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Oxford® Partial Knee

Cementless Implantation

Surgical Training Simulator

FOXPAT

Master Thesis

NITHIN GURRAM

Foxpat

Training simulator for
Cementless Oxford Partial Knee Replacement Surgery

4745736
Nithin Gurram

Graduation thesis
MSc in Industrial Design Engineering with specialization in
Integrated Product Design(IPD)

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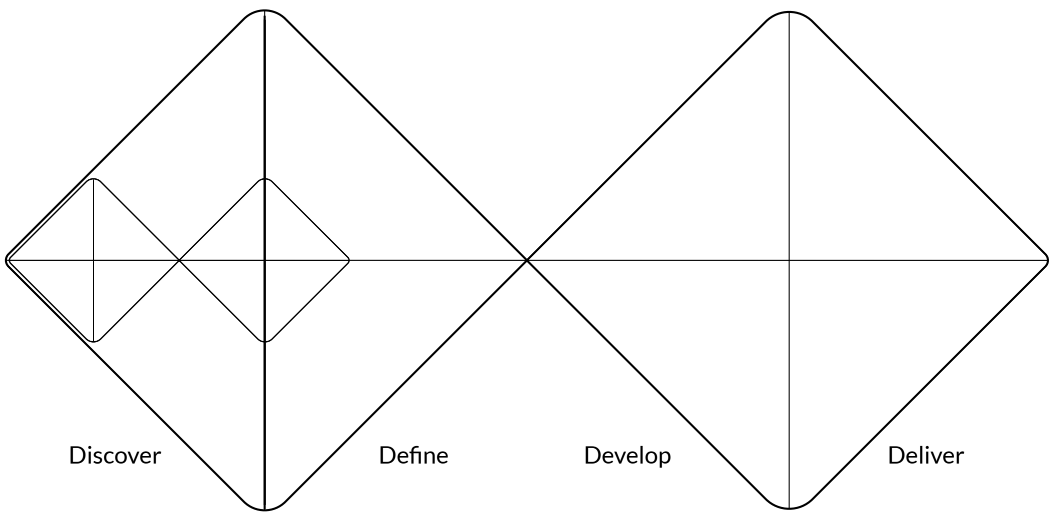
EXECUTIVE SUMMARY

This project was started as a part of Hipp project which is a collaboration between Zimmer Biomet and TU Delft. Cementless Oxford Partial Knee Replacement (PKR) was one of the most successful products of Zimmer Biomet over the past 10 years. The company offers a unique training course for surgeons specifically interested in the Oxford Partial Knee. Zimmer Biomet approached TU Delft for developing a training tool that allows surgeons to more realistically experience implanting the Cementless Oxford PKR ahead of surgery. With my interest in Healthcare and having a mechanical engineering background this project provided a great fit to my interests and would be challenging as well. One of the requirements of this project was to have a manufacturable design and the company quickly wants to procedure it in a large number. Zimmer Biomet plans to use the outcome of this project to train the surgeons across the world. Particularly as they are currently preparing for the launch of Cementless into the US market. To make sure the final design deliverable is foolproof, the project was carried out in two phases. During the first phase I developed a quick iteration of design and tested this with a group of surgeons. During the second phase, the final design development took place.

PROJECT STRUCTURE

The project was carried out in two different phases. During the first phase of the project, a quick prototype was made and tested with a group of users. This has helped me to understand the practical requirements of the product. The research inputs that were carried out combined with the feedback from the first phase to develop a final manufacturable design. When viewing the project from a double-diamond perspective, the first phase could be represented as a smaller double diamond inside a bigger one. The first phase can be considered as a part of the 'discover' phase for the bigger diamond. Along with the first design iteration outcomes, the discovery phase has also considered other research input to define the final product. Thus, a concrete product definition was established before developing the final design.



GLOSSARY

Anterior and posterior	Front and back
Anti-impingement	Avoiding the bone-implant interference
Condyle	A rounded protuberance at the end of some bones, forming an articulation with another bone.
Cementless fixation	Fixing the implant to the bone without any cement
Femoral component	The part of the implant that is attached to femur
Femur	The bone of the thigh
Flexion	Bending or closing the knee joint
Impaction	Hitting an implant with a mallet
Impactor	The tool used to impact an implant
Implant	The artificial knee joint that is inserted into the body
Implantation	The process of inserting and fixing the implant inside the body.
Incision	A hole or a cut made on the skin to reach the bones
Inserter	The tool used to insert the implant into incison
Insertion	The process of inserting the implant using an inserter
Learning curve	The rate of a person's progress in gaining experience or new skills.
Novice surgeons	Surgeons with no or minimal experience
OXMP	Oxford Microplasty instrumentation
Knee Replacement	A surgical procedure to replace the weight-bearing surfaces of the knee joint to relieve pain and disability. It is most commonly performed for osteoarthritis, and also for other knee diseases such as rheumatoid arthritis and psoriatic arthritis
Oxford PKR Training	A training course provided by Oxford surgeons to train the young surgeons to do the surgery.
Sawbones	Polyurethane bones used for training the novices surgeons. These are dummy plastic bones made out of polyurethane
Soft tissue	The skin, fat, muscles and other body tissues that surround the bones.
Tibia	The bone of lower limb/leg
Tibial component	The implant that is attached to tibia
Valgus	A Varus deformity is an excessive inward angulation of the distal segment of a bone or joint
Varus	The opposite of Varus is called valgus. The terms Varus and Valgus always refer to the direction that the distal segment

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RESEARCH

CHAPTER 1. SECTION 1

INTRODUCTION

Oxford Knee Replacement is a world renowned artificial knee reconstruction. The research for this project has begun with understanding why has it been such a successful knee replacement technique so far. This section includes the brief history of Oxford Knee Replacement, Cementless Oxford Knee implant and its components, Oxford Microplastic Instrumentation, Oxford Knee group and Oxford training course.

BACKGROUND

Every year, more than 2 million patients receive Total Knee Replacement (TKR) worldwide, while in fact almost half of those might qualify for a Partial Knee Replacement (PKR). If only one compartment of the knee is damaged, then PKR could be a viable surgical option. With the correct indications, PKR can offer patients superior outcomes[1], satisfaction, and fewer, less severe complications, than the more widely used TKR[2].

OXFORD KNEE REPLACEMENT

The Oxford Partial Knee is the natural evolution of the original meniscal arthroplasty, which was first used in 1976. Its design continues to offer the advantage of a large area of contact throughout the entire range of movement for minimal polyethylene wear. Since 1982, the Oxford Partial Knee has been successfully used to treat anteromedial osteoarthritis. The benefit of PKR to the patient is that it provides better outcomes and a lower risk of complications than TKR[3]. Zimmer Biomet's Oxford Partial Knee is the most widely used partial knee in the world. One of the main barriers of wider adoption is the higher revision rate of PKR compared with TKR found in registries.

HISTORY OF OXFORD KNEE

Mr. John Good fellow and Professor John O'Connor developed the Oxford PKR. In 1966 Prof. O'Connor who was a lecturer of Engineering Science at the University of Oxford unexpectedly met with Mr. Goodfellow, an orthopedic surgeon and researcher at the Nuffield Orthopedic Centre. Combining their knowledge of the human body and engineering they created a much awaited knee replacement that is long lasting and reliable. Ten years later they implanted a first implant in a patient in June 1976, using it as a TKR. From 1982 Oxford PKR has been exclusively used a PKR. During the early 1990's Prof. David Murray, now a Consultant Orthopedic Surgeon at the Nuffield Orthopedic Centre and Manor Hospital, arrived in Oxford to learn about the Oxford PKR from Mr. Goodfellow. Prof. Murray, together with Prof. O'Connor, Mr. Goodfellow, and Mr. Chris Dodd went on to develop Oxford Phase 3 (1998) and subsequently Oxford Microplasty Instrumentation (2011) in collaboration with Zimmer Biomet.

1. UNIVERSITY OF OXFORD. (2019, July 17). Increased use of partial knee replacement could save the NHS £30 million per year [Press release]. Retrieved July 28, 2019, from https://www.eurekalert.org/pub_releases/2019-07/uoo-iuo071719.php

2. Limited, B. U. (n.d.). Oxford® Partial Knee. Retrieved from https://www.zimmer-biomet.com/medical-professionals/knee/product/oxford-partial-knee.html

3. Wang, H., & Rolston, L. (2012). The influence of partial knee replacement designs on tensile strain at implant-bone interface. International journal of rheumatology, 2012, 607872. doi:10.1155/2012/607872

CEMENTLESS OXFORD PARTIAL KNEE

Cementless Oxford Partial Knee is the implant used on Cementless Oxford PKR surgery. The radiolucent lines are a common phenomenon in knee replacement, and particularly in PKR. When a patient reports pain, these radiolucencies can be misinterpreted as indicating that the components are loose, leading to unnecessary revisions. Cementless fixation has shown a great reduction of radiolucency without compromising the outcome. National Registry data from New Zealand and England and Wales suggests that the revision rate of the cementless Oxford PKR at 5 years is about half that of the cemented Oxford PKR.

Eliminating cement has the following additional advantages:

- Saves time and reduces cost
- No cost for cement and cement accessories
- Removes the risk of retained cement, which may increase wear of the polyethylene bearing (3rd body wear, impingement, etc.)

As in figues 1, the cementless Oxford Partial Knee consists of three components femoral component, tibial component and meniscal bearing.

Tibial component
The tibial component is the bottom most component that is fixed to the tibia. It is made of cast cobalt chromium molybdenum alloy and comes in six sizes handed right and left. For the cementless Oxford PKR, the bottom protrusion keel press fits into the tibial slot. The inferior surface of the tibial component and keel have the rough porous structure from titanium plasma spray (PPS) to allow for bone ingrowth. The PPS is further coated in hydroxyapatite (HA) to encourage bone ingrowth. The tibial superior surface is highly polished for the lowest friction for bearing movement.

Meniscal bearing
The bearings are made of direct compression molded ultra-high molecular weight polyethylene, sterilized in inert argon gas. There are 5 sizes of bearing to match the radii of curvature of the 5 sizes of femoral components. For each bearing size there is a range of 7 thicknesses from 3mm to 9mm. The current instrumentation platform for Oxford (Oxford Microplasty Instrumentation, OXMP) allows a surgeon to target either a 3 or 4 mm bearing during the first steps of the surgery.

Figure.1 Cementless Oxford Partial Knee Implant

Femoral component
The "top" component of the implant, which is fixed to the femur, is a single radius spherical component made of cobalt chromium molybdenum alloy. The femoral component is highly polished to optimize wear resistance of the polyethylene. The femoral components come in 5 sizes to ensure optimal of different patient morphologies. The two pegs projected from in inner spherical surface are inserted into the femur. For the cementless Oxford PKR, the inner surface is sprayed with PPS and HA, with the exception of the two pegs which remain uncoated. The appropriate size of femoral component is chosen preoperatively by overlaying templates on a lateral radiograph of the knee, or by using a height-gender matrix.[4]

OXFORD MICROPLASTY

OXMP are the surgical tools used for the implantation of the Oxford Partial Knee. This simplified instrumentation, showed a reduction in OR time of almost 9 minutes[5] compared to the previous instrumentation platform. Oxford Microplasty instrumentation has also been shown to reduce the risk of bearing dislocation[6] compared to the other instrumentations and improve the reproducibility of implant positioning and resection levels. As shown in figure2, OXMP takes place in 5 major steps; Tibial Preperation, Femoral Preperation, Ligament Balancing, Anti-Impingement and Implantation.

4. Fawzy, E., Pandit, H., Jenkins, C., Dodd, C. A., & Murray, D. W. (2008). Determination of femoral component size in unicompartmental knee replacement. The Knee, 15(5), 403-406. doi:10.1016/j.knee.2008.05.011

5. Berend, K., Hurst, J., Morris, M., Adams, J., & Lombardi, A. (2015). New Instrumentation Reduces Operative Time in Medial Unicompartmental Knee Arthroplasty Using the Oxford Mobile Bearing Design. Reconstructive Review,5(4), 19-22. doi:10.15438/rr.5.4.126

6. Koh, I., Kim, J., Jang, S., Kim, M., Kim, C., & In, Y. (2016). Are the Oxford ® medial unicompartmental knee arthroplasty new instruments reducing the bearing dislocation risk while improving components relationships? A case control study. Orthopaedics & Traumatology: Surgery & Research, 102(2), 183-187. doi:10.1016/j.otsr.2015.11.015

Step1: Tibial Preperation
After making the incision, the first step is to remove the Osteophytes. Then the tibial resection takes place by performing vertical and horizontal saw cuts on the tibia.

Step 2: Femoral Preperation
The Intra medullary rod is inserted during this step to position the femoral drill guides. Femoral saw cuts are first performed and then using a right spigot, the femoral condyle is milled.

Step 3: Ligament Balancing
During this step, the knee joint is extended and flexed to ensure the flexion and extensions gaps are equal. If not, a second milling is performed according to the difference of gap from flexion to extension.

Step 4: Anti-impingement
The posterior and anterior Osteophytes are removed from femur to reduces the risk of impingement of bone against the bearing in full extension and full flexion.

Step 5: Implantation
Lastly, keel cuts are made on the tibial condyle to insert the tibial implant. The implant is impacted using a tibial impactor to ensure proper fixation. The femoral component is placed and impacted using a femoral impactor. A trial bearing is inserted to check the tension and swapped with an actual bearing.

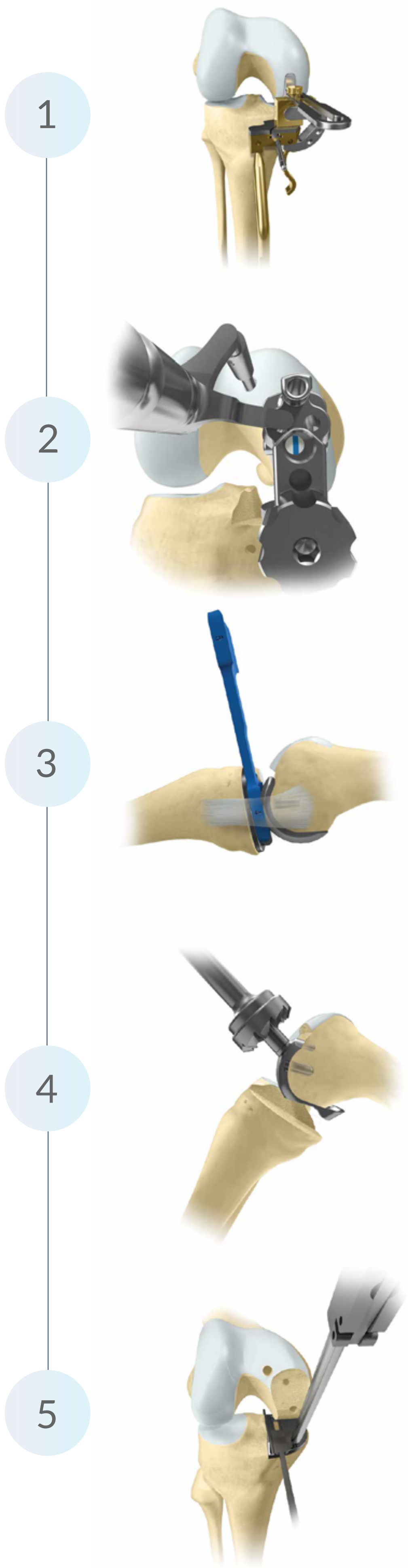


Figure 2. Oxford Microplasty Instrumentation

OXFORD KNEE GROUP

7. Oxford Knee Group - Our Team. (n.d.). Retrieved from https://www.oxfordknee-group.com/our-team

For the last 40 years the Oxford PKR has seen a number of innovations, including the application of minimally-invasive surgery. Additionally, since its initial use in 1976, the Oxford has been studied in great detail, and is currently the most widely publicized PKR in the world. The combination of excellent results and the new minimally-invasive approach stimulated great interest in the Oxford PKR. Mr. Goodfellow, Prof. Murray, Mr. Dodd, and a number of other experienced Oxford PKR users, started teaching surgeons around the world how to identify the correct patients and the correct use of the instrumentation. Currently[7], the Oxford group involve Prof. David Murray (fig. 3), Mr. Christopher Dodd (fig. 4), Prof. Andrew Price (fig. 5), Mr. William Jackson (fig. 6), Mr. Nicholas Bottomley (fig. 7) and Abtin Alvand (fig. 8). The group of surgeons based in Oxford UK, and who actively use the Oxford PKR, are often referred to as the Oxford Knee Group. All of the surgeons practice within the NHS at the internationally renowned Nuffield Orthopedic Centre. The group have a particular expertise in the Oxford PKR, and use it in over 50% of their patients. The group is involved in training other surgeons both nationally and internationally on all aspects of the Oxford PKR.

Figure 3. Prof. David Murray

Fig.4. Mr. Christopher Dodd

Figure 5. Prof. Andrew Price

Figure 6. Mr. William Jackson

Fig. 7. Mr. Nicholas Bottomley

Figure 8. Mr. Abtin Alvand

OXFORD PKR TRAINING

8. Oxford Partial Knee Training Course [Advertisement]. (2018, October 01). Zimmer Biomet TV. https://zimmerbiomet.tv/videos/1649?a=surgeon

Oxford PKR training is offered to surgeons who are starting with Cementless Oxford PKR, or who would like a refresher. During the early 80s and 90s surgeons in different countries were using different indications and different techniques to perform the procedure, and consequently achieved different outcomes.[8] The Oxford Instructional Course brings surgeons together to learn the correct surgical technique and patient selection. The course is didactic, and walks the attending surgeons focuses on patient selection and surgical technique. It includes an opportunity for surgeons to perform the surgical steps on sawbones, which simulates the surgical setting . The instructional course ends on the second day after a live surgical demonstration followed by discussions, a few more closing topics, and a quiz. More than 2,000 surgeons are trained at over 15 Oxford Instructional Courses around the world each year.

Figure 9. Oxford Training course[8]

CHAPTER 1. SECTION 2

FIELD RESEARCH

As part of the research, live surgeries were observed at different Hospitals. This has helped in understanding the difference between the training session and an actual surgical procedure. The first visit was to Haga Ziekenhuis in The Hague. The second visit was to the Oxford city where the Oxford Knee Group perform the Oxford Knee Replacements. The second field visit includes observation of two live surgeries performed by the surgeons of Oxford Knee Group.

HAGA ZIEKENHUIS

Design methodology
User observations[32] helps to study what do the intended users do in a specific situation. Observations enable to understand phenomena, influential variables or other elemental interrelation in 'real life'. In this case, in an operation theatre.

The first in-field visit was an observation of two Cementless Oxford PKR procedures at the Haga Ziekenhuis in The Hague, The Netherlands. Both the procedures were performed by Dr. Sander Spruijt and assisted by his fellow surgeon Wouter Eilander. Before the start of each surgery, Dr. Spruijt walked me through the radiographs and discussed patient selection. The surgeons depends on three types of feedback:

- visual
- haptic, and
- auditory

Not all the all the three senses have an input at every stage. For example, when inserting the implant, the inserter is first hit on the front face to move into the joint and once the tip of inserter reaches the posterior part of tibial cut, the inserter is hit on the top. In such case there is no visual cue about proximal reach. The surgeons depend on the impact resistance and change of impact sound.

The visit has been summarised as the key observations listed below and a more detailed overview can be found in Appendix B.

Key observations

- *The actual surgical workspace has very limited visibility and less freedom to move the instruments around.*
- *After sizing, the surgeon communicates his decision of implant size to the whole team and the scrub nurse arranges everything accordingly.*
- *It is quite harder to do the tibial recut in patients with high bone mineral density.*
- *Dr. Spruijt prefers applying many smaller impacts over few larger impacts*
- *There were more impacts on the inserter than on the impactor, and 70% the impacts are given from the front and only 30% were from top*
- *Visual, Haptic and Auditory senses together feedback the surgeons during operation*

Figure 10. Dr. Sander Spruijt performing the Cementless Oxford PKR at Haga Ziekenhuis, The Hague

UK VISIT

The second in-field visit was part of a trip to the United Kingdom. We visited the city of Oxford, and spent time with the Oxford PKR developers team, visiting two hospitals and the University of Oxford's research center. Appendix C provides a more detailed overview for each of the surgery observations/meetings that took place

NUFFIELD ORTHOPEDIC CENTRE, OXFORD

Nuffield Orthopedic Centre (NOC) is a world-renowned orthopedic center which specializes in Oxford PKR. The Oxford knee group work at NOC as consultants. During this visit I attended two live surgeries with Mr. Jackson William, a tibial fracture correction and an MCL repair were observed.

NUFFIELD HEALTH OXFORD, THE MANOR HOSPITAL

The Manor is a private hospital in Oxford. I had a chance to observe a cemented total knee replacement and an Oxford Fixed Lateral Partial Knee, performed by Mr. Dodd. He was able to provide some key areas to focus during this project.

Figure 11. Nuffield Orthopedic Centre (NOC), Oxford on 04 March 2019

Figure 12. Mr. Christopher Dodd performing the Cementless Oxford PKR at The Manor Hospital, Oxford

Figure 13. The Botnar Research Centre, Oxford[9]

THE BOTNAR RESEARCH CEN-

9. Botnar Research Centre. (2018). Research Strategy Review[Brochure]. Author. https://www.ndorms.ox.ac.uk/about/botnar_research_centre_strategy_2018.pdf

The Botnar is a research center for musculoskeletal research and hosts the University of Oxford's Institute of musculoskeletal sciences. The Botnar also performs research and publicizes around knee replacement, and Oxford PKR in particular. During the visit I had an elaborated discussion with Prof. Murray and Mr. Dodd. It was understood from the meeting that the exact points of focus are insertion and impaction of the tibial component that are the crucial steps for better outcomes. The Appendix-C talks more in depth about the visit and discussion with Prof. Murray and Mr. Dodd.

Key observations

- *Novice surgeons will have a hard time predicting the posterior position of the implant due to constrained visibility.*
- *It is not just the impact but the way of insertion and positioning that are crucial as well.*
- *The simulator/trainer could have soft tissue around the knee joint seizing the visibility just like in real life, but still have a window of sorts, posteriorly, to allow for review*
- *The training model should be able to simulate the workspace constraints like visibility and freedom of tool movement.*
- *The lateral Oxford PKRs are offered as fixed- and mobile bearing PKR*
- *The first most important factor for periprosthetic fracture is making the right size of keel cut and clearing out the bone residue.*
- *Second, accidental slip of tibial template during keel-cut saw. This happens if the template is not held with the pin firmly.*
- *The procedure seems a lot easier than it is to a novice surgeon. All I have to do is to get their attention to these crucial steps.*
- *The aim of this project needs to be towards providing real experience to the surgeons.*

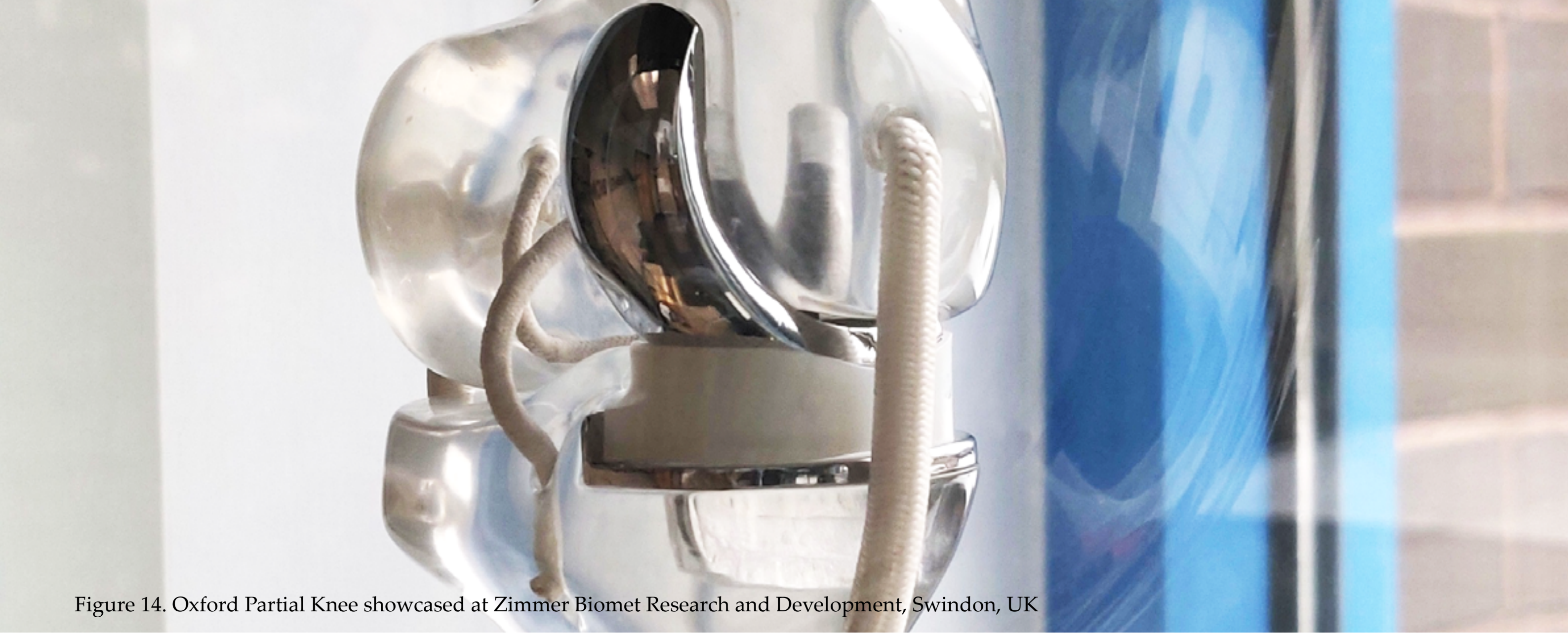


Figure 14. Oxford Partial Knee showcased at Zimmer Biomet Research and Development, Swindon, UK

RESEARCH AND DEVELOPMENT, SWINDON

Research and Development of the Oxford PKR takes place in Swindon, UK and Warsaw, Indiana, USA. Duncan Ridley, the development engineer for Oxford at the Swindon R&D office has been involved with the development of the Oxford PKR for about 10 years. He has been one of the key people involved in the development of tibial component keel design. Appendix-D contains a detailed overview of the discussion with Ducnan about the project.

10. Weißmann, V., Ramskogler, T., Schulze, C., Bader, R., & Hansmann, H. (2019). Influence of Synthetic Bone Substitutes on the Anchorage Behavior of Open-Porous Acetabular Cup. Materials,12(7), 1052. doi:10.3390/ma12071052

Key observations

- *PCF20 sawbones[10] have been considered as the closest simulation to actual bone.*
- *So far, a realistic representation of bone has never been a requirement at Zimmer Biomet R&D as most of the tests were comparative studies.*
- *It is nice to relook into finding out the best possible sawbones density to simulate the exact bone mineral density*
- *Milling right size of keel slot directly on the PCF20 sawbones is the best way to simulate the keel cut.*
- *Keel slot width on sawbones is best measured with slip gauge / Silicone molding is an easiest option to simulate soft tissue.*
- *Impact and insertion patterns will be different for every patient and also differs with left right knee implants.*
- *Comparing the impact and insertion patterns of novice surgeons with designer surgeons may not give a reasonable outcome to draw a conclusion.*
- *It is good to track the position of the impactor on the tibial component as some surgeons place it too posterior.*
- *To track the position of impacting, an electronic Fujifilm can be used at the metal to metal contact point.*
- *There has never been a study on the effect of hammering/ impacting the implant into bone.*
- *There has been no study to find out the right amount of force to be applied on the tibial component.*
- *The range of acceptable force is difficult to find out as it changes patient morphologies.*

Design methodology
Interviews[32] are face-to-face consultations that can be useful for understanding a stakeholder's perception and opinions concerning products or to gather information from experts in the field. In this case Duncan has been involved with development of instrumentation and was the right person to provide his opinions and suggest some prototyping materials.

CHAPTER 1. SECTION 3

LITERATURE RESEARCH

This section of research was conducted in two parts. The focus of the first part of the research was the effectiveness of Cementless Oxford Knee Replacement procedure. This includes research publications on the effectiveness of cementless PKR, the cause of possible complications and measures to avoid pre and post-operative complications. The second part of the research focused on learning curve of surgeons starting with cementless PKR. This includes the current learning curve of the surgeons, different techniques to measure and improve learning curve.

CEMENTLESS OXFORD KNEE

11. Clarius, M., Haas, D., Aldinger, P., Jaeger, S., Jakubowitz, E., & Seeger, J. (2010). Periprosthetic tibial fractures in unicompartmental knee arthroplasty as a function of extended sagittal saw cuts: An experimental study. The Knee, 17(1), 57-60. doi:10.1016/j.knee.2009.05.004

Since the aim of this project is to train the surgeons to minimize possible pre and post-operative complications, it was important to understand the proven advantages of the cementless procedure over the cemented procedure, how is the procedure different from the cemented procedure, what are steps of procedure that require most attention. Besides the advantages, one research was studied tha indicated the fracture load of tibial condyle. A total number of 12 research papers were studied. This section summarizes the aspects that contribute most to the project. These aspects further helped in conceptualizing the most effective solutions to minimize the probability of complications that may occur either intra operatively or post operatively.

In 2009, Clarus et al.[11] have used six human tibial bone pairs as in figure 15, to understand the effect of extended sagittal cut in perioperative tibial fracture. Sagittal cut was extended in the dorsal end by 10 degrees in 6 randomly chosen bones and compared with regular cut bones over load test. The first group with regular tibial cut has resulted in a mean fracture load of 3.9kN where as the second group with extended sagittal cut has resulted in a fracture load of 2.6kN. The mean Bone Mineral Density BMD was 0.62gm/cc for all the tibial bones. The mean fracture load of first group is 645% of donor's body weight and fracture load of second group is 470% donor's body weight. So the study concludes that extended sagittal cut decreases the load bearing capacity and at the same time the bone mineral densitylargely effects the fracture load.

/ Cadaveric study shows that mean load of 645% of person's body weight can fracture the tibial condyle which is 3.9KN

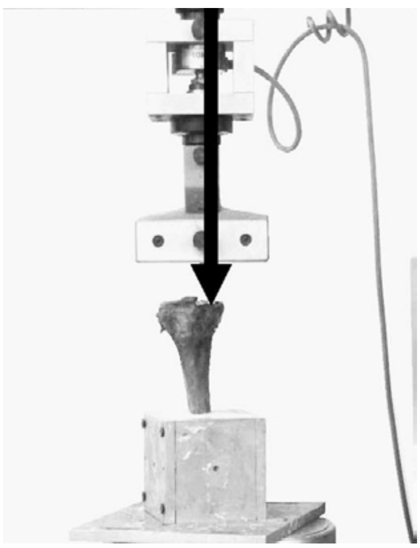


Figure 15. fracture loading of fixed specimens[11]

In 2009, Pandit et. al[12] studied 66 UKA to understand the reduction of RLLs in cementless over cemented procedures. 32knees received cemented procedure and 30 cementless. The functional outcome of the implant in both the cases is some after one year. Although 43% of cementless implants showed radiolucent lines right after the surgery, it decreased to 7% at 1 year. Whereas 75% of the cemented implants showed radiolucent lines at 1 year of which 43% are partial adiolucencies and 32% are complete radiolucencies.

/ Cementless implantation is proven to be having almost no radiolucency compare to cemented implantation.

In a Randomized Controlled Trial[13], it was observed that the cementless fixation has the equivalent outcome as cemented fixation based on a randomised controlled study of 22 patients with each fixation for over a period of 24 months. Although the tibial migration was more in cementless than in cemented, the stabilization happened early and there was no migrate on observed after 6 months. This study backs the claim that cementless fixation is as good as the cemented fixation in terms of outcome and likely to have a healthy long-term survivorship.

/ Cementless fixation gives same outcomes as of cemented with added advantages

Prof David Murray has presented during 2012 AAOS annual meeting[14] that cementless fixation is a safe and reproducible treatment option for medial osteoarthritis. Cementless fixation is more reliable than cemented fixation due to reduction of radiolucency at higher level. Aseptic loosening and pain being the common causes for revision in UKR. Surgeons interpret the radiolucency in the cemented version as cause of pain and revise early. The incidence of these early revisions are lower with the case of cementless fixation due to reduction of radiolucency.

/ Cementless fixation is more reliable than cemented fixation due to incidence of lower RLLs.

12. Pandit, H., Jenkins, C., Beard, D. J., Gallagher, J., Price, A. J., Dodd, C. A., . . . Murray, D. W. (2009). Cementless Oxford unicompartmental knee replacement shows reduced radiolucency at one year. The Journal of Bone and Joint Surgery. British Volume, 91-B(2), 185-189. doi:10.1302/0301-620x.91b2.21413

13. Kendrick, B., Bottomley, N., Gill, H., Jackson, W., Dodd, C., Price, A., & Murray, D. (2012). A randomised controlled trial of cemented versus cementless fixation in Oxford unicompartmental knee replacement in the treatment of medial gonarthrosis using radiostereometric analysis. Osteoarthritis and Cartilage, 20. doi:10.1016/j.joca.2012.02.566

14. Murray, D. M., MD, Pandit, H. G., FRCS, O'Brien, S., PhD, Burn, J., FRACS, Jackson, W., FRCS, Price, A. J., FRCS, . . . Maxwell, R. R., MD. (2012, February 09). Cementless Unicompartmental Knee Arthroplasty is Safe and Improves Implantation Fixation: A Multi-center Study. Speech presented at 2012 AAOS Annual Meeting in Moscone Convention Center, San Francisco. 28-Adult Reconstruction Knee II, presentation number 415

In 2013 Liddle et al.[15] have studied over 1000 cases of cementless UKA and disproved the previous claim that patients with softer bone, should not be treated cementless procedure. Also in 2013, there were three other following publications[16, 17, 18] backing the previous claims that cementless fixation has reduced the incidence of radiolucnecies and resulted in lower revision rates. Also the studies have the testimonials of cases where the cementless fixation has resulted in better outcomes than cemented fixation. Another study in 2015 published[19] a 5 years radilogical result showing a great survivorship.

/ The claims of advantages of cementless UKR over cemented UKR are backed by a study of 1000 OUKRs performed among three independent centres outside the design centre.

/ In a study of 150 consecutive OUKRs a 98.7% of survivorship is observed over a period 5 years.

In a study in 2015, Pegg et al.[20] into the effect of tibial resection on the tibial fracture. Out of the several causes for tibial plateau fracture, tibial plateau preparation for implantation is one potential cause. Although there could be several parameters in the resection that might lead to tibial fracture. It was observed from a generalised regression model that depth of regression and posterior depth of vertical cut are the two parameters that largely influence the risk of fracture (fig. 16). In contrast, the anterior and posterior horizontal cut has reduced the risk of fracture but still the negative implication of excessive vertical cut is predominant in tibial fracture. The study suggested that instrumentation can be altered in a way to perform the horizontal cut first which helps regulating the vertical cut by means of a shim.

/ A deep extension of vertical cut is dangerous than extension horizontal cut during tibial resection.

/ It is recommended to do the horizontal tibial cut first and then vertical to make sure vertical cut doesn't extend deep.

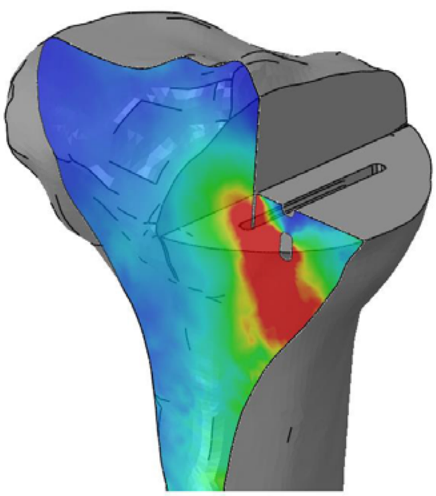


Figure 16. Risk of fracture after UKR for a deep posterior vertical cut[20]

15. Liddle, A. D., Pandit, H., O'Brien, S., Doran, E., Penny, I. D., Hooper, G. J., . . . Murray, D. W. (2013). Cementless fixation in Oxford unicompartmental knee replacement. The Bone & Joint Journal, 95-B(2), 181-187. doi:10.1302/0301-620x.95b2.30411

16. Liddle, A. D., Pandit, H., Murray, D. W., & Dodd, C. A. (2013). Cementless Unicondylar Knee Arthroplasty. Orthopedic Clinics of North America, 44(3). doi:ISBN 9781455776023

17. Pandit, H., Liddle, A., Kendrick, B., Jenkins, C., Price, A., Gill, H., . . . Murray, D. (2013). Improved Fixation in Cementless Unicompartmental Knee Replacement. The Journal of Bone and Joint Surgery-American Volume, 95(15), 1365-1372. doi:10.2106/jbjs.l.01005

18. Hooper, G. J., Gilchrist, N., Maxwell, R., March, R., Heard, A., & Frampton, C. (2013). The effect of the Oxford uncemented medial compartment arthroplasty on the bone mineral density and content of the proximal tibia. The Bone & Joint Journal, 95-B(11), 1480-1483. doi:10.1302/0301-620x.95b11.31509

19. Hooper, N., Snell, D., Hooper, G., Maxwell, R., & Frampton, C. (2015). The five-year radiological results of the uncemented Oxford medial compartment knee arthroplasty. The Bone & Joint Journal, 97-B(10), 1358-1363. doi:10.1302/0301-620x.97b10.35668

20. Pegg, E., Christopher, Murray, D., & Pandit, H. (2016, November 09). Conservative Tibial Resection and Vertical Cut Minimise Risk of Tibial Plateau Fracture after UKR. Retrieved from https://researchportal.bath.ac.uk/en/publications/conservative-tibial-resection-and-vertical-cut-minimise-risk-of-t

21. Murray, D., Zimmer Biomet. (2016). Oxford Cementless Partial Knee Replacement: Optimising Tibial Preparation. Retrieved from http://www.oxfordpartialknee.net/content/dam/zb-minisites/oxford-partial-knee-hcp/documents/0221.1-INTL-en%20Oxford%20Cementless%20Partial%20Knee%20Replacement%20White%20Paper-Final.pdf

In 2016, Prof. Murry published a white paper[21] claiming that the revision rate of cementless fixation has been half of the cemented fixation at 5 years. He mentioned that the incidence of complications were similar in both but the patter is different. He suggested that surgeons switching from cemented to cementless should be aware of complications that could possibly be avoided. The common early complications with the Oxford Cementless Partial Knee are related
to the tibia. A spectrum of problems could occur including tibial plateau fracture and tibial subsidence. The observation that these complications tend to occur early in a surgeons' experience with cementless and only occurs with some surgeons suggests that they are a result of surgical technique. The fundamental problem is that when the surface of the tibia is removed the tibia is weakened. If the technique is appropriate the bone will be strong enough to support the tibial component and with time , in our experience, the bone will remodel and fix to the tibial
component. However, if the tibia is substantially weakened during its preparation complications may occur. The surgical factors that may contribute to tibial complications are listed as. For a complication to occur multiple factors usually have to be present:

- A vertical tibial cut that is too deep posteriorly.
- A vertical cut that is too far medial.
- A horizontal tibial cut that is too distal or uneven, as may occur with a tibial recut.
- Multiple pin holes in the proximal tibia.
- A keel slot that extends too far posterior and damages the posterior cortex.
- A keel slot that is too deep or irregular.
- A trial reduction in which the tibial trial does not fully seat.
- Use of a heavy hammer to impact the tibial component.
- A tibial component that is not supported all around its rim by the cortex.

/ Although the incidence of complications in cementless fixation are similar to cemented, the patter is different

/ Surgeons switching from cemented to cementless understand the difference in complication and take more seriously to avoid possible complications

LEARNING CURVE

The second part of literature was focused on learning curve of Cementless Oxford PKR surgeons. Besides this, the general behavior of learning curve was also studied and how can learning curve be measure and improved. This research section summarizes two research publications on current learning curve of cementless Oxford PKR surgeons and 4 other researches proposing different techniques to measure and improve the learning. These research aspects helped in directing the conceptualization phase towards an efficient solution to reduce the learning curve.

Roberston et al. in 2000[22] have performed a study of 10,474 Unicompartmental knee arthroscopies has indicated the correlation between the number of procedures performed per year to the revision rate. The plot represents that 58 units of 78 units have performed less than 20 procedures per year. From the observation of these 10474 cases, the author concludes that the number of procedures performed per year has a great impact on the declining revision rate of technically demanding implants.

/ *The number of procedures per year have an impact on the patient outcome*

The study in 2017 by Benjamin et al,[23] is theonly study among the considered researches, that documented the effect of learning curve in cementless oxford partial knee. The study was conducted observing the first 30 cementless procedure performed in a single center. The intention of the study is find out the effect of cementless fixation and find out the survival rate. But one of the interesting find out of the study was incidence of a low survival rate compared to the other studies. The study has recorded a survival rate of 89.7% in cementless fixation, whereas most of the other studies have recorded a survival rate of 95% or more. One of the main reasons mentioned was that the study has uniquely considered the very first 30 procedures of cementless fixation while the other studies have included either outcomes of procedures performed by experienced surgeons or have included large number of procedure into the study. These two factor would have reduce the effect of the learning curve in finding out survival rate if the procedure. Although a clear analysis is not available, it can be said that the first 30 cases of cementless fixation largely impact the survival/ revision rate of cementless oxford partial knee.

/ *Experienced and novice surgeons in their first 30 surgeries, clearly have a difference in outcome of survival rate.*

22. Robertsson, O., Knutson, K., Lewold, S., & Lidgren, L. (2001). The routine of surgical management reduces failure after unicompartmental knee arthroplasty. The Journal of Bone and Joint Surgery. British Volume,83-B(1), 45-49. doi:10.1302/0301-620x.83b1.0830045

23. Panzram, B., Bertlich, I., Reiner, T., Walker, T., Hagmann, S., & Gotterbarm, T. (2017). Cementless Oxford medial unicompartimental knee replacement: An independent series with a 5-year-follow-up. Archives of Orthopaedic and Trauma Surgery, 137(7), 1011-1017. doi:10.1007/s00402-017-2696-9

Another study in 2010 by Hamilto et al,[23] has observed 445 cemented UKAs to find out the effect of learning curve on the revision rate. The author has divided the patient cohort into two groups. The first half of the procedures as group 1 and the second half of the procedures as group. Eventually observed a revision rate of 5% of revision rate in the first group and a 2.7% revision rate observed in the second group. Although the study is based on cemented fixation, it showed some evidence that the learning curve definitely make an impact in revision rate.

/ It was an evident in cemented procedure that surgeons in the top of the learning curve have better patient outcomes

24. Hamilton, W. G., Ammeen, D., Engh, C. A., & Engh, G. A. (2010). Learning Curve With Minimally Invasive Unicompartmental Knee Arthroplasty. The Journal of Arthroplasty, 25(5), 735-740. doi:10.1016/j.arth.2009.05.011

25. Ramsay, Craig & Wallace, Sheila & H Garthwaite, Paul & F Monk, Andrew & Russell, Ian & M Grant, Adrian. (2002). Assessing the learning curve effect in health technologies: Lessons from the nonclinical literature. International journal of technology assessment in health care. 18. 1-10.

Another study[25] conducted by Ramsay et al. in 2002 had a unique approach to identify novel statistical techniques that could be used to assess the learning curve effect in HTA(Healthcare Technology Assessments) by searching the non-HTA literature. Filtering through 10,000 abstracts, the study found out 18 novel techniques that were used to find out learning curve in HTA literature. There is an important distinction between methods for identifying a learning effect and those for measuring (characterizing) a learning effect. The study concluded that the following methods are used to identify the learning effect in HTAL.

Exploratory data analysis
- Graph
- CUSUM techniques

Techniques for simple series data
- T-test, one way ANOVA
- Chi-squared test (for trend)
- Repeated measures ANOVA
- Curve fitting
- Multiple regression
- Logistic regression

/ There has not been a straight forward way to measure the learning curve

26. Subramonian, K., & Muir, G. (2004). The learning curve in surgery: What is it, how do we measure it and can we influence it? BJU International, 93(9), 1173-1174. doi:10.1111/j.1464-410x.2004.04891.x

27. Zhang, Q., Zhang, Q., Guo, W., Liu, Z., Cheng, L., Yue, D., & Zhang, N. (2014). The learning curve for minimally invasive Oxford phase 3 unicompartmental knee arthroplasty: Cumulative summation test for learning curve (LC-CUSUM). Journal of Orthopaedic Surgery and Research, 9(1). doi:10.1186/s13018-014-0081-8

A study in 2004 by Muir et al,[26] looked into the origin of learning curve and what was it defined. Based on these facts the authors defined the learning curve fore surgeons as: The time taken and/or the number of procedures an average surgeon needs to be able to perform a procedure independently with a reasonable outcome'. One of the important suggestions in the study is to involve the whole surgical team in preoperative training.

The study analyzed the factors that influence learning curve as:

- Frequency of procedures performed
- Volume of surgical workload
- Experience of supporting surgical team
- Patient factors
  - Complex anatomy
  - Varying case-mix
- Surgeon becomes more experienced and tend to tak more challenging tasks
- Facilities/ infrastructure of the training

The study concludes that measuring the learning curve is complicated and depends on several parameters in different scales and every surgical procedure will have these parameters at of
different importance. that learning curve is measured by.

- The study says the learning curve is majorly measure based on the criteria of: Measure of patient outcome (Incidence of complications, survival rate)
- Task efficiency (measure of clinical processes like duration of surgery, blood loss and period of hospitalization)

/ Learning curve is dependent on several parameters and these parameters are subjective and different for each procedure

Lastly Qidong et al,[27] in 2014 have studied 50 consecutive cemented UKAs to measure the learning curve and find the number of procedures required before an acceptable outcome. The study defines learning curve as an improvement in performance over time or with increasing experience or training. The study used CUMSUM method to measure the learning curve. The clinical outcomes are evaluated by measuring range of motion (ROM) and Hospital for Special Surgery
Knee Score (HSS). Considering the revision for any reason as the end point of survival, the study found out that minimum of 25 cases are required before a consistently low failure rate is achieved.

/ It takes about 25 surgeries for novice surgeons to reach the top of learning curve in cemented procedure.

/ The similar number can be even considered for cementless procedure

TECHNOLOGY RESEARCH

This section of research summarizes the different that were looked into during this project. To training the healthcare professional, digital simulation have been an efficient solution so far. During this research the advantages and disadvantages of these solutions were studied and summarized why the digital simulations are not suitable for arthroplasty. This research also includes a brief study on Motion tracking, impact tracking and visual tracking technologies and methods to analyze the learning process using these technologies.

MEDICAL SIMULATION

It is important to train the novice surgeons in a realistic environment where they could relate to an actual surgical process. To simulate the look and feel there have been several advancements in medical training by implementing virtual reality, augmented reality and mixed reality.

VR, AR & MR
Starting with virtuality reality(VR), the digital simulation technology has improved gradually through augmented reality(AR) and mixed reality(MR). At the same time, every technology has its own limitations. Virtual reality in medical training(fig. 17) was a good advancement from conventional video trainings. Later when augmented reality was introduced in healthcare, it gave a better understanding of minute body parts and critical surgical procedures. But these graphics based simulations lack the interaction. Then the mixed reality was one step forward by letting the user to interact with the virtual objects. Again the technology was limited to virtual interaction where the body muscles were not really involved in interaction. This has pushed the technology into integrated haptics. It was a substantial improvement from the mixed reality where the user feels the resistance of holding an object in the hand. Although these simulation platforms are still far away from actual reality, there was a strong evidence from the research studies[28] that these simulations improved the outcomes in medical training.

28. Vaughan, N., Dubey, V. N., Wainwright, T. W., & Middleton, R. G. (2015). Does virtual-reality training on orthopaedic simulators improve performance in the operating room? 2015 Science and Information Conference (SAI). doi:10.1109/sai.2015.7237125

29. Apple is making Augmented Reality more accessible. Here's how it is transforming Healthcare... (2018, November 22). Retrieved from http://www.scientificanimations.com/apple-is-making-augmented-reality-more-accessible/

Figure 17. Augmented reality in medical training[29]

SIMULATION IN ORTHOPEDIC TRAINING

30. Abas, T., & Juma, F. Z. (2016). Benefits of simulation training in medical education. Advances in Medical Education and Practice,Volume 7, 399-400. doi:10.2147/amep.s110386

31. Uemura, M., Tomikawa, M., Kumashiro, R., Miao, T., Souzaki, R., Ieiri, S., . . . Hashizume, M. (2014). Analysis of hand motion differentiates expert and novice surgeons. Journal of Surgical Research, 188(1), 8-13. doi:10.1016/j.jss.2013.12.009

Although computer simulations have a proven positive effect on the training outcomes in healthcare[30], there is not a lot of evidence proving this in orthopedics. Researchers believe this could be due to the limited number of simulators, which exist today. This is due to complexity of orthopedic procedures. Orthopedic surgical procedures are usually of two types, arthroplasty and arthroscopy. Arthroscopy is a minimally invasive surgery that uses catheters to introduce the tools into the body. Unlike arthroplasty, arthroscopy has no need for a large skin incision and exposure of soft tissue. The cameras of the catheters provide a view by displaying it on a digital screen. So it is easier to simulate arthroscopy using computer generated graphics. There are studies[31] with proven positive effect of VR and AR on training outcomes in arthroscopy.

While these simulation technologies have been competing with each other to be the closest imitation of reality, there comes the question of balance. What kind of effort is involved in making something closer to reality and is it worth the outcomes we achieve. Maybe yes in case of arthroscopy or other surgical procedures but not in arthroplasty. The novice orthopedic surgeons need a good amount of time to train the complex tactile skills. Simulating all the force feedbacks that are involved in arthroplasty is not possible without making a complex training robot. So having a physical training tool is quite important to train arthroplasty procedures.

33. FUNDAMENTAL SURGERY The virtual reality surgical simulator. (n.d.). Retrieved from https://www.fundamentalsurgery.com/

34. ARTHRO MENTOR. (n.d.). Retrieved from https://simbionix.com/simulators/arthro-mentor/

Figure 18. Fundamental Surgery using geomagic haptic handles to train the surgeons[33]

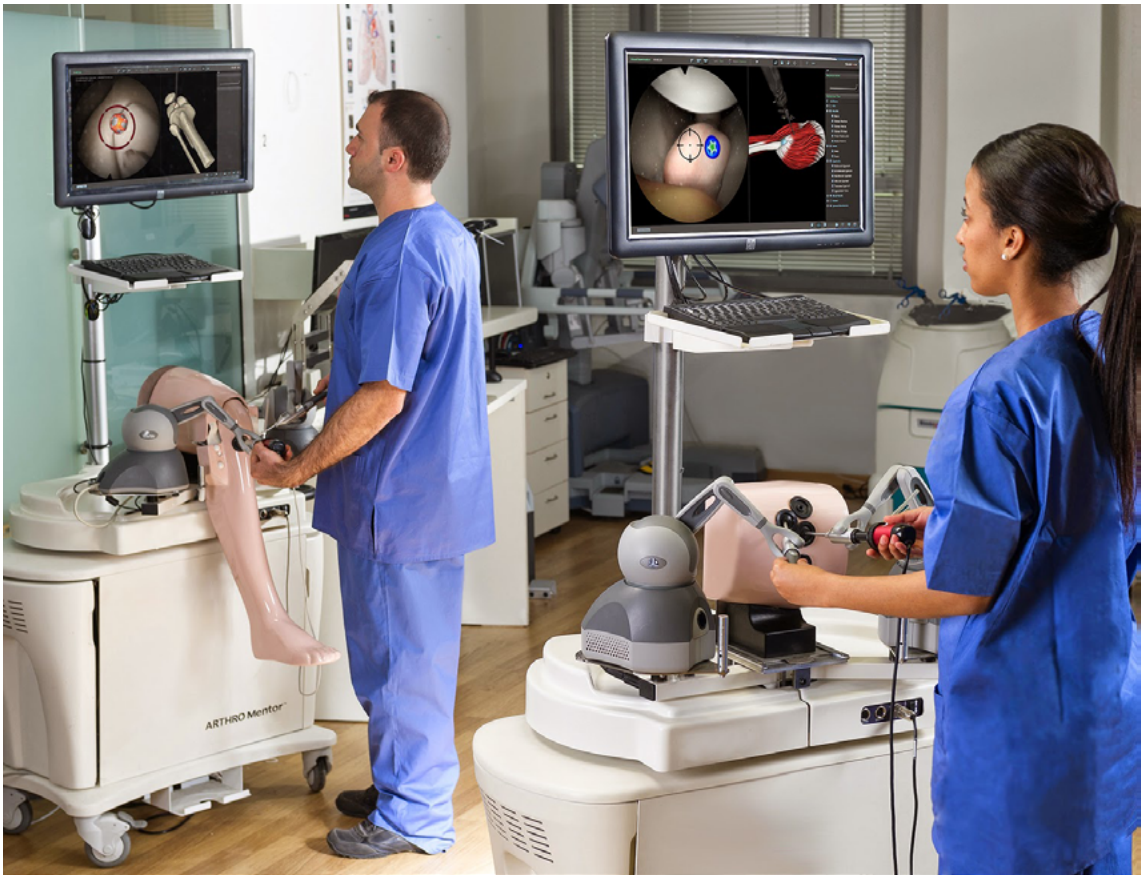


Figure 19. Training device for arthroscopy by ARTHRO mentor[34]

TRACKING

As the major focus of the project is the insertion and impaction steps involved in the Cementless Oxford PKR with Oxford Microplasty Instrumentation, this chapter explores motion tracking and impact tracking procedures.

Feedback loop is an important part of training education in healthcare. Medical trainings are more process oriented than outcomes.[35] R. As the surgical process for the Cementless Oxford PKR involves using many surgical tools, it is important to track the usage and to be able to provide feedback to the user. There are different steps involved in the procedure like drilling, milling, cutting and hammering. Each of these steps require some skills that are acquired with experience. When a novice surgeon performs a procedure, it is helpful if there could be a feedbacking system that can analyze the procedure by comparing it to that of an experienced surgeon.

Motion tracking

Motion tracking has different classifications based on the tracking procedure. In case of Microplasty instrumentation, the tibial component is implanted with an inserter. To track the motion of inserter, the most obvious methods were to use an accelerometer or a visual based analysis. There are several accelerometers like Polhemus tracker are available in the market that can track the object movement. As of today, Polhemus sensors are widely being used for similar purposes and are proven to be accurate.[36] Polhemus patriot has been chosen for the current application. Patriot has features that are most suitable for the project. It can handle multiple tackers attached to different tools and each sensor updates at a rate of 60Hz. Patriot trackers can track the motion precisely with a resolution of 1.5mm. But when the tracker is placed on a tool like inserter or impactor which are subjected to repeated impacts from hammering, the readings may not be accurate.

35. Burton, T. (2016, March 13). Why Process Measures Are Often More Important Than Outcome Measures in Healthcare. Retrieved from https://www.healthcatalyst.com/insights/process-vs-outcome-measures-healthcare

36. Polhemus Patriot. (2019). Retrieved from https://polhemus.com/motion-tracking/all-trackers/patriot/

Figure 20. Polhemus Patriot sensor[36]

Impact tracking

Hammer impacts can also be measured using a piezo sensor. Unlike the camera, these sensors are quite reliable irrespective of working environment. There were impact hammers readily available to measure the impacts. The Kristler hammer is one example of this, it uses an amplifier and a filtering software to measure. There were also some stand-alone piezo sensors available separately. It works in the same way as the impact hammer does. KM load cell was one of such sensors that was used to track the impact forces. Although the sensor was too big to be mounted on the hammer, it helped to measure the amount of forces involved in insertion and impaction.

Visual tracking

As visual based sensors are contactless sensors they are not affected by the impacts. There were different motion tracking cameras available to track objects in a defined space. Before I finalize on a most suitable sensor, I wanted to test how the visual tracking results are going to help in analyzing the procedure. There was a video based analyzer called ‘tracker’ that can track an object from a video that was captured in controlled conditions. It is a video analysis and modeling tool built on the Open Source Physics (OSP) Java framework. This is generally used in physics education to create particle models based on Newton’s laws.

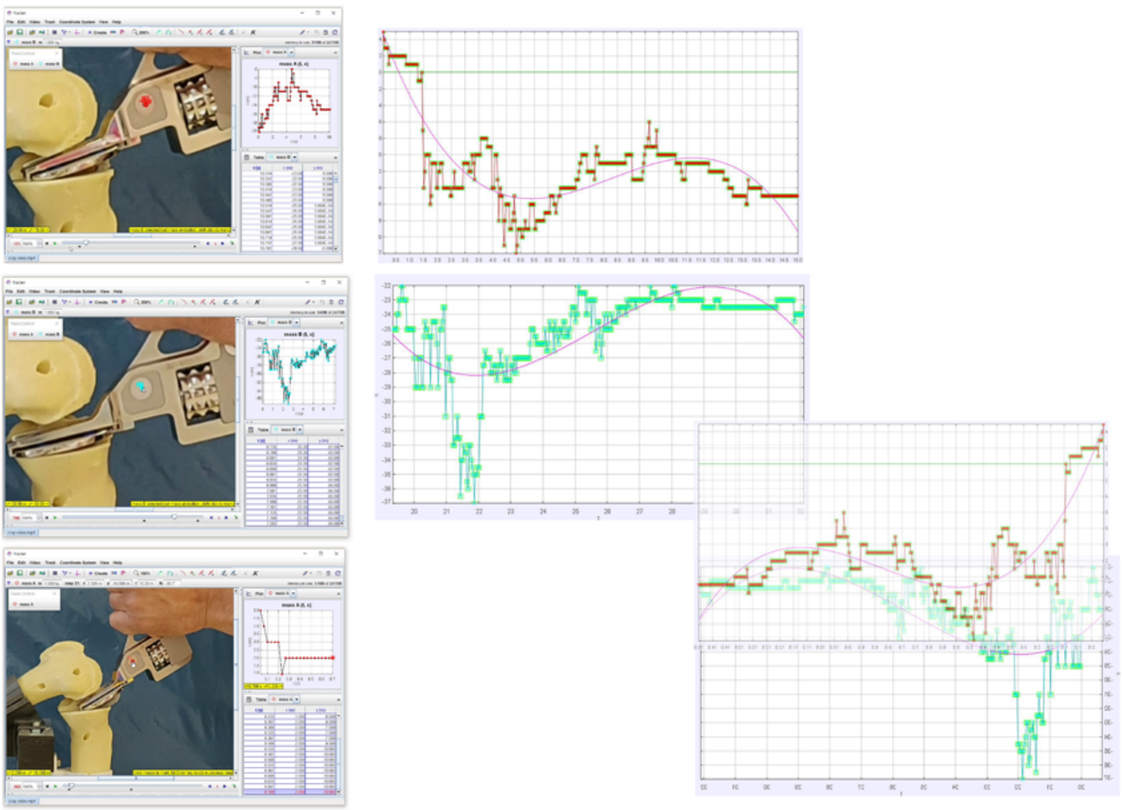


Figure 21. Using video tracker software to plot motion of surgical tools from two conscutive tests

A video has been captured with a subject performing the insertion two times. This was imported into the tracker tool(fig. 21) to track the path of the inserter and to analyze the paths from two tests and compare how they differ from each other. Once the analysis has been done, there were several fundamental values which can be used to calculate the physical parameters like force, momentum, angle of impact and so on. In case of the insertion procedure using the inserter, 7 possible parameters were listed that could help in analyzing the procedure.

1. Horizontal tilt of inserter
2. Vertical tilt of inserter
3. 2D path of implant
4. Change of slope of implant during the whole travel
5. Hammer impact
6. Hammer contact point
7. Angle of contact of hammer to know X and Y components of impact

HOW TO ANALYZE?

37. Beard, J. D. (2008). Assessment of Surgical Skills of Trainees in the UK. The Annals of The Royal College of Surgeons of England, 90(4), 282-285.

31. Uemura, M., Tomikawa, M., Kumashiro, R., Miao, T., Souzaki, R., Ieiri, S., . . . Hashizume, M. (2014). Analysis of hand motion differentiates expert and novice surgeons. Journal of Surgical Research,188(1), 8-13. doi:10.1016/j.jss.2013.12.009

Here comes the next question: If the above parameters have been calculated, how do these parameters help in analyzing the surgical procedure? The results need to be compared with ideal results. But it is hard to define an ideal procedure in this case. Assessment[37] in medical training on a simulator has usually[31] been a comparative study. The surgical procedure performed by a novice surgeon is compared with that of an experienced surgeon. This helps to assess if a novice surgeon has gained the competencies required to perform a surgery. Similarly, the plan was to capture a video while an experienced surgeon is implanting the implant on a sawbones. The data from this experiment can act as a standard procedure to compare with the novice surgeons.

But just comparing the surgical steps of each procedure may not help to draw strong conclusions to feedback the user. There are different assessment methods being used in medical training to evaluate the novice clinicians(12).

Traditional Assessment
An expert surgeons directly observes a novice surgeons performing in an operating room. This assessment is not based on any criteria and extremely subjective.

The Global Rating index for Technical Skills (GRITS)
Grits has a set of parameters to analyze but the assessment is still done by an expert observing directly in an operating room. This method deals with 9 items that are considered as general mistakes. These are again measured by an expert surgeon by rating on a scale.

Structured Assessment of Microsurgery Skills in the clinical Setting (SAMS)
In this method, digital microscope system is used to record a video of a trainee surgeon performing a microvascular anastomoses. These videos are also observed by 3 expert surgeons independently. They rate the performance of the trainee using 12 parameters on a Global Rating Score(GRS).

Patient Robot
This method uses skill trainers/simulator to assess the novice surgeons. These patient robots are just like a regular skill trainer but with integrated sensors to track different fundamental parameters. When a surgeon performs a procedure like suturing on the dummy skin, the sensors embedded in the skin and an image processing algorithm to measure the forces in tissue, tension in the incision, position of sutures and procedural time.

Conclusion - how to analyze?

All of the methods but patient robot are based on a direct or indirect observation by an expert. These methods could not be considered in the current project as it is not efficient to have an expert monitoring the procedure of every trainee surgeon during the sawbones demonstration. The patient robot method was an ideal technique in this case. The patient robot in the study examines a specific task of suturing. The robot uses an image processor to capture the suture pictures and analyze the process. But in the case of sawbones demonstration, the working space is much larger than the suture pad in the patient robot. It need multiple cameras to know the type of tool that was picked up from the tray, the working posture of the surgeon while hammering and how much force is being applied. This was still possible by implementing the motion tracking algorithms in two cameras position in different views. This might require some calibration before the start of every procedure to know where the tools are. Especially during the hammering procedure, the algorithm should be able to track the movement of hammer at higher speeds to assess the forces involved in the impact. When two cameras are placed in different axes of movement, the orientation of the tools and position in 3d space could be measured. Having an expert surgeons perform the procedure under these conditions for several times, an algorithm can outline an average of all of them. This can act as a standard procedure and assess the novice surgeons by calculating an assessment factor.

MARKET RESEARCH

Most of the simulators in the market use digital haptics to simulate arthroplasty procedures. During this research no simulator has been found that specializes for a certain procedure of arthroplasty that completely simulates using real instruments. This section includes the business limitations of making a simulator for arthroplasty, and the existing surgical simulators of arthroscopy and other surgeries similar to arthroscopy.

38. ScanTrainer: Curriculum-Based Ultrasound Skills Training Simulator. (n.d.). Retrieved from https://www.intelligentultrasound.com/scantrainer/

This could be due to the fact that developing a mechanical or fully tangible simulator for arthroplasty two downsides for a simulator company. Two of them include:

1. **Reusability:** arthroplasty is an invasive surgery. It is difficult to reproduce the physical models after every training process.
2. **Limited Application:** Second downside of it could be the fact that a standardised simulator cannot be made for multiple procedures of arthroplasty.

These could have been the two main reasons that none of the medical simulator companies have developed an arthroplasty simulator using actual instruments.

SCAN TRAINER

Scan trainer[38] is an ultrasound skills training simulator that offers curriculum-based teaching using real patient scans with haptic feedback, real-time assisted guidance and comprehensive metric based assessment in one system. This device is also available with subscription-based cloud service with ScanTrainer Case Generator. This enables tutors to upload and publish their own patient scans, create cases, and share these with other users within their organization or around the world.

Figure 22. Transvaginal simulator by Scan Trainer[38]

ScanTrainer Transvaginal Simulator
This particular simulator(fig. 22) from ScanTrainer provides real-feel transvaginal haptic uses force feedback technology to replicate the 'feel' of what it is like to scan a real patient. The endo-cavity haptic will track the movement of the probe to measure a trainees' performance and technique and then provide feedback. The trainer helps to :

- Learn TV(Transvaginal) probe handling skills to acquire accurate, diagnostic ultrasound images
- Identify and interpret image relationships between anatomy and ultrasound views
- Recognize pathology relevant to obstetrics and gynecological practice
- Learn and enhance diagnostic skills

ScanTrainer Transabdominal Simulator
Just like the TV simulator, this(fig. 23) trains for Transabdominal handling skills for young clinicians
Learn TA(Transabdominal) probe handling skills to acquire accurate, diagnostic ultrasound images

- Identify and interpret image relationships between anatomy and ultrasound views
- Recognize pathology relevant to obstetrics and gynecological practice
- Learn and enhance diagnostic skills

Figure 23. Transabdominal simulator by Scan Trainer[38]

Figure 24. Dynamic Tactile Feedback in Arthro Mentor[34]

38. ScanTrainer: Curriculum-Based Ultrasound Skills Training Simulator. (n.d.). Retrieved from https://www.intelligentultrasound.com/scantrainer/

34. ARTHRO MENTOR. (n.d.). Retrieved from https://simbionix.com/simulators/arthro-mentor/

SIMBIONIX ARTHRO MENTOR

The ARTHRO[34] Mentor Express has one universal anatomical model that includes knee arthroscopy in Flexed and Extended positions, shoulder arthroscopy in Beach Chair and Lateral positions, and hip arthroscopy in the Supine position(fig. 24 and fig. 25). This results in all-in one training solution that is compact and portable for industry product demonstrations as well as orthopedic department The simulator features a line of simulated procedures, combining fiberglass / polyurethane anatomical models (shoulder, knee and hip) with 3D images and haptic sensation, to allow users to learn key aspects of the procedures. Simulated procedures are performed utilizing a realistic set of tools as used in the OR including the arthroscopic camera, which allow the trainee to acquire a true-to-life hands-on experience.

- Enables performing complex arthroscopic procedures (including cutting, drilling, suturing, etc.) without damaging the physical model.
- Allows practicing procedures that cause changes to the anatomical structures and feel how their resistance changes throughout the procedure.
- Provides the option to switch between anatomical cases virtually in order to train different pathologies and anatomical variants without the need to change the anatomical model.

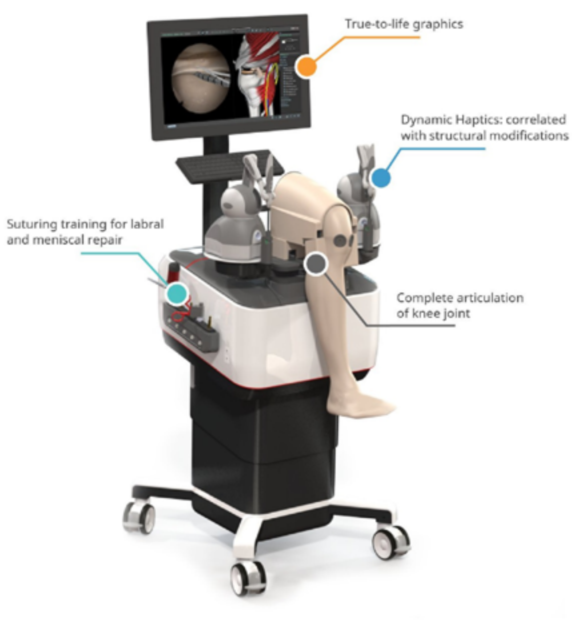


Figure 25. Sybionix Arthro Mentor[34]

VIRTAMED ARTHRO S

39. VirtaMed ArthroS™. (n.d.). Retrieved from https://www.virtamed.com/en/medical-training-simulators/arthros/

ArthroS is a virtual reality arthroscopy trainer[39] for knee(fig. 26), shoulder, hip, ankle. The switch between the four models is done in around 30 seconds. The knee, shoulder, hip, and ankle model with magnetic tracking provide realistic tactile sensation.

For an optimal learning experience, the trainee uses original OR instruments and tools such as an original arthroscope, palpation hook, grasper, cutting punch, or shaver. The instruments are equipped with sensors and allow for fluid handling, camera technique, and familiarize trainees with the concept of 0, 30, and 70-degree optics. The anatomic model and a PC are mounted on a movable display cart with height-adjustable 23” multi touch-screen.

Figure 26. Virtamed Arhtro S Knee module[39]

Figure 27. Fundamental Surgery VR tainer in action[33]

33. FUNDAMENTAL SURGERY The virtual reality surgical simulator. (n.d.). Retrieved from https://www.fundamentalsurgery.com/

40. Haptic gloves for VR training, simulation, and design. (2019, July 09). Retrieved from https://haptx.com/

FUNDAMENTAL SURGERY

Fundamental Surgery combines a cutting edge VR experience with haptic feedback (the sense of touch) to create a near real operating experiences. They combine VR platform with haptic feedback to bring good level of immersive interactivity; the user being able to feel the different tissue types at each stage of the procedure in this. The company developed a service based system to make it possible to as SIY if the haptic sensors and a VR box are available.

Fundamental Surgery HaptX
Fundamental Surgery has joined with HaptX[40] to develop a more realistic haptic feedback for surgical simulations. HaptX is a glove(fig. 29) that takes a fundamentally different approach to haptics. Their patented microfluidic technology lets the user feel the shape, movement, texture,
and weight of virtual objects. Microfluidic skin is a flexible, silicone-based smart textile containing an array of high-displacement pneumatic actuators and microfluidic air channels. Microfluidic skin panels are embedded throughout HaptX Gloves(fig. 28) to provide realistic touch sensations across the hand. Each glove contains 130 microfluidic actuators that provide haptic feedback by pushing against the user's skin, displacing it the same way a real object
would when touched.
HaptX's magnetic motion tracking and hand simulation system leverages proprietary software and electronics to deliver submillimeter accuracy hand tracking with six degrees of freedom per
finger and no occlusion.

Figure 28. Micro fluidix skin inside haptX[40]

Figure 29. HaptX sensory gloves[40]

CHAPTER 2

PHASE - I

CHAPTER 2. SECTION 1

PROBLEM DEFINITION

The first phase of the design started with defining the problem statement. The research phase has helped in understanding that achieving better patient outcomes involves a lot of parameters. This section focuses on which of these factors are to be considered during this project and what kind of solution to be designed around parameters. This section also looks into Kolb's learning process and projects a guidelines for the conceptualization section.

DESIGN FOCUS

There are 9 critical factors[41] that Oxford Knee Group published as crucial to have better outcomes. Insertion and impaction were two of those that are not usually addressed at the Instructional Course. Microplasty instrumentation has been designed to help the surgeons perform an Oxford procedure just right. However, for novice surgeons, it was important to have prior experience with using these instruments to have a shorter learning curve. The Instructional Course provides training from the correct patient selection through to implantation. But the Insertion and impaction of an actual implant are the two steps that were not part of the course. A novice surgeon performs these steps for the first time on a real patient. For both these steps the surgeon is hammering. Hammering with a mallet is subjective and completely a skill based step. A surgeon needs actual experience to know the right amount of force to apply. Secondly, most of surgical steps in the training can be assessed by visual observation via surgeon to surgeon visitations. But it is hard to assess the insertion and impaction processes until the procedure has finished. Therefore, the key focus of the project was decided to be the final steps of procedure which are the insertion of actual implant and the impaction with the toffee mallet.

41. Murray, D., Zimmer Biomet. (2016). Oxford Cementless Partial Knee Replacement: Optimizing Tibial Preparation. Retrieved from http://www.oxfordpartialknee.net/content/dam/zb-minisites/oxford-partial-knee-hcp/documents/0221.1-INTL-en%20Oxford%20Cementless%20Partial%20Knee%20Replacement%20White%20Paper-Final.pdf

42. Ranking the factors of influence to reduce learning curve for cementless UKA [E-mail to the author]. (2019, March 11).

	Factors	Microplasty	Surgical simulator
1	A keel slot that extends too far posterior and damages the posterior cortex, due to surgeon not holding long pin.	Yes it explains but lacks the real feel until few real surgeries are done	May be good to provide some real effect of holding the pin
2	A trial reduction in which the tibial trial does not fully seat with finger pressure	Yes and No	
3	A vertical cut that is too far medial. To guide the saw cut the apex of the medial spine should be identified and a mark made with a diathermy just medial to the apex of the spine.	Yes it explains about it	Need to emphasize it
4	A keel slot that is too deep or irregular, due to not using a keel cut saw or using a pick	Yes it explains	May be good emphasize it
5	A horizontal tibial cut that is too distal or uneven as occurs after a recut. Avoid doing a recut by removing cartilage from posterior femur if the femoral drill guide is tight.	Tells the exact opposite of it. The white paper tells it right	
6	Use of a heavy hammer to impact the tibial component. If the component does not fully seat leave it slightly proud	Yes explains it, but lacks the real feel may be	Need to provide some assistance in recognising it
7	AA tibial component: In a very small patient requiring a AA component it is probably better to use a cemented rather than a cementless component.	Doesn't eplain it. To be added	
8	A tibial component that is not supported all around its rim by the cortex.		
9	Multiple pin holes in the proximal tibia.	Not mentioned	

Figure 30. Ranking the factors of influence to reduce learning curve for Cementless UKA[42]

Design methodology
Reasoning in design[32] is a generic representation of how designers reason while designing. This model is primarily based on the design of tangible product, in the current project, it is the Oxford Microplasty. This model acts as a stepping stone for the synthesis of design problem.

SYNTHESIS

Design methodology
Mind map[32] is a graphical representation of ideas and aspects organised around a central theme. In this case, it is the current problem to be solved and finding out the possible solution space.

There were several possibilities to make sure these two steps are performed correctly. The mind map in the figure 31 gives a clear flow of the thought process. The map starts with a most ideal scenario and expands towards solution space by considering different constraints and possibilities. The map expands the solutions space into three different design directions:

1. Making a better implant
2. Implanting the current implant correctly and
3. Making sure that surgeons implant it right

1. Making a better implant
The first design direction was to make a perfect implant that does not lead to any complications or always gives positive outcomes. This may be preposterous statement as creating something to replace a natural knee is an ambitious process. The knee joint is developed naturally along with the body anatomy. It can be argued that a personalized implant will be patient specific. But that does not promise a better outcome.

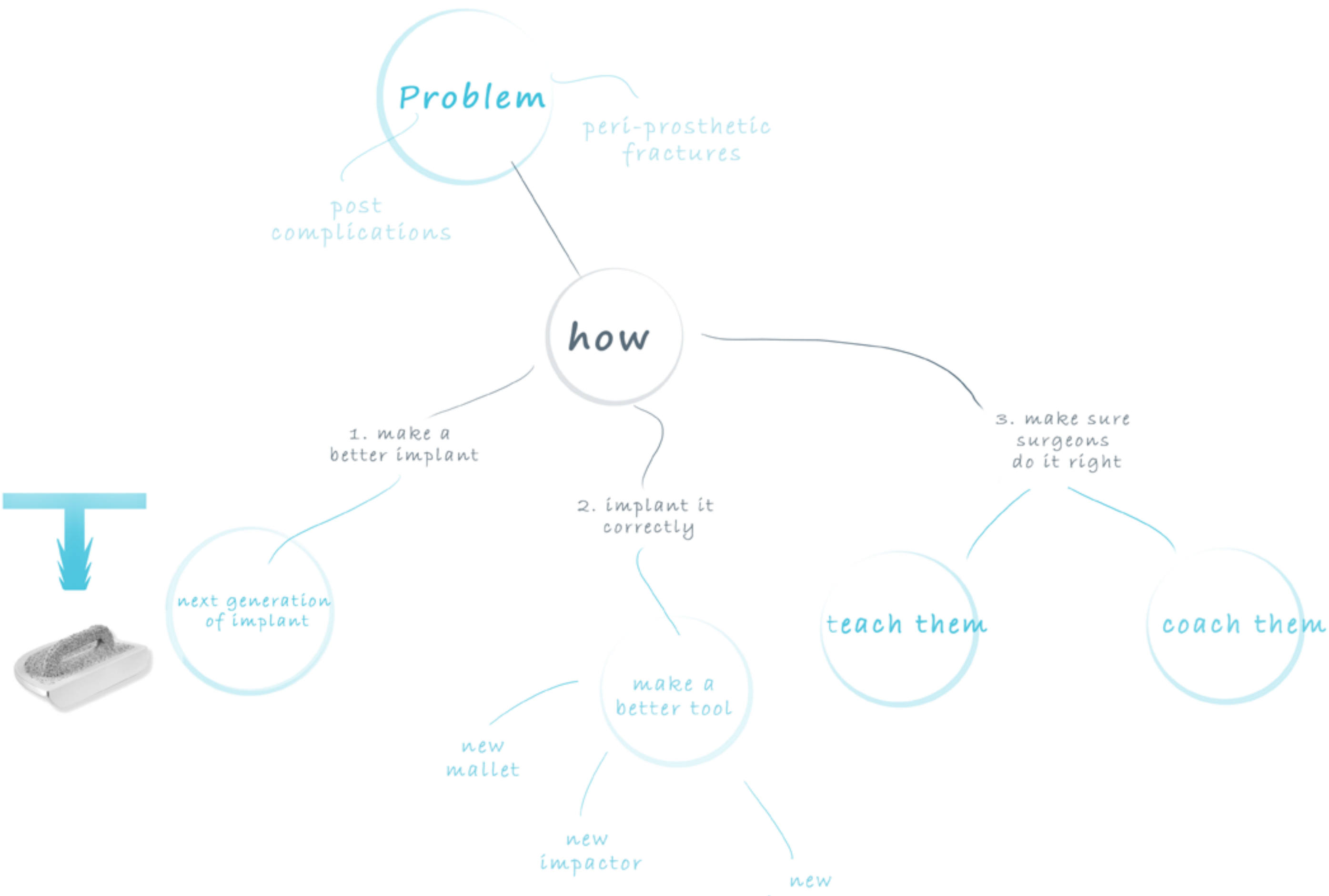
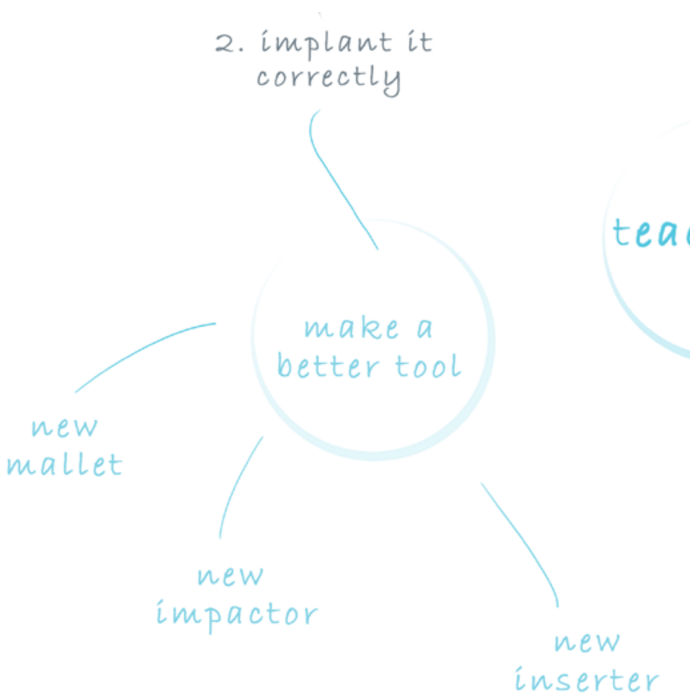


Figure 31. Mind map



2. Implanting the current implant correctly

The second direction was to make a tool that can help implant correctly. The Oxford Microplasty Instrumentation provides a better platform to implant the knee implant. But the tactile skills of surgeons are crucial to have the procedure done right. These skills vary from a novice surgeon to an experienced surgeon. To avoid this uncertainty there needs to be something that makes sure that the implantation is always done in the same and correct, way. This could be a new inserter replacing th current inserter(fig. 32) that can be attached to an Intramedullary(IM) rod. As the IM rod guide is already placed into the intramedullary canal, it can serve as a guide for the new inserter tool to locate the tibial cut and place the implant accurately in the right position. Once the trial implantation is done, the new inserter tool can itself implant the final implant directly. Although this involves some serious developmental complexity, it is quite possible to achieve. Similarly a new impactor can be developed replacing the current inserter(fig. 33) and it can impact the implant with the right amount of force in the right direction. This might even eliminate the need for surgeons to hammer manually. Lastly a new hammer that can apply right amount of force on the inserter and impactor. This can be a pneumatic hammer, an impact driver, or an auto hammer. These hammers can be adjusted to apply a specific amount of force. This will eliminate the need to have the surgeons apply the right amount of force in every impact. Developing such a hammer has an advantage of not disrupting the designs of current inserter and impactor. Developing new inserter and impactor has an advantage of eliminating the hammer and thus reducing an instrument.

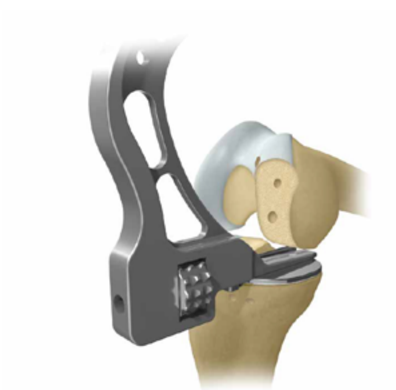
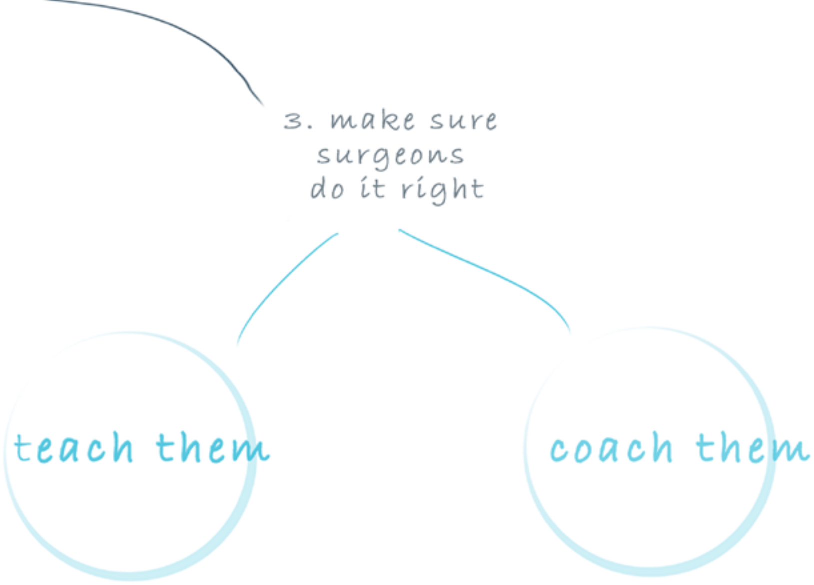


Figure 32. Current inserter from OXMP

Figure 33. Current impactor from OXMP



3. Making sure that surgeons implant it right

The final design direction aims to help the surgeons perform the procedure perfectly right from their first surgery. This is done by teaching and coaching them. Novice surgeons are always taught the surgical procedure. But just teaching is not enough for being competent. A continuous coaching is necessary to be great at something. In critical procedures like insertion and impaction, it is not about being good or bad. It is the difference between being excellent and being competent. To be precise,[42] it is the matter of difference between 99.5 % and 99.95%. This is acquired with 'fallibility'- a tendency to make mistakes. That is why experienced surgeons have better outcomes than novice surgeons. It is not necessarily that they make mistakes but they learn from previous procedures and try to improve. For a novice surgeon to have a short learning curve, they need to make more mistakes which is only possible within the training. A realistic training simulator will provide an opportunity to make mistakes and learn from it. Besides helping novice surgeons to learn the procedure, it could even let the experienced surgeons to try new techniques.

42. Gawande, A. (n.d.). Atul Gawande: The Difference Between Coaching and Teaching. Speech presented at Harvard Graduate School of Education in Harvard University, Cambridge. https://www.youtube.com/watch?v=VabtGPVVihA&t=4149s

"PERFECTION, IT COMES WITH THE TENDENCY TO MAKE MISTAKES"

- ATUL GAWANDE

KOLB'S LEARNING CYCLE IN PRODUCT DESIGN

According to Kolb's experiential learning, an effective learning process covers all the four stages of Kolb's learning cycle[43]. Irrespective of the entry into the cycle, a good learning process is something that makes the learner complete the entire cycle before exiting. Kolb's learning cycle consists of four stages: feeling, reflecting, thinking and doing. During this project, Kolb's learning cycle was considered as a perfect analogy for the Oxford training. It was compared as follows: first, feeling; it is important to have a concrete experience of the surgical procedure. Reflecting: then it is the time to reflect upon the procedure by observing it. Understanding what was the feel? What were the forces involved in the procedure? What were the outcomes? Thinking: Then it is important to draw conclusions out of it. Understanding what types of skills help in improving the outcome and how to acquire them. Lastly, doing: implementing the above thought process in doing it better. No matter where the learning starts, an effective training process should help a novice surgeon or an experienced surgeon to complete all the four stages of Kolb's cycle.

43. McLeod, S. A. (2017, Oct 24). Kolb - learning styles. Retrieved from https://www.simplypsychology.org/learning-kolb.html

44. Kolb's Learning Cycle. (n.d.). Retrieved from https://www.inspiring.uk.com/how-to-create-effective-learning-within-your-organisation/kolbs-learning-cycle/

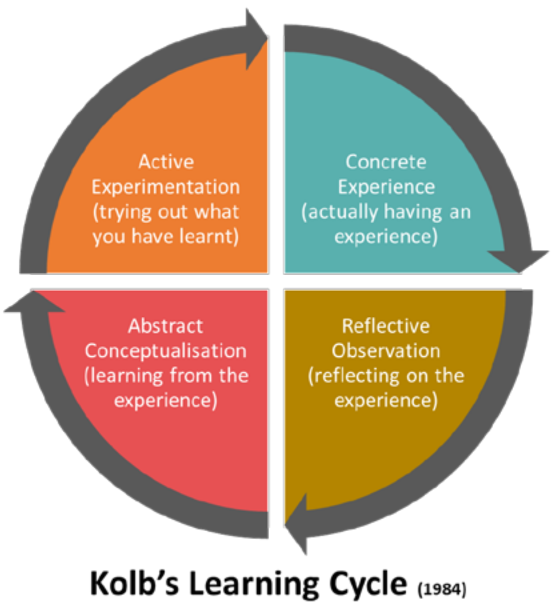
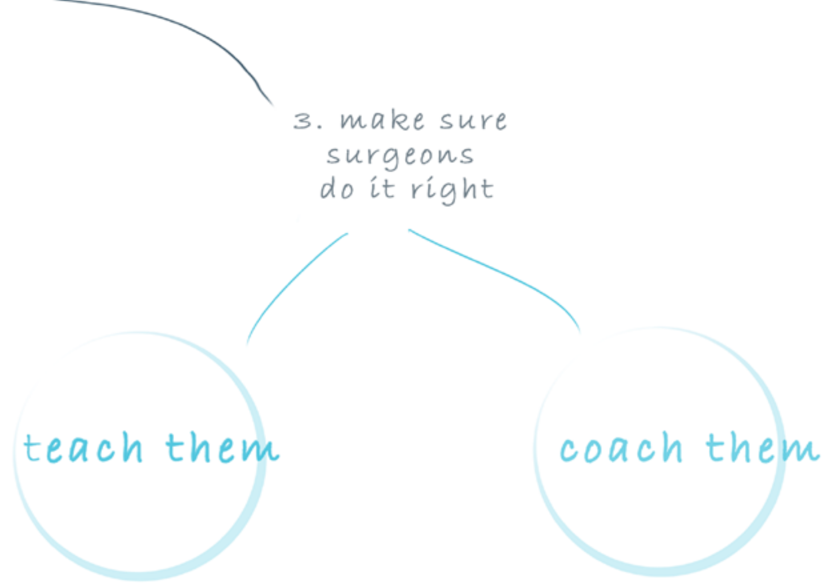


Figure 34. Kolb's learning cycle[44]



45. Learning in Healthcare Helps Faculty to Understand the Impact of Experiential Learning Styles. (n.d.). Retrieved from https://www.newswire.com/news/learning-in-healthcare-helps-faculty-to-understand-the-impact-of-11942914

From the brain map it was clear that the first direction leads to a nice opportunity to design the next generation of knee implant. The second design direction leads to development of surgical instruments for Microplasty instrumentation. During this project, Zimmer Biomet is more focused towards having an immediate solution that will complement an upcoming launch of the product. The first and second design directions lead to class III medical devices that require some serious development time. It is said that class III devices only make 10% of all medical devices and takes about 5 to 7 years of development to get an approval from FDA before entering the market. The third design direction will be an improvement to current Oxford Training course. As Zimmer Biomet already have the infrastructure and human resource for the training process, it will be convenient to implement such an outcome of this design direction as quickly as possible.

So it has been decided that the outcome of this project is the design and development of a training simulator that is based on Kolb's experiential learning cycle to help reduce the learning curve of novice surgeons and act as an experimental platform for experienced surgeons.

User's learning style

It was clear that the primary users of the product are orthopedic surgeons who are learning how to perform the Oxford PKR. These surgeons are either new surgeons that are starting their practice with the Cementless Oxford PKR or experienced surgeons that are shifting to Cementless procedure from the cemented Oxford PKR. When compared to the young surgeons, experienced surgeons are much familiar with the standard steps of bone cutting, milling and so on. But both of them are new to the implantation steps for the Cementless Oxford PKR. Although impaction takes place in other surgical procedures, knowing the right amounts of forces to apply in this specific implant is important for both surgeon groups.

To understand the best way to help them learn these skills, Kolb's theory was applied once again.[45] The theory classifies learning behaviors based on the four quadrants of the learning cycle. Every person has a tendency to learn in one of these styles. These styles are essentially a combination of any two stages of learning cycle. Based on a study(R), most of the orthopedic surgeons have a converging style of learning. Converging learners emphasize the practical application of ideas. They like decision making, problem-solving and practical application. They try to use their learning to solve problems. They are less concerned with interpersonal aspects and more attracted to technical tasks and problems. They like to experiment with new ideas to solve practical problems. In terms of Kolb's cycle, they have a natural learning tendency of thinking (abstract conceptualization) and doing (active experimentation). On the other hand, the least percentage of orthopedic surgeons are assimilating learners. Unlike converging learners, assimilating learners try to pull a number of thoughts and observations to make theories around them. Assimilating learners value a good explanation more than a practical experience. Kolb presented these learning styles to help orient a learning process to a preferred style of a group of people.

Design methodology
Designing is often referred to as problem solving. Before starting to solve anything, it is important to be sure that the focus is towards the right problem. Finding and defining the rea problem is a significant step towards a solution.[32]

So the outcome of this project should ensure that the designed activities are engaging for converging learners At the same time provide an opportunity to complete the learning cycle by touching all the four bases.

Derivative - Providing an opportunity to make conclusions out of something. The product should provoke an initial thought process to get the learner enter the learning cycle.

Experimental/ Innovative - Motivating to try the new ideas out of derived conclusions. The product should be versatile to let the user make changes and deviate from a standard thumb rules to understand the process better.

Professional - Providing a complete experience of a process. The product should act as a platform to have concrete experience of the surgical procedure.

Reflective/ Intelligent - Providing information about what happened. The product should be intelligent enough to understand the measure/track the procedure to help then user to reflect on the procedure.

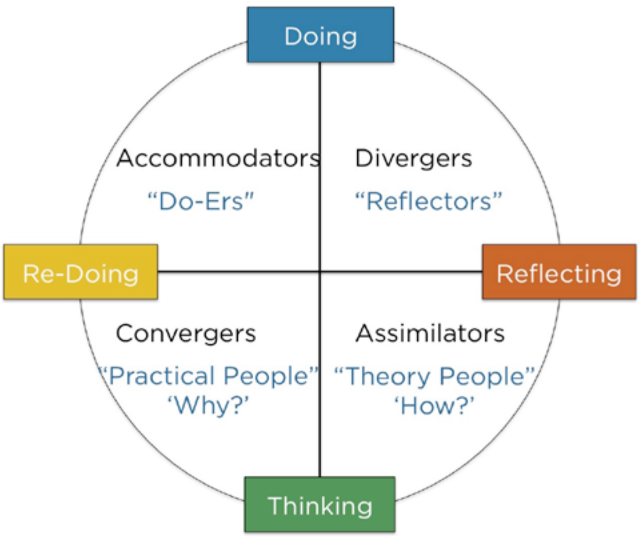


Figure 35. Experiential Learning Styles[45]

PROBLEM STATEMENT

Develop a training tool with a realistic simulation of knee joint to train the insertion and impaction steps of Cementless Oxford partial knee replacement surgery.

CHAPTER 2. SECTION 2

DESIGN

As the aim of the project is to deliver a manufacturing ready design, it was important to know the practical requirements of the product before developing the actual product. Although synthesis gave an idea of the desired qualities of the product, the functional requirements were not clear yet. During this design phase, a quick design was developed with basic requirements obtained from the design synthesis of previous section. The plan was to plan was to demonstrate this prototype in an upcoming Oxford training course to get a detailed feedback.

PRODUCT PLANNING

Sawbone demonstration is a part of current Oxford training course. During this workshop the surgeons are demonstrated with bone preparation and trial implant. Every surgeon receives a sawbones set and performs the tibial, femoral saw cuts and trail implantation. But they do not perform the final implantation step. So it was planned to make a setup in the upcoming Oxford training course in a way that these pre-cut sawbones are used to do the insertion and impaction.

From the observations it was known that the insertion and impaction are mostly done in a flex position. Thus the bone placement has been decided to be in a position that there the tibia and femur are 120 degrees apart. Moreover the full bone is never used in these two steps. So the plan was to use only a smaller length of each bone by cutting out the rest of the part. One of the main reasons that the insertion and impaction are not done with the current sawbones model in the training course was that, it is structurally not strong enough. It was true that the tibia sawbone was hanging without any support except the ligament threads. Although in a real scenario the lower limb is also hanging with the only support at the thigh, the soft tissue surrounding the knee joint makes it stay intact. As the patient is sedated the muscles do not pose any resistance and the second surgeon always helps the surgeon by holding the foot in a flex position while impacting the implant. Thus it was understood that the bones positioned in 120 degree flexion need to be fixed rigidly before impacting.

During an interview with Mr. William Jackson at NOC, Oxford, he mentioned that one of the major differences between what the surgeons experience in Oxford training and in an operating room is the visibility. The knee joint is exposed in the training course without any soft tissue. As the surgery being a minimally invasive surgery, a small incision is made in a Cementless Oxford PKR. The visibility is constrained to only the anterior-medial part of the tibia and femur. It is difficult for the novice surgeons to assess the proximal reach of the tools. But in the Oxford training course, the sawbones model is completely open giving a clear view of the tools. Also the usage of the tools is much easier in the sawbones demonstration than in the operation theatre. The soft tissue around the knee joint constrains the movement of tools. Thus it was decided that a soft tissue is necessary around the bone to have a realistic feel of the procedure. But at the same time Mr. Will argues that it is also important for a trainee surgeon to see the outcome after the implantation to reflect up on the process. So soft tissue needs to be a modular addition to the training tool.

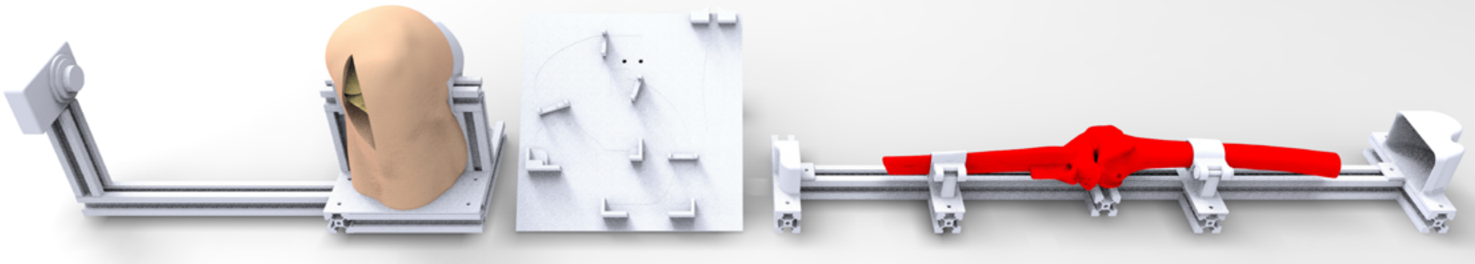


Figure 36. Oxford demonstration setup

From the synthesis of previous section, it was also known that the product needs to be intelligent enough to track working parameters of the procedure. As mentioned in tracking section of the research chapter, it was important to know the insertion patterns of faculty surgeons and novice surgeons. This prototype acted as a feasible tool to understand this. So the plan was to record the procedure in the same way as mentioned in the tracking sub-section of section4 in previous chapter. But this time it were the surgeons that are operating in workshop. These videos were later used to analyze the insertion patterns of novice surgeons using the tracker software. This needed a digital camera to be mounted on one side of the prototype. Thus the plan was to make sure that the following elements were addressed in the prototype.

- Implantation - insertion & impaction
- Flex position (120 degrees)
- Rigid fixture
- Removable soft tissue covering
- Sizing the bones to smaller length
- Digital camera

Design methodology
Function analysis[32] is a method for analyzing and developing the function structure of an existing product or new product concept. It helps to describe the intended functions of the product and relate them to its parts and 'organs'. A good analysis can be helpful in finding and exploring new possibilities to embody certain functions in a product or product concept.

In the current project, this part of product planning was the first point where the functional analysis has started that suggests what kind of functions are necessary in the product.

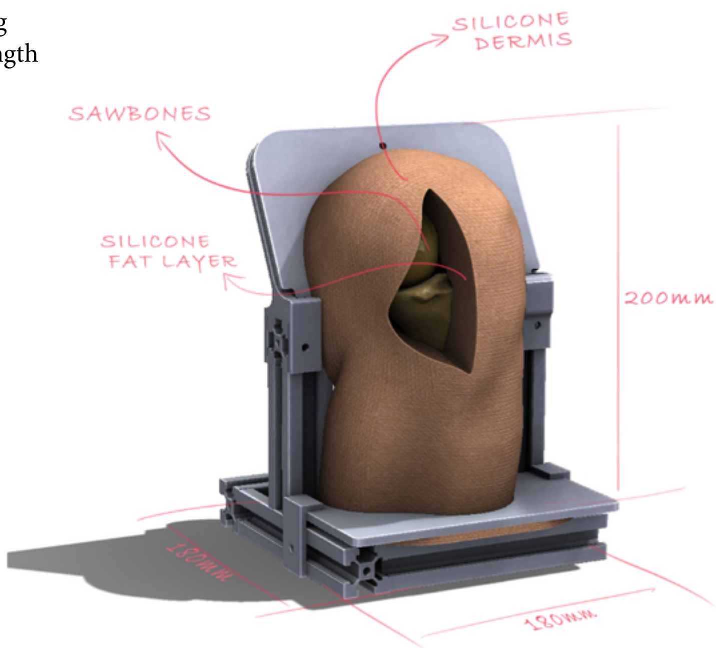


Figure 37. First prototype with silcone soft tissue

QUICK PROTOTYPING

A quick prototype was developed with basic requirements from the product planning. This included silicon molding to simulate soft tissue, jig development out of aluminum profiles and bone sizing template.

Jig
A table top jig was designed using 30x30mm aluminum profile. The holders for tibia and femur were designed to ensure 120 degrees of flexion between the bones. These holders were 3d printed and fastened with a Velcro. The jig was designed to attach to the table using two regular c-clamps. An extension of aluminum profile was attached to the jig to mount a digital camera.

Bone sizing
A bone sizing template was fabricated using the same 30x30mm aluminum profile. Two bone end caps were 3d printed to position the bones. Two 3d printed cutting guides on each side of the bone indicate the cutting position. This template helps to cut the sawbones in a specific length to be able to fit in the jig.

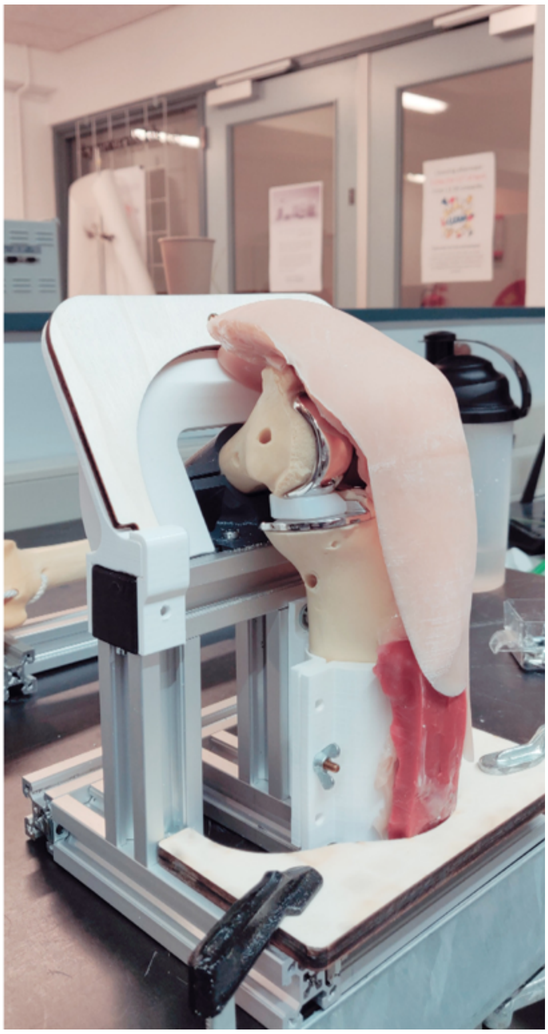


Figure 38. Silicone soft tissue around the sawbones

Soft tissue
Silicone prosthetics that are used in film-making have been the closest the simulation to real soft tissue. These are made by prosthetic artists in the during a film-making. Form X is a well-known supplier for Hollywood prosthetic artists. It is an Amsterdam based company that supplies Smooth-on silicones that are also used in medical simulations. Different types of silicone have different shore harnesses to differentiate between different layers of skin. Three types of silicone with shore harnesses 2A, 00-30 and 000-35 were sourced for this project to simulate dermis, muscle and fat layers of soft tissue.

To have a soft tissue covering the bones, a real knee of a person was 3d scanned. It was made sure that the knee is flexed in 120 degrees while scanning. Since the plan was to use the same sawbones from the training workshop, these bones were also 3d scanned but separately. A 3d assembly of the skin and bones was made in SolidWorks. This acted as a referenced to design a 3D printable cast to mold silicon. Firstly, the muscles were casted separately with a mix of Ecoflex-30 and Dragon Skin Fx-Pro in a different mold. A thin layer of Dragon skin FX-Pro was poured in the cast to form the dermis layer. The casted muscles were then placed and the mold was closed. Through an injecting hole, Ecoflex Gel, that simulates the fat was injected into the mold and left for curing. 3 hours later the mold was opened to extract the casted silicon soft tissue. The silicone was painted with SilTone skin texture to make it look realistic.

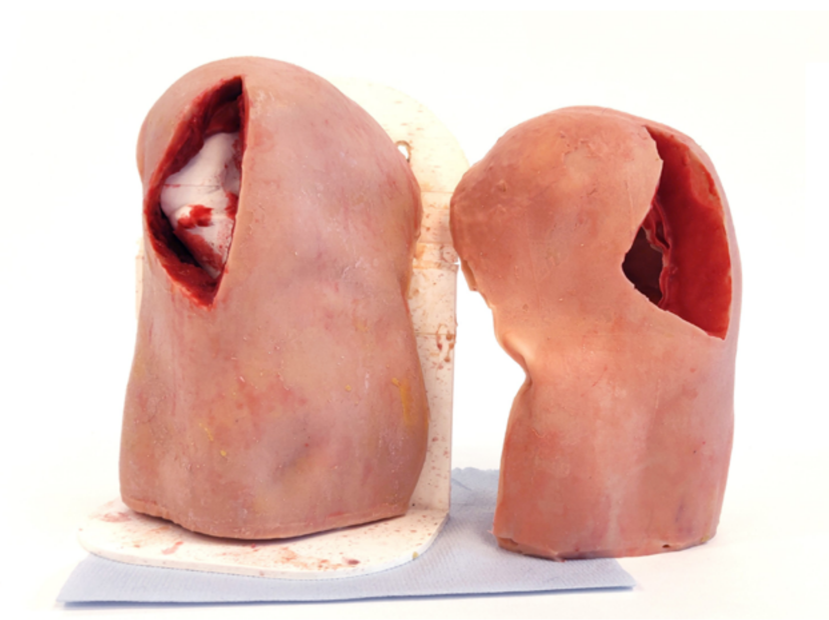


Figure 39. Silicone soft tissue with skin texture

CHAPTER 2. SECTION 3

VALIDATION

Oxford training course was the right place to demonstrate as both the faculty surgeons and novice surgeons are available at the same place. The prototype was shipped to Oxford to demonstrate during the training course. This prototype was used to know in detail about what does the surgeons expect from such a product.

OXFORD DEMONSTRATION

On the day of Oxford training at Keble College in Oxford, the Foxpat prototype was set up. The prototype was placed at the end of the workshop hall so that the trainee surgeons could finish the demonstration and come to the test prototype. Although the jig was rigid enough, the tables were not quite sturdy. The faculty surgeons made a quick visit to see the prototype. Prof. Murry said the setup looks very realistic and agreed for letting the surgeons to try on it during workshop. They saw the prototype as a good advancement from the current sawbones setup they have in the training workshop. They liked the idea that surgeons could bring their own sawbones to work on the prototype so that they cannot blame the tibial cuts.

It was an honor that John O'Connor, the Inventor of Oxford partial knee visited the workshop to see the prototype. He wanted to understand the added value of this setup to the existing workshop. He personally believed it would be a good addition to the workshop but wanted to see it in action when the surgeons are working on it during workshop.

Figure 40. Prof. Murray and Abtin Alvand testing the prototype at Oxford training course

FEEDBACK FROM SURGEONS

Trainee surgeons
The trainee surgeons were divided into two groups for the sawbones demonstration. Three trainee surgeons from the first group and two from the second group were able to perform the implantation on the prototype. These surgeons were told that the setup was a developmental model for training the implantation of actual implant. All the trainees find it interesting to work with. But most of them were there for their first time at the Oxford training. So they don't know what is the training like without the implantation part. So the performances by trainee surgeons were recorded only for understanding user's behavior and way of approach to the product.

Experienced surgeons
Besides the trainee surgeons, there were also some non-faculty surgeons that are well experienced in doing Cementless Oxford PKR. After a short explanation they find it interesting. Dr. Hemant Pandit liked the idea that this product can not only help novice surgeons in the workshop, but also experienced surgeons to keep practicing in their own hospitals.

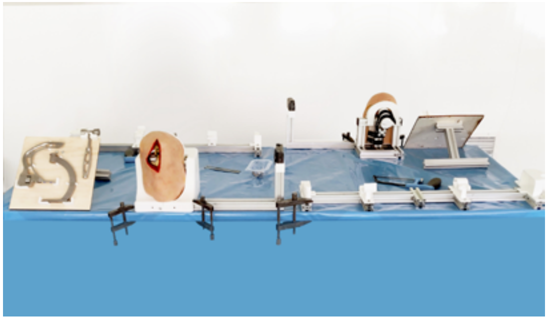


Figure 42. Two prototypes ready to be tested at Oxford training

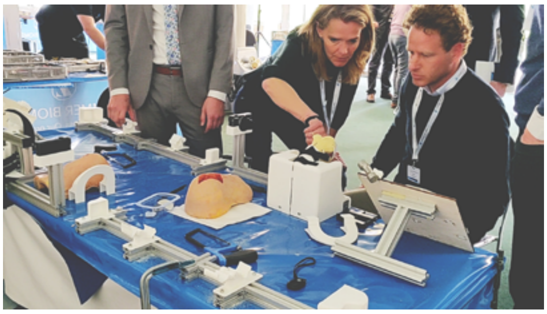


Figure 43(a). Novice surgeons practicing the implantation

Figure 41. Prof. Price testing the prototype

Figure 43(b). Novice surgeons practicing the implantation

Figure 44. Prototype testing at Keble College, Oxford

Oxford knee group

At the end of the training course, Prof Murray was able to come back to test the prototype. A pre-cut sawbones was already prepared and fixed in the jig for him. When he started to inserting the implant he thought that he would need a little freedom to move the bones(fig. 45). He mentioned that although it's good to have the tibia fixed, there needs to be a little freedom to fix it wherever the surgeons want. So he removed the sawbones from the jig and put it over to show me the Valgus deformation that they like they to do. This is usually done during the surgery to increase the joint gap during tibial insertion. This was one of the requirements that were not known until that moment. When we look back into the surgery observations, it was true that every surgeon adjusts the foot before inserting the implant by flexing the leg and moving sideways to create more working space at the joint.

Dr. Abtin Alvand identified that the bone positioning was not anatomically correct. He said although the bones are flexed at 120 degrees, the axis of each bone does not align with the natural axes. It was not observed until he pointed that out. It was true that when a fully extended knee anatomy is observed, the femoral and tibial axes are not naturally collinear. There is always a deviation of about 7degrees.

Mr. Price was able to test the prototype during that second day and quite satisfied with the design. He pointed out that the soft tissue is anatomically incorrect. He was right that there is only a few millimeters of skin tissue covering tibia in real anatomy. Whereas the silicon soft tissue has a 15 millimeter thick silicone layer in front of the tibia and at the incision. Mr. Price also mentioned about the light. As the surgeons are much used to operate under powerful surgical lights, he found the incision in the prototype to be darker. When asked about feedbacking the trainee surgeons, he said that the current prototype was already able to solve the purpose, but tracking and feedbacking would be a nice addition to it.

Figure 45. Prof. Murray not using the jig to show that freedom to move tibia is important

Figure 46. Wouter Eilander testing the prototype at Haga Ziekenhuis

Young surgeons outside Oxford
The trainee surgeons at Oxford training were not asked for a feedback as it was too soon for them to reflect upon. But these novice surgeons are the primary users of the product. So it was important to test the prototype with them as well. Wouter Eilander is a fellow of Dr. Sander Spruijt at Haga Ziekenhuis. He attended an Oxford training course 4 months before the date of prototype testing. Since then he was working in the operation theatre along with Dr. Spruijt for about 30 Cementless PKRs. He mentioned that they get to do one step in each surgery by themselves. Thus they have an experience of trying all the steps at least once on a real patient before trying out a complete procedure by themselves. As he attended the training before and also has an experience of real surgery, he was chosen as a right person for testing the prototype and assess its effectiveness.

Figure 47. Wouter Eilander testing the prototype at Haga Ziekenhuis

ANALYSIS

The recorded videos from the Oxford training were analyzed to find the insertion patterns using tracker program. Since the digital camera was directly attached to the jig, there was some noise observed during every impact. These noises were neglected to find an approximate 2d curve of the movement of inserter. A specific point on the inserter was chosen to track the movement of the tool. Two results from the faculty surgeons and two from trainee surgeons were analyzed. When the four 2d plots were compared , there were some interesting conclusions. The two plots from experiences faculty surgeons were also quite different from each other. From this, it was hard to say how close were the trainee surgeons to the faculty surgeon's procedures. When the same discussion was taken back to discuss with the faculty surgeons, it was understood that the 2d patterns of insertion cannot be right or wrong. There could be several possibilities of doing it right. So it was wise to define what is not right and train the surgeons not perform those errors. In this case of insertion, the key assessment factor lies in the excess amounts of force in the unnecessary directions.

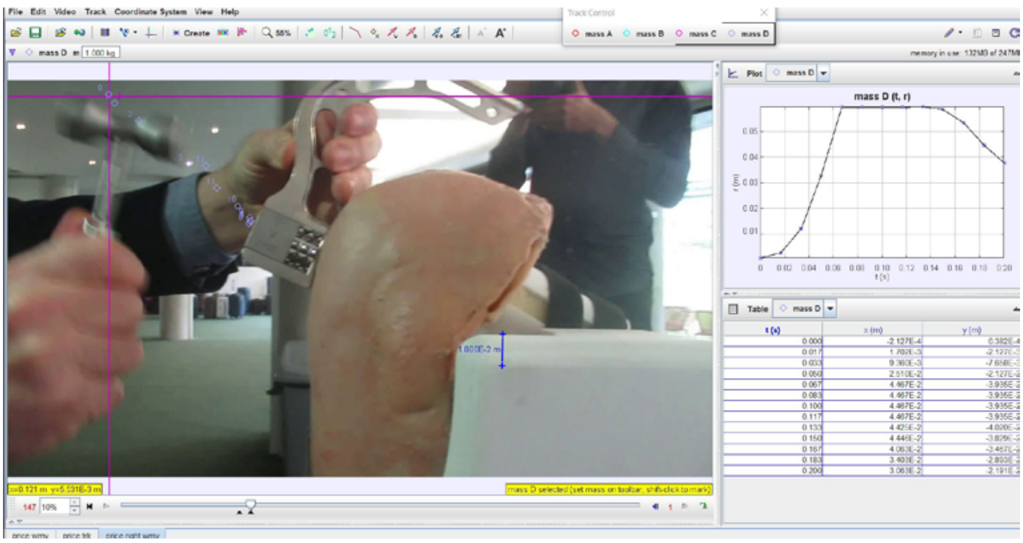


Figure 48. Video recordings from Oxford demonstration being analyzed in the Tracker software

To define these assessment factors like excess forces, it is important to divide the insertion process in 3 detailed operations. This was done from the surgery video observations recorded during research phase.

The first operation is inserting the standard inserter obliquely at an angle beyond 30 degrees from horizontal. Then a toffee mallet was used to impact on the front part of the inserter to insert the implant. This is continued until the tip of inserter touches the tibial plateau. At this point it, the posterior part of the keel has almost have entered into the keel slot. It is important to stop impacting at that point as the excess number of impacts may damage the bone.

Second operation is to impact on the top of the inserter to push the anterior part of the keel into the slot. During this step the orientation of inserter will help to understand if the implant is completely horizontal. It is also important to not impact too many times from the top as it may destroy anterior wall of keel slot.

The third operation is to push the implant further into the incision by impacting from front and push further down into keel slot by impacting from the top.

From this, it was easier to define the undesired elements of the operation. Excess amounts of force at the end of first and second steps are not advisable. So it is important to know the amount of impact necessary in each position.

Bone mineral density

It was observed from Oxford sawbones demonstrations that it was easy to implant on a sawbones than on a real bone. Also Prof. Murray said that these sawbones feel much softer than actual one. This has never been a problem as the implantation was never demonstrated on the sawbones during the workshop. To identify the difference, a quick auditory analysis was carried out. The videos from the live surgery observations from the field trips and the recordings from Oxford demonstration were used to analyze and compare. Audacity was used to zoom into the waveforms of impact sounds from both the videos. The waveforms plot the loudness on a scale from +1 to +1. Although the maximum amplitudes were reached in a similar fashion in both the videos, the transition or the reaction sounds were not similar. There was a large transition in real implantation whereas the sawbones recordings had an immediate transition to low amplitudes. Although the Audacity tool was not made for scientific observations, the waveform plot comparison gave an idea that the impaction on the sawbones was different from actual bones.

Conclusion - Analysis

The insertion patterns will be different for every surgeon. There cannot be a one standard insertion pattern that every surgeon should follow to get the implementation right. Any insertion procedure is acceptable as long as it does not apply excess amounts of impact when the tip of the tool is touching tibial condyle. So it was decided to track the impact forces and angles of hit rather than trying to track the movement of inserter and compare with an ideal pattern.

Oxford demonstration was quite helpful to obtain some key inputs. Such observations/inputs would have not been possible with regular research methods. On the other hand, the Oxford demonstration also gave an idea of how the product is going to be used by the primary and secondary users in a real scenario. These inputs and observations were summed up as following.

/Bone sizing needs to be simplified or eliminated

Cutting the bones to shorter length to fit into the product was not well appreciated by the surgeons. As this is not the part of the actual procedure, it was not recommended to have this step in the final product.

/ Adjustable height

Working height was also another important element that was ignored in the first prototype. As the working tables are much lower at Keble College, the surgeons had to bend down most of the times to see into the incision.

/ Silicon soft tissue was anatomically incorrect

During the soft skin preparation, the 3d scan of the knee and the bones were assembled in the CAD without any reference. Due to this there was an unrealistic thickness of silicone soft skin around the knee joint.

/ Tibia needs to be fixed but adjustable

This was a preposterous requirement that the surgeons want to move the tibia round to find the right working space, but want to be fixed in the desired position.

/ Retractor for soft tissue

When the soft tissue was introduced in the training, there were additional requirement of tools. In the operating room, surgeons use a retractor to clear the soft tissue out of the working space. Retractor has never been a part of the training tool kit before and is necessary if there is a skin involved.

/ The lighting wasn't good

Due to the lack of surgical lamps in the training hall, the incision was not bright enough for the surgeons to work.

/ Bone density is not similar

The sawbones that were being used in the training were not as stiff as a real bone. Although the jig was prepared to ensure a realistic simulation of surgical procedure, the softer bones were not able to simulate the impaction process very well.

CHAPTER 3

PHASE - II

CHAPTER 3. SECTION 1

DESIGN IMPROVEMENTS

There were some important design aspects discovered during the validation of first prototype. This aspects require some research before synthesizing the design requirements. Some of these aspects were the improvements to design features from the last prototype and some of them were new aspects that we discovered during design validation. This section focuses on such aspects and presents the solutions that were evolved.

SOLUTIONS FOR DESIGN PROBLEMS

Except for few, most of the design requirements from the user tests were easily resolvable. One of such unique requirements from the faculty surgeons was that the tibia need to be fixed and free at the same time. This was important for them to hyper-flex the lower limb to create more working space. So the foot needs to have a freedom of movement in natural reach which is 0 to 160degrees of Flexion, 6-8 degrees of Varus, Valgus angulations. And 25-30 degrees of internal rotation. Due to the incision and removal of some soft tissue at incision there could be even more freedom than these angles during the surgery. It was not researched further on how much does these angles increase during the surgery as it depends on different factors of incision length, age of the patient and muscle mass.

Swivel arm

To make sure that most of this rotation is possible during the training, a double joint swivel arm was developed. A quick proof of concept(POC) with two ball joints and a linkage was proved to be a feasible option to allow the knee rotation and at the same time a strong fixture for tibia at any desired position. Although full Flexion was achieved, reaching the full extension was not possible with such a fixture. It was a design compromise that the fixture can only reach 35 degrees from the maximum Flexion. Beyond this point the fixture should be detached to reach the full extension. It was a reasonable design compromise because the surgeons extend the leg to evaluate the joint tension during trial implantation and actual implantation. In these steps there was never a procedure done that needs a rigid fixture for the leg.

So it was acceptable to provide the fixture in Flexion positions as there was still a freedom of movement to some extent. The POC was able to achieve 5 degrees of Flexion and 25 degrees of Varus Valgus angulations. So this was considered as a mandatory component of the final design. Unlike the way the quick POC was build, the aim was to achieve such angles in a custom designed swivel arm for the final design.

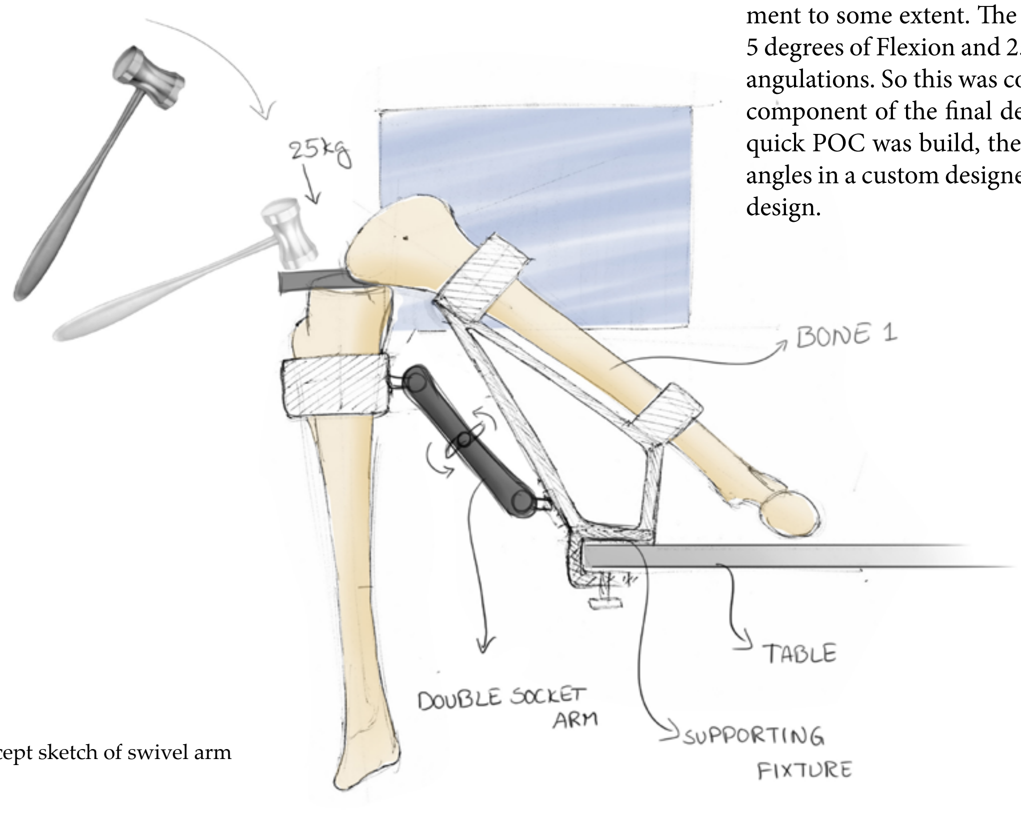


Figure 49. Concept sketch of swivel arm

Impact tracking
From the Oxford demonstration results, it was clear that insertion patterns cannot be an assessment factor of the performance. The most effective way was to track the impact forces and angles of impact. A force sensor FX901 that has integrated piezoresistive strain gauge was used for this. As the hammer impacts are instantaneous forces that take place in 1/10 of the second, traditional load cells could not pick up the forces accurately. FX901 has uses piezoresistive strain gauge fused with high temperature glass to a high performance stainless steel force measuring flexure. FX901 with a range of 0- 440N was used to track the impact forces by placing it on the hammer. For the amount of impact was extracted from these sensor was planned to be used to display the user as a feedback.

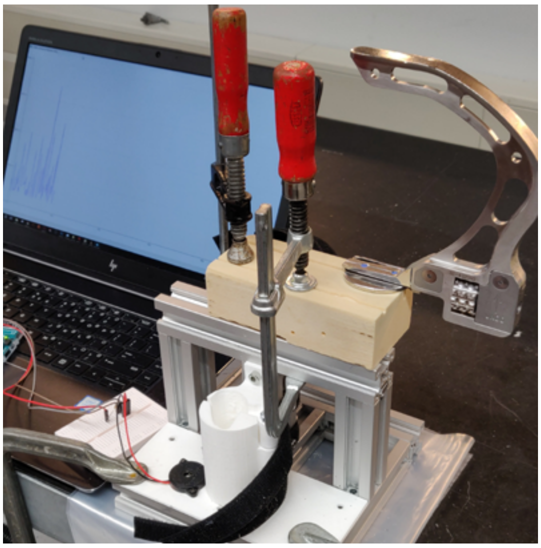


Figure 50. Using force sensors to track the impact forces

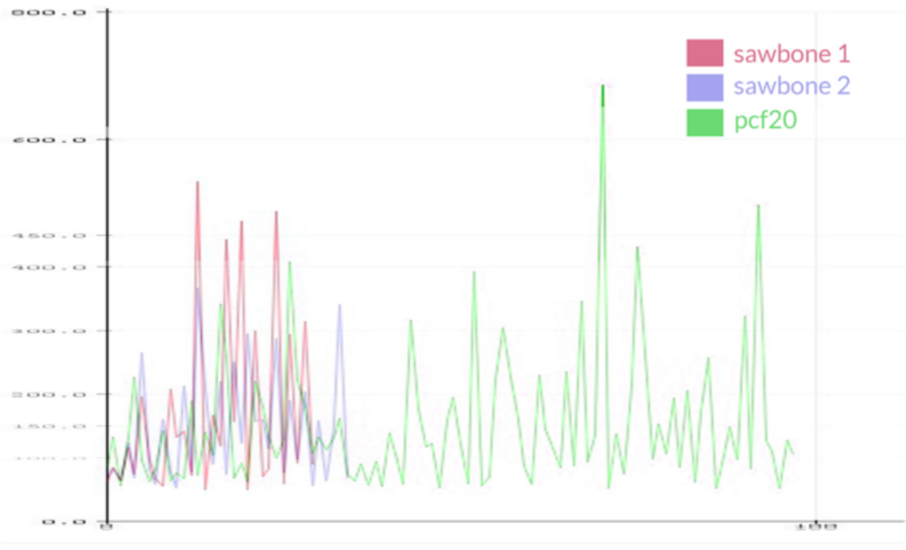


Figure 51. Plot overlap of impact values from three different bone sampes

46. Ramaswamy, R., Evans, S., & Kosashvili, Y. (2010). Holding power of variable pitch screws in osteoporotic, osteopenic and normal bone: Are all screws created equal? Injury, 41(2), 179-183. doi:10.1016/j.injury.2009.08.015

Sawbones

The current sawbones that are used in Oxford training were being manufactured by a London based company called The London Bone Company. These bones were made out of polyurethane, molded in a volume constrained mold. When Oxford training was introduced, the Oxford Knee Group together with this company developed a mold for these bones. Although a clear design logs were not found on the development of this, it was said by Zimmer Biomet that the mold was developed in casting method in according to the surgeons requirement. These casted bones had to simulate the development of osteophytes around the medial side of the joint. Besides this, there were not many constraints during the development of these bones. Hence there were also not any detail specifications found about the parameters like density and stiffness. It was also clear from the discussion that the sawbones are based on the bones sizes of an European middle aged small woman. As this was unknown during the first iteration, the 3d scanning was not done according to the size of the bones. That could have also been one of the reasons for an unrealistic thickness of silicone soft tissue at the incision.

A quick test was conducted to determine the density of existing sawbones. Archimedes volume principle was used to extract the densities of different samples collected from the Oxford demonstration. Five samples were tested to find the consistent results. It was determined that these sawbones were of density 220gm/cc. From the literature study it was known that PCF20 sawbones that are of density 320gm.cc are considered by different researchers[46] as the closest simulation of actual bone density.

Figure 52. Milling tibial condyle out of PCF20 sawbones block

Figure 53. Dr. Sander Spruijt testing the prototype at Haga Ziekenhuis

IMPROVING THE DESIGN ELEMENTS

To have a realistic implantation feel, it was understood that the sawbones need to be thicker than the current ones. The FDA states that PCF20 were the most accurate simulation of actual bones. The PCF20 sawbones solid foam blocks were sourced from the SAWBONES company from Washington. Although this company also manufactures the femoral and tibial sawbones, they were of density of 250gm/cc(PCF16). So to have the denser bones, the PCF20 sawbones blocks were CNC milled into the shape of tibia to replace the current sawbones tibia from Oxford demonstration.

Validating the improvements

The improved sawbones were used with the same jig from first iteration to test with an experienced surgeon and a novice surgeon. Dr. Spruijt Sander from Haga Ziekenhuis in The Hague, who is also an faculty surgeons for Dutch training course, has agreed to perform the implantation on the sawbones. His co-surgeons, Wouter Eilander who was also interviewed during the phase -I, agreed to perform the implantation. During this user test, tibia of three different densities were prepared to understand which one of them was the closest simulation to a real bone. One of those samples was an existing one saw from Oxford demonstration. The other sample was a CNC milled sawbones from PCF20 block. Lastly a tibia 3d printed in Polylactic Acid (PLA) with an infill density of 30%. Thus the three different density of 220gm/cc and 320gm/cc of polyurethane and 375gm/cc of PLA samples were used to test the implantation.

During the user test with Dr. Spruijt, it was quite easier to implant on the existing sawbones. Secondly when he performed on the PCF20 he finds it more realistic in terms of reaction force while impacting. Lastly implanting on the 3d printed PLA was way harder than usual. He commented that the 3d printed bone was way harder than anything he experienced in the operation theatre.

Conclusion

The sawbones with a density of PCF20 which is 320gm/cc were considered as the most suitable option for implantation. The London Bone company was contacted in this regard. As the company follows a traditional process of manufacturing, the densities were difficult to maintain at their end. Sawbones company currently produces sawbones of PCF15. They were able to make the PCF20 sawbones on demand but Zimmer Biomet already has a line of production going on with The London Bone company for PCF20 sawbones. So they prefer to source from them instead of other third party companies. The London Bone company team was able to send two samples of two different densities of sawbones which were later tested to be 240gm/cc and 280gm/cc. These bones were prepared to test with the faculty surgeons in the final design.

DESIGN SYNTHESIS

From the Oxford demonstration and the user tests, there were several design improvements recognized. The second iteration of the design was aimed at addressing most of these requirements. Also the product qualities from the synthesis were maintained while developing the final design. These desired characteristics of the product acted as values that the product needs to possess. These values were then translated into needs which helped to determine the required form and function of the required in the product.

VALUES	NEEDS	FUNCTIONS	PROPERTIES
Reduce learning curve	Persistent work	Train multiple times	Re-usability
Early fallibility	Reflection & learning	Feedbacking	Intelligent
less complications	Being inventive	Versatile	Adaptive

Figure 54. Design synthesis - From values to properties

The functions generated from synthesis and the design inputs from the first iteration of design were considered in this section to develop a detailed list of the requirements. This list was generated using the following design checklist:

Performance
Realistic simulation of actual surgical process is necessary
Visual constraints - soft tissue enclosure
Physical constraints - supporting fixture for tibia
Strength - Should be strong enough to bare 200N of force at the incision
Tracking - Should be able to differentiate between higher and lower impacts from a calibrated impact.
Fixture - The product should not move or deform while performing the procedure.

Life in Service:
The product should withstand vibrations from continuous usage of hammers power drills during surgical procedure.

Maintenance
The Oxford training crew should be able to assemble the product and maintain any repairs by sourcing the components.

Target production cost
The production cost should not exceed 3000 euros.

Transport
The product should be able to fit in flight cases with a volume not exceeding 3.5 cubic meters and weighting less than 50.

Packaging
The product packaging should withstand transportation vibrations and movements.

Quantity
The product should be produced in quantities of 50-100 per year.

Aesthetics
The product should fit in a training environment and hospital environment without distracting the surgeons.

Product lifespan
The product should last for up to 5 years with an approximate intensity of 500 times of usage a year.

Standards
If exist, the power supply for the product should follow standard voltage regulations of the US, UK and Europe.

Ergonomics
The surgeon should be able to use the product in any of their regular postures of surgery.
Surgeons with most of the heights should be able to comfortably work with the product.

Safety
The product should not harm the user during accidental breakdowns.
The product should not constrain the safety measures of the tools used in training procedure.
Inflammable components of the product like battery should be avoided. If used in the product, should be able to detach easily without disassembling the product.

Installation & initiation
The product should be open-able from flight case and install on to most of the tables that are used in hospitals and training facilities. This training crew should be able to do this installation with a brief explanation.
The product installation, initiation time should not exceed more than an hour.

LIST OF REQUIREMENTS

From the above list, the most important requirements have been extracted as 'demands' that the product should be able to meet during the evaluation. The other requirements from the list were considered as 'wishes' that are good to have in the product.

The demands were ranked in order of most important to the least important.

Demands
1. Product should be able to simulate a realistic surgical process (Trial and final Implantation).
2. The product should be reusable (Except the sawbones)
3. Soft tissue enclosure should be removable when necessary.
4. Sawbones should be replaceable between every procedure.
5. Full Extension and Flexion(160 degrees) of the joint should be possible.
6. One surgeons alone should be able to do the procedure.
7. Surgeon should be able to operate conveniently in any posture.
8. Should have height adjust-ability.
9. Should be able to fit to most to the tables.
10. Should be portable (Weight less than 50kgs and volume 3m3).

Wishes
1. Product should provide feedback on impact force & insertion procedure.
2. A good simulation of light is necessary.
3. Clamping the bones should be as simple as a click of a button.
4. Soft tissue sleeve should be easy to put on and off.

Design methodology
List of Requirements[32.] states the important characteristics that a design must meet in order to be successful. A List of Requirements describes concretely all of the design objectives and can be used to select the most promising ideas.

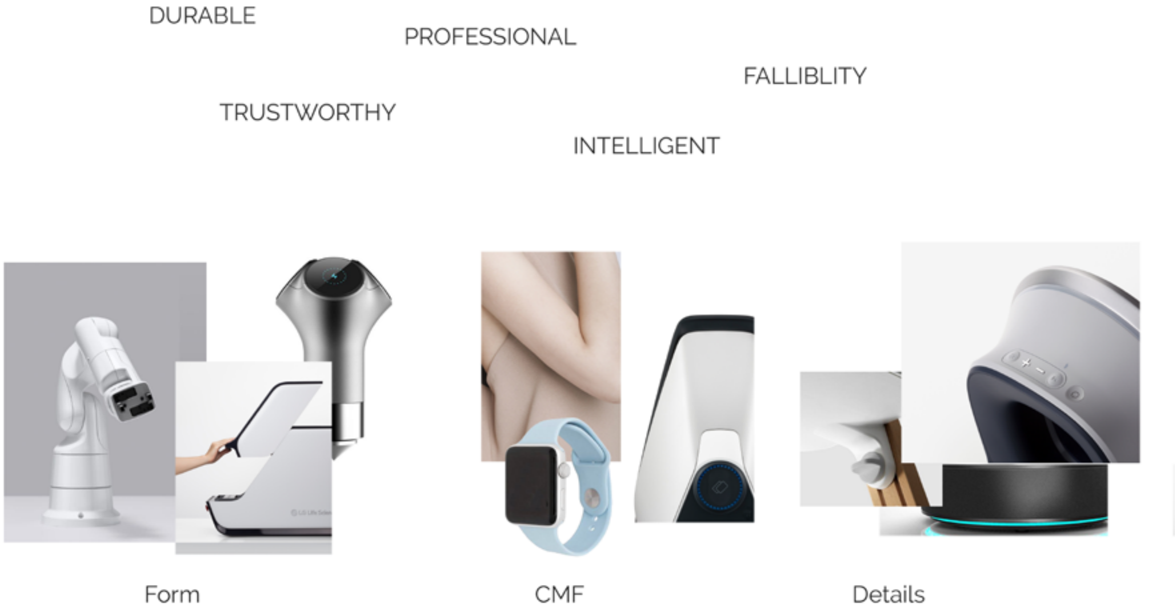


Figure 55. Moodboard

MOODBOARD

A mood board was made before starting with the ideation. The theme of the mood board was represented with 5 keywords that best describe the outcome of the project. This theme has helped to find the desired look and feel of the product. A collection was made that represents the desired form of the product. A collection of desired forms was made to represent a strong and well balanced stable structure. The sliding parts of product need to be easy to operate and at the same time need to have a trustworthy impression. Secondly a collection of color, material and finish (CMF) was made. The aim was to make the product look professional and at the same time encouraging the users(surgeons) to try experimenting. A combination of semi white plastic and aluminum were chosen with few complementary parts in black. As the skin tissue is involved, the silicon fasteners were planned to have in light blue-green. Lastly a collection with all the desired details was made. This deals with the type of button, fasteners and LED lights that can possibly be on the product enclosure.

CHAPTER 3. SECTION 2

CONCEPTUALIZATION

The design inputs from the synthesis section of previous chapter and the design improvements that were proposed in this chapter were considered to ideate the form and function of final product. But this ideation process was not constrained by any technical limitations to explore the ideas in a wider perspective. The list of requirements and mood board were the starting points of this process. This section contains the concepts that were finalized and the process of concept selection.

Design methodology
Brainstorm[32] prescribes a specific approach with rules and procedures for generating a lrge number of ideas. It is one of many methods used in creative thinking, based on the assumptions that quantity leads to quality.

In the current project this quantity to quality was achieved in three levels of brainstorming by narrowing down the focus of solution space. This resulted in 5 final concepts out of 48.

PRODUCT ARCHITECTURE

To start with ideation a product architecture was developed to make sure that the following components are the integral parts of the product

1. Sawbone set of Femur and Tibia
2. Complete lower limb
3. A detachable silicone soft tissue
4. Bone holder/ Chassis
5. Visual feedback (display/ light)

CONCEPTS

After a comprehensive brainstorm, five concepts were finalized out of 48 concepts, These five were chosen with different usability and product complexity. During the initial exploration, concepts were generated without being constrained by the list of requirements. Right from the initial exploration, these five concepts were finalized after a couple of brainstorming sessions. These concepts were then evaluated using a Harris profile method based on the list of requirements.

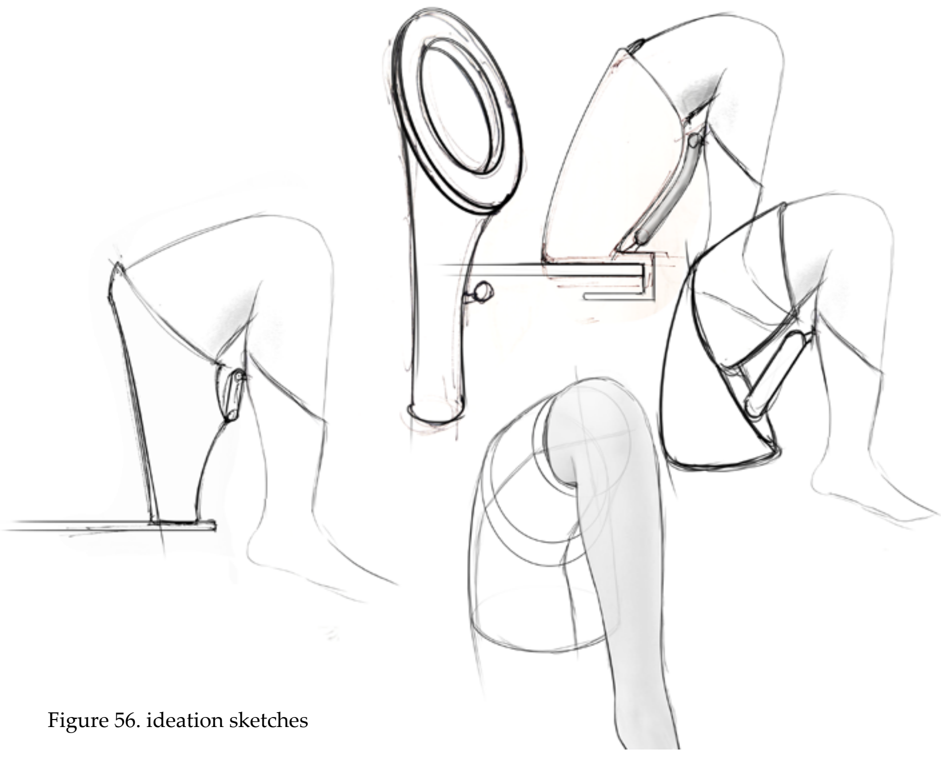


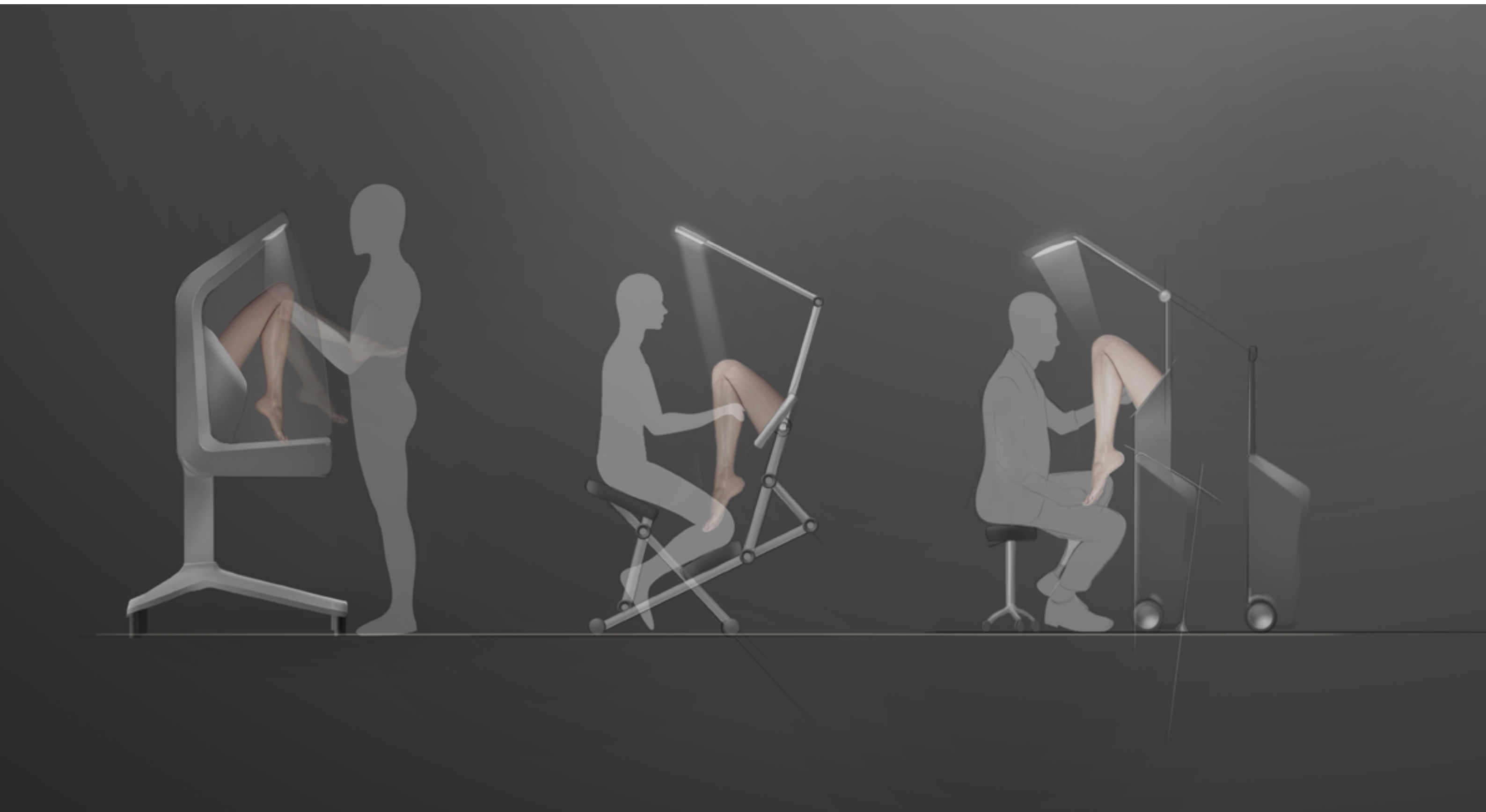
Figure 56. ideation sketches

ORIGINAL

As the name suggest this concept was generated with an intention to provide a closest simulation of an original patient knee. Just as in an operating room the leg will be fixed at the thigh. The rest of the leg will not be supported by any support. A surgeons helping the main surgeon need to hold the leg. This would even simulate the process of working as a team in an operation theatre. The product can be attached to a table and work. This concept also had an optional lamp that can be folded into the product when not necessary.

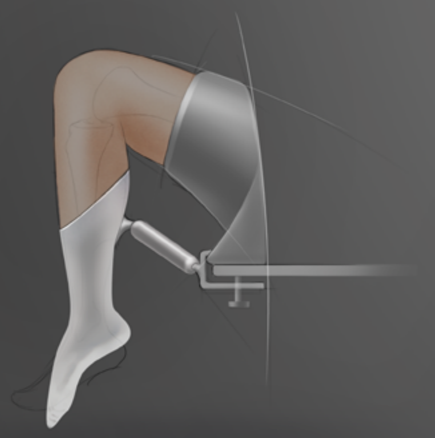
STANDALONE

This is a complete Oxford knee training station. Although the knee joint is similar to the previous model, this device has inbuilt fixtures. No external support like table is necessary. Designed to work anywhere irrespective of the external conditions. The usability is similar to the previous model requiring an assistant to help and has full extension , flexion, internal rotation, Varus and Valgus deformities.



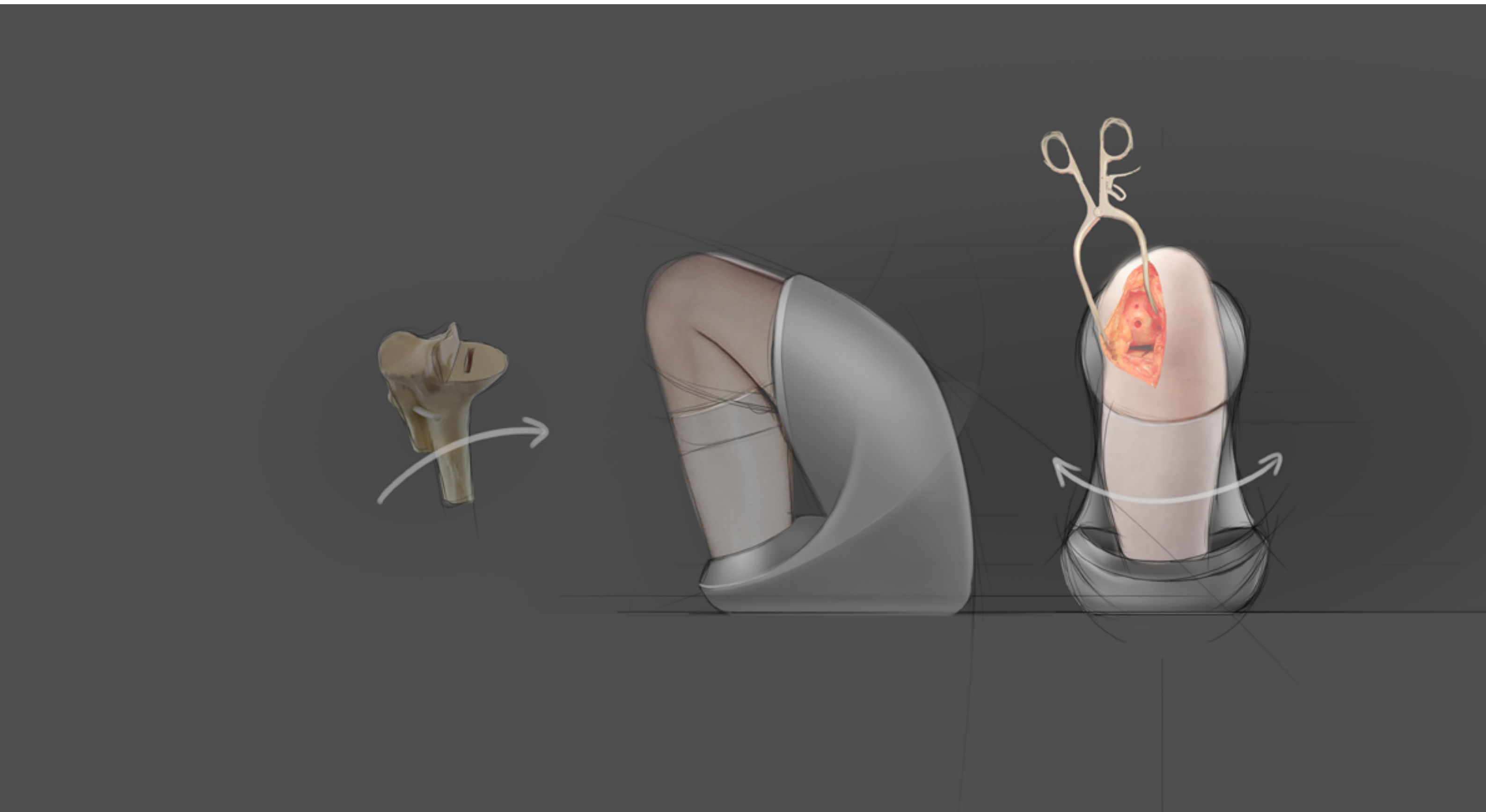
STRONG

The soft tissue is only extended up to some part of leg and the rest is a rigid plastic with strong fixture. The leg fixture allows the leg to move up to 20-degree of flexion and extension with 10 degrees of Valgus and Varus deformity. When the fixture is tightened in a desired position, the leg is locked for the surgeon to perform implantation. A regular sawbones can be inserted and work.



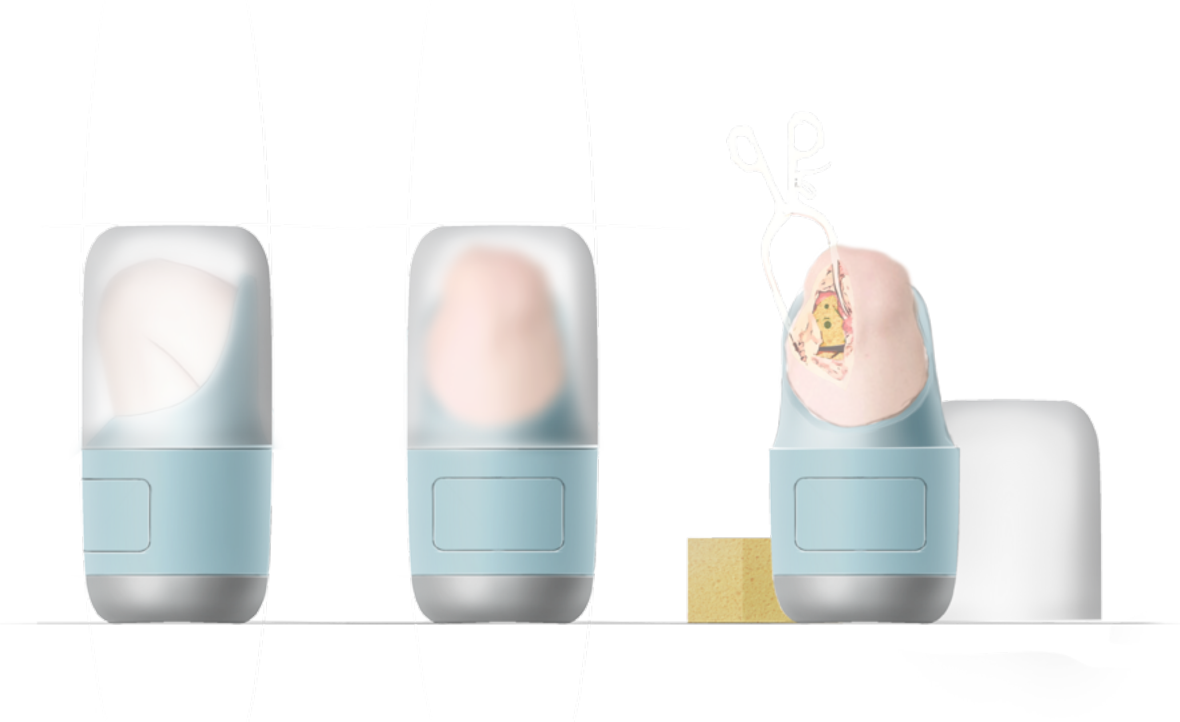
COMPACT

This device is made for training only the implantation steps like insertion and impaction. Only a precut tibia is inserted into the device. A non-functional femur is always attached in the device. The knee joint is already in full flexion and allows 10 degree Valgus and Varus deformity before locking the position.



MINIMAL

This is the most simplest form of knee joint that is required for training the implantation steps. A sawbones block is inserted into the device from the bottom. The device bring the block up to the knee join internally u to the incision. When looked through incision, it looks exactly like a regular tibia below the soft tissue. Valgus and Varus deformity can be adjusted with the click of a button. The knee joint is internally lit and doesn't require a surgical lamp.



HARRIS PROFILE

The concept strong turned out to be the best concept with standalone being the second best. Besides this evaluation, the same concept was also chosen based on few discussions with the mentors. The leg fixture was necessary for surgeons to be able to work alone. And during the training session, a surgeon is usually not accompanied by another surgeon. So a leg fixture that can allow full Valgus and Varus angulation and some flexion and extension is necessary so that surgeons can position in a convenient position.

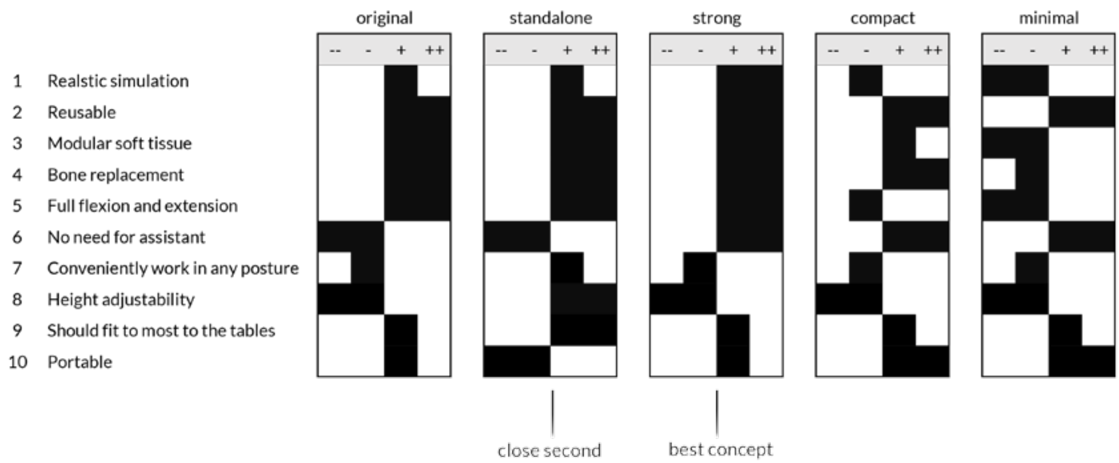


Figure 57. Using a Hrris profile to choose the best concept

Design methodology
A Harris Profile[32] is a graphic representation of the strengths and weaknesses of design concepts with respect to predefined design requirements. It is used to evaluate design concepts and facilitate decisions on which concepts to continue with in a design process.

CHAPTER 3. SECTION 3

FINAL DESIGN

As the concept exploration of the previous section was more explorative, the chosen concepts were to be detailed further to finalize the form. In this section, the chosen concept was detailed further by incorporating the surgeons' feedback from the Phase I and the technical limitations of usability, structural stability and manufacturability.

Looking back at the Harris profile, this chosen concept 'strong' was missing a few design requirements like height adjust-ability and manufacturability. The concept was iterated further by incorporating these elements into the design. The core idea of the chosen concept was to provide a strong leg fixture. Having the core idea as same, the design was iterated further with adding height adjust-ability. To make this happen, a quick POC was made to validate the usability. This POC has helped to understand the height adjust-ability mechanism, working height in different postures and comfortable visibility angles. Several height adjust-ability mechanisms were observed by considering the ergonomics and usability. Besides these factors, manufacturability was one of the important decision factors in this case.

Two different kinds of height adjust-ability mechanisms(1&2) from the figure 58 were finalized based on the product complexity. As the design has not been finalized at this point, it was too soon to evaluate the mechanisms based on the standard evaluation procedures like DFMEA or component list. The first mechanism was based on a telescopic cylinder and the second was a linear slider. These two mechanisms were detailed further to finalize the most suitable mechanism for the product.

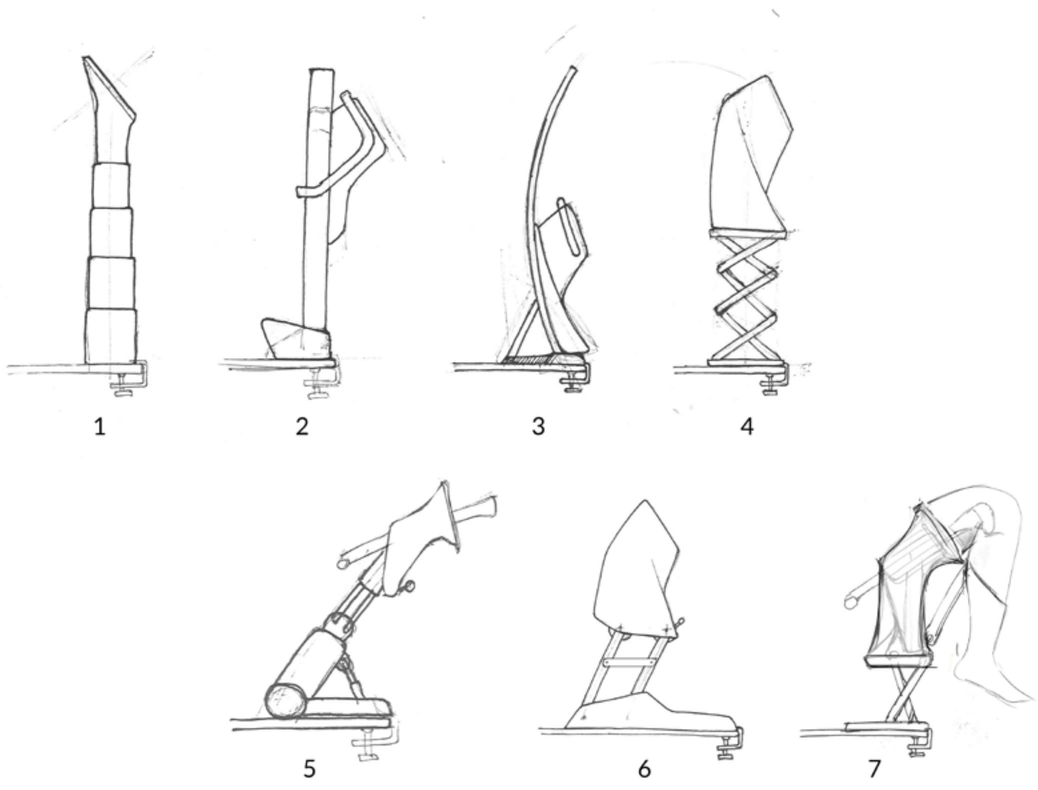


Figure 58. Sketches o different types oh height adjust-ability designs

HEIGHT ADJUST-ABILITY

To validate the height adjust-ability, it was important to determine the product dimensions and the required range of height adjust-ability. The user – product interaction is determined in three ways.

1. Locking the swivel arm with right hand at the same time hyper flexing the leg in desired position.
2. Attaching the Extra Medullary(EM) rod on the leg.
3. Working at the incision for bone preparation and implantation

The EM rod is only attached in the beginning of the procedure and the swivel arm locking is used only once in a while to adjust the position. So the first and second interactions are not seen as continuous interactions. Thus the third interaction was prioritized for determining the suitable working height. Dined database[46] of Dutch adults of ages between 20 to 60 were considered to determine these dimensions. From the field trip observations, it was known that some surgeons prefer sitting on surgical stool while operating and some prefer standing. As the procedure takes about 45 minutes, it is important that the surgeons has have comfortable hand position and viewing angles at the incision.

47. DINED anthropometric database. (n.d.). Retrieved from https://dined.io.tudelft.nl/en/database/introduction

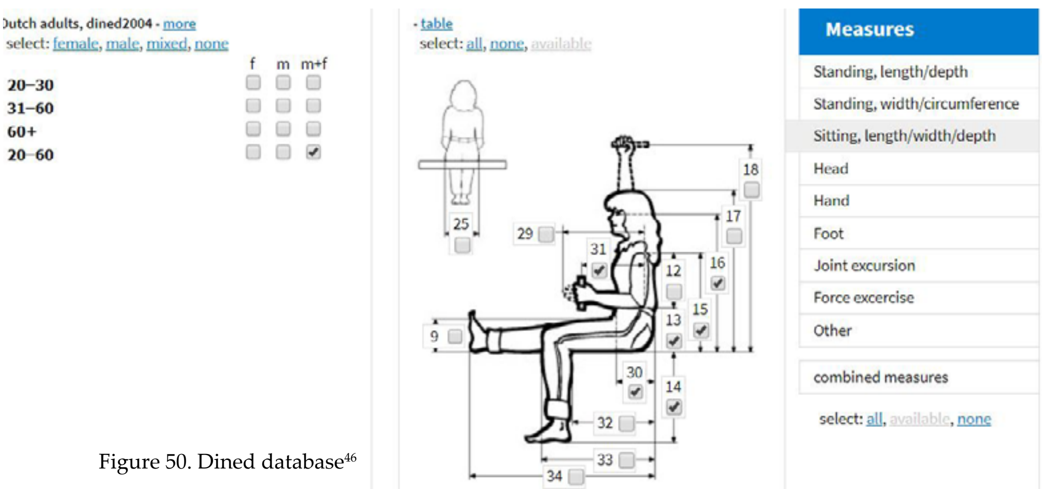


Figure 50. Dined database[46]

VIEWING ANGLES

48. Gedliczka, A. (n.d.). Atlas mira czlowikea. Retrieved from http://nop.ciop.pl/m3-7/m3-7_4.htm

As per A . Gedliczka,[47] a comfortable viewing angle is up to 30 degrees below the horizon of eye without tilting the head. The comfortable tilting angle for head is 20 degrees. So it will be comfortable for the surgeons if the incision is between 0 to 50 degrees from horizon.

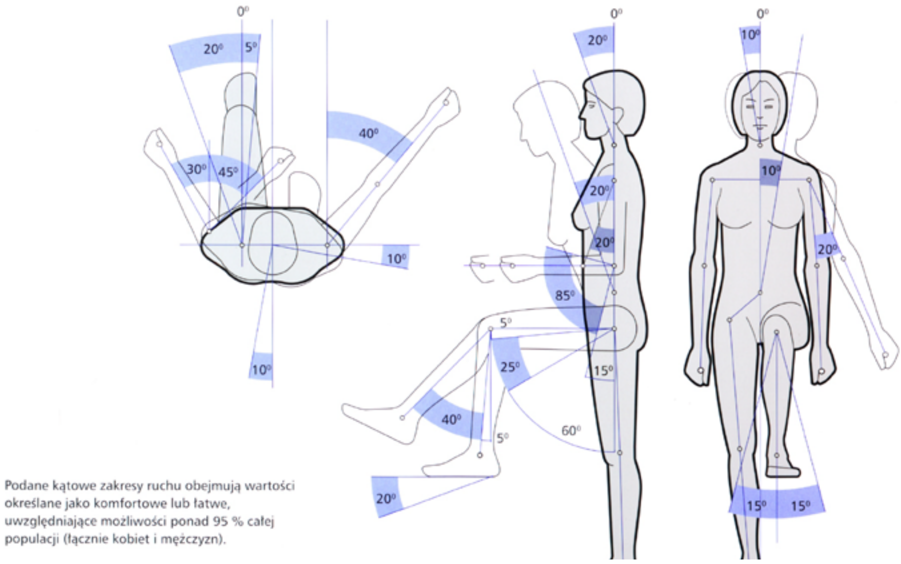


Figure 51. Comfortable flexion angles[47]

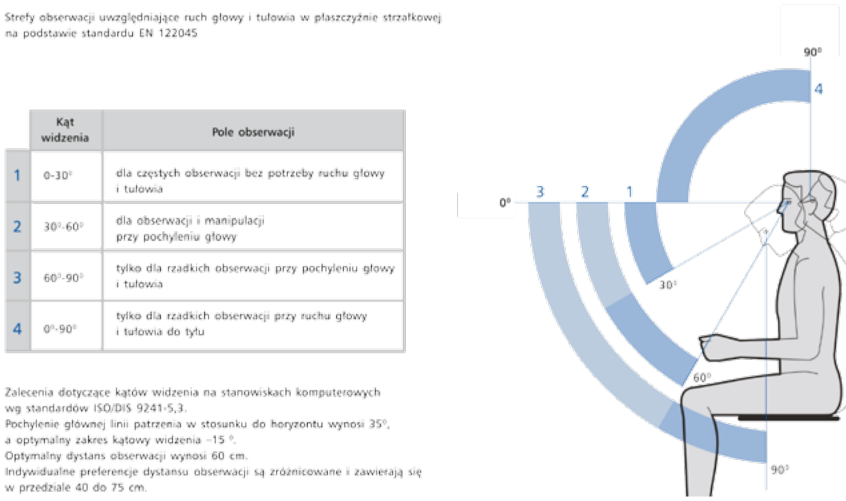
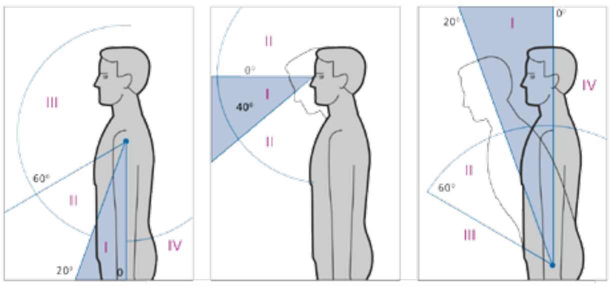


Figure 52. Comfortable visibility angles[47]

HAND POSITION

As per A . Gedliczka, et al., the hand movement is relative to comfortable angles at shoulder and elbow joints. 20 degrees at the shoulder joint and 85 degrees(+15 degrees from normal plane) at the elbow joint are considered as comfortable. The user interaction at the incision is majorly operating the surgical tools like, milling, drilling, cutting saw and hammer. The maximum time of using the tools continuously has not exceeded two minutes when observed in the videos captured during field trips. According to A. Gedliczka, the shoulder joint angle is acceptable within the range of 20 – 60 if there is a support or of the operation does not exceed 4minutes.



Podniesienie ramienia w płaszczyźnie strzałkowej | Pochylenie głowy i szyi określone kierunkiem patrzenia | Pochylenie tułowia

	Podniesienie ramienia w płaszczyźnie strzałkowej: Pozycja statyczna	Częstość ruchu < 2/min	Częstość ruchu ≥ 2/min	Pochylenie głowy i szyi: Pozycja statyczna	Częstość ruchu < 2/min	Częstość ruchu ≥ 2/min	Pochylenie tułowia: Pozycja statyczna	Częstość ruchu < 2/min	Częstość ruchu ≥ 2/min
Akceptowany zakres kątowy	I	I, II	I	I	I	I	I E	I, II	I
Warunkowo akceptowany zakres kątowy	II A	III C, IV C	II D		II C		II A, IV B	III C, IV C	
Nieakceptowany zakres kątowy	III, IV		III, IV	II		II	III		II, III, IV

Figure 52. Comfortable shoulder and elbow positions[47]

Within these limitations, the product was placed in an environment with mannequins of 5th, 50th and 95th percentiles of dined population database. These mannequins represent the average dimensions of Dutch male and female population of age 20-60 years. The product environment includes a table of height 688.5mm (As per akerblom 1948,1954 and1958 the recommended height for working desk 60-70cm) and a surgical stool adjusted respective popliteal heights of the mannequins.

populations	Dutch adults 20–60, mixed		
measures	P5	P50	P95
Eye height, standing (mm)	1466	1634	1802
Shoulder height (mm)	1275	1430	1585
Eye height, sitting (mm)	725	802	879
Shoulder height, sitting (mm)	532	598	664
Popliteal height, sitting (mm)	397	463	529
Elbow height, sitting (mm)	203	252	301
Elbow-grip length (mm)	297	341	385
Arm length (mm)	630	720	810
Abdominal depth (mm)	193	270	347

Figure 53. The dined values that were considered for design calculations

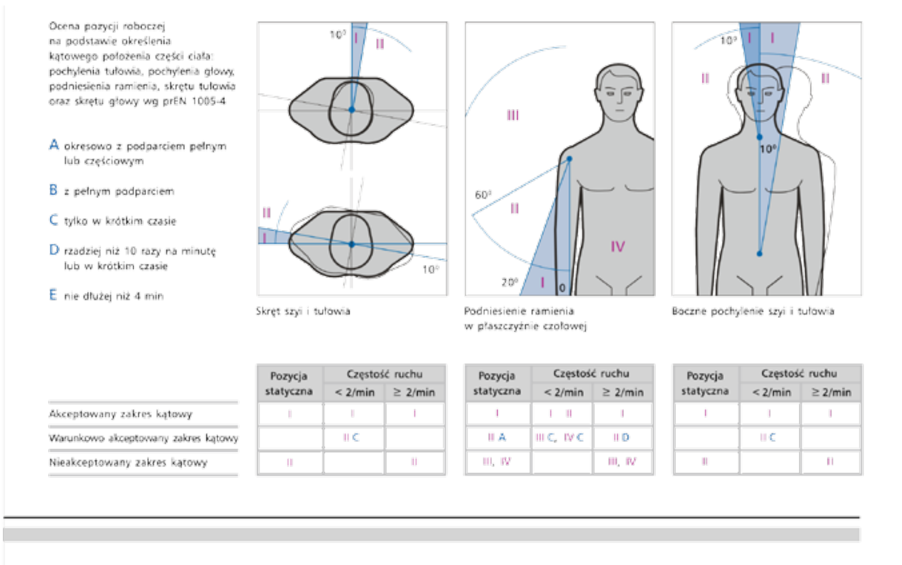


Figure 54. The ergonomic chard indicating the A, B, C, D and E zones for comfortable body movements

LOWEST WORKING HEIGHT

To extract lowest required height a sitting mannequin of 5th percentile population was used. This made sure that the working height of incision is comfortable for population of lowest heights. Dined database provides a popliteal height, elbow eight, shoulder height and eye heights. To extract the comfortable working height of incision, these dimensions were mapped in the product environment. The Dined dimensions were used in combination with the comfort angles extracted from A. Gedliczka. A comfortable viewing angle up to 50 degrees below horizon was mapped out first. The elbow joint can comfortably range up to 85 degrees starting from 15 degrees from the normal plane. But shoulder comfortable angle being only 20 degrees, the hand could not reach into visibility area. However from 20 to 60 degrees at the shoulder joint, it is also comfortable for shorter periods of less than 4mins. So using these comfortable ranges, the hand reach was placed into the comfortable visibility area. This was possible with 35 degrees at shoulder joint, 75degrees at elbow joint and a viewing angle of 50degrees below the horizon of eye. In such conditions, the hand reach i.e., the lowest working height of the incision was determined as **830mm** from the ground. The same procedure was repeated with a mannequin of 50th percentile of the population, and the respective working height of incision was determined to be 973mm from the ground.

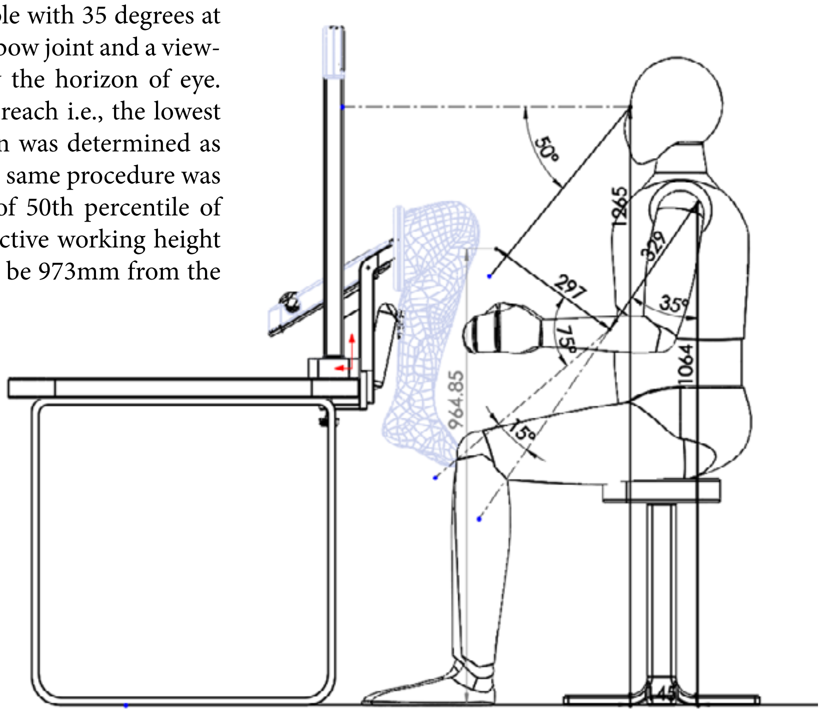


Figure 55. P50 mannequin in the lowest working position

HIGHEST WORKING HEIGHT

To determine the highest working height, standing mannequins were considered from the same dined population as before. But here, the 50th and 95th percentiles of Dined population were considered to make sure the working height of incision is comfortable to the most of the tall people. From Dined database the eye height, elbow height were for 95th percentile were extracted. Implementing the comfort angles from A. Gedliczka, the possible hand reach within the comfort visible angle at a height of **1450mm** from the ground. This was possible with 35 degrees at shoulder joint, 65 degrees at elbow and 50d degrees of viewing angle. To achieve this height from the lowest working height, which was 830mm, the sliding head should have a vertical travel of 620mm. The same procedure was repeated by implementing a 50th percentile mannequin and the highest working height was determined as 1290mm.

So if the frame design could achieve 620mm of travel from lowest working height, that would be the most suitable scenario. But if the frame design could only achieve shorter travel, it needs to be compensated either by a higher table or having the surgeons seated while operating.

Required working heights incision from the ground level:

P5 sitting – 830mm
P50 sitting – 973mm

P50 standing – 1290mm
P95 standing – 1450mm

Ideal case of height adjust-ability is from P5 sitting to P95 standing which is from 830mm from the ground to 1450mm from the ground - 620mm travel.

Acceptable case of height adjust-ability is from P50 sitting to P50 standing which is from 973, from the ground to 1290mm from the ground – 317mm travel.

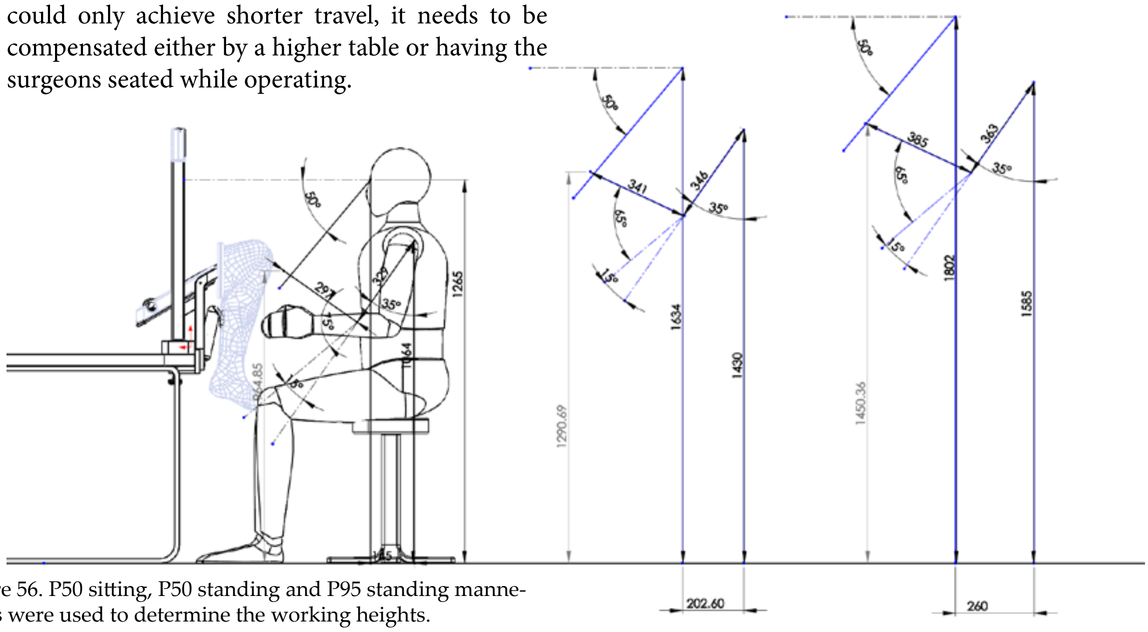


Figure 56. P50 sitting, P50 standing and P95 standing mannequins were used to determine the working heights.

DESIGN SELECTION

To determine the most suitable design for the frame that satisfies the working heights and structural stability, two types of designs were explored. These two designs differ in the way they function to achieve the sliding travel. The first design uses a telescopic cylinder to increase the working height. The second design has a fixed tall frame on which the working head slides up and down.

1. TELESCOPIC CYLINDER

The idea behind this construction was to make the product look compact. The telescopic cylinder helps to increase the height of the product. When fully retracted, the product looks smaller and does not occupy much of the training view. The silicon holder and swivel arm are fixed to the product head. The whole head of the product is mounted on top cylinder of the telescope. The silicon soft tissue and swivel arm are completely detachable. To be able to place the Femur and clamp, an aperture was made at the top of the head through the cylinder. The Femur is clamped after inserting the bone through this aperture. It was conceptualized to have the visual feedback as an led strip at the top arc of the mounting head.

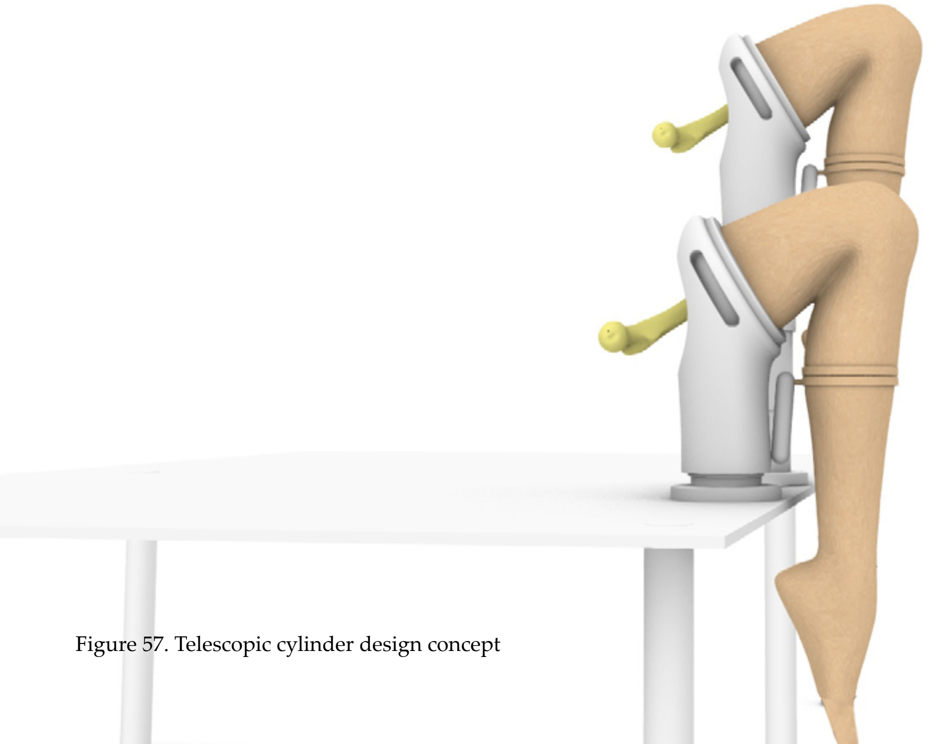


Figure 57. Telescopic cylinder design concept

2. LINEAR SLIDER

This construction was based on simple rollers that slide on a linear frame. The silicon soft tissue and swivel arm are mounted on a head that slides linearly on vertical frame. The handle around the mounting head will help to adjust the working height. An aperture has been made through the mounting head to place the femur and clamp.

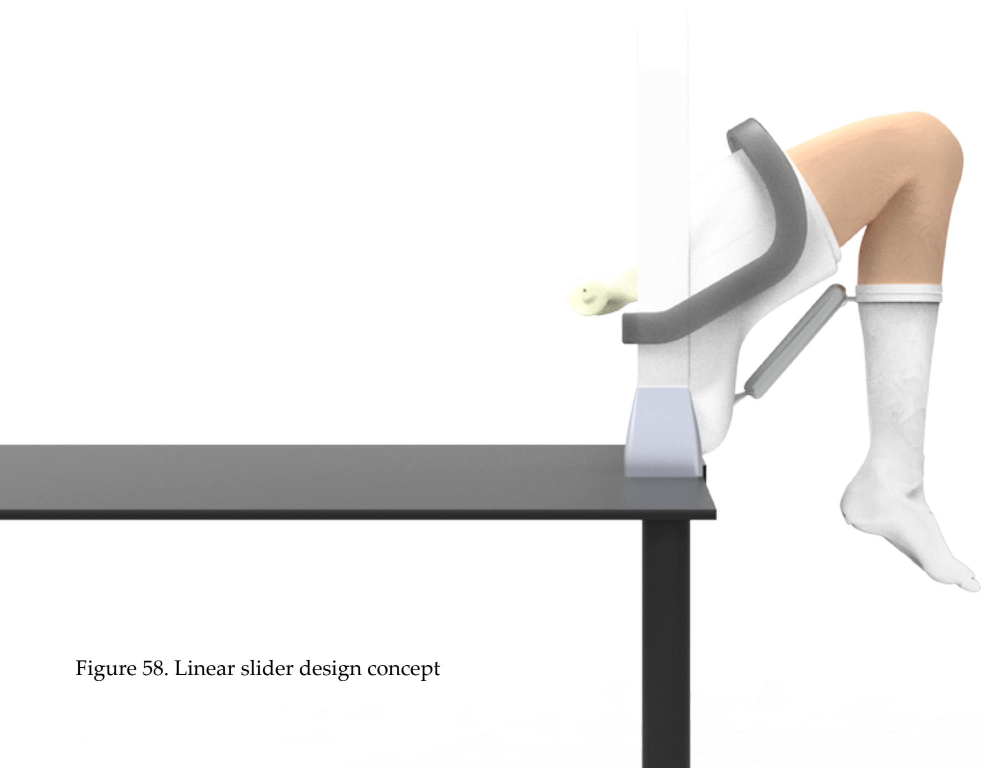


Figure 58. Linear slider design concept

MANUFACTURABILITY

As the project ‘deliverable being a manufacturable design, it was also important to consider the availability of materials and ease of component sourcing. One of the main components of the first design was, a telescopic cylinder. When a longer travel is required in telescopic cylinder, the collapsed height of the cylinder is also higher. There were not any standard telescopic cylinders found during the research that have the required amount of travel(620mm) within a smaller collapsed height. A few manufacturers agreed to manufacture custom telescopic cylinders, but they were not able to promise the locking tension. When the telescope is locked at a specific height, all the working forces are dependent on locking friction. Whereas the linear slider suppliers were confident about the locking tension but It was a tough decision to take the risk without a proof of validation.

STRUCTURAL STABILITY

Comparing both of the designs, it was evident that telescopic was compact. Linear slider was bulky but has a simple construction compared to telescopic. To determine the structural stability of both the designs, a quick structural analysis was carried out. The silicon soft tissue was estimated to be around 6kgs and the hammer impacts of 200N from the tracking section were considered for the design calculations. As a higher factor of safety, double the actual amount of load was considered (500N).

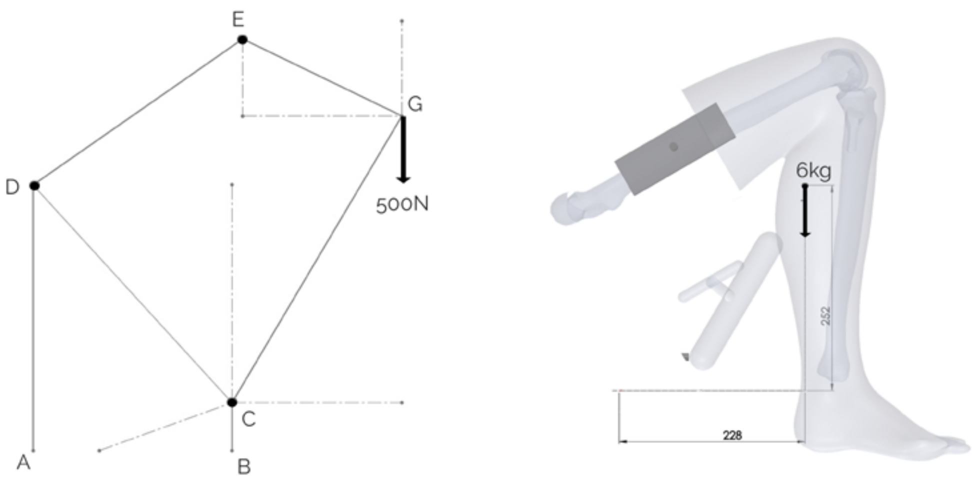
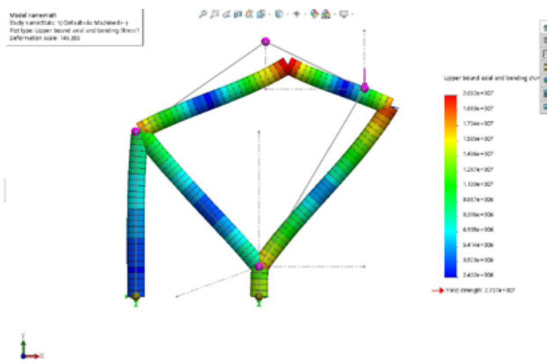
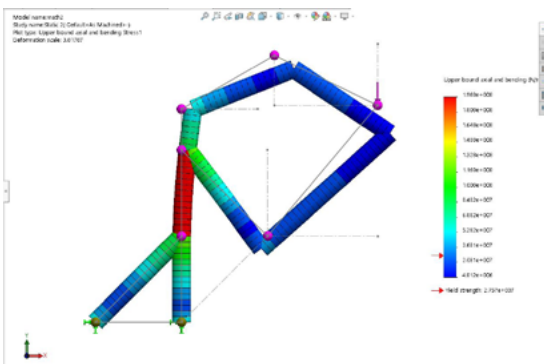


Figure 59. Free-body diagram (FBD) of telescopic cylinder design

The structures were translated into a simplified free body diagram(FBD). The forces in each member were calculated by translating the momentum at each joint. The supporting members in telescopic design were subjected to 926N and 426N. The similar supporting members in linear slider design have experienced higher loads of 1612N, 1140N and 500N. The results from design calculations were validated through finite element analysis using weldments an Aluminum(1060 alloy) profile.



The weldment FBD representing the linear slider design has exhibited highest stress values(2.032 X 108 N/m2) than the telescopic design (1.968 X 108 N/m2). But these stress values were calculated at a general height of 250mm from the table. As per the ergonomics design requirement, the moving head need to travel up to 620mm higher from the lowest working height. It was also important to consider the displacement of deformation as the product needs to be rigid enough to perform the surgical procedure. To validate this, the same frames were simulated with 500N of load in lowest and height working heights from the table. This study was only a comparative study to determine the most stable structure among linear and telescopic designs.
So the material was changed to stainless steel (AISI 1020) as the aluminum was too week for the selected weldment profile. Two simulations were performed for each of the design, one at the least required working height and the other at maximum required working height. Two plots of stress and displacement of deformation were recorded for each test.



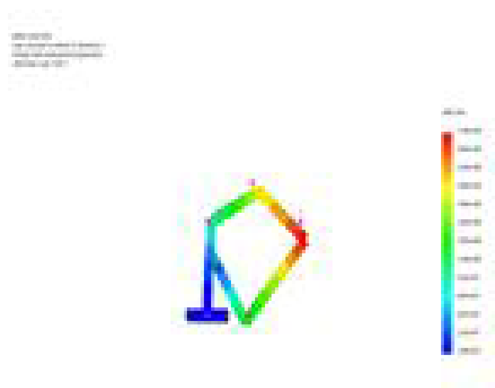


Figure 60. Static structural simulation results of FBD frames of both the designs

CONCLUSION

The stress values were observed to be the same in both telescopic and linear sliders. The displacement of most deformed point of the body was observed to be more in telescopic design than linear slider. This implied that although the structure of the frame in telescopic design is stable in lower heights, the deformation was more in higher heights compared to linear slider design. The linear slider can be more structurally strong if the supporting vertical members are replaced with special profile members. These special profiles are generally metal extrusions that are available in many standard sizes. Also the telescopic design can be more stable if a wider telescopic cylinder is used a base. But a conscious decision need to be take considering the ergonomic design requirements, structural stability and manufacturability.

All the three factors were crucial in deciding up on the design. Every factor has its own limitations with the ideal scenario of the other two. Firstly, to achieve the ideal travel(620mm), the telescopic cylinder should have a higher collapsed length of approximately 250mm and a diameter of 240mm. Moreover, the lowest possible height with telescopic cylinder starts with the collapsed height(250mm) which will not satisfy the lowest incision working height. Secondly the telescopic design has higher displacement of deformation in highest working height. So the linear slider mechanism was chosen but with a stronger frame of 40x40mm aluminum extrusion. The structural analysis was repeated with the increased from cross-section. The forces on the supporting frame were greatly reduced and the maximum stress was found to be less than the yield point. Although, in the actual scenario, the 500N were not continuously applied. It is an instantaneous force that is generated while hammering. So the linear slide was chosen as the most suitable design and detailed further.

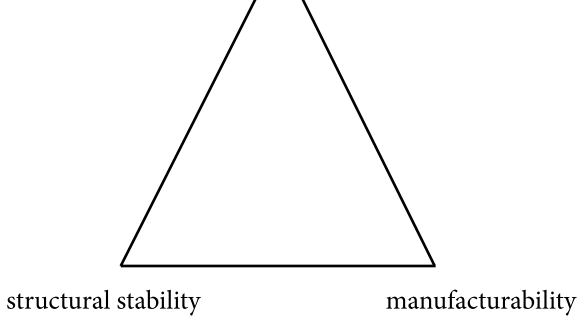


Figure 61. design selection criteria

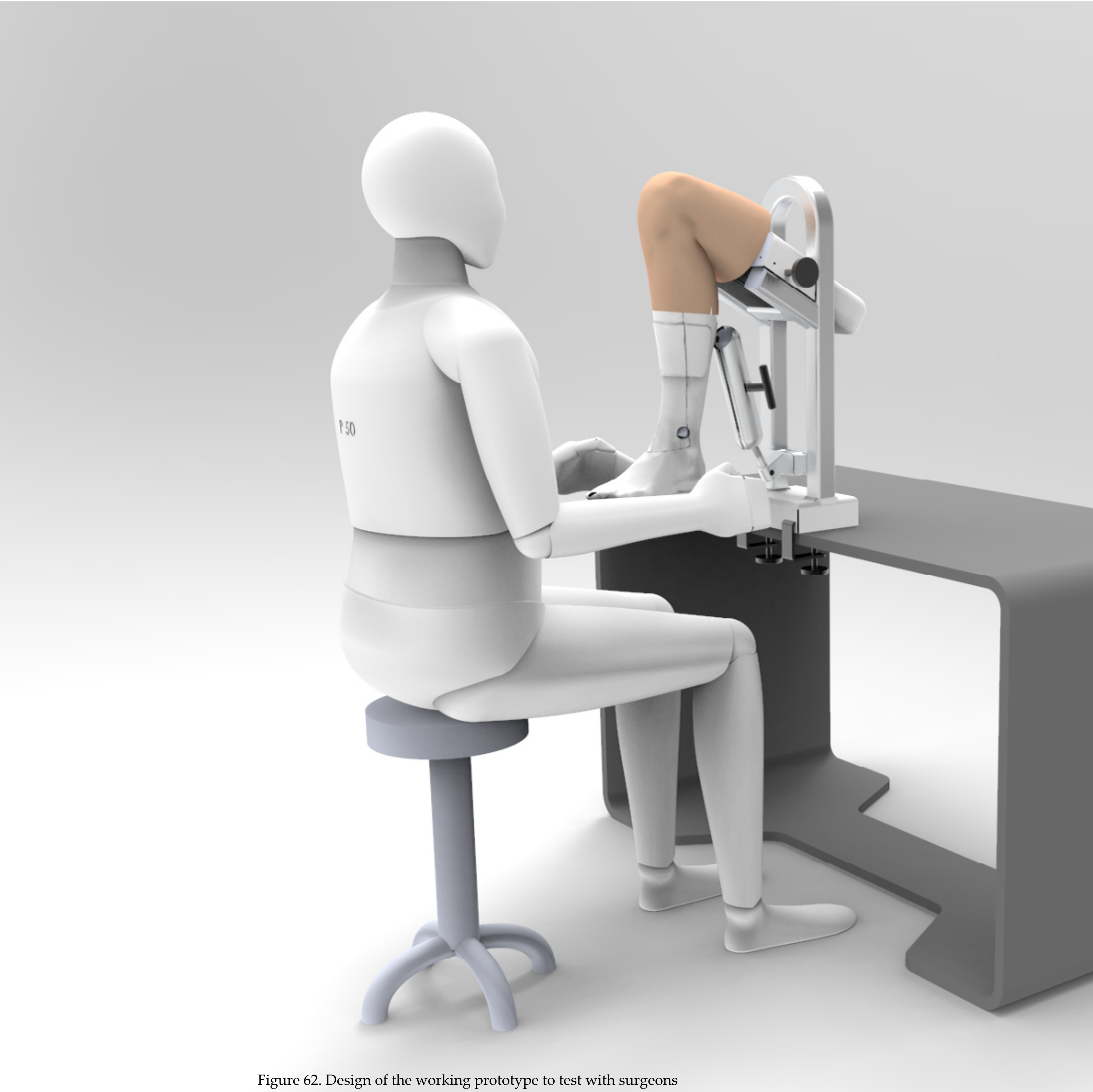


Figure 62. Design of the working prototype to test with surgeons

PROTOTYPING

The prototyping started with the 3d scanning of a subject's full leg in different postures like 140degree, 120 degree and 90degree flexion. The selection of subject was based on the size of sawbones used in Oxford training course. To make sure that the bone alignment inside the soft tissue will be anatomically accurate, CT scans were also used in combination with the 3D scan data. These CT scans have helped to align the 3d scan of the soft tissue accurately with the 3d model of femur and tibia. These designs were used to create a mold to cast the silicone soft tissue.

Figure 62. 3D scanning of a leg in different angles of Flexion

The mold was 3d printed and assembled with plastic inserts. These inserts were pre-assembled in the mold to get the silicon around them. This plastic-silicone composite acted as a detachable latch for silicon soft tissue. This prevented the silicone from slipping off while flexing and extending the lower limb. The frame was made out 40x40mm aluminum extrusions. The bone was attached to the frame in an angle of 30 degrees. The lower limb was 3d printed to make sure that tibia is rigidly fixed. A Velcro strap was used to fasten the tibia into the lower limb. One of the ball joints of swivel arm were used connect the lower limb to swivel arm. The swivel arm was machined in CNC out of Aluminum. The swivel arm was attached to the frame through an another aluminum profile placed below the bone holder. Thus the prototype has ended up working as it was intended to be. Since the bone holder and swivel arm were attached to the frame in two different positions, the height adjust-ability was one step more complicated than it was expected to be. To make it more easier in the final design for the users to adjust the height, this dual fixture needs to be eliminated. Except the height adjust-ability all the other list of requirement were validated .

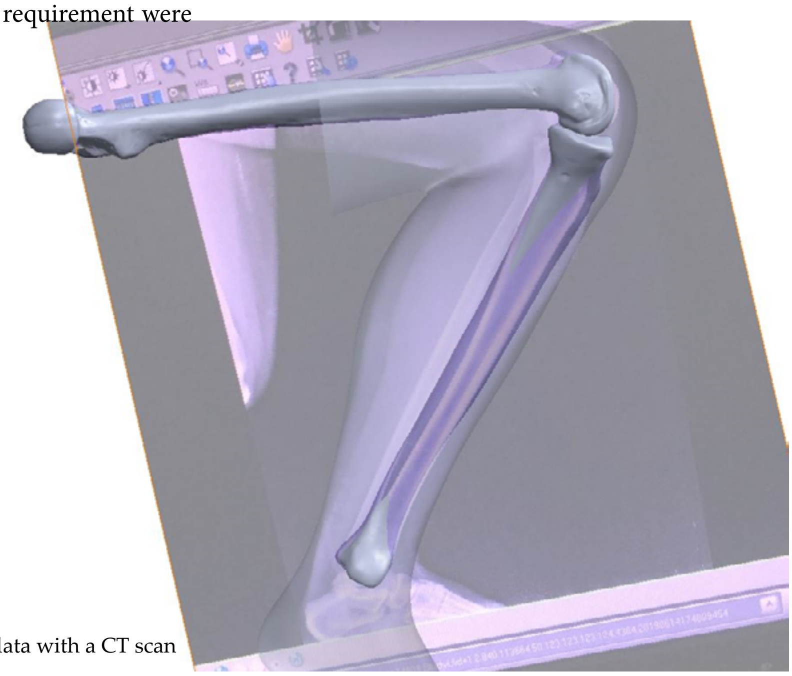


Figure 63. Overalpping the 3D scan data with a CT scan

EVALUATION

Firstly, the prototype was made sure working in the way it was expected to be by making sure that all the aspects of the list of requirements were implemented. Right after this, the prototype was taken to Oxford to test with the Oxford Knee Group surgeons. Another detailed evaluation was carried out with an another faculty surgeon in the Netherlands. This section summarizes the product usability evaluation from both of these tests.

OXFORD EVALUATION

The working prototype was taken to an Oxford training course to validate with the surgeons. During these tests, new sawbones of higher density (320gm/cc) were used. Four of the Oxford knee group surgeons were able to try implanting on the prototype.

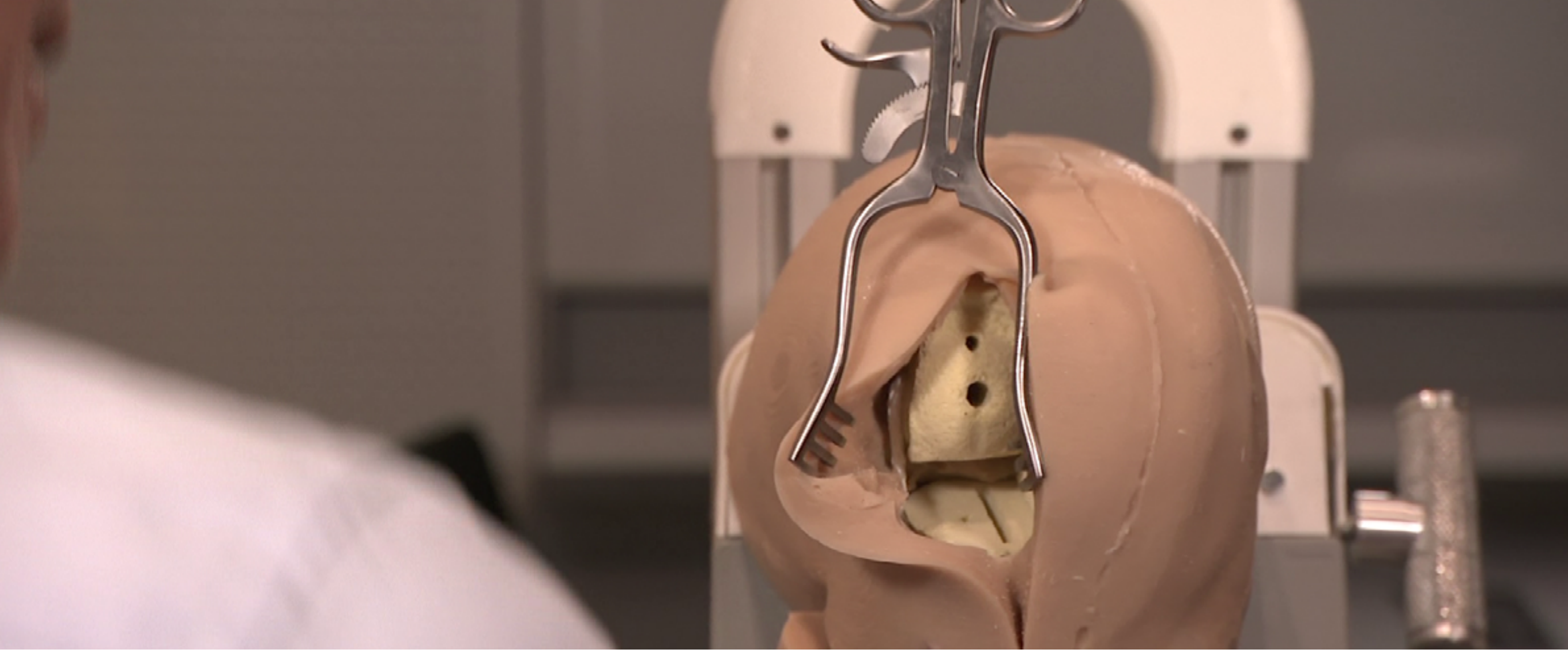
Figure 64. Mr. William Jackson making an incision to the silicon soft tissue

Prof. Murray was impressed with the update from the last prototype tested in phase I. He thought the leg fixture is definitely an advantage for training purpose. Although it is not the part of the actual procedure to lock the lower limb, he identifies it as a conscious addition to let the surgeons train independently. Prof Murray rated 9 to the overall produce in simulating the surgical process.

Mr. Dodd didn't had a chance to try the prototype during the phase-I. He was pleased to try implanting the implants on the prototype. He suggested a few improvements about the silicon soft tissue. Due to the excess amount of thick silicon, the extension was not perfectly simulating the real skin tissue. He rated the prototype as 7 out of 10 in simulating the surgical procedure.

Mr. Will Jackson, who was also unavailable during phase-I testing, had a chance to test the current prototype(fig. 64). Starting with an incision, he was able to try whole procedure including femoral preparation, tibial preparation, anti-impingement and implantation. He rated the product as 8 out of 10 in simulating the surgical procedure.

Figure 65. The working prototype at the Oxford training course



DETAILED EVALUATION - I

Dr. Sander Spruijt

Dr. Sander Spruijt is a faculty surgeon for Oxford training course in The Netherlands. He was able to test the prototype and attend an interview to feedback on the usability of the product. Dr. Spruijt rated the product as 8 out of 10 in simulating the surgical procedure. During the interview, he was able to feedback on the ergonomics of working with the product, simulation of bone resistance and soft tissue. The complete interview transcription can be found in the appendix. The key feedback points were listed as follows:

- Foxpat simulates the impaction and insertion steps very well
- The simulation of whole procedure is better than the existing training model
- The product would be more ergonomic if there could be a possibility to adjust height.
- The flexion and deep flexion are much closer to reality than the extension
- The simulation of bone resistance was been improved from existing sawbones, but still not perfect.
- The leg fixture(swivel arm) is a good addition for training. So they can focus of procedure without having to instruct the other surgeons on how to hold the leg
- If there can be one more step of improvement, it could be the simulation of different anatomies of a patients.
- Dr. Spruijt personally likes to have Foxpat trainer in his hospital so that trainee surgeons can practice for multiple times.
- Foxpat might also be useful for experienced surgeons to try some new tricks.

Figure 66. Dr. Spruijt testing the second working prototype at TU Delft

Figure 67. The working details of the prototype while being tested by Dr. Spruijt

Figure 66(b). Dr. Hardeman testing the second working prototype at TU

DETAILED EVALUATION - II

Dr. Francois Hardeman

Dr. Hardeman is a Belgian surgeon living in Kortrijk. He was able to test the prototype in Kortrijk. He thought the product would add a great value to the Oxford training course. After testing the implantation procedure, he rated the product as 9 out of 10 in simulation the surgical process. The detailed interview is available in the appendix section C. The following points summarize his feedback.

- Dr. Hardeman thinks the most important part that novice surgeons might make mistakes is the excess amounts of impact forces.
- He finds the leg fixture as an addition in the training but as it is not a part of actual surgery, he doesn't recommend for having in the training session as well.
- He agrees with having an option to adjust the working height of the product.
- The soft tissue enclosure was seen as an important addition to the training course.
- The problem in extension was also emphasized by Dr, Harmedan just like the other surgeon did
- Mr. Hardeman tries to leave the leg rest on a table while implanting. In such cases he think it's a valuable for the training
- In contrast to Dr. Spruijt's feedback. Dr. Hardeman do not think that the product is valuable for experienced surgeons. If they ever want to try new techniques they usually prefer to try on cadavers than a product like this.

CHAPTER 3. SECTION 5

FOXPAT

As the working prototype was validated to be satisfying all the design requirements, a final design was developed. During this part of design phase, the aesthetics and manufacturability were the key factors. This section details all the components of the final design and the designated process of production.

Bone holder

The detailing has started from fixing the femur and tibia. A fixed screw clamp was used to fix the femur. Since the surgeons move the lower limb often, a static clamp has not been provided for tibia. A hand operated knob is provided to clamp and unclamp the femur. This clamp was positioned in 30 degrees from the bottom plane, similar to the thigh support used in operating theatre. The clamping faces are designed to be CNC milled in Aluminum. These clamping faces are supported by stainless steel plate of 3mm thickness. The clamp assembly is enclosed by an enclosure with an indent of femur on the top. This makes sure that femur is always positioned in the same position and clamped at the exact same position. This was important to be able to attach the soft tissue over the bones. The bone holder enclosure is designed to be made in ABS plastic with silver white matter surface finish.

Lower limb

The tibia is fixed rigidly to the lower limb. This made sure that lower limb is fixed firmly in a desired position and provides a strong support for the implantation. The lower limb is split into two parts to insert in the tibia. Both the parts are designed to be made in ABS plastic through CNC and are fastened by a Velcro. The lower limb is attached to the swivel arm with a detachable lock. When detached, the lower limb is free to extend during the procedure. When implanting the prosthesis, the lower limb is attached to swivel arm and locked in a hyper-flexion.

Soft tissue

The soft tissue is made up of silicone. One of the challenged using the last working prototype was to lock the silicon soft tissue in place. The silicon part casted in the last working prototype as mentioned in the section 3 of this chapter was quite heavy. It was due to the large amounts of Dragon Skin FX-Pro which is the densest of all the other silicones that were used. This also has made it difficult to extent the lower limb. So the final design of silicone contains foam inserts replacing large chunks of silicone. These inserts need to be pre molded and placed into the final mold while casting the silicone. The soft tissue was designed to be casted in a reusable mold. The production for this part is a manual process. A company called Kelatow FX from Amsterdam has agreed to produce 50 pieces of the soft tissue.

U arm

U arm is one of the unique parts of the Foxpat. This part possesses functional and usable and aesthetic part in the product. Being able to lock the lower limb in desired hyper flexion is one of unique points of Foxpat. This locking was possible with the unique swivel arm design. This arm is supported by the U arm providing a strong and rigid support for the lower limb. Unlike the last working prototype, the swivel arm is attached to the bone holder directly with the help of this U arm. This improves the usability of the product by having to unlock two knobs to adjust the height instead of four knobs. The lower part of the U arm is attached with a swivel holder. One of the ball joints of the swivel arm will be welded to this part. This part was designed to be CNC milled in Aluminum and anodized to have a matte surface finish.

Swivel arm

The swivel arm follows the same design formula as in the working prototype. The angle of rotation for bottom ball joint was adjusted to have more freedom of rotation while locking the lower limb in shallow flexion angles. The swivel arm contains two parts connected with a locking screw. A knob is attached to the locking screw. Both the parts of swivel arm and knob were designed to be CNC milled in aluminum.

Hammer

A hammer module was designed to attach to the existing hammer. This module contains two FX901 sensors on both the sides. These sensors were positioned in a way so that the every hammer impact is recorded through the sensors. The hammer module contains two parts and was designed to be CNC milled in aluminum.

Costing
The finalised design was sent to manufacturers to obtain a quotation. Few components were planned to manufacture. Suppliers were identified for few of the shelf components. The const estimation was as follows:

	Quantity	Material	Manufacturing process	Surface finish	Cost (euro)
Off the shelf components					
Aluminium profiles*					
40x40mm I-type - 600mm	2	Aluminium			15.00
40x200 I- type - 100mm	1	Aluminium			30.00
Right angle 40 I-type - 100mm	2	Aluminium			15.00
I-type profile sliders	2	Zinc			30.00
Silicone**					
Smooth-On silicone set	1	Silicone			140.00
Casting & Post production	1		Silicone casting	Natural skin	160.00
Quoted components**					
Table clamp flange	2	Aluminium	CNC	Anodizing Silver	50.00
knob	2	Aluminium	CNC	Anodizing Silver	140.00
Arc block	1	Aluminium	CNC	No finish	60.00
Top dome enclosure front	1	ABS Plastic	CNC	Silver white matte	85.00
Button pad	1	ABS Plastic	CNC	Silver white matte	15.00
Top dome enclosure back	1	ABS Plastic	CNC	Silver white matte	85.00
30 degree flange	1	Stainless steel	Sheet metal bending	paint dark grey	80.00
Bone holder plate	1	Stainless steel	Sheet metal bending	No finish	150.00
Main shell bottom	1	ABS Plastic	CNC	Dark grey matte	80.00
Static wall	1	Stainless steel	Sheet metal bending	No finish	20.00
Clamp face 1	1	Aluminium	CNC	Anodizing Silver	15.00
Moving wall protector flange	1	Stainless steel	Sheet metal bending	No finish	30.00
Main shell top	1	ABS Plastic	CNC	Silver white matte	125.00
U arm final	1	Aluminium	CNC	Anodizing Silver	550.00
Swivel holder	1	Aluminium	CNC	Anodizing Silver	30.00
Ball final	2	Aluminium	CNC	Anodizing Silver	70.00
Swivel arm part 1	1	Aluminium	CNC	Anodizing Silver	40.00
Swivel arm part 2	1	Aluminium	CNC	Anodizing Silver	40.00
					2055.00

** Average cost, ** Changes with the quantity.*
The above costs were true to the quotations as per 08-08-2019 and subjected to change in the fututre.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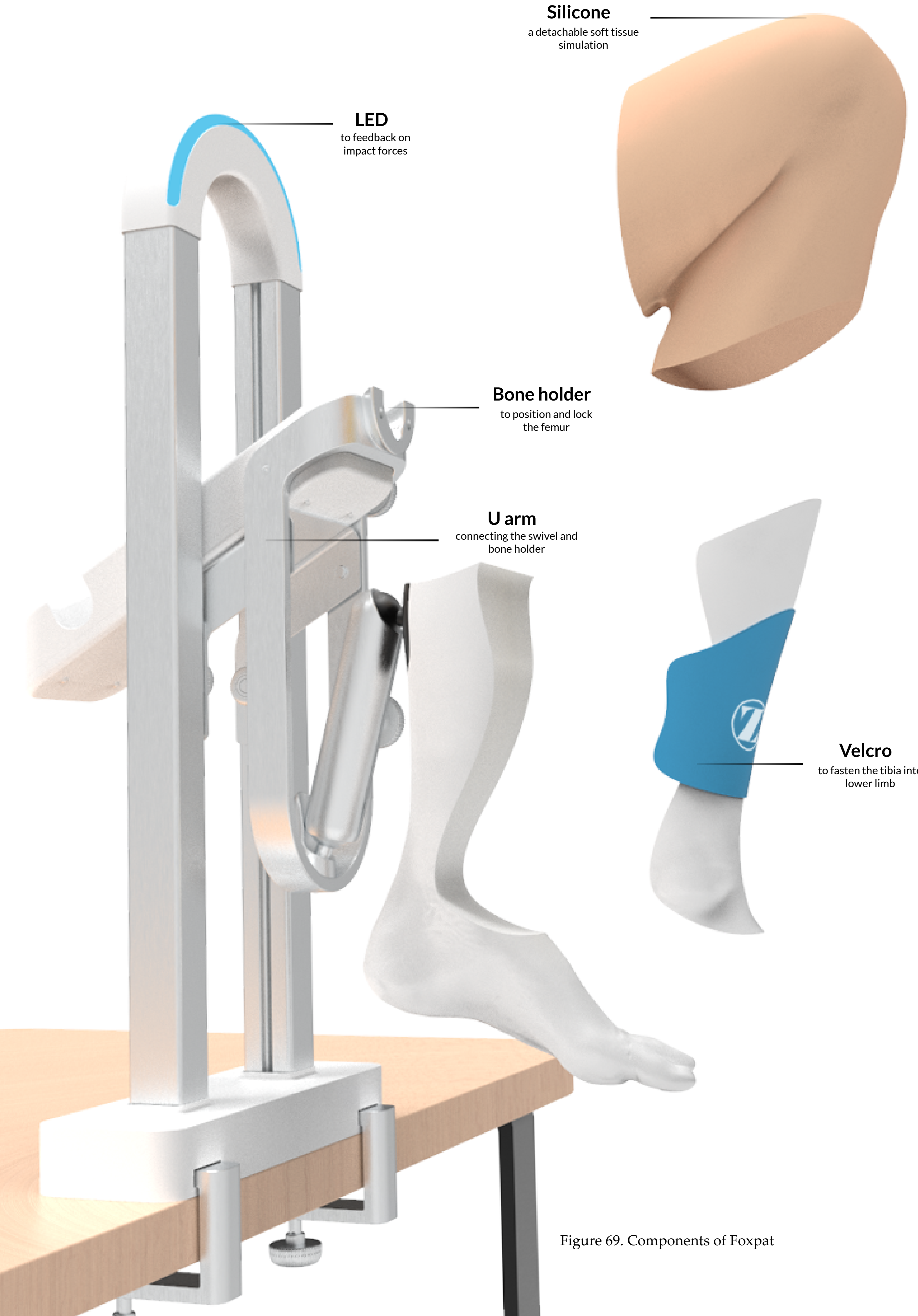

Figure 69. Components of Foxpat

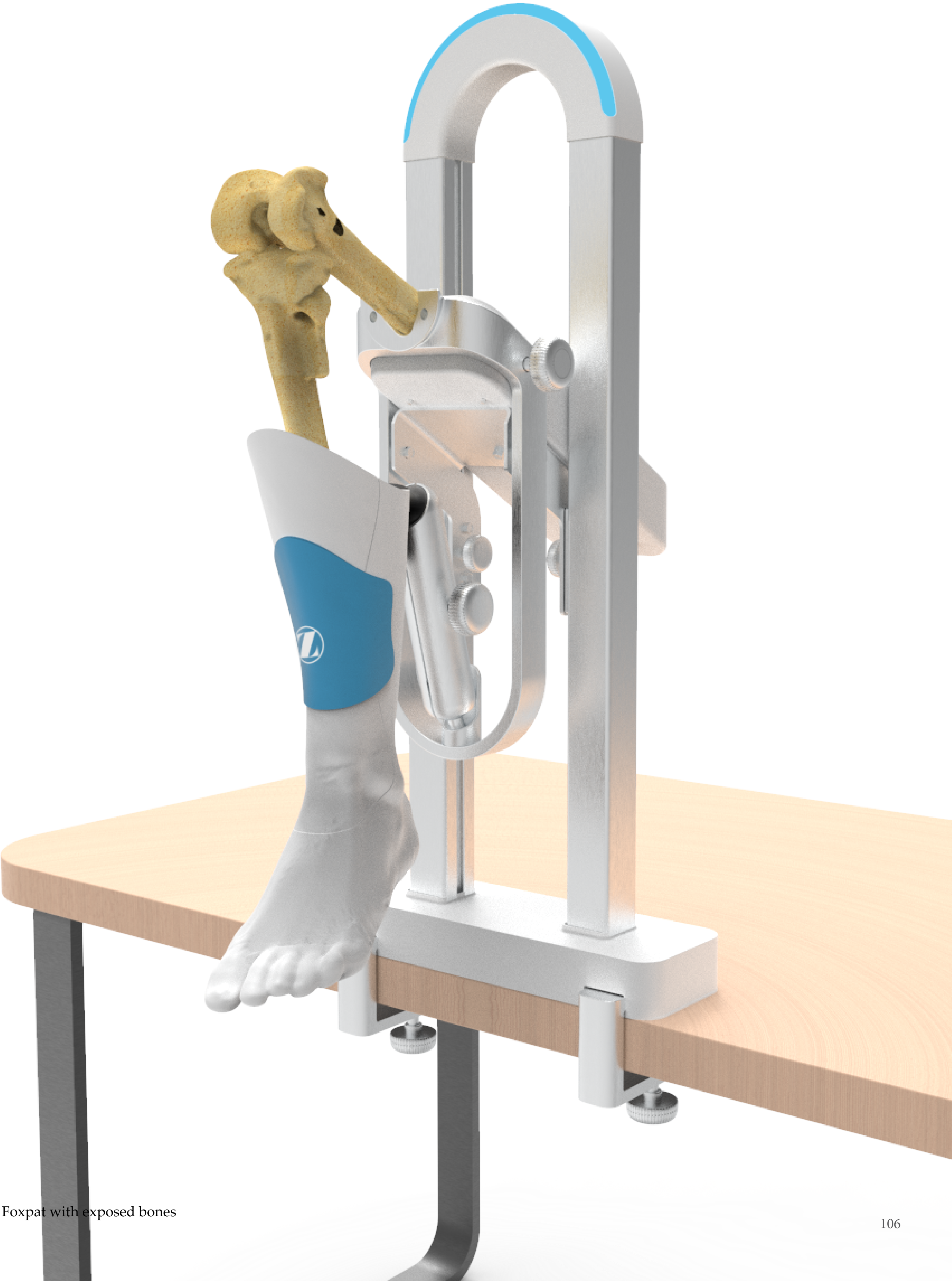

Figure 70. Foxpat with exposed bones

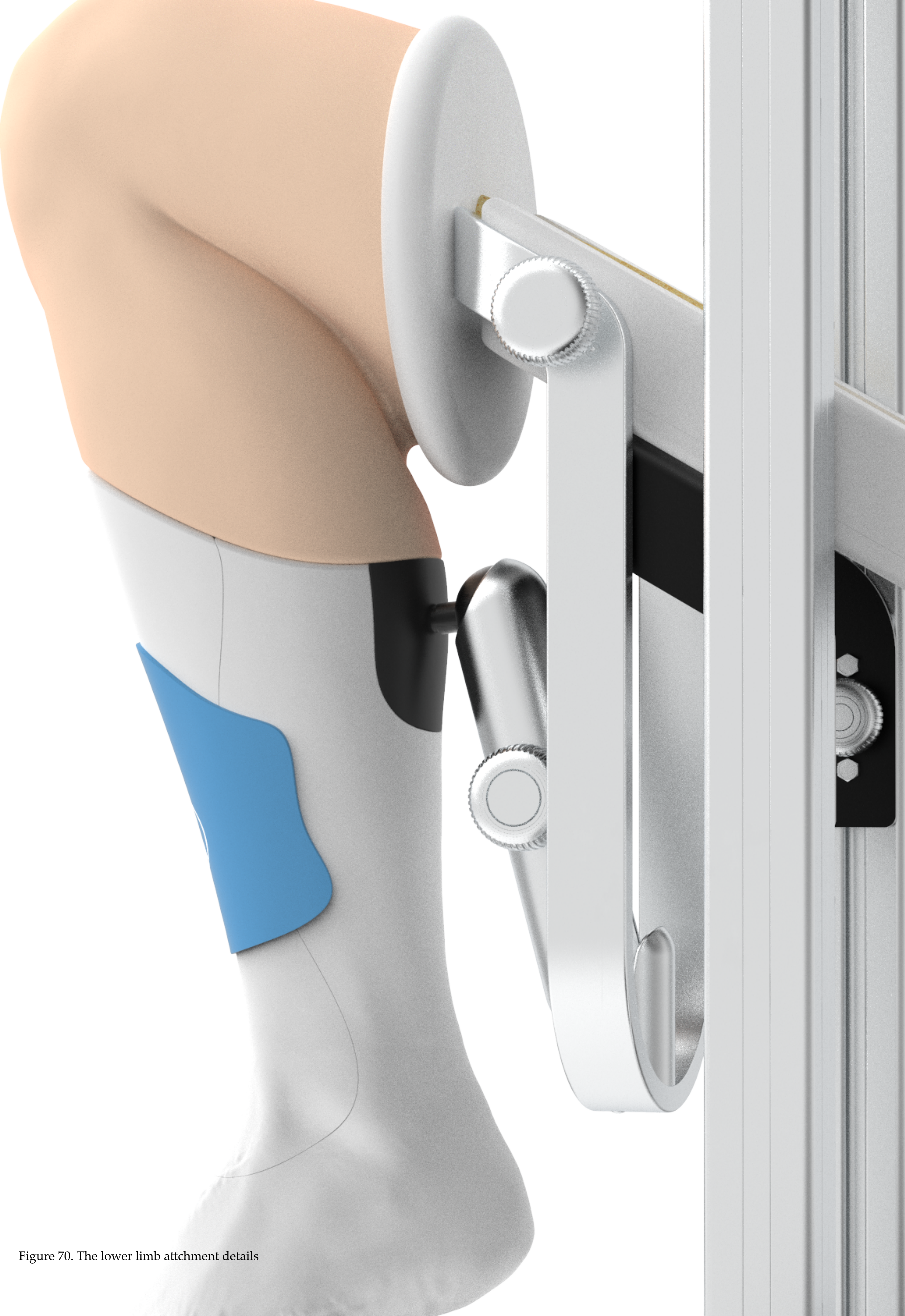

Figure 70. The lower limb attchment details

DESIGN RECOMMENDATIONS

Foxpat is a training simulator for training novice surgeons on Cementless Oxford Partial Knee Replacement. Foxpat has its final matured shape after two iterations of design development and now it is ready to be produced in smaller quantities. However there could be more improvements done to the product to make it more intelligent and more user friendly. This section includes such design recommendations from the author's perspective.

FOR USABILITY

Stool
Ergonomics has been one of the important elements of the design of Foxpat. Surgeons have different preferences on postures while working. For the very same reason, the product was designed to be able to adjust the working height. However, a surgeons' comfort is largely dependent on the stool as well. It is recommended to use a stool with height of 80-125% user's popliteal length.

Sturdy table
The structural elements of Foxpat were designed to be strong enough to give a stable and rigid support while working. But this is dependent on the built of the table to which the product will be attached. So it is strongly recommended to choose a stronger table to work with the product.

Sawbones
Sawbones are replaced from the product for every training session. Although Foxpat was tries to simulate the surgical process as much as possible, sawbones are the main contact point that the surgeons work with. So it is recommended that any polyurethane bones of 250gm/cc to 350gm/cc are used in the product to simulate the bone resistance.

FOR NEXT STEPS

Better feedback
During the research phase, it was known the providing a feedback is crucial for successful learning process. The current surgical process can be assessed in different ways. Foxpat currently provides a feedback on the amount of hammer impact given during insertion and implantation. But the most ideal way to feedback on the insertion is to track the movement and the position of actual implant. This data can be used to visualize the implantation process in a 3 dimensional space after every training session to help the user reflect up on the procedure. Although this requires some expensive sensors to be placed inside the model, it would be greatly helpful for the novice surgeons in understanding the way they implanted compared to an experienced surgeons. This contributes to much shorter learning curves and better outcomes.

Polhemus sensors was mentioned in the tracking section of chapter 1 were found to be the most suitable sensors for this purpose. It was not possible to test these sensors during this project due to shorter time lines. These sensors can be placed on the inserter to track the position of the implant without having to place any sensors in the implant.

More intelligent
Foxpat is smarter than the exiting training model of Oxford course, but it can be more intelligent to keep a track of the training process. The current design of Foxpat includes an add on to the hammer to track the impact values. These values are translated over a factor to directly indicate though an LED. This process can be made smarter by letting by adding few more features: When a user starts to practice, he can indicate his identity start working. The hammer can log all the impact values along with the time. This data can be used to visualize through info-graphics on different aspects like, number of times the impact exceeded a certain limit, total number of impacts, frequency of impact and so on. When a user practices for multiples of times, the data can even be used to show the progress over every practice session. Such a progressive feedback helps to complete the complete cycle of Kolb's learning cycle which will contribute for shorter learning curves.

Design methodology
The Cost Price Estimation[32] method helps to roughly define the cost price of the design in a design process.

Battery
Foxpat contains few electronics in the upper part of the frame. These electronics were not optimized to manufacture in multiples of number. The electronics are currently powered by direct supply of electricity. During the Oxford training sessions it was observed that not all the locations have a network of power supply all over the training halls. This might require the training crew to arrange for extension boxes. Any kind of fluctuations in the power supply may also lead to interruptions of training process. To avoid this, there need to be a batter than can be detached from the product after every session and charge using a dedicated charging dock.

Light
It was mentioned in one of the user tests that the working space was poorly lit in the prototype. This was due to the addition of soft tissue. Although the purpose was to constrain the visibility, the visible part of the incision needs to be well lit. The surgeons are used to working in a powerful surgical lamps in operation theater. Due to the product complexity and limited time, the addition of a surgical lamp was not possible to in this project. It would be a great addition for the next iterations of the design to have a surgical lamp.

ACKNOWLEDGMENTS

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