scale (here represented by an older model). The colour coding for these components is unique to load sensors, with white being plus (+), black being minus (-) and red being the constant (C). From there the load sensors are being combined into a load cell with red being Excitation+ (E+ or VCC), black being Excitation- (E- or GND), white being the Amplifier- (A-) and green being Amplifier+ (A+). Exiting the Qwiic scale are four wires, red for 3,3V, black for ground, blue for Serial Data (SDA) and yellow for Serial Clock (SCL). These colour codes are the same for the alphanumeric display and the haptic driver, which features an additional interrupt (INT) pin. On the other side of the haptic driver board sits the haptic motor which has a positive and negative lead.

Towards the top of the schematic, above the Arduino there is the LED button (visualised by a simplified button), which features red and black leads for 3,3V and GND respectively, yellow for the LED signal (SIG1) and white for the button status (SIG2). The Magnetopot on the right hand side has a green line for analog data and otherwise the usual red and black line for 3,3V and GND. With the battery backpack, which the battery is connected to, the colour coding changes a little. The black line is still GND, the green line is the 3.3V output to the Arduino, whereas the red line is the 5V input for the battery charging circuit on the board, which is only activated when the Arduino's micro USB is given power (not visualised: Qi receiver coil). The Arduino, although running on 3,3V logic, can pass through 5V if a jumper on the backside of the board is connected, which has been done. Additionally the 3,3V trace on the back of the board can be cut in order to reduce power consumption, by bypassing the onboard converter and supplying pre-regulated power from the battery backpack. This has not been done, as it would require resoldering the trace every time a new code needs to be uploaded.

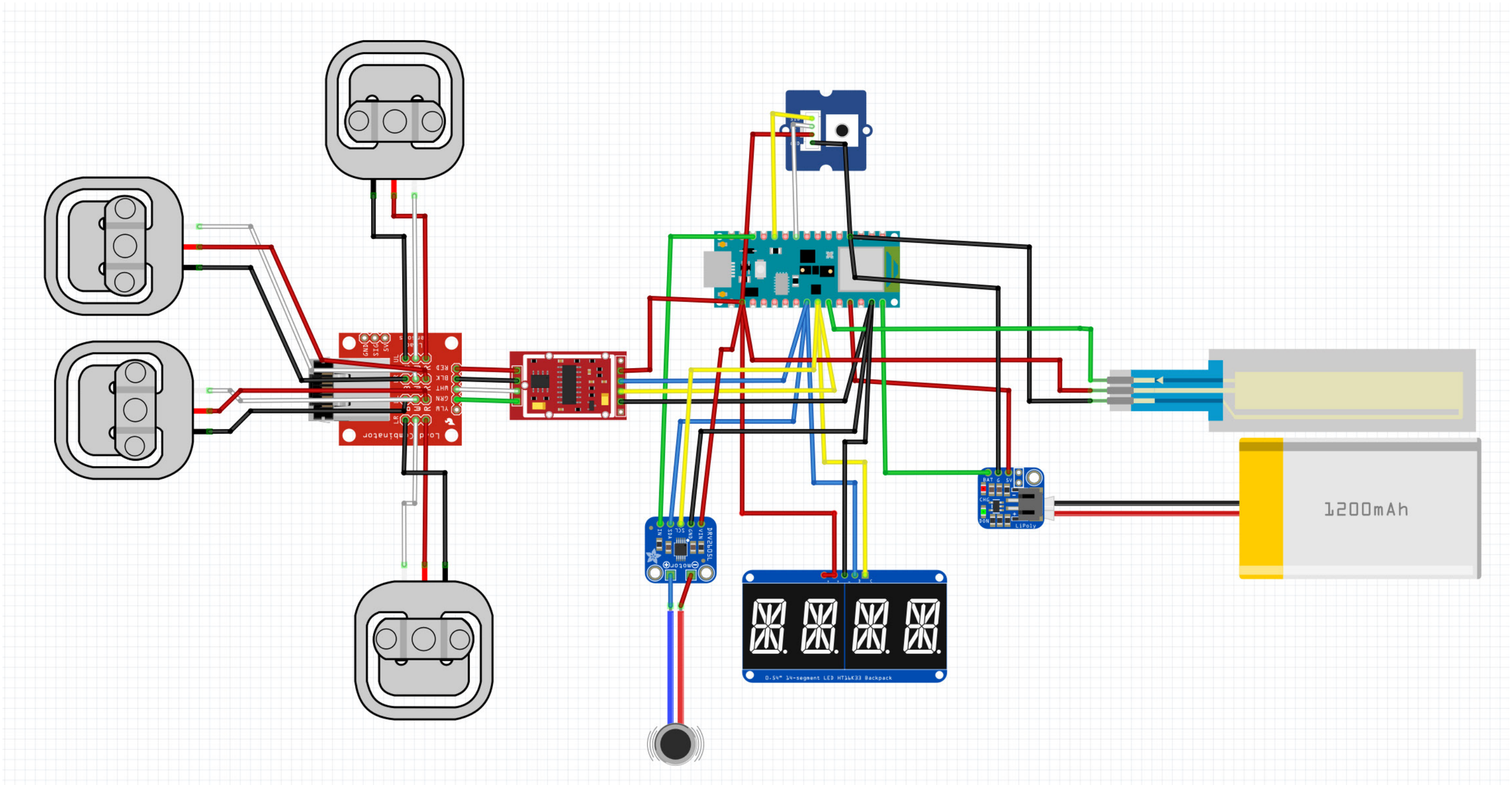


Fig. 86 - *Wiring Schematic*

8.3.2 Assembly

Electronics

After all components and their wiring schematics were tested separately with component library examples, they were soldered and fitted into the respective pressure unit frames. All connections on the Arduino side received a female pin connector, whereas all components received male pin connectors. The cables were colour coded according to the schematic in section '8.2.1 System Overview'. Only in a few cases the colour code was altered due to the lack of available cable colours.

After having soldered all connectors, the library examples were uploaded again in order to check the solder connections of each component individually. Having tested all components, it was time to integrate the code one component at a time. Firstly, the data reading of the Magnetopot were calibrated and the conversion to the alphanumeric display was coded and tested. Afterwards the LED and button states were integrated and the code was tested again. Next, the loadcell readings were calibrated and linked with the haptic driver, which was programmed with a simple vibrating pattern. This code section was then integrated into the first section and successfully tested. Finally, the BLE connection was programmed and tested, which caused some intermediate errors and lead to the connection loosing at times. Overall, the code was relatively stable at that point, so it was decided to secure all cables within the unit and continue the assembly.

Housing

Assembly of the housing was relatively straight forward, as all parts had been 3D printed previously. Firstly, the pressure plate had to be assembled, which included inserting the wireless charging coil and placing small 20 mm square steel raisers (1 mm thickness), that would be the contact point for the load sensors (Fig. 90).

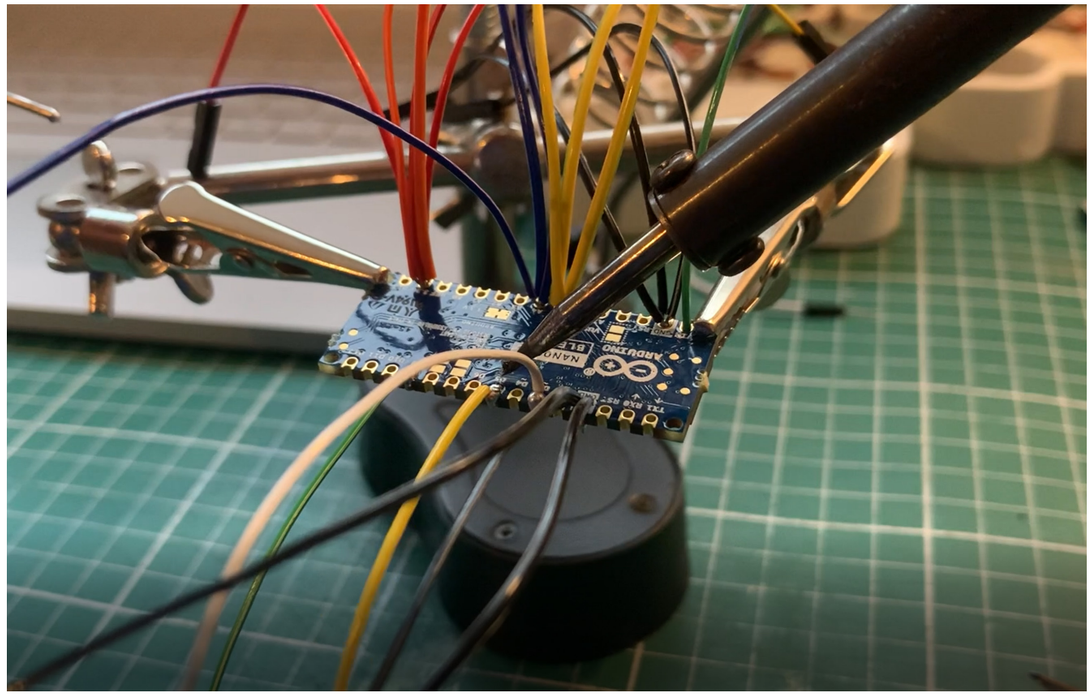


Fig. 87 - *Arduino Soldering*

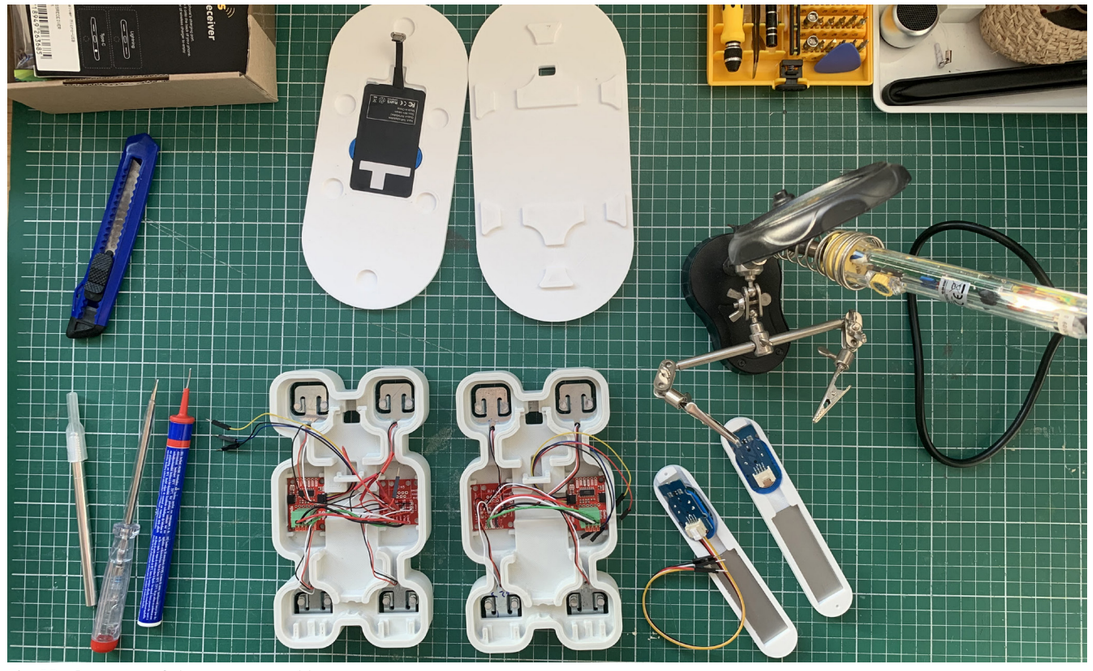


Fig. 88 - *Beginning of electronics assembly*

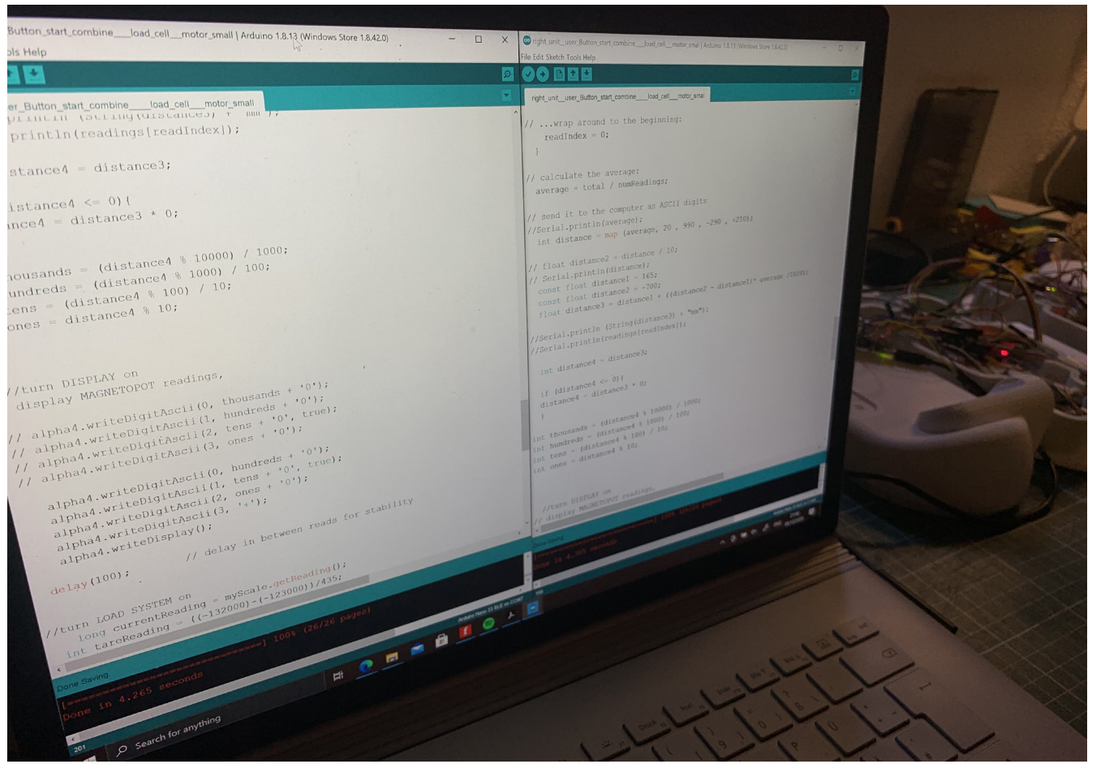


Fig. 89 - *Arduino Coding*

Fig. 90 - *Load sensors and steel raisers (background)*

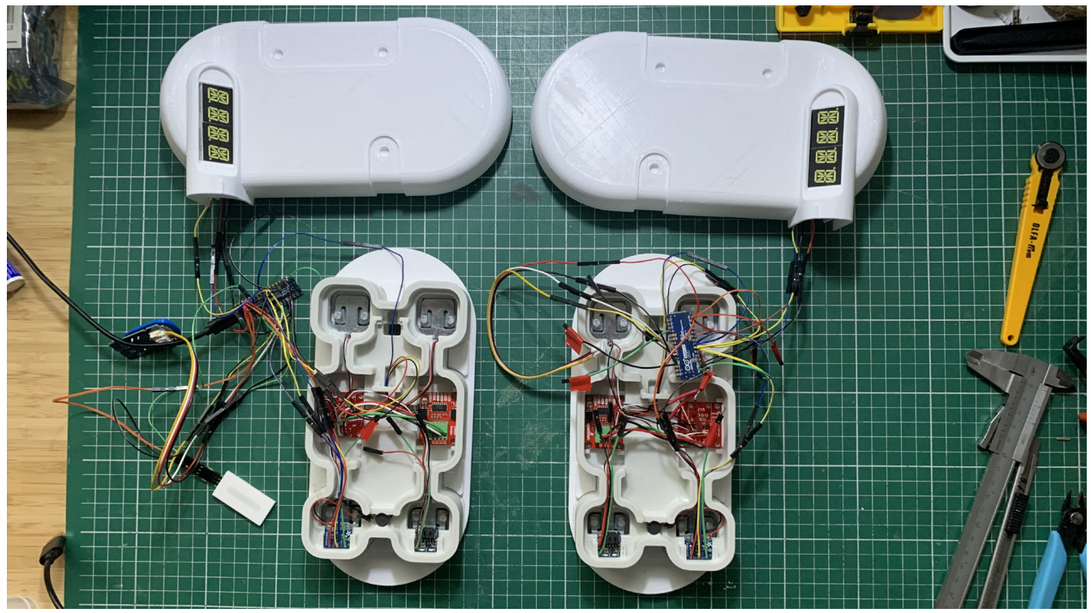


Fig. 91 - *Integrated electronics assembly*

Fig. 92 - *Fully assembled prototype (back view)*

Fig. 93 - *Switched on Prototype displaying 0mm discrepancy (front view)*

Fig. 94 - *Display close-up*

Fig. 95 - *Bottom view of inserts and LED shine*

Fig. 96 - *Bottom view of inserts*

After that had been done, the coil was connected to the Arduino and the pressure unit was placed upside down onto the pressure plate. All cable connections were checked to be flush, before placing the front cover over the assembly, with the cables to the Magnetopot and the LED button routed through a channel to the outside. Next, the slider element was assembled, the Magnetopot secured with double sided tape, the magnet placed and secured by the LED button. The slider assembly was then connected and placed into the front cover after which the preassembled back cover (foot restraint + insert) was positioned. The entire assembly is being held in place by four screws, one below the insert securing back cover and slider, two under the handle cover securing back and front cover and the last one under the top alignment slider, also securing back and front cover. Another set of magnets was placed into the top alignment slider, before it and the handle cover were snap-fitted onto the housing, covering the screws. Last but not least, a black tint film was applied to a clear piece of acrylic and fitted into the display portion of the housing.

8.4 Discussion

8.4.1 General

Overall, the prototype in its physical form was satisfactory. The print quality on some cosmetic parts were not the greatest, but this was also not the main goal. Considering component fit, all tolerances were extremely tight, to the point that during assembly close attention had to be paid to clinched cables. The construction of such tight spaces was deliberate, so that the overall volume of the prototype would be a closer representation of a final product. Overall, the prototype can be streamlined significantly, as the wall thicknesses were exaggerated for structural stability. In fact, the volume and weight of the device could be decreased significantly if electronics are optimised into a single printed circuit board (PCB) and product architecture is optimised. Making use of more industrial manufacturing methods (e.g. injection moulding) and stiffer and lighter materials would improve structural stability even further, as would be required from such a device.

8.4.2 Limitations

The primary limitation of this prototype is the fact that it is based of prototyping electronics and prototyping production methods. A more stable code could have been developed in order to enhance the BLE functionality and capabilities of the prototype. Nonetheless, time constraints did not allow for that.

Key Insights

- Assembly was straight foreward

- BLE connection was not stable

- Overall, the prototype can be streamlined significantly, as the wall thicknesses were exaggerated for structural stability.

Chapter 9

Testing & Evaluation

Testing & Evaluation

9.1 Background

In order to test the functional performance of the prototype and validate its conceptual expectation, this chapter will be dealing with a brief investigation of both, before concluding with limitations and improvements for future iterations.

9.2 Test Setups

Functional Performance

A simple test setup has been created in order to validate the accuracy of the prototype in terms of measuring relative position discrepancy. The units were placed onto a reference grid and displaced in cycles of 5mm increments and measured against their actual position on the grid. All functional expectations were evaluated during this test.

Conceptual expectation

In this test a participant was asked to lay on the floor with the referencing grid placed underneath their feet (fig. 99). Then the participant was asked to introduce artificial pelvic tilt which was first measured without applying any pressure and checked against the reference grid (+ calliper). Afterwards pressure on the feet was applied until the vibration stopped. Also here, every time the device indicated movement of 5 mm, the position of the device will be checked against the reference grid.

9.3 Findings

Overall, the prototype performed poorly at first. The BLE connection did not perform as expected, therefore it was excluded from the code and a hardware change to 25mm Magnetopots in either unit was made to display the discrepancy locally (see Appendix K).

Additionally, the haptic force feedback was reversed to shut of vibrations once a pressure limit has been reached, so to say encouraging the user to push. Once set-up, the testing resumed with the 5mm displacement test, which were showing stable readings, yet some code errors remained (e.g. display flikkering). Overall reading values had error tolerances of 0.5 - 0.9mm, which was deemed acceptable. Unfortunate however was the CAD dimensioning error, that limited the travel in one direction to 13mm instead of 25 mm resulting in a discrepancy measurement range of 38 mm instead of 50 mm. Another logic mistake from the code resulted in the display showing a '+' instead of a minus, causing slight confusion when the measurement was taken at first.

The magnetic connection between the units was surprisingly stable, but one may consider experimenting more with the magnet position and configuration for a more advanced setup. Certainly tolerances of the sliding components can be improved, as the units had a little too much play between them, yet not too much to render the measurements inaccurate. It could be argued that tighter tolerances would decrease the error margin of measurements.

During the participant test, the haptic feedback performed as coded, but at times it was difficult to distinguish which side was still vibrating. This may have been due to the positioning of the motors and arguably the position could be adjusted to produce more touch-local vibrations (e.g. underneath the handle). Other than the coding errors and the vibration confusion, the participant tests were rather successful providing confidence that further developments into this direction would create a user-friendly and reliable product interaction.

Fig. 97 - *Left display error*

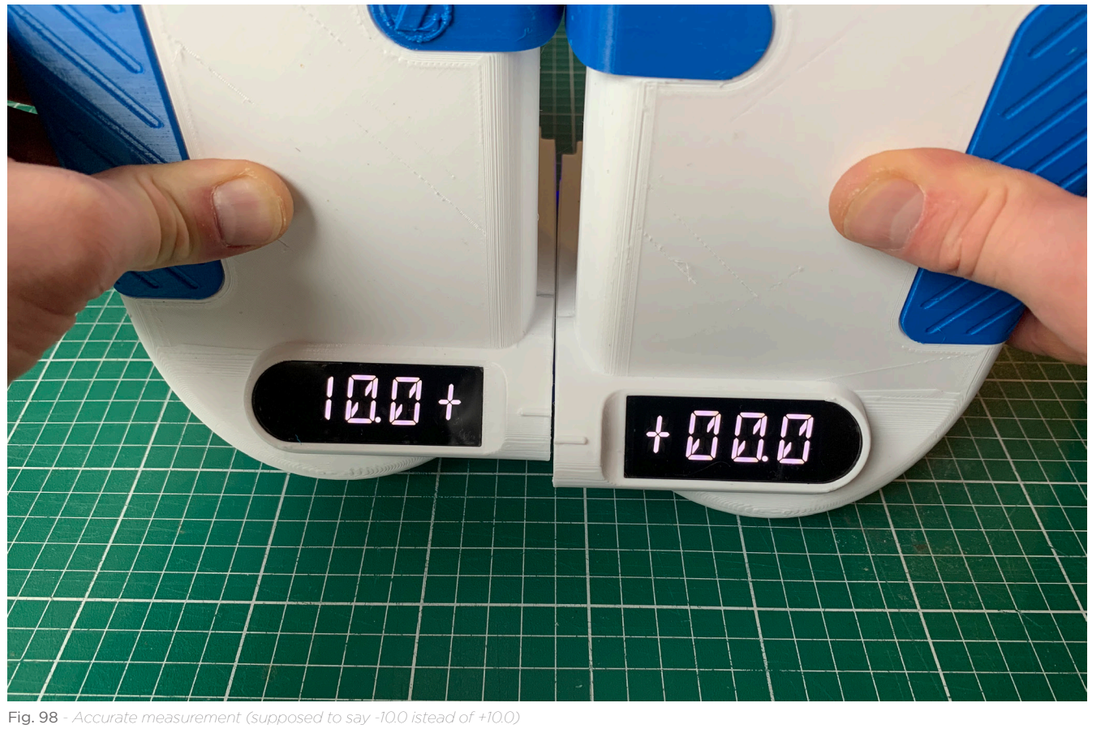


Fig. 98 - *Accurate measurement (supposed to say -10.0 istead of +10.0)*

Fig. 99 - *Prototype testing on participant*

9.4 Discussion

9.4.1 General

These tests and evaluations are extremely basic, just so that the general working principle of the prototype can be evaluated. It is to be said that even though more extensive testing would be required, this simple setup provided enough insights for further iterations. Firstly, the position of the magnet in relation to the slider needs to be changed so that equal distances in both directions can be measured. Secondly, a more reliable and robust code needs to be scripted that provides stable BLE connections and communication. Also, the calibration of all sensors can be scripted better than in this prototype where the same basic averaging logic has been applied as for the PoCs (Chapter 6). Furthermore user-product interactions can be explored more in terms of (cognitive) ergonomics (e.g. handle / haptic feedback).

9.4.2 Limitations

As with all experiments performed throughout this project, also these tests were performed in a home office context. Therefore, no laboratory conditions were given and no laboratory equipment was used. Certainly, the quality of assessment could have been improved with more sophisticated methods. One test that could have benefited from such methods could have been a way to validate the forces applied to each unit. The test setup does not validate accurate force measurements, which may be unequal due to slight differences in print settings on both units. Unfortunately, the device also couldn't be tested by medical professionals before handing in this thesis, as a meeting was organised for after the final paper deadline. Insights and feedback from medical professionals would have provided a more well-rounded impression of the result and would have rendered the evaluation less singular.

Key Insights

- Overall performance as expected
- Robustness of code needs improving
- Magnet configuration can be otimised
- Tolerances can be optimised

Chapter 10

General Discussion

General Discussion

10.1 Background

After having gone through the entire process, this chapter is dedicated to evaluating the overall process and results, answering the research questions and offering a reflection on the project.

10.2 Research Asnwers

How to more accurately reference, assess and dimension lower limbs while considering a patient's individual anatomical differences?

Although there is a lack of clinical studies and long-term insights to provide an adequate answer to this question, this research offers an investigative direction. When accurately referencing and assessing lower limbs one should focus mainly on the functional requirement, which in this case is standing and walking. Therefore, it is advised to simulate these conditions, whereas the later may prove to be difficult to implement. However, the former can be simulated partially, by performing a dynamic or loaded assessment, meaning to apply pressure to the patient's feet, as proposed in the design solution. This does not simulate the patient's entire weight and a deliberate choice against a device that could do so was made in order to enhance the medical staff's skills, keep the human aspect (as opposed to being actuator powered) and retain human / hands-on control over the assessment.One could develop a device though that would allow to simulate an orthostatic position on the patient while in supine position. Such a device would likely need to be integrated into the OR table in order to fulfil the desired functionality. Regardless of the embodiment, the most important aspect is that a measurement standard is created that makes interphase results comparable.

How can symmetry be evaluated and created in an asymmetric biomechanical system?

Symmetry in a biological system is a relative concept and the focus should rather lie on creating relative symmetry, considering patient anomalies and focussing mainly on functional requirements. These functional requirements include standing and walking, as well as functional joint performance. In the future, such analyses could be performed in simulation software and based off CT and MRI scans. Until then, the proposed design solution would enable to evaluate a patient's functional symmetry pre-, intra- and postoperatively and provide a basis for informed decision making.

What role does the patient's position play during repeated LLD assessments?

The patient's position is crucial when assessing LLD and can lead to false positives. In particular the patient's pelvic orientation or pelvic tilt influence an assessment and are one of the leading sources of false positives. Thereby, knowing the patient's pelvic orientation proves valuable. For using the proposed design solution it is advised to lift the patient's legs to the point that the pelvis is slightly suspended. When lowering the legs in a symmetrical fashion, the pelvis self-orientates and an assessment can be performed. These type of movement protocols are already used by some medical professionals, but should really become part of standard procedure. In context of the developed device, a training session to be familiarised with the device is advised and should include this step before every assessment. Nonetheless, future solutions should integrate a feature to evaluate pelvic tilt non-invasively in order reduce the risk for false positives.

How can post-operative LLD be prevented during THA, without disrupting conventional surgical workflows?

As the design solution proposes, the most sensible way of answering this question is to improve what is already being done and enhance the medical professional's skills, by quantifying their actions and translating them into data. This way one enhances human capabilities instead of replacing them by other processes. Additionally, this approach offers the advantage of a minimal learning-curve, improving the adaptability of technologies that take such approaches.

How can high-tech solutions be empowering to the user and provide a sense of control?

High-tech solutions for the OR must always have the user at the centre of product-user interactions. In an OR the surgeon remains end-responsible and therefore no misinterpretation or confusion caused by high-tech solutions may occur. In order to mitigate such risks, communication channels must be separated and safety mechanism need to be integrated in order to make the usability of the device 'poka-yoke' (Japanese term for 'mistake-proofing). Some of these approaches were integrated in the design solution and provide an implementation example.

10.3 Limitations

This thesis encountered many limitations, the first of which being the Covid-19 crisis. Initially, this project was supposed to start much earlier, but was ultimately delayed by three months. Once it actually started, all necessary changes that forced a different style of working had to be incorporated into the project and all safety precautions had to be met. This included getting approval from the collaborating hospitals, as well as access to required university facilities. After everything was set, home office remained the norm which limited some aspects of the development process, but also offered positive opportunities such as meeting availability with the supervisory team and co-creation participants not being tied to location. Ultimately, this thesis was primarily limited by time as the complexity of the topic would easily allow for PhD work. Therefore, it is advised to view this thesis as an initial starting point which could be further developed with more thorough research opportunities.

10.4 Reflection

To enhance conventional surgical workflows was the goal of this thesis, which resulted in the proposed design solution. Although the final prototype can merely be seen as a proof of concept, it and the entire process leading up to it, should be used as the basis for further developments into that direction. Much of the theoretical framework that was developed during this thesis may also apply to other workflows within the healthcare sector and should be considered when designing new solutions within it. Considering the value proposition of the design solution in relation to the most relevant stakeholders of this project, one can consider this project a success. Most criteria on the 'List of Requirements' (Chapter 4) have been met, thereby allowing for its expansion and investigation into future iterations, if desired. In particular user-testing would provide many more valuable insights into potential development directions.

Taking into consideration the circumstances under which this project was conducted, the complexity of the topic and the fact that it was carried out in an academic graduation context (meaning by a single person instead of a team of product developers), it can be said that the process as well as the final results are satisfactory. There always remains room for improvements, even in a professional setting, therefore finding points of improvement in this project will not be difficult. Afterall, perfection just like symmetry within the human body, is an unattainable standard. In fact, in many cases minor flaws make a process, object or human that much more likeable.

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