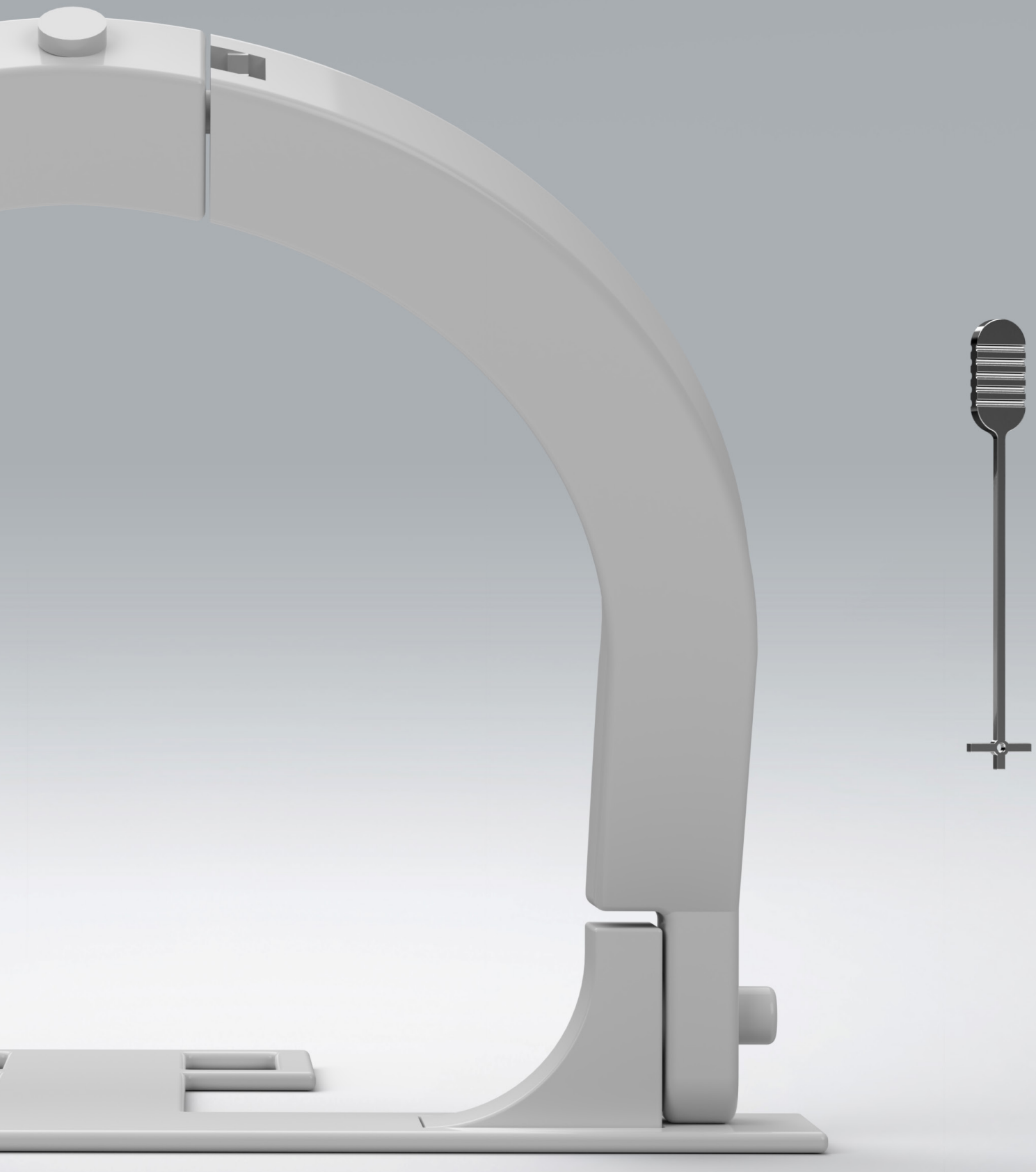
Laser-Guided Surgery for Thumb Joint Arthroplasty



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Abstract

Total Joint Arthroplasty (TJA) of the thumb base is an advancing surgical treatment for osteoarthritis (OA) in the carpometacarpal (CMC-1) joint. While TJA offers improved mobility and faster recovery compared to traditional treatments such as trapeziectomy, the procedure presents challenges in accuracy and precision. Current semi-freehand surgical techniques lack standardized landmarking, leading to complications such as prosthesis misalignment, cup loosening, and ultimately revision surgeries.

This thesis explores the use of laser guidance during surgery as an innovative approach to enhance the precision of prosthesis placement in thumb joint arthroplasty. Through a collaborative design process with surgeons at Reinier Haga Orthopedisch Centrum, a concept for laser-guided surgery was developed. This concept aids surgeons in accurate k-wire placement by improving alignment and reducing intraoperative variability. The final design focuses on integration into the surgical workflow and ease of use during surgery.

Evaluation through interviews, feasibility testing and validation testing demonstrated the potential of the concept to improve accuracy while maintaining surgical efficiency. Future recommendations include further embodiment of the design, cadaver studies for validation, and exploration of additional technologies such as surface mapping. The proposed solution offers a promising step towards reducing complications and improving outcomes in thumb joint arthroplasty.

Keywords: osteoarthritis, thumb joint arthroplasty, total joint replacement, CMC-1 joint, surgical instrumentation, laser-guided surgery, medical product design

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Abbreviations

- RHOC Reinier Haga Orthopedisch Centrum
- RdGG Reinier de Graafgasthuis
- OA Osteoarthritis
- CMC-1 Carpometacarpal joint 1 or Trapeziometacarpal joint
- SST Scaphotrapezeal trapezoid joint
- TJA Total joint arthroplasty (also called Total joint replacement)
- THA Total hip arthroplasty
- TKA Total knee arthroplasty
- PRISMA Preferred Reporting Items for Systematic Reviews and Meta-analysis
- CT Computed tomography
- MRI Magnetic resonance imaging
- CRPS Complex regional pain syndrome
- UHMWPE Ultra high molecular weight polyethylene
- AR Augmented reality
- VR Virtual reality

Terminology

• Articulation	A joint; the location where two or more bones meet.
• Conservative treatment	Non-surgical treatment, e.g. physical therapy.
• Dislocation	The displacement of a joint or implant.
• Dissection	The careful cutting and separation of tissues during surgery or anatomical study.
• Osseointegration	Bone growth on artificial material.
• Ostephytes	Bone growths, also named bone spurs, due to OA.
• Osteotomy	Surgical removal of a bone fragment or bone spur.
• Ligaments	A short band of tough, flexible fibrous connective tissue which connects two bones or cartilages or holds together a joint.
• Periprosthetic ossification	Abnormal bone growth around an implant.
• Reaming	A surgical technique in which bone is drilled or prepared for an implant.
• Synovitis	A condition in which the lining of a joint becomes swollen and painful.
• Sclerosis	Abnormal hardening of (nerve) body tissue.
• Tenosynovitis	Inflammation of the tendon sheath, often causing pain with movement.

1.

Introduction

1.1 Project description

Hands, and particularly thumbs, are essential for performing daily tasks such as grasping a coffee cup, typing on a smartphone, preparing meals, driving, and buttoning clothing. Any loss in hand function can have a tremendous effect on an individual's quality of life (Kwok et al., 2010).

A primary cause for loss of hand function is **osteoarthritis**, a degenerative joint disease in which the cartilage of the joints gradually wears down. As osteoarthritis progresses, people experience pain, stiffness and weakness, making even the most basic movements difficult (Kapoor & Mahomed, 2015). The resulting physical limitations often lead to persistant pain, functional limitations and a reduction in independence. Gripping objects, writing, or even shaking hands can become painful and frustrating.

One treatment for osteoarthritis is **total joint replacement (TJA)** of the thumb base, which is considered a last resort, performed only when conservative treatment options have been exhausted. While TJA is a known procedure in orthopedics, its application to the thumb remains relatively new, compared to e.g. hip and knee joint arthroplasty (Van Langelaan & TU Delft, 2023).

A key challenge in current thumb base arthroplasty is the lack of precision in prosthesis placement. Experts in the field highlight the need for additional or improved surgical instruments to enhance the accuracy of implantation (*personal communication*). Currently, the procedure is performed using a "freehand" technique, without standardized landmarking or precise guidelines. This means that no landmarking or precise guidelines are available which might lead to revision surgery - a time consuming and expensive consequence which is often accompanied by pain from the patient. Observations of this surgical procedure further show the need for improved instrumentation to both aid the surgeon and create better surgical outcomes.

This project focuses on developing surgical instruments to aid the surgical staff - consisting of hand surgeons, surgical nurses, anaethesists, and surgical interns - to improve the quality of life of the patient. Other stakeholders that influence this project are the clients, Reinier Haga Orthopedisch Centrum and Reinier de Graafgasthuis. Moreover, Keri Medical is the manufacturing and developing company of the prosthesis used in Reinier Haga Orthopedisch Centrum. Keri Medical collaborates with distribution companies as ProMotion to distribute their products to the Netherlands. Lastly, healthcare insurance companies also play an important role in providing insurance for patients.

1.2 Project scope

With help of the PICO framework, the initial scope is formulated. PICO stands for Population, Intervention, Comparison, and Outcome (Richardson et al., 1995) and it is used as a structural approach for doing research and defining a clear scope.

- **Population**: people suffering from severe osteoarthritis in the thumb base (CMC-1 joint).
- **Intervention**: joint arthroplasty of the thumb base performed with a (semi-)freehand approach.
- **Comparison**: joint arthroplasty of the thumb base performed with a novel (set) of surgical instrumentation.
- **Outcome**: improved accuracy of the prosthesis placement and ease of surgical procedure.

The scope focuses solely on the comparison between the freehand approach and the surgical procedure with additional surgical instrumentation. At the moment the client, RHOC, implements a freehand approach for surgical procedure of the thumb base prosthesis. Both the course of treatment and surgical procedure can differ per hospital and even per surgeon. This can lead to a very broad scope, making it difficult to further investigate the specific approach used by doctor Kraan and his colleagues within the limited time frame. Therefore, this research solely focuses on the surgical treatment provided by RHOC and other surgical techniques are not included in this research.

Subsequently, the scope was used for literature research according to the PRISMA method - using the databases PubMed, TU Delft database, and Google Scholar. This literature research has been integrated into Chaper 2. Analysis.

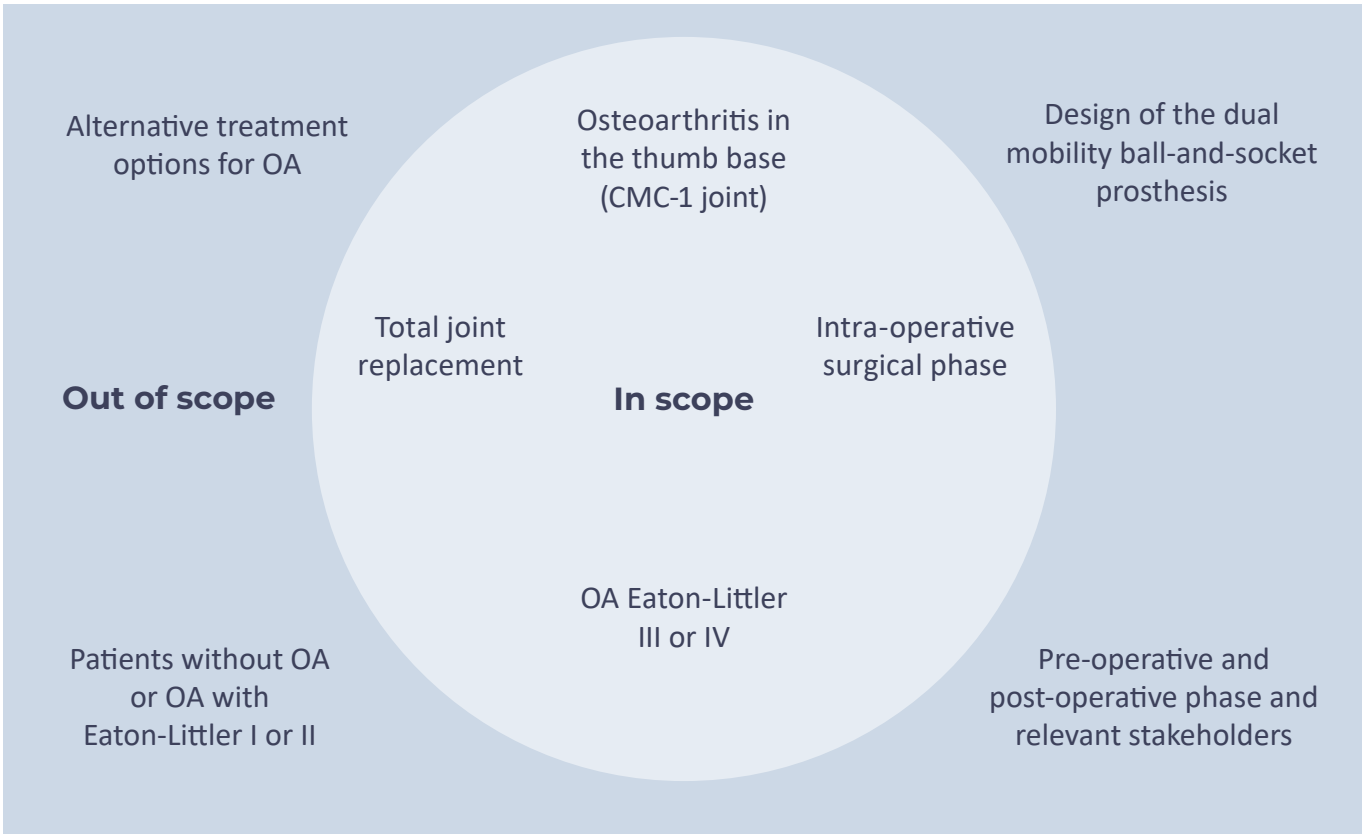


Fig 1. Scope of this thesis.

Fig 2. Operating room (RHOC).

1.3 Objective of this thesis

The objective of this thesis is to improve the accuracy and precision of the placement of the Touch dual mobility prosthesis by development of a (set of) surgical instrument(s). This will be done with help of the double diamond approach (Fig 3. Double diamond method.), which is further explain in next section. The assignment from the project brief is described as follows:

Initial assignment

"Design a prototype of a surgical instrument to improve joint arthroplasty of the CMC-joint for hand surgeons in surgery."

1.4 Approach

This thesis focuses on the first phase of the product development process: the front-end. In this phase, the desirability and feasibility of designing surgical instruments for thumb base prostheses will be evaluated. In terms of deliverables, the project should end with a working prototype that 'works like', 'looks like' but 'is not manufactured like'. In addition, the project considers the future embodiment, aesthetics and ergonomics of the design, based on testing and evaluation. As a result, beyond the functional prototype, the project aims to deliver recommendations for further steps.

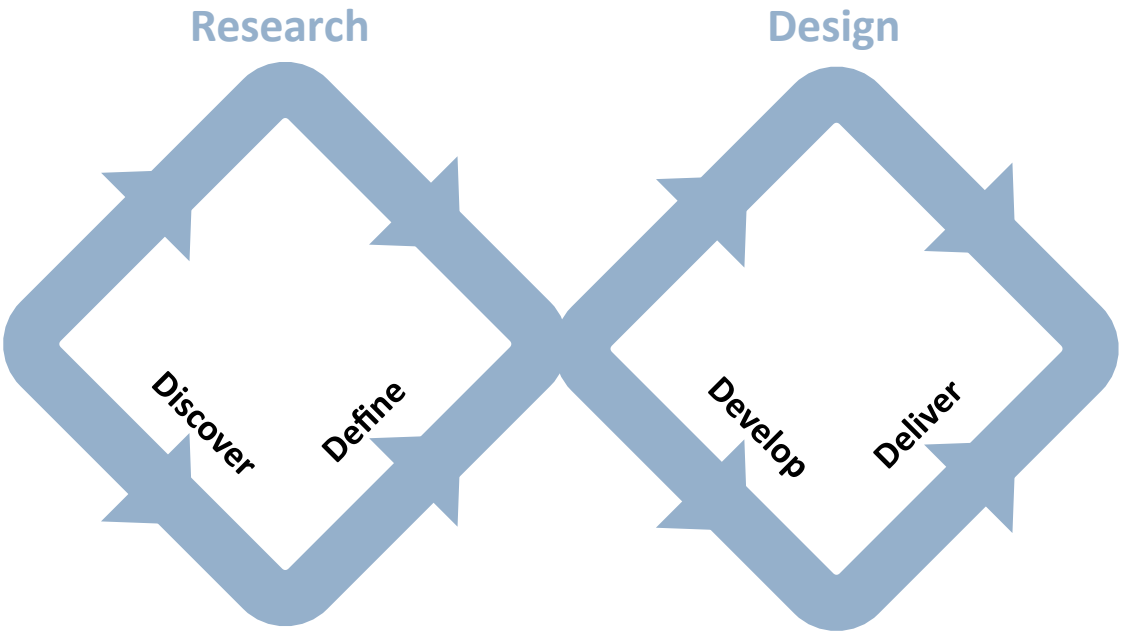
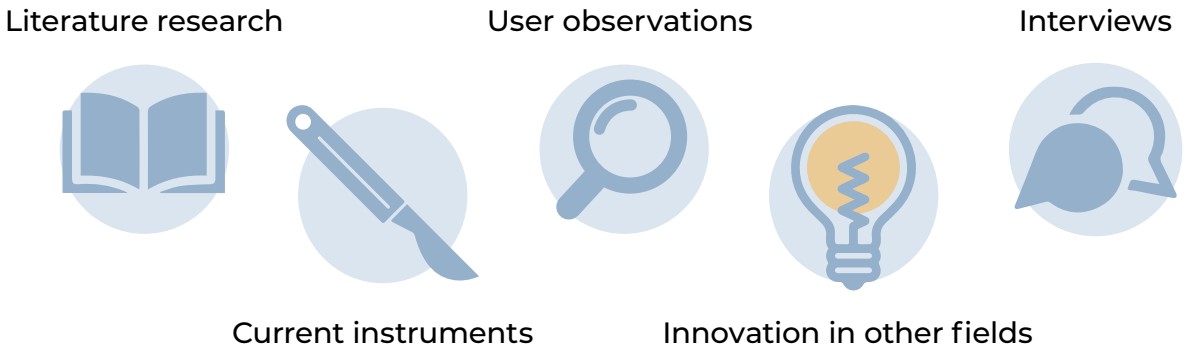


Fig 3. Double diamond method.

Discover

The first phase consists of a literature review to develop a foundational understanding of hand anatomy and osteoarthritis diagnosis. Additionally, surgical interventions for osteoarthritis were thoroughly analyzed through interviews and user observations. The focus was on analyzing the current surgical procedure for prosthetic placement in the thumb and examining the surgical instrumentation used in other arthroplasty surgeries. These analyses helped identify challenges in the existing procedure, particularly the lack of precision in prosthesis placement, which often leads to revision surgeries and prolonged recovery times for patients.



Define

Based on the key challenges identified in the discovery phase, a clear problem definition was formed. The primary issue was the inaccuracy and inconsistency in k-wire alignment during thumb arthroplasty procedures, which affects the overall success of the surgery. The design goal was defined as the development of a surgical instrument or a set of instruments aimed at improving the accuracy and precision of k-wire alignment. This design goal resulted into multyiple explorations for potential solutions that would enhance surgical precision and reduce the risk of complications.

Develop

With the problem clearly defined, several design directions were investigated using synetics and group brainstorming sessions with peers. These concepts were evaluated in collaboration with the graduation team and further refined. After multiple ideation cycles, the concepts were assessed through weighted objectives to determine their feasibility and effectiveness. The most promising solutions underwent feasibility testing, ensuring their practicality in a real surgical environment. Through this iterative process, a viable approach was identified that focused on improving k-wire placement accuracy using an optimized centering guide and laser-guided technology.

Deliver

The final stage resulted in a proof of concept with a working prototype that successfully demonstrated the proposed solution. The prototype was tested to assess its effectiveness in enhancing k-wire alignment while ensuring it integrated seamlessly into the surgical workflow. Although not yet optimized for mass production, the prototype validated the concept's potential in improving surgical precision, reducing errors, and supporting better patient outcomes. The next steps will involve further refinement and validation to advance the design for clinical implementation.

2.

Analysis

This chapter provides the knowledge required for understanding the scope and significance of this research. As the thesis aims to improve the accuracy and precision of prosthesis placement for thumb base joint arthroplasty, this chapter is divided into eight sections to analyze this. By addressing these key topics, this chapter presents the groundwork for the research of this thesis. The insights gained from this chapter are used to design and develop new surgical instruments. These key topics and insights are summarized in 2.9 Conclusion.

2.1 Stakeholders

The stakeholder analysis offers an overview of all parties involved within the scope of the research, while analysing their levels of influence and interest in the total joint replacement (TJR) of the thumb base. This approach helps ensure that all relevant perspectives are considered throughout the research process. The stakeholders can be categorized based on influence and interest:

- **Influence**: the extent to which a stakeholder can directly or indirectly make decisions or impact the execution of the surgical procedure.
- **Interest**: the level of engagement or interest a stakeholder has in the success of the procedure. A stakeholder may have high interest if they are directly involved (e.g., surgeons) or if the procedure's outcome significantly affects them (e.g., patients).

Table 1. Stakeholders influence-interest presents the stakeholders involved in this scope, categorized in influence and interest. This categorization is further explained below.

Table 1. Stakeholders influence-interest

Stakeholder	Level	Influence	Interest
Hand surgeons	Primary	High	High
Surgical assistans	Primary	Medium	High
Patient	Primary	Low	High
Keri Medical	Primary	High	High
Anesthesist	Secondary	Low	Medium
Physical therapy	Secondary	Low	Low
RHOC	External	High	High
RdGG	External	High	Medium
Healthcare insurance	External	High	Low
Caregivers	External	Low	High
DIstribution companies	External	High	Medium

Primary stakeholders are parties with both high influence and high interest in the surgical procedure of thumb base TJR. This group includes **hand surgeons,** who perform the procedure and are responsible for the decision-making during the surgery. The hand surgeons depend on the **surgical assistants,** who are responsible for assisting and providing the surgeon with the correct surgical instrumentation. Furthermore, **patients** are considered primary stakeholders as their outcomes are directly influenced by the procedure, and they rely on surgery to restore hand function and enhance their quality of life. Though they do not have direct influence on the surgical procedure, the patient is the decision-maker in choosing to undergo the surgery. **Keri Medical**, the manufacturing company of the Touch prosthesis used at Reinier Haga Orthopedisch Centrum, is also considered a primary stakeholder. In addition to supplying the prosthesis, Keri Medical also provides hospitals with a specialized surgical instrumentation set required for implantation. Therefore their level of interest and influence in success of the thumb joint replacement (with the Touch prosthesis) is defined as high.

Secondary stakeholders hold a high influence but have little interest, or vice versa, with regard to the scope. These include the **anesthesiologists**, who are essential for ensuring patient safety and comfort during the surgery. Their influence over the procedure is high, but their level of interest on the research scope is lower. They also include **physical therapists**, responsible for the recovery of the patients. Physical therapists play an important role in pre- and post-surgical rehabilitation, but since this thesis focuses on the intraoperative process, their involvement is limited.

Together, the primary and secondary stakeholders form the **internal stakeholders**, who are directly or indirectly involved in the execution of the surgical procedure and its immediate outcomes. The internal and external stakeholders are visualized in Fig 4. Stakeholder map.

Lastly, the **external stakeholders** form a group that influences the surgical procedure indirectly but they must be well informed. This group includes **Reinier Haga Orthopedisch Centrum** and **Reinier de Graaf Gasthuis,** responsible for providing the best care for the hospitals within the regulations. **Healthcare insurance** providers are also involved with regard to determine coverage and reimbursement for the procedure. While they do not engage in individual surgeries, their financial decisions influence patient access to the treatment. Moreover, companies like **ProMotion** help facilitate the Touch prosthesis for the hospital. Next to companies, **caregivers** and family members are also considered external stakeholders since they provide support to patients undergoing the procedure without having influence on the procedure itself. While they do not have any direct influence over the surgical process itself, their role is to help patients navigate their recovery journey.

While all stakeholders contribute to the broader context of thumb base TJR, this thesis primarily focuses on **hand surgeons and surgical assistants**, as they are the key actors in the intraoperative process. Their decisions and actions during surgery directly impact the success of the procedure, making them the central focus of this thesis. However, the role of secondary stakeholders, such as anesthesiologists and physical therapists, remains relevant in shaping the conditions under which the surgery takes place.

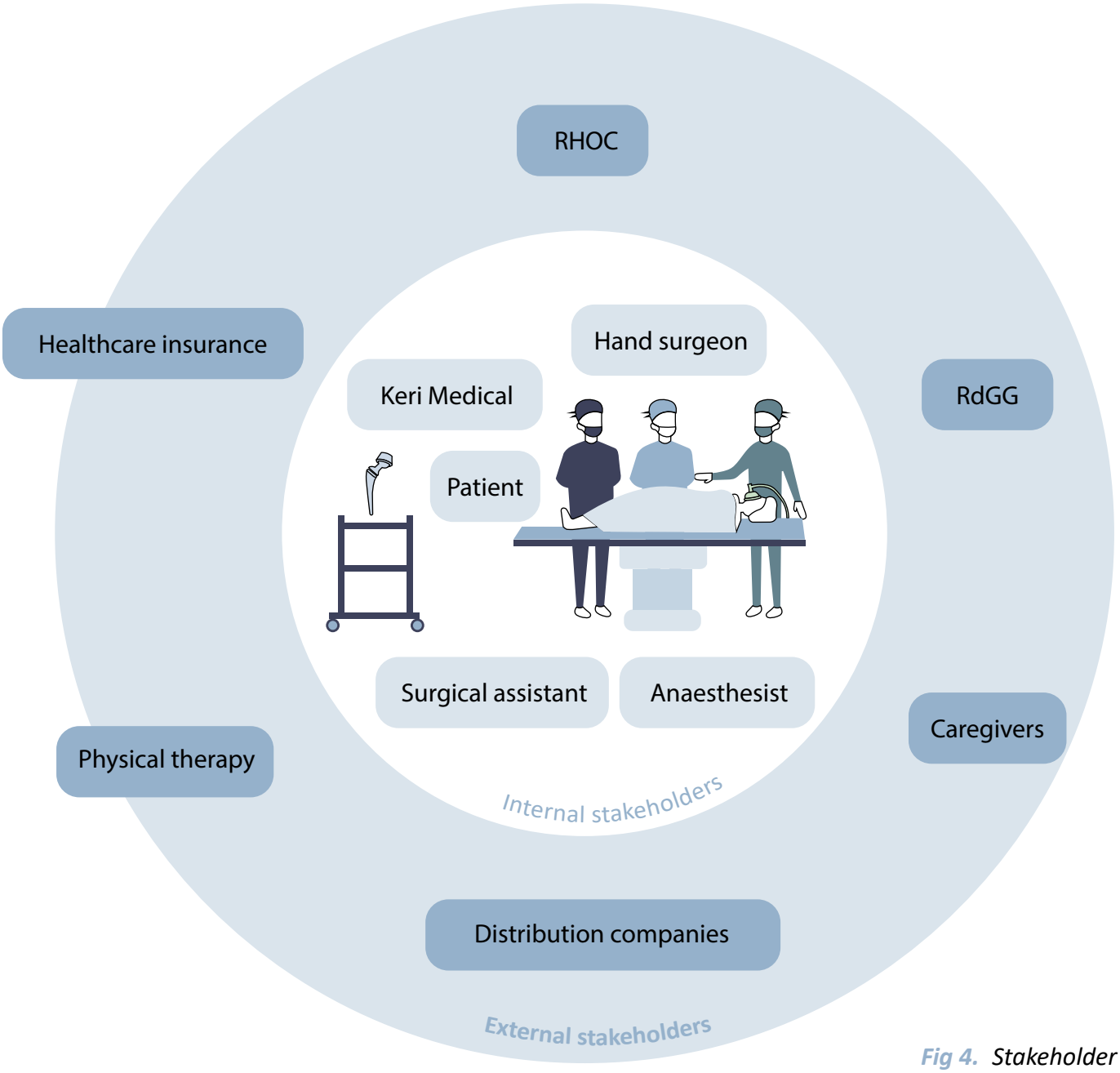


Fig 4. Stakeholder map

2.2 Anatomy of the hand

Understanding the anatomy of the base of the thumb is crucial to the process of understanding osteoarthritis and the need for joint replacement.

The thumb is responsible for 40% of the hand function (Kapoor & Mahomed, 2015). The thumb joint consists of the metacarpal-1 (MC1) and the trapezium bone (Fig 5. Bones of the thumb). This joint, also named the carpometacarpal (CMC-1) joint is a complex saddle joint. Together, these bones interact to move the hand in the desired direction and pinch or grip certain objects.

Adjacent to the trapezium is the scaphoid and trapezoid, which also form a joint together: scaphotrapezeal trapezoid joint (SST-joint). The scaphoid connects to the trapezium, helping with wrist mobiltiy and stability (Kapoor & Mahomed, 2015).

The CMC-1 joint is a saddle joint, known for the convex and concave surface that articulate with each other, shown in Fig 7. Anatomical planes of the CMC-1 joint. on page 19. As a saddle joint, the thumb enables three degrees of motion: flexion-extension, abduction-adduction, and opposition-reposition (Fig 6. Movements of the thumb). The trapezium is stabilised by ligamentous restraints and movement is limited by the trapezoid and scaphoid (Komatsu & Lubahn, 2017).

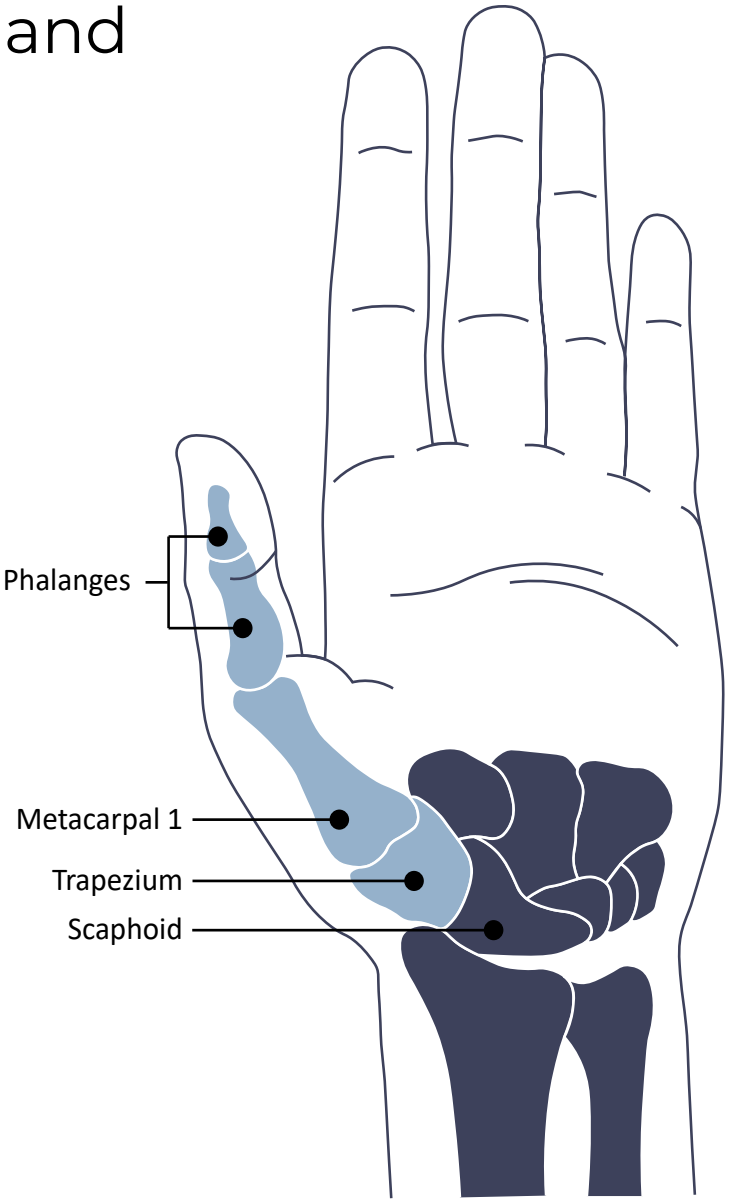


Fig 5. Bones of the thumb

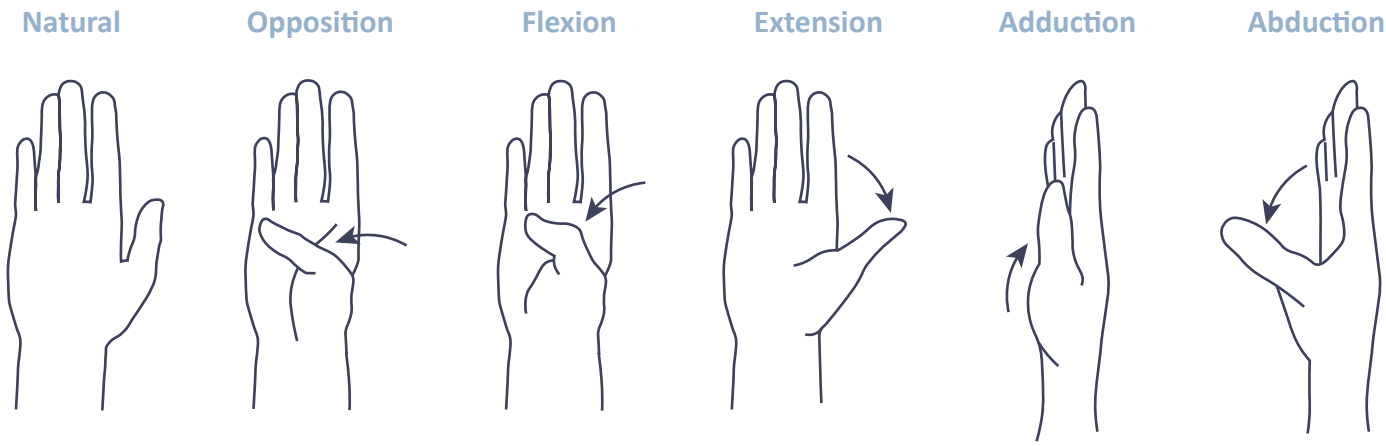


Fig 6. Movements of the thumb

The thumb carpometacarpal (CMC-1) joint presents significant challenges in joint replacement due to its complex biomechanics. Unlike ball-and-socket joints, which have a single fixed center of rotation, the CMC-1 joint has two centers of rotation - one within the trapezium and another at the base of the first metacarpal (Komatsu & Lubahn, 2017). The joint has a shifting centre of rotation along a helical axis, meaning its rotation is not fixed. During opposition, the axis of rotation is located in the trapezium, while in abduction, it shifts toward the base of the metacarpal, allowing for complex motion, Fig 7. Anatomical planes of the CMC-1 joint..

When a prosthesis is implanted at the thumb base, the joint structure shifts from a saddle joint to a ball-and-socket configuration, restricting its natural motion and imposing a single center of rotation (Andrzejewski & Ledoux, 2019). While this may improve stability, it alters the thumb's functional biomechanics, potentially leading to reduced dexterity and unnatural movement patterns.

This high mobility, while essential for hand function, also makes the CMC-1 joint prone to instability. Over time, ligamentous laxity can lead to excessive motion and misalignment, contributing to the development of osteoarthritis (De Raedt et al., 2012). The volar-ulnar corner of the trapezium, where joint contact is most concentrated during opposition, is a common site for degenerative changes, as it experiences significant stress throughout daily thumb movements.

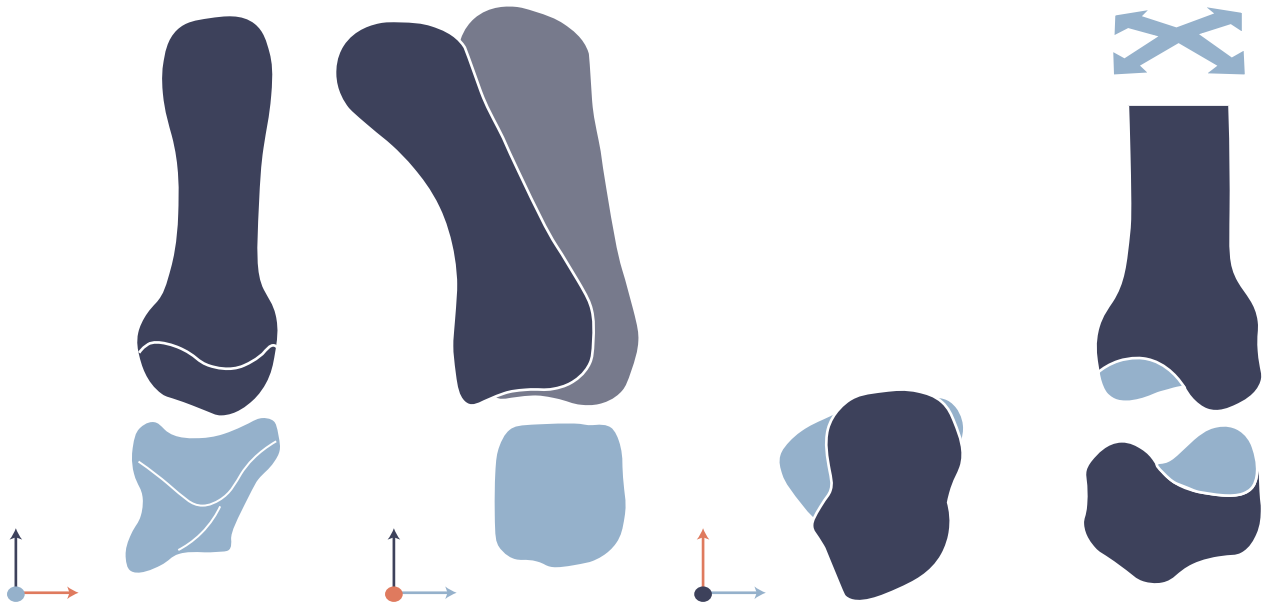


Fig 7. Anatomical planes of the CMC-1 joint.

2.3 Relevant dimensions of the hand

The dimensions of the hand are crucial in the development of a surgical instrument for thumb surgery, as they directly influence both patient-specific product adaptability and surgeon usability. The **patient's hand size** determines the required size of the instrument to accommodate anatomical variations, ensuring it aligns properly with the surgical environment. Since hand dimensions vary between individuals, accounting for these differences is crucial for precision and effectiveness in surgical applications.

Furthermore, the **surgeon's hand size** plays a key role in the ergonomic design of the instrument. A tool that is too large or too small may hinder dexterity, cause discomfort, or lead to fatigue during procedures. Considering grip comfort, movement constraints, and force application helps optimize the instrument for both accuracy and ease of use. Ensuring a well-balanced design that suits the surgeon's hand while maintaining adaptability for different patients is fundamental to integrating it effectively into surgical practice.

The relevant measurements for the hand are presented in Table 2. DINED data of the hand (DINED, 2020), which contains data extracted from the Dutch adults (2004) DINED database (mixed gender, age groups: 20-60 years and 60+ years) (DINED, 2020). While osteoarthritis is most commonly observed in individuals over 60, it can also develop in younger patients. Therefore, both age groups are included in the design. The table provides the mean values for each measurement along with the corresponding standard deviations. The measurements that are explained below and visualised in Fig 9. Relevant dimensions of the hand..

- **Hand width (with and without the thumb)** is essential for determining the dimensional constraints of the instrument, ensuring that it fits comfortably within the working area and aligns effectively with anatomical structures. The difference between these measurements provides insight into thumb positioning, which is particularly relevant for procedures involving the thumb base.
- **Hand length and thickness** influence the overall proportion of the instrument, ensuring that it accommodates variations in hand size while maintaining accuracy in its function. These dimensions also help in designing a tool that balances well in the surgeon's grip, preventing strain and improving maneuverability.
- **Thumb breadth and length** are crucial for understanding the range of motion and positioning within the surgical field. Since the thumb plays a pivotal role in both fine motor control and stabilization, these measurements inform the design of any contact points or guiding structures within the instrument.

By incorporating these anatomical dimensions into the development process, the instrument can be tailored to fit both the patient's unique anatomy and the surgeon's hand, ensuring, comfort and precision in surgical practice.

Table 2. DINED data of the hand (DINED, 2020)

#	Measures (mm)	Dutch adults 60+ (mixed)	Dutch adults 20-60 (mixed)
1	Hand width (with thumb)	103 ± 9	103 ± 8
2	Hand width (without thumb)	85 ± 6	85 ± 7
3	Hand length	184 ± 12	187 ± 13
4	Hand thickness	28 ± 6	26 ± 6
5	Thumb breadth	23 ± 2	22 ± 2
6	Thumb length	106 ± 9	106 ± 8

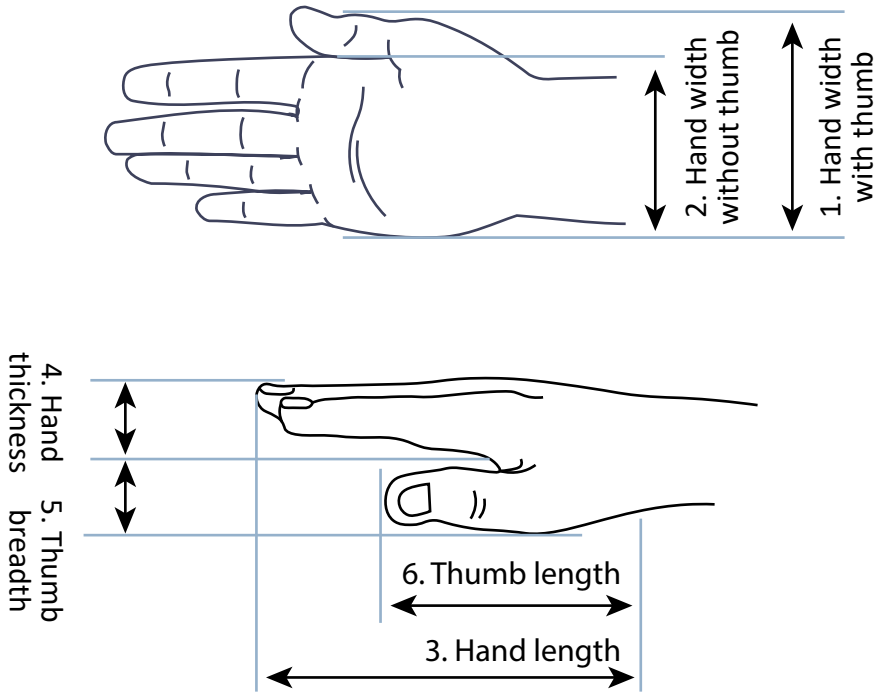


Fig 9. Relevant dimensions of the hand.

2.4 Osteoarthritis in the thumb base

This section analyses the diagnosis and classification of osteoarthritis. This section is crucial in determining when surgical intervention is necessary. The classification of OA also functions as a clinical boundary for identifying suitable candidates for total joint arthroplasty.

Osteoarthritis (OA) is the most common degenerative joint disease, characterized by the gradual breakdown of cartilage and subsequent structural changes in joints, leading to pain, stiffness, reduced mobility, and functional impairment (Wilder et al., 2006). While the exact cause of OA remains unclear, age is the strongest predictor, with other contributing factors including inflammation, mechanical wear and tear, and hormonal imbalances (Kapoor & Mahomed, 2015).

The prevalence and impact of OA have increased considerably, largely due to an aging population. Among the various joints affected, the thumb carpometacarpal (CMC) joint is particularly important, as it accounts for approximately 40% of overall hand function. It represents the second most common site of hand OA (Moran & Berger, 2003). Loss of thumb function can greatly impair daily activities and quality of life. Notably, thumb OA is especially common among women, affecting up to 25% of post-menopausal females (Gonzalez-Espino et al., 2021).

To clinically classify thumb OA, the Eaton-Littler scale is frequently utilized (Barrera & Yao, 2022). This classification system describes four progressive radiographic stages, shown in Table 3. Eaton-Littler classification (PlasticsFella, 2024) and Fig 10. Radiographical imaging of the joint per Eaton-Littler classifcation stage (Nuessle et al., 2021).on the next page. This classification method can be used to assess how far the disease has progressed and whether surgical intervention is necessary.

The first stage, Eaton-Littler I, begins with a mild widening and inflammation of the CMC-1 joint. The radiographic image shows joint widening while the bones maintain healthy contours, with minimal to no cartilage loss (Fig 10. Radiographical imaging of the joint per Eaton-Littler classifcation stage (Nuessle et al., 2021).).As the condition progresses to Eaton-Littler II, the joint space begins to narrow, and small osteophytes (bone spurs) measuring <2 mm develop. This stage is also known for increased instability due to advanced inflammation. The radiographic image shows that the clear boundaries of the bones become less clear and the bone spurs are forming.

By Eaton-Littler III, the osteophytes have grown beyond 2 mm, cartilage loss becomes widespread, and the ligaments of the trapezium become increasingly lax, leading to joint instability. Finally, in Eaton-Littler IV, arthritis spreads to the SST joint, causing severe narrowing of the joint space and degeneration, affecting adjacent joints and further compromising hand function. The radiographic image shows the collapse of the CMC-joint.

These four stages are summarized in Table 3. Eaton-Littler classification (PlasticsFella, 2024) supported by the Fig 10. Radiographical imaging of the joint per Eaton-Littler classifcation stage (Nuessle et al., 2021)..

Table 3. Eaton-Littler classification (PlasticsFella, 2024)

Stage	Description
Eaton-Littler I	Mild **widening** of the **CMC-1 joint** due to synovitis (swollen joint). Minimal to **no cartilage loss**.
Eaton-Littler II	Presence of **osteophyte formation** (smaller than 2 mm). More advanced synovitis and **severe laxity**. **Reduction** of CMC-1 **joint space** and **sclerosis** of the bone.
Eaton-Littler III	**Osteophytes** are exceeding 2 mm. Advanced, widespread **loss of cartilage**. Very **lax** (volar) **ligaments**.
Eaton-Littler IV	Spreading of OA to the **SST joint.** **Severe space narrowing** and joint degeneration involving adjacent joints.

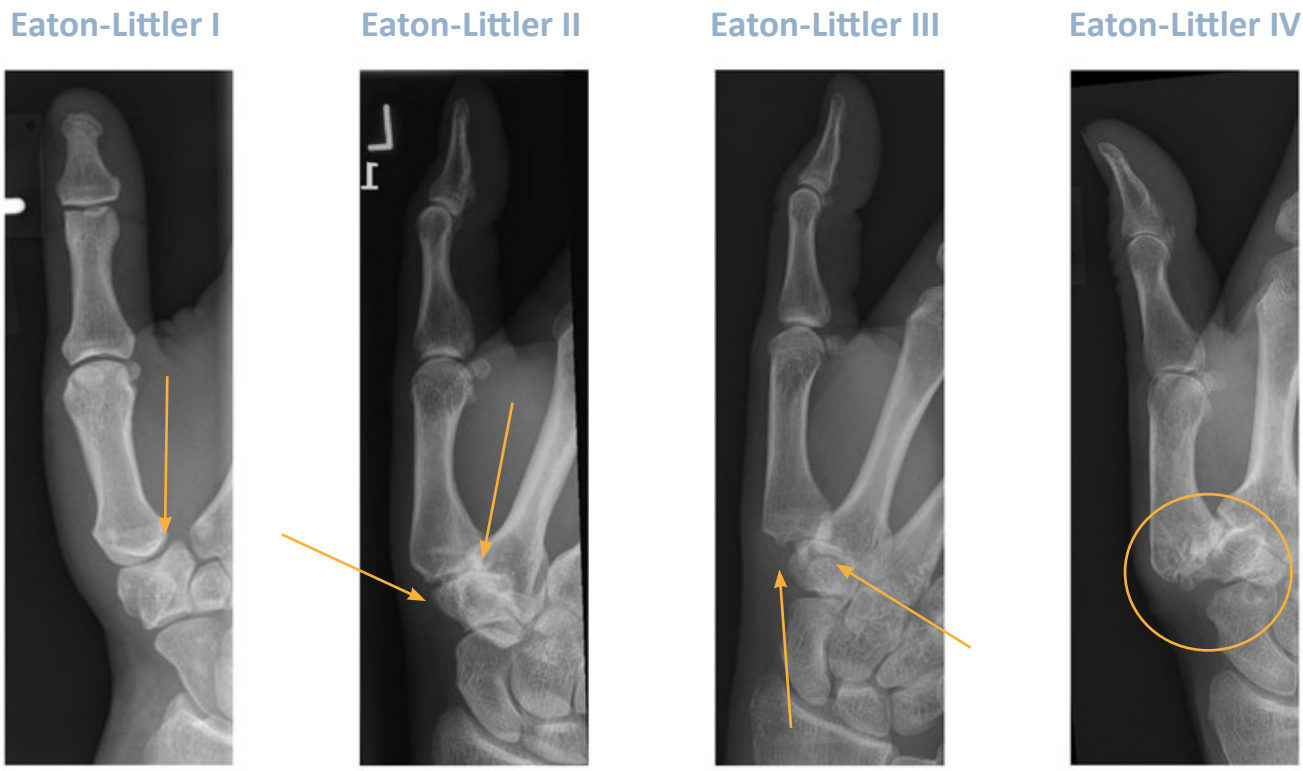


Fig 10. Radiographical imaging of the joint per Eaton-Littler classifcation stage (Nuessle et al., 2021).

Treatment options for osteoarthritis (OA) can be categorized into conservative, injection-based, and surgical approaches. Selecting the appropriate treatment often relies on the Eaton-Littler classification system, which assesses the severity of the condition.

In Eaton-Littler stage I, damage to the CMC-1 joint is minimal, and surgery is generally not indicated based on radiographic findings. Conservative or injection-based treatments, as outlined in Fig 11. Treatment options for OA on page 23, are typically sufficient at this stage (Cerny et al., 2021).

For Eaton-Littler stages II and III, total joint replacement (TJR) becomes a suitable surgical option. At these stages, the joint exhibits significant damage, but adjacent joints remain unaffected, making TJR an effective treatment choice.

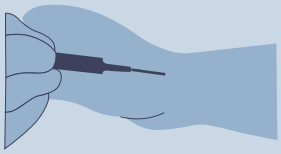
In Eaton-Littler stage IV, while TJR can still be considered, the presence of osteoarthritis in adjacent joints such as the scaphoid significantly increases the risk of surgical failure. Therefore, careful evaluation is necessary to determine the most appropriate treatment approach.

Conservative (non-surgical)

Analgetics
Splinting
Physical therapy

Injection

Steroid hyaluronic acid
Fats (experimental use)



Surgical

Ligament reconstruction
Resection athroplasty
Arthrodesis
Trapeziectomy
Total joint replacement (prosthesis)

Fig 11. Treatment options for OA

2.5 Surgical intervention for osteoarthritis

This section provides an analysis of the current surgical procedure for thumb prosthesis placement, with particular emphasis on complications and their underlying causes. Understanding the limitations of existing techniques helps to identify areas where improvements in surgical instrumentation could enhance accuracy of the procedure and patient outcomes.

2.5.1 Prevalence

The primary treatment for osteoarthritis in the thumb base consists of conservative approaches, including pharmacological therapy (medication), orthoses (splint and brace), and physical therapy. If conservative treatments are exhausted, surgical alternatives are necessary - i.e. trapeziectomy and joint replacement (Odella, 2018).

For many years a trapeziectomy has been the golden standard as surgical intervention for severe osteoarthritis of the thumb (Gonzalez-Espino et al., 2021). A trapeziectomy is the procedure where the trapezium bone of the wrist is removed, leading to significant restriction in thumb movement (Jager, 2021). A novel alternative for this treatment is total joint replacement, where the damaged joint is replaced with an artificial component (King & Rizzo, 2021). Over the past years this novel procedure has been implemented in Reinier Haga Orthopedisch Centrum (personal communication).

However, there are some trade-offs between a trapeziectomy and total joint replacement for osteoarthritis in the CMC-1. Liukkonen et al. (2024) reported no clinical difference in pain relief at one year follow-up. Yet, for total joint replacement both the grip and pinch strength remain higher than a trapeziectomy. TJA also shows a faster recovery rate, but a limiting factor for this procedure may be the increased costs of the surgery. Therefore a careful consideration should be made when implementing this procedure.

Table 4. Percentage of TJA per Eaton-Littler stage (Cerny et al., 2021) presents an overview of European surgeons using Total Joint Arthroplasty as surgical intervention per Eaton-Littler classification of osteoarthritis. This procedure is primarily used in the second and third classification of Eaton-Littler, which is also reflected in the data from the Table. Eaton-Littler IV represents an advanced stage of the disease where joint degeneration has spread to adjacent joints, thus limiting the effectiveness of the procedure. Stage I, on the other hand, is typically less severe that can often be effectively managed with conservative treatments. Therefore, Eaton-Littler Stages II and III are considered the most appropriate for TJA, as these stages balance disease progression with the potential benefits of surgery.

Table 4. *Percentage of TJA per Eaton-Littler stage (Cerny et al., 2021)*

Stage	Percentages of European surgeons using TJA
Eaton-Littler I	8,6 %
Eaton-Littler II	41,7 %
Eaton-Littler III	63,2 %
Eaton-Littler IV	32,5 %

2.5.2 Current surgical procedure at RHOC

This subchapter provides an analysis of the surgical instruments used at each step of surgical procedure and is followed by a complication and failure analysis integrated into the journey map, identifying critical points where procedural adjustments or improved instrumentation could enhance surgical outcomes.

The surgical procedure for total joint arthroplasty (TJA) of the CMC-1 joint typically lasts around sixty minutes. During this time, the skin is incised, bone spurs (osteophytes) are removed, the prosthesis is carefully measured and positioned within the bone, and the incision is closed. Successful execution of the procedure relies on seamless collaboration among the surgical team and the effective use of surgical instruments, which must support the surgeon in accurately placing the prosthesis while minimizing damage to surrounding tissues.

Throughout the qualitative research – i.e. interviews and observing – a journey map has been developed (Fig 13. Journey map of surgical procedure on page 27). This map is divided into three phases: (1) pre-operative, (2) intra-operative, and (3) post-operative. While this thesis focuses primarily on the intra-operative phase, understanding the interactions between all phases is essential, as they influence one another. The mapping process provides insight into the sequence of surgical steps, identifies key challenges, and highlights opportunities for improvement.

Additionally, the journey map identifies touchpoints within the surgical procedure that offer potential areas for improvement. The intra-operative procedure is divided into four key phases (Fig 12. Intra-operative phase of surgical procedure (Journey mapping).): patient and hand preparation, metacarpal dissection, trapezium dissection, and the final validation of the prosthesis followed by wound closure. Each phase is discussed in detail in the next section.

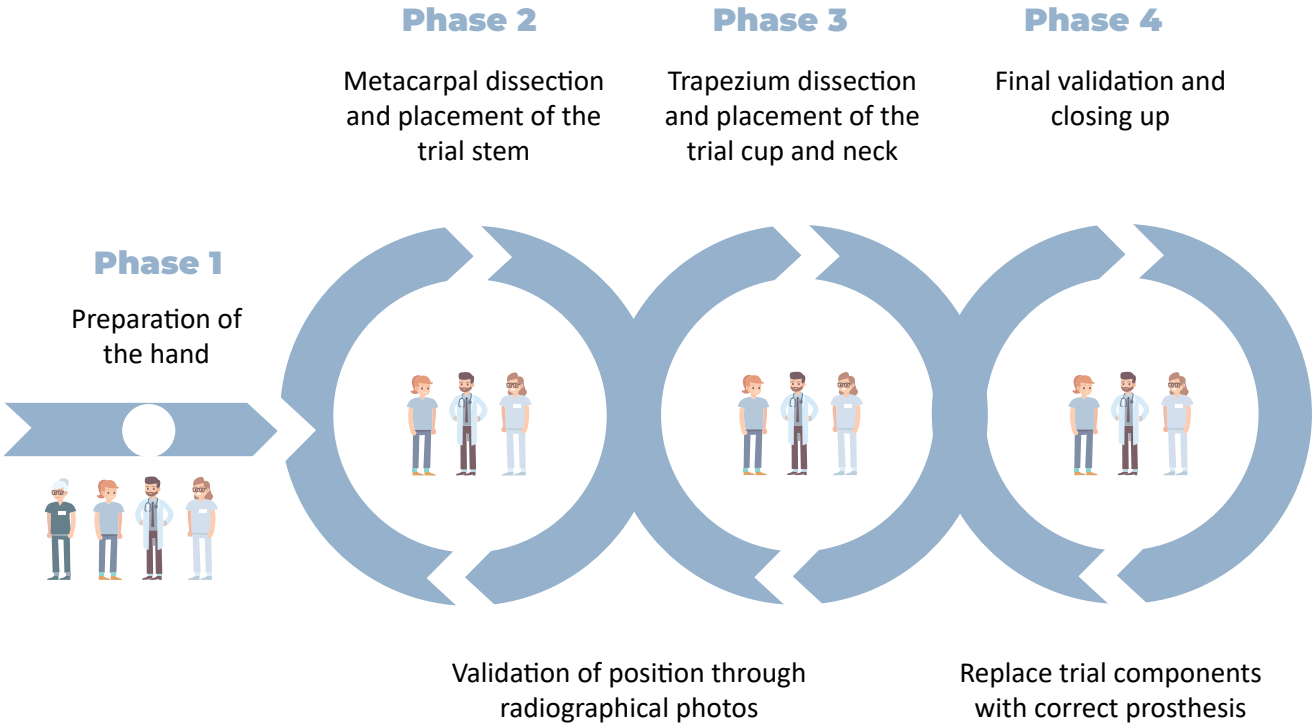


Fig 12. Intra-operative phase of surgical procedure (Journey mapping).

Surgeon perspective

Legend

Time surrounding surgery
Day of the surgery pre/post
Intra-operative phase
Complication route

1 Intra-operative trapezial complications resulting in change of procedure

Phase 2

Metacarpal dissection and placement of the trial stem

Phas

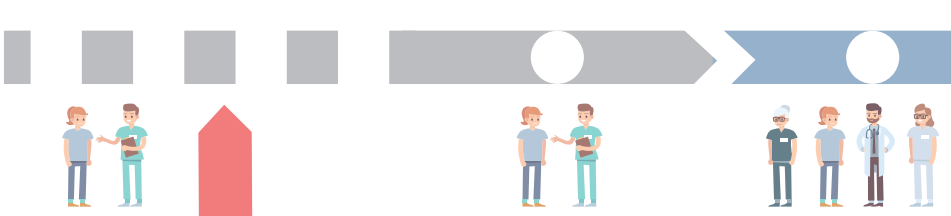
Trapezium and placem trial cup a

Phase 1

Diagnostics through X-Ray and treatment plan

Preparation of the patient

Preparation of the hand



Validation of position through radiographical photos

Alternate su

Desired outcome

Diagnostics of Eaton-Littler II or III osteoarthritis with failed conservative treatment

Fully prepared patient for surgery

Exposure of the CMC-1 joint with minimal bleeding and soft tissue damage.

Placement of the (trial) stem of the Touch prosthesis.

Placement cup of t prost

Touchpoints

1 Intra-operative: fracture of trapezium or poor bone quality

2 Early complications: dislocation, infection, tenosynovitis

3 Late complications: wear, cup loosening or tilting

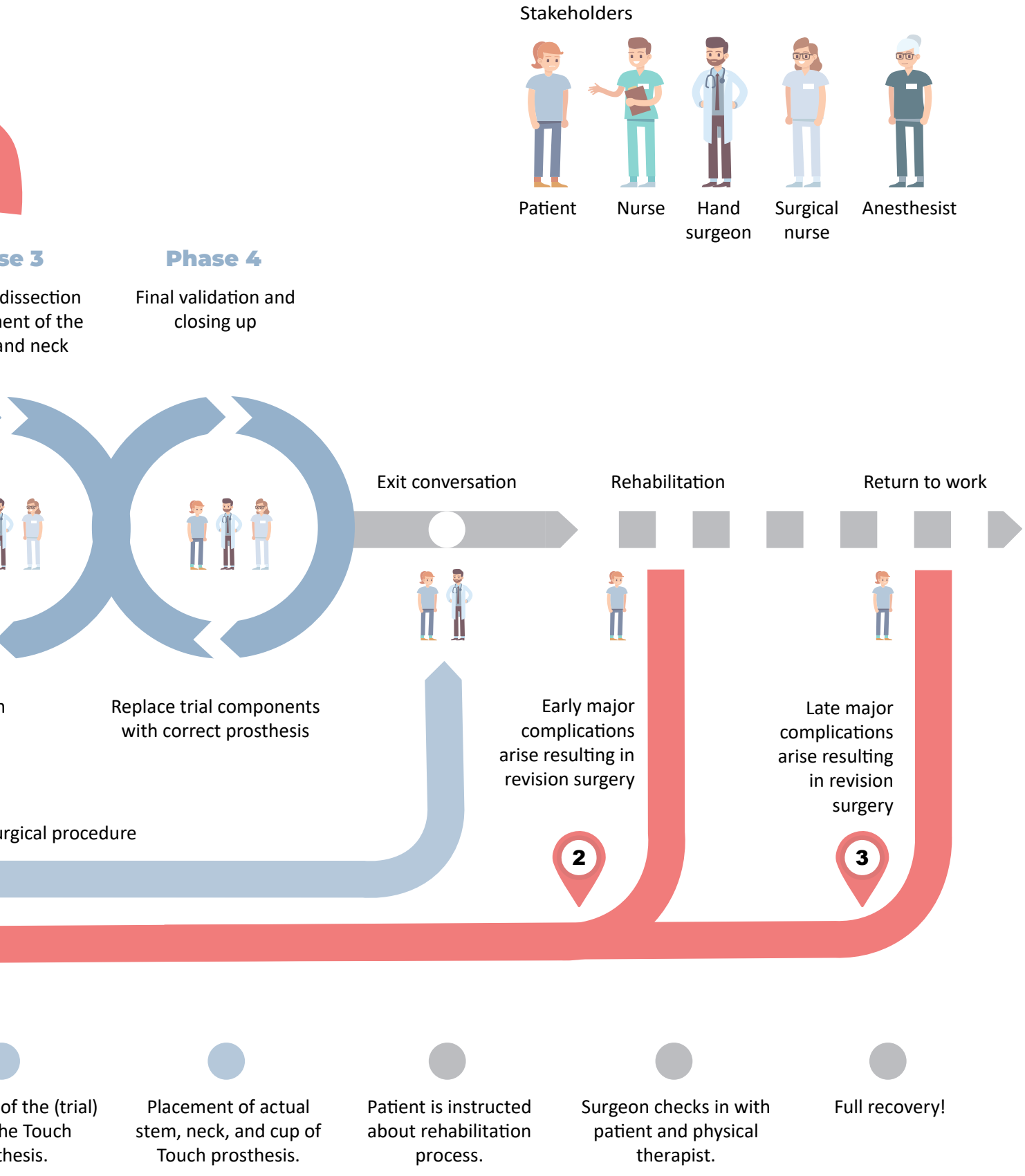


Fig 13. Journey map of surgical procedure

2.5.5 Intra-operative phase

Phase 1: preparing the hand

The intra-operative phase begins when the patient enters the operating room. At RHOC, the operating room is specifically designed for hand surgeries, equipped with specialized add-on tables for positioning of the hand (Fig 14. Operating room specialised for hand surgeries). On top of that, the medical trays, positioned in the back, are equipped with prosthetic components and plates which are specific for the wrist and hand.

Once the patient is carefully transferred from the hospital bed to the surgical table, ensuring stability, the necessary surgical trays are arranged next to the hand undergoing surgery, ensuring that all required instruments are within reach. Once the procedure starts, the operating room transitions into a controlled, airtight state to maintain sterility, with minimal movement in and out of the space.

Fig 14. Operating room specialised for hand surgeries

During surgery, a team of at least five medical professionals is present: the acting hand surgeon, an assisting hand surgeon, an anesthetist, and two surgical nurses - one sterile and one non-sterile. The sterile nurse directly assists the surgeons by providing the necessary surgical instruments, while the non-sterile nurse manages components and materials outside the sterile field, including the final prosthesis components.

The patient is positioned on the operating table, with the arm secured using straps. Surgical drapes are then placed over the table, leaving an opening for the arm. Typically, a single-use hand drape with an expandable arm opening is used for this purpose, as illustrated in Fig 15. Nurses draping the patient and preparing the surgical field surrounding the hand.. The nurses are responsible for draping the patient and preparing the surgical field around the hand.

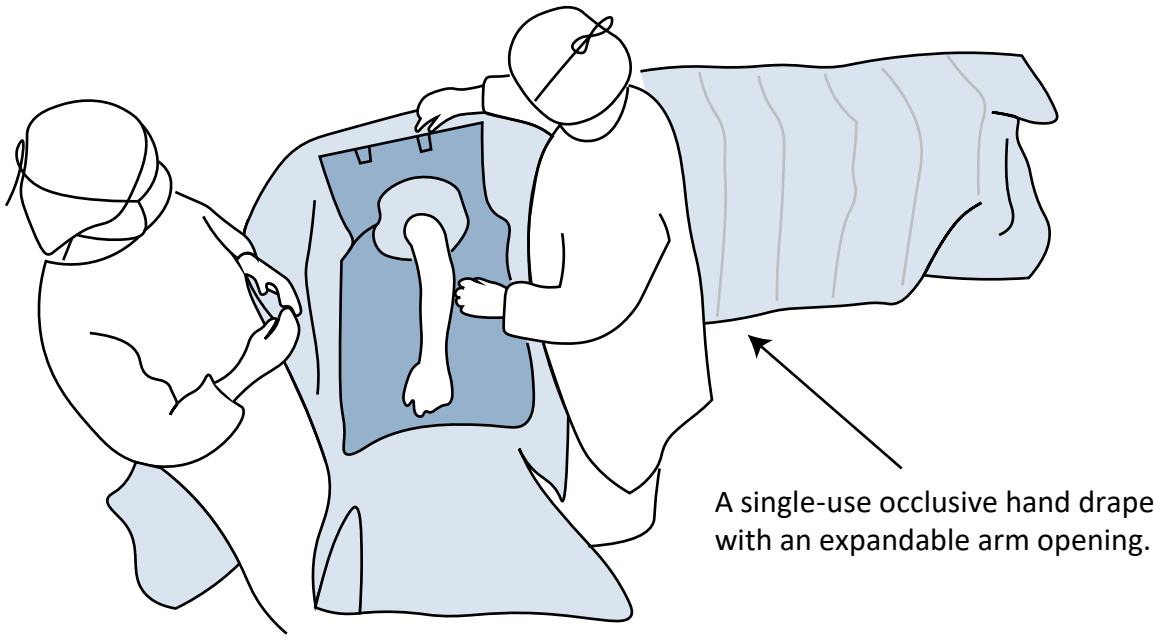


Fig 15. Nurses draping the patient and preparing the surgical field surrounding the hand.

Other products that cannot be sterilised are protected by plastic draping, for instance the C-ARM X-ray, see Fig 16. C-ARM X-ray in the operating room at RHOC.. This portable machine is used to validate the position and angulation of the metacarpal reamer, k-wire, and cup reamer. The non-sterile nurse provides the components and materials outside of the sterile field, in this case moving the portable x-ray machine from and to the surgical table during surgery (Fig 17. Illustration of the portable x-ray in use during surgery.).

Fig 16. C-ARM X-ray in the operating room at RHOC.

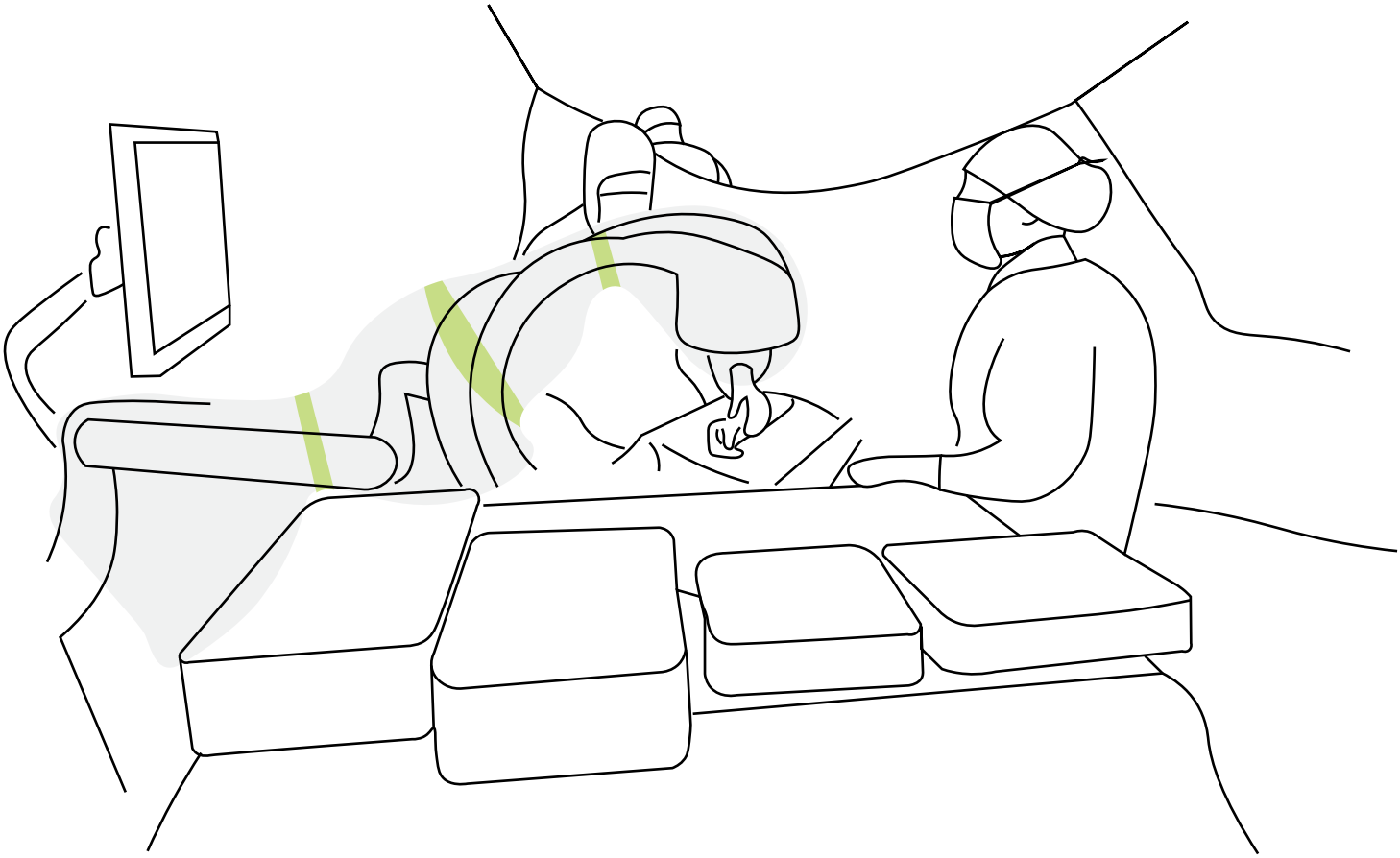


Fig 17. Illustration of the portable x-ray in use during surgery.

Phase 2: metacarpal dissection

Once the surgical field and hand are prepared, the surgeon prepares for the metacarpal dissection, reaming and (trial) prosthetic stem placement.

According to surgeons this step can be considered as relatively easy. The surgeon uses an awl to determine the point were the reaming should start. This point can be found through the guidelines, described in Fig 19. Guidelines for metacarpal reaming (Keri Medical, n.d.).

A series of larger reamers is then used to carefully enlarge the cavity within the metacarpal. It is important to avoid contact between the reamer and the cortical bone, as this could impair osseointegration and potentially compromise the long-term stability of the prosthesis. Once the surgeon evaluates the reamed cavity by x-ray, the prosthetic stem is placed, as shown in Fig 18. Prosthetic stem correctly placed in the metacarpal, cadaver study (RHOC).

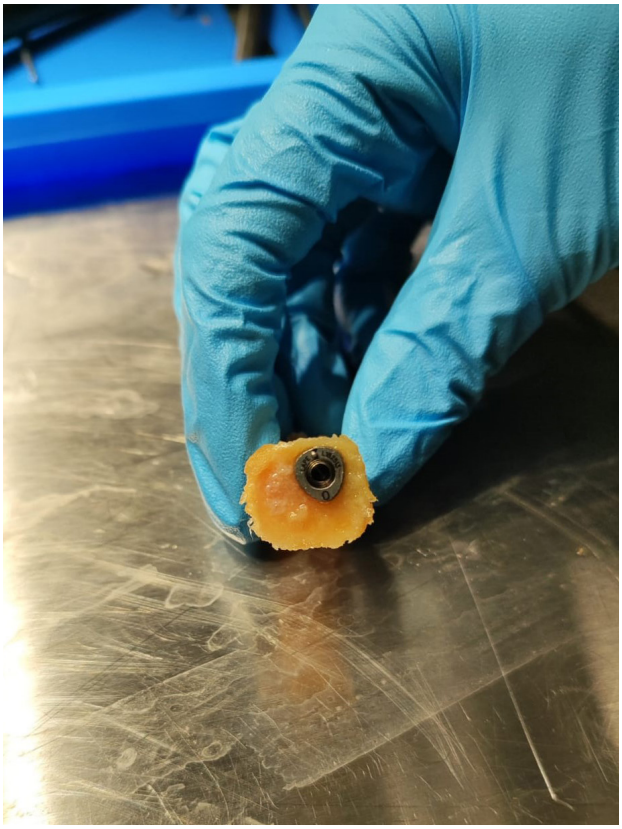


Fig 18. Prosthetic stem correctly placed in the metacarpal, cadaver study (RHOC).

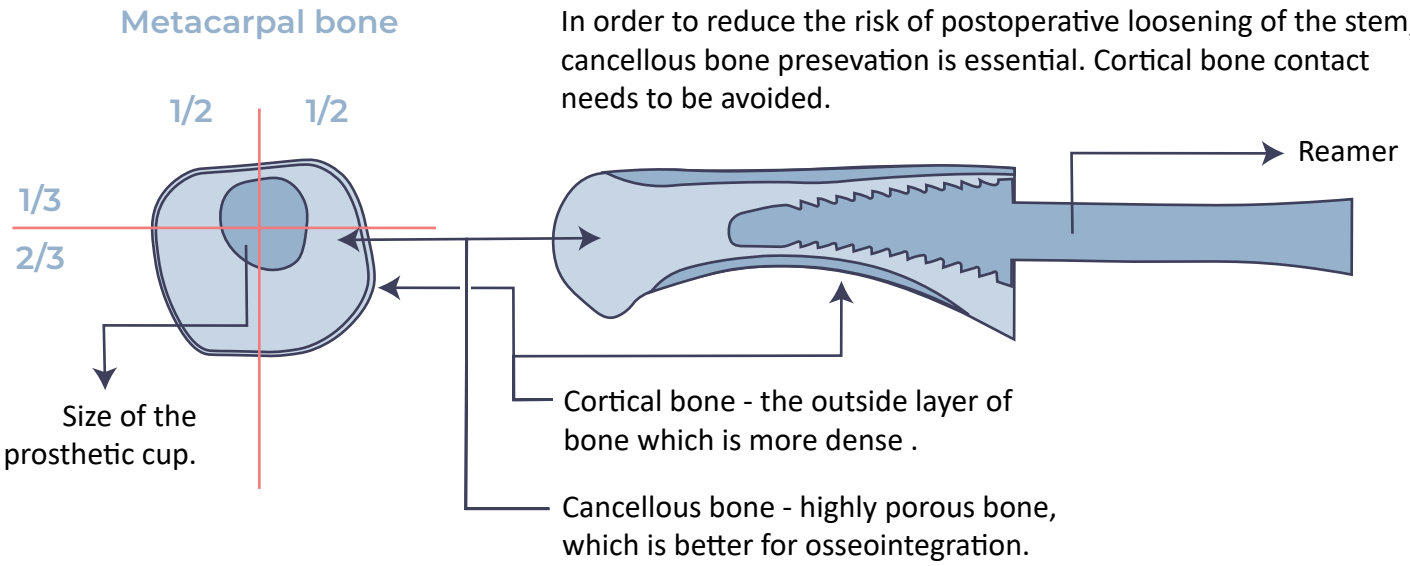


Fig 19. Guidelines for metacarpal reaming (Keri Medical, n.d.)

Phase 3: trapezium dissection

During surgery the surgeons are positioned on the side of the table (Fig 20. Positions of the surgeons during surgery.). However, an adjusment occurs from the second to the third phase: the surgeons must switch positions while maintaining sterility. This ensures that the dominant hand is used for precision tasks such as sawing and burring. To facilitate this movement, the surgical tables are pushed aside, allowing the surgeons to reposition efficiently. The lay-out of the operation room and the switch of positions is shown in Fig 21. Lay-out and movement in the operation room. on the next page.

Once the have changed positions the surgeons continue surgery by dissecting the trapezium and the placement of the cup and neck.

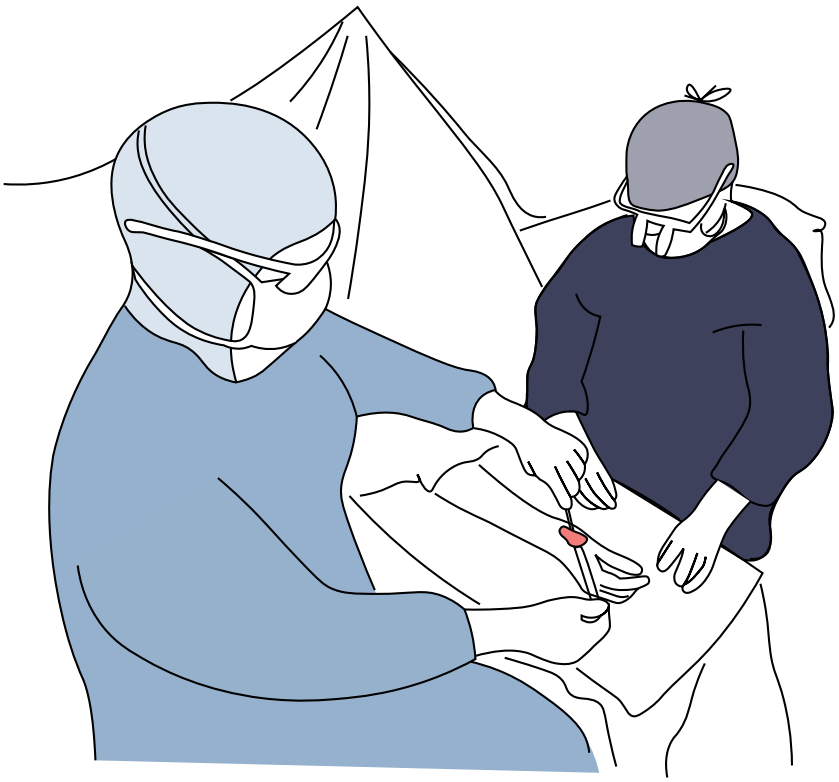
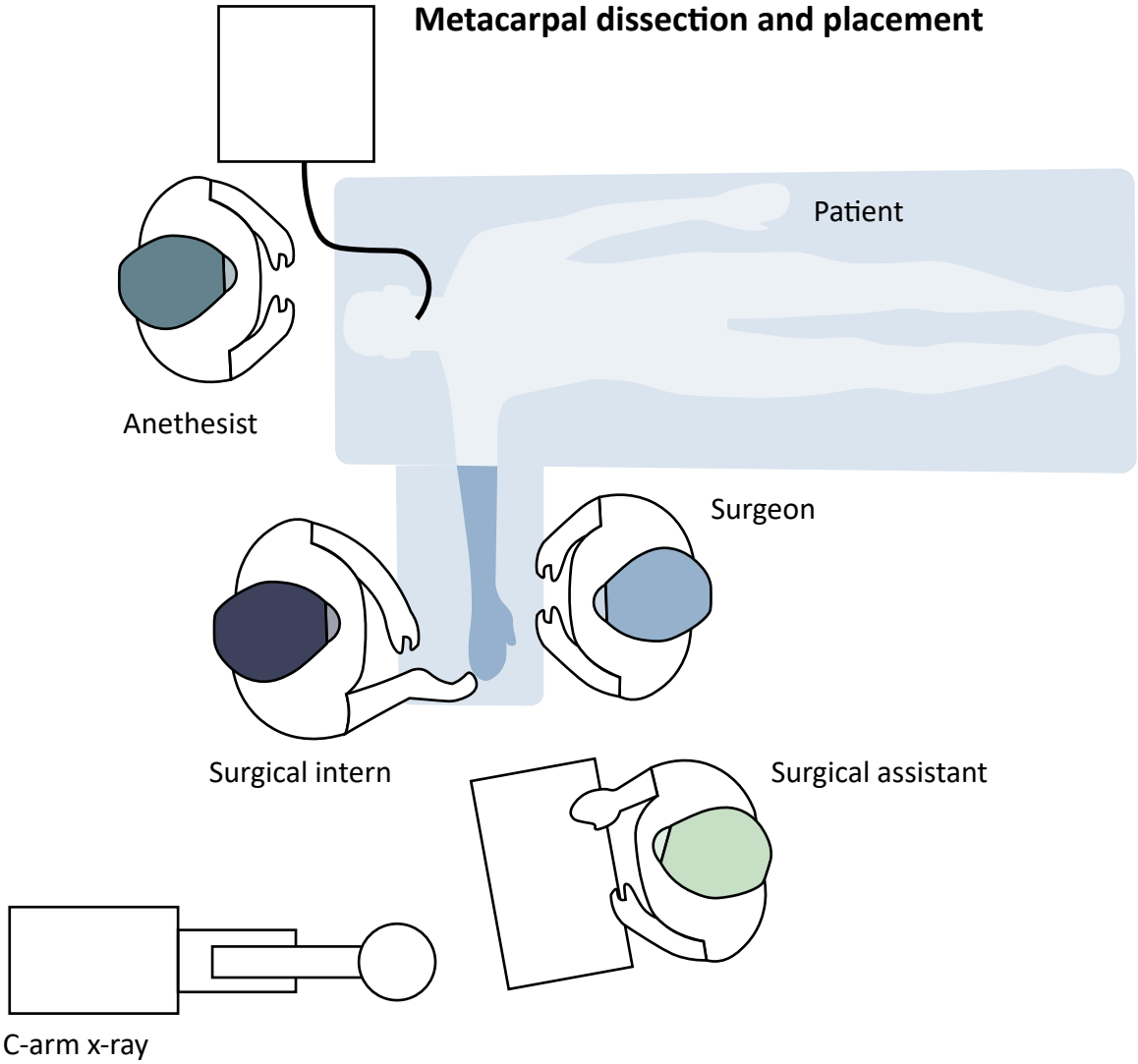


Fig 20. Positions of the surgeons during surgery.



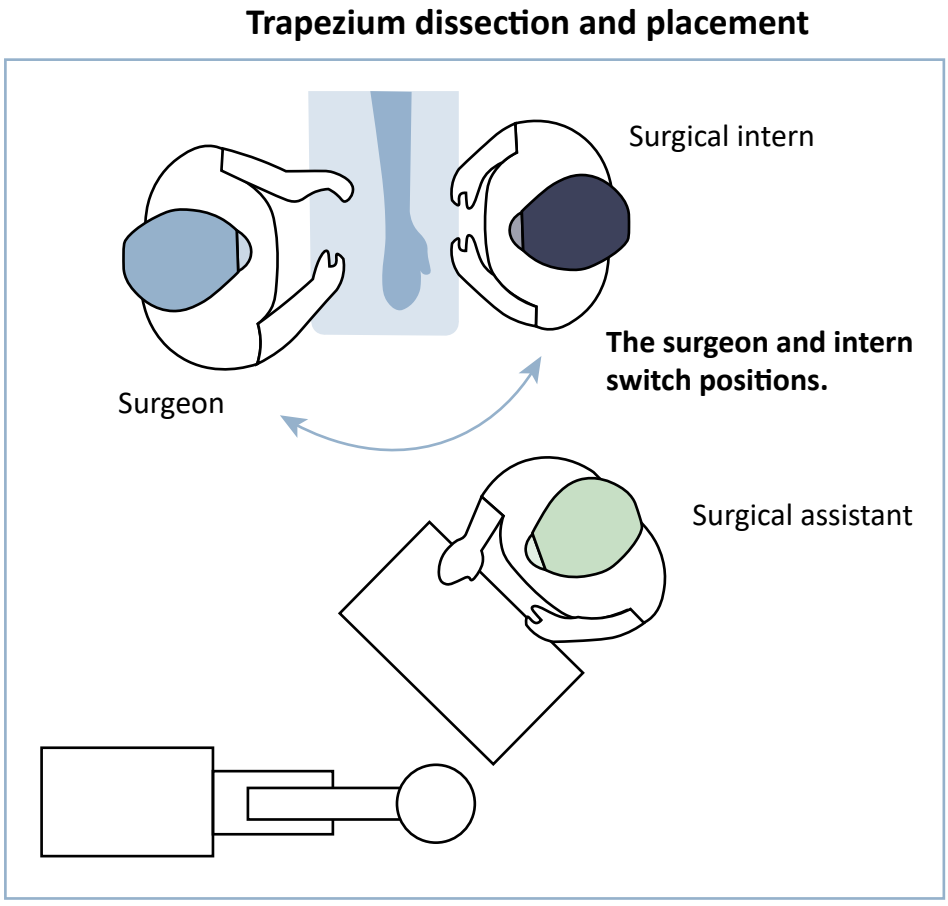


Fig 21. Lay-out and movement in the operation room.

This phase relies entirely on a critical step: the precise positioning of the k-wire. The k-wire functions as a guide for the reamer, making its accurate positioning essential for the success of the procedure. Its placement is verified using x-ray imaging and is adjusted as needed until it is correctly aligned in all planes.

Fig 23. Reamed trapezium bone with k-wire in place, cadaver study (RHOC). shows a trapezium of a cadaver study, where the bone has already been reamed. The Figure highlights the limited remaining space around the trapezium. Successful osseointegration is essential for maintaining the stability of the prosthetic cup. However, the restricted bone volume increases the risk of insufficient cancellous bone, which may compromise osseointegration. This challenge is further illustrated in Fig 24. Illustration of the reamed surface on the trapezium..

Wrongful placement can lead to misalignment in the prosthetic components, poor osseointegration of the cup and thus loosening or dislocation of the cup.

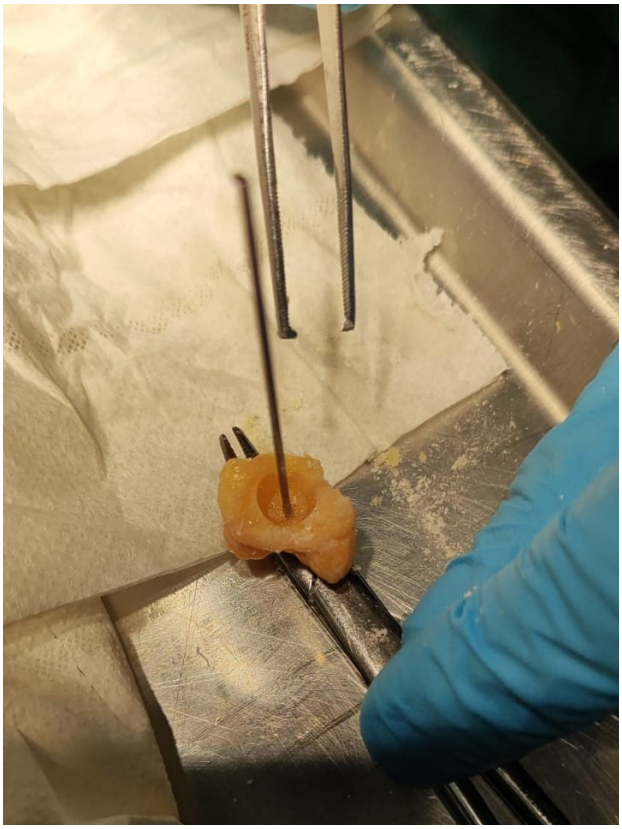


Fig 23. Reamed trapezium bone with k-wire in place, cadaver study (RHOC).

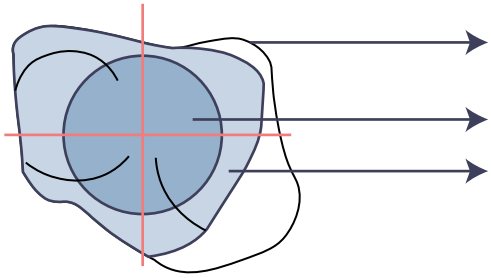


Fig 24. Illustration of the reamed surface on the trapezium.

Phase 4: validation

The final stage of the surgery involves validating the prosthetic placement and closing the incision. To ensure a proper fit, the surgeon manually moves the joint through its three degrees of motion to ensure that no impingement occurs. Then, the surgeons gently pulls the thumb to check that the prosthetic neck is neither too loose nor too tight. The final composition of the prosthesis is shown in Fig 22. Prosthesis placed in metacarpal and trapezium bones, cadaver study (RHOC)..

Beforehand, the surgeon marked the incision on the hand. Subsequently, a marking is made at the crease of the thumb on the rest of the hand. This serves as a reference point to prevent any elongation or shortening of the thumb during the procedure. After validation, the surgeon checks the thumb crease mark to ensure the thumb has maintained its original length.

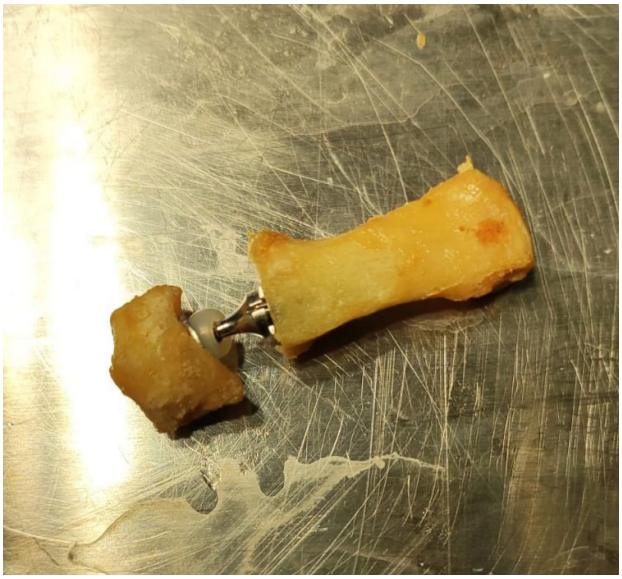


Fig 22. Prosthesis placed in metacarpal and trapezium bones, cadaver study (RHOC).

2.5.3 Current surgical instruments

Each intra-operative phase presents its own set of challenges and requires specific surgical instruments to ensure success. Fig 27. Three surgical instruments specifically used for the Touch prosthesis. shows three instruments specifically designed for the placement of the Touch prosthesis.

The metacarpal cutting guide (left) is used for the osteotomy of the metacarpal. This guide operates with a standardized distance (5mm) from the edge of the metacarpal, providing consistent positioning per different anatomy, as shown in Fig 25. Use of the metacarpal cutting guide (Keri Medical, n.d.). A small metal strip attached beneath the guide serves as an alignment mechanism, ensuring that the bone removal is performed precisely and perpendicularly to the bone surface. The surgeon typically holds this instrument in their non-dominant hand while performing the osteotomy with the saw in their dominant hand.

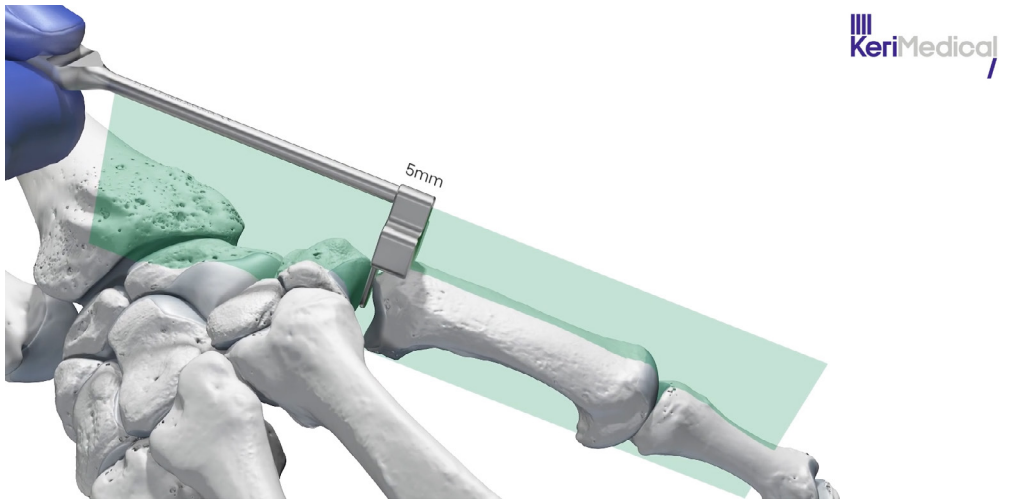


Fig 25. Use of the metacarpal cutting guide (Keri Medical, n.d.)

The second instrument (middle) is the fork retractor, an instrument that assists the surgeon in both the metacarpal dissection and trapezium dissection. The fork retractor is used to either elevate and lower the metacarpal for better visibility of the bone surface. The surgical assistant typically holds the fork retractor, in combination with other retractors, in their hand. Fig 26. Use of the fork retractor (Keri Medical, n.d.) shows how the fork retractor is placed beneath the trapezium bone to provide better visiblity for the surgeon. Subsequently, the k-wire can be placed perpendicular to the surface, as shown by the planes in the Figure.

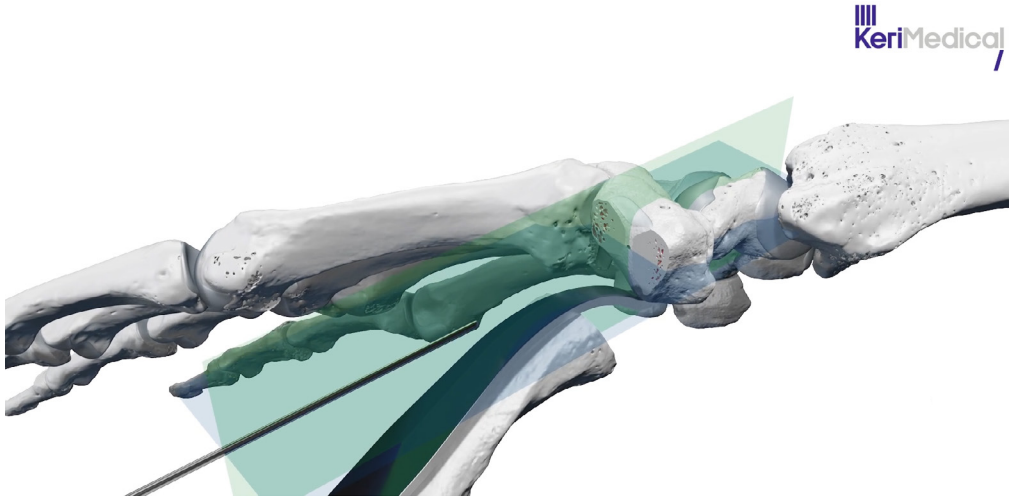


Fig 26. Use of the fork retractor (Keri Medical, n.d.)

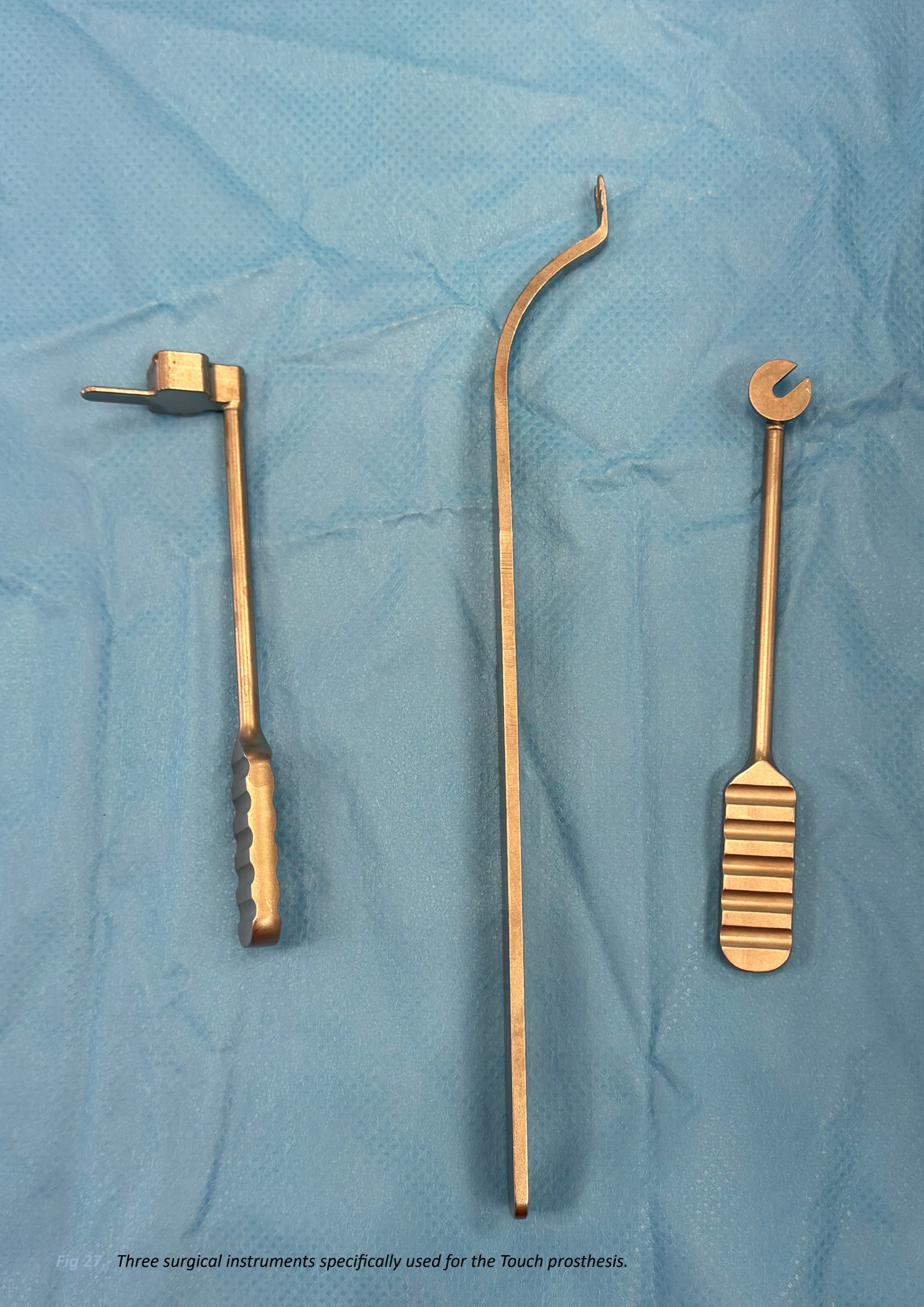


Fig 27 *Three surgical instruments specifically used for the Touch prosthesis.*

During the trapezium dissection and placement of the cup and neck, osteophytes are carefully removed from the trapezium to prepare the bone for prosthetic cup.

Following this, a centering guide is used to assist the surgeon in determining the center point of the trapezium (right, Fig 27. Three surgical instruments specifically used for the Touch prosthesis.). The surgeon operates the burr with their dominant hand while simultaneously holding the centering guide with their non-dominant hand, requiring precise coordination.

As illustrated in Fig 28. Current centering guide featuring a circle with a slot hole in the middle., the centering guide allows the surgeon to position the burr within it. The purpose of the circular shape is to mimic the diameter of the prosthetic cup on the trapezium surface.

However, this design leaves room for error, as the open space in the slot can lead to slight misplacement of the burr or drilling at an incorrect angle. Additionally, the centering guide itself does not provide direct guidance in locating the true center, making it less effective in ensuring optimal positioning.

Fig 28. Current centering guide featuring a circle with a slot hole in the middle.

Another interesting instrument for this surgical step is the center point guide, see Fig 29. Current centre point guide. Once the trial metacarpal stem is in place, this component can be positioned onto the stem.

At this stage, the thumb can be rotated and moved, allowing the sharp point of the guide to subtly scratch the surface of the trapezium. The underlying concept is that the surgeon's movements should help the tool naturally locate the center of the trapezium.

However, this method is not foolproof. The point may scratch an incorrect area of the trapezium surface, leading to potential inaccuracies. Despite its existence and presence in the surgical tray, surgeons do not actually use the tool in practice. This is mainly due to the unreliability of the product (*personal communication*).

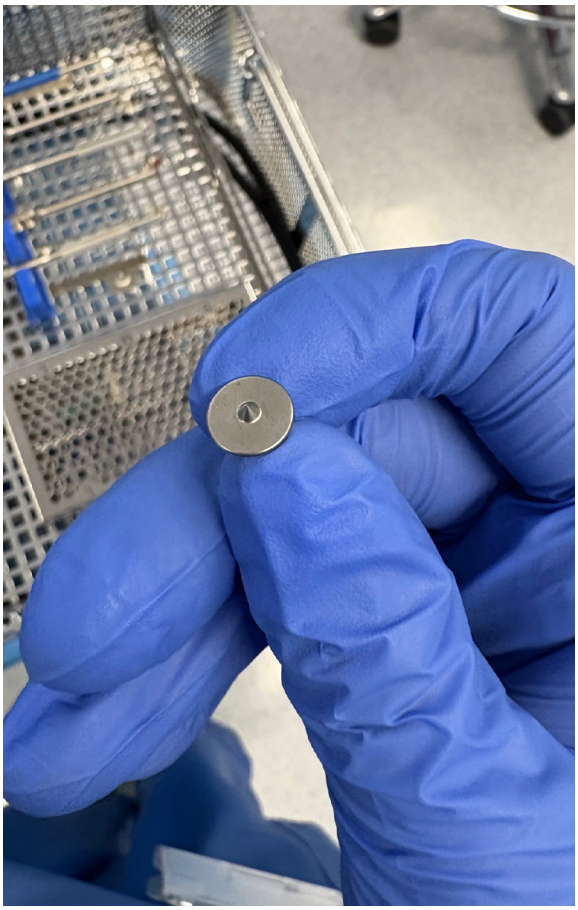


Fig 29. Current centre point guide

2.5.3 Complication and failure analysis

Fig 13. Journey map of surgical procedure shows three touchpoints; intra-operative complications, early major complications, and late major complications. Intra-operative complications can include difficulties with the anatomy, for instance poor bone quality, lack of surgical instruments or difficulty with executing certain surgical steps. Both early and late major complications can be a result of steps that occured in the intraoperative phase.

In this subsection, the cause of these complications are analysed in depth. This is done throughout a literature review focusing on the complication, revision, and failure rates of dual mobility prostheses (Table 5. Summarized complication, revision, failure rates of scientific articles). All studies were short- to mid-term and the participation rate of the studies differed from 40 to 381 people. Nine studies were used for this review. The full review of these studies can be found in Appendix A: PRISMA method. The aim of this review is to analyze complications related to Total Joint Replacement of the thumb base and define causes for failure during and after surgery.

The complication rate can be divided into minor and major complications. Minor complications can be resolved with non-surgical treatment, whereas major complications often require surgical intervention (Farkash et al., 2023). Initial complications of the first-generation prostheses were primarily related to the cemented and metal-on-metal designs (Froschauer er al., 2021). However, these complications were resolved with the implementation of the dual mobility design. Studies were excluded if they did not use dual mobility prostheses in their research.

Next, the revision rate includes procedures where further intervention was required to correct problems with the implant, but not necessarily complete removal of the prosthesis. For example, this could include adjustments to stabilize the implant or to address complications such as dislocation or cup loosening.

Lastly, the failure rate refers to cases where the implant did not function as intended and needed to be removed or replaced. This is often due to complications such as fracture, dislocation or infection, and may require an alternative surgical route, i.e. trapeziectomy.

Table 5. *Summarized complication, revision, failure rates of scientific articles*

Type	Range of complication, revision, and failure rate
Complication rate	7,5% - 35,9%
Revision rate	0% - 12,4%
Failure rate	0% - 7,7%

The duration of follow-up in these studies affects the type and frequency of complications reported. Shorter-term studies, such as Gonzalez-Espino et al. (2021) with one year follow-up, reported only minor complications such as De Quervain's tenosynovitis. However, longer term studies such as those by Lussiez et al. (2021) and Herren et al. (2023) report more serious problems such as dislocation and loosening, which typically occur later in the recovery period. Moderate cup migration, was also documented by Lussiez et al. (2021) over a three to four year period. In some cases this complication can be managed without revision surgery, if a new mechanical stability is achieved.

Tchurukdichian et al. (2023) reported a significantly lower complication rate than the other studies. Their study primarily aimed to evaluate the time needed for patients to return to work after surgery, highlighting that outcomes are positively affected when rapid recovery is considered. The study consisted of a population group where 17% was aged under fifty years old, which is a higher percentage than other studies. This is also likely to have contributed to the lower complication rate.

Revision rates varied between studies, with Andrzejewski & Ledoux (2019) reporting the highest at 12.4%. The main cause of revision in this study was periprosthetic ossification, which is abnormal bone growth around the implant that restricts joint movement and increases the likelihood of late dislocation. No other studies mentioned this cause of revision, which raises questions about the cause of this complication.

Touchpoints: intraoperative complications

Challenges in Accuracy of Prosthesis Placement

Cup migration and prosthetic loosening were common complications in longer term studies. Lussiez et al. (2021) observed moderate cup migration in 12/107 cases, probably due to over-reaming, which can compromise osseointegration within the trapezium. While most migrated cups achieved mechanical stability, two cases resulted in painful loosening and required revision. As mentioned by Tchurukdichian et al (2023), achieving accurate depth during reaming is critical to ensure that osseointegration and primary stability are maintained over time.

These findings show that most surgeons experience challenges when preparing the trapezium bone: determining the correct cup placement and deciding how much bone should be reamed. Incorrect positioning of the cup can compromise the alignment and function of the entire prosthesis, potentially leading to implant failure.

Technical Challenges and Learning Curve

The analysis by Farkash et al (2024) reported that the influence of the learning curve was significant, finding that major complications occurred predominantly early in the learning period. According to Maes-Clavier et al. (2015) that a surgeon should perform at least thirty surgeries before they can accurately perform thumb CMC TJA. Dislocations and early cup loosening were often due to inadequate stabilisation techniques, particularly with the Touch® prosthesis. These findings support that careful surgical technique and experience have a significant impact on complication rates (Farkash et al, 2024).

Froschauer et al. (2021) reported a complication rate of 25%, largely due to technical errors. These include challenges with reaming, positioning and correct sizing of components. This also highlights the complexity of the procedure and the learning curve for less experienced surgeons. Lussiez et al. (2021) also highlight the importance of correct reaming depth and positioning to avoid compromising osseointegration, which can lead to cup migration. Deep reaming can cause osseointegration problems that may worsen over time.

Incorrect component selection, such as neck size, has also led to revision surgery, as noted in two cases in the study by Froschauer et al. (2021). In addition, Farkash et al. (2023) observed intra-operative fractures of the trapezium as a major reason for revision surgery, which further shows the technical precision that is required during prosthesis placement and reaming to avoid these problems.

Touchpoints: early complications

Tendinopathy and De Quervain’s Tenosynovitis

Bricout & Rezzouk (2016) identified tendinopathy as a prevalent complication, with the highest overall complication rate at 35.9%, of which 67.9% were minor. Tendinopathy is a broad term for any tendon condition that causes pain and swelling (Cleveland Clinic, 2024). Contributing factors include tension on the tendons from surgical errors, such as lengthening of the thumb. Changes in surgical techniques, such as releasing the

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tendons during surgery, have been recommended by Gonzalez-Espino et al. (2021) to reduce tension and lower the risk of tendinopathy.

De Quervain's tenosynovitis is another significant complication, which causes painful inflammation of the tendon sheath (Reinier Haga Orthopedisch Centrum, 2024). Herren et al. (2023) reported 11 cases related to this condition, often associated with thumb lengthening or conversion to a ball-and-socket joint prosthesis. These complications are believed to be linked to the estimation-based 'freehand' approach for prosthetic placement during surgery (*personal communication*). Farkash et al. (2023) also reported a notable rate of De Quervain's tendinopathy, which was among the most frequently observed minor complications in their study. This reinforces the importance of improved placement techniques to reduce post-operative tendon tension (Farkash et al., 2023).

Prosthetic Loosening and Dislocation

Dislocation is a painful complication in which the prosthesis neck dislocates from the cup. Bricout & Rezzouk (2016) describe this as a common early complication. Andrzejewski & Ledoux (2019) report that dislocation was the most common problem in their study, occurring in 11 out of 113 cases, likely related to the extensive release of ligaments during the procedure. This surgical technique can compromise joint stability, leading to misalignment and subsequent dislocation. In this cohort, approximately half of the dislocated prostheses required revision surgery.

Touchpoints: late complications

Multiple studies identify cup loosening as a complication, with Lussiez et al. (2021) observing a 4.6% revision rate due to loosening-related issues. Prosthetic instability can be worsened by patients who engage in heavy manual work after surgery, placing excessive stress on the prosthetic components. Herren et al. (2023) reported four cases of cup loosening, which were related to difficulties in achieving primary stability in the trapezium during surgery.

Findings from the study by Farkash et al. (2023) support these conclusions, highlighting an overall 2.9% short-term failure rate among 381 patients treated across six medical centers. The most common major complication in this study was an inability to stabilize the cup within the trapezium, often leading to trapeziectomy as an alternative surgery. This study particularly emphasizes the technical challenges of achieving primary cup stability, especially with the Touch® and MAÏA™ implants, and underscores the need for precise placement to prevent early loosening and dislocation (Farkash et al., 2023).

Touchpoints: design and education

Prosthesis Design and Surgical Technique

The choice of prosthesis design, surgical technique and instrumentation can influence stability and complication rates. All studies used a similar dual mobility design, such as the Ivory and Moovis prostheses. Bricout & Rezzouk (2016) observed a complication rate of 35.9%, with tendinopathy as the leading complication. A possible cause of this complication may be the spread of osteoarthritis to the SST joint, scaphotrapezoidal osteoarthritis (SST OA), which may be considered a contraindication for joint replacement.

Other studies point to design-specific advantages in reducing minor complications. Gonzalez-Espino et al. (2021) reported a 0% revision rate at one year, noting that their study employed a sawing guide for metacarpal preparation, which improved alignment and stability of the prosthesis. While these shortterm findings show promise, complications like dislocation and loosening may still develop over longer periods. Design adjustments that enhance stability and accommodate variations in patient anatomy could help minimize these complications and improve overall outcomes.

2.6 TOUCH Dual Mobility Prosthesis

This section explains of which components a Touch Dual Mobiltiy prosthesis is made and what makes this specific prosthesis a success. It is important to understand which components fit together and how the prosthesis behaves as a whole.

The Touch dual mobility prosthesis is developed by the Swiss manufacturer Keri Medical. The prosthesis is one of the most recent dual mobility, ball-and-socket, cementless, modular, and hydroxyapatitecoated implant (Tchurukdichian, 2023). A dual mobility prosthesis is a prosthesis with an additional liner between the cup and the neck, enabling smooth movement of the prosthesis. The Touch prosthesis aims to improve stability, increase range of motion, and facilitate quicker recovery, while minimizing common complications associated with thumb base joint replacements.

The prosthesis consists of four components: the stem, the neck, the liner, and the trapezial cup, see Fig 30. Components of Touch CMC-1 prosthesis (Keri Medical, 2023). The Figure shows components and their materials. Two trapezial cups are available, conical and hemispherical, with diameters of 9 and 10 mm (Keri Medical, 2023). At Reinier Haga Orthopedic Centre the conical shaped cup is used at all times (doctor Kraan, 2024). Yet, according to Herren et al. (2023) it remains unknown whether the shape of the cup affects the clinical and patients outcomes.

The stem is made of a double coating of porous titanium and hydroxyapatite (HA) providing secondary stability, also known as osseointegration (Keri Medical, 2023). HA is osteoconductive, meaning that is stimulates bone growths on the surface (Albrektsson and Johansson, 2001), whereas the porous titanium interface provides mechanical stability.

The neck component, made from stainless steel, is available in two configurations: a straight neck and an offset neck angled at 15 degrees. The offset neck option helps in restoring the anatomical offset of the CMC-1 joint, enhancing rotational stability and improving overall joint mechanics (Bricout and Rezzouk, 2016). This design flexibility is intended to allow surgeons to tailor the implant to the patient's anatomical needs, reducing the risk of instability and ensuring a more natural range of motion post-surgery.

The liner poses an important part of the dual mobility function by ensuring smooth movement. The liner is made of Ultra High Molecular Weight Polyethylene, which proves to be 6,4% better resistant to wear than standard PE (Keri Medical, 2023). This increased durability is very important for ensuring smooth articulation within the ball-and-socket joint, thus reducing friction.

Lastly, the cup is made from stainless steel with hydroxyapatite (HA) coating and it is implanted in the trapezium bone. The stability of the is reinforced by a press-fit technique. At the Reinier Haga Orthopedic Centre, a conical-shaped cup is consistently used, though the prosthesis is also available with a hemispherical shape. While the conical design ensures stable fixation in the trapezium, there is still limited evidence on how cup shape might affect clinical outcomes and patient satisfaction (Herren et al., 2024).

So, dual mobility prostheses are being increasingly used for the surgical treatment of thumb base osteoarthritis. This can be related to their potential to improve stability, reduce pain and restore function in a faster recovery time (*personal communication*). However, it still remains a big challenge to limit the complications during and after surgery.

1. Trapezial cup

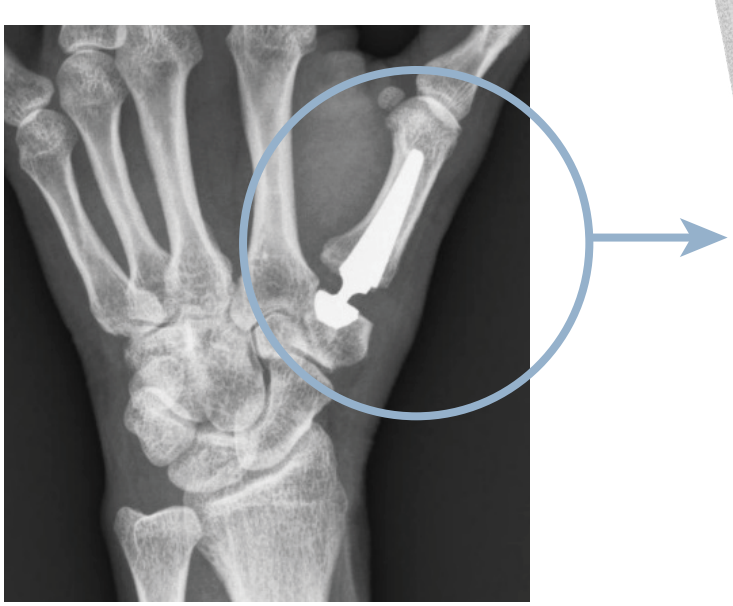
Material: stainless steel (SS) dual coating of titanium and hydroxyapatite (HA) coating
Variants: concial and spherical cup
2 cup sizes (Ø 9 mm and 10 mm)

2. Neck

Material: highly cross-linked polyethylene (UHMWPE)
Variants: straight and offset (15°) neck.
3 heights (6, 8 and 10 mm)

3. Metacarpal stem

Material: titanium with dual coating of titanium and hydroxyapatite (HA) coating
Variants: 6 stem sizes



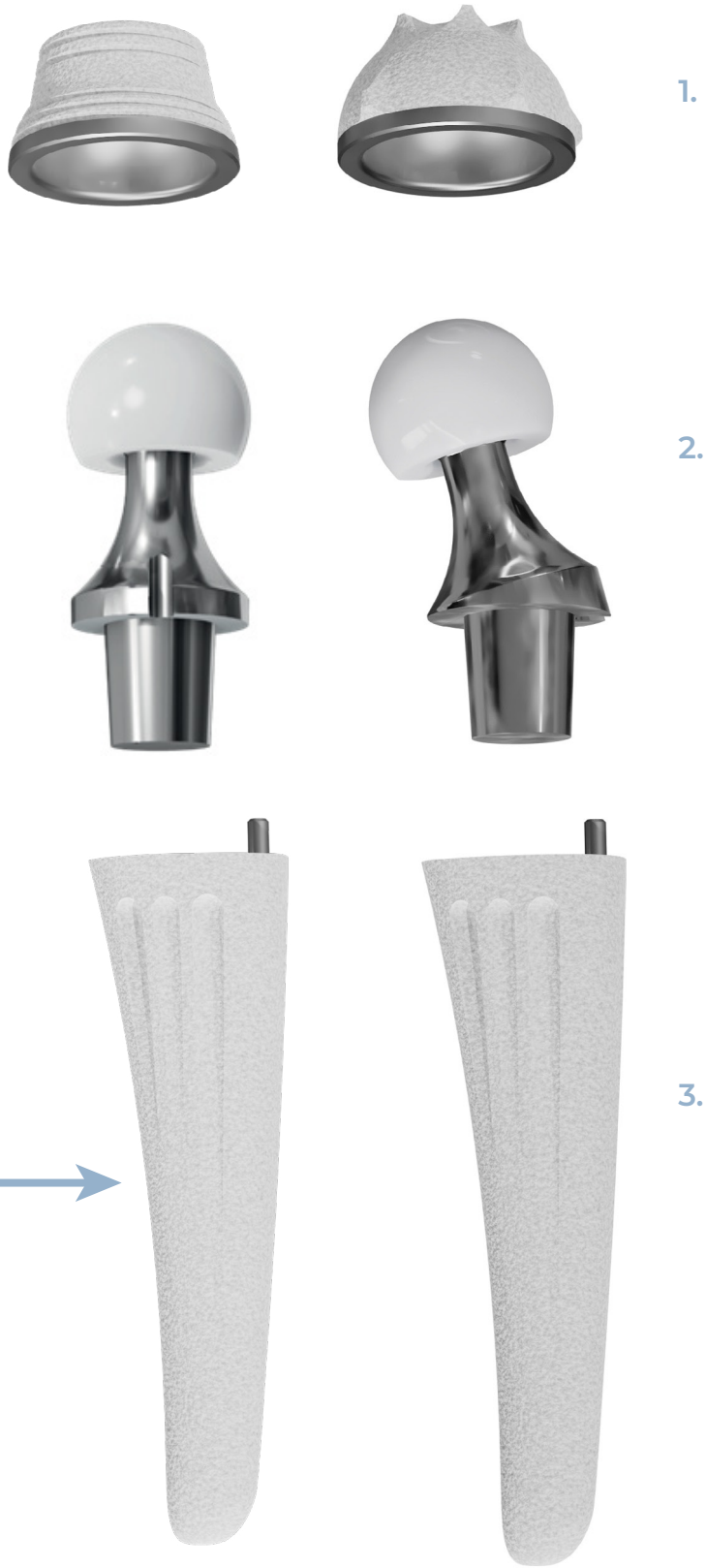


Fig 30. Components of Touch CMC-1 prosthesis (Keri Medical, 2023)

2.7 Surgical innovation in Joint Arthroplasty

2.7.1 Mechanical instrumentation

Mechanical instruments, such as sawing guides and alignment tools, are fundamental in arthroplasty procedures. For instance, sawing guides assist the hand surgeon to accurately prepare the metacarpal of the thumb. These tools are designed to assist surgeons in precise bone cutting, alignment, and component placement during surgeries, without the addition of digital or robotic intelligence. The main advantage of mechanical instruments lies in their simplicity and ease of use, making them accessible to surgeons across various surgical settings. However, this lack of robotic intelligence also creates limitations. Mechanical instruments can lead to challenges in consistent and accurate results, leaving room for potential technical errors or unintended use by surgeons.

Examples of technologies in the field of arthroplasty include traditional surgical instruments, such as self-retaining retractors and cutting guides (Fig 32. Cutting guide for metacarpal osteotomy), and also novel concepts like the patient-specific surgical instruments for the placement of finger prostheses. The latter was a Master Thesis project from Schijf (2022) during which personalised 3D-printed guides were developed, see Fig 31. Mechanical instrument, concept MSc Thesis.

Fig 31. Mechanical instrument, concept MSc Thesis

Fig 32. Cutting guide for metacarpal osteotomy

Advantages

+ Can be used for multiple patients.
+ Easier integration into the surgical process.
+ Potentially lower costs.

Disadvantages

- Not patient-specific, limiting adaptability.
- May not be effective for every anatomical variation.
- Limited accuracy; not precise to the millimeter.
- Still susceptible to manual errors by the surgeon.

2.7.2 Robotics

Robotic systems are already being used in other TJAs, but not yet in hand arthroplasty. The initial design goals of robotics in orthopedics are to improve the accuracy of component placement and alignment, thereby improving implant survival and reducing the need for revision surgeries. Robotic systems are used to minimise human error and deliver consistent, accurate results.

According to Jacofsky (2016), robotic platforms in orthopedics can be classified into three categories. **Active systems** operate independently of the surgeon, performing tasks autonomously. **Semi-active systems**, also known as haptic systems, involve the surgeon's participation while providing tactile feedback to enhance control. **Passive systems** function under the continuous guidance of the surgeon, assisting in specific procedural steps without autonomous execution.

Robotic-assisted surgery can also be categorized into **image-based** and **imageless systems**. Image-based systems utilize pre-operative imaging, such as CT or MRI scans, to generate detailed 3D models of the patient's anatomy, enabling precise pre-surgical planning and accommodation of complex anatomical deformities. In contrast, imageless systems rely on intra-operative surface mapping to register the patient's anatomy in real time, allowing for adjustments during surgery. While imageless systems eliminate the need for extensive pre-operative imaging, they require additional intraoperative steps, leading to longer exposure times. However, they offer the advantage of real-time adaptability, making them suitable for cases with less complex anatomical variations.

At RHOC, hip surgeons make use of the Mako robot (Fig 33. Mako robots, Stryker (Stryker, 2024)) for complex cases. This robot used a pre-operative planning system in which CT-scans are used to analyse the anatomy of the patient and create a solution that fits them best. During surgery, the system behaves semi-active, providing both haptic and visual feedback on a remote screen.

Fig 33. Mako robots, Stryker (Stryker, 2024)

The NAVIO™ Surgical System by Smith & Nephew is a robotic-assisted surgical system designed for total knee arthroplasty (TKA) (Smith & Nephew, 2018). Unlike fully autonomous robotic systems, NAVIO operates as a surgeon-controlled, handheld robotics-assisted device that enhances precision, alignment, and implant positioning during knee replacement procedures.

The system utilizes imageless navigation, meaning it does not require pre-operative imaging such as CT scans. Instead, it constructs a virtual model of the patient's knee using intraoperative data collected through bone tracking and surface mapping. This allows for real-time adjustments based on the patient's unique anatomy, helping surgeons improve implant fit and joint alignment while minimizing bone loss.

Fig 34. *NAVIO* ™ Surgical System (Smith & Nephew, 2018)

Advantages

+ Enhanced accuracy in implant placement and burring.
+ Reduces human error by providing real-time guidance and automation.
+ Improves procedural consistency and repeatability.

Disadvantages

- High cost for development, maintenance, and training.
- Requires integration with pre-operative imaging, increasing complexity.
- May increase surgery duration in initial implementations.

2.7.3 Augmented Reality

Augmented Reality (AR) is a new technology in orthopedic surgery that allows surgeons to visualise real-world environments overlaid with virtual information to guide implant placement and alignment. This technology provides real-time visualisation to help the surgeon make more accurate decisions during the procedure, which can improve implant positioning, alignment and thus patient outcomes.

A systematic review by Jud et al. (2020) evaluated the applicability of AR in orthopedic surgery, analyzing 31 studies across various categories, including instrument and implant placement. The review concluded that AR has the potential to be a time-saving, risk-reducing, and accuracy-enhancing technology in orthopedic surgery.

Despite its potential, AR in orthopedic surgery is still in its early stages, with challenges such as calibration errors and the need for smooth integration with existing surgical workflows. Additionally, cost and training requirements remain a barrier as well. However, as AR technology continues to evolve, it is expected to become an essential tool in improving precision and efficiency in joint arthroplasty and other orthopedic procedures.

One conceptual implemention of AR in orthopedic surgery is the Hololens, a headset aiding the surgeon to accurately perform surgery without extensive pre-operative planning and risk of contamination. During surgery the surgeon can overlay the patient anatomy (X-ray, MRI scans) into to actual surgical environment to help the surgeon determine the best course of action (Accenture, 2025).

Advantages

+ Enhances visualization without requiring the surgeon to look away.

+ Can improve surgical accuracy without requiring complex hardware integration.

+ Provides intraoperative patient-specific options compared to rigid mechanical guides.

Disadvantages

- Still in early development, requiring validation and workflow adaptation.

- May cause dizziness or other side effects for surgeons.

- Prone to calibration issues affecting precision.

- Requires hardware and software investment, increasing costs.

2.7.4 Conclusion

The choice of surgical technology for joint arthroplasty involves a critical balance between cost, accuracy, ease of integration, and patient-specific customization.

Mechanical solutions, including standard instrumentation and mechanisms, offer cost-effective and easy-to-integrate solutions into existing surgical workflows. However, their reliance on manual operation introduces variability, lacks patient-specific customization, and leaves considerable room for human error.

In contrast, robotic-assisted systems likely provide the highest precision and reproducibility, significantly reducing surgeon-dependent variability. Yet, these advantages come at a cost: robotic systems demand a big financial investment, complex integration into existing surgical workflows, and extensive staff training. Consequently, their adoption may be limited to specialized or high-volume surgical centers.

Augmented reality (AR) technology emerges as a promising intermediate solution, offering real-time enhanced visualization and improved accuracy without the full complexity of robotic systems. Nonetheless, implementing AR requires investment in equipment, infrastructure adjustments, and staff training, presenting moderate barriers to widespread adoption.

The best solution depends on the balance between precision, cost, and practicality within a surgical environment. A hybrid approach, combining mechanical stabilization with AR or sensor-based enhancements, could offer a cost-effective yet accurate solution for improving orthopedic surgery outcomes.

2.8 Relevant rules and regulations

This section explains the relevant sterilization regulations for surgical instruments and medical devices used in thumb joint arthroplasty based on their classification.

Medical product development has to comply to strict rules and regulations, particularly concerning use and sterilization. Medical devices are categorized into four distinct classes depending on their intended use, duration of patient contact, and associated risk factors: Class I, Class IIa, Class IIb, and Class III (International Organization for Standardization, 2024). The explanation of each class is described in Table 6. Description of classification of medival devices. Each classification has specific requirements for sterilization to ensure patient safety.

Table 6. Description of classification of medival devices

Classification	Risk	Example
Class I	Low risk	Reusable surgical instruments - reamers, drills.
Class IIa	Low-medium risk	Single-use surgically invasive intended for transient use - k-wire.
Class IIb	Medium-high risk	Software intended to monitor vital physiological parameters.
Class III	High risk	CMC-1 prosthesis
Class Ir	*Ir (notified body involvement). To approve aspects related to cleaning, disinfection, sterilization, maintenance, and function testing.*	

Class I devices pose the lowest risk and typically include reusable surgical instruments such as reamers, drills, and retractors, which must undergo sterilization after each use. Class IIa and Class IIb devices, such as single-use k-wires or software-assisted systems, require sterilization protocols before use. Class III devices, including CMC-1 prostheses, involve the highest risk level and therefore necessitate validated sterilization procedures, detailed documentation, and regulatory approval before clinical deployment.

Sterilization methods often include steam sterilization (ISO 17665) and dry heat sterilization (ISO 20857). Instruments such as centering guides and cutting guides should be sterilized using autoclaving at 134°C for 3–5 minutes or dry heat sterilization at 180°C for 30 minutes, depending on material specifications. Surgical instruments are placed on the trays (as shown in Fig 35. Surgical trays used during total thumb joint replacement.) and autoclaved simultaneously. For electronic components, direct autoclaving is not suitable. Instead, UV-C sterilization or medical-grade disinfectant wipes should be used (International Organization for Standardization, 2024). These requirements should be used as criteria to determine appropriate materials during this thesis.

During the design and development process, the surgical instruments must **comply with Class I classification** and to the **appropriate sterilization methods** to ensure safe use in clinical settings.

Fig 35. Surgical trays used during total thumb joint replacement.

2.9 Conclusion

The initial project assignment focused on the need for new surgical instruments to improve the placement of the thumb prosthesis. This chapter provided an analysis of key factors influencing the accuracy and effectiveness of thumb base joint arthroplasty, highlighting the importance of precision in prosthesis placement.

Through extensive literature review, it became clear that the surgical procedure has a significant learning curve, with technical inaccuracies contributing to major complications such as prosthesis misalignment, trapezium fractures, and cup loosening or dislocation. These complications are often worsened by limited surgical visibility, restricted working spaces, and the complexity of achieving precise alignment, thereby emphasizing the need for improved instrumentation.

The analysis of current surgical instruments highlighted limitations, especially with the existing centering guide, which lacks sufficient reliability and stability. This further emphasizes the need for more precise and supportive tools. Moreover the exploration of innovative technologies, such as laser-guided surgery, augmented reality, and robotics, presented laser-guided systems as particularly promising due to their potential to enhance accuracy without overly complicating surgical workflows. This resulted in the following six key challenges (Fig 36. Overview of the six key challenges):

One of the key challenges lies in **preparing the trapezium**. The surgical field often has limited access and visibility, resulting in a narrow working space. These factors complicate the removal of osteophytes and the accurate cutting of a straight surface on the trapezium bone for the prosthesis cup. Technical errors during this preparation phase can complicate the followings surgery steps and increase the chance of misalignment or unstable prosthesis placement.

The **placement of the prosthetic cup** introduces another set of challenges. Surgeons consider this the most complicated surgical step since they must carefully position the k-wire, ream the trapezium bone correctly, and ensure the cup fits through press-fitting. Errors at any of these steps, such as incorrect k-wire placement, improper reaming, or suboptimal press-fitting, can compromise osseointegration or lead to dislocation.

In addition to these problems, there are also challenges associated with the **alignment of the prosthesis**. Misalignment, such as placing the prosthesis in a varus position or selecting the wrong prosthesis neck, can result in altered biomechanics and thumb lengthening or shortening. These complications are often due to technical inaccuracies during surgery, highlighting the need for precision throughout the procedure.

The **steep learning curve** associated with this surgery further exacerbates these challenges. The literature emphasizes that the procedure is complex, requiring significant training and practice for surgeons to achieve proficiency. Improving surgical tools and techniques could reduce this complexity, easing the burden on surgeons and improving outcomes.

While the **rehabilitation process** presents its own set of issues, such as improper execution of physical therapy and the risk of patients engaging in heavy manual work too soon after surgery, these concerns fall outside the intraoperative phase and are therefore out of scope. Addressing rehabilitation challenges might involve altering postoperative protocols or developing strategies to screen patients engaged in physically demanding occupations.

Finally, the **design of the prosthesis** itself, though initially considered out of scope, has emerged as a point of discussion. Research has questioned the suitability of ball-and-socket prostheses for the base of the thumb, suggesting that the design may influence long-term outcomes, including osseointegration and joint biomechanics.

Overall, the challenges mainly arise during the preparation and placement of the prosthesis, which require precision in a complex and narrow-spaced environment. By addressing these challenges, the surgical technique could become less complex and reduce complications in the postoperative phase.

1 Preparing the trapezium.

- Limited access and visibilty of the surgical field.
- Difficulty removing osteophytes and creating a straight surface.
- High chance of technical errors.

2 Placement of cup

- Difficulty placing the k-wire.
- Improper reaming of the trapezium.
- Wrong angulation of the cup.

3 Alignment of prosthesis

- Wrongful selection of the prosthesis neck.
- Misplacement of the cup.

4 Steep learning curve

- Literature shows a learning curve of 10-30 surgeries (see 2.5.3 Complication and failure analysis).
- A semi-freehand approach leads to a steep learning curve.

5 Rehabilitation process

- Improper execution of physical therapy.
- Returning to work too quickly.

6 Design of prosthesis

- Change in kinematics of the hand.
- Poor osseointegration.

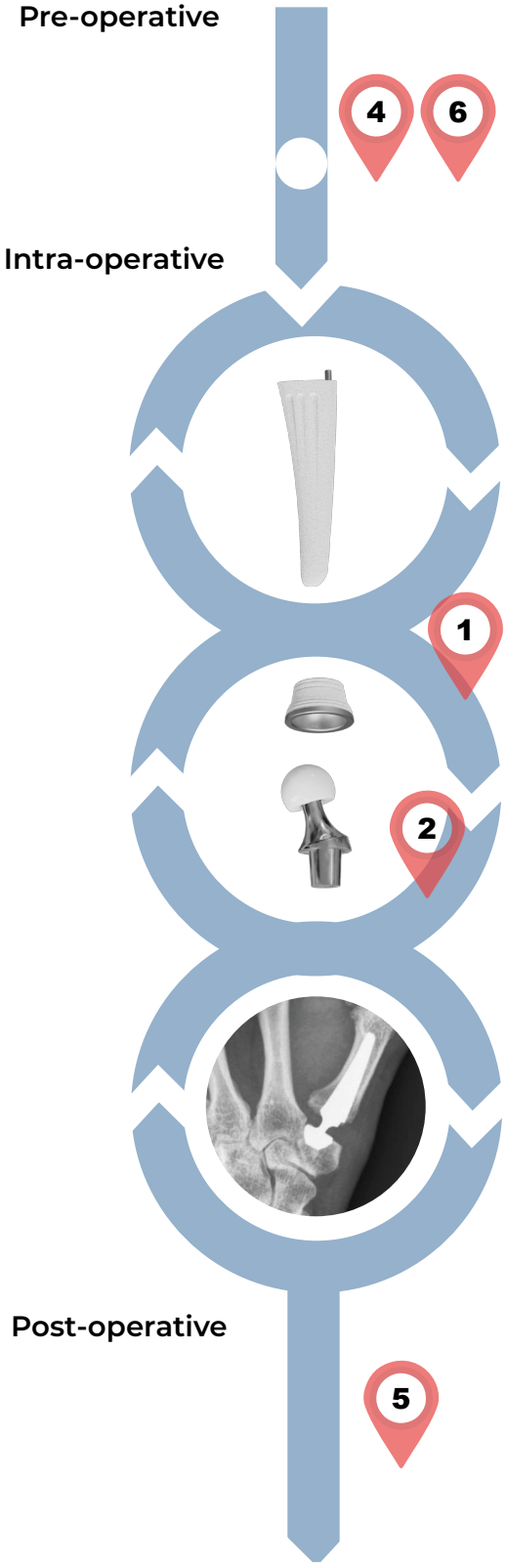


Fig 36. Overview of the six key challenges

3.

List of requirements

The list of requirements is an integral part of medical product design, defining all important characteristics the design must have (Van Boeijen et al., 2013). These requirements are categorized into general criteria and component-specific criteria. The source explains the origin of the requirement, written below in *italic*.

3.1 General requirements

Performance and validation

	Requirement
1	The concept must **enhance the precision** of k-wire placement, **minimizing variation** between similar surgical procedures. ***Source**: defined in design goal (4.2 Design goal)*
2	The concept must **enhance the acccuracy** of k-wire placement, **minimizing failure** of the prosthesis. ***Source**: defined in design goal (4.2 Design goal)*
3	The concept should achieve an accuracy within ≤ 1 mm of the official centre point for k-wire placement. ***Source**: 1 mm is based on the laser thickness.*
4	The surgeon must have used the product at least ten times in a training setting before using the product in surgery. ***Source**: learning curve shown in the tests and literature.*
5	The concept must remain mechanically stable throughout the entire surgery and not make unintended movements that could potentially harm the patient. ***Source**: safety during use.*
6	The product should not increase the surgical procedure by more than 10% (six minutes). ***Source**: prolonging a surgical procedure increases costs for the patient which is not wished.*
7	The concept should be assembled/dissassembled within one minute. ***Source**: observations during srugery.*
8	The concept must be adaptable for both left- and right-handed surgeons. ***Source**: inclusive design.*
9	The product should reduce the need for repositioning the k-wire during surgery. ***Source**: positioning the k-wire is a complicated step and often needs to be done again (Analysis).*

	Requirement
10	The concept should reduce the misalignment between the prosthetic cup and the prosthetic stem. ***Source**: problem definition (4.1 Problem definition)*
11	The concept must withstand accidental drops from a height of at least 1 meter without functional damage. ***Source**:* height of operation table (10-390-K Arm & Handchirurgie Tafel Kort, 2022)
12	The electronic components must have a minimum battery life of 12 hours of continuous use. ***Source**: the product should be used for a full day of surgeries.*
13	The electronic component (the laser) should be designed for tool-free removal, allowing for easy disassembly without requiring additional instruments. ***Source**: separate sterilization methods (2.8 Relevant rules and regulations).*

Material and sterilization

	Requirement
14	The concept should be sterilizable using standard hospital sterilization methods (ISO 17665 and ISO 20857) ***Source**: separate sterilization methods (2.8 Relevant rules and regulations).*
15	The materials used must be biocompatible and non-toxic according to medical standards. ***Source**: classification of surgical instruments (2.8 Relevant rules and regulations).*
16	The system must be corrosion-resistant under repeated sterilization conditions. ***Source**: classification of surgical instruments (2.8 Relevant rules and regulations).*
17	The product should be reusable for multiple surgeries. ***Source**: classification of surgical instruments (2.8 Relevant rules and regulations).*

3.2 ArC requirements

Performance and usability

	Requirement
18	The ArC must assist the surgeon in positioning the k-wire at the correct x-, y-coordinates before drilling. ***Source**: defined in design goal (4.2 Design goal)*
19	The ArC should remain securely fixed to the surgical table during the entire surgical procedure. ***Source**: preference of the surgeons (6.3 Validation interviews with surgeons)*

Ergonomics

	Requirement
20	The ArC must be compatible with existing surgical instruments and workflows. ***Source**: -*
21	The ArC must be operable with surgical gloves on. ***Source**: observations of surgery.*
22	The ArC should transition from passive to active mode through a single, clear action, such as pressing a button, rotating a knob, or flipping a switch. ***Source**: preference of the surgeons (6.3 Validation interviews with surgeons)*
23	The ArC should be positioned and removed through a single, clear action, such as pressing a button, rotating a knob, or flipping a switch. ***Source**: -*
24	The ArC must be operable with one hand. ***Source**: -*
25	The ArC's laser and positioning technology must minimize shatter and reflections. ***Source**: observations during validation test (Evaluation and validation)*

Material

	Requirement
26	The ArC must not interfere with fluoroscopy and intraoperative imaging. ***Source**: x-rays are a crucial step for validation of the prosthesis placement (2.5.2 Current surgical procedure at RHOC).*
27	The material should be applicable to the production methods: CNC machining and injection moulding. ***Source**: -*
28	The material must exhibit high yield strength to resist bending and deformation under mechanical stress. ***Source**: -*

Dimensions

	Requirement
29	The product should fit on the surgical table (625 x 340 x 70 mm). ***Source**: dimensions operation table (10-390-K Arm & Handchirurgie Tafel Kort, 2022)*
30	The product should not interfere with the movements of the surgical staff when not in use during surgery. ***Source**: -*

3.3 Centering guide

Performance and usability.

	Requirement	Source
31	The centering guide must keep the k-wire perpendicular to α- and β-planes to prevent misalignment. ***Source**: defined in design goal (4.2 Design goal)*	
32	The centering guide must remain securely in place without slipping during drilling. ***Source**: observation during validation test (Evaluation and validation)*	
33	The product should not harm surrounding tissue. ***Source**: -*	

Ergonomics

	Requirement	Source
34	The centering guide must be easy to handle and attach within the confined space of the surgical site. ***Source**: -*	
35	The centering guide must allow surgeons to apply minimal force while keeping it stable. ***Source**: -*	
36	The centering guide must be designed for one-handed use. ***Source**: the other hand is used for drilling (observations).*	
37	The centering guide must provide clear visual markers for alignment with the ArC laser system. ***Source**: -*	
38	The centering guide must accommodate varying patient anatomies. ***Source**: inlcusive design.*	

Materials

	Requirement	Source
39	The material must have high hardness to resist deformation and prevent damage when drilling k-wires through it. ***Source**: the centering guide needs to be reusable.*	
40	The material must exhibit high yield strength to resist bending and deformation under mechanical stress. ***Source**: the centering guide should not break during use.*	
41	The centering guide must be made of durable, non-degradable surgical-grade metal. ***Source**: -*	

Dimensions

	Requirement	Source
42	The centering guide must have a maximum thickness of 5 mm to fit within the limited space of the trapeziometacarpal joint. ***Source**: surgical procedure shows 5 mm bone is removed from the metacarpal, leaving space (2.5.2 Current surgical procedure at RHOC).*	
43	The centering guide must have a maximum width of 20 mm to fit within the limited space of the trapeziometacarpal joint. ***Source**: average width size of the trapezium (Loisel et al., 2015).*	
44	The material thickness should not intefere or distort the laser. ***Source**: observations during validation test (Evaluation and validation)*	

4.

Design process

In this chapter the design process is explained. The key challenges formulated in the previous section are clustered and evaluated. From this, the problem defintion is defined. This problem definition is split into three specific design goals, as described in the second section. These design goals were explored with help of how-tos, brainstorming, and synetics (Van Boeijen et al., 2013).

How-tos were used to find initial (out-of-the-box) ideas with relation to the design goals and context. This was done with the following three:

- How-to place an object at the precise location in complex surroundings.
- How-to restrict an object effectively in its movement.
- How-to accurately determine cutting planes on a uneven shape.

Brainstorming was used in combination with the graduation team and peers. During the brainstorming peers were asked to contribute ideas to the how-tos, provide feedback on them and iterate further.

The how-tos and brainstorming were part of the problem solving methods, synetics. **Synetics** is used to help facilitate creative problem solving. This is also done by creating analogous situations and reformulate these into the problem defintion.

This lead to the desired design solution space from which a portable laser guidance system was shown. The following sections detail design process and further development of this concept.

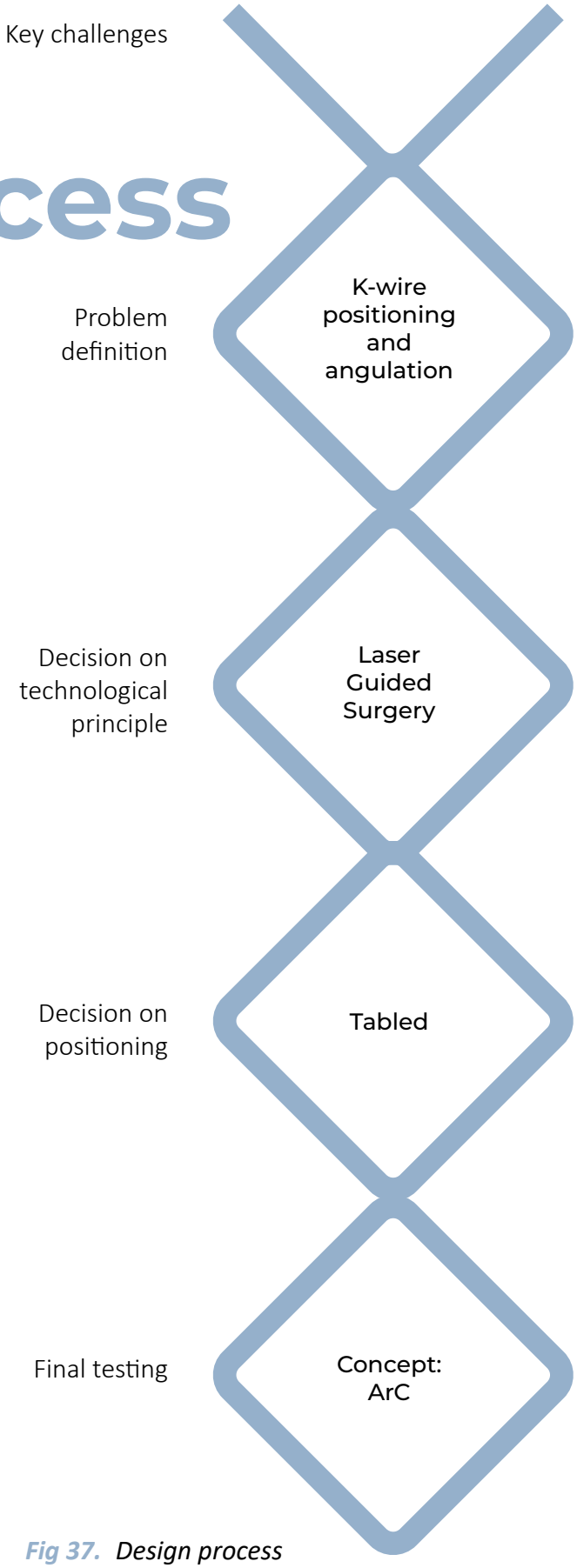


Fig 37. Design process

4.1 Problem definition

The six key challenges can be clustered into pre-operative, intra-operative, and post-operative domains. As previously defined, this thesis focuses solely on the intra-operative phase. Therefore, only the first three challenges are relevant for this research: preparing the trapezium, placement of the prosthetic cup, alignment of the prosthesis. Though, the other challenges have a lot of potential for improvement as well, they will not be further investigated in this thesis.

The preparation of the trapezium (key challenge 1) is closely related to the success of the prothesis by ensuring all osteophytes are removed and no impingement can occur. Yet, the complication rate of cup loosening and tilting remains one of the largest challenges. By ensuring that the k-wire is placed in the correct position and angle the reaming process will become more reliable. Therefore, the alignment of the prosthesis (key challenge 3) is an indirect consequence of the placement of the cup (key challenge 2).

The design solution should address the **challenge of accurately positioning the prosthetic cup in the trapezium**. Misplacement of the trapezium cup leads to complications and potential failure. An important step in the procedure is the precise placement of the k-wire, which functions as a guide for the surgeon during the reaming process to ensure accurate cup positioning.

4.2 Design goal

Based on the problem definition the design goal is to **develop (a set of) surgical instrument(s) that improves the accuracy and precision for the placement of the guide wire during surgery**. This design goal is separated in three specific objectives:

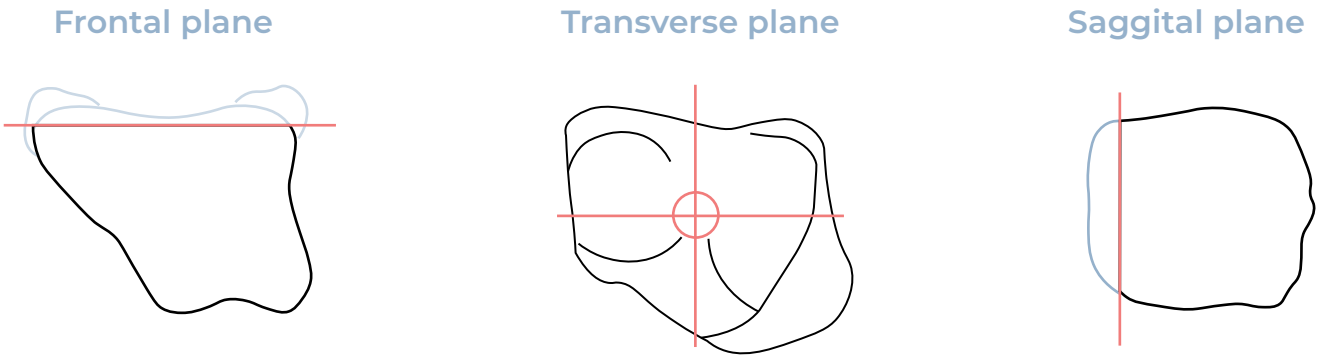


Fig 38. Three design goals.

The correct angulation with respect to the alfa and beta planes is defined as perpendicular to the plane. The centre of the trapezium is identified as the centre point of the surface in the transverse plane.

The intended effect is to ensure the correct alignment and depth of the reamed cavity, improve the pressfit of the prosthetic cup, and minimize errors with k-wire placement. This will lead to better surgical outcomes and reduce the risk of post-operative complications.

The solution will be designed for hand surgeons who perform thumb base prosthesis procedures with the touch dual mobility prosthesis. It is intended to be used in surgical settings where the complex and narrow workspace of the anatomy pose a huge challenge. The aim of the solution is that it must also fit in the current surgical workflow at RHOC and support surgeons in their tasks.

4.3 Solution space

This section explores possible solution for the design goal: “development (a set of) surgical instrument(s) that improves the accuracy and precision for the placement of the guide wire during surgery”. This was done with various methods, such as how-tos and brainstorming with peers, shown in Appendix D: Ideation with how-tos and synetics.. Subsequently, these ideas were placed in a design matrix and the desired solution space was defined.

4.3.1 Technological principle

In Chapter 2.7 Surgical innovation in Joint Arthroplasty several innovative technologies within this surgical field were discussed. In this paragraph, additional technologies will be used for the ideation of potential solutions.

These technologies have been mapped on a design matrix, with technology readiness on the x-axis and level of complexity on the y-axis. The full ideation per quadrant of the design matrix can be found in Appendix E: Exploration of the solution spaces. This design matrix visually represents the different solution spaces based on complexity (vertical axis) and technological timeline (horizontal axis) for improving guide wire placement accuracy in surgery.

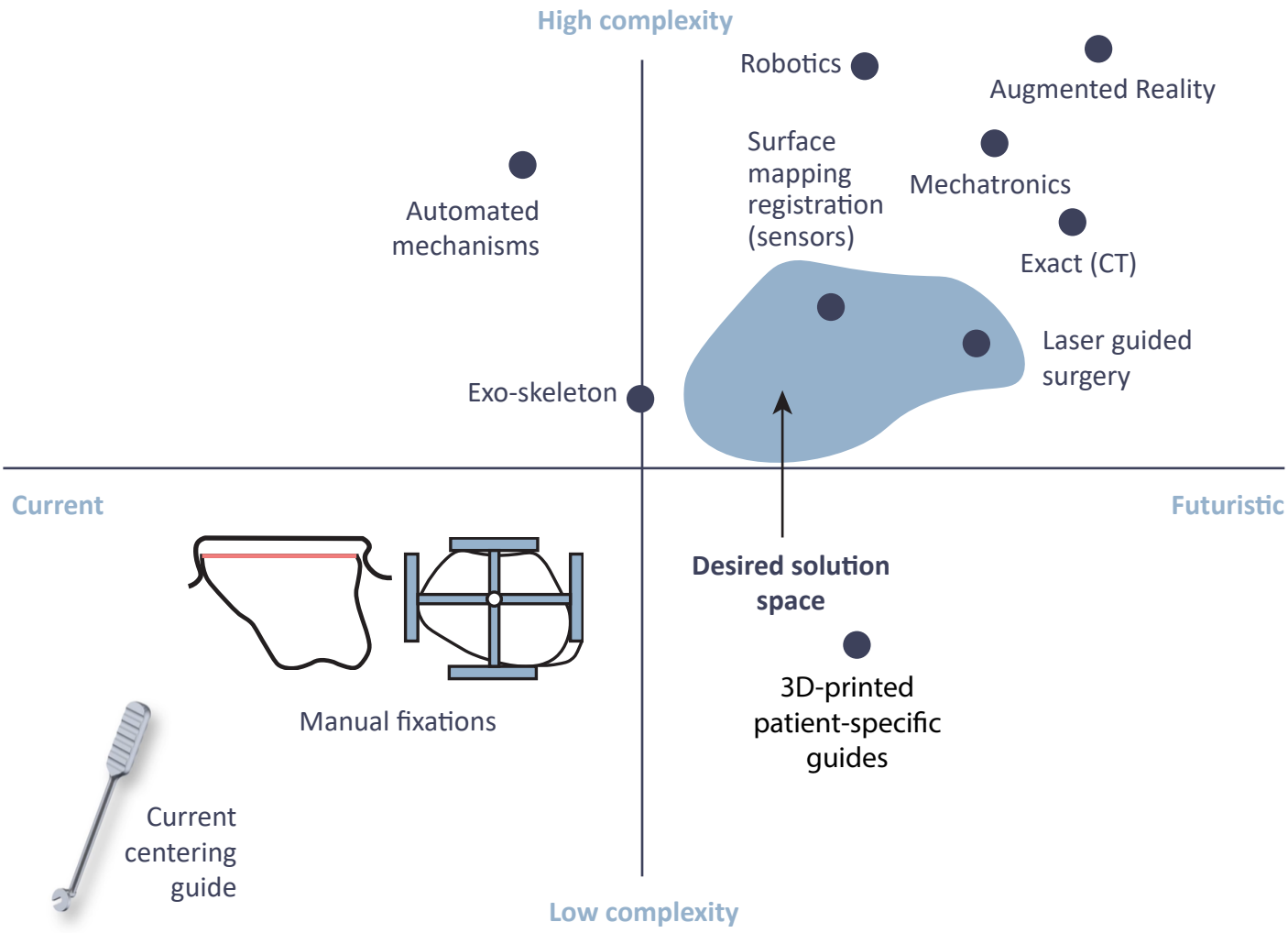


Fig 39. Design matrix with envisioned solution space

The current-low complexity solutions, such as manual fixations and centering guides, depend on user precision rather than automation. While it could be effective, they require high skill and accuracy. In contrast, current-high complexity approaches, including automated mechanisms and exoskeletons, enhance precision by restricting movement or improving stability. The solutions offer mechanical assistance to the surgeon.

On the futuristic side, low-complexity solutions include 3D-printed patient-specific guides, which are already in use for osteotomy and hip surgeries. While promising, these require preoperative scanning, and innovation in this solution space the goal is to avoid technological complexity. Meanwhile, futuristic-high complexity solutions, such as robotics and augmented reality, have potential but remain cutting-edge and largely unexplored in thumb surgery. However, emerging technologies like laser-guided surgery and surface mapping sensors provide a balanced approach, offering enhanced precision without excessive complexity.

By integrating this design matrix with the findings from Appendix D: Ideation with how-tos and synetics and Appendix E: Exploration of the solution spaces, a desired solution space was created.

4.3.2 Desired solution space

The objective of this exploration was to identify a solution space that balances innovation and feasibility, ultimately leading to more accurate prosthetic cup placement. The chosen semi-futuristic, medium-complexity solution space presents a practical yet forward-thinking approach, investigating new technical advancements while remaining within the time frame of this thesis.

A semi-futuristic approach is particularly relevant as medical innovations require time to transition from concept to clinical practice. By incorporating emerging technologies, the proposed solution remains flexible for future advancements while still being feasible for shorter-term implementation. Initially, lower-complexity, more futuristic solutions were explored, but during the ideation phase, it became clear that these options prestended multiple challenges without guaranteeing effectiveness. As a result, the scope was refined toward a moderate complexity level, allowing for a practical, scalable, and effective solution.

Within this solution space, several promising technologies were evaluated for their ability to enhance surgical precision. Among these, laser-guided surgery and surface mapping registration (sensors) stood out for their ability to provide real-time feedback, improve accuracy, and maintain a feasible level of complexity for intra-operative application.

Selection of laser-guided surgery

After a co-creation session with both the client and graduation team, it was decided that Laser Guided Surgery showed the most promise with regard to viability and desirability. Laser guidance provides a practical yet innovative method for improving prosthetic cup placement. Moreover, lasers guides are already part of some surgical steps, for instance the positioning of the x-ray c-arm. To validate the feasiblity for this application, a rapid test set-up was created. More about this test can be found in Chapter 6.1 Research questions.

The design solution can be divided into multiple components, including a laser positioning instrument for the operating room (C(x,y)) and a surgical instrument designed to assist the surgeon in accurately aligning the k-wire (alpha and bèta planes).

4.3.3 Placement of laser guided surgery

Following the selection of laser-guided surgery, the concept was divided into several design factors to ensure a structured and effective development process. The first and most critical design factor addressed was the placement of the laser system within the operating room.

This challenge was prioritized because it functions as a basis for the embodiment of the design. The positioning of the laser in the operation room directly influences the interaction, precision, and usability of the entire system. It affects how the surgeons interact with the laser and how it integrates into the existing surgical workflow. By focusing on the placement in the operation room first, a set of requirements can be defined that focuses on a outcome with optimal alignment, efficiency, and compatibility with existing surgical workflow.

Once the principle of using laser guides had been proven in the feasibility study (Evaluation and validation), the next step is the placement of the laser guides within the operation room. Therefore, multiple solutions were investigated and evaluated. The solution directions can be divided into wearable, portable and fixed positioning in the operating room.

Wearables

Within the domain of wearables two solutions had viable potential. The first one is a wearable on the head of the surgeon that could either be clipped on to the glasses the surgeon is wearing or be a separate product. This design allows for direct alignment with the surgeon's field of view, ensuring that the laser guidance follows their natural movements. However, stability is a critical factor; movement or misalignment could reduce precision, which could result in the need for advanced stabilization technology or real-time calibration features.

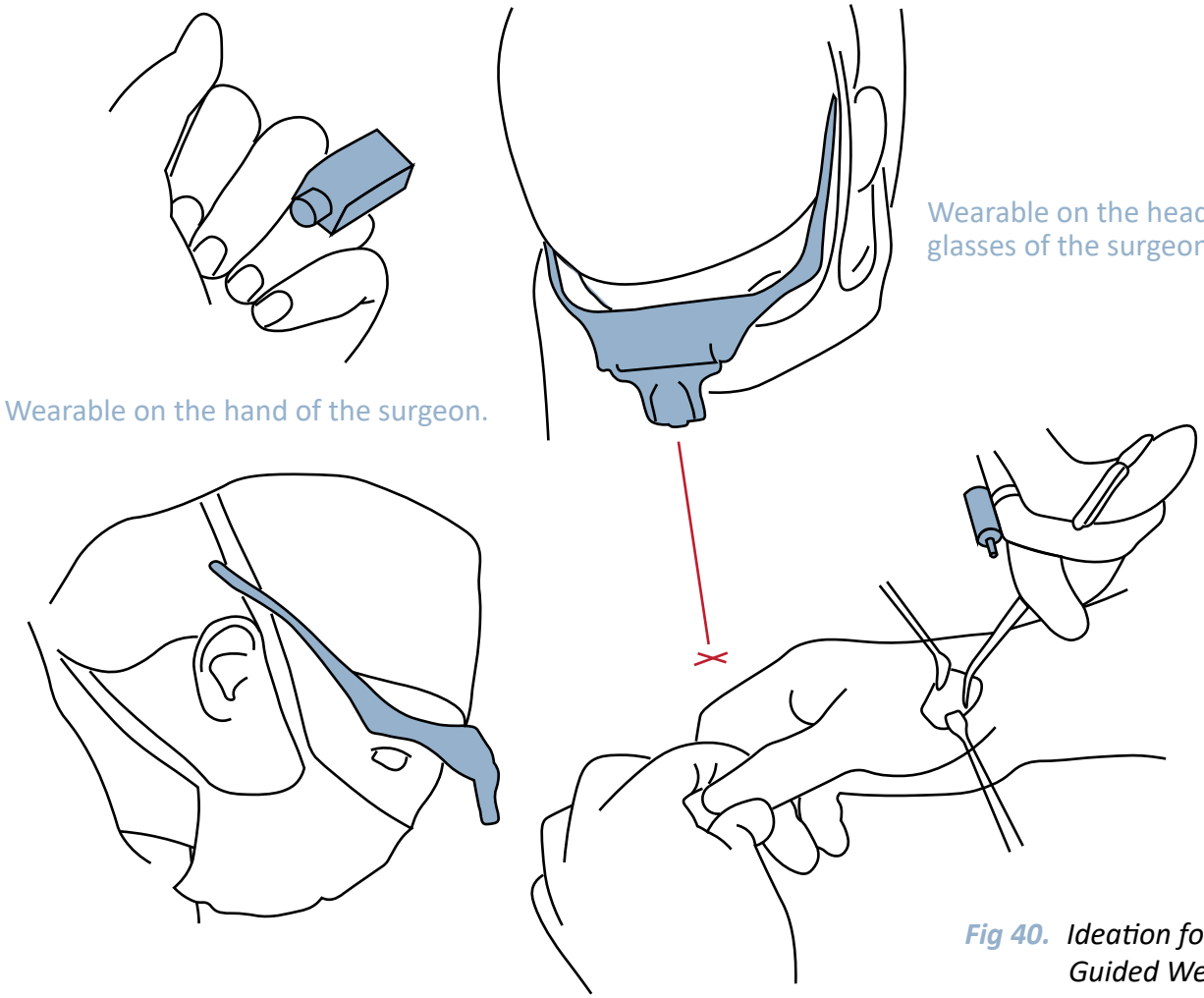


Fig 40. Ideation for Laser Guided Wearable

Portable system

The envisioned portable system is a quick click-and-go solution, designed to fully integrate into a surgeon's workflow. Unlike wearables, which can be unstable, this approach offers more precision, reliability, and stability while remaining non-obstructive. It can be easily positioned for a specific surgical step and removed just as effortlessly, ensuring that it does not interfere with the overall procedure.

A key advantage of this system is its ability to provide laser-guided precision without becoming a permanent fixture in the operating field. By being portable and adaptable, it offers surgical teams the flexibility to deploy it only when necessary. The challenge, however, lies in ensuring that the system is both stable and easy to install or remove. If setup takes too long, it may interrupt the surgical flow, so an efficient mounting mechanism should be developed. The device should be firmly secured to prevent accidental displacement while maintaining a lightweight and compact design that does not clutter the surgical space.

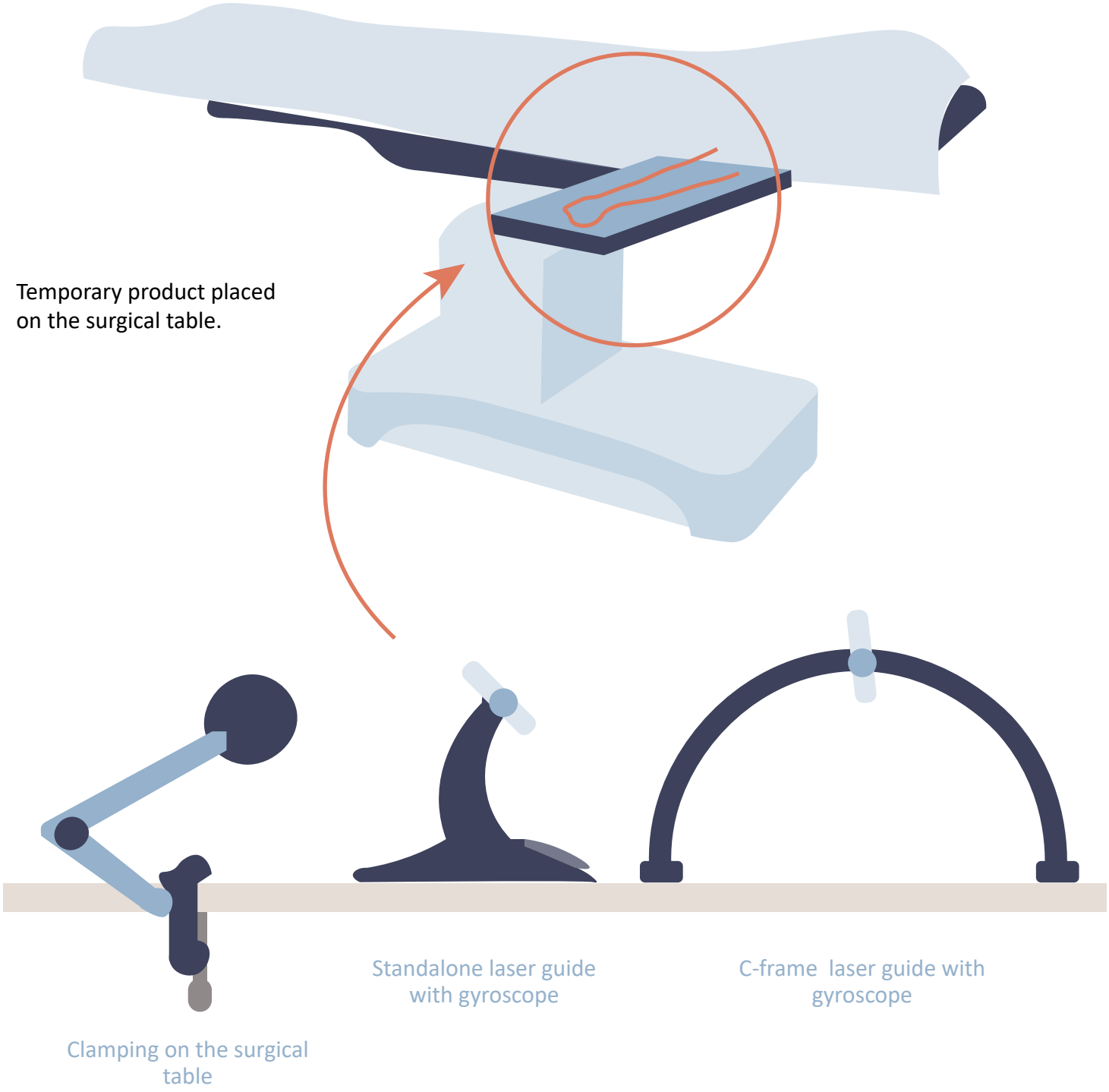
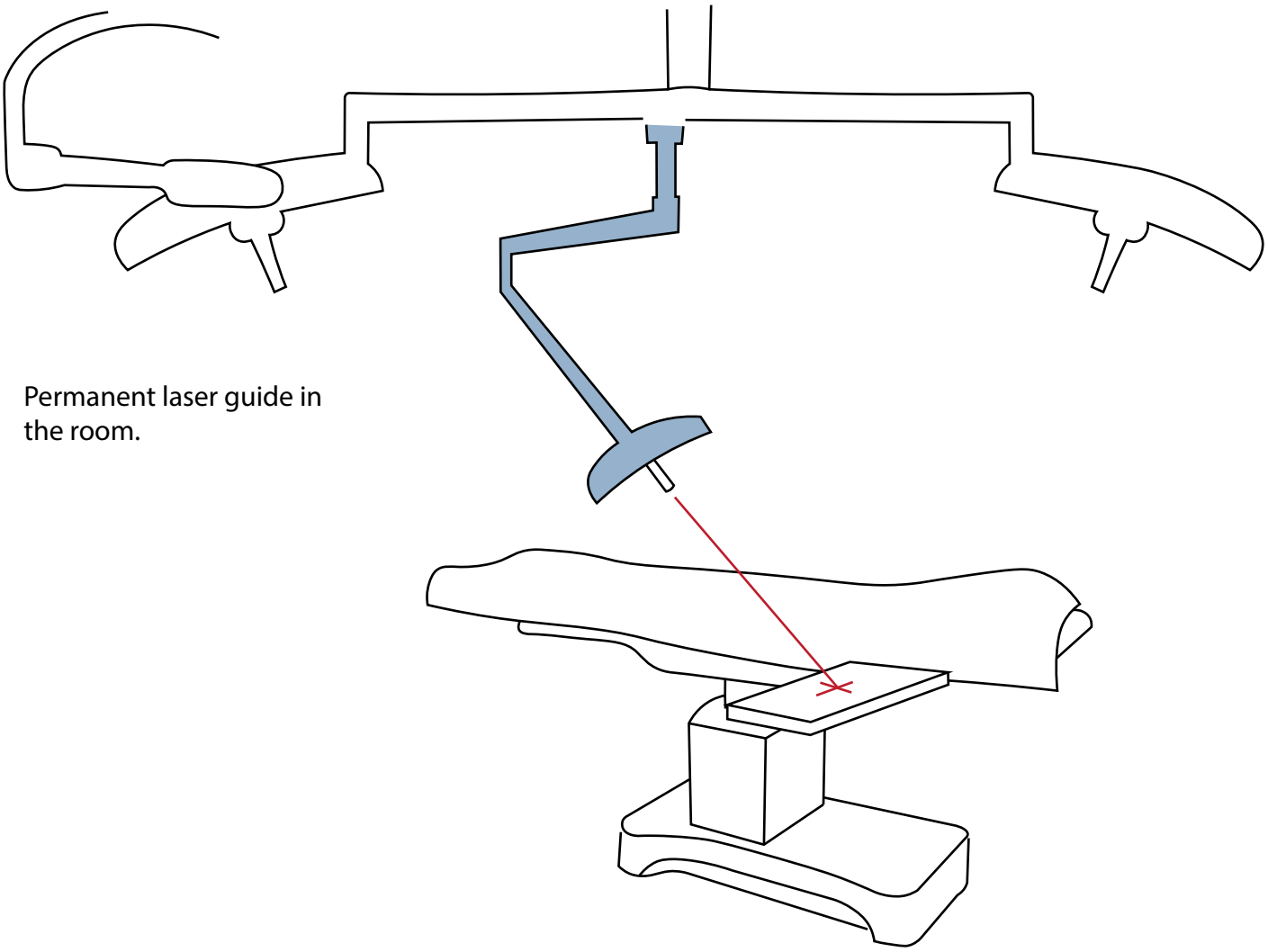


Fig 41. Ideation for Laser Guided Portable

Permanent system

A permanent installation of laser guidance within the operating room presents an opportunity for the integration with existing surgical operation room. Given that operation rooms are already equipped with overhead lamps and various support systems, embedding laser guides into these structures could provide a stable and continuously available solution.

However, implementing a fixed system comes with big challenges. This would require modifications to existing surgical lighting and equipment, making it a highly invasive change for hospitals. At the current stage, this level of adjustment is impractical, as the system is still in its early phases of development.



Permanent laser guide in the room.

Fig 42. Ideation for Laser Guided Permanent placement

Conclusion

Decision making on the placement of wearables was done through the approach of weighted objectives (Van Boeijen, 2013), see Appendix G: Weighted objective for positioning of LGS. Based on this evaluation of the portable system seems to be the most practical and effective solution for further development at this stage. A portable laser guidance system provides the best **balance of stability, flexibility, and ease of integration to the surgical workflow**. It enables rapid use without the challenges of instability in wearables or the additional costs and integration of permanent installations.

4.4. Concepting of portable Laser Guided Surgery

The design of the laser guide evolved through an iterative process, exploring key design factors such as stability, user interaction, and laser movement to improve usability and surgical integration. The goal was to create a stable and precise concept that integrates into the current surgical workflow.

1. Fixation and stabilization on the table

The first iteration involved three options for placement of the laser guide on the operating room: clamped to the table, a standalone half-arc, and a c-frame, as shown in Fig 43. Three options for positioning of the laser guide on the table. The key design considerations are to balance **stability, adjustability, and visibility** for the surgeon.

A decision was made to continue with the principle of the c-frame, due to its stability and position of the laser. The clamping mechanism seemed to be less stable and the standalone laser positioned the beam too far to the side of the arm, potentially affecting surgical accuracy.

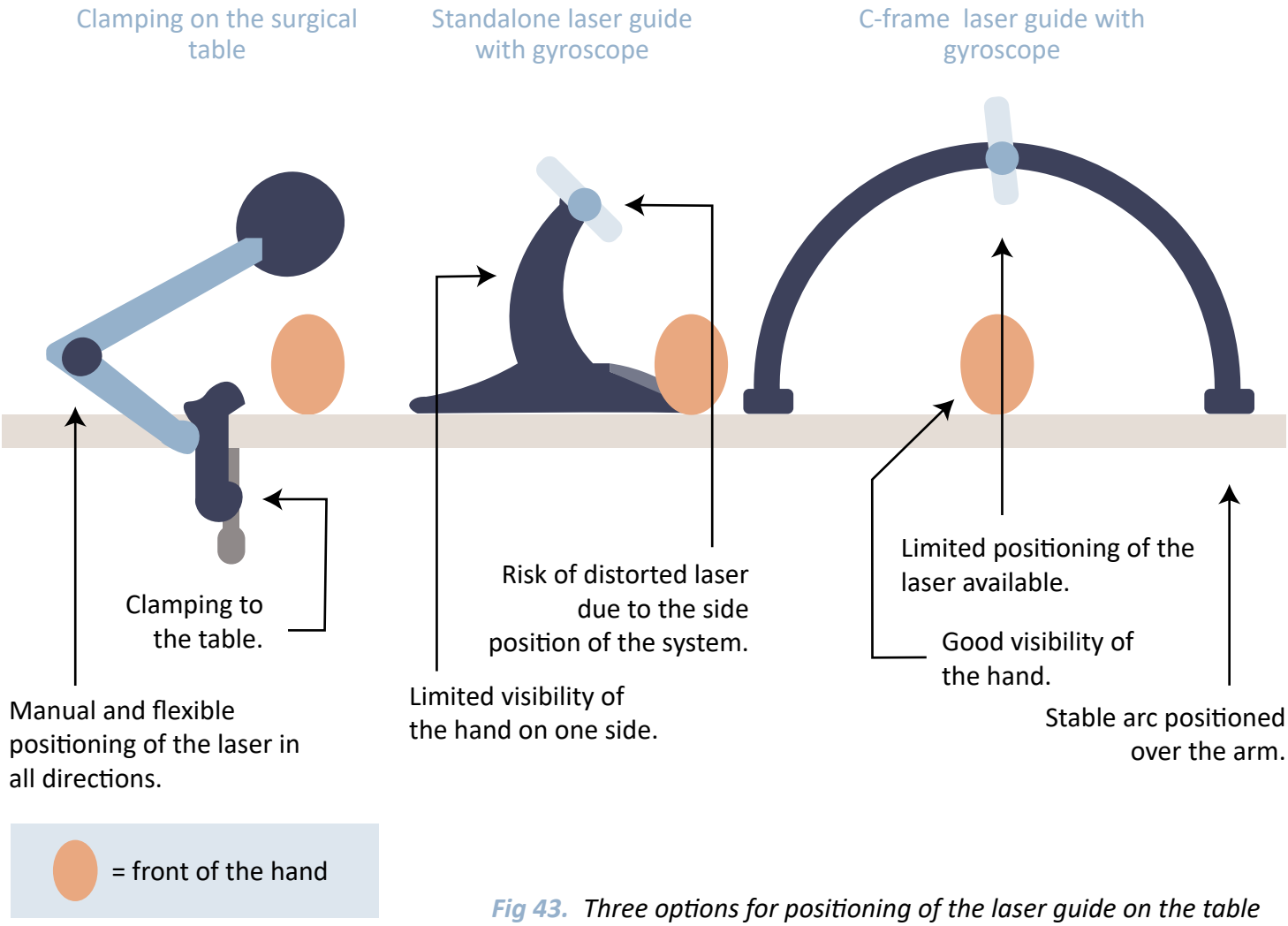


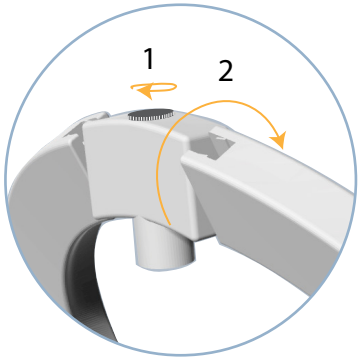
Fig 43. Three options for positioning of the laser guide on the table

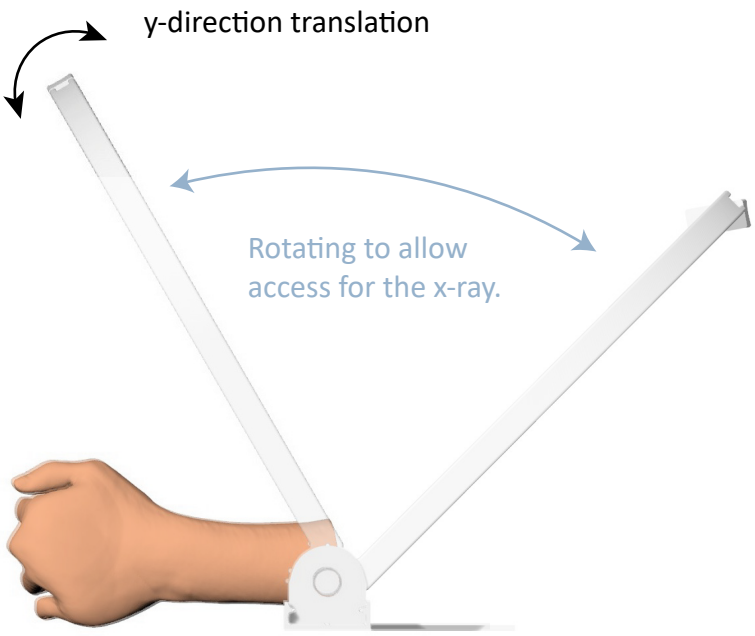
2. Movements of the laser

The laser's movement was another key factor of the design process. The feasibility test showed that participants wished for the following degrees of freedom to position the laser:

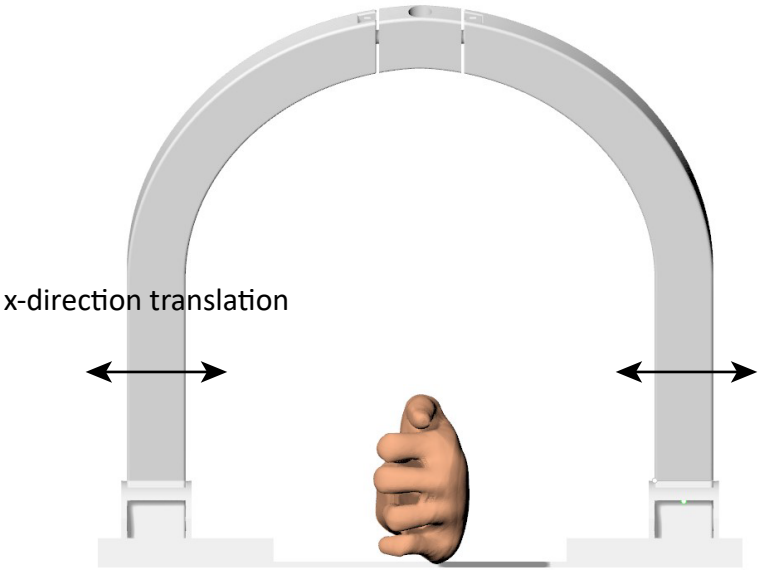
1. **Angular adjustments**: changing the orientation of the laser for the surgeon to align the anatomy.
2. **Translational movement** (horizontal and vertical): necessary for aligning the laser in the correct position.

The vertical alignment and the angular adjustmenst can be solved with the laser component:





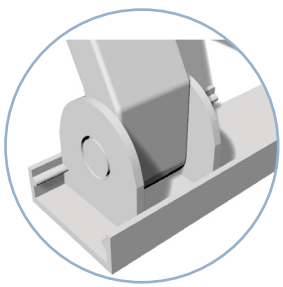
The **feasibility test** also revealed that precise adjustments in the x-direction were challenging, as minor shifts could misalign the laser and reduce accuracy. Three solutions were explored to aid the surgeon in **stable movement in the x-direction**.



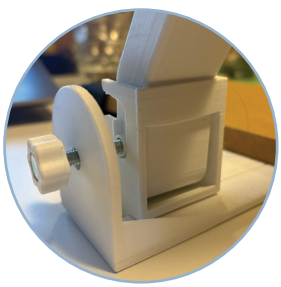
The first option involved a rail system for smooth sliding, but testing showed insufficient stability. Next, existing surgical tools were analyzed, leading to the implementation of a rotating knob, which provided a more controlled interaction.

However, after validation with surgeons (more information can be found in Chapter 6.3 Validation interviews with surgeons, it became clear that some surgeons actually prefer to move the hand rather than the laser. As a result, **x-direction movement was removed**, and the design was adapted to focus on direct hand interaction.

Slider rails



Rotating knob



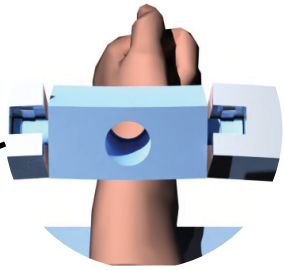
No movement

3. Design for (dis)assembly and sterilization

When desigining for the operation room, fast and easy movements are required to assemble the concept, without compromising the function and safety. Therefore, the concept was made to fit within the sterilization methods and surgical workflow.

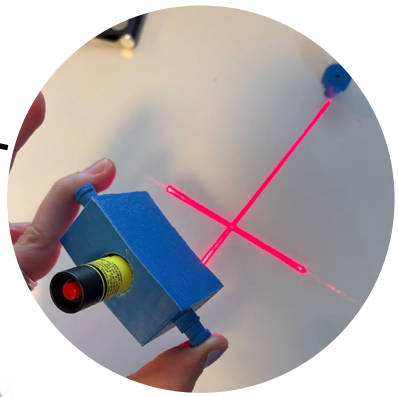
Surgical assistants generally clean and disassemble all instruments within approximately five minutes, including removing drapes and returning tools to their trays (personal observation). To align with this workflow, the electronic component (the laser) should be designed for quick, tool-free removal, easy (dis)assembly without the need for additional instruments.

Additionally, all other components should also be designed for easy, tool-free removal, as requiring extra tools would be too time-consuming for the surgical assistant.



Easy click and go system so electronics can be separated from the other components.

Rotation axis to move the crossline laser in the y-direction.



Prototype with laser.

Trade-off: optimal angle for the laser versus proper visisbility for the surgeon.

Baseplate and separate arms for easy and quick (dis)assembly).

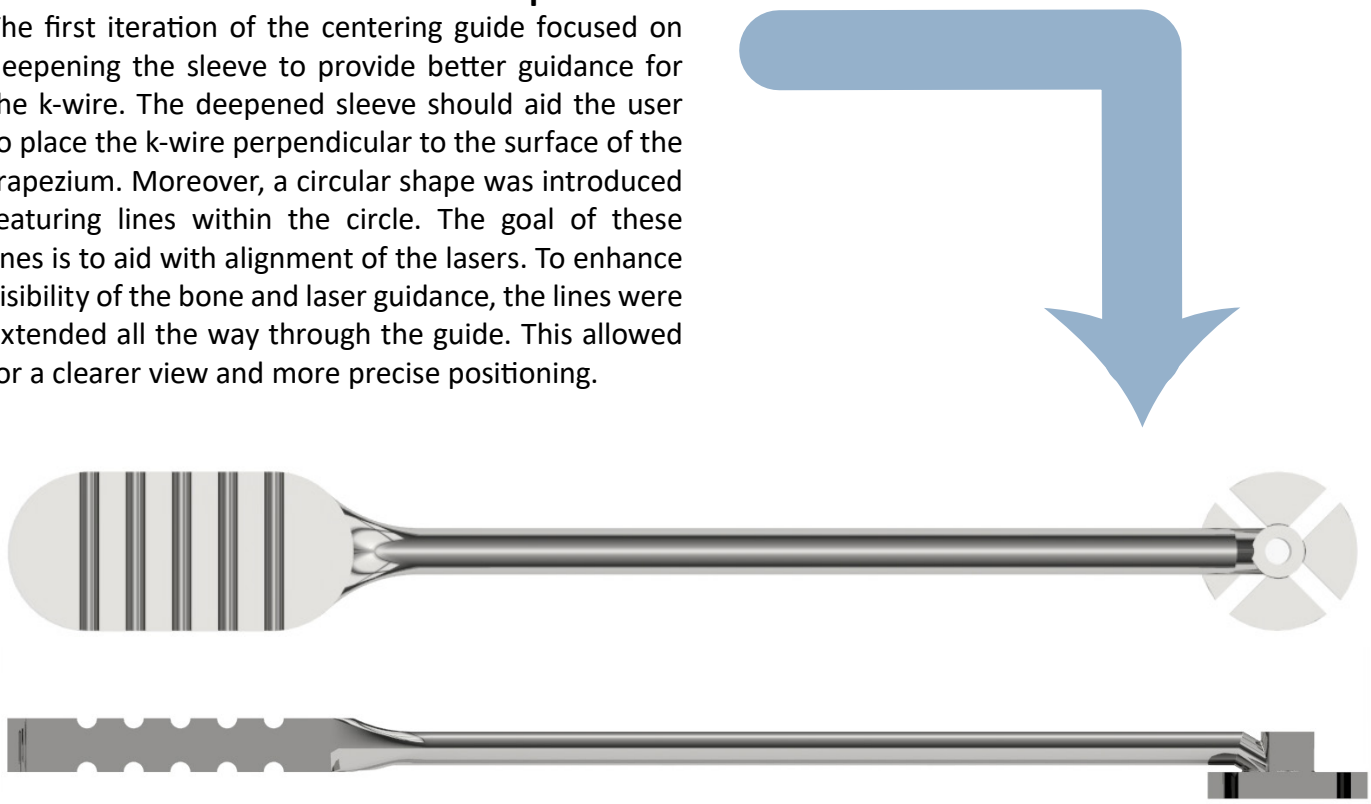
Arms can be pushed onto baseplate.

4.5. Optimization of centering guide

The current centering guide is designed to play an important role in ensuring the correct positioning of the K-wire. However, the initial design lacked intuitive use, necessary support and stability for precise placement. Therefore, a series of design iterations were done for improving its functionality and usability.

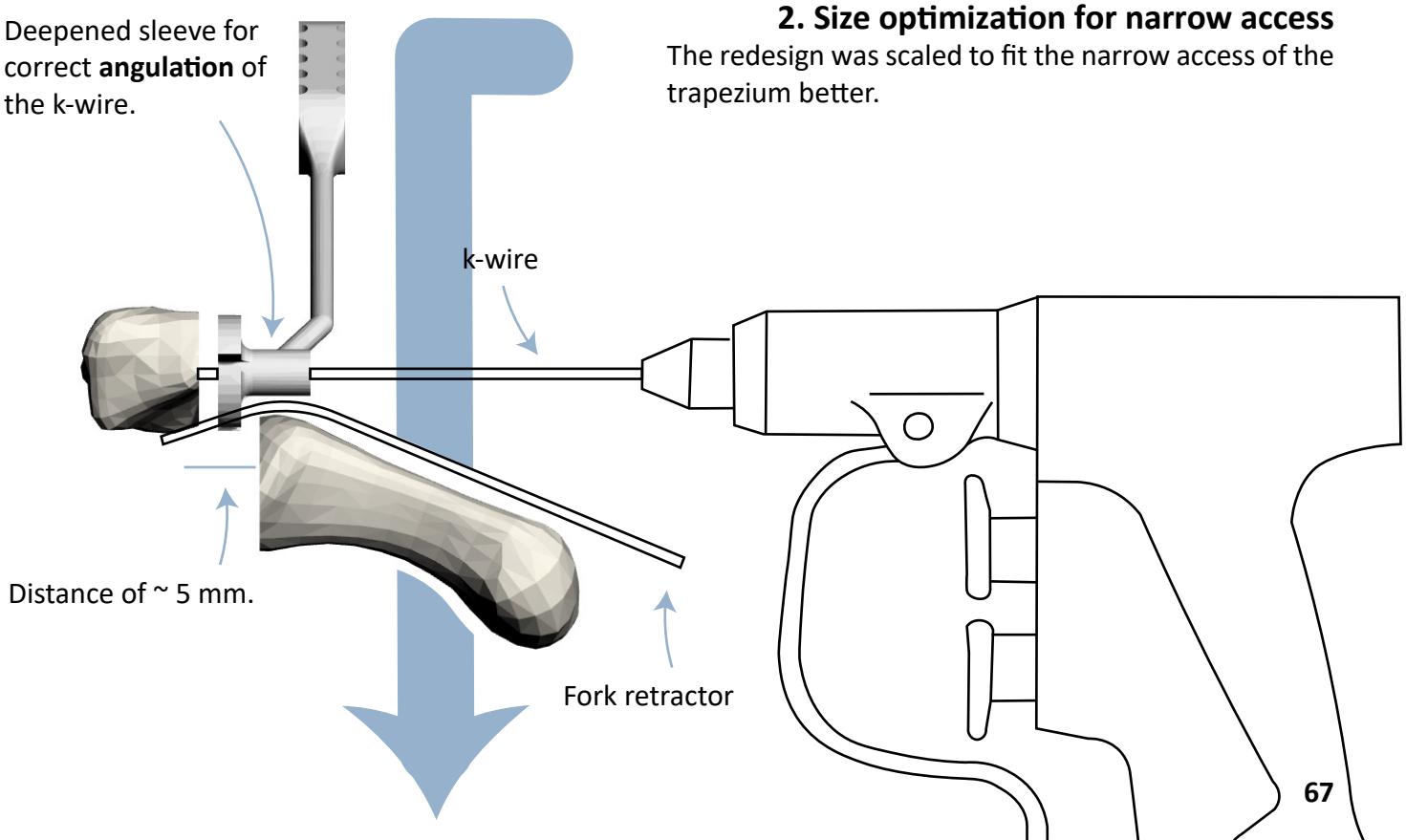
1. Enhanced sleeve and circular shape

The first iteration of the centering guide focused on deepening the sleeve to provide better guidance for the k-wire. The deepened sleeve should aid the user to place the k-wire perpendicular to the surface of the trapezium. Moreover, a circular shape was introduced featuring lines within the circle. The goal of these lines is to aid with alignment of the lasers. To enhance visibility of the bone and laser guidance, the lines were extended all the way through the guide. This allowed for a clearer view and more precise positioning.



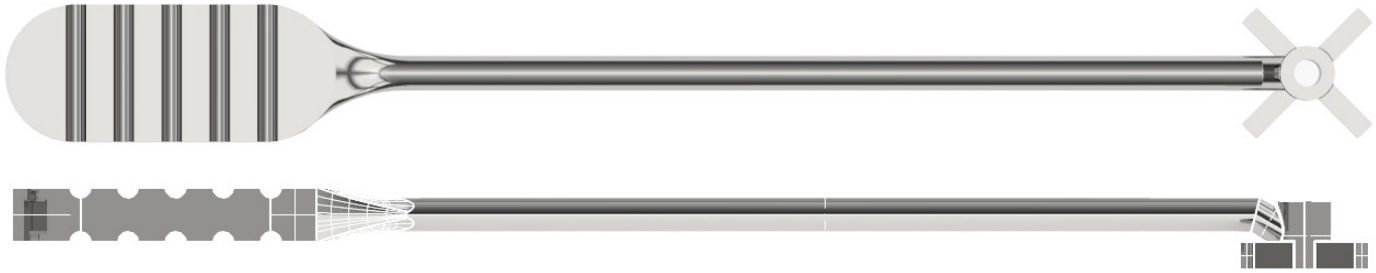
2. Size optimization for narrow access

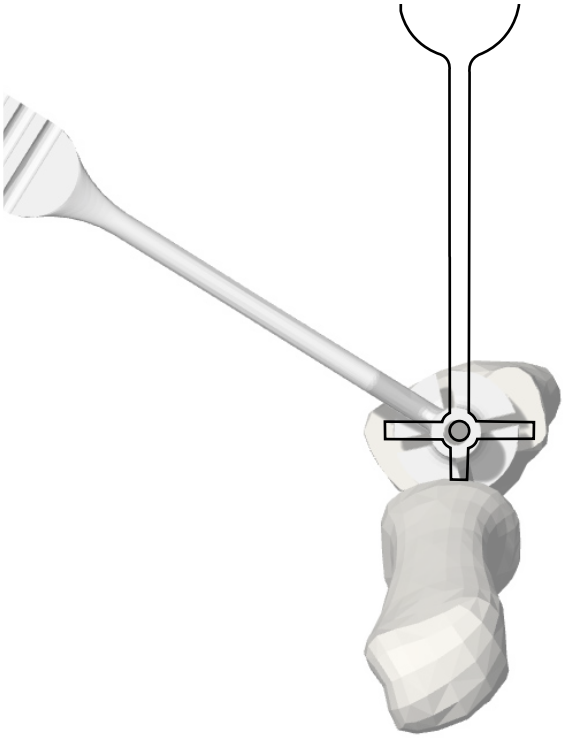
The redesign was scaled to fit the narrow access of the trapezium better.



3. Cross-shaped and thinner profile

The guide was further redesigned into a cross shape and thinned down to improve visibilty and reduce interference with laser lines, preventing them from jumping excessively and ensuring more accurate alignment.





4. Guided usage for proper orientation

During observation of the surgery it became clear that the surgeon prefers to hold the centering guide vertical rather than angled. Therefore the crossed pattern was altered accordingly. As a result, the cross lines were resized to fit the trapezium surface (Loisel et al., 2015).

Additional stability feature

A small stabilizing extension on the lower side of the hole can be used to improve the guide's stability. This feature was designed to work together with fork retractor, further enhancing usability.

4.6. Conclusion

The iterations of the frame and the centering guide resulted in the following design, see Fig 44. Prototyping (3D-printing) of the centering guide and frame.. Since the models were 3D-printed, some components had to be divided into multiple parts to fit the printing bed. The prototypes were designed with a focus on functionality, featuring an additional extrusion in the laser component to ensure proper fit and balance. These models were used during the validation test shown in Chapter Evaluation and validation.

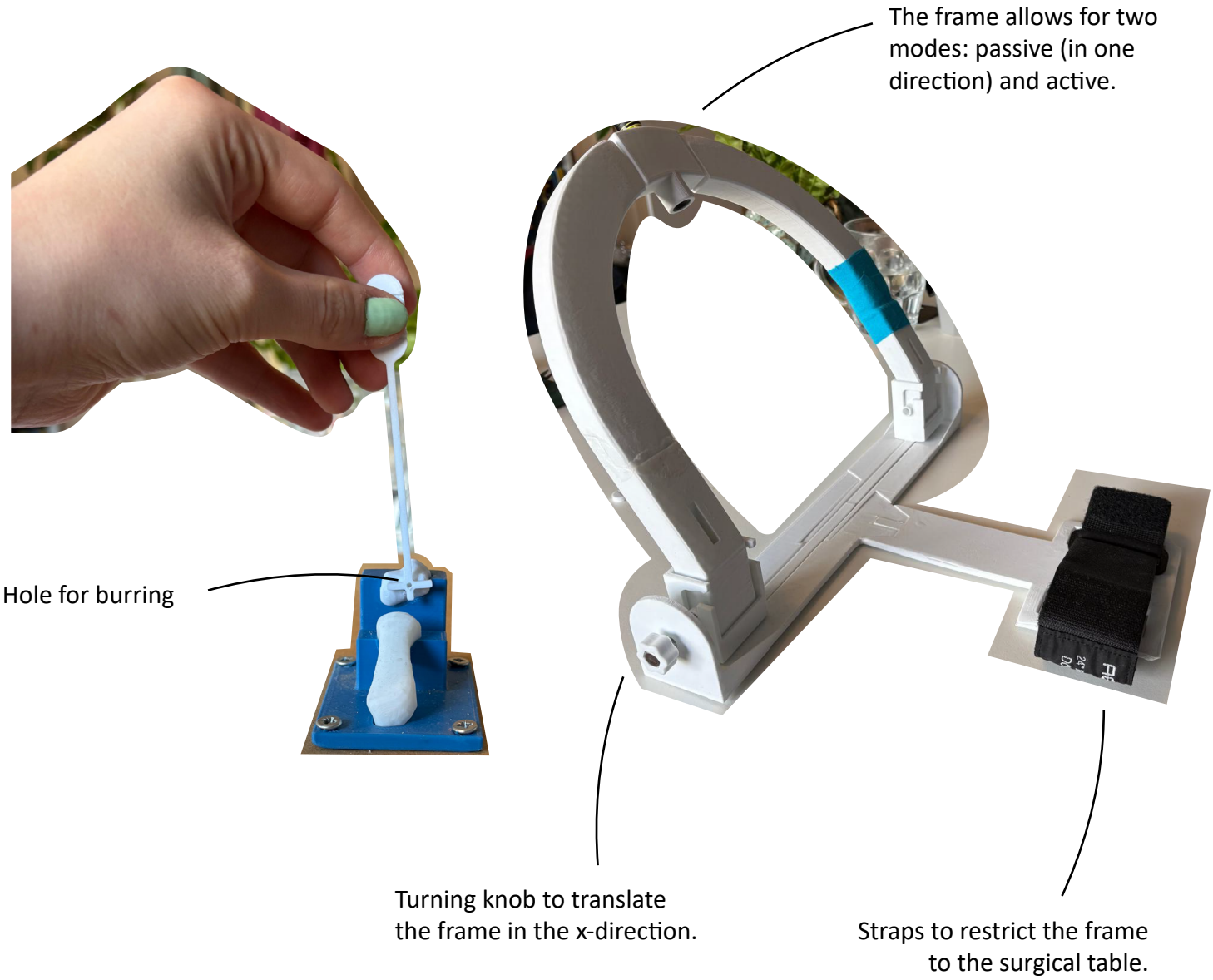


Fig 44. Prototyping (3D-printing) of the centering guide and frame.

5.

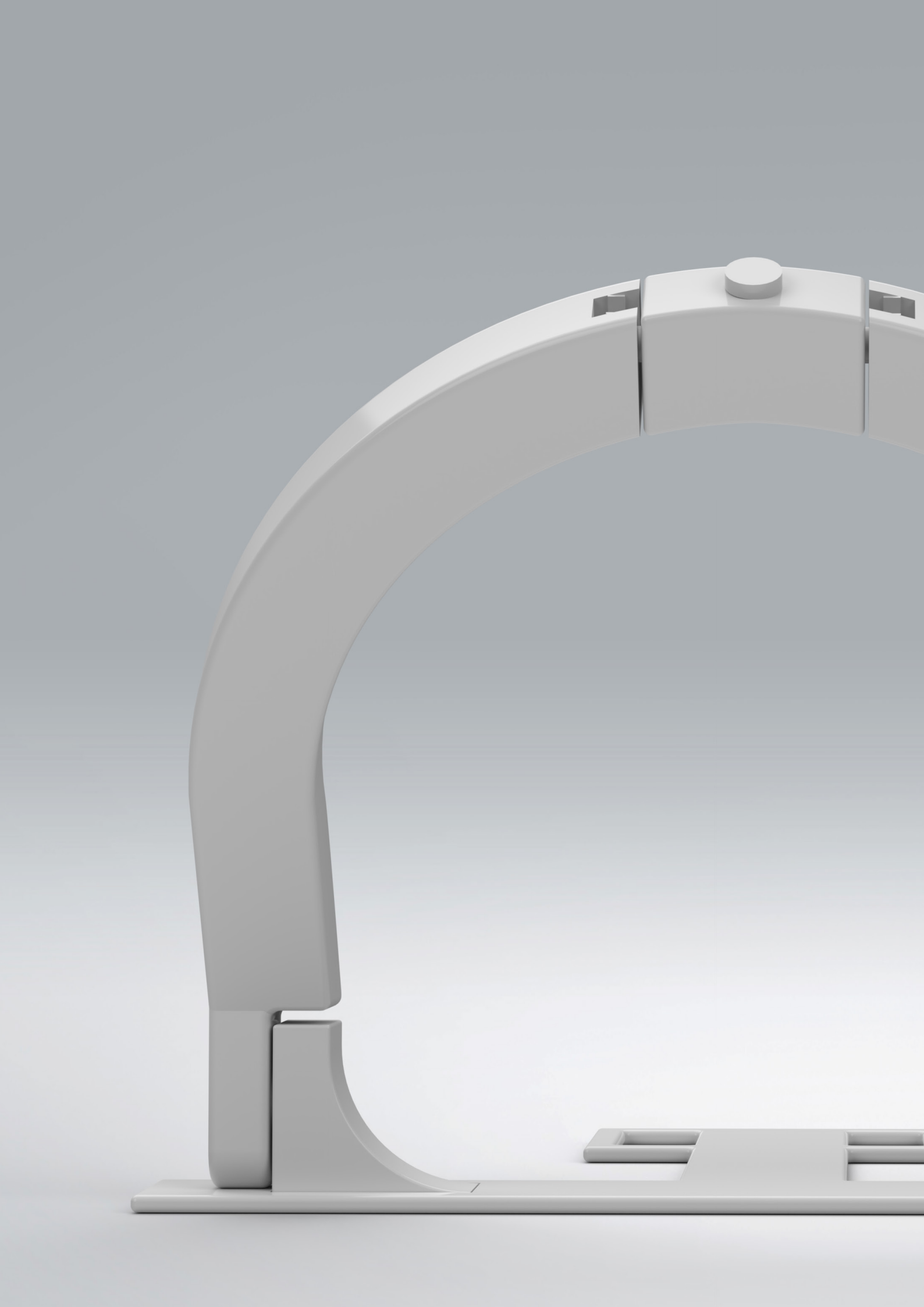
Final design

In the previous Chapter the iterative design process was presented. In this Chapter the final concept is discussed in more detail, beginning with an overview of its key components and features.

Next, the interaction between the concept and its users into the surgical workflow is illustrated. This is followed by an overiew of relevant product dimensions, based on data from the DINED database and existing operating room standards.

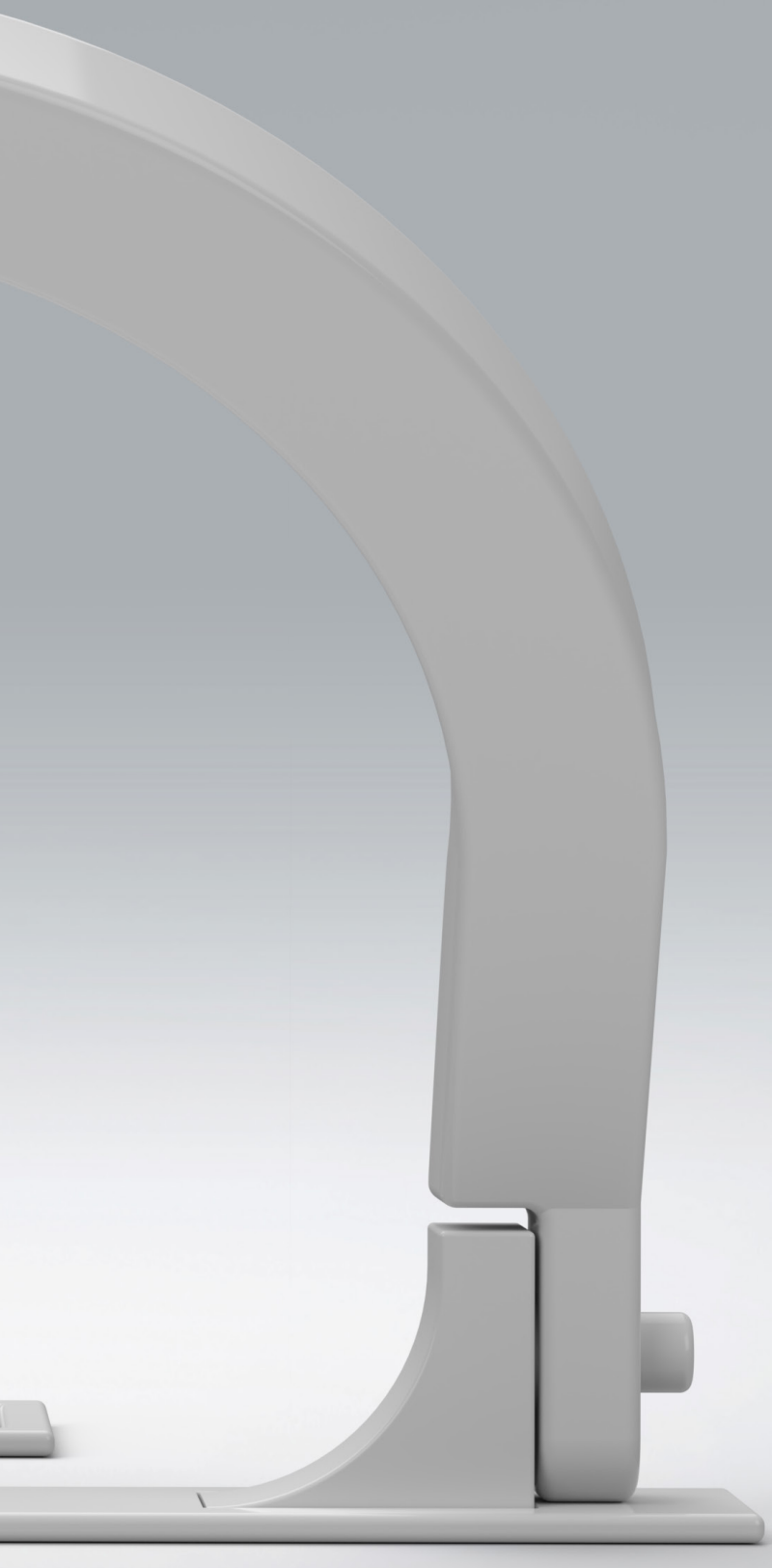
Moreover, the material selection combined with manufacturing methods for both the centering guide and the laser-guiding frame will be discussed. Material choices were evaluated using Granta EduPack, comparing their properties against those of Class I reusable surgical instruments to ensure compliance with medical standards and durability requirements.

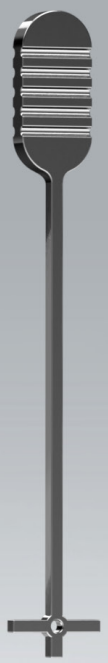
Finally, the chapter evaluates the final concept by three key components for a succesful concept: **desirability, viability, and feasibility**.

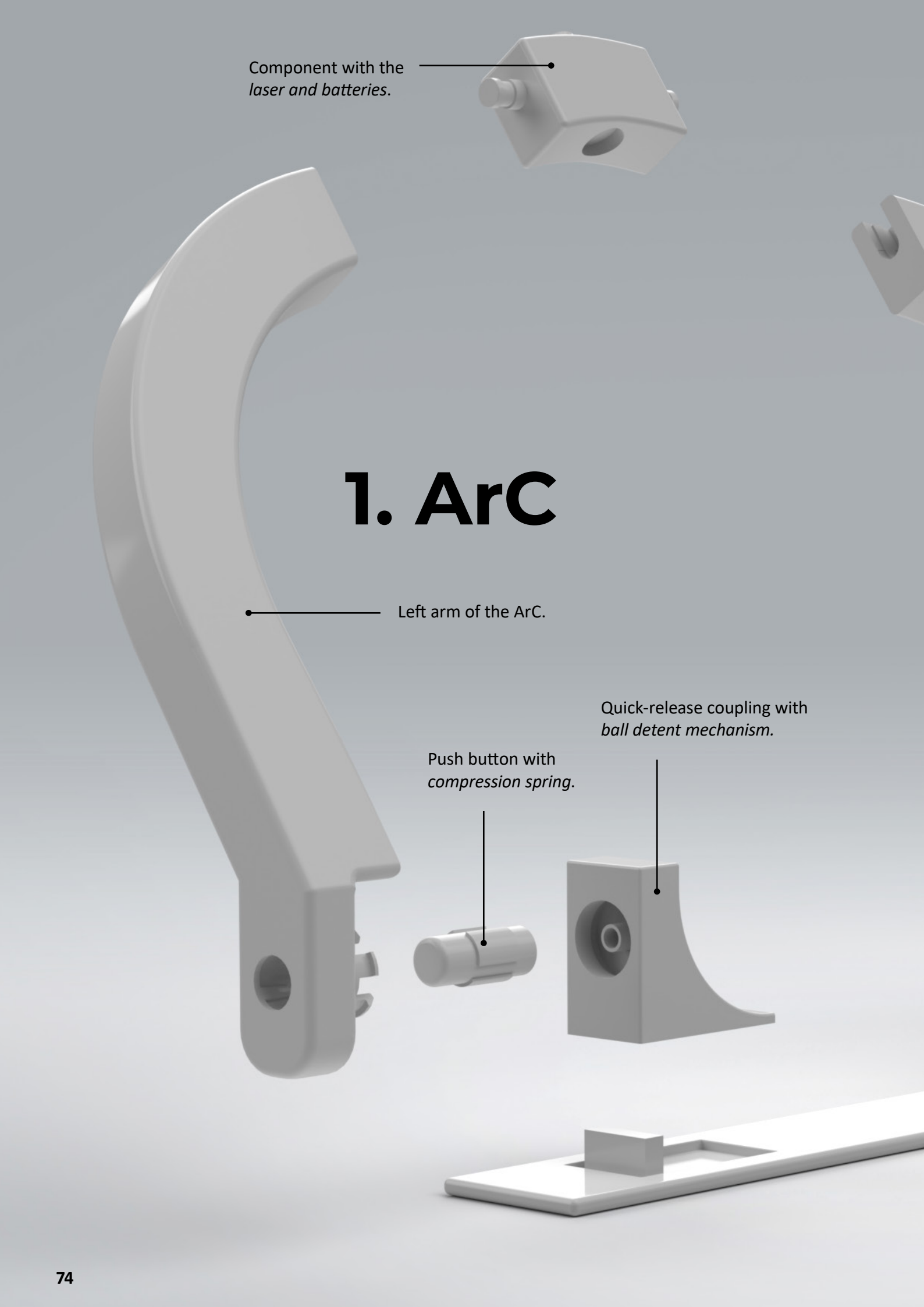


ArC+

Laser Guided Surgery for precise and accurate placement of the k-wire during CMC-joint replacement.

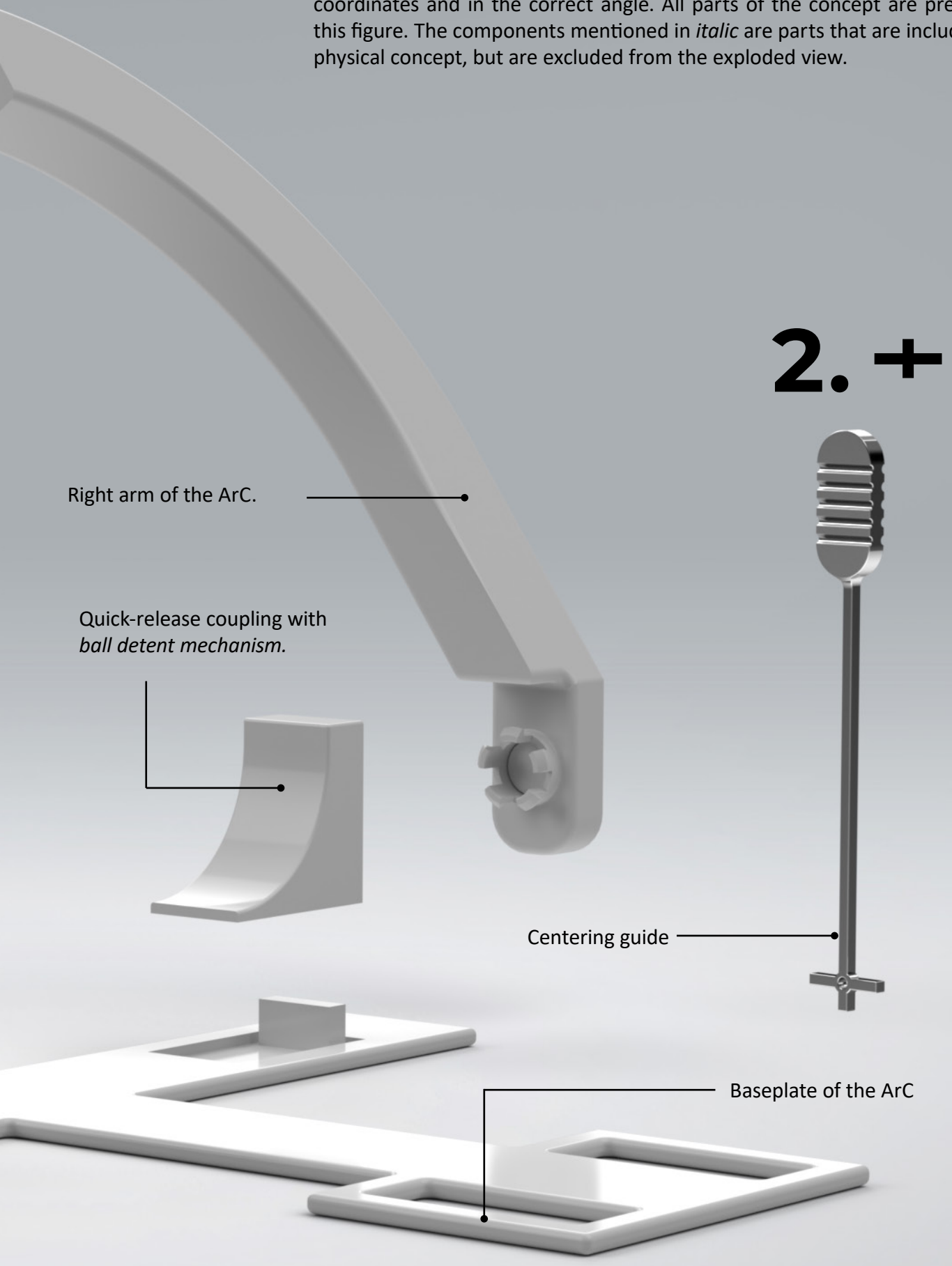





Component with the
laser and batteries.
1. ArC
Left arm of the ArC.
Quick-release coupling with
ball detent mechanism.
Push button with
compression spring.

5.1 Components

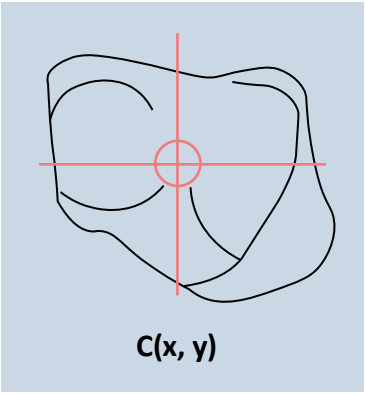
The final concept can be divided into two parts, the ArC and the redesigned centering guide. Together, they aid the surgeon in placing the k-wire at the correct coordinates and in the correct angle. All parts of the concept are presented in this figure. The components mentioned in *italic* are parts that are included in the physical concept, but are excluded from the exploded view.



5.2 Key features of the concept

5.2.1 Determining the centre point

Design goal 1



Based on feasibility testing with peer students, the degrees of freedom for laser positioning were initially defined as: angular and translational. However, after evaluation with surgeons not all surgeons showed a preference for this. Therefore, a decision was made to remove the movement option in the x-direction. Instead the surgeons move the hand to the position of the laser. This lowers the amount the surgeon is required to touch the product which is beneficial in terms of sterility.

The laser can still be moved in the y-direction by rotating the laser component. Figure X shows how the component can be rotated to achieve the envisioned centre point. Moreover, the user can rotate the crossline laser (Fig 45. Rotating button on the laser component.).

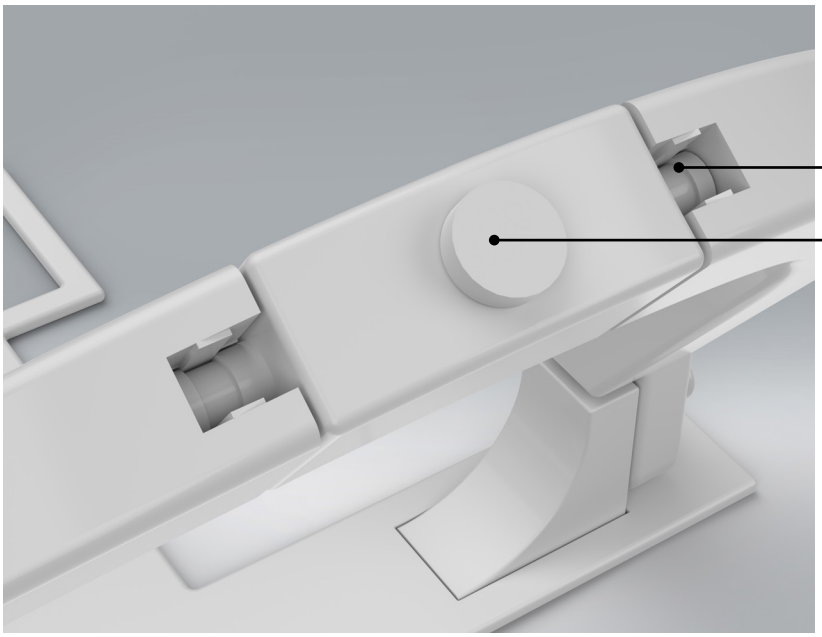


Fig 45. Rotating button on the laser component.

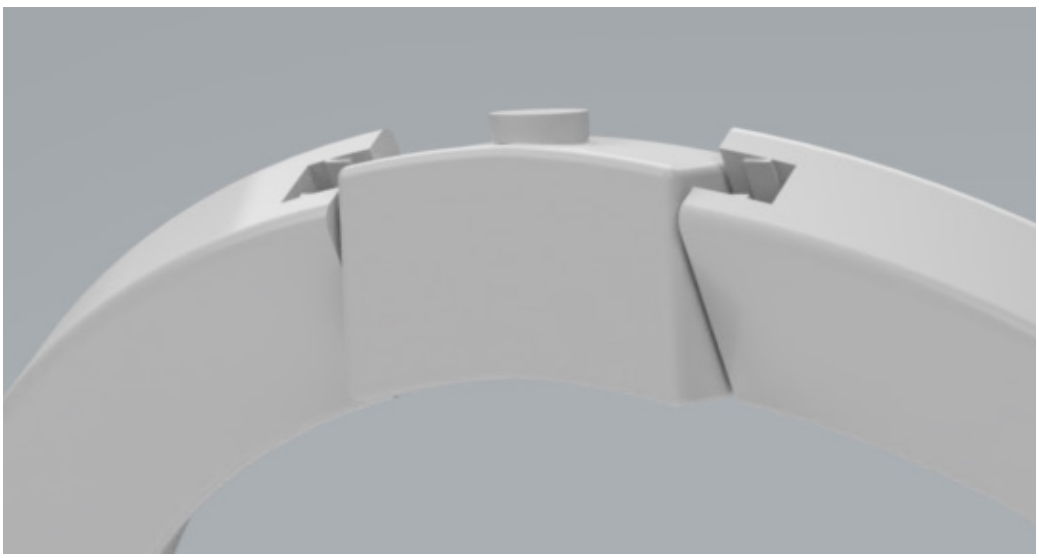


Fig 46. Rotating the laser component for change in y-direction.

5.2.2 Push button for active and passive mode

The evaluation with two surgeons revealed a preference for moving the ArC away when not in use. Initially, the concept allowed movement in only one direction: toward the patient. However, both surgeons expressed a preference for an additional option to lay the ArC on the table. Based on this feedback, this feature was integrated into the design following the validation test (Fig 48. ArC in its maximum positions (passive states): positioned on the table (above) and positioned on the arm of the patient (below). on page 77). To prevent accidental movement, a push button mechanism was added in combination with this feature (Fig 47. Pushing button in use.).

Pushing the button allows for movement of the ArC. Once the ArC has reached its maximum movement the spring inside the button presses it outwards again.

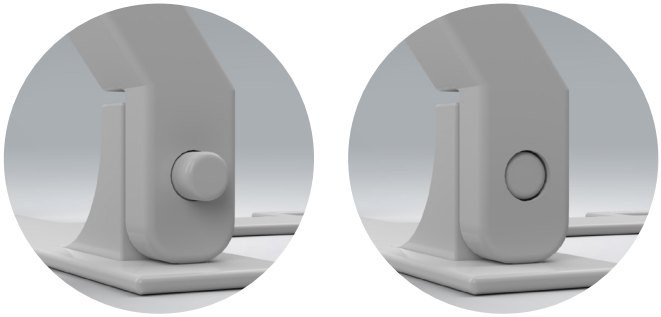
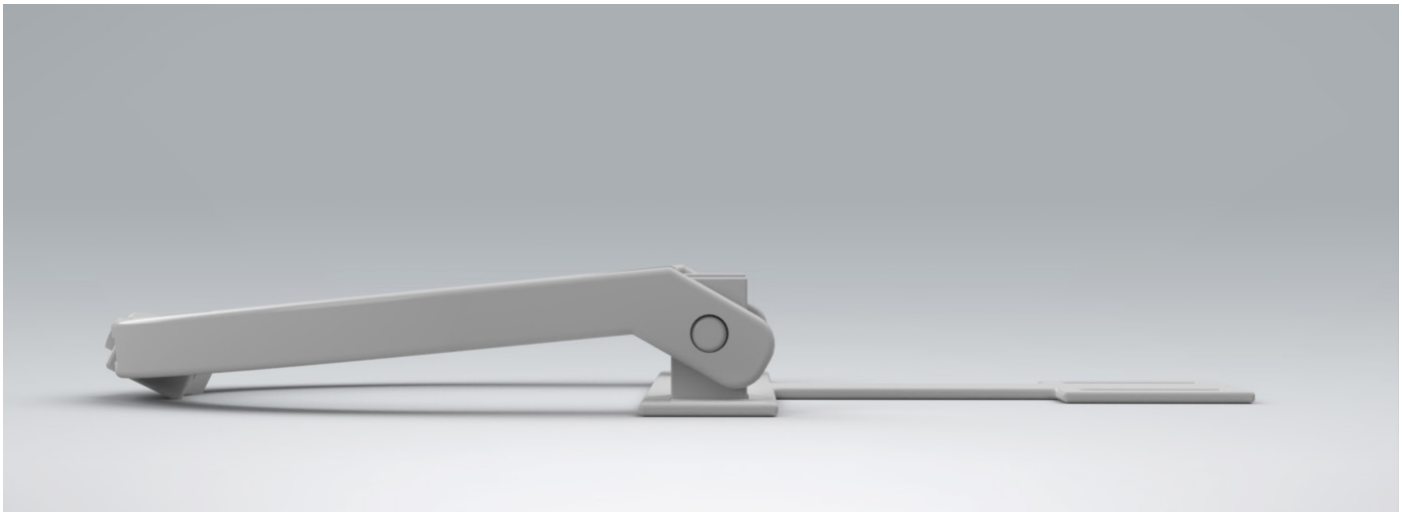


Fig 47. Pushing button in use.



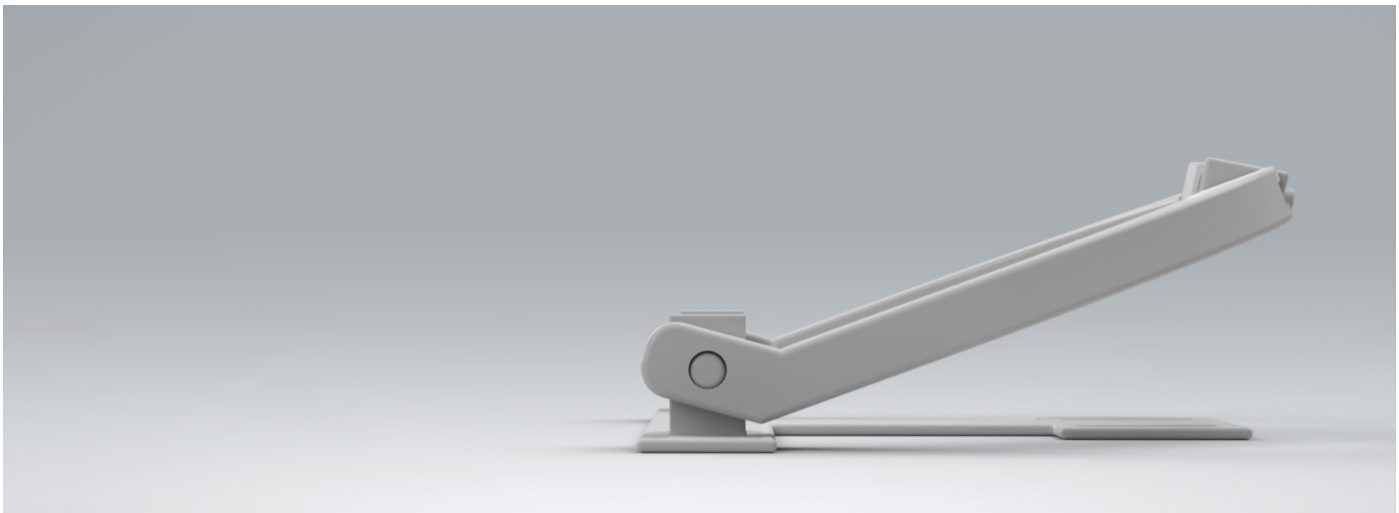


Fig 48. ArC in its maximum positions (passive states): positioned on the table (above) and positioned on the arm of the patient (below).

5.2.3 Secure placement to the table

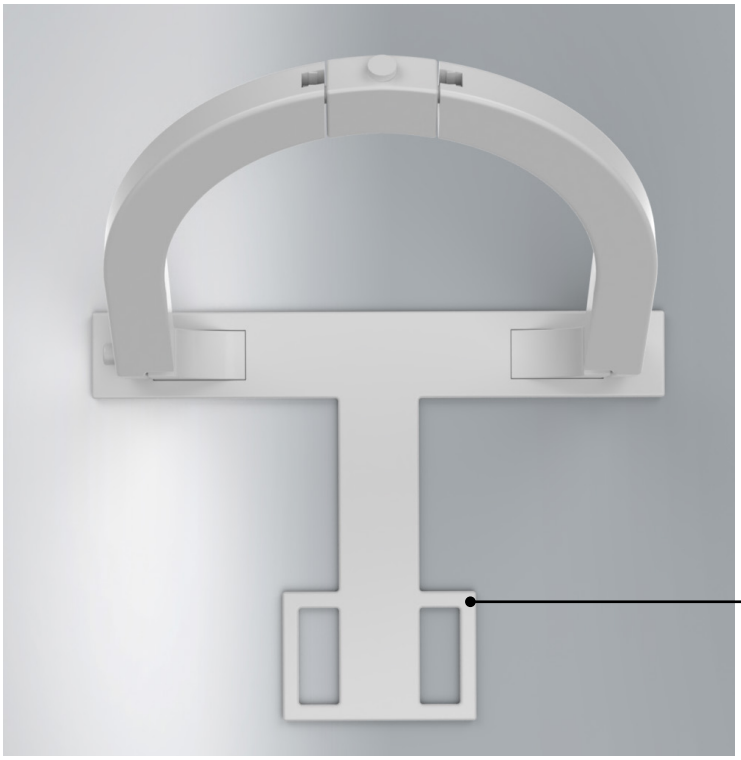


Fig 50. Top view of the ArC.

The evaluation with the surgeons also addressed the fixation of the product, whether to secure it to the table or directly to the patient. Opinions were divided, with each surgeon favoring a different approach.

The design had already integrated the option to use straps, which are commonly employed to stabilize patients during procedures. This flexible design accommodates both preferences, allowing for either method of fixation to be used.

5.2.4 Design for (dis)assembly

Several considerations have been integrated to the design of the ArC to optimize the assembly time during surgery. Before use in surgery the press button should be assembled with the following steps.

Step 1: place the button in the ArC arm. The indentations of the button can only fit one way.

Step 2: place the compression spring (not in the figure) in the button and use the snapfit connection to attach the arc arm to the quick release coupling.

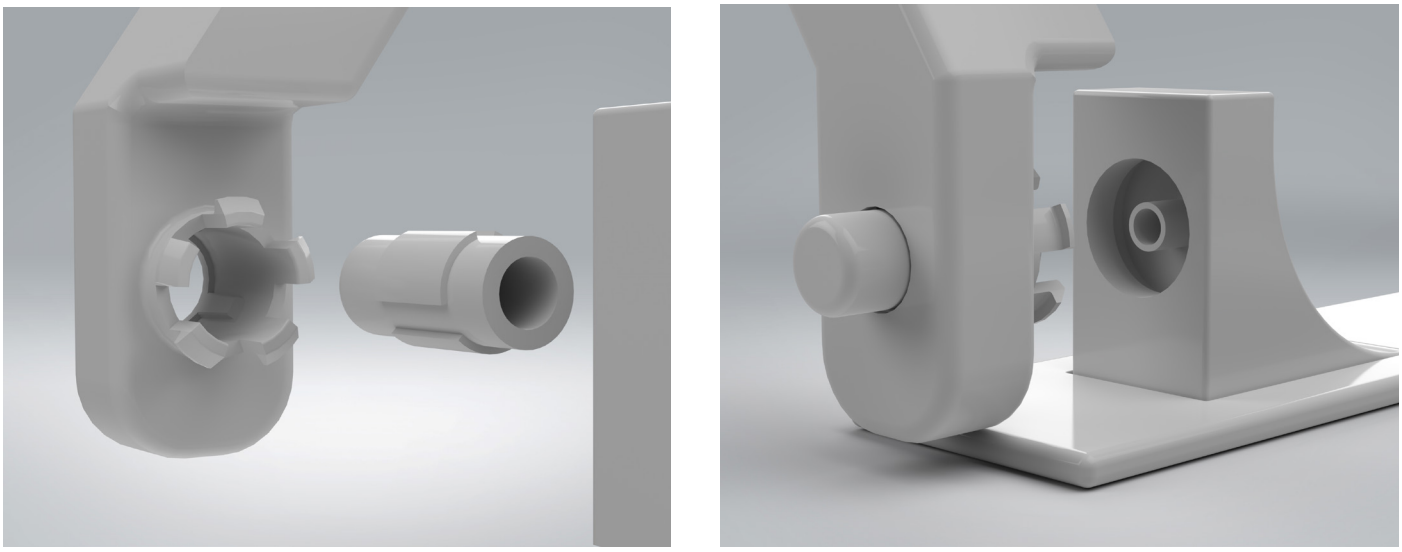


Fig 49. Detailed view of the press button: the snapfit connection of the arm with the button (left) and the quick release coupling to the baseplate (right).

Step 3: click the laser component into the ArC arms.

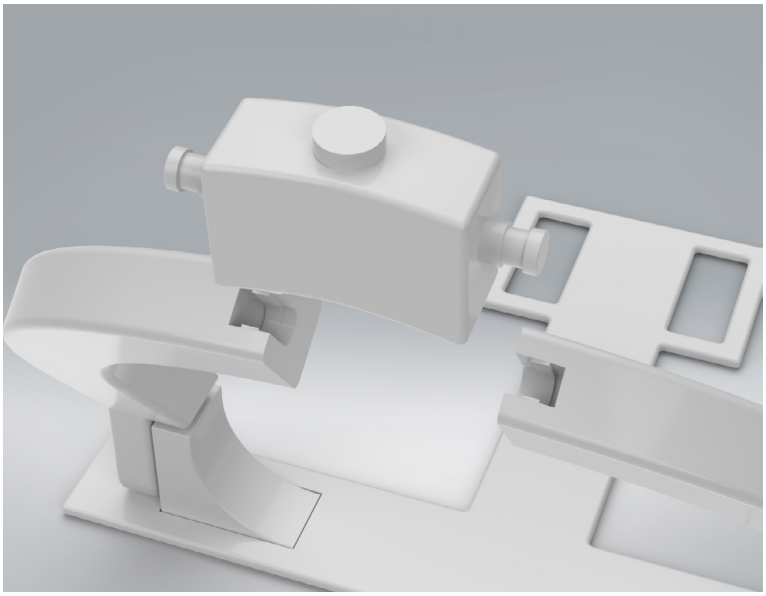


Fig 51. Placement of the laser component into the ArC arms.

Step 4: click the subassembly into the baseplate.

Fig 52. Placement of the ArC into the baseplate.

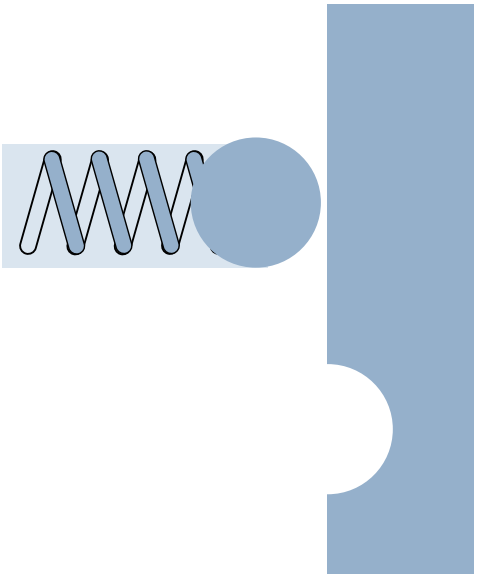


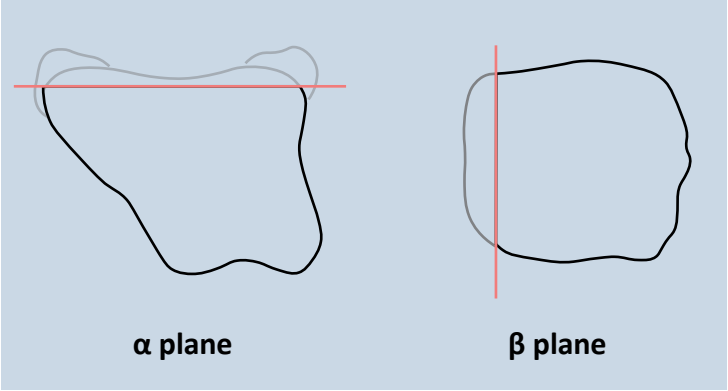
Fig 53. Schematic overview of a ball detent mechanism.

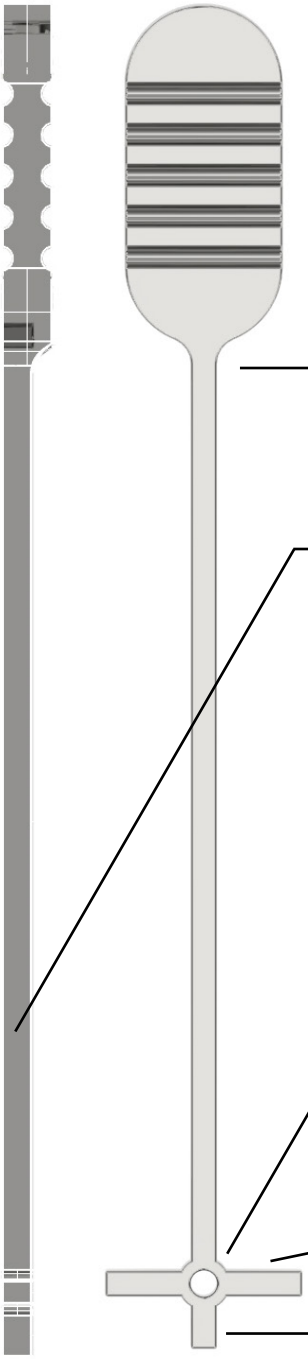
A ball detent mechanism is a simple and effective locking system in which a small ball is pressed inward and held in place by spring force, shown in Fig 53. Schematic overview of a ball detent mechanism.. This could act as a straightforward solution for securing the ArC to the baseplate. Since this improvement was implemented after the final validation test, further investigation is required to evaluate its effectiveness.

The centering guide introduces several optimizations compared to the original design, improving alignment accuracy and stability during k-wire placement. This improved guide is designed to achieve the primary objective:

“The proper angulation relative to the alpha and beta planes which is defined as perpendicular to that plane.”

Design goal 2 and 3





Handle of the centering guide with a grip pattern, supporting the surgeon to use the product while wearing gloves.

Medical grade **stainless steel**

- **The thickness** reduces the chance for the user to drill in different angles, yet it does not force the user.
- **The thickness** also tries to minimize scatter of the laser.

Hole for the k-wire to go through.

Extended horizontal lines conform the anatomy of the trapezium to guide the user in proper usage of the tool.

The lower leg can be used for **stability** by placing it against the fork retractor.

5.3 User interaction with the concept

The integration of the laser-guided system into the operating room requires a smooth interaction between the device, the surgical team, and the surrounding environment. Designed to be both efficient and effective, the product must maintain stability and precision while allowing surgeon and assistants to work freely without obstruction.

Pre-Surgical Setup and Positioning

Before the procedure begins, the baseplate is positioned on the surgical table, ensuring it remains secure without interfering with other essential surgical equipment. The baseplate is stabilized using adjustable straps, which prevents unwanted movement. The user interaction with the system is designed to be intuitive and require minimal contact. Once secured, the ArC component is clicked into place and set in passive mode until needed later in the procedure.

Laser alignment and surgical workflow

Once the trapezium dissection is complete, the surgeon activates the laser system and aligns the crossline laser to the desired centre point. Small, precise adjustments are made by either shifting the laser or moving the arm, ensuring optimal accuracy. Once aligned, the laser remains fixed in place, allowing the surgeon to focus entirely on the procedure without needing to readjust the system. Throughout the surgery, the team must remain mindful of the frame's placement, ensuring that it remains undisturbed while maintaining its alignment.

Interaction Between the Laser Frame and the Surgical Assistant

The surgical assistant plays an important role in holding the retractors to keep the incision site open. To ensure uninterrupted access to the surgical field, the laser-guiding frame is strategically angled to provide sufficient clearance for the assistant's hands and instruments. This positioning prevents obstruction, allowing the assistant to perform retraction without requiring adjustments to the frame during the procedure.

Post-Surgical Handling and Sterilization

Once the procedure is complete, the click mechanism containing the electronic component can be removed separately for sterilization. The remaining non-electronic components can be placed on standard surgical trays for routine sterilization, following standard hospital protocols.

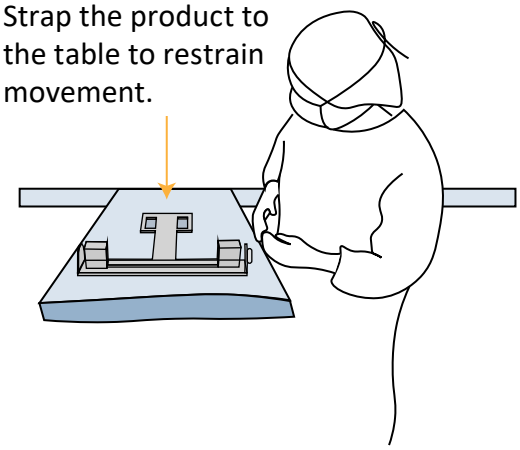
A System Designed for Precision and Efficiency

By minimizing unnecessary disruptions, the laser-guided system enhances surgical precision while maintaining a smooth, ergonomic workflow within the operating room. The intuitive user interaction, combined with strategic positioning and sterilization-friendly components, ensures that the system integrates into surgical procedures - offering surgeons a reliable, stable, and user-friendly tool for enhanced accuracy and efficiency.

Step 1

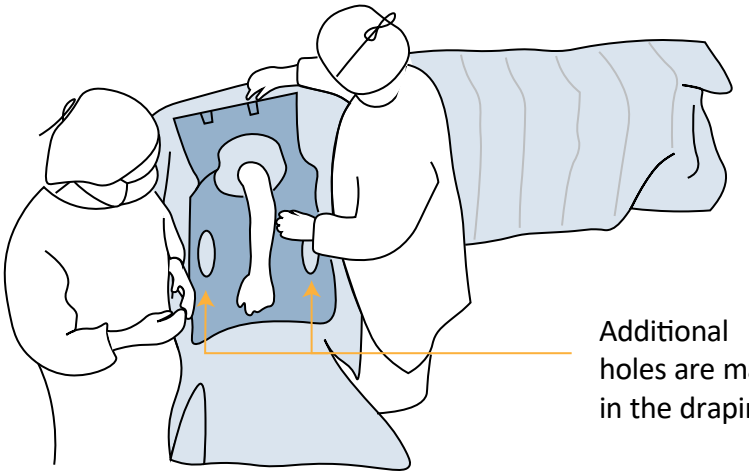
Place the baseplate of the ArC on the surgical table.

Strap the product to the table to restrain movement.



Step 2

Place the single-use draping over the surgical table and ensure that the holes align with the ArC baseplate.

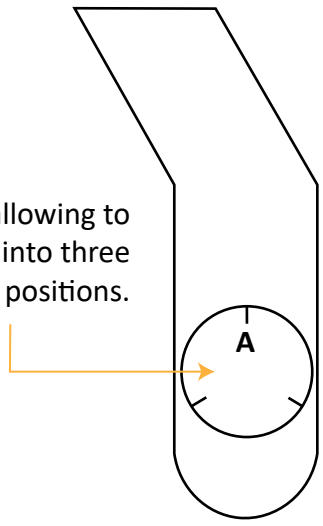


Additional holes are made in the draping.

Step 3

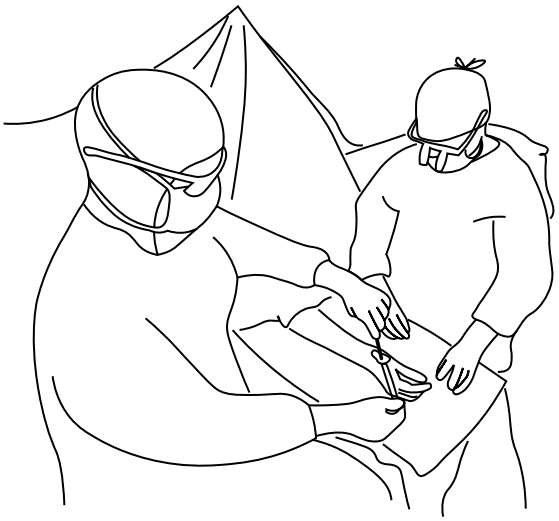
The ArC can be clicked into the baseplate with a simple 'lock' and placed into the passive mode awaiting usage.

Push button allowing to move the ArC into three locking positions.



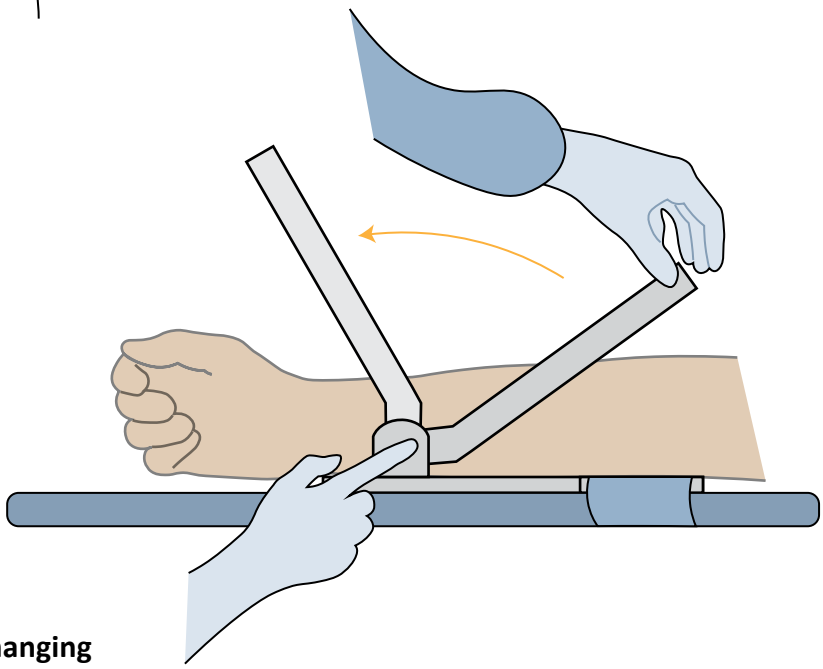
Step 4

The surgeon can follow regular surgical procedure until the trapezium dissection sis finished.



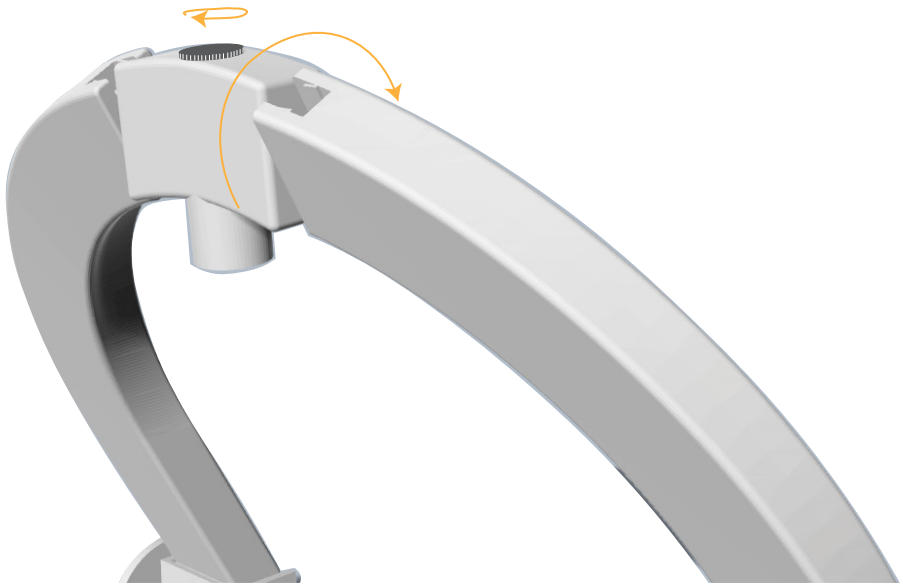
Step 5

Put the Arc into active mode.



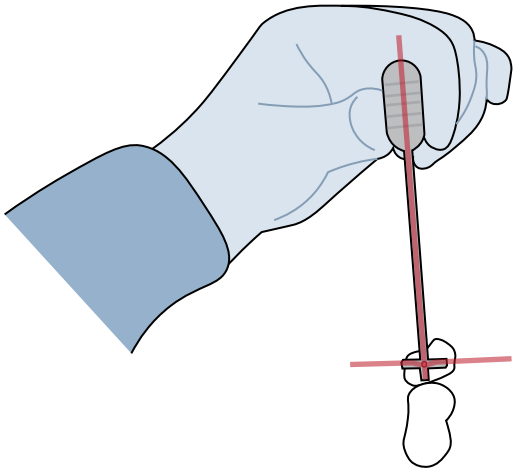
Step 6

Place the laser at the centre point by changing the y-angulation, the crossline, and if needed the hand.



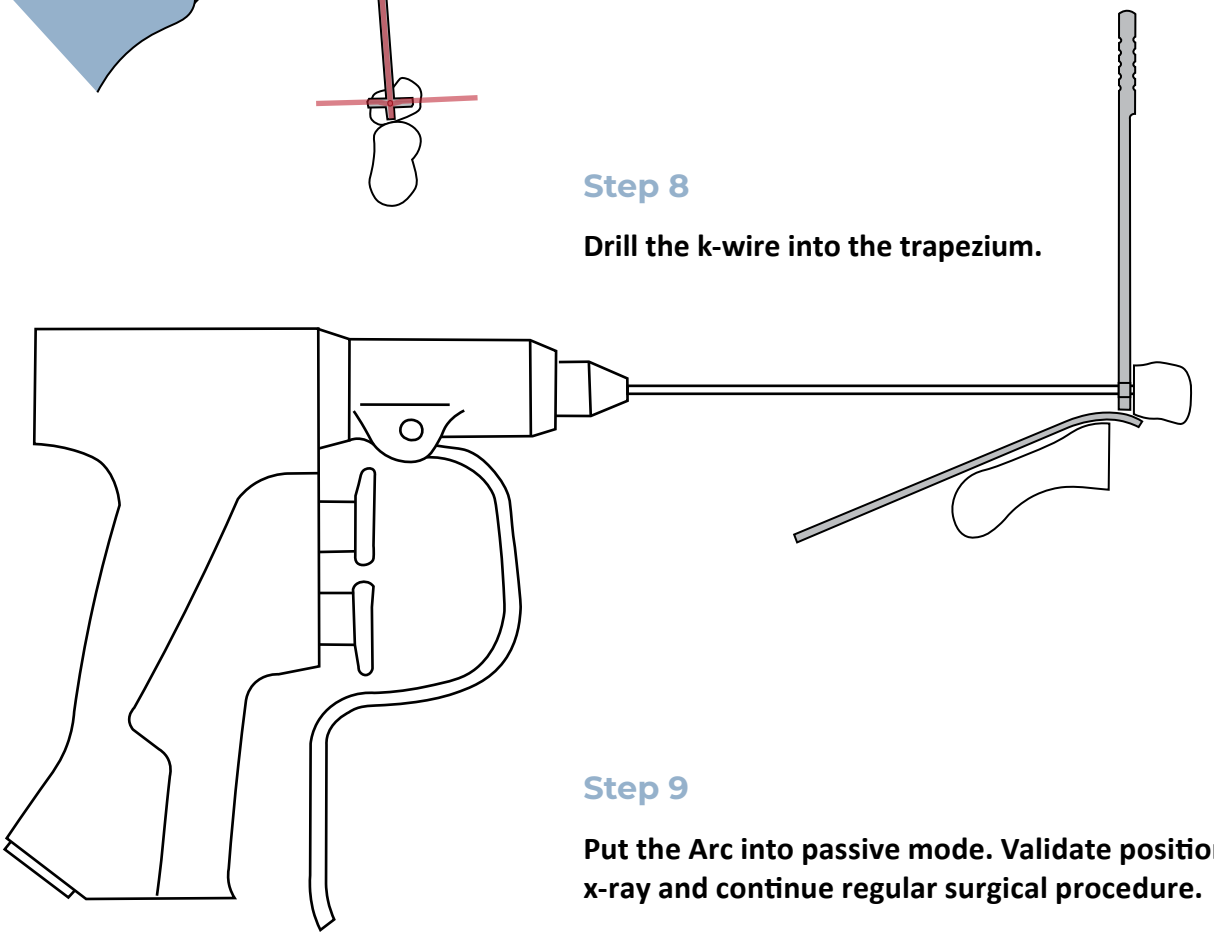
Step 7

Use the optimized centering guide to align with the lasers.



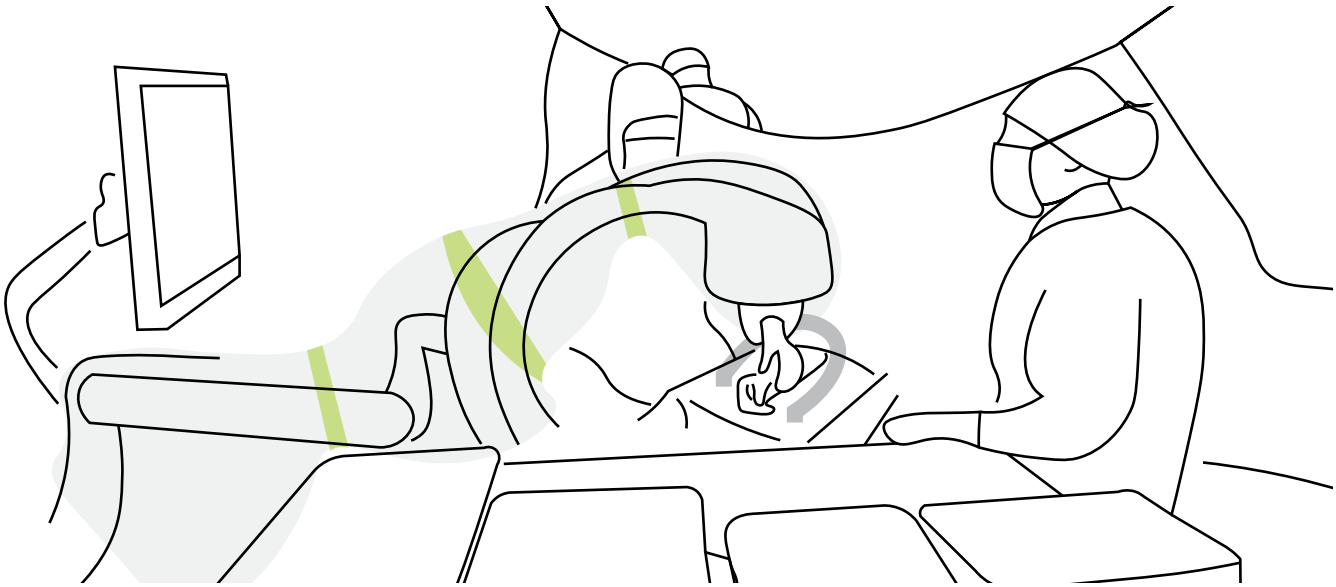
Step 8

Drill the k-wire into the trapezium.



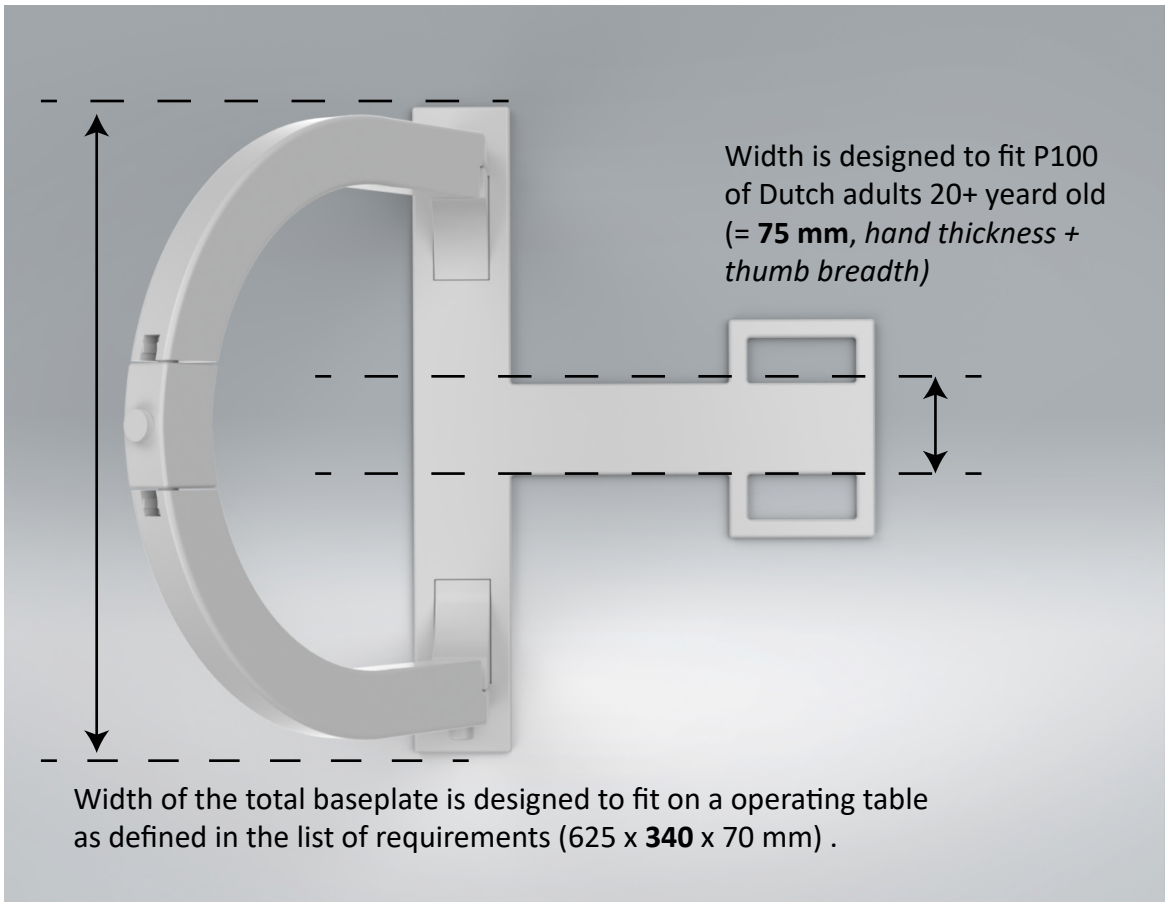
Step 9

Put the Arc into passive mode. Validate position via x-ray and continue regular surgical procedure.



5.4 Dimensions

In section 2.3 Relevant dimensions of the hand the relevant dimensions of the hand were shown. This section provides an overview of how these measurements were used to design the concept.



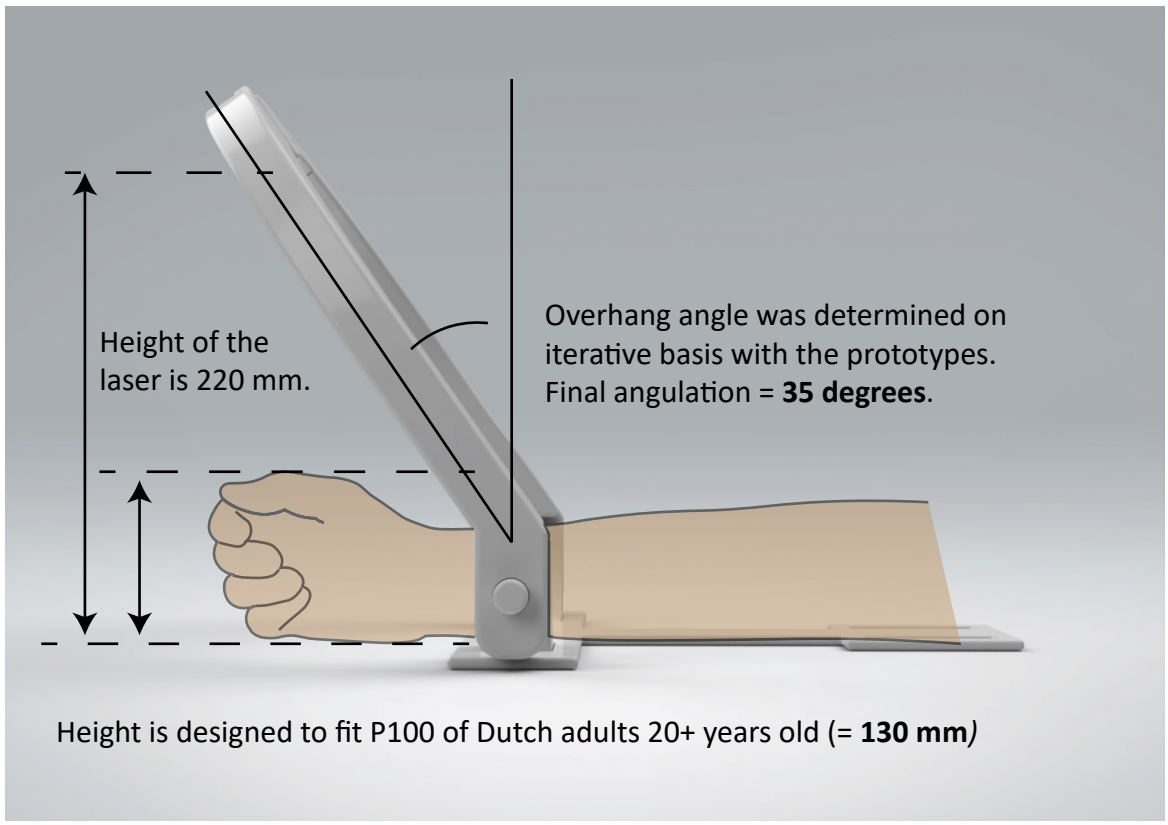


Fig 54. DINED dimensions used for the design.

5.5 Materialisation and production

In this section the materialisation of the ArC and centering guide is dicussed, followed by the corresponding production methods. Surgical instruments require specific material properties for sterilization and safety during use.

5.5.1 Centering guide

Material selection

The centering guide is classified as a reusable surgical instrument (Class I), as defined in 2.8 Relevant rules and regulations. To determine a suitable material for the centering guide, an analysis was conducted using Granta EduPack (Level 2 - Bioengineering), which is a large material database (GrantaEdupack, 2025). This was done by focusing on the following requirements (List of requirements):

1. **The material must be of Medical Grade**.
The material must be certified as medical grade, meaning it has passed biocompatibility testing. This certification can streamline the approval process for medical devices.
2. **The material must be able to withstand at least 160 degrees**.
A common method used at RHOC for sterilization of metals is dry heat sterilization. During dry heat sterilization the product should withstand 160 °C for 2 hours or 170 °C for 1 hour.
3. **The material must have high hardness properties.**
The hardness (Vickers) of a material is measured by pressing a pointed pyramidal diamond or hardened steel ball into the surface of the material under a load. This property is crucial to prevent damage to the centering guide during use, specifically when drilling K-wires through it.
4. **The material must have high yield strength properties.**
The material must exhibit high yield strength to resist bending and deformation during use.

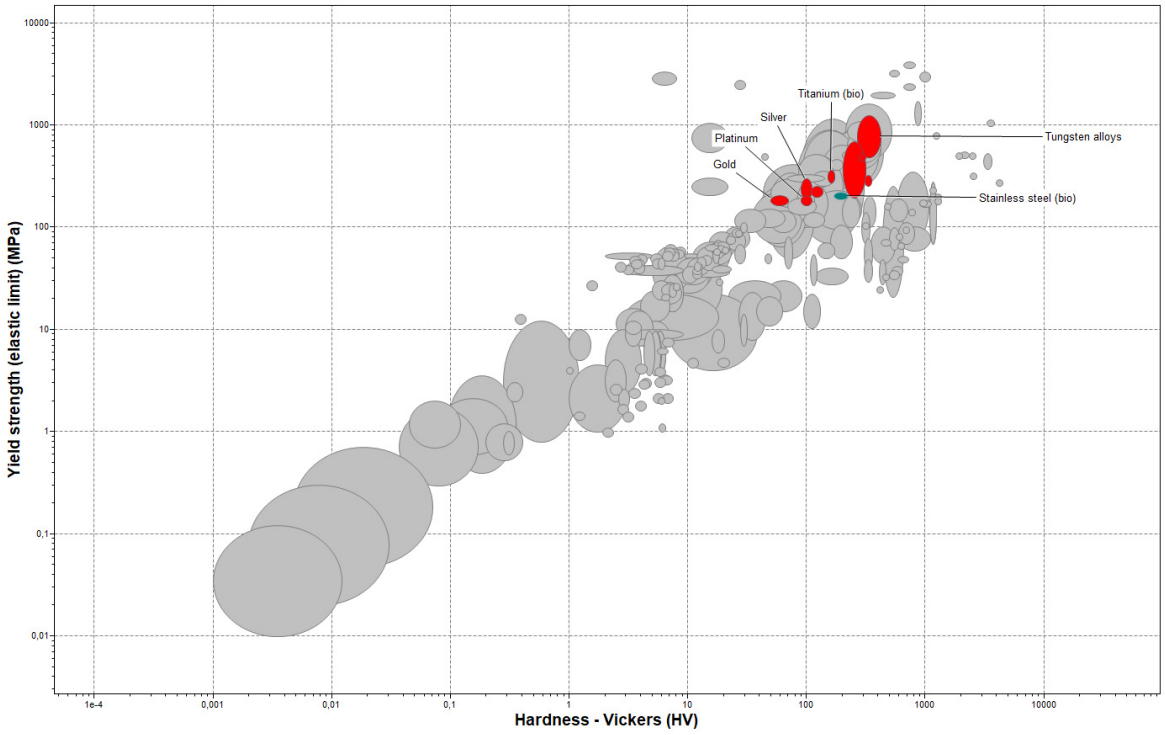


Fig 55. Material properties for the centering guide, plotting hardness (x-axis) versus yield strength (y-axis).

The first two criteria were established as absolute requirements, while the last two were used as comparative factors in material selection. These properties were plotted in Fig 55. Material properties for the centering guide, plotting hardness (x-axis) versus yield strength (y-axis)..
The analysis identified six potential materials for the centering guide: gold, platinum, silver, titanium (bio), and Tungsten alloys. To further analyse these materials, two additional wishes were used:

1. The material must be as easy to process as possible.
2. The material must have be as cost efficient as possible.

Tungsten alloys demonstrate the best (relevant) thermal and mechanical properties, making them highly suitable for the centering guide. However, their low processability poses a challenge, as conventional manufacturing techniques such as casting and machining are not recommended for this material. Gold and platinum also meet the necessary material requirements, but their high cost makes them less practical for this application. Moreover, silver presents difficulties in machining (CNC milling) and remains relatively expensive, leaving only stainless steel and titanium. Both these material are broadly used during surgical procedures. Stainless steel is easier to process than titanium and is more affordable. The cost of stainless steel ranges from €5,38-€5.92 per kilogram, whereas titanium is priced between €12,70-€16,40 per kilogram.

By evaluating these factors, the selection of the most suitable material for the centering guide must balance mechanical performance, manufacturability, and cost efficiency - thus resulting in **stainless steel**.

Production method

An overview of the advantages and disadvantages of different production methods is presented below, focusing on three approaches that are based on the commonly used methods for stainless steel (Ashby et al., 2007).

Metal printing (Additive manufacturing)

Advantages

+ Excellent for small and detailed products.
+ No need for much additional tooling.
+ Compatible with lots of metal materials.

Disadvantages

- Surface finishing may be required to avoid rough edges.
- Only suitable for low-barch production due to high costs and long production times.

CNC milling (substractive manufacturing)

Advantages

+ High precision for details.
+ Easy to scale for mass production.
+ Well-known for medical grade metals.
+ More cost-effective than metal printing.

Disadvantages

- Surface finishing may be required to avoid rough edges.
- Waste material generated during production.
- Small design might lead to difficulty in machining.

Advantages

+ Efficient for large scale production.
+ Can produce complex shaped.
+ Compatible with lots of metal materials.

Disadvantages

- Not ideal for small design.
- High initial production costs for mold design.

Based on the advantages and disadvantages, CNC milling has been selected as the production method for the centering guide, in combination with the stainless steel as the material. This choice is based on the CNC milling's ability to achieve high precision and excellent surface quality, which is crucial for ensuring the centering guide's functionality and durability. Compared to metal printing, CNC milling is more cost-effective for medium-to-large production volumes, and unlike casting, it allows for tight tolerances and flexibility in design modifications without high upfront tooling costs. Additionally, stainless steel offers biocompatibility, corrosion resistance, and mechanical strength, making it an ideal choice for a reusable surgical instrument.

5.5.2 ArC

Material selection

The ArC should also be classified as a reusable surgical instrument (Class I), meaning it should be sterilised according to RHOC protocols. Additionally, the material must be X-ray transparent to prevent the need for surgeons to reposition the product's baseplate during imaging. Considering these factors, the following requirements have been established for the material analysis:

1. **The material must be of Medical Grade**.

The material must be certified as medical grade, meaning it has passed biocompatibility testing. This certification can streamline the approval process for medical devices.

2. **The material must be transparent on the x-rays.**

Ceramics, metals and alloys are visible on x-rays and therefore excluded from the analysis.

3. **The material must be able to withstand at least 160 degrees**.

A common method used at RHOC for sterilization of metals is dry heat sterilization. During dry heat sterilization the product should withstand 160 °C for 2 hours or 170 °C for 1 hour.

4. **The material must have high yield strength properties.**

The material must exhibit high yield strength to resist bending and deformation during use.

The first two criteria were established as absolute requirements, while the last two were used as comparative factors in material selection. These properties were plotted in Fig 56. Material properties for ArC, plotting yield strength (x-axis) versus temperature in service (y-axis)..

These criteria resulted into eight materials that can be considered for the ArC: epoxies (EP), polyamides (Nylons, PA), polybutylene terephthalae (PBT), polyetheretherketone (PEEK), polyamide (PI), polytetrafluoroethylene (Teflon, PTFE), silicone (medical grade), and thermoplatic vulkanite (TPV). Two material results - cortical bone (longitudinal) and cortical bone (transeverse) - were manualy excluded since these biological materials cannot actually be used for product development.

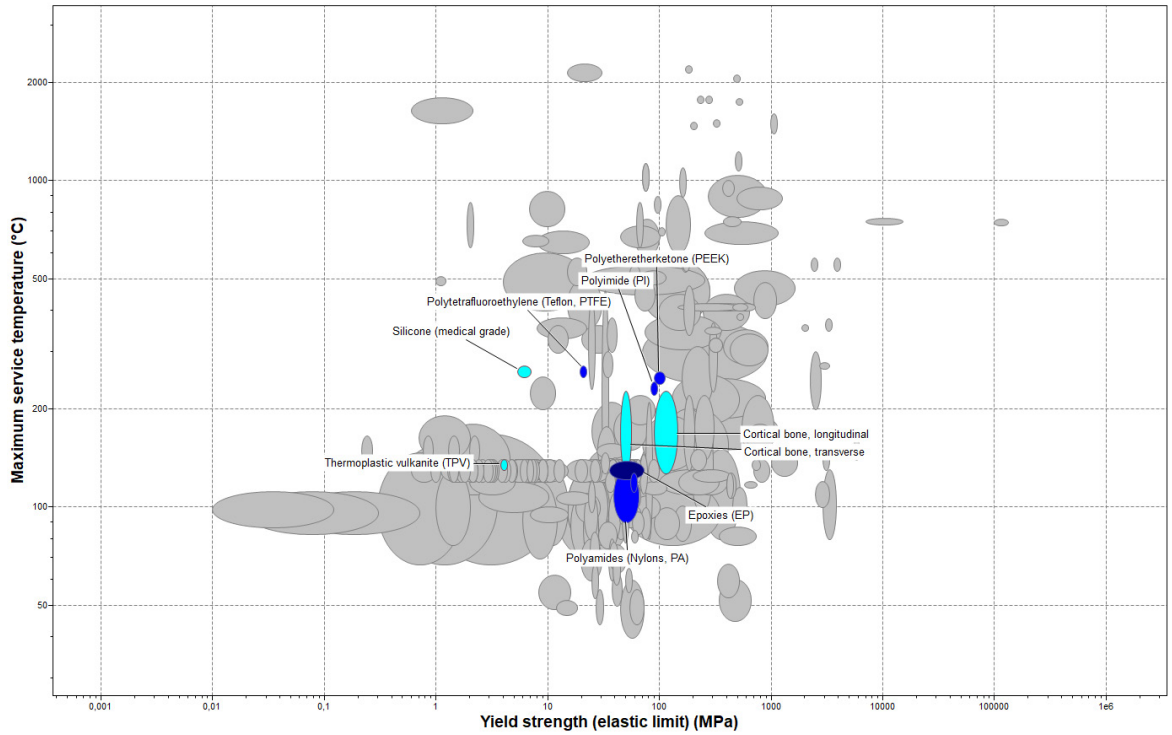


Fig 56. Material properties for ArC, plotting yield strength (x-axis) versus temperature in service (y-axis).

To further decrease the selection, the compatibility of these materials with moldability was assessed. Moldability enables manufacturing processes such as injection molding and thermoforming, which are good production methods for scalable production. This assessment narrowed the options down to five materials: epoxies (EP), polyamides (Nylons, PA), polybutylene terephthalate (PBT), polyetheretherketone (PEEK), and thermoplastic vulcanizate (TPV).

Based on the defined critera polyetheretherketone (PEEK) is the most suitable material for the ArC frame due to its unique combination of properties that align with the design requirements. It is x-ray transparent, allowing surgeons to keep the baseplate in place during imaging without interference. Its excellent biocompatibility makes it safe for medical applications, reducing the risk of adverse reactions. PEEK can withstand high-temperature sterilization methods such as autoclaving, ensuring it remains a reusable surgical instrument. The material also offers strong mechanical properties, maintaining structural integrity while being moldable through injection molding or machining. While alternatives like polyamides or polybutylene terephthalate offer moldability, they lack the durability and sterilization resistance needed for long-term medical use. Thermoplastic vulcanizate is too soft for this application, and epoxies are not ideal due to limited moldability and poor heat resistance. This resulted in the decision to use PEEK as material for the ArC.

Production method

An overview of the advantages and disadvantages of different production methods is presented below, focusing on three approaches that are based on the commonly used methods for PEEK (Ashby et al., 2007).

Injection moulding

Injection moulding is a highly efficient method for production of PEEK products and also allows large scale manufacturing. The process involves melting the polymer and injecting it into a mold, enabling the production of complex shapes with consistent quality. Although PEEK's high melting point requires specialized equipment, this method offers fast production, repeatability, and minimal material waste. However, the high initial tooling costs make it more suitable for high-volume production.

CNC machining

For low-to-medium production volumes, CNC machining is also a good alternative. This subtractive manufacturing method enables high precision and customization, ensuring strict tolerances for the ArC design. While CNC machining works well with PEEK, it generates more material waste compared to injection molding. It is particularly useful for a small-batch production. CNC machining also results in solid products rather than shelled products which can affect the weight distribution.

3D printing

3D printing offers a highly flexible manufacturing approach for complex, custom-designed PEEK parts. Technologies, such as Selective Laser Sintering (SLS), allow for the production of detailed geometries without the need for moulds or extensive post-processing. However, PEEK's high processing temperature makes 3D printing more challenging and requires specialized high-temperature printers. While this method is not as fast or cost-effective for mass production, it is an excellent choice for low-volume production and highly customized components.

Based on the evaluation of advantages and disadvantages, two production methods have been selected for the ArC concept. The **baseplate** will be manufactured using CNC machining, providing a durable and cost-effective solution for a relatively simple design.

In contrast, the **ArC arms** must remain lightweight, making injection molding the preferred manufacturing method. This approach allows for efficient mass production, ensuring consistent quality and reduced material waste, while also maintaining the necessary structural integrity for the application.

5.5.3 Conclusion

The selected materials for the ArC concept provide optimal performance, durability, and compatibility with medical applications. PEEK was chosen for the ArC arms due to its x-ray transparency, biocompatibility, and moldability, making it ideal for lightweight injection-molded components. Stainless steel was selected for the centering plate, providing stability, mechanical strength, and resistance to sterilization, with CNC machining as the preferred manufacturing method to achieve high precision.

If this concept were to be further developed, it could be integrated into Keri Medical's standard surgical kit, thus requiring scalable production methods to support larger manufacturing volumes. This also why scalable manufacturing methods have been chosen for this design.

The table below provides an overview of the selected materials and corresponding production methods for each component.

Table 7. Components with material and production selection.

Components	Material	Material costs	Production method
Baseplate	PEEK	79,05 euro/kg	CNC machining
ArC arms	PEEK	79,05 euro/kg	Injection moulding
Centering guide	Stainless steel	5,65 euro/kg	CNC machining
Laser	-		Buy in

5.6 Conclusion

This section reflects back on the concept and evaluates how it helps the surgeon to improve **the accuracy and precision for the placement of the guide wire during surgery**.

5.6.1 Desirability

The desirability of the concept shows why the surgeons want to use laser guides during surgery. This system significantly enhances the current surgical workflow for thumb joint arthroplasty. This section outlines the benefits and explains why it represents a valuable improvement in hand surgery at Reinier Haga Orthopedisch Centrum (RHOC).

Improved surgical precision and reproducibility

Accuracy and precision in thumb joint arthroplasty is crucial for implant stability and long-term success. The current semi-freehand approach relies entirely on the surgeon's experience, leading to variability in k-wire placement and inconsistent results. This variability increases the risk of incorrect prosthesis alignment, which can affect joint function and durability.

The ArC with centering guide improves the accuracy, precision, and reproducibility by:
- Providing a consistent **visual guide** to align the k-wire with accuracy of 1 mm.
- Providing a **stable centering guide** for improved control during placement.
- Reducing the need for intraoperative k-wire repositioning, leading to a shorter surgical time and fewer disruptions.

While the ArC system does not automate placement, it minimizes variability between surgeons and procedures by introducing a consistent, objective reference. The surgeon remains in control of the positioning but now works within a structured and repeatable framework, reducing extreme variations in placement.

Additionally, the ArC system is standalone, allowing the surgeon to easily switch to surgical instruments for the next step without losing focus on the centre point. Combined with the redesigned centering guide, this improves surgical reproducibility, reducing the need for intraoperative k-wire repositioning.

By integrating laser-assisted precision into the procedure, the risk of cup loosening, cup migration, and prosthesis failure could potentially be reduced. This could lead to better long-term implant stability and patient outcomes, which is desirable for both surgeons and RHOC.

Reducing post-operative complications

Precise k-wire placement is essential not only for efficient surgery but also for minimizing post-operative complications. Incorrect implant positioning can result in cup loosening, migration, and joint instability, ultimately increasing the need for revision surgeries. The ArC system with the optimized centering guide addresses these risks by enhancing placement accuracy and ensuring stable implant positioning from the start, leading to greater long-term implant success.

Accurate positioning of the trapezium cup plays a key role in osseointegration, allowing for better bone integration and improved fixation within the trapezium. This reduces the risk of cup loosening and implant failure. Additionally, placing the trapezium cup in the correct angles improves the alignment with the other components of the prosthesis.

5.6.2 Feasibility

Next, the feasibility of implementing the ArC system and optimized centering guide at Reinier Haga Orthopedisch Centrum (RHOC) is evaluated. This section explain why the concept can be realistically applied into the operating room, based on technical performance, integration with existing workflows, and surgeon feedback.

Technological feasible

The ArC and centering guide use existing technologies such as laser guidance and centering tools but apply them in a new way to thumb arthroplasty. This approach reduces the technical barriers during implementation, as no entirely new technology needs to be developed. Instead, established techniques are optimized for surgical use.

Unlike robotic-assisted navigation, the ArC does not rely on complex imaging technologies such as CT or MRI scans, making it simpler to integrate into the existing surgical workflow. The system is also independent of software or digital platforms, avoiding concerns regarding compatibility issues in the hospital.

Valdation through testing

The concept was evaluated and validated by two test with peer students and two interviews with surgeons, more information about this can be found in Chapter Evaluation and validation.

The concept of using laser guides in surgery was positively received by surgeons at RHOC, whose feedback provided valuable recommendations and validation. They saw the potential of a redesigned centering guide in combination with laser guides to aid them in positioning the centre. Although they acknowledged that the embodiment of the concept could still improve, they saw promise in the proof of concept.

Furthermore, initial testing with peer students has already shown promising results. Despite their limited surgical experience, participants were able to use the laser guidance intuitively, demonstrating that the system provides a clear and consistent reference. The results indicated that even non-expert users could achieve more accurate placements, highlighting the system's user-friendly design and short learning curve. These findings suggest that, with surgeon involvement, performance and outcomes could improve even further.

Material selection

Throughout the entire project, factors as sterilization were kept in mind. This resulted in careful material selection and manufacturing methods. Stainless steel, a widely used material in surgical environments, was chosen for its durability and compatibility with standard sterilization protocols. Additionally, PEEK, a medical-grade material known for its potential to resistance to repeated sterilization and its invisibility on x-rays, was selected.

5.6.3 Viability

The viability of the ArC system and optimized centering guide at Reinier Haga Orthopedisch Centrum (RHOC) depends on its technical feasibility, integration into the existing surgical workflow, cost-effectiveness, and long-term impact on patient outcomes. This chapter evaluates how the ArC meets these criteria and why it could present a viable solution for improving thumb joint arthroplasty at RHOC.

Integration into RHOC's surgical workflow

The ArC system with the Optimized Centering Guide is designed for seamless integration into RHOC's surgical workflow, enhancing precision without disrupting existing procedures. Unlike robotic-assisted systems, it does not require preoperative imaging, eliminating the need for CT or MRI scans and reducing preparation time.

The concept's quick setup is in accordance with the defined requirement, ensuring minimal impact on surgery duration. Since the design solution focuses on aiding the surgeon, rather than taking over from the surgeon, the system can be incorporated relatively easy without the need to change their standard technique.

Sterilization requirements have been carefully considered, with autoclavable materials ensuring compliance with hospital protocols. The one-handed usability of the system allows for easy adjustments without interrupting the surgical process, maintaining efficiency in the operating room.

Future potential

The ArC system also provides a start for future integration of advanced technologies. In a later stage of the product development, surface mapping technology could be incorporated, offering real-time anatomical data to further analyse prosthetic cup placement. This would allow for automated decision support, enabling surgeons to assess bone contours and determine optimal positioning with greater accuracy.

With its flexible design, the system has the potential to evolve with sensor-based enhancements or AI-driven placement guidance, reducing reliance on manual adjustments and improving reproducibility. This adaptability ensures that the ArC system remains relevant as surgical technology advances, making it a future-proof investment for RHOC.

Cost-effective solution

The ArC system offers a cost-effective alternative to robotic-assisted navigation while maintaining high surgical precision. Unlike robotic systems that require substantial investment in equipment, software, and specialized training, the ArC system is an affordable enhancement that works within existing surgical techniques.

By reducing revision surgery rates, the system lowers long-term treatment costs, as fewer complications mean less need for corrective procedures. This benefits both patients and healthcare providers. Its adaptability also allows it to be applied to other orthopedic procedures, further increasing its value in surgical use.

With affordable implementation, fewer complications, and potential for broader applicability, the ArC system presents a practical and sustainable solution for RHOC.

6.

Evaluation and validation

In this chapter the concept is evaluated with three tests. Firstly, a feasibility test is done with participants without a surgical background. This test explored the feasibility of using laser guides for accurate k-wire positioning in thumb base joint arthroplasty.

Following the validation of the feasibility of laser guides, further development of the concept has been carried out. This consisted of an iterative process for designing a frame and centering guide that could be easily integrated into the surgical workflow and hindered the surgeons as little as possible, as described in Chapter Design process. This concept was then evaluated across multiple aspects, including the usability of the optimized centering guide, the positioning of the frame, and its overall effectiveness in assisting with alignment and drilling accuracy. This evalauation was done with the five best performing participants from the previous test.

Lastly, the concept was evaluated with two surgeons from RHOC. The was done by a evaluation session, during which the surgeons were interviewed separately. The surgeons were asked to engage with the prototype of the concept and simulate the surgery, while thinking aloud. The results of this evaluation is summarized in 6.3 Validation interviews with surgeons.

6.1 Research questions

6.1.1 Feasibility test

A rapid feasibility test was used to investigate the use of laser guides for correct positioning of the k-wire. The goal of this study is to investigate the feasibility of this idea. The feasibility test evaluated the accuracy and precision of laser-guided k-wire positioning using 3D-printed trapezium models and a crossline laser. Eight novice participants manually aligned the laser to the center of four trapezium variants, with measurements analyzed via Rhinoceros Grasshopper and GeoGebra.

Research questions

1. What is the accuracy and precision of freehand placement of the laser guides on the trapezium surface?
2. How many degrees of freedom or required/desired to move the crossline laser to the correct position?

6.1.2 Validation test

Following the validation of laser guides for accurate and precise positioning, further development of the concept has been carried out. This was analyzed by the following three research questions.

Research questions

1. Can users achieve an accuracy and precision of ±1mm using the frame and optimized centering guide?
2. Does the optimized centering guide assist users in drilling at the correct alpha and beta angles?
3. How effective is the interaction for adjusting the laser's angle and position using the frame?

By analyzing these factors, this test aims to assess the improved system's usability, functionality, and potential for integration into surgical workflows.

Several hypotheses were made for this test.

1. The data of the centre point will be less accurate than the previous test.

This is due to the fact that the participants are now challenged with a trapezium model that is more accurate and realistic, thus provdining more differences in depth. Moreovver, the trapezium models are shaped to the actual size of the bone. Laslty, the material used to mimic the bone is PLA, combined with a regular burr without the actual k-wire. This can cause the burr to slip over the smooth surface which creates more challenges for the participants.

2. The angulation of the the crossline laser is too high.

A big trade-off within this design is the access for the surgeon to operate and the angulation of the crossline laser. This test will be used to find the optimal position for the laser, however, it is expected that the laser is currently a bit too high resulting in scatter of the horizontal line.

3. The participants will experience a learning curve throughout the test.

The participants have little prior knowledge of the research. It is expected that they know how to use the laser, yet do not have a full understanding of using the centering guide and the actual burring in the trapezium. It can be expected they will perform better throughout the test and once the have found a method that works for them.

4. Effect of the varying trapezium shapes

- **Trapezium 1** features an evenly shaped, almost flat surface but contains rough edges and irregularities. These irregularities may make it more challenging for participants to correctly identify and drill at the center point.
- **Trapezium 2** has a well-defined saddled surface with a smooth texture. Previous testing indicated that participants found it easier to locate the center, making it a valuable comparison model.
- **Trapezium 3** has a larger, smoother surface, which can make identifying the center more difficult. The absence of distinct reference points adds complexity to alignment, testing the effectiveness of the frame and centering guide under less defined conditions.

6.2 Method

6.2.1 Participants

Feasibility test

The participant group consists of students of which four males and four females with an age range of 20-29 years old. All participants are students with different study backgrounds, but all from the TU Delft. The participant have no prior knowledgde about the use of laser guides and the anatomy of the hand.

The participants recruited do not represent the actual target group. The actual target group consists of specialised hand surgeons, however, this test is to prove feasibility of the laser guided principle. It is expected that hand surgeons would perform better at this test than the student participants. This will be taken into account during evaluation of the results.

Validation test

The participant group consists of the five best-performing students of the feasibility test. This group consisted of two males and three females with an age range of 22-26 years old. All participants are students with different study backgrounds, but all from the TU Delft. The participant have little prior knowledge about the use of laser guides yet no knowledge the anatomy of the hand.

The participants recruited do not represent the actual target group. The actual target group consists of specialised hand surgeons. However, by using the best-performing participants of the previous test it can be expected that they perform better that participants with no prior knowledge of the research. Still, it will be taken into account during evaluation of the results.

6.2.2 Procedure and materials

Before both tests started, it was explained to the participants what the test consisted of and what was expected from that. Subsequently, the were asked to read and sign the informed consent form (Appendix C: Informed Consent form).

Feasibility test

The materials used in this study include a combination of 3D-printed components and a rough set-up of the laser system.

- Vonroc laser with a beam thickness of 3 mm
- Four different shapes of 3D printed plaques of trapezium (white PLA) scaled x3. *The k-wire has a diameter of 1mm. The envisioned laser thickness is also 1 mm, yet due to availability a 3 mm laser beam is used. Therefore, the 3D printed trapezium plaques are also scaled x3.*
- A placeholder for the trapezium shapes mimicking the anatomy of the hand.
- A camera with holder so all images are taken from the same position.
- A pole with a ball-and-socket attachment for the laser beam.

The test setup was designed to ensure consistency across all participants. A crossline laser (Vonroc) with a 3 mm beam thickness was positioned at a fixed height of 40 cm and a predetermined distance to maintain uniform conditions. The trapezium model was securely placed on the designated blue holder, ensuring stability throughout the test.

A camera was positioned centrally between the trapezium and the laser to gather alignment results. The crossline laser was mounted on a ball-and-socket joint, allowing full rotational movement in all directions. Participants were instructed to manually adjust the laser to align its intersection point with the perceived centre of the trapezium. Once satisfied with their alignment, the participant pressed a camera button to capture an image of their final positioning. An example of a participant positioning the crossline laser, together with the acquired result can be seen in Fig 58. Example of result (L) test set-up with a participant (R).. These images were later analyzed to assess accuracy and precision in the laser-guided placement of the k-wire.

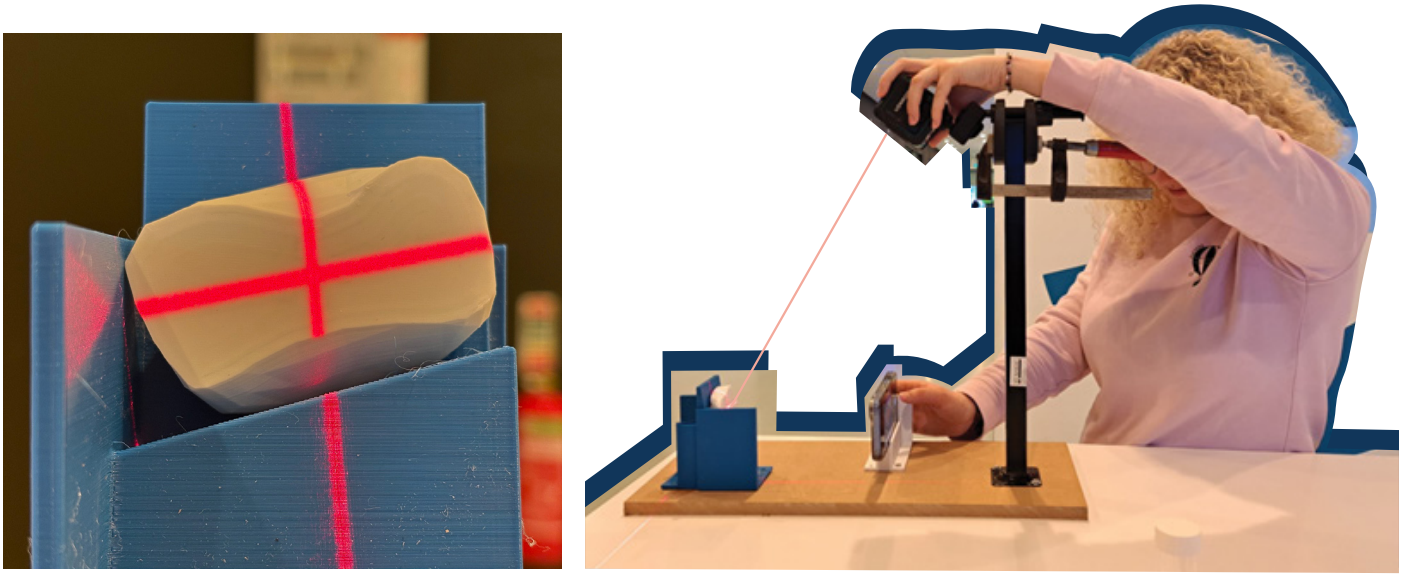


Fig 58. Example of result (L) test set-up with a participant (R).

Each participant completed four alignment attempts per trapezium shape, totaling 16 trials per individual. After each attempt, they rated their confidence in the alignment on a scale from one (not confident) to seven (very confident). This self-assessment helped assess the relationship between perceived accuracy and actual performance.

After each try the laser is turned back in its neutral position and the participant is asked to rate their confidence (scale: 1 = not confident and 7 = very confident) that the found the true centre point. After four tries the participant is asked their overall rating of the ease of finding the position and their approach to finding the centre. These steps are repeated for all variants. Participants were also asked to reflect on their approach and explain how the specific shape influenced their alignment strategy. This qualitative feedback provided insights into the challenges posed by different anatomical variations and how participants adapted their technique accordingly.

These evaluations helped identify patterns in user performance, highlighting the strengths and limitations of manual laser-guided positioning. The collected data, both quantative and qualitative, were analyzed to assess the feasibility and inform potential refinements in laser-assisted surgical instrumentation.

The materials used in this study include a combination of 3D-printed components, a laser system, and optimized model of the centering guide to evaluate the effectiveness of the final design. The key materials are as follows:

- A set of 3D-printed (PLA) trapezium-shaped models per participant retrieved from Yuan (2023).
- Laser system with a beam thickness of 1mm.
- 3D-printed model of the laser guided frame used for alignment testing.
- 3D-printed (PLA) model of the optimized centering guide, designed for precision in drilling.
- Set-up for environmental control and fixation of the trapezium, ensuring stable positioning during testing.
- Makita DF488D burr (2.5 kg) with a 1.5mm drill bit, used for evaluating drilling accuracy.

For this study, three trapezium models from the PhD study were selected due to their varied shapes and surface characteristics, as shown in Fig 59. Trapezium shapes, 3D models.. These models were chosen to assess how different anatomical variations influence the ease of alignment and drilling accuracy.

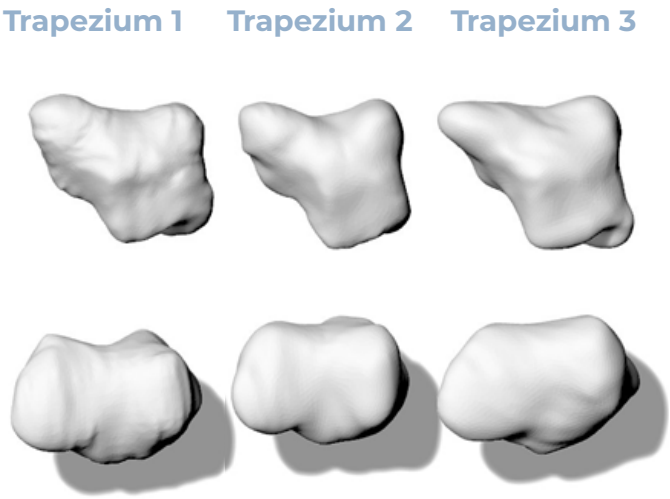


Fig 59. Trapezium shapes, 3D models.

First, the participants were asked to position the laser at the centre of the trapezium. During the positioning the participants were allowed to use all features of the concept they found neccessary to finding the correct centre. The possible features are shown in Figures 61-64.

Once the particpant was confident they found the centre point, the centering guide and drill were given to them. Without explaining, the purpose of the centering guide, the participants were asked to drill a hole in the 3D model. This resulted in three quantative data points: the centre point (x,y), the angulation in the frontal plane, and the angulation in the saggital plane, shown in Fig 60. Quantative data: centre point, top plane, side plane.

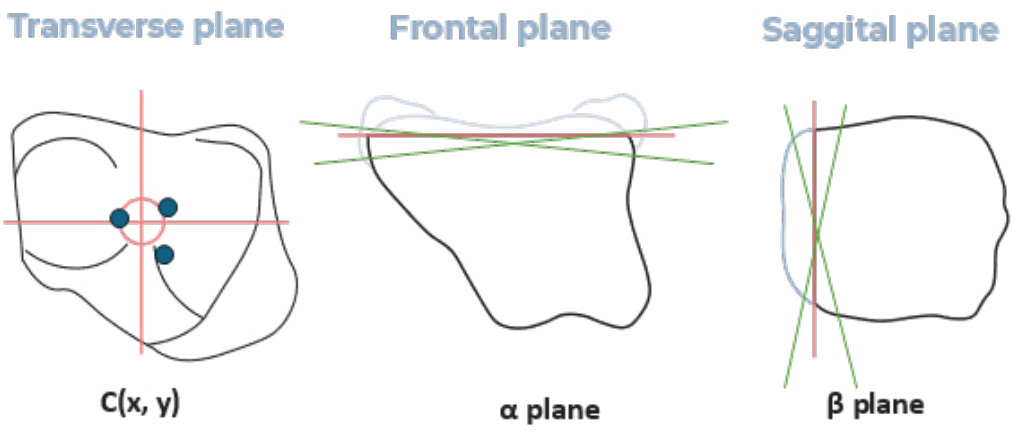


Fig 60. Quantative data: centre point, top plane, side plane.

Throughout the entire test the participants were interviewed and observed to analyse why they made certain decisions in their approach, how they interperted the concept, and gather feedback for improvement. This resulted into valuable qualitative data.

The setup was designed to ensure consistency and fast interchangable across all participants.

A prototype of the ArC concept was 3D-printed, with a crossline laser (1 mm beam thickness) precisely positioned within the ArC model. The trapezium model was securely placed on the designated blue holder, ensuring stability throughout testing.

Additionally, a clay model was created to replicate the dimensions of a hand, highlighting the limited working space and helping participants better understand the anatomy and objective of the procedure.

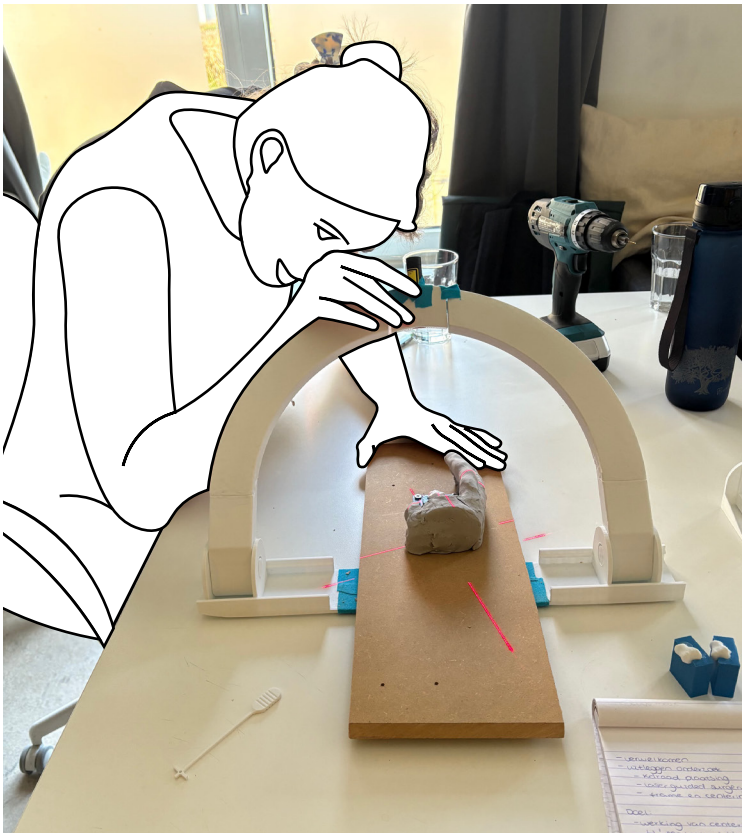


Fig 61. Test set-up of the pilot study with a participant.

The model operates in two modes: active and passive.

- Active mode: The laser is positioned over the patient's arm, ready for use.
- Passive mode: The ArC and laser can be rotated to the side of the arm when not in use.

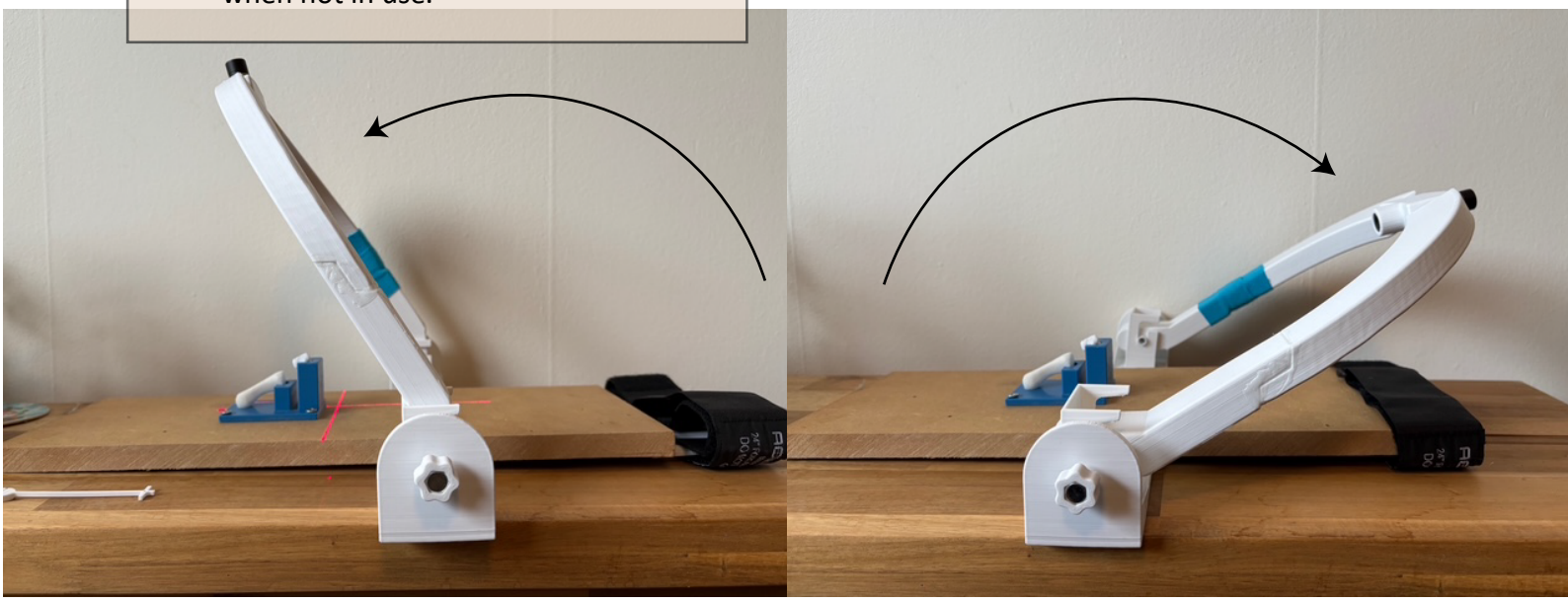


Fig 62. 3D printed model of the ArC, feature: passive and active modes.

A knob is positioned on the left side of the ArC. Turning the knob will move the arc the laser in the x-direction.

Fig 63. 3D printed model of the ArC, features: restricting model and x-translation.

The laser can be angled to adjust the y-direction, and the device itself can be rotated for optimal positioning.

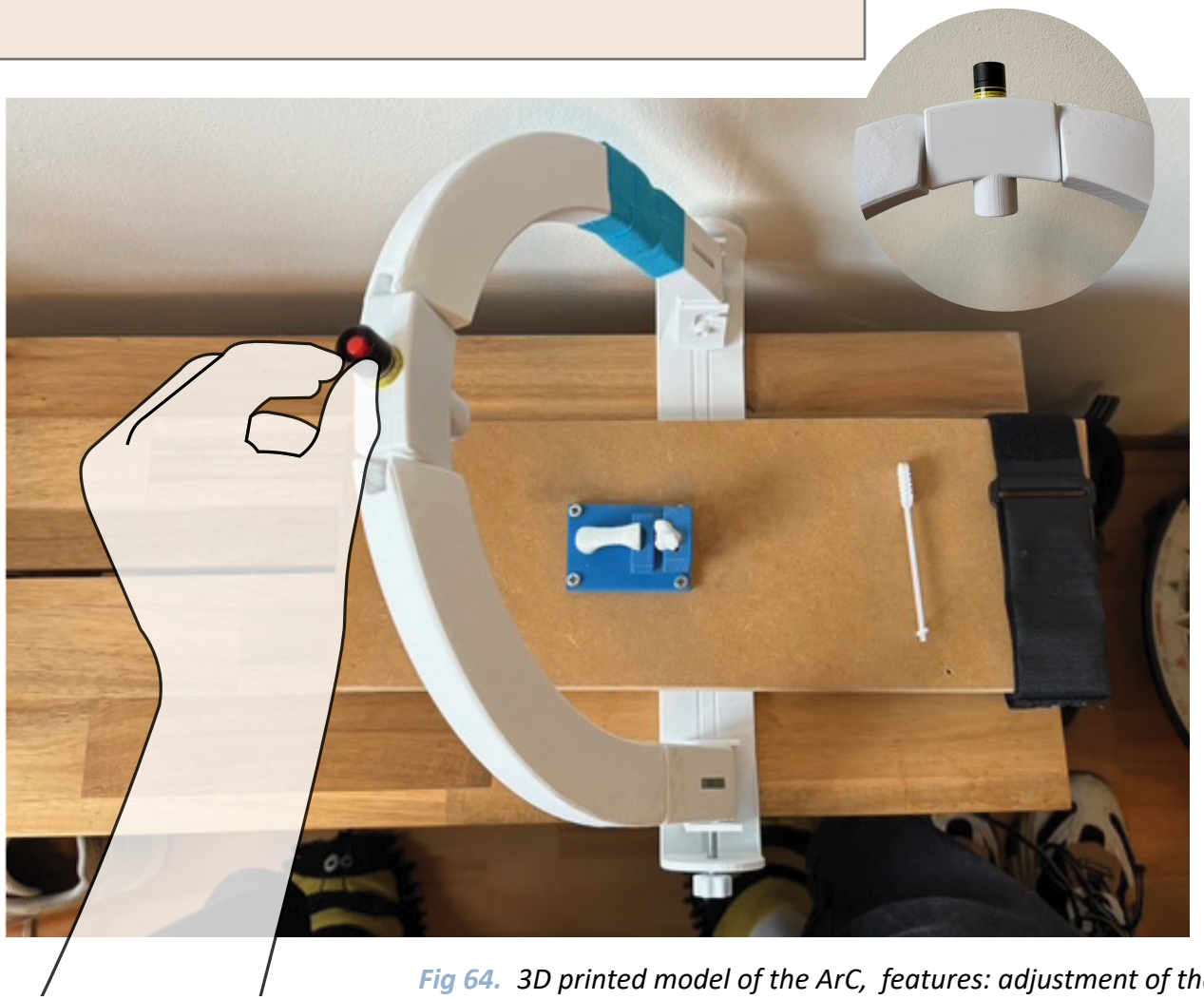


Fig 64. 3D printed model of the ArC, features: adjustment of the laser.

6.2.3 Data analysis

For each variant of the trapezium shaped model, the coordinates of the centre point are extracted via a self-made script with the software Rhinoceros Grasshopper. For the data analysis of the quantative data of the participants, the program GeoGebra Calculator Suite was used. Through this software it was possible to extract the centre points and the angulation in the correct planes. This was done by defining parameters, such as size of the trapezium and appointing the correct planes. For both studies a boundary was set to evaluate whether a measurement was classified as a success or failure:

- Feasibility test: for this study a variation radius of 1,5mm was accepted as the margin for accuracy, due to a laser beam thickness of 3 mm.
- Validation test: for this study a variation radius of 0,5mm was accepted as the margin for accuracy, due to a laser beam thickness of 1 mm.

Once the centre points and planes were derived from GeoGebra, standard deviations were calculted to assess the variability in participant accuracy and precision. This analysis provided insight into the consistency of the laser-guided alignment, identifying deviations in x- and y-coordinates as well as angular differences across the sagittal and frontal planes.

6.2.4 Ethics

A consent form and research ethics checklist was created and can be read in Appendix C: Informed Consent form. This consent form and research ethics checklist ensures that the safety and privacy of the participants is protected to the fullest extent possible. Participants are referred to by number (1, 2, 3, etc.) and no identifyable data was saved. Some participants allowed for pictures to be taken, however, their faces are not visible.

6.3 Results

6.3.1 Feasibility test

Qualitative results

The qualitative results provided insight into participant performance and confidence levels. The participants were asked to rate their confindence on a scale from 0-7 (low-high). When combining those results with their actual performance, it shows that some participants overestimated their accuracy, while others underestimated their ability due to external factors such as laser reflections. A summary of these results combined with the actural performance is presented in Table 8. Overview of total results per participant. below.

Table 8. Overview of total results per participant.

	Confidence	Performance	Self-assessment
Participant 1	High	Poor	Overconfident
Participant 2	High	Strong	Consistent
Participant 3	Low	Poor(est)	Consistent
Participant 4	High	Moderate	Overconfident
Participant 5	Low	Moderate	Consistent
Participant 6	Low	Moderate	Underconfident
Participant 7	High	Strong	Consistent
Participant 8	Moderate	Moderate	Consistent

Participant 1 displayed high confidence but poor accuracy, particularly in the x-direction, suggesting an overestimation of their capabilities when dealing with simpler shapes. On the other hand, Participant 3, who had the lowest accuracy, also demonstrated the lowest confidence levels, but their self-assessment accurately reflected their struggles. The impact of laser reflections was particularly evident with Participant 6, who reported difficulties in positioning due to glare, leading to lower confidence scores despite a moderate level of accuracy. This suggests that managing laser projection angles or incorporating anti-reflective measures could improve usability and reduce performance inconsistencies.

Some participants also adjusted their alignment strategies over time, which influenced their results. Participant 8, for example, experimented with new alignment tactics, leading to improved confidence and accuracy in later trials. This suggests that learning effects or refined techniques could enhance user performance over time, highlighting the potential benefits of training or additional guidance mechanisms.

Quantative results

The following section presents the quantative results of the feasibility study, evaluating the accuracy and precision of laserguides for k-wire positioning across different trapezium models. The primary objective of this study was to determine how effectively participants could align the laser with the centre of the trapezium. A detailed breakdown is available in Appendix F: Feasibility Test.

The results are structured per trapezium model, showing differences in alignment performance and the impact of shape complexity on positioning accuracy. Fig 65. Legend of the results shows the legend of the scatterplots, indicating which colored dot corresponds to each participant and the true centre point of that shape. All participants have four results per trapezium.

Trapezium 1 (centre: 28,72;14,24) demonstrated the highest accuracy and consistency among participants. The standard deviations remained relatively low, with a standard deviation of 0,632-1,406 mm in the x-direction and a standard deviation of 0,484-0,964 mm in the y-direction. These results indicate that participants were able to align the laser with the centre point with a small variability. The overall consistency suggests that simpler geometric structures provide clear reference points, aiding in more precise alignment.

Fig 66. Scatterplot for Trapezium 1: (Top) Alignment outcomes relative to the trapezium surface, (Bottom) Zoomed-in view highlighting variance among participants. shows a tightly clustered set of points near the true center, indicating that deviations were limited. The zoomed-in view highlights minor variations in positioning, with most placements concentrated within a narrow range.

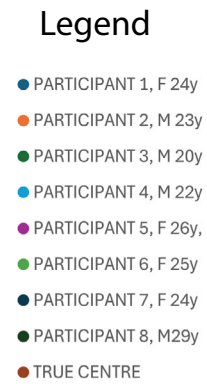


Fig 65. Legend of the results

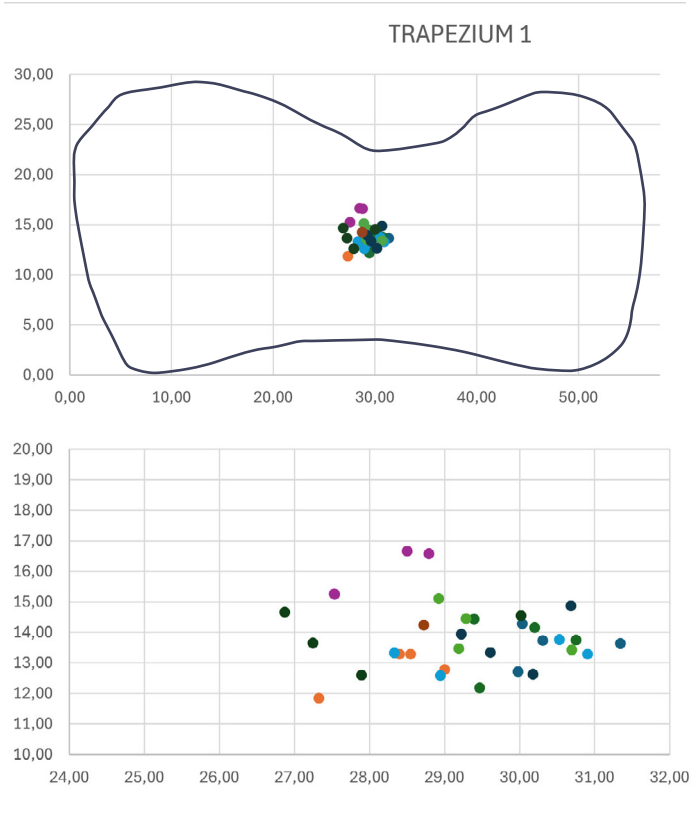


*Fig 66. Scatterplot for **Trapezium 1**: (Top) Alignment outcomes relative to the trapezium surface, (Bottom) Zoomed-in view highlighting variance among participants.*

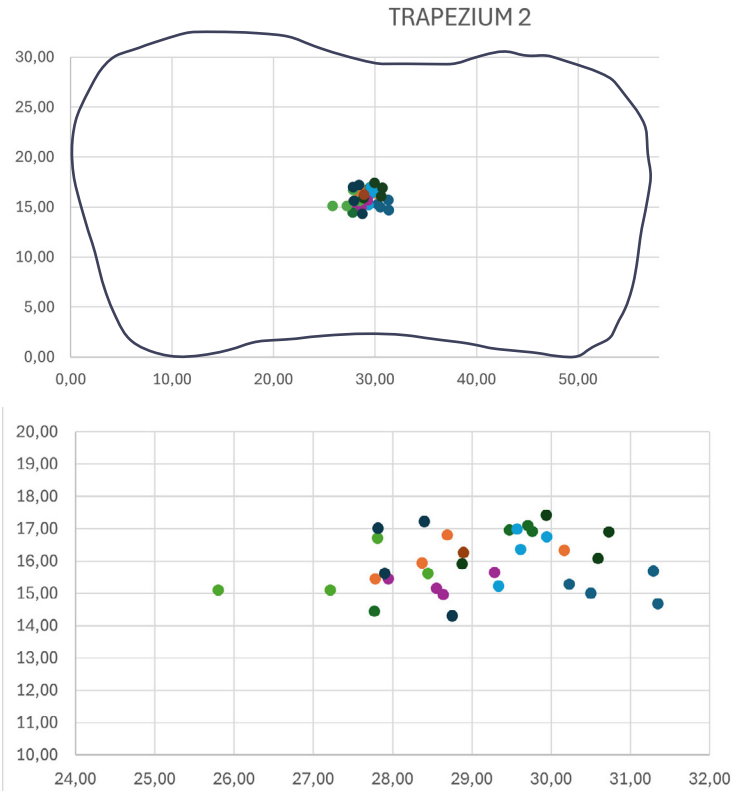


*Fig 67. Scatterplot for **Trapezium 2**: (Top) Alignment outcomes relative to the trapezium surface, (Bottom) Zoomed-in view highlighting variance among participants.*

Trapezium 2 resulted in relatively low deviations and high precision. Standard deviations were slightly higher than in Trapezium 1, with with a standard deviation of 0,560-1,239 mm in the x-direction and a standard deviation ranging from 0,234-1,360 mm in the y-direction.

Fig 67. Scatterplot for Trapezium 2: (Top) Alignment outcomes relative to the trapezium surface, (Bottom) Zoomed-in view highlighting variance among participants. shows a slightly broader distribution than Trapezium 1, but with a dense cluster of points near the center. The zoomed-in view illustrates small variations in placement, with some outliers.

Trapezium 3 showed the highest mean deviations and standard deviations, particularly in the y-direction. The standard deviation in x-coordinates was 0,255-1,452 mm, while the standard deviation in the y-direction ranged from 0,307 mm to 2,008 mm, the highest among all models.

Fig 68. Scatterplot for Trapezium 3: (Top) Alignment outcomes relative to the trapezium surface, (Bottom) Zoomed-in view highlighting variance among participants. shows a more scattered distribution of placements, particularly in the vertical direction. The zoomed-in view highlights a greater spread of data points compared to Trapezium 1 and 2, with visible differences between participants.

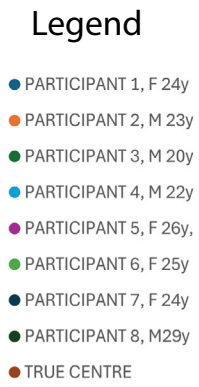


Fig 70. Legend of the results

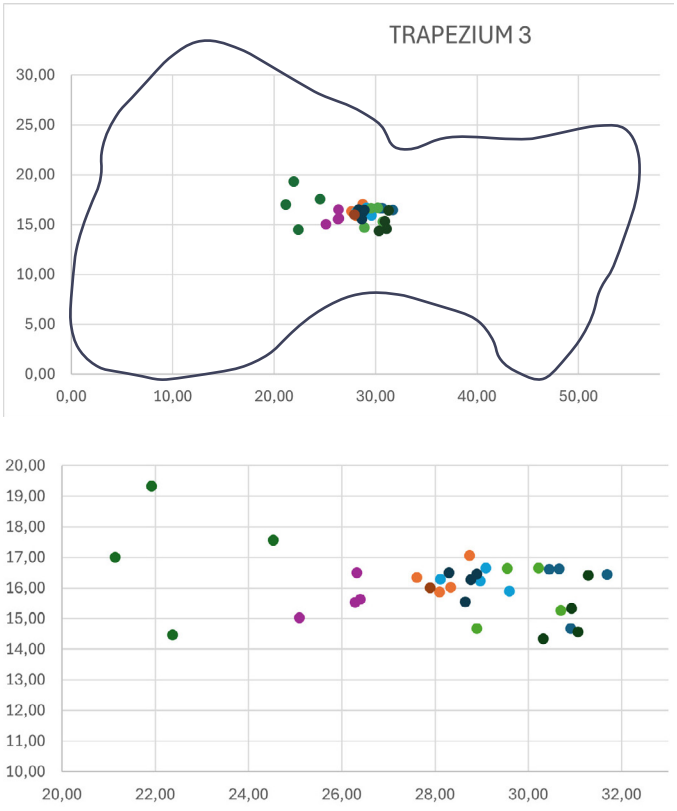


*Fig 68. Scatterplot for **Trapezium 3**: (Top) Alignment outcomes relative to the trapezium surface, (Bottom) Zoomed-in view highlighting variance among participants.*

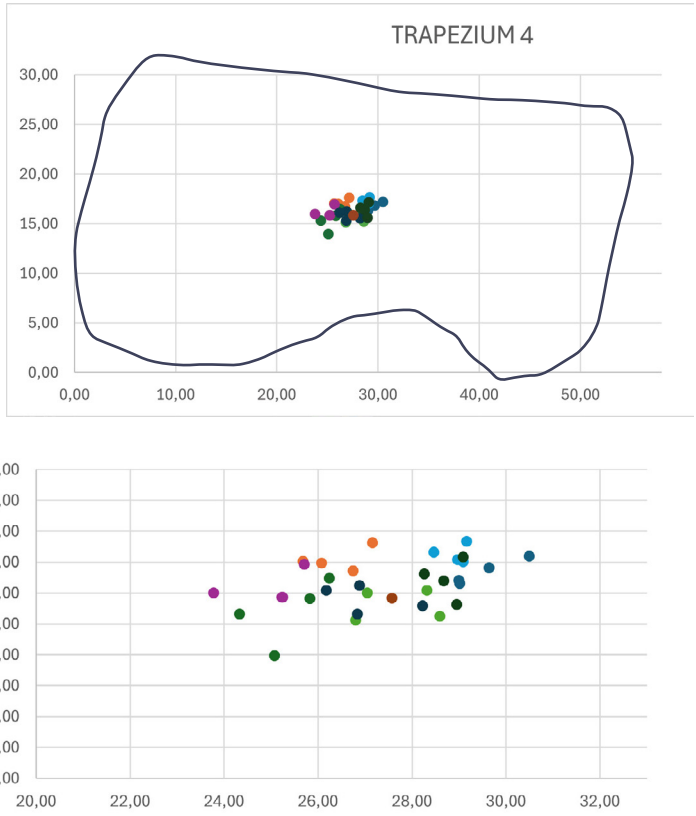


*Fig 69. Scatterplot for **Trapezium 4**: (Top) Alignment outcomes relative to the trapezium surface, (Bottom) Zoomed-in view highlighting variance among participants.*

Trapezium 4 resulted in moderate performance improvements over Trapezium 3. The standard deviation in x-coordinates was between 0,365-0,839 mm, whereas the standard deviation in the y-direction ranged from 0,298-1,060 mm.

Fig 69. Scatterplot for Trapezium 4: (Top) Alignment outcomes relative to the trapezium surface, (Bottom) Zoomed-in view highlighting variance among participants. shows a distribution pattern similar to Trapezium 3 but with slightly less dispersion. The zoomed-in view highlights deviations, particularly in the y-direction, with multiple points positioned at varying heights.

6.3.2 Validation test

Qualitative results

In addition to the quantitative data, qualitative feedback was gathered from participants regarding their experience using the ArC and centering guide. Participants expressed a need for better stability of the device, suggesting that the centering guide could be more securely fixed to prevent movement during use. This feedback was also provided by the doctors at RHOC and a potential solution has already been investigated.

Some found it necessary to use both hands to stabilize the burr, which felt unnatural. This is can be related to the heavy weight of the burr. Perspective and visibility were also a concern, as some participants preferred sitting directly in front of the arm rather than at the side, indicating that the positioning of the tool should accommodate different viewing angles. This is related to the inexperience of the participants, since they have no surgical background. Moreover, shadowing and laser scatter were mentioned as factors affecting precision, and some suggested improving the lighting to make the laser guidance clearer.

The learning curve was steep for some participants, particularly when transitioning between different trapezium models. However, most reported that their confidence improved with continued use. Some found they could operate the system more effectively per trapezium model.

Lastly, the laser functionality and horizontal alignment of the centering guide raised some concerns. While the vertical laser was effective, the horizontal laser line was less clear due to scattering, making it more difficult to determine the centre point accurately.

Additionally, the centering guide was found to be useful for ensuring perpendicular burring, but some participants found the resistance of the guide to be unnatural, preferring a more intuitive method of stabilization. Several suggested making the guide slightly more rigid to prevent unintended flexing during use. This was due to the fact that this model was made of PLA rather than the intended stainless steel.

Quantative results

The quantitative analysis of the test results for the concept focuses on the accuracy and precision of placing the centre point and the angles when drilling the k-wire. By evaluating the deviations in the X and Y coordinates and the angulation in the sagittal and frontal planes, it can be determined how well participants were able to achieve the desired positioning. For each measurement, the deviation of the centre point (X and Y coordinates) and angulation (sagittal and frontal planes) was calculated compared to the expected values, as shown in Fig 71. Quantative data: centre point, top plane, side plane.. These deviations were analyzed based on average the mean and (standard) deviations. Full results can be found in Appendix H: User testing.

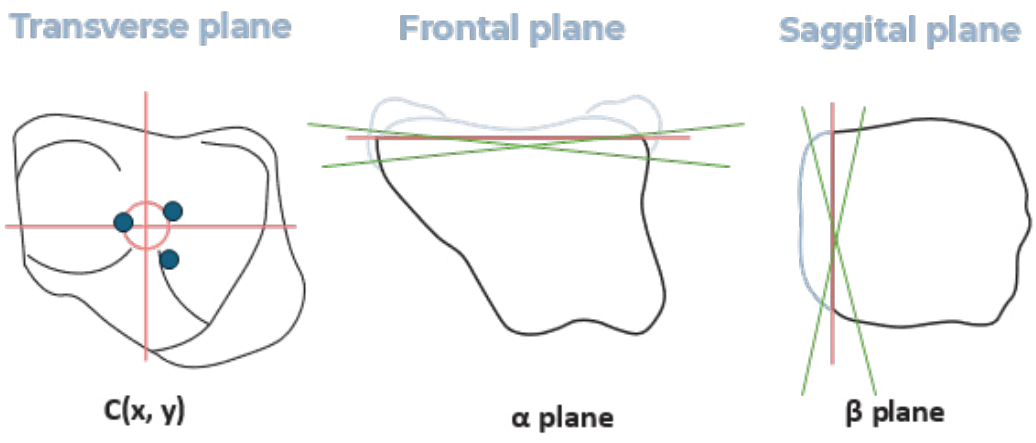


Fig 71. Quantative data: centre point, top plane, side plane.

Table 9. Actual trapezium measurements

	Actual centre point (x,y)	Actual sagittal and frontal planes
Trapezium 1	(8,57;4,53)	90 degrees
Trapezium 2	(8,48;4,75)	90 degrees
Trapezium 3	(8,89;4,61)	90 degrees

Overall analysis

The average deviation in the X coordinate was 0.67 mm, with a standard deviation of 0.62 mm. The Y coordinate showed a higher average deviation of 2.04 mm, indicating greater variability in vertical positioning. The sagittal angle showed an average error margin of 4.93 degrees, while the frontal angle had an average deviation of 6.23 degrees. The standard deviation of 12.17 degrees in the frontal angle suggests the most significant variation among participants.

The minimum deviation in X and Y coordinates was 0.08 mm and 0.30 mm, respectively, indicating that some participants performed with high accuracy. However, the maximum deviations reveal that others were significantly less precise, potentially due to differences in experience, technique, or the effectiveness of the centering guide.

The best-performing participant was Participant 3, with the lowest average total error of 7.83. This indicates that Participant 3 achieved the most accurate and precise placements in comparison to the expected centre points and angles.

Table 10. Average results of all measurements

	Mean	Standard deviation	Minimum deviation	Maximum deviation
X-error (mm)	0,67	0,62	0,08	1,50
Y-error (mm)	2,04	1,90	0,30	4,50
Sagittal error (°)	4,93	6,77	0,23	15,90
Frontal error (°)	6,23	12,17	0,33	39,30

Analysis per trapezium

The accuracy and precision of the drilling varied per trapezium model. Some models exhibited higher error margins in both coordinate placement and angular deviation, likely due to differences in surface structure or participant interaction. The data suggests that certain shapes posed greater difficulty in correctly positioning the center point, leading to variations in error magnitude.

Among the three tested trapezium models, Trapezium 3 exhibited the lowest average total deviation, making it the best-performing shape in terms of accuracy and precision. Participants were generally able to achieve closer center points and maintain better angulation with this model. Conversely, Trapezium 1 had the highest average total error, indicating that it was the most challenging for participants to work with. The results suggest that the surface geometry and structure of Trapezium 1 may have contributed to these difficulties, requiring more precise adjustments from the users. Trapezium 2 ranked in between, showing moderate levels of error across all metrics.

These findings highlight that variations in anatomical geometry significantly impact the ease of use and accuracy of the ArC and centering guide. Future improvements could focus on refining the adaptability of the system to different bone structures to enhance overall performance and usability.

Trapezium 1 showed the most significant outlier in the overall results, due to Participant 5. The inconsistency is likely related to the learning curve, as this participant initially struggled with the centering guide. However, a noticeable improvement was observed in their later attempts, indicating a progression in skill. Despite this outlier, Trapezium 1 remained challenging for the other participants, thus in line with the previously identified difficulty associated with its shape.

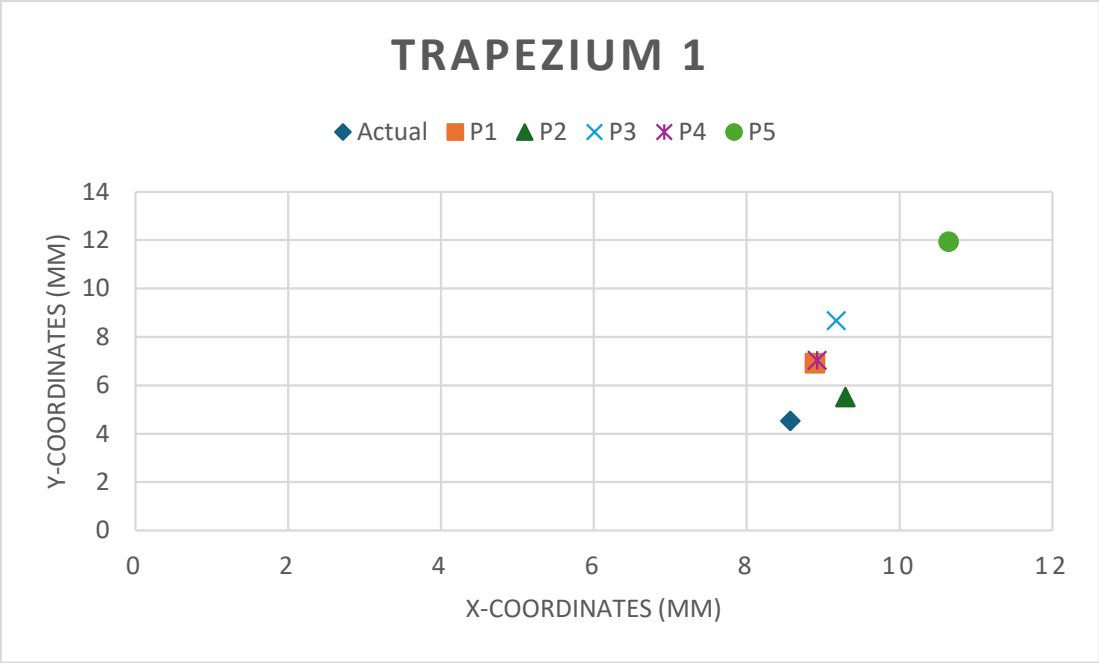


Fig 72. scatterplot results of trapezium 1.

Trapezium 2 showed moderate average errors, indicating a balanced level of difficulty compared to the other trapezium models. It showed less variability in results than Trapezium 1, suggesting that participants were more consistent in their placements and angulations. Additionally, the smaller range between the minimum and maximum deviation implies that most participants performed at a similar level. This can be related back to the flat and smooth surface of trapezium 2, making it easier for the participant to accurately place the laser.

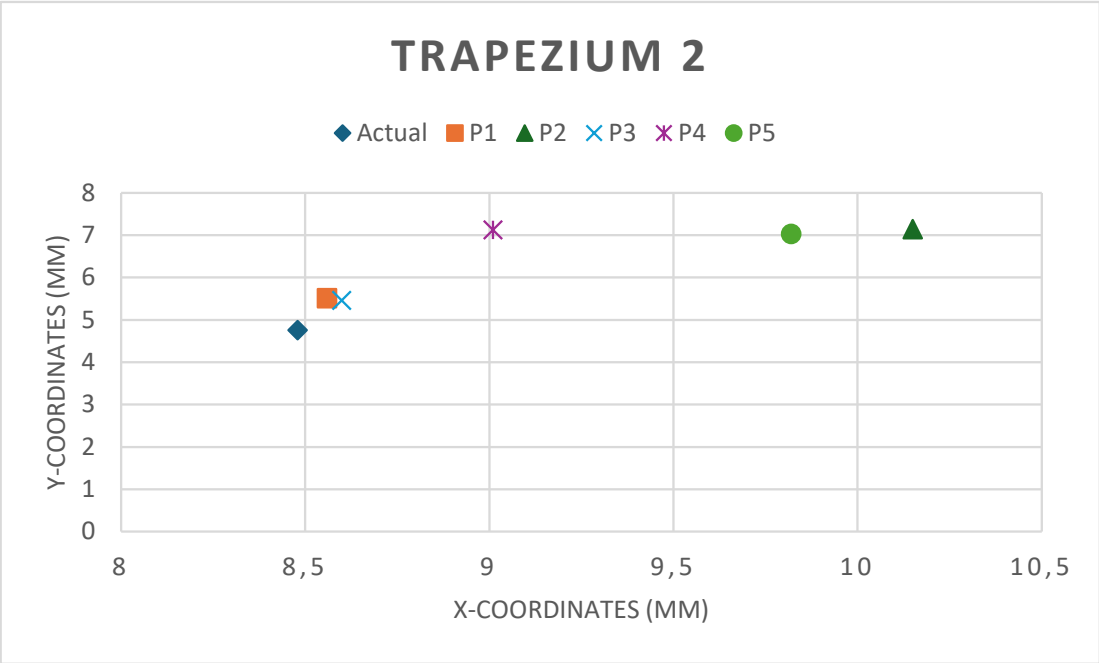


Fig 73. scatterplot results of trapezium 2.

Participants showed the best results, suggesting that its anatomical structure or orientation provided better guidance for correct positioning. Additionally, Trapezium 3 presented the least variation in deviations among participants, indicating that it was the most predictable and consistent to work with.

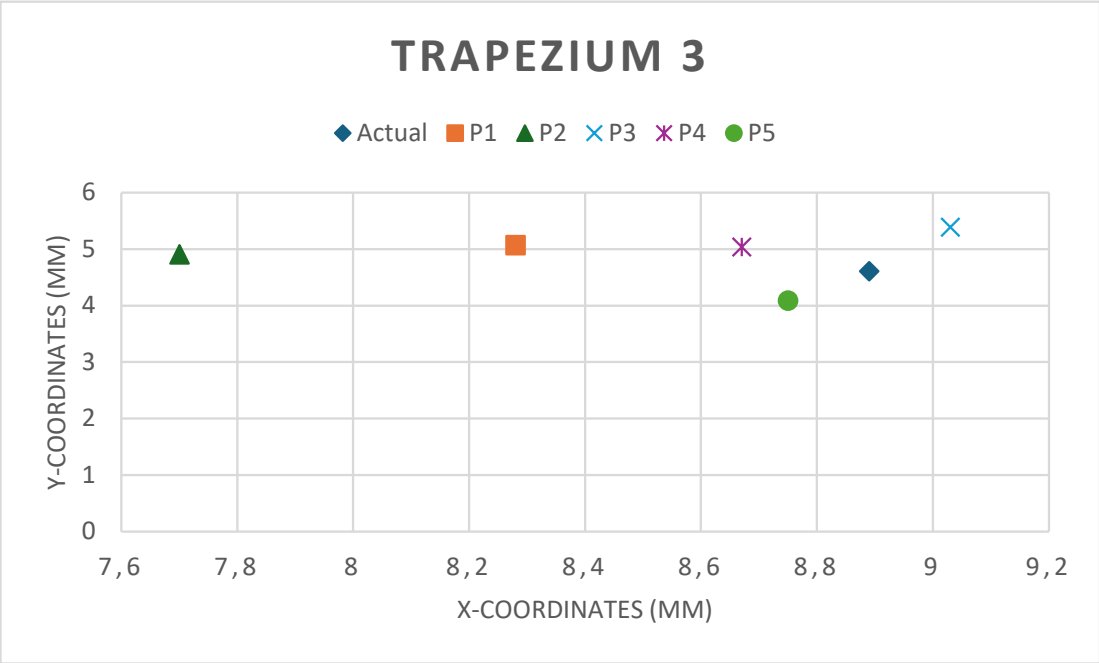


Fig 74. scatterplot results of trapezium 3.

6.4 Discussion

6.4.1 Feasibility test

The feasibility study provided valuable insights into the accuracy and precision of laser-guidance for k-wire placement, highlighting both its potential and its limitations. The results indicate that simpler, symmetrical trapezium shapes led to higher accuracy, while more complex and asymmetrical shapes introduced greater variability in placement. However, the use of the laser remained a challenge.

One of the key observations was that participant performance varied, suggesting that both individual skill level and shape complexity influenced accuracy. A learning curve was evident, as many participants improved their placements over multiple attempts. However, even with practice, some participants struggled to maintain consistency, particularly with Trapezium 3, which exhibited the highest mean deviations and standard deviations. The scatterplots confirmed these findings, with more concentrated points for Trapezium 1 and 2, while Trapezium 3 and 4 showed a wider distribution of placement errors.

A major limitation observed was stability and control. Since the laser guide was positioned on a ball-and-socket mechanism, some participants found it difficult to move the laser as wished. This instability contributed to larger deviations, especially in the x-direction, reinforcing the need for additional guiding mechanisms to improve horizontal alignment.

6.4.2 Validation test

The qualitative feedback aligns with the quantitative findings, showing that precision could be further improved with adjustments to the device's ergonomics and stability. Addressing visibility issues, refining the centering guide design, and providing clearer laser guidance would contribute to more consistent accuracy. Additionally, ensuring a smoother user experience through minor design tweaks may further optimize the effectiveness of the ArC.

The participant data suggests that while initial performance varied, most participants showed improvement over time, indicating that training and familiarization play a crucial role. This underscores the importance of instructional materials and user guidance in the implementation of the ArC.

Participants

The participant pool consisted of novice users (students) with no prior experience with the ArC or similar surgical tools. This provided insights into how quickly users could adapt to the system. Several novice participants struggled with the initial placements but showed improvement over time, supporting the presence of a learning curve.

Originally, the study aimed to validate the concept through testing with surgeons. However, due to limited time of the surgeons, they were only available for interviews and were unable to participate in the test.

Materials

The PLA trapezium models have a smoother surface compared to actual bone, causing inexperienced participants to struggle with maintaining stability, as the burr tended to slip off. However, a steep learning curve was observed, with participants improving over time.

Additionally, the burr used in testing was heavier than the actual surgical burr, which may have affected handling and accuracy during the experiment. For some participants, the increased weight made it difficult to position the burr at the correct angle, as they struggled to maintain precise control.

Learning curve

The analysis of participant performance based on drilling order indicates that a learning curve may have influenced precision. Initially, participants showed greater deviations, but their accuracy improved with subsequent attempts. Interviews with participants confirmed this trend, as many noted that they lacked a clear approach at first but gained confidence after repeated trials.

6.5 Conclusion and recommendations

6.5.1 Feasibility test

Answering the research question on the accuracy and precision of freehand laser placement, the feasibility test demonstrated that results varied depending on the complexity of the trapezium shape. Simpler anatomical structures allowed for more consistent placements, whereas more complex and asymmetrical shapes led to greater variability. Positioning of the laser was generally more precise in the vertical direction than in the horizontal direction. While the system improved overall accuracy, the challenges defined in the discussion still remain.

The scatterplots support these findings, showing tight clustering of points for simpler shapes and more scattered distributions for complex geometries. Participants encountered the most difficulty with asymmetrical surfaces, where larger deviations were observed, especially in the vertical direction. Additionally, some participants struggled to maintain control over the laser positioning, which was influenced by the weight of the burr and the absence of guiding mechanisms.

The research question regarding the degrees of freedom required or desired for laser positioning was also addressed. The test identified two key degrees of freedom essential for accurate laser placement:

- Translational movement (horizontal and vertical): necessary for aligning the laser in the correct position.
- Angular adjustments: aiding the user in their approach to follow anatomical landmarks or lines.

Reproducibility of the results was moderate, with results varying based on participant experience and trapezium shape. Simpler, symmetrical surfaces led to more consistent results, whereas complex structures introduced greater variability. A learning curve was observed, as participants improved their placements over multiple trials, suggesting that training plays a role in increasing precision.

To optimize the use over laser guides in surgery, improving laser stability, integrating guiding mechanisms, and addressing laser reflection issues will be necessary. Further testing with experienced surgeons is needed to validate usability and refine the system for surgical workflows. By addressing this, laser-guided k-wire placement can become a reliable tool for enhancing surgical accuracy.

6.5.2 Validation test

Answering the research question "**Can users achieve an accuracy and precision of ±1mm using the frame and optimized centering guide**?", the validation test demonstrated that while the ArC system and centering guide provided structured k-wire placement, accuracy and precision varied among participants. **40% of the placements met the ±1mm accuracy threshold**, indicating that some users were able to achieve the required precision. However, variability in performance suggests the need for further advancements in stability and guidance mechanisms. **Larger deviations in the y-coordinate** highlighted challenges in vertical alignment, which could be related to the steep angulation of the laser with respect to the trapezium.

Regarding the research question "**Does the optimized centering guide assist users in drilling at the correct alpha and beta angles**?", results indicated that the guide was **helpful in achieving perpendicular burring**, but some ergonomic limitations affected usability. While the centering guide provided structural assistance, **frontal angulation control varied among users**, suggesting that additional stability improvements are necessary. Participants also noted that maintaining the correct angles was challenging due to scatter in the horizontal laser line and difficulty in achieving a clear perpendicular perspective.

The research question "**How effective is the interaction for adjusting the laser's angle and position using the frame?**" revealed mixed user experiences. While participants generally found the vertical laser effective, the horizontal laser line suffered from scatter, making alignment less intuitive. A steep learning curve was observed, with participants gaining confidence as the test progressed. Additionally, variability in perspective preferences was noted, with some preferring a frontal view of the arm, while others favored a side view, suggesting that the positioning of the frame and laser system should accommodate different user perspectives for optimal alignment and usability. This can be related back to the fact that the participants have no surgical experience, so being positioned to the sides of the table feels unnatural.

The following design takeaways can be taken into account to further develop the concept:

- **Perspective and visibility**: raising the arm could improve visibility of the trapezium and enhance control during drilling.
- **Ease of use and learning curve**: While the system was not initially intuitive, user control improved with repeated attempts.
- **Laser functionality and horizontal alignment**: the vertical laser was effective, but the horizontal laser suffered from scattering, making alignment difficult. A more precise locking or guiding mechanism could help.
- **Burring guidance:** additional securing methods (such as fixation with the fork retractor) are needed to minimize movement of the centering guide.

6.3 Validation interviews with surgeons

To further evaluate the potential of this concept, two surgeon were interviewed at RHOC. Both surgeons are specialised and the hand and wrist and had no previous knowledge of the concept. During the interviews the concept was placed on the table and the surgeons were asked to engage the prototype and simulate the actual surgery. These interviews provided insights which are divided into the five topics below.

The role of the laser in surgery

The laser poses as a visual reference for surgeons, aiding in alignment verification and the precise positioning of the prosthesis. One surgeon noticed that this concept could have the potential to reduce subjective estimations by making the surgical process more consistent and reproducible across different procedures.

Surgeons particularly appreciated that the laser serves as a reminder to carefully consider the anatomy and approach before proceeding. It encourages them to analyze bone structures and alignment more thoroughly, enhancing decision-making during the procedure. Furthermore, the remaining laser line could not only used for positioning the prosthesis but also serves as a guideline for aligning with the metacarpal.

However, the system still presents challenges and limitations. The laser does not autonomously determine the exact centre point, meaning surgeons must still rely on manual adjustments to ensure proper placement. While this requires additional decision-making, it was not unanimously considered a disadvantage, as some surgeons valued the autonomy to assess and refine placement based on individual patient anatomy.

Additionally, osteophytes and bone deformations caused by osteoarthritis can distort laser markings. This can result in false determination of the middle. When the surgeons were asked to determine the middle with help of the laser, they seemed to feel the need to tilt their head to the level of the laser. However, this could also be related that the surgeon usually wears magnifying glassed to observe the structure of the trapezium.

Fixation of the frame: patient versus table

The topic of frame fixation was discussed in both interviews, with surgeons sharing their preferences on whether the frame should be attached to the patient's arm or the operating table for improved stability. Interestingly, the opinions were divided. One surgeon favored attaching the system to the arm emphasizing that this approach ensures stability during drilling and prevents unintended movement of the limb. In contrast, the other surgeon preferred fixating the frame to the table, arguing that over-fixation of the arm could restrict movement and potentially reduce the ergonomics for the surgeon.

The current model offers a hybrid solution, allowing the baseplate to be secured to either the table or the patient. This flexibility enables surgeons to adjust the setup according to their individual workflow, ensuring both stability and adaptability during the procedure.

Placement of the prosthesis

According to one of the surgeons the preferred angulation of the k-wire is not actually perpendicular to the surface but perpendicular to the SST-joint. However, the joint is not visbile during surgery, so x-rays are made to confirm the position. What the actual correct position should be, needs to be further investigated with biomechanical research of the thumb. However, for this thesis the hypothesis is that the correct angulation of the k-wire is perpendicular to the trapezium surface.

Surgical accessibility and obstruction of the surgical field

The ability to move the frame away when not in use was well received by the surgeons. However, both agreed that the product should be able to move away in multiple directions, rather than solely to the side of the patient, to provide greater flexibility during surgery.

In addition to discussing the placement of the device when not in use, the surgeons also provided feedback on its ergonomics during potential surgery. While they acknowledged that the product could potentially obstruct the surgical field, they did not feel this obstruct much in its current design. However, they noted that improper positioning of the laser setup could interfere with drilling, highlighting the importance of ensuring optimal placement to maintain an unobstructed working area.

Sterilisation

The sterilization of the frame remains a significant challenge in the current design. Since the product requires direct interaction from the surgeon to rotate it into passive mode or to adjust the laser position along the y-axis, there is a risk of contamination. Given that surgeons aim to minimize physical contact with the device during the procedure, exploring alternative interaction methods, such as foot controls, motion sensors, or sterile drape-friendly adjustments, may be necessary to enhance usability while maintaining strict sterilization protocols.

7.

Recommendations

This chapter provides recommendations for further development and embodiment of the laser-guided surgical instrumentation for thumb joint arthroplasty. Based on the evaluation and validation tests, key areas of improvement have been identified in terms of accuracy, usability, ergonomics, and implementation. These recommendations focus on further embodiment of the current concept and show a roadmap to successful integration into clinical practice.

7.1 Enhancing accuracy and precision

The feasibility study and usability testing demonstrated that laser-guided surgery has the potential to improve k-wire placement. However, some inconsistencies were observed in user precision, particularly in the x-direction. To further improve the accuract and precision the following steps can be taken

- **Refinement of laser positioning mechanism**: the laser alignment system should incorporate a more stable positioning mechanism, by fine-tuning the laser.
- **Reduction of laser scattering**: reducing scatter of the laser is crucial. Therefore, further testing with professional lasers and on actual trapezium bone should be done.
- **Optimizing the laser angle**: current testing indicated that the horizontal laser angle may be too high, leading to inconsistencies in alignment. Adjusting the laser to a lower angle and refining the projection method may improve usability. The optimal angulation of the laser should be further invesitgated.

Instead of relying solely on the surgeon's manual estimation of the centre point, a hybrid system could be developed, combining sensor technology, machine learning, or augmented reality (AR) to assist in identifying the true centre point of the trapezium. This approach could reduce human estimation errors, enhance precision, and further standardize the placement process across different surgeons. A smart centre point detection system could be integrated, for instance infrared depth mapping, computer vision, or AI models trained on preoperative imaging (MRI or CT scans) to assist in k-wire positioning. Lastly, real-time augmented reality overlays using AR headsets or on-screen projections could be used to provide precise alignment data.

7.2 Embodiment of the ArC

While the usability testing showed promising results, there is still potential for embodiment and improvement of the concept:

- **Investigate trade-off between angulation of the laser and the visibilty of the surgeon**: one key finding from the validation test was the scattering of the horizontal laser line. While material properties also may have affected this issue, the steep laser angle is also a likely factor. To address this, the optimal laser positioning must be determined to minimize scatter while maintaining clear visibility for the surgeon.
- **Enhancing robust deisng and shock resistance**: the newly push-button system and ball detent locking mechanism have been integrated into the model after the validation test. Therefore, these features have yet to be validated. Impact and stress testing should assess durability, ensuring the system remains stable and resistant to unintentional displacement.
- **Elevating the hand for better visibility and control**: during usability testing, participants noted difficulties in analyzing the trapezium bone's structure from a top-down perspective. Elevating the patient's hand could provide a better angle for visualization, reduce strain on the surgeon's wrist, and improve control during drilling. This could be achieved using an adjustable support system integrated into the surgical table.

7.3 Embodiment of the centering guide

The centering guide plays a crucial role in ensuring correct angulation of the k-wire. While the optimized guide improved alignment in testing, further refinements are necessary:

- **Further testing with a stainless steel model**: it should be investigated whether the metal centering guide causes more scatter of the laser or not.
- **Improved stability**: users suggested the addition of a stable point where the centering guide could lean on. A potential concept for this is to make use of the fork retractor and 'lock' the centering guide into it. A quick set-up can be seen in Fig 75. Integration of the centering guide with the fork retractor for additonal stability.
- **Additional reference of the trapezium cup**: the original centering guide informed the surgeon about the space the trapezium cup would occupy on the trapezium's surface. While some surgeons find this feature reassuring, its necessity into this design requires more investigation and evaluation.

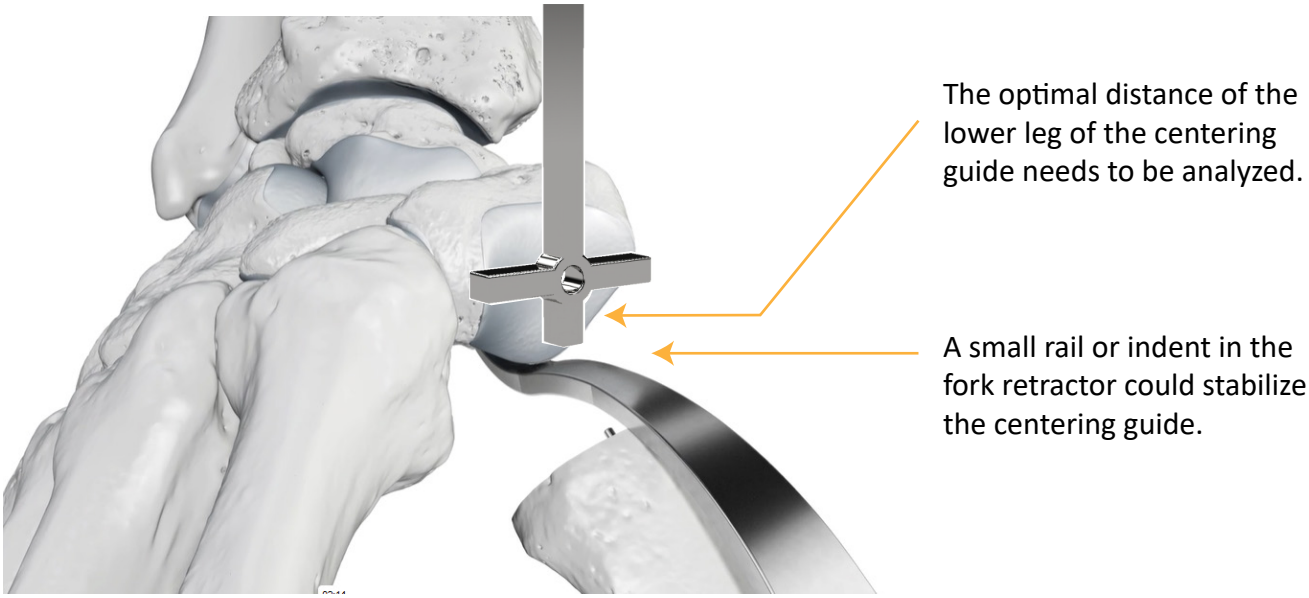


Fig 75. Integration of the centering guide with the fork retractor for additonal stability.

7.4 Surgical workflow integration

For the laser-guided system to be adopted in real-world surgical settings, it must integrate into the operating room environment:

- **Sterilization considerations**: the system must comply with sterilization protocols, ensuring that all components can be efficiently cleaned without degradation. These regulations needs to be further analyzed. For stainless steel it is known that autoclaving is possible, however, for PEEK it should be further investigated.
- **Minimizing obstruction in the surgical field**: some surgeons expressed concern about potential interference with their workflow. The design should prioritize minimal intrusion while maintaining precision.
- **User training**: since laser guidance introduces a new methodology within this surgical procedure, designing and providing training sessions for surgeons will be necessary to ensure proper use and maximize benefits.

7.5 Future research

While this thesis focused on the intra-operative phase, additional research could further improve outcomes in thumb joint arthroplasty:

- **Biomechanical validation**: determine the actual centre point that needs to be used for a ball-and-socket prosthesis.
- **Long-term clinical testing**: clinical trials with experienced surgeons should be conducted to validate the effectiveness of the system.
- **Potential for smart centre point detection system integration**: while laser guidance improves precision, other technologies may further enhance visualization. Future iterations of the system could explore the feasibility of overlaying patient-specific anatomical data in real-time.

7.6 Roadmap: from concept to clinical use

In order to integrate the implementation of the proposed improvements, a structured roadmap has been developed, divided into three key phases: **Embodiment, Validation, and Implementation**. Each phase consists of multiple stages to facilitate continuous refinement and integration of changes. Additionally, further research is required to enhance the product, including the long-term performance of the prosthesis, which remains unavailable at this stage.

Phase 1

Embodiment and further prototyping (0-6 months)

Goal: improving the existing concept based on further research and testing to optimize accuracy, precision, ergonomics, and workflow integration.

Stage 1

Improve the laser system for accuracy. **Chapter 7.1**

- Fine-tune placement of the y-coordinate.
- Investigate optimal laser specifications.

Stage 2

Improve embodiment of the ArC. **Chapter 7.2**

- Investigate trade-off angulation laser and visibility surgeon.
- Improve robust design.

Stage 3

Improve embodiment of the centering guide. **Chapter 7.3**

- Improved stability.
- Integrate trapezium cup size into design.

Stage 4

Improve ergonomics and usability. **Chapter 7.2**

- Investigate repositioning of the hand by elevation.

Future research topics

Topic 1

Biomechanical studies of correct positioning of the k-wire. **Chapter 7.5.**

Topic 2

Investigate a smart detection system to integrate with the product. **Chapter 7.5.**

These topics should be researched throughout all phases to optimize the concept even further.

Phase 2

Validation and clinical testing (6-18 months)

Goal: validate the system with cadaver studies and in accordance with the ISO standards.

Stage 1

Preclinical testing and performance validation. **Chapter 7.5**

- Cadavar studies with the concept.

Stage 2

Sterilization and material testing.

Stage 3

Surgeon training and workflow optimization. **Chapter 7.4**

Stage 4

Application for for approval and CE marking.

Phase 3

Implementation

Goal: clinical validation and preparation for implementation.

Stage 1

Long-term testing of the product. **Chapter 7.5.**

Stage 2

Integrate the ArC into the surgical instrumentation set of Keri Medical.

8.

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