Reduction of harmful noise pollution during hip replacement surgery

Graduationproject - Integrated Product Design

C.L.H. Broekmeulen | June 2020

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ZIMMER BIOMET

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WARNING!

this report and appendixes

CONTAIN GRAPHIC IMAGES

from surgical observations and validation tests

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COLOPHON

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PREFACE

This report is the result of my graduation project, a combination of Integrated Product Design (IPD) and the medical design specialization (Medisign) at the Delft University of Technology. The goal of the graduation project was to solve the noise emitting problem during hip replacement surgery. This resulted in a new surgical instrument to impact and extract various implant components to successfully complete a total hip arthroplasty.

Managing this project all by myself was one of the biggest challenges during graduation, therefore I was really happy with the enthusiastic team surrounding me. Hereby I want to thank the people who supported me during my graduation thesis project.

Firstly, I want to thank my supervisory team, chair Elif Ozcan Vieira and mentor Sonja Paus-Buzink for guidance and advise during my project. I would like to thank both for thinking with me concerning the project and future prospects.

Inspired by a previous project done for Zimmer Biomet, which sparked my interest in orthopedics, I was very enthusiastic by the challenge and opportunity Zimmer Biomet provided for my graduation project. I want to thank Hilbrand Bodewes, Yvonne Ywema and their colleagues, who provided me with their knowledge on surgical instruments, Zimmer Biomet's current orthopedic product portfolio and connecting me with valuable contacts.

As clinic partner, I want to thank orthopedic surgeon Heinse Bouma, OR staff and colleagues of Bergman Clinics for their feedback and enthusiasm, when user-testing session, sharing knowledge and know-how concerning hip replacement surgery.

Fellow student and soundlab enthousiast, Zoë Luck, for accompanying me and exchanging information on the Total Hip Arthroplasty context, as we both did measurements and observations for our simultaneous projects.

Finally, I want to thank my Dad, the one who sparked my interest in engineering and his tips and directions when finding solutions. Not to mention other family and friends for their backing to finish my study.

ABSTRACT

This graduation project is on behalf of TU Delft and Zimmer Biomet in collaboration with Orthopedic surgeons from Bergman Clinics, Orthopedic Clinic, in Naarden. The aim of this master thesis was to design a product which could reduce the pollution of harmful noise during hip replacement surgery.

Noisy workplaces and especially within this procedure carry a large risk of noise-induced hearing loss, as sound levels of more than 120 decibels are generated by the usage of (powered) instruments. In the analysis phase observations in the operating theatre and interviews with experts are conducted to get insights and background information about the total hip arthroplasty procedures. It was found that noise levels experienced during surgery generated levels above the human pain threshold, ranging between 120-130 decibels and caused temporary and long-term noise induced hearing loss. Via a design vision and a list of requirements multiple concepts where generated. In the embodiment and evaluation phase, cadaver and saw bone testing showed that the new instrument design functioned and implant parts and/or tools could be implanted successfully.

The outcome of this project is a new surgical instrument, which can press-fit (impact) and extract various implant components used during surgery. The instrument has multiple unique selling points compared to the currently used mallet as it reduces the noise level with more than 15 decibels and is scores better on aspects of safety when looking into the risks at musculoskeletal disorders and improved surgical ergonomics. The instrument could be improved further when looking at the design and the current surgical workflow. Further research and clinical testing is necessary to see if this product is suitable for hip replacement surgery.

EXECUTIVE SUMMARY

INTRODUCTION

In orthopedic surgey and hip replacement surgery in general high sound levels are reached due to the usage of (powered) surgical instruments. Noise levels can reach up to 130 dB (Fritsch MH, 2010) and may cause permanent noise-induced hearing loss.

As Noise-induced hearing loss may be temporary during surgery, it could become permanent, resulting in requiring hearing aid and may be accompanied by tinnitus. In research, was found that 50% of orthopedic personnel with long-term exposure to power instruments showed early signs of hearing loss. (Willet K.M, 1991) The challenge of doing something about the noise is that sound is important to surgeon and staff, as they use sound as feedback to validate succesfull implantion.

ANALYSIS

In the current procedure of total hip arthroplasty (THA) a surgical mallet is used in most of the surgical steps. This instrument gets used to impact implants into the bone by hitting impactor tools or handles where the implants/tools are attached to. The metal-on-metal impact causes large sound peaks of more than 120 dB, above the human pain threshold. Soundpeaks of these levels will cause short term hearing loss, what affects communication during surgery. Longtime exposure to these peaks can even result in permanent (longterm) hearing loss.

Next to finding that the sound level peaks are of great magnitudes, the usage postures when handling the instruments have a high risk of muscoskeletal disorders. From these findings the main requirements followed and a design vision was made: "A surgical instrument/impactor has to be designed which is able to implant (press-fit) and reduces the level of noise exposure, risk for musculoskeletal injury and give tactile feedback to its user"

CONCEPTUALIZATION

Based on the list of requirements and the made design vision, ideas were generated. The ideas were based on occupational health guidelines to reduce soundlevels in the work environment and other industry tools and principles. From these ideas, three concept directions were selected and elaborated. Concept 3 came out the best, which was further developed into a combination of a (pile)driver and slide hammer which makes the user able to drive and extract implants into and out of the bone with lineair forces. Applying lineair force may result in better implant fit due to the fact that more bone can be preserved.

At the end of this phase was decided upon to only focus on the Driversystem and not the modular attachment which have to fit to the different implants and tools.

EMBODIMENT

In the embodiment, the Driver system was further developed and a first prototype was made.
This prototype was used for physical testing with a loadcell, to show if the product was able to generate enough force to make implanting possible. After testing it became clear the prototype was able to generate 12 % more force than the mallet and reduces the sound level. Next to testing the forces coming from the prototype, it underwent sound level testing in a soundstudio, where the prototype showed being able to reduce the soundlevel by almost 16 dB.

After testing prototype 1, a detailed design was made, DriveFit V1. In this part of the embodiment stage the product materials where chosen and the geometry was optimized with the data gathered from testing prototype 1. Resulting in changing the length of the product (main body) and the geometry calculation of the threaded connections that are in the product. This optimizing was done via mathematical models in Maple 2017. Finally DriveFit V1, got an extra modular function of changing handle weight. This was done so larger force could be generated. After prototyping DriveFit V1 in the PMB, TU Delft the prototype was used during the placement of Acetabular cups in a cadaverlab.

After testing on the cadaver, it became clear the prototype functioned as intended. But some changes had to be made to the design, replacing the straight cilinder handle, for three half sphere handles to fit hand size, weight preference and natural angle of the wrist.

FINAL DESIGN

The final design was prototyped with the adaptions coming from cadaver testing, the final instrument consists of parts made out of medical grade stainless steel and POM-C. This piston is the only POM-C product and is there to make sure metal-on-metal impact is not occuring, combining this with the enclosement of the sound source it reduces the sound level with 16 dB.

The production cost of the product was estimated for a batch size of 100,000 pieces, with a the production price estimate around 60 Euro. Multiple evaluations where done: sound level testing, broaching the femoral canal (saw bone test), workflow testing, psychoacoustic test and ergonomic assessment. The test resulted in a decrease in soundlevel when impacting of almost 16 dB. Broaching of the Femoral canal was possible and extraction of the broaching rasps worked extremely well. Workflow testing showed that the product will slow down surgery, as the product needs to be changed in modularity concerning the next surgical step. In the psychoacoustic test health care professionals rated the sound as a more pleasant and less loud compared to the old/current sound. Finally the ergonomic assessment showed that the working posture of the surgeon improved and the risks of injury is decreased.

Recommendations coming from the evaluation testing is changing the threaded connection design to a camlock connection, as attaching the broach handle was found clumsy. As the product is new in any form of usage and sound emmitting, training with the product is necessary to get grip on the new usage scenario/workflow.

EVALUATION

Looking back at the project, the sound frequency should be analyzed as well. The focus within this project was put on sound pressure, as the measuring device could only register one data set. Before putting the product into production, there should be looked if sound frequency is used as surgical feedback. When frequency gets used by surgeons, the DriveFit should undergo testing to see if it could give a similar frequency flux as feedback.

The outbreak of COVID-19, asked for a lot of assumptions and improvising in testing which made evaluating harder. Luckely there was enough material collected in phases before making sure the final design could be evaluated.

It is concluded that procedure workflows are important to take into account during the design process. Especially the action of assembly and disassembly between surgical steps. The DriveFit is designed for one specific procedure: the extraction and impaction of implants into/from a patient. With minor adaptions DriveFit can be used in other orthopedic surgeries and industries.

To conclude: DriveFit can be used as an impacting and extracting device within THA, decreasing the soundlevel to a value below the human pain threshold (-16 dB(C). By its modularity it can be used throughout the surgical steps of total hip replacment surgery replacing the surgical mallet and decreasing the amount of instruments needed. Looking at the working posture and ergonomics the surgeon has less risk of muscoskeletal injuries.

Finally, it is recommended to do clinical testing to see if the product complies to medical device regulations for a class 1 medical device.

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Introduction

A hip replacement surgery is a major surgery and usually takes around 60-90 minutes to be completed. Due to the use of powered and manual instruments (e.g., drills, saws, hammers) the orthopedic surgeon, support staff and patient get exposed to significant levels of noise pollution.

Noise levels experienced during this procedure carry a risk of noise-induced hearing loss.
In addition, it constitutes to a higher possibility of adverse events due to a loss of communication and dexterity among personnel. Prolonged exposure to potentially damaging noise levels in the workplace has become a subject of interest in recent years.

In this project, the operation room could be described as a sonic environment, where sound(scape) is defined by acoustics (dB) and human sensation of sound (e.g. quiet, noisy). Perception of these sounds can differ for listeners therefore; we should consider multiple types of listeners and the way they interact with this information within the context. A differentiation can be made for three types of listeners: sound users that are required to interact with sound (surgeons), active listeners that voluntarily interact with sound (operation room staff) and passive listeners that are exposed to sound by force (patients). (Figure 1)

During the procedure (powered) instruments generate sound levels as high as 131 dB.
The different listeners are exposed to the sound levels at varying distances on site. Many (powered) instruments use generated noise levels greater than the threshold for hearing loss under health and safety legislation. These instrument emissions eventually become hazardous within the length of an average surgical procedure. (Fritsch MH, 2010).

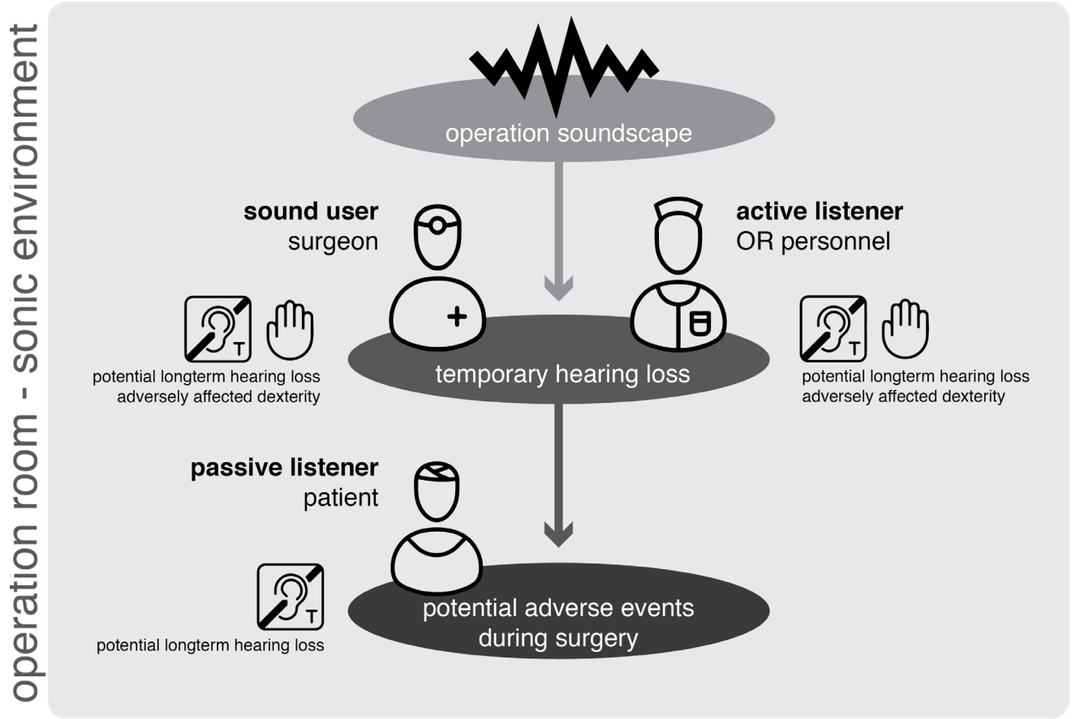

Figure 1. Operation room - sonic environment

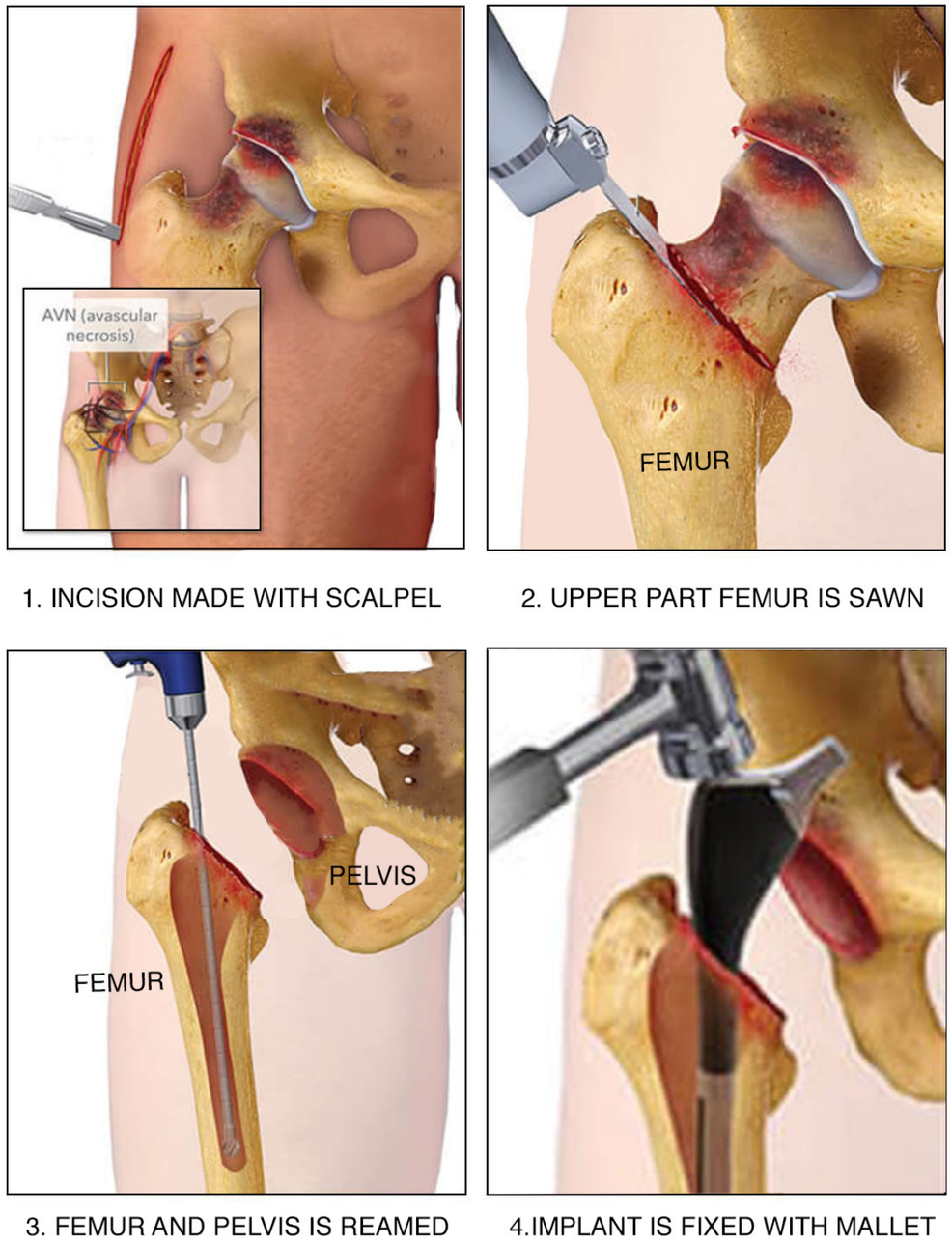

Figure 2. Procedural steps hip replacement surgery

When looking at the procedure, the main used surgical tools can be described using four simplified steps. (Figure 2)

1. Incision is made when patient is anesthetized.
2. With an oscillating saw the upper part of Femur is removed
3. A Surgical Reamer used to hollow out the Pelvis and upper part of the Femur.
4. Using a mallet to fixate the cup into the pelvis hollow and a Femoral stem into the hollow Femur.

Orthopedic surgeons and operation room staff want to reduce the risk for noise-induced hearing loss and improve operation room communication during hip replacement. By the reduction of noise, communication and dexterity will improve and the risk of surgery related complications will decrease. Zimmer Biomet wants to develop instruments with lower noise emissions. By doing this, protective equipment and instrument sounds will not interfere with the normal communication between surgeons and staff. This will all be in favor of the patient, whom will not be exposed to harmful noise levels and most likely will have no adverse events during his/her procedure.

The major challenges of this project are:
1. Surgeons (sound users) have learned to interpret the currently produced sounds as an indicator for achieving surgical goals, such as proper fixation of the implant. Therefore, the solution to be developed needs to convey this feedback information or present this essential information to the surgical team in a different way.

2. The current precaution is to wear hearing protection, but this can block the necessary feedback and subsequently results in a loss of communication. Additionally, hospital masks and sterile operating suits already negatively affect verbal communication.

Problem Definition

During the hip replacement procedure, the problems arose when surgeons and/or personnel started using (powered) instruments. The noise produced was considered as the major contributing factor for temporary and potentially long-term hearing loss for all people in the operation room. Therefore, finding a solution against hearing loss during hip replacement surgery was chosen as the focus for this project.

Noise-induced hearing loss may be temporary during surgery, but could become permanent, resulting in requiring hearing aid and may be accompanied by tinnitus. In research, was found that 50% of orthopedic personnel with long-term exposure to power instruments showed early signs of hearing loss. (Willet K.M, 1991) To tackle this problem, a basic analysis of the hip replacement procedure in relation to the produced sound levels (dB) needed to be conducted. Such context and acoustic analysis will be the foundation of the project and is required in order to identify key problem areas and opportunities within hip replacement surgery and the noise exposure. After having an overall feel for the essence of the complete procedure and noise producers, the focal point can be shifted towards finding optimal solutions to the main issues and challenges.

To specify the research, the information-flow between people and instruments within the OR and during surgery was investigated. Further, knowing more about the used sounds and the current flow of information between personnel. Additionally, research was done into the project's main challenges such as surgical sound cues, instrument feedback and current hearing loss precautions. Main research questions which arise are:
- How does the surgeon handle surgical sound cues during the procedure?
- What and how does the surgeon handle instrument feedback during the procedure?
- What are the current precautions for hearing loss within this OR environment?
- How does the flow of information between people and instruments is handled by staff and surgeon?

Assignment

The graduation assignment was formulated as follows:

"During this project a tool or instrument will be designed that focuses on the (perceived) reduction of harmful noise in order to prevent temporary and long-term noise-induced hearing loss."

The solution that I aimed to deliver was a product prototype, which proved a working principle that significantly lowered the perceived noise levels during hip replacement surgery. The goal of the final prototype was demonstrating the working principle during my final presentation and proving the feasibility and fit within the use environment and the surgeons' workflow.

Method and Approach

When starting-off this design project research needed to be conducted. The goal of this research was integrating (new) findings into insights. These insights were the foundation for new product ideas and problem solutions.

For the first phase of the project the gathering of information through research of relevant topics was necessary. Tackling this project, the main stakeholders were analyzed, Zimmer Biomet, orthopedic surgeons and OR staff. Approaching the problem from the orthopedic surgeon's point of view was necessary as it should fit within the surgical procedure and its operation room context.

Research methods used to gather insights included reading literature, doing desk research, taking observations within the OR and conducting interviews. All findings were documented in chapters according to different attributes: surgical procedure, sound-levels, tasks, context, and ergonomics. For each chapter, the topic was further specified when affecting the potential risks within the OR and in special of temporary and long-term noise induced hearing loss.

This graduation project was divided in six diffent chapters, starting of with Analysis, Conceptualization Embodiment, Final Design with the accompanying recommendations and finally an Evaluation on the project, design and process. Figure 3 shows the approach scheme which covers the different steps of the design cycle.

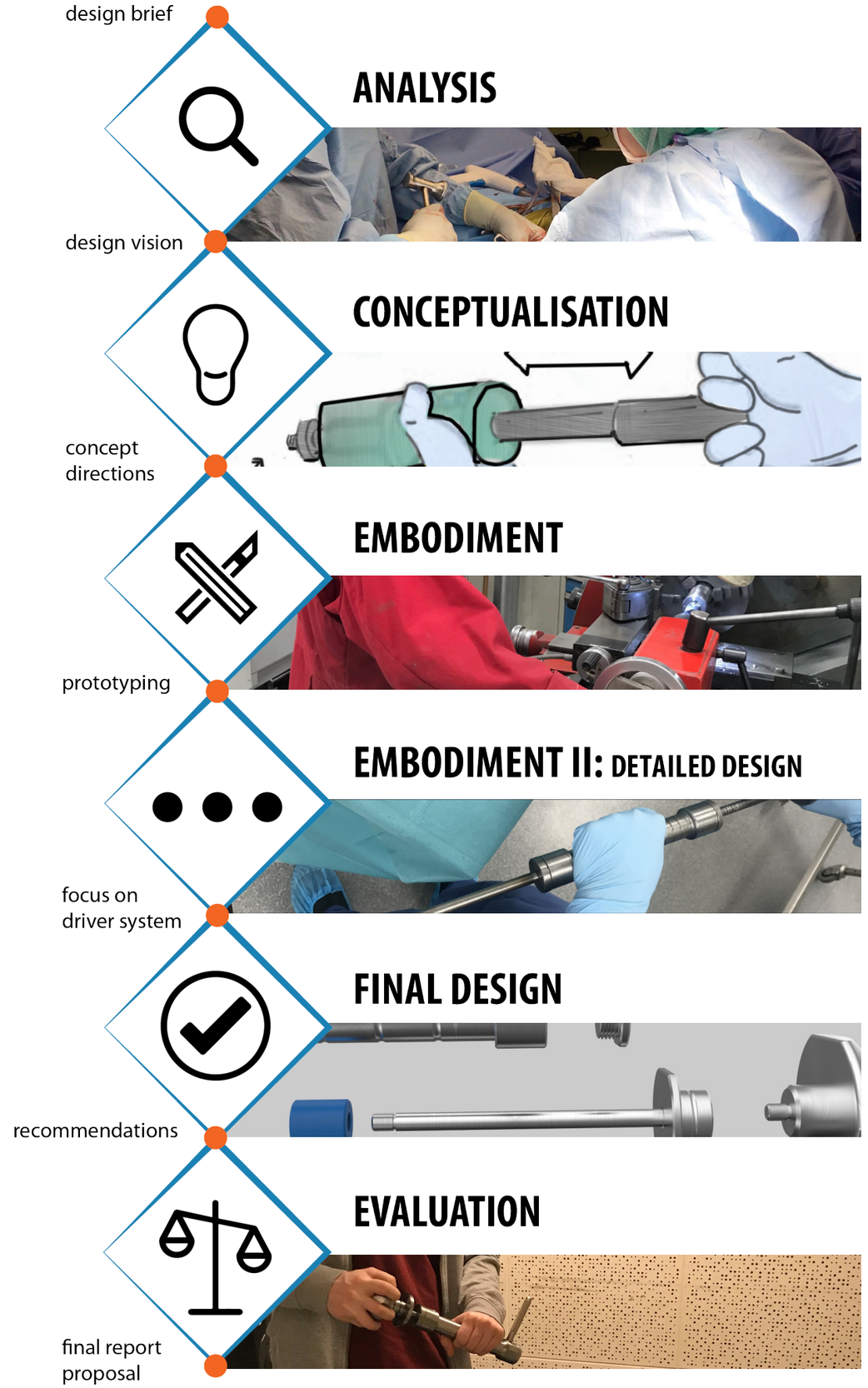

Figure 3. Project approach scheme (page 15)

5. ANALYSIS

Picture of total hip arthroplasty procedure (01-11-2019)

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1. ANALYSIS

In order to design a new instrument or tool, it is important to know the stakeholders and context where the new product will be used. In this chapter the total hip replacement procedure is analyzed by observing surgeries and interviewing staff and surgeons. All in all, to get insights of the user, the problem context and operational techniques. This chapter ends with answering main question derived from the project brief and a design vision.

1.1. Stakeholders

Company

Zimmer Biomet is a company, who design, manufacture and markets orthopedic reconstructive products. As a global leader in musculoskeletal healthcare, they have a close collaboration with healthcare professionals to keep increasing they rate of innovation.

Zimmer Biomet is a merger between Zimmer and Biomet which happens in 2017, but Zimmer was founded in Warsaw, Indiana, back in 1927. (Zimmer Biomet Holdings Inc., 2018) As a business-driven company they operate throughout the world with customers ranging from large multinational enterprises to independent clinicians and dentist.

For this graduation project a focus was put on the product category Hips, one of their most constant (growing) and largest product categories. Hip reconstructive products consist of prosthesis for the Femur head and pelvis sockets; plus, the related surgical products. These products are marketed and sold to healthcare institutions, through distributors and dealers. (Zimmer Biomet Holdings Inc., 2018)

Bergman Clinics Bewegen

Bergman clinics is healthcare provider with 63 clinics throughout The Netherlands. These private clinics are all specialized in a certain treatment, for this graduation project the "Bewegen" (Movement) clinics were visited which are specialized in anterior approach hip replacement surgery.

Bergman Clinics was one of the most experience institutions in 2016, if it comes to hip replacement surgeries. (576 replacements in total) After surgery 94% of the clients experienced significant improvement, with an infection rate below 0.2%. (Bergman, 2016)

Bergman Clinic has the responsibility of providing their employers with a safe workplace in this case the operation room. Where occupational hazards are kept at a minimum and are conform legislation. This needs to be done so surgical staff have the least risk of work-related injury and the patient the best hip replacement outcome possible.

1.2. Noise?

The main problem in this project are the high noise levels registered in the operation room during a hip replacement surgery. Lower these noise levels is necessary to reduce the risk of temporary and long-term hearing loss. But what is noise?

Noise is unwanted sound that is unpleasant, loud or disruptive to your hearing. (Elert, 1998) But what is sound? Sound is what we hear when a sound waves passes through a medium to the ear. All sounds can be seen as vibrations of air or another medium being picked up by the human ear.

Vibrations of the medium make air molecules move. These vibration can be called, sound waves, moving away from their source (origin), traveling onto air molecules. When the vibrating molecules reach the ear, the eardrum vibrates. The bones of the ear then start vibrating in the same way that of the medium (product) that started the sound wave.

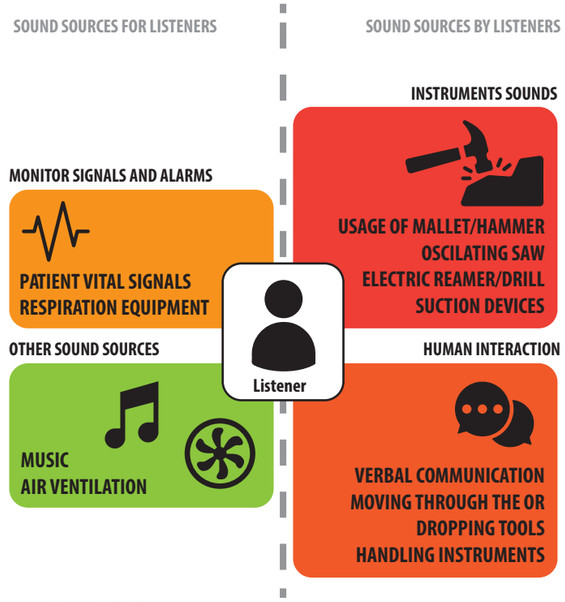

Figure 1.2. Sound sources in context

1.3. Context: operation room

In this chapter the context is analyzed. Specifically looked at the operation room and surgical procedure. Observations were conducted during hip replacment surgery in operation rooms at Bergman Clinics Naarden and The Hague.

Operation Room

An operating room or operating theater is a room where surgical procedures are carried out in an aseptic environment. Aseptic conditions mean that the objective is to maintain contamination-free. Within the operation room, the sterile area can be found around the operation table. This specified area is considered free of micro-organisms. To have an overview of the operation room see Figure 1.1.

Within the operation room there are multiple sound sources (Figure 5) that contribute to the overall noise level. The sounds made by these sources are picked up by three different listeners but also "made for", monitor signals, or "made by" these listeners, instrument usage and human interactions (Figure 1.2).

Conclusion

When observing in the operation room most noisy actions where taken inside the sterile area and are coming from the users of surgical instruments and human interactions. As verbal communication and tools emmit the loudest perceived noises within the OR. (Appendix A.1)

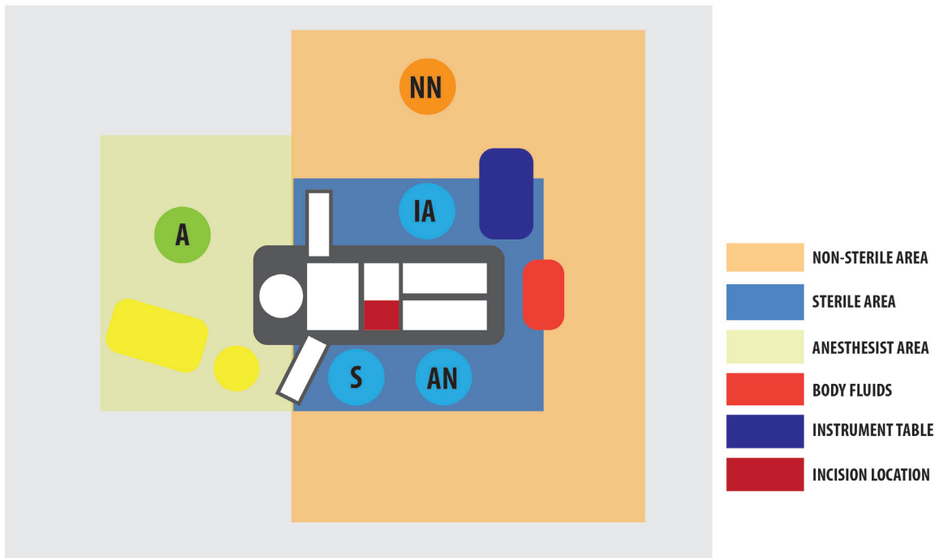

Figure 1.1. Operation room lay-out

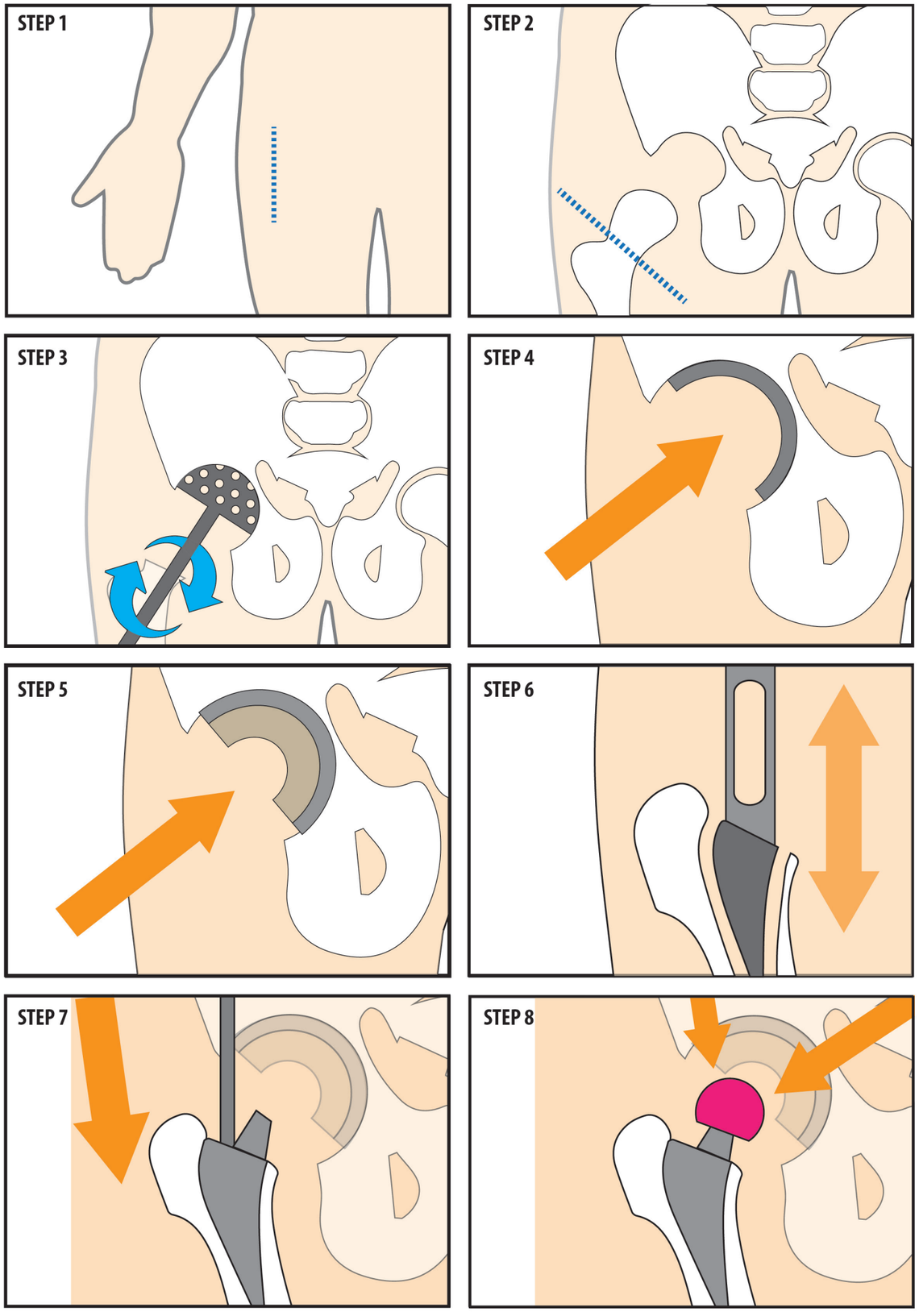

Figure 1.3 THA procedural steps

1.4 Total Hip Arthroplasty

In total hip arthroplasty surgeries, the head of the femur and the socket part of the pelvis (acetabulum) of the natural hip get replaced. Hip procedures include first-time or primary joint replacement as well as revision of older implants. Within this project there is specifically research done on anterior approach procedures where the hip implants are press-fitted into the bone, which means that they get fixated to the bone through on-growth or ingrowth technology. (Annual Report Zimmer Biomet Holdings Inc., 2018)

To get a better grip on the procedure, it is divided in eight steps. (Figure 1.3) This division is made after observing thirteen hip replacement procedures at Bergman Clinics, Naarden and The Hague. (Appendix A.1)

Step 1. Incision

When the patient enters the OR, the anesthetist (assistant) and surgical team lift the patient from his bed onto the surgery table. On the table the patient gets anesthetized and the operative field gets disinfected. After this the patient gets covered with plastic and papers sheets, so the surgery can be performed in most sterile conditions.

The replacement starts with an incision of the skin, in this case via the anterior approach. (procedure done at the anterior side of the hip joint.) When the surgeon gets through the skin and underlaying tissues. By pushing aside, the upper leg muscles and dislocating the hip joint, an overview of the arthritic tissues can be located.

Step 2. Cutting the Femoral neck

The first step is the Femur is cut on the Femoral neck, a few centimeters below the Femoral head. This is done with a bone saw, in the surgeries observed an oscillating saw was used.

Step 3. Reaming the Acetabular

Once the arthritic head of the Femur is removed, the worn-out hip socket part of the pelvis bone (Acetabular) gets addressed. A reamer is used to scrape away the damaged cartilage and bone. This leaves a smooth, perfectly dome-like surface to accept the the Acetabular cup.

Step 4. Placement of Acetabular cup

When the arthritic bone is removed from the acetabulum, the new Acetabular can be inserted. The Acetabular component, cup, is held tightly in the pelvis by making the socket slightly smaller than the Acetabular component, by wedging the cup into the bone. The cup has a rough outer surface to allow bone to grow into the surface of the implant over time.

Step 5. Placement of Acetabular cup liner

In this step of the procedure, the acetabular cup, most of the time made out of titanium gets lined with a cup, made out of ceramic or polyethylene. The liner is there to reduce wear and facilitate smooth movement within the joint.

Step 6. Opening the Femoral canal

The Femoral gets opened up by rasping/broaching the bone marrow out of the Femur. With special rasps the center of the femur is hollowed out to accommodate the Femoral stem, this part of the artificial joint must be held in place tightly by press-fitting it into the Femoral canal.

Step 7. Placement of Femoral stem

When the Femur is fully prepared for the stem, the stem is wedged into the canal made in the femur, by using a mallet. The Femoral stem is the implant that supports the fixation of the Femoral head. Due to the outer surface of the stem, the implant allows bone to grow into the implant over time.

Step 8. Placement of Femoral head

With the stem press-fitted down the center of the Femur, the Femoral Head (ball like shape) is tightly fitted onto the top of the Stem. This Femoral head is mostly made out of ceramic, plastic or even metal and facilitates the connection and movement between the Acetabular and the Femoral components of a THA. After placement leg lenght is checked and the wound is sutured.

Conclusion

During the observations was perceived that the instruments used in step 5 to 7 gave the loudest noises. In all of these steps a surgical hammer/mallet was used to impact and/or extract implants and accompanying components. (Figure 1.4)

Therefore, changing the surgical mallet to a less noise emitting product could significantly reduce the overall noise level during hip replacement surgery.

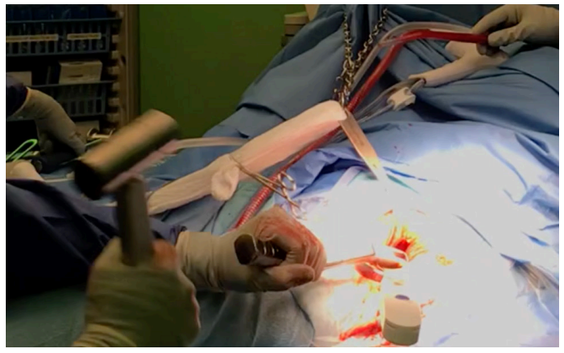

Figure 1.4 Surgical Mallet and Acetabular cup impactor (01-11)

1.5 Task Analysis

During the total hip replacement surgery, a team of 5 people is working to replace the natural hip successfully. The team consists of a surgeon, two operating assistants (sterile scrub nurses), one non-sterile nurse and an anesthetist assistant or anesthetist. All of them have a certain responsibility within the operation room. (Figure 1.5)

Orthopedic Surgeon (S)

The surgeon is responsible for the diagnosis of the patient preoperative. Preoperative diagnosis leads to templating of the replacement hip, so the surgeon is preparing the operation beforehand. During surgery, the leader of the surgical team and responsible person for making decisions on the patients' health, safety, sizing of the implant and fitting it into place.

After surgery he is there to provide the patient with postoperative care and the necessary treatment such as rehab. All actions done by the surgical team, are given approval by the surgeon, if there is no approval actions are not taken.

Two operating assistants (sterile scrub nurses)
The operating assistant are assisting the surgeon during procedure from within the sterile area. There are ***two types*** of sterile scrub nurses.

1. Instrumental scrub nurse (IN)

This assistant faces the surgeon during operation and hands instruments to the surgeon and (dis)assembles them after actions taken by the surgeon. Next to that he/she prepares the surgery together with the assisting scrub nurse, by laying out and assembling all necessary equipment. The instrumental nurse is an expert in the field of instrument learning and monitoring sterility.

He/she checks all instruments for soundness and usability. Furthermore, she is jointly responsible for the counting of the gauze and used instrumentation.

2. Assisting scrub nurse (AN)

The assisting scrub nurse stands next to the surgeon during the procedure and support the surgeon to give him the best view the operative field by keeping the wound dry with the aid of gauze or suction. Next to presenting the incision site in the best way possible she helps with disinfecting and covering the operative field. Occasionally the assisting nurse can suture the incision or wound after surgery.

Non-sterile nurses and sterile operating assistants rotate function between each surgery to ensure acerbity during procedure to assist surgeon as best as possible.

Non-sterile scrub nurse (NN)

This assistant prepares the operation together with the instrumentation assistant. She is not part of the sterile operating team. She does all the non-sterile work in relation to the surgery.

She indicates all sterile materials before and during the operation and helps with dressing the sterile team. At the start of the procedure she helps with the positioning of the patient on the operating table. During surgery she ensures the connection and adjustment of all peripheral equipment and the correct illumination/ lighting of the operating area. Plus she is the one finding the implant in stock and opening the packaging. After this she hands it over to the assisting scrub nurse aseptic.

Anesthetist assistant/Anesthetist (A)

The anesthesiologist is the doctor specialized in providing the patient with anesthesia and pain relief medicine. During surgery responsible for monitoring vital functions such as blood pressure, heart rate and blood loss before, during and after surgery.

In addition to the anesthesiologist, there an anesthetist assistant. Together they give the anesthesia to the patient and control its values during the operation. The anesthetist assistant will guide the patient, monitor its vital functions and will be present during the entire operation. Extra responsibility the anesthetist assistant has during surgery is the remote controls of the surgery table, by raising, lowering or tilting the table on surgeon request.

Conclusion

The only people who handle and use the instruments in this context are also the ones who contribute to the harmful noise level.

Via a task analysis made out of observations it can be concluded that both orthopedic surgeon and instrumental nurse are the people who handle the instruments and tools which are causing loud sounds during surgery, they are the main sound producers. As they are the ones that use, check and prepare the instruments before, during and after the procedure.

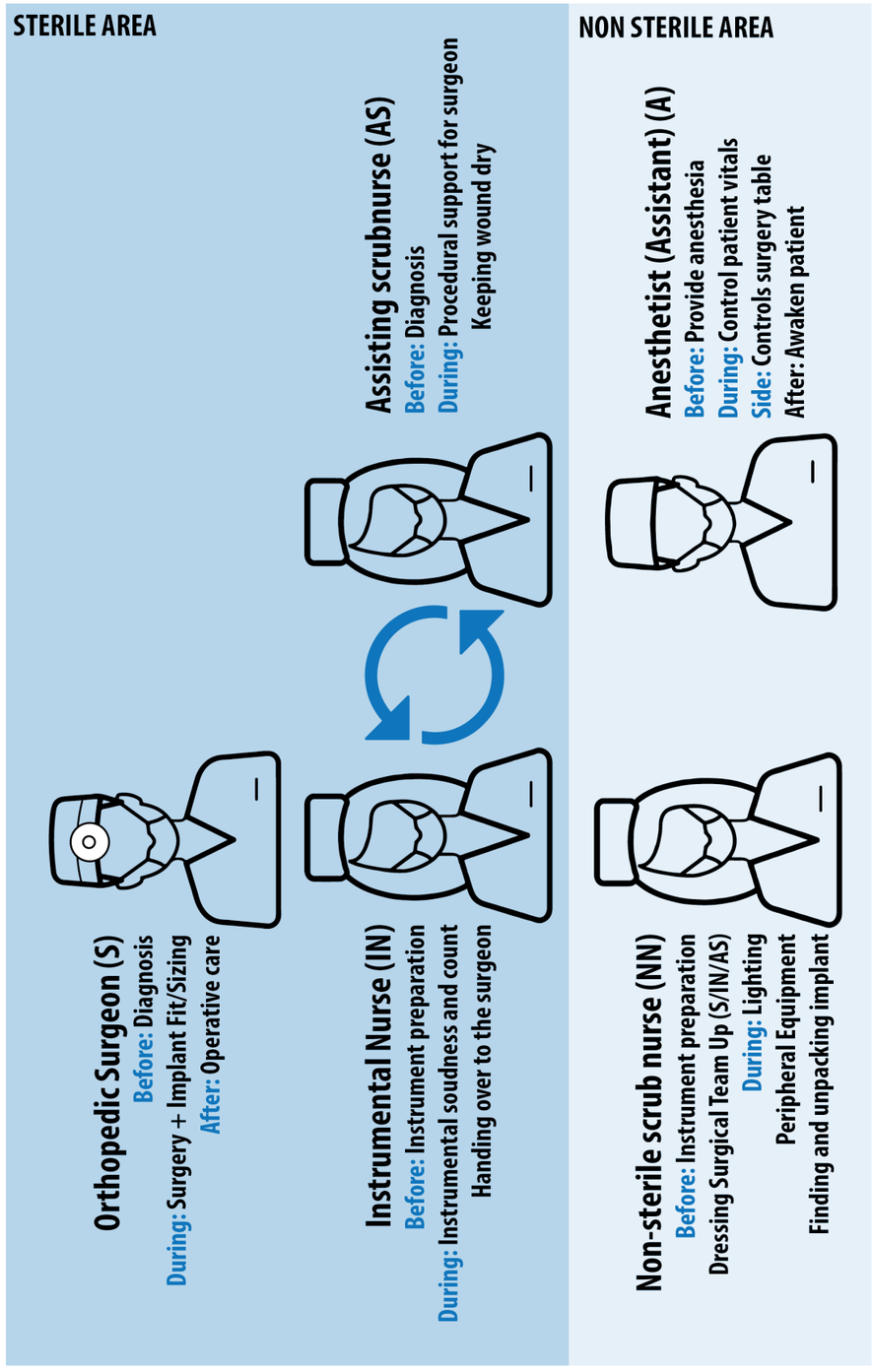

Figure 1.5 Task Analysis - Responsiblities

1.6. Soundscape

A soundscape is the combination of sounds that arise in the acoustic environment of an operation room created by humans, instruments and machinery.

In the operation room an exposure to loud sounds may result in a hearing impairment, such as noise-induced hearing loss (NIHL), tinnitus or a sound sensitivity. The World Health Organization estimated that one-third of all cases of hearing loss can be attributed to noise exposure (National Institutes of Health, 1990) To find out what the effect of noise exposure is on the hearing of OR personnel, the acoustics within this soundscape had to be investigated. To damage human hearing the threshold of pain for hearing needs to be exceeded. A frequently used figure for this threshold is 130 decibels, while the threshold for hearing and pain meet at 120 decibels. (Nave, 2016)

While doing observations at Bergman Clinics Naarden and The Hague, a focus was put on examining individual sources of sound, in special for surgical (powered) instruments. As these consist of noise types that are characterized by single or repeated impulses. (Hansen, 2017) Maximum noise levels of these impulses during orthopedic procedures generated sound levels as high as 131 decibels (Fritsch et al., 2010) and peaks exceeding 140 decibels. (Love, 2003) Plus these sounds where quantified as the main problem, when talking to people from Zimmer Biomet and orthopedic surgeons and staff. (Appendix A.5)
The decibel scale is a logarithmic scale in which 0 decibel stands approximately for the threshold of hearing in and in which the threshold of discomfort starts between 85 and 95 decibels. The threshold of pain therefore is met between 120 and 140 decibels. (Franks, 2016) (Figure 1.6)

Concluding from above literature, the human pain and discomfort level can be exceeded during hip replacement surgery. The set threshold is a sound pressure level of more than 120 dB wil can be

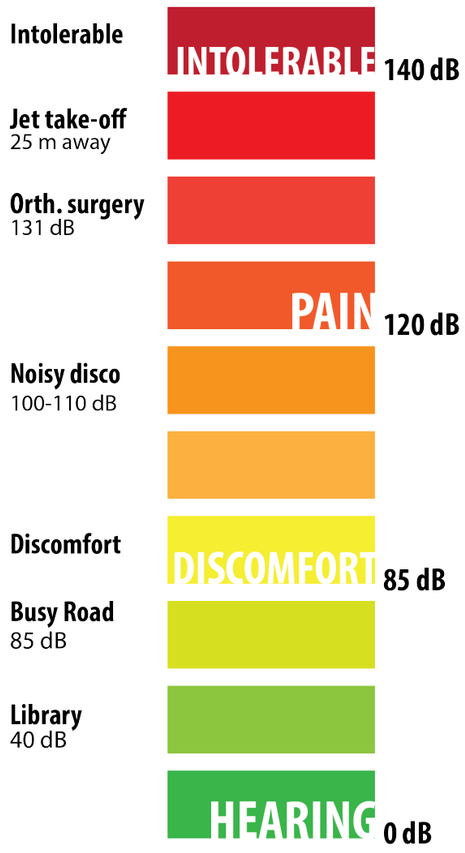

Figure 1.6. Threshold of hearing, discomfort and pain (Franks, 2016)

Measurements

To get a grip on the sound levels emitted by surgical instruments during a hip replacement procedure, the sound level in the OR was measured, with a calibrated Bedrock SM30 class 2 measuring instrument, approximately 0.5-1.0 meter away from the operative field. (Appendix A.2)

During surgery an average sound level was measured in dB(A) (LAeq), which correspondents with sound levels that can be perceived by the human ear and it's called time-average sound level. The average sound level measured during a surgery was 80 dB (Appendix A.1), this gives a total weighted average of 74 dB(A). See Figure 1.7 for the calculation of the total weighted average.

This total weighted average can be seen as a fairly good condition concerning sound level within the workplace. Most occupational health and safety organizations define noise exposure as hazardous when the level is 85 dB (and over) by a duration of 8 hours per day. (ARBO, 2019) The allowed duration is reduced by half for each 5 dB increase. (NIOSH, 2019) In this case the action limit of 85 dB is not reached so hearing protection or reducing noise emissions is not necessary. (Inspectie SZW, 2019)

More on legislation in Chapter 1.9.

<u>Calculate the time weighted average of an 8-hour workday.</u>
A surgeon is exposed to 80 dB(A) for half an hour when performing a THA surgery.
His total workday consists of 7 surgeries of 30 minutes.

<u>First the noise dose needs to be calculated.</u>

$D = 100(\frac{C1}{T} + \frac{C2}{T} + \frac{C}{T} + \cdots)$ in our case, $D = 100(\frac{C1}{T} * 7)$ as there are seven surgeries

C is the total length of the workday consisting of multiple shift and thus exposures of 0,5 hours.
T is the reference duration corresponding to the measured sound level
T is this case is 32 hours for 80 dB(A) (ARBO, 2019)

Results in $D = 100(\frac{0,5}{32} * 7)$, gives a noise dose of 10,94

$TWA = 16.61\log\left(\frac{D}{100}\right) + 90$ results in $TWA = 16.61\log\left(\frac{10,94}{100}\right) + 90$, gives TWA=74 dB

Figure 1.7. Calculation for Time-weighted average for an 8 hour workday.

Conclusion

As hearing loss due to noise can be temporary, a reduced sensitivity to sound over a wider frequency range resulting from exposure to brief extremely loud noises (120 dB(A) or over) may cause permanent hearing loss. (Trung, 2017) As levels above this value do exceed the pain threshold of the human ear which is set around 120 dB. (Nave, 2016) Regularly exposure to these high levels will results in noise induced hearing loss and tinnitus. Looking at the sound level peaks within the total hip replacement procedure these values range from 116 to 127 dB. These peaks where measure in a C-weighted frequency (LC,peak), as these allow the sensibly correct measurement of true peak noise. (Wong, 2010) For the measurements the procedure was divided into 8 different steps (see chapter 1.4.), where the peak decibels where registered. (Appendix A.2)

As seen in step 5 and step 7 (Figure 1.8), placement of the Acetabular cup and opening of the Femoral canal, account for the highest peaks and are around and above the human pain threshold of 120 decibels. Therefore, we can conclude that surgical steps that include hammer blows within the THA procedure are most malicious because of the duration (Appendix A.1)) and the sound level reached. Femur opening (123 dB(C) and Acetabular cup (124 dB(C).

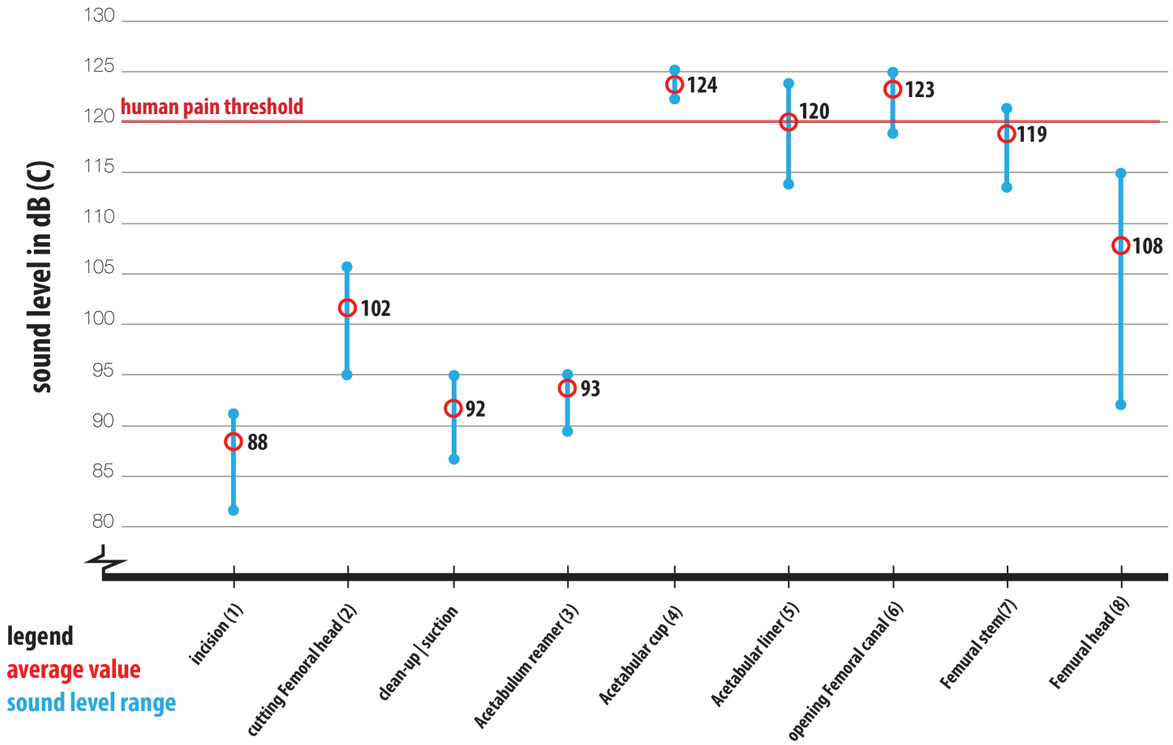

Figure 1.8. Sound level peaks measured in THA

1.7. Sound cues and instrument feedback

When starting this graduation project, the people of Zimmer Biomet and orthopedic surgeon at Bergman Clinics said; surgeons use tactile feedback and sound cues coming from instruments and tools to validate if the procedural steps are performed successfully.

Sound cues

As said in the introduction multiple types of listeners and the way they interact with this information are considered, because perception of sound differs per listeners; sound users that are required to interact with sound (surgeons), active listeners that voluntarily interact with sound (operation room staff) and passive listeners that are exposed to sound by force (patients).

By doing observations at 13 total hip replacement surgeries, a focus was on the users of sound as the surgeons are the ones that require to interact with sound to evaluate procedural steps. To find out how they interact with sound coming from instruments and tools, sound measurements were taken during the hammering of the Acetabular cup and by opening of the Femoral canal. The Acetabular cup wedging is done in 3-4 blows, the opening of the Femor had more steps and thus blows. (Figure 1.9)

The data captured during surgery shows that the sound level is not significantly increasing with every hammer blow/rasp broach size. To state that sound cues are used we have to look at loudness of sound, because sound can only be detected by the human ear when its "loud" enough. (Hansen, 2017)

In Figure 1.10, a subjective interpretation of sound pressure level. (Gloag, 1980) Changes in sound level during surgery and steps are just perceptible pro hammer blow or clearly noticeable. When referring to this table and measurements, the role of sound cues remains controversial not only by the fairly small changes in sound level but also the constant high-level of background music in the operating room what makes detecting small loudness changes nearly impossible. Music can bring the OR decibel level up to 87 or more next to the already considerable ambient noise levels in the operating room, coming from pumps, alarms, vents and others.

Next to that music can have a detrimental effect on surgical performance, especially among less experienced surgeons. In randomized trials of novice surgeons, music during training procedures caused distraction and impaired performance. (Miskovic, 2008)

Conclusion

Sound cues are not used by surgeons as the sound level changes during surgical steps are just perceptible, change in sound level of 3 dB.

When combining just percetible increases of sound level with the music playing in the OR. It can be concluded that sound cues are not used by the orthopedic surgeon. To validate this conclusion, in one of the observed surgeries the surgeon was striking the broaching handle on the beat of the music.

Rasp number	dB(A)	Peak level, dB(C)
starter 9	6	124.9
1	91	121.1
2	92.8	124.6
3	93.8	124.6
4	96.8	125.1
5	95	125
6	97.7	124.5

Figure 1.9. Opening Femoral Canal, dB measurements (Surgery 01/11/19, Naarden)

Change in sound level (dB)	Change in apparent loudness
3	Just perceptible
5	Clearly noticeable
10	Half or twice as loud
20	Much quieter or louder

Figure 1.10. Subjective interpretation of sound (Gloag, 1980)

Instrument feedback

To see if instrument feedback is present during surgery, the "talk-out-loud" protocol (Appendix A.4) was used, where the surgeon was asked to think-aloud when performing surgery specified tasks. The surgeon was asked to say whatever comes up into his mind as he completes the procedural steps. This might include what they are looking at, thinking, doing, and feeling.

During this protocol the surgeon mentioned hitting the broaching handle multiple times, until the rasp has a tight fit inside the Femoral canal. A tight fit is reached when it is wedged in-between the hard parts of the bone, this is done so a "press-fit" of the stem can be guaranteed. (Figure 1.11) During this protocol the surgeon did not talk about sound at all, but only spoke up on the tactile feedback he received from his tools, instruments and vision of the operative field.

Conclusion

The data in Figure 1.12 shows that the sound peak level is not really increasing with every blow, till the surgeon said he had "no more movement" of the rasp during the surgical step of opening the Femoral canal. This feeling of "no movement" can be seen as large amount of friction or resistance between rasp and bone, in essence this tactile feedback.

Next to the data shown from the Naarden Clinic, the observed procedures in the Bergman Clinic in The Hague Clinic gave similar results and the surgeon in that clinic was sure he didn't use sound at all, he mentioned that "the broaching was purely a tactile feeling of getting more broach/rasp friction towards to end of the procedure."

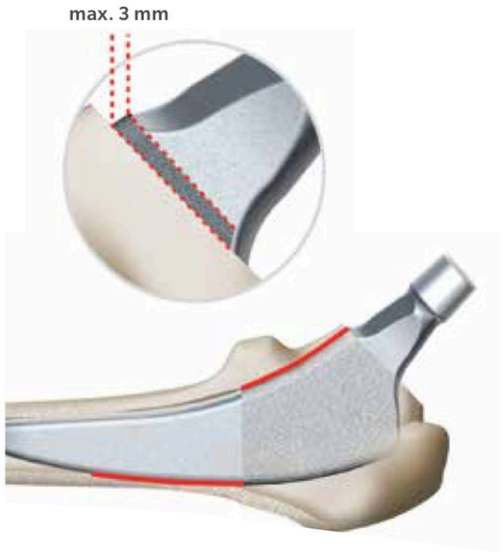

Figure 1.11. Femoral Stem press-fitted into the bone (Zimmer Biomet, 2019)

Rasp number	dB(A)	dB(C), peak level	
Starter	92.9	129.9	
1	90.8	123.8	
2	90.3	124.5	
3	92.5	124.4	
4	97.3	124.6	
5	98.3	124.6	
6	96.7	124.9	
7	101.4	124.7	No movement
8	96.2	124.7	No movement
9	100.7	124.8	No movement

Figure 1.12. Measurements of talking out loud protocol, No movement of rasp + no significant change in dB (Surgery 2 , 01-11-19)

1.8. Information flow

Information flow can be seen as movement of information between people and systems. One of the most harmful acute effects of noise pollution in the operating room is the interference it imposes on verbal communication and thereby affecting an efficient flow of verbal information.

Communication among staff members is a major component when looking at patient safety. Communication failures during surgery are common and are one of the leading causes of error and poor patient outcomes (O'Daniels, 2008). The ability of noise to disrupt communication in the OR was demonstrated in a study where auditory processing functions of surgeons were diminished by operating room noise and music. (Way, 2013)

Next to degraded auditory information, visual cues can be used to improve understanding (Kawase, 2005) Although this tactic can be used during surgery, the use of surgical masks obstructs visual cues, such as lip reading and hinders the auditory signal, making communication even more difficult. It is suggested to obtain understanding of around 90% accuracy, your speech sound level must be presented at 10 to 15 decibels above the noise source. (Stinger, 2008)

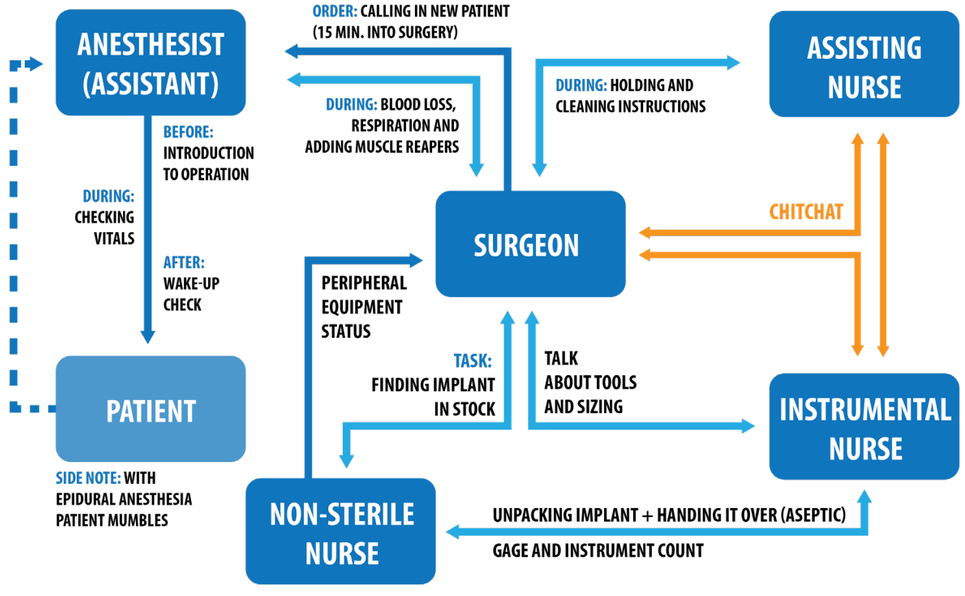

Figure 1.13. Information flow diagram

Concluding from observations within the operation room. The flow of information is stopped during the usage of (powered) instruments. Staff and surgeon do not exchange information at these moments. Owing to the temporary loss of hearing by large sound peaks the staff tends not to communicate at all. In these moments hand gestures were enough to spark an action in the operation room. For example, the surgeons open his hand and the surgical assistant places the next tool in his palm, that is the level of habituation they have working together. In that sense we could say that hand gestures or body language contributes to the flow of information.

Moments of verbal communication during surgery and the exchange of significantly import information such as patient vitals and implant sizing only applies to a very small part of the surgery. A total of 8 minutes important information gets exchanged against 30 minutes of total surgery time, where remaining exchange of verbal information flows are unrelated to direct patient care and can be seen as chitchat. (Figure 1.13) (Appendix A.4)

Conclusion

If obtaining understanding in speech surgery staff needs to present their speech level at 10-15 dB above the noise level. With this being said operation room staff have to communicate at speech levels of 90-100 decibels, measured average decibel was around 80 decibels and during peaks at levels of more than 130 dB(C), which is painfull and will permanently damage your own hearing. (Chapter 3.6)

All observations where done in THA procedures, where surgeons, the surgical assistants and scrub nurses had lots of experience because of their specialization in the THA procedure. Besides that, they have been working together for an extensive period of time, so they are used to each other's ways of communication, have know-how of the routine and are well-coordinated. The surgeries visited can almost be seen as assembly line work.

For example, the surgeon is finished using an instrument and even before asking the following instrument is presented. (Figure 1.14) Because of all the above can be concluded that the instrument emmisions do not negatively affect the flow of information in the observed surgeries. On other hand can be stated that if instrument sounds would affect the information flow, because talking is needed due to emergence, the human voice has to exceed a value over the decibel peaks measured. Values of over 135 dB have to be reached with the human voice. This is not possible because the loudest human scream is measured at 129 dB. (Guiness world record, 2000)

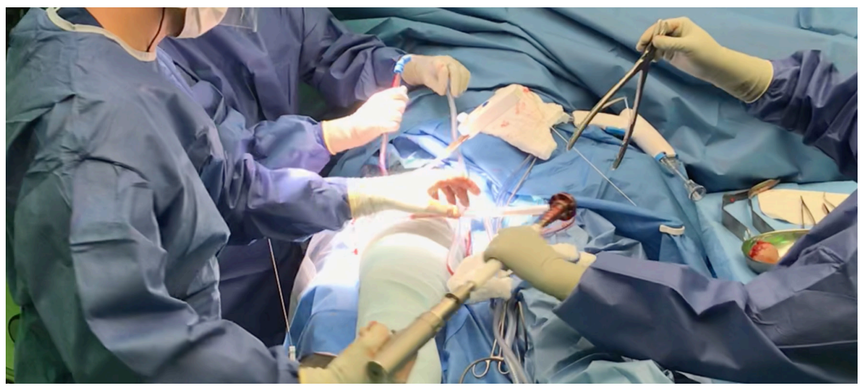

Figure 1.14. Instrumental scrub nurse (right) handing instruments before surgeons order. (left) (Naarden, 11-09-2019)

1.9. Legislation and noise precautions

In this chapter the current noise precautions and occupational health guidelines and legislation were analysed.

Legislation

Occupational guidelines and regulations were established to protect workers against the health effects of exposure to loud noises. ARBO is the occupation health and safety organization in Holland that work with recommended standards for noise exposure and have set legal limits.

Because ARBO is the Dutch Governmental Agency, that offers employees safety and healthcare regulations in connection with the work environment, a focus was put on ARBO legislation as all measurement are done in The Netherlands. Dutch ARBO law states in Artikel 6.8. Maatregelen ter voorkoming of beperking van de blootstelling; that exposure to loud noises should be limited, technical or organizational measure should be taken to eliminate or minimize the risks of exposure at the source, taking technical progress and availability of measures into account.

Artikel 6.8. states that when your daily exposure to loud noise is 85 dB(A) or higher, 8 hours average (time-weighted-average), or the registered peak sound level is 140 Pa (136 dB) or higher individuals should wear hearing protection, because exposures above these levels is considered hazardous.

Occupational standards specify a maximum allowable daily noise dose, expressed in percentages. For example, a person exposed to 85 dBA per over an 8-hour work shift, will reach 100% of their daily noise dose. The noise dose is based on both the sound exposure level and duration. Each increase of 3 decibels, the duration of the exposure should be cut in half. Figure 1.15, illustrates the relationship between sound exposure levels and durations for Arbeidsomstandighedenbesluit (ARBO, 2019).

Even when individuals are wearing hearing protection, the sound level may not exceed the daily limits of 85 dB(A) and a peak sound pressure of 200 Pa (140 dB). All-in all, if the daily dose of noise exposure is exceeded when taking into account the dampening functioning of hearing protection. There should be taken actions to reduce to exposure immediately to a level below the set limits and the causes of excessive exposure need to be established. (ARBO, 2019)

Conclusion

The 8-hour weighted average (dB(A)) is not reached within the THA procedure and peak sound pressure levels are not exceeded either for the done measurements, (Chapter 1.6) so no actions have to be taken to reduce to sound level following ARBO legislation. This would mean that the procedure is conform ARBO legislation, this is strange as the human pain threshold is at 120 decibels (Nave,2016) and will be damaging human hearing. (Chapter 1.6)

Time to reach 100% daily noise dose	Exposure level per ARBO
8 hours	85 dBA
4 hours	88 dBA
2 hours	91 dBA
1 hour	94 dB

Figure 1.15. Relationship between sound exposure levels and duration (ARBO, 2019)

Noise Precautions

Reducing the sound pressure level at the source or for the receptor of the sound can be seen as protection against noise pollution.

Receptor

Personal hearing protection are worn devices that reduce the level of sound entering the ear. (ARBO, 2019)When looking at the peak levels measured it would not be a bad idea when working within this environment. However only 2 out of the 10 people observed did wear hearing protection during surgery. (Appendix A.5) After observing unstructered free flowing interviews were taken inbetween surgeries asking staff and surgeons why they are not wearing hearing protection such as earplugs.

Some reactions received when asking for the reason they did not wear hearing protection where:
- **Anesthetist assistant:** *You cannot wear earplugs in the OR – I need to hear the equipment and eventual calls for help when a calamity happens.*
- **Sterile scrub nurse:** *I already wear this surgical cap, a face mask, eye protection and rubber gloves…. wearing more protection will… if I add earplugs – I would feel completely disconnected from my environment*
- **Sterile scrub nurse:** *I'm doing this job for almost 30 years now already – So, now it is not necessary anymore – the damage is already done!*

Only two of the observed operation room staff members wore hearing protection:
- **Orthopedic surgeon:** *I already have tinnitus and don't want my hearing to get worse even more. (Fig. 1.16)*
- **Sterile scrub nurse:** *I only wear one of the plugs, otherwise I cannot understand/hear the things people tell me – as you cannot read lips because of the masks.*

To conclude staff, tends not to use hearing protectors as it disconnects them from their environment and hinders auditory information being communicated correctly. Referring to Chapter 1.8 miscommunication is one of the most blamed factors resulting in medical errors. Adding hearing protections makes communication even more difficult than it already is due to obstruction of visual cues and background music. (Way, 2013)

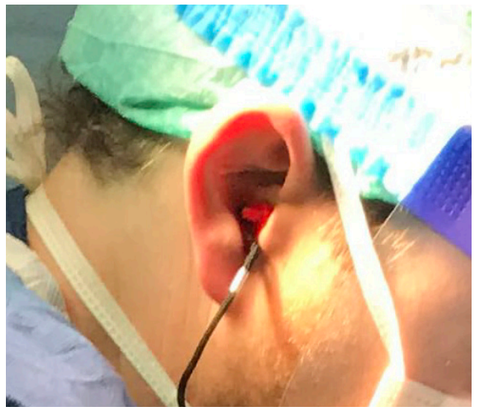

Figure 1.16. Surgeon wearing earplugs

Figure 1.17. Deadblow hammer does not work sideways. (The Hague, 14-11-2019)

Source

A sound source creates vibrations in the surrounding medium, air. As the source continues to vibrate the air, vibrations start moving away from the source, forming a sound wave. This sound wave can be picked up by the human ear and results in hearing.

When attending surgeries at the Bergman Clinic in The Hague, the surgeon did not wear earplugs either. But dampened the hammer blows, by folding the plastic wrapping of the implant multiple times and holding it against the tools which was with the mallet. This reduced the peak level with 8 to 10 decibels, but only worked for a few strikes (3 to 4), until the plastic wrap broke or melted. (Appendix A.1)

As both surgeons observed, supported the idea of reducing the sound level of mallet use. A mallet with the dead blow principle was brought into the operation room. With the current "solid-head" hammer, the force of the entire solid mass of the head is delivered at impact. Comparing it to the current hammer, a dead blow hammer conveys less peak force and spread its force over a longer time.
At the moment the face of the hammer head contacts the striking surface, the sand or shot (lead beads) within the hollow head do not make contact with the hammer face. (Figure 1.25) Due to a moment of inertia, the shot is collected at the opposite end of the head. The shot or sand instead descends to fill the "face" end of the head after impact to reduce recoil. (Hoffman, 2015) In the operation room we measure the sound level of 3 different hammers with and without plastic wrapping. (Figure 1.18)

Conclusion

Comparing the mallets, the dead blow hammer was heavier and reduced the sound by 13 decibels. The downside of this hammer that it does not function when using it side-ways. (Figure 1.17)The principle of lead beats does not work, as all there is no real circular motion/swing all weight stays in the long side of the mallet.

To conclude surgeons are aware of the sound level and try to reduce the sound level with plastics or different hammer types. Both surgeons spoke about discomfort when using a dead blow hammer and the plastic is just a improvised solutions, that works for a fraction of the impacts.

Blue Handle Mallet	Dead blow Mallet	Most common mallet
Weight: 0.735 kg	Weight: 1.12 kg	Weight: 0.7695 kg
91.5 dB(A) – 122.6 dB(C)	79.2 dB(A) – 109 dB(C)	93.8 dB(A) – 123.2 dB(C)
With plastic wrap: 85 dB(A) – 117 dB(C)	With plastic wrap: 74.9 dB(A) – 105.4 dB(C)	With plastic wrap: 90 dB(A) – 120.8 dB(C)
	When plastic broke: 86.5 dB(A) – 114.7 dB(C)	
	Striking sideways: 89.1 dB(A) – 116 dB(C)	

Figure 1.18. Sound level measurment of 3 types of hammers (The Hague, 14-11-2019)

1.10 Posture and risks

The goal of human factors is to reduce human error and increase productivity, while enhancing safety and comfort. All with a focus on the interaction between human and machine. In this analyze part of the report a focus was put on the working posture of the surgeon and observed safety hazards.

Orthopedic surgery asks for high physical demands on surgeons and assisting staff. The high demands involved in retracting, using tools and simply holding limbs in a certain position. These are all risks that can result in musculoskeletal injuries. Next to standing for prolonged periods of time and operating in potentially nonergonomic positions can create even more physical stress. Orthopedic surgeons have more reports about physical injury than general surgeons. (Mirbod, 1995)

Surgeons' use of nonergonomic devices can generate unnecessary additional stresses to the body. (Soueid, 2010) Most common injuries occur in the back, neck, shoulders, arms and hands. (Figure 1.19) Nevertheless, static stresses caused by non-ergonomic postures can lead to fatigue and disability, approximately 70% of intraoperative postures are static. (Rademacher, 1996) much of the back and neck pain is likely caused by prolonged head-bent and back-bent postures, mainly static (Kant, 1992).

To avoid these injuries, surgeons must start operating with more ergonomic instruments and adopt standing postures that keep the body in its most natural position. Ideally instruments should be redesigned to fit ergonomic ease. (Park, 2010) Other actions surgeon should take is frequent changes in body position, stretching and when possible supporting the body with a stool or footrest. (Esser, 2007) During observations it was noticed that right and left side hip surgeries are not done after eachother, but first all right side surgeries are done and then all left sides on a working day.

It was noticed that surgeon did not only complain on the sounds surgical tools emitted where present. Both orthopedic surgeons complained about wrist and elbow injuries coming from their working posture and hammer strikes. (Appendix A.5) During observations non-ergonomic awkard postures where visible in multiple surgical steps. (Figure 1.21 and 1.22) and assessed via a Rapid Entire Body Assesment. (Hignett, 2000)

Common locations of pain in orthopedic surgeons

Pain	% Surveyed
Neck	66
Neck with radiculopathy	29
Shoulder	49
Elbow	28
Wrist	26
Hand/finger	31
Low back	66
Low back with radiculopathy	29

Figure 1.19. Most common injuries for othopedic surgeons (Mirbod, 1995)

Costs

Research showed that orthopedic surgeons have a yearly median absens of 7.3 days ± 21 days due to injury. (Amaro, 2016) This volume of work days suggests that occupational injury could have economic implications for the healthcare system and providers. Next to that occupational injury may impact the quality of surgical care offered to the patient due to performance issues the surgeon may face while dealing with or recovering from the injury. (Davis, 2013)(Davis, 2014)

As orthopedic surgeon generate a annual net revenue of $3,2 million USD, their absenteeism of 7.3 days yearly, can lead up to a revenue loss for a healthcare institution of $92.000-$189000 USD. (Merrit Hawkings and DePuySynthes, 2019).

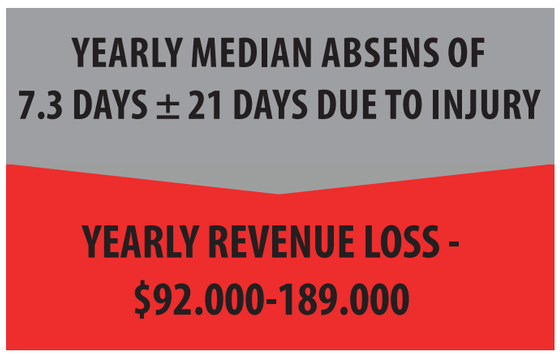

Figure 1.20. Revenue loss due to absenteeism (Mirrit Hawkings, 2019)

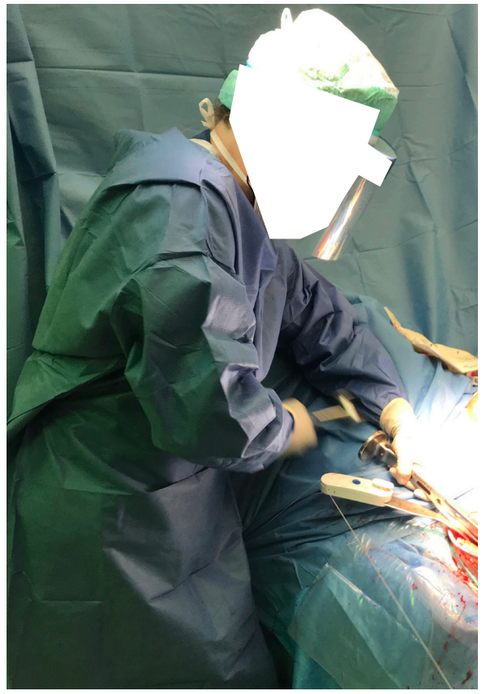

Figure 1.21. Opening of Femoral canal; High Risk posture (01-11-2019)

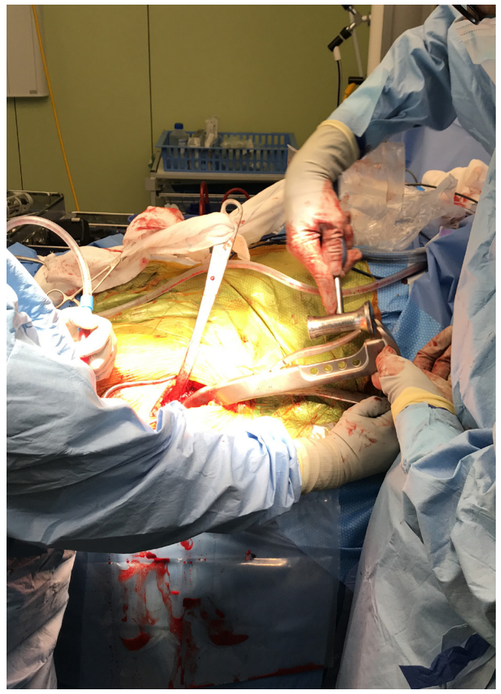

Figure 1.22. Extracting rasp after opening the Femoral canal (14-11-2019)

Ergonomic assesment

When looking into the working posture of surgeons during THA surgery. It was quickly noticed that the handling of tools and their postures are strange and could form potential hazards while performing surgery

During the opening of the Femoral canal the surgeon (Figure 1.21) and extraction of the rasp after Femoral canal broach were seen as non-ergonomic stances, especially when looking at the coupling of the mallet and position of the wrist. (Figure 1.22) To prove these posture are risky an analysis on these posture was done using a REBA (Rapid Entire Body Assesment) worksheet. (Appendix A.6) (Hignett, 2000)

The postures are assessed on position of the neck, trunk, legs, upper and lower arm, wrist and coupling. All of these position are scored, adding the scores gives a risk value ranging from negligible to Very High Risk/Implement change.

Results

When assessing this position via a REBA worksheet, the working positions of the surgeon were scored, High risk, which means the working postures have to change. Working position need to be adapted in the nearby future, to reduce the risk for musculoskeletal injury.

Other things noticed is that the surgeon has difficulties hammering out the rasp. (1.22) The handling of the mallet is weird, as he is not able to apply sufficient force. While handling the hammer he has no enclosed grip (fist) onto the mallet handle. This may cause hazards when striking with the mallet; he could lose his grip and drop the mallet or even impact his own hand or fingers. (Figure 1.22)

Conclusion

Orthopedic surgeons have to be able to operate with more ergonomically designed instruments avoiding strange working postures to reduce the risks of potential hazards and musculoskeletal injury. The new instrument should change the working posture of the surgeon to a less riskful.

1.11. Competitor Analysis

In the global market for hips, orthopedic reconstructive care industry, there are multiple competitors. The four major market share leaders in this branch next to Zimmer Biomet (31%) are DePuy Synthes/Johnson & Johnson (31%), Stryker (25%) followed by Smith & Nephew (9%). (Sarah Collins, 2016) (Annual Report, 2018)

Total hip replacement surgery has evolved dramatically throughout the last couple of years. Advances in technology made it possible to improve surgical techniques. Computer- and Robotic-assisted total hip replacement surgery is one of the latest revolutions in total hip replacement. Stryker and Smith & Nephew are strongly innovating in robotic guided surgery or integrating surgical assisting robots to their portfolio; DePuy Synthes is producing technologies that lower the risk of work-related injury, for example with KINCISE, (Figure 1.22) and patient templating during surgery. For a full competitor analysis, see Appendix A.7.

Zimmer Biomet is focusing in biological fixation, advanced materials and infection diagnosis. Therefore, more cautious when looking at robots and puts their attention mainly on its patient recovery program, to improve the care process and saving costs for the healthcare system. (Annual Report, 2018)

Future Strategy?

Due to the fact Zimmer acquired Biomet in 2015, their focus was on commercial integration towards a combined company (2017), others gained market share by new and innovative devices. This market share is mostly gained through the successes of robotic assisting systems, such as the MAKO hip system from Stryker. (Annual Report, 2018)

Robotics enable surgeons to increase efficiency and minimize human error compared to manual hip procedures. Referring to the sound problem, robots could be a solution to harmful noise during surgery but at this moment this is not clear. To keep their position Zimmer Biomet needs to have close collaborations with healthcare professionals by fulfilling their needs. Helping surgeons and healthcare professionals having the best materials and instruments will result in a treatment with increased efficiency and minimal (human) error.

Conclusion

By adding products to their portfolio that may reduce the OR sound level they will make a strong move to strengthen their market position. Especially because none of its major competitors is working on a solution to reduce the sound level.

Figure 1.22. DePuy Synthes, KINCISE System is designed to eliminate the need for repeated mallet use, there may be less surgeon fatigue and potentially less work-related injuries in the operating room (OR). (DePuy Synthes, 2019)

1.12. Main Questions

In the project brief different challenges emerged that needed to be taken into consideration and be researched before starting to design a new instrument or tool for the total hip replacement procedure.

How does the surgeon handle surgical sound cues during the procedure?

The surgeon does not use surgical sound cues during the procedure, because small changes in sound level during surgery are just perceptible or clearly noticeable. The role of sound cues remains controversial not only by the fairly small changes in sound level but also the constant high-level of background music in the operating room what makes detecting small loudness changes nearly impossible. (Analysis 1.6)

What and how does the surgeon handle instrument feedback during the procedure?

During the "talk-out-loud protocol" in Analysis 1.7, it became clear that instrument feedback was a tactile feeling. When wedging implants or rasps into the bone, the sound level stopped increasing (measurement) and the surgeon stated he felt an increasing amount of friction or resistance on his hammering blows, indicating the implant/rasps are fixed.

What are the current precautions for hearing loss within this OR environment?

Operation room staff is not wearing hearing protectors as it disconnects them from their environment and hinders auditory information being communicated correctly. (Chapter 1.9) It is also not necessary if you follow ARBO legislation guidelines as the TWA is not 85 dB(A) or over. (Analysis 1.6)

Miscommunication is one of the most blamed factors resulting in medical errors. (Analysis 1.8) Adding hearing protections makes communication even more difficult than it already is due to obstruction of visual cues and loud background music.

How does the flow of information between people and instruments is handled by staff and surgeon?

Concluding from observations within the operation room, the flow of information is stopped during the usage of (powered) instruments. Owing to the temporary loss of hearing by large sound peaks the staff tends not to communicate verbally at all. During these periods of time hand gestures and body language contribute to the flow of information. (Analysis 1.8)

Most communication is verbal during surgery and the exchange of significantly import information such as patient vitals and implant sizing only applies to a very small part of the surgery. All observations where done in THA procedures, where surgical staff had lots of experience and had been working together for an extensive period of time. They are used to each other's ways of communication, have know-how of the routine and are well-coordinated. (Analysis 1.6)

New Challenge emerged?

Looking at the human factors engineering in this project, such as occupational health and the risks for musculoskeletal injury. Physical injuries are a big problem among orthopedic surgeons and their assistants, due to high physical demands required during surgery. The new product design should enable the surgeon to keep a more natural posture and ergonomic ease when handling. (Analysis 1.10)

As stated above surgical instrument has to be designed which reduces the

1.13. Design vision

A design vision and list of requirments was made coming from the previous chapters. To start the ideation and conceptualization phase with.

A design vision was created to set a scope and function as a reminder for the set challenges in the project brief.

From the analysis phase came forward that the working posture when opening up the Femur and implanting the Acetabular cup with the surgical mallet are most malicious to the surgeon's hearing. (Analysis 1.6) Next to high noise levels the working postures and current product usage can be a risk for musculosketal injury. (Analysis 1.10)

From the insights above a vision was created to generate ideas. This vision is the following:

"A surgical instrument/impactor has to be designed which is able to implant (press-fit) and reduces the level of noise exposure, risk for musculoskeletal injury and give tactile feedback to its user"

Figure 1.23. Design vision

1.

2.

3.

4.

5.

1.14. Requirements

After the analysis phase the most important criteria/requirements are listed below. (Figure 1.23) Meeting these brings the design closer to the project goal/vision. (Figure 1.24)

1. ***Reduce sound level (needs testing):*** is it possible to reduce the sound with sound reducing workplace principles? (Chapter 1.6) (Analysis 2.1)

Wish: Dropping 10 dB in soundlevel, below the human pain threshold of 120 dB (50% of current soundlevel)

2. ***Ergonomically improving:*** getting rid of current working posture and reduce risk for MSD. (Analysis 1.10)

3. ***Easy to clean:*** sterility; can the product be taken apart, cleaned manually before sterilization.

4. ***Ease of use:*** makes the product the procedure more efficient, when looking into actions needed. Can it speed up some procedural steps?

5. ***Fit within surgical flow:*** can the product be fitted into the workflow and current used products "non-hammers" of a hip replacement surgery.

A full list of requirements can be found in Appendix A.8.

Figure 1.24. Main requirements

2. CONCEPTUALIZATION

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2. CONCEPTUALIZATION

In the conceptualization phase a list of requirements is made from the design vision and written assignment. These are used in this chapter to generate ideas. A brainstorm session is used to stimulate idea solutions. From the ideas, multiple concept directions were selected. These concept directions are explained. One concept will eventually be chosen to be developed into a prototype.

2.1. Design Opportunities

The main problem in this project is the high noise levels registered in the operation room during a hip replacement surgery. But how can be lower the noise levels? To reduce the risk of temporary and long-term hearing loss.

With the help of "How-Tos" problem statement are written in the form of questions that will function as support for idea generation.

How to reduce the noise level? (Figure 1.1)
As to reducing the sound emissions of instruments creating awareness among personnel is important. Next to creating awareness, tackling the immediate risk can be done by providing hearing protection. The development of a quieter product is a solution but needs time to get marketed and produced, while creating awareness to wear hearing protection is a short-term measure. For this reason, creating awareness among orthopedic surgery teams goes hand in hand with designing a new noise reducing solution.

There are multiple ways (Health and Safety Executive, 2019) to reduce sound level and thus the risk of noise induced hearing loss:

Use of engineering principles:
• Avoid metal-on-metal impacts (same materials)
In Figure 2.2, you find a soft impact orthopedic mallet made out Delrin (abrasion resistance plastic). Due to the fact that the strike face is of a different material these hammers are quieter and leave less marking on the materials being struck.
• Add material to reduce vibration, "dampen vibration" or "absorbtion of sound" or noise cancelling by generating anti-noise.

Modify the sound path by which the sound waves travel through the air to the ear: Enclose the sound source, to reduce the amount of noise emitted into the operation room. Use barriers and screens to block the sound path.

Limit your stay or time spent in noisy environment: Halving your time spent in a noisy area will reduce noise exposure by 3 dB (Analysis 1.6)

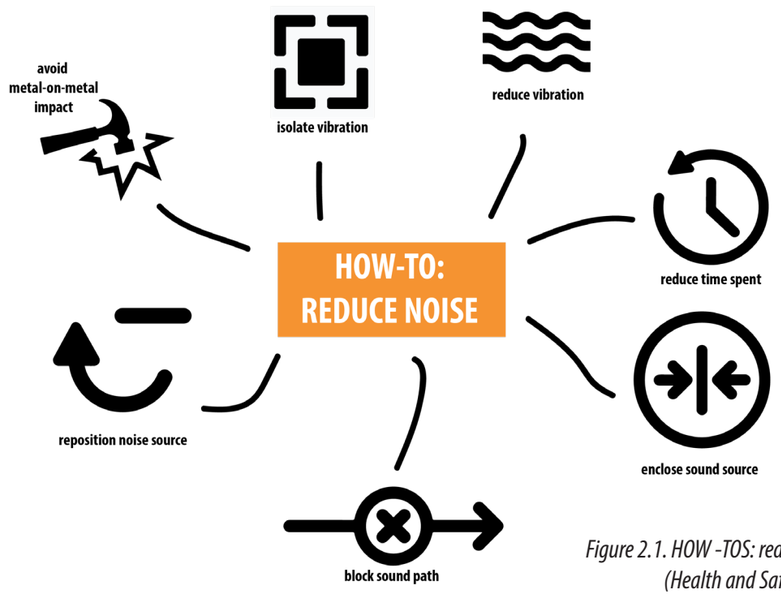


Figure 2.1. HOW -TOS: reduce noise level (Health and Safety Executive, 2019)

Figure 2.2. Soft faced mallet, reducing impact sound by avoiding metal-on-metal impact; Delrin strike face (Innomed, 2019)

How to reduce risk of musculoskeletal injury?
When looking into musculoskeletal disorders research has to be done to see what work-related factors are associated with risk. These disorders are difficult to define, but are mainly named, repetitive strain injuries. Repetitive strain injuries suggest repetition causes these disorders, but non ergonomic postures also contribute. For this reason, the term MSD (Musculoskeletal disorder) is used. (Sandul, 2014)

Work related risk factors are: (Kilbom, 1998)
• Fixed or constrained unnatural body positions
• Continuous movement repetitions
• Force concentrated on small body parts, for examples hand or wrist.
• Work pace that does not allow recovery between movements.

How to get rid of these factors? (CCOHS, 2020)
• Design of ergonomically better equipment. Can be done by; Significantly decrease the force needed to complete a task. Provide worker with proper holding elements to avoid awkward positions.
• Participate in ergonomic training or education, because prevention is always better than curing.

An overview of reducing MSD risks can be found in Figure 2.3.

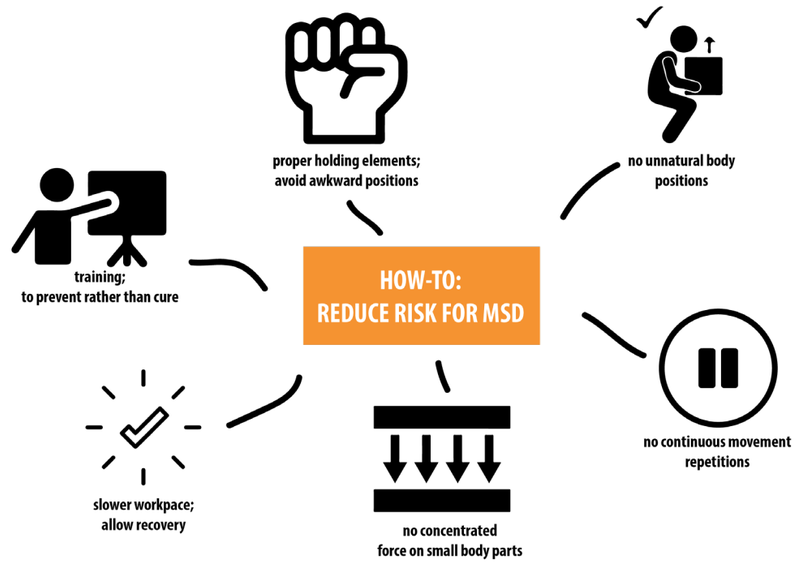


Figure 2.3. HOW-TOS; Reduce risk of MSD (Kilbom, 1998) (CCOHS, 2020)

2.2 Design Directions

When thinking about directions to reduce noise and how to integrate this into the working environment of a hip replacement surgery.

There are some questions to think about: (Figure 2.4)

• Can you work with a less noisy process or with quieter equipment?
• Can you do the work in some other quieter way?
• Can you replace the noise source with something that is less noisy?
• Is it possible to introduce a low noise purchasing policy for tools and instruments by creating awareness?

All above question go hand-in-hand, but introducing a low noise purchasing policy for tools and instruments is wrong in this case. Working as graduate intern for a company that designs and manufactures surgical instruments and tools, not emitting low noise levels when being used within the operation room.

Therefore, designing quieter equipment or new ways of working is the way to go. Not only concerning their risk of sales loss when there is a low noise purchasing policy, but also a new unique-selling point to strengthen their market position as the competition is not designing solutions to reduce noise. (Analysis 1.1)

2.3 Noise cancelling

As noise cancelling was a common discussion point when talking about reduction of sound level with the coaching staff. In this paragraph is explained why it was dropped out of the ideation.

Noise cancelling can be passive or active. Passive noise cancelling is physically blocking noise before entering the ear. Active noise cancelling is when microphones register ambient noises present and generate a mirror soundwave of this unwanted sound. By generating this anti-noise, the resulting sound wave is free of the unwanted noise and constant ambiance noise is filtered out. (Wang, 2016)

First it is the question if it will work in operation rooms as they mainly focus on low frequency noises and impact sound are of high frequency. Second, this idea does not fit the design vision of the project, a product that reduces the noise level and the risk for MSD. Only Noise cancelling will put a band-aid on the mallet using problem and not solve it entirely.

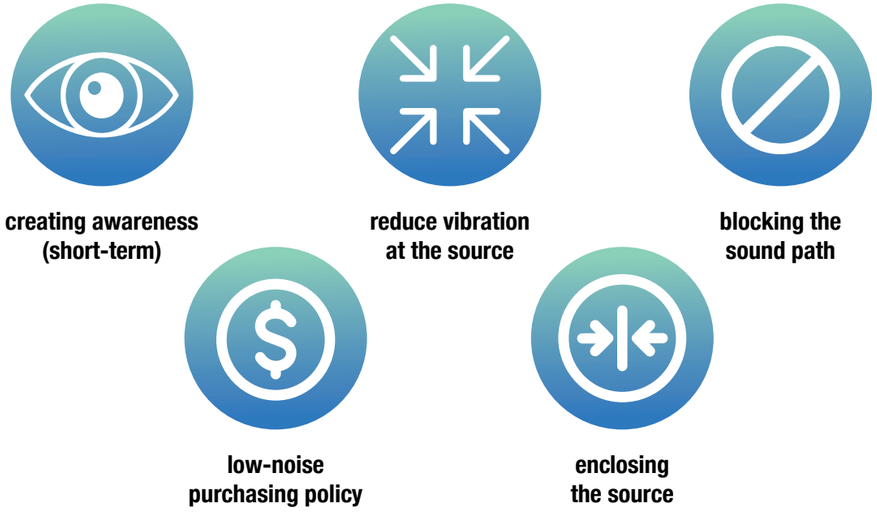


Figure 2.4. Promosing Design Directions + Opportunities (Conceptualization 2.1 and 2.3)

Figure 2.5. Impacting with mallet; could result in compromised fit. (Johnson and Johnson, 19)

Figure 2.6. Impacting with KINCISE; Impacts on same location, guarantee better implant fit and less tissue damage (Johnson and Johnson, 2019)

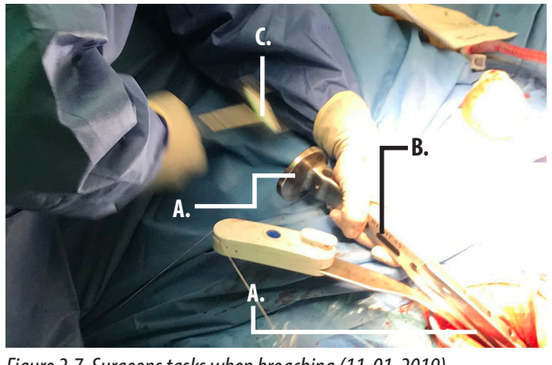


Figure 2.7. Surgeons tasks when broaching (11-01-2019)

2.4 A surgical mallet problem?

As the surgical mallet is used in most THA surgical steps. The reason for mallet usage is the press-fitting of implants, by wedging implants into bone tissue by impact.

Going through hip replacement surgical techniques it became clear that care had to be taken to preserve as much bone as possible to guarantee implant fit. Therefore, stability in instrument use is of great importance to preserve bone especially when opening the Femoral canal. Striking the broach handle not directly flat on the striking plate, may cause shifting of the rasp in the wrong direction taking away to much cartilage or damage bone tissue. Add to this that striking onto the same location is hard with every blow. Johnson and Johnson made a video showing the benefit of lineair impaction with their Kincise automated impactor (Johnson and Johnson, 2019) (Figure 2.5 and 2.6) Next to that Zimmer Biomet advises, when broaching: *" Care must be taken to stabilize the rasps handle ... during the whole rasping procedure in order to avoid the creation of a gap on the anterior or posterior metaphyseal side, which could compromise proximal fit." (Fitmore Surgical Technique. Zimmer Biomet, 2019)*

When using a broach handle with a mallet, surgeons have to hold the "to strike handle" and the hammer to impact with. Surgeons have to watch there striking location, stabilize the tool he strikes and has to make sure his work at the other end of the tool does not create damage, which may compromise the implant fit.

The surgeon has multiple tasks when broaching with the use of a mallet: (Figure 2.7)
A. Watch the "to strike location" on the broach handle or impactor tool and the attached implant.
B. Stabilize the to strike tool as best as possible, to ensure propper implant fit after broaching and preserve bone.
C. Very hard to hit the "to strike location" in the middle and same spot every time. The rasps/ broach handle will start to find his own way into cartilage/bone.

Conclusion
The new product has to make sure the surgeon hits in the same direction with every blow, making it easier to stabilize instruments when using, resulting in the least amount of tissue damage and best implant fit possible.

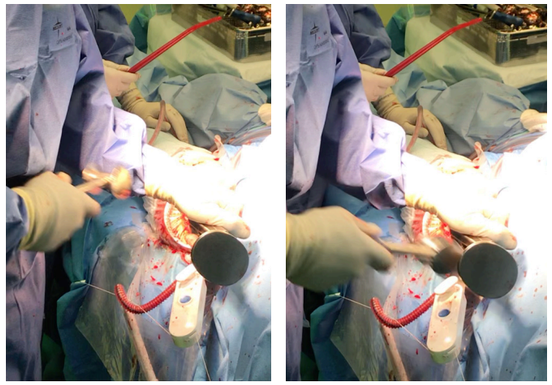


Figure 2.8. Extracting of rasps by impacting the broach handle's assymetric strike plate (21-10-2019)

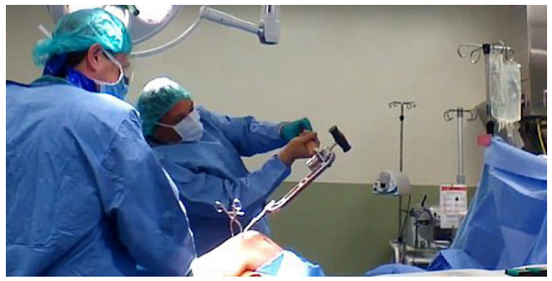


Figure 2.9. Hitting striking plate for extraction of Tibia nail (IM) (Dailymail, 2016)

Figure 2.10. Stem extractor with extraction frame (top); Stem Extractor with slide/slap hammer attached. (bottom) (Innomed, 2019)

2.5. Orthopedic industry - extraction

As the surgical mallet is used for impaction and extraction in various surgical steps. The new product, a mallet replacement, should give the surgeon the opportunity to do both with the same product.

In the surgeries observed the broaching handle is impacted to drive the broaches/rasps into the bone. Extracting the broach handle plus rasps out of the femoral canal by hitting the assymetric striking plate outwards, gives unnatural postures and users have the risk of hitting their hands. (Figure 2.8 /2.16) (Analysis 1.10) The combination of mallet swings and impactor/broach handle stability makes working with these tools even harder. (Conceptualization 2.4)

Extraction of cups and stems in orthopedic hip surgery is a common thing, due to wear, implant instability or infection components have to be revised or taken out definetely. (Laffosse, 2016) Performing extractions of these press-fitted or even cemmented implants is done with multiple different extraction instruments.

For example tibia nails after a leg breakage are extracted by hitting an extraction frame, this changes the working posture an makes use of a surgical mallet aswell. (Figure 2.9 and 2.14) This principle is also used in hip replacement surgery where a stem can be attached to an extraction frame or slide/slap hammer. (Figure 2. 10) After attaching the stem to the extractor, the strike plate can be struck with a mallet to assist with component extraction. With the slap/slide hammer principle a weight/handle is moved allong a guiding rod, when it hits a stop at the end of the rod, it generates a pulling forces. This results in a force which is able to take the stem out of the bone. (Figure 2.10-2.11))

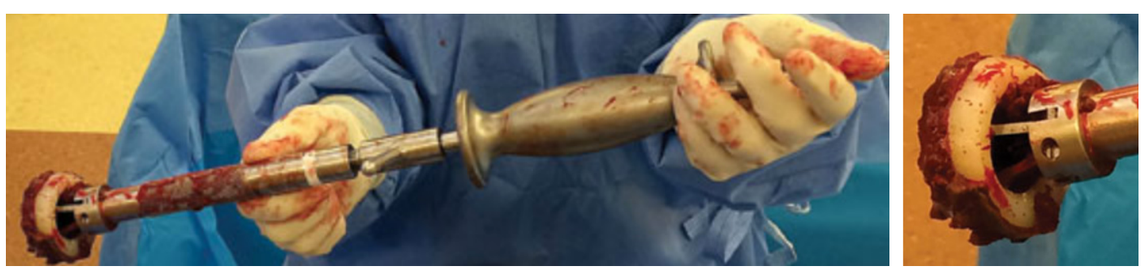


Figure 2.12. Expendable flanges biting into Acetabular cup; Extractor with slide hammer attachment (Innomed, 2019)

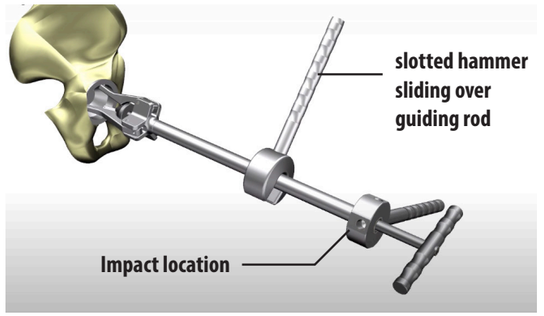


Figure 2.13. Cup extractor bitinging into cup (Innomed, 2019)

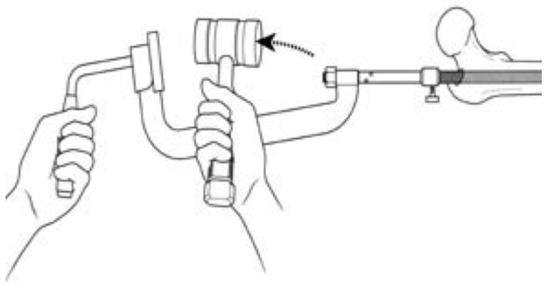


Figure 2.14. Hitting extraction frame to extract IM Tibia nail (Zimmer, 2004)

Figure 2.15. Assymeteric broach handle strike plate; used for extraction blows (21-10-2019)

The extraction of Acetabular cup liners happens with a similar slap hammer principle, attached to a tool with expandable flanges (Figure 2.12) or a biting into the Acetabular cup so it can be extracted. (Figure 2.13) I orthopedic surgery most extraction instruments have the same principle. In essence it is a rod where a slotted weight can be guided over and stopped at one end, in some cases the handle can swivel along the head or a solid straight handle as in Figure 2.13.

Conclusion

To extract rasps when broaching with the current tools available, users have to strike backwards hitting the assymetric strike plate. (Figure 2.15) This is a risky action as surgeons could hit their hands or fingers. (Analysis 1.10) The extraction of rasps can be made less riskfull when working with an extraction instrument. As these blows are guided surgeon do not have to watch their hands or fingers. Furthermore, extraction instruments have a large benefit compared to the use of a mallet. Exerting force with a mallet is an unguided movement and may cause instability of the tool you strike and may even result in the creation of a proximal gap. (Conceptualization 2.4) Extraction impacts with sliding hammers are all guided, making the blows lineair and moving into one direction (axis) only. This makes the usage of these tools more stable plus it ensures a hit on the same location with every repeated strike.

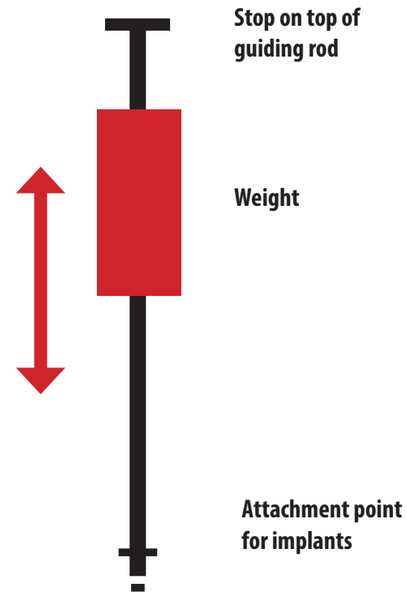


Figure 2.16. Slide/slap hammer principle

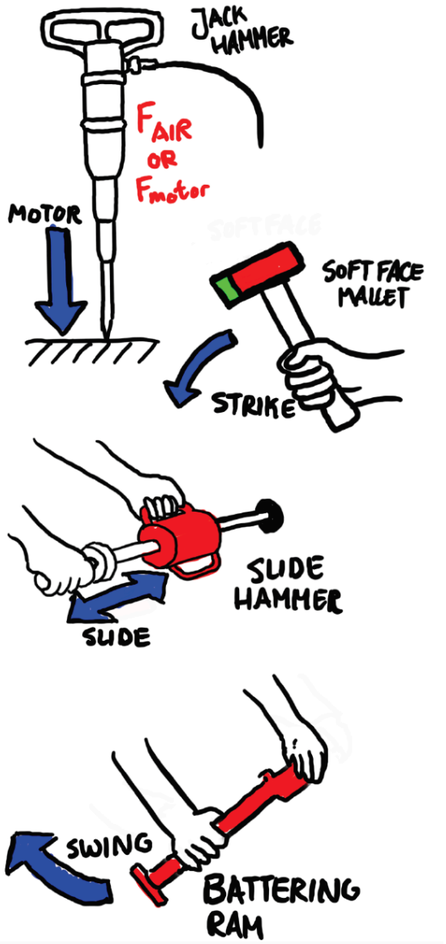


Figure 2.17. Interesting other industry principles

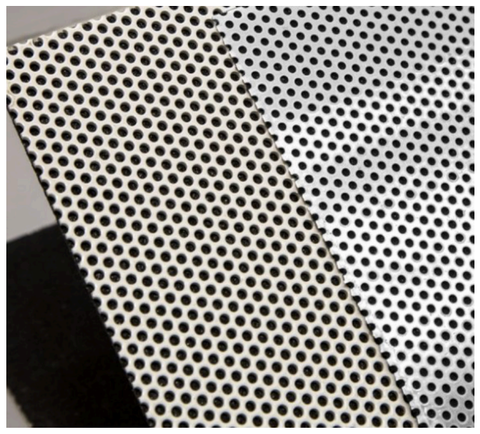


Figure 2.18. Metal Sound absorbing panels (Pyrotek, 2019)

2.6. Other industries?

As other industries can be of interest and inspiration, concerning tools used to impact or sound reduction principles. (Figure 2.17)

Soft faced hammers and deadblow hammer
Soft face hammers, these are made out of rubber or abrasion resistance plastic. Due to the fact that the strike face is of a different material these hammers are quieter and leave less marking on the materials being struck. When similar materials collide there is no dampening of vibration, thus more sound.

The usage of a deadblow hammer was analysed and did not function when using sideways, as this is done in Femoral canal broaching the deadblow principle will be rejected.

Jack Hammer
Pneumatic or electro-mechanically driven hammer, a combination of driven by compressed air or electric motor. This is a large heavy instrument which is not implied easily into surgery. J&J Kincise is designed on this principle and patented.

Piledriver
Raising a weight over a guide shaft or pully, finally dropping the weight onto the upper end of the pile. In most cases only gravitational forces apply to the pile, as its solely dropping a large weight.

Slide hammer
A weight can slide along a shaft and is stopped at the end, to impact on the opposite sides' attachment point, used for extraction. Used in the automotive industry to pull pulleys and driveshafts.

Battering ram
A heavy object is swong horizontally, to gain speed, used to battering down doors. Assumed there is no room to swing in an operation room this idea is dropped.

Sound absorber
Operation rooms are acoustically not preferable, as the hard surface walls reflect sound. Sound can also be absorbed by materials, this absorbtion works for particular frequencies only. Soundproofing panels are an example for this (Figure 2.18), these absorb sound waves to reduce amount of noise and limit reverberation of enclosed areas.

In general, non-porous surfaces have no ability of absorbing sound waves. Making them textured or porous (by perforating them) will give those materials the ability to disperse sound as well. An product example are metal screens these are perforated metal sheets with 28% open area. (Pyrotek, 2019) This open area allows sound to be passed through from the noise and it will be absorbed by an air layer (behind it) resulting in a reduction of noise and noise reflection. The level of sound absorption can be increased by enlarging the air gap behind the sheet or changing the insulation material. (h in Figure 2.19)(IPA,2019)

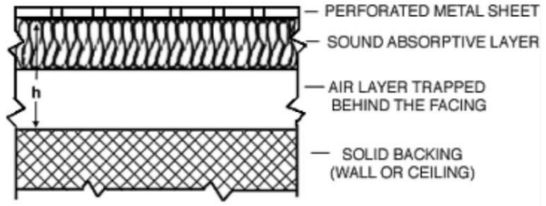


Figure 2.19. Perforrated panel (IPA, 2019)

2.7. Ideation

Having looked at all design opportunities stated in previous chapters and inspired by products coming from the orthopedic surgery and other industries, Ideation was started with brainstorming to stimulate idea solutions.

In the ideation phase a brainstorm session with my dad was done to come up with surprising ideas and idea directions. There were several interesting and innovative ideas that had to be dropped out during selection.

• For example customizing the operation room, making it more sound absorbing. This was dropped, because strict rules and regulations are set for surfaces and easy cleaning of the operation room

• Another idea was to design a noise cancelling headphone but due to not solving the risk of MSD by mallet swings this idea was dropped. As it only focussed on sound and not the ergonomic issues of the sound emmitting mallet. (Conceptualization 2.3)

In Appendix A.9 the outcomes of the brainstorm are shown. Some of the promising ideas can be found in Figure 2.19.

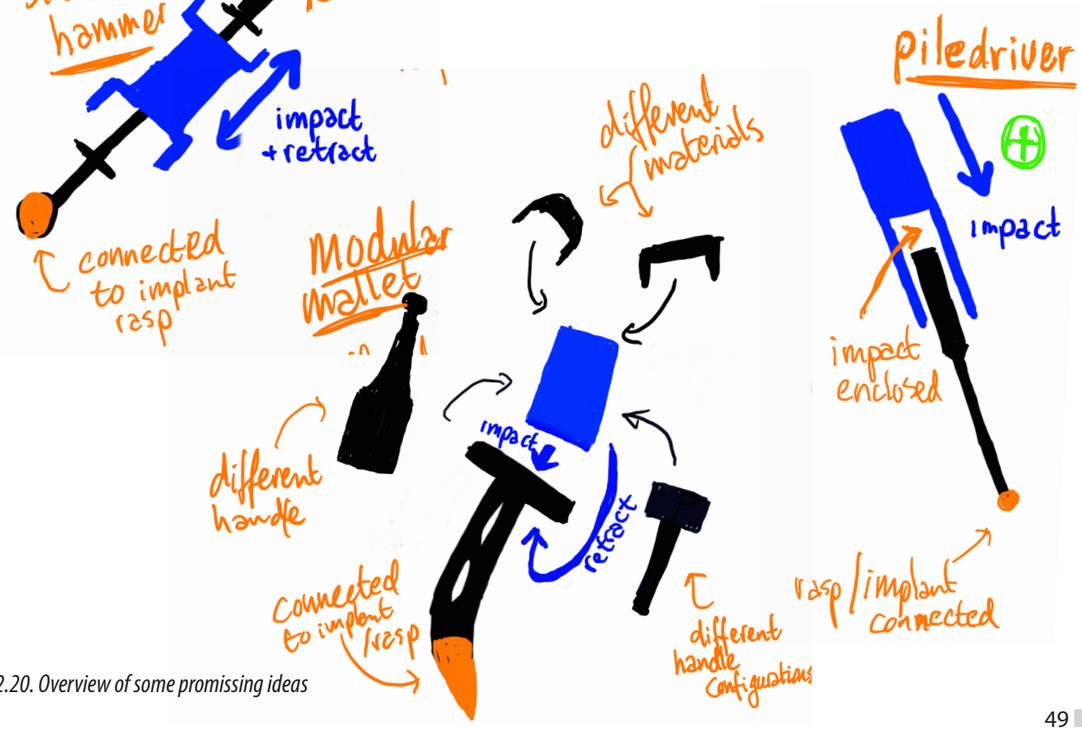


Figure 2.20. Overview of some promissing ideas

2.8 Criteria

The most interesting concept directions developed, coming from ideation need to be evaluated by criteria created in the analysis phase.(Full list of requirements, Appendix A.8)

1. *Reduce sound level (needs testing):* is it possible to reduce the sound with sound dampening principles (Analysis 1.6) (Conceptualization 2.1)
Wish: Dropping 10 dB in soundlevel, below the human pain threshold of 120 dB (50% of current soundlevel)

2. *Ergonomically improving:* getting rid of current working posture and reduce risk for MSD. (Analysis 1.10)

3. *Easy to clean:* sterility; can the product be taken apart and cleaned manually before sterilization. (autoclave sterilization / steam sterilization)

4. *Ease of use:* makes the product the procedure more efficient, when looking into actions needed. Can it provide more impact stability to get better implant fit? Is the force lineair? (Conceptualization 2.4)

5. *Fit within surgical flow:* can the product be fitted into the workflow and current used products "non-hammers" of a hip replacement surgery.

2.9 Concept directions

Concept 1: Modular hammer (Figure 2.21)
Concept 1 is a modular hammer, were different head shapes, shaft configurations and materials can be assembled into a surgical mallet. The shaft of this product can be a ergonomical desig suitable for every striking situation, so it reduces the risk for MSD. Next to different shafts or handle shapes, the strike faces can be interchangeable (disposable) and made from a "impact-quieter" material.

Pluspoint: Pluspoint for this device that it can be made to the wishes and demands of every surgical step where a mallet is being used and even being adapted to make it quieter.

Concern: The product is still is hammer, striking can cause dangerous situations, by hitting hands or loosing grip. Next to that a hammer strike is not always parallel on the striking face. The strikes can be glancing blows or over/under strikes, which can cause problems for impact fixation. (Conceptualization 2.4)

Concept 2: Sound absorber (Figure 2.22)
Concept 2 is a sound absorber, which consist of the sound diffusion principle. Soundwaves pass through a perforated surface where the sound wave energy is absorbed, opposed to reflecting the sound energy. (Encyclopedia Britannica, 2020)

Plus or Minus: The principle of a sound absorber is that it can acoustically absorb sound, but most of the head still needs to be made out of hard solid materials as it should be able to withstand impact forces.

Next to the fact that it will be hard to clean because of its perforations, this striking face needs to be adapted to a high frequency range and sound levels. The measured sound levels were very high (125 dB(C)), therefore the absorption room (hollow hammer head) should be very large. This will lead to really large product, which could give problems when working with it.

This idea was showed during the midterm meeting on 5 december, but decided upon that it is not feasible.

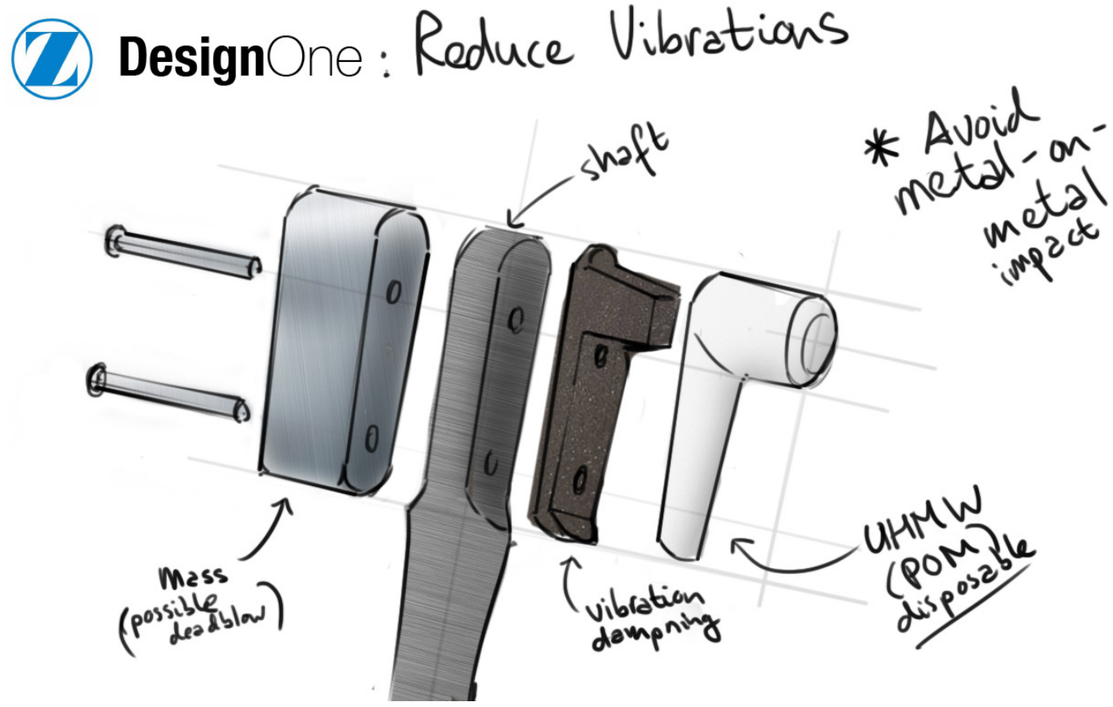


Figure 2.21. Concept 1; Modular Hammer

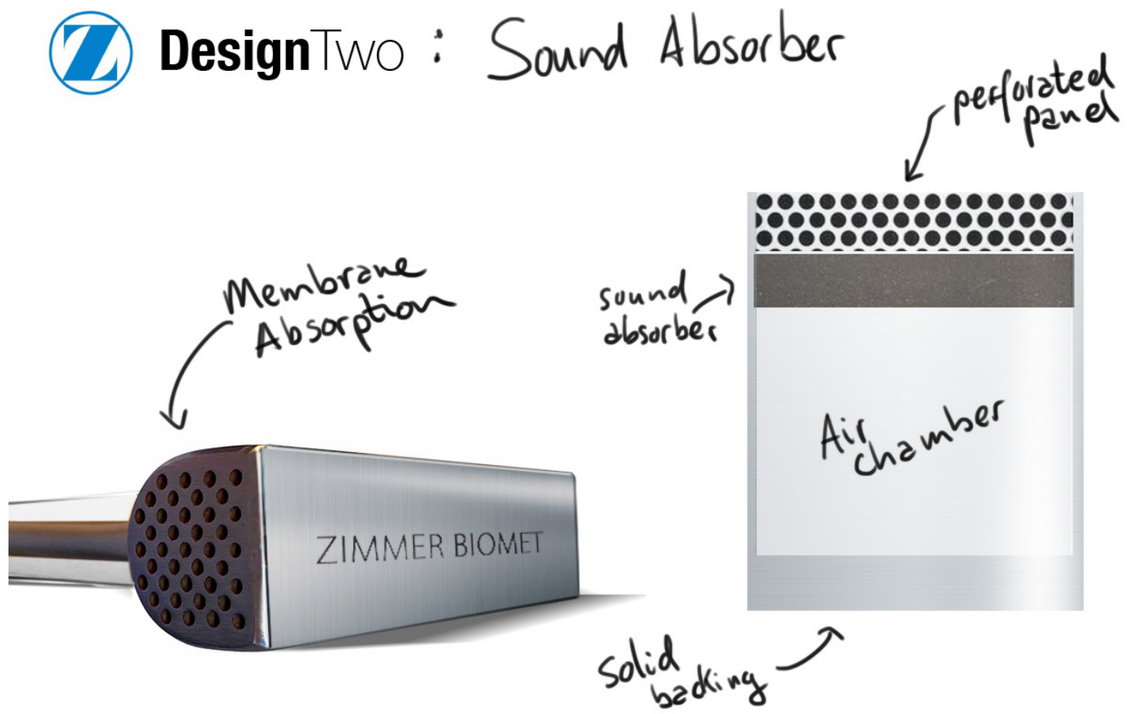


Figure 2.22. Concept direction 2; Sound absorber

DesignThree : Sliding Hammer/Handle

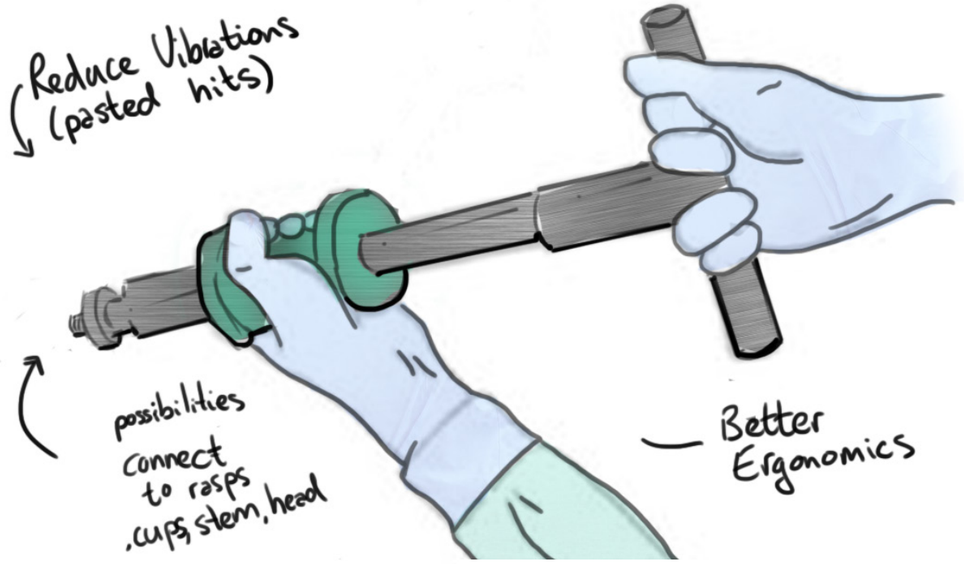


Figure 2.23. Concept 3; Slide hammer

Product	Description
	Extended Awl
	Boxed Chisel
	Long Bar
	Stem Impactor
	Handle For Reduction & Impaction Attachment
	Repositioning Top
	Ball-Head Impactor Attachment
	Extractor with Sliding Hammer
	Trial Neck Holder

Figure 2.24. Concept direction 3; Extraction Instruments not needed anymore (Avenir Surgical Technique Zimmer Biomet, 2019) (in red)

Concept 3: Slide hammer (Figure 2.23)

Concept 3 is a slide hammer which can be used for extraction and impaction of objects. In essence it's a weight that is guided over a rod with a stop at the end. When sliding the weight against the stop it transmits an impact force without striking the object that needs to be pulled itself.

Pluspoint: The slide hammer can become a multi-functional instruments being able to impact and extract with. By making a stop at both ends of the guiding rod. One instrument with multiple functions, makes extra tools not necessary anymore. As extractors are always present during surgery, there only used when implants need revision or are not placed properly. (Figure 2.24)

Concern: Is the instrumental feedback received from a slide hammer similar to mallet use? Due to a new geometry the tactile feedback received from instrumentation will be different than currently used products. Steering/stability of the product is done with the outside hand (rightside Figure 2.23) small differences over that lenght can result in large displacements at the side where the implant is located. The steering and stabilizing hand is far from the pivot.

DesignFour : Driver

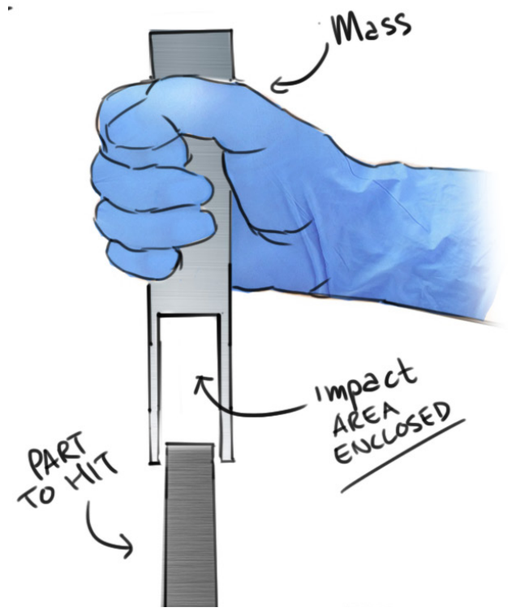


Figure 2.25. Concept direction 3; Driver

Concept 4: Driver (Figure 2.25)

Concept 4 is based on the working principle of a piledriver or driver in general. Where a weight is impacting a pole. The force of the movement downwards plus the gravitational forces are combined, to drive materials into the ground, in this case bone (marrow).

Pluspoint: The blow is contained inside of the driver and lineair, this makes it less loud and should guarantee proper implant fit. Making use of a noise reduction principle. (Conceptualization 2.1 and 2.4) (Figure 2.26 more explained)

Concern: This product still consists of two products one that holds the implant and the other that is forced down. In that sense it is a mallet which can strike lineair, but stabilizing will still be hard.

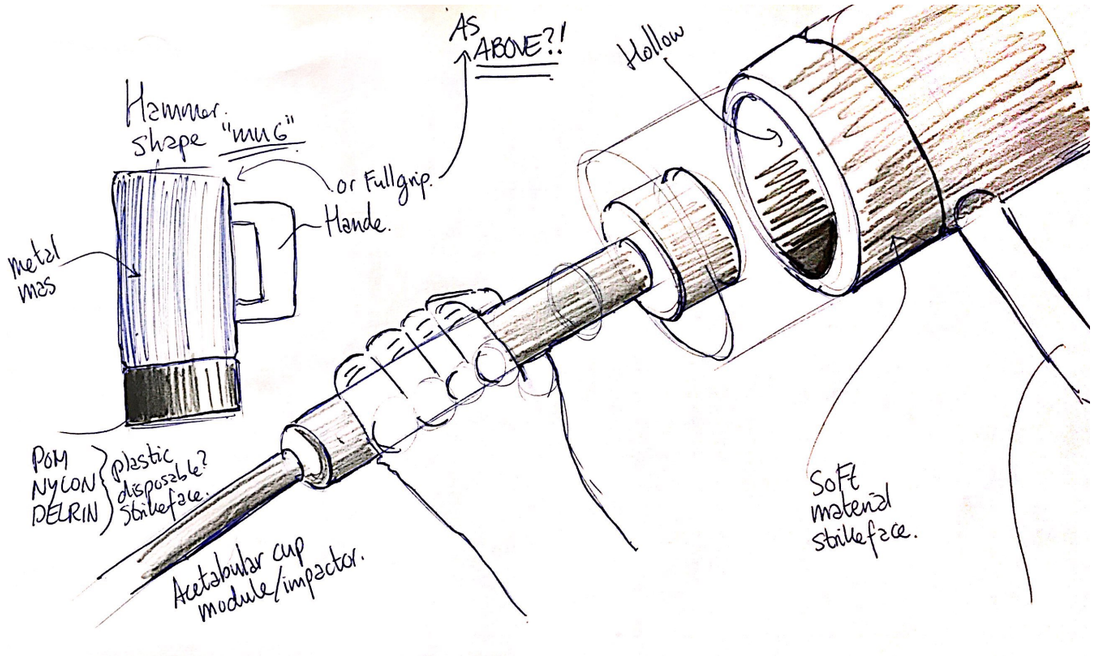


Figure 2.26. Concept direction 3; more detail

2.9. Evaluation and decision

To compare and evaluate the four concepts a Harris Profile was used (Figure 2.27). A Harris Profile is a graphic overview of the strengths and weaknesses of design concept direction with respect to predefined criteria. This way of profiling can be used after the ideation phase of a design process. Where the top criteria have a higher weighing than the bottom criteria. (Roozenburg, 1995).

In the team meeting (midterm) of 5 December 2019 it is decided that concept 2 is not feasible to develop within this project. Therefore, concept 2 was not further considered going forward to the Evaluation of concepts.

Reduction of the sound level
The first criterion is how well the concepts are able to reduce the sound level as this has to be measured. Assumption can be made looking at noise reduction principles. (Conceptualization 2.1) For Concept Directions 1, 3 and 4 it is assumed that they are able to avoid metal-on-metal impact by changing materials of the impact faces. Concept 4 is able to enclosing the sound sources and Concept 3 could reduce vibration by pasted hits. No bounce of the hammer head and always hitting the strike face/stop on the same spot. Therefore, Concept 3 and 4 score (+ +).

In concept direction 1, the modularity makes it easy to change strike face material what will dampen impact to reduce sound when striking (++) Take away for the next step could be combining modularity into the design, as the adds to the functionality of the product.

Ergonomically improving
When looking into criteria 2, both the sliding hammer and driver can possibly change the current working posture getting rid of the current unnatural working posture with a surgical mallet. (++) Further iterations will be needed. Concept 1 is in essence still a hammer which caused unnatural positions and risk for its user in total hip replacement (- -) (Analysis 1.10)

Ease of use
When looking at this criteria, Concept direction 1, scores (++) as this has the same functionality of the currently used surgical mallet and can easy be implemented with the currently used tools and surgical technique. As stabilizing the "to-strike" implant attachment is of great importance for implant fixation (Conceptualization 2.4) Concept 3, will score (++). Stabilizing the slide hammer can can be hard, as the not-striking hand is located far away from the implant connection/pivot point. This may result in movement during impaction and not preserving enough bone for proper implant fixation. This is not super negative as the slide hammer makes the user able to apply lineair forces, which are more easy to adapt to.

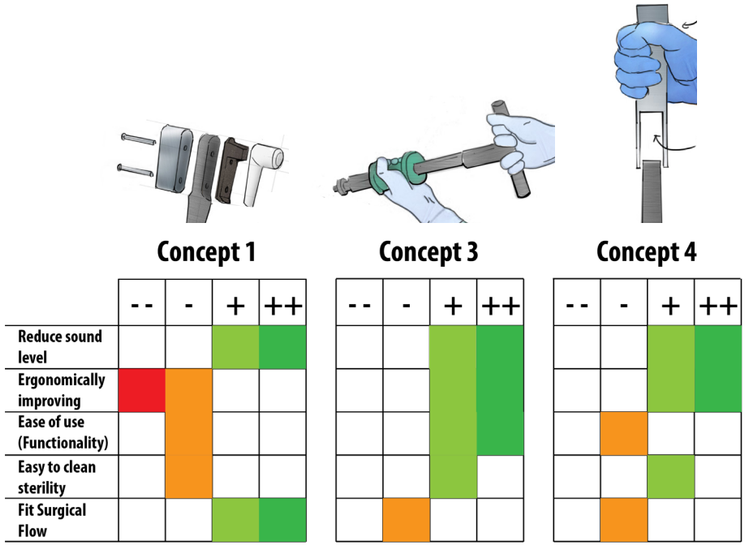


Figure 2.27. Harris Profiles of Concepts

Further more concept 3 has the ability to connect to different implant specific drivers or broaching handles. These have to be altered a little bit making sure this is possible. Surgeons then can use concept 3 for both impaction of implants and extraction of rasps and implants. This improves the functionality of the product, scoring (++)

Concept direction 4 can be altered making sure it can work for impaction in combination with the currently used tools/instruments, when these are adapted this could make the action of impaction easier. (+)

Easy of clean
An important aspect of medical instruments and devices is that they need to be cleaned thoroughly after surgery to be sterilized and used again. Therefore, products need to have the ability to be disassembled for manual cleaning before sterilization. All products can be disassembled, cleaned and sterilized. Note that all concepts are made from medical grade materials that can withstand sterilization processes. The modular hammer, Concept direction 1, consist of a large number of parts, some parts can be dispossed after use but due to its modularity it takes more effort to disassemble and clean. (-) The slide hammer can be dissassembled, by taking off the weight, the guide hole can be cleaned. (+) For concept 4 it is harder to clean the impact area, as it is open at one side, creating a cavity to clean (- -).

Fit to surgical workflow
Criteria 5 is on how well the concept fits within surgical flow; Concept directions 3 and 5 score negative as it comes to fit within the workflow. The concepts need to be altered to be ready for the next surgical step. Therefore, they both score (-), as it increases procedural time. Concept 1, scores (++) as all other insturments in the procedure can stay the same only the mallet changes.

Conclusion
From the Harris profile, can be seen that concept 1, scores the most negative and therefore is being dropped. Concept 3, the sliding hammer is scores the best as it is solution that can reduce sound level and combine impaction and extraction into one design.

When designing this Harris profile (Figure 2.27) and evaluating the criteria it was noticed that the sound source enclosement of Concept direction 4 can be put in Concepts 3. Sparking an idea of a slide hammer were the sound source or impact is enclosed. (Conceptualization 2.10) Putting this concept next to the other evaluated it is assumed that this concept will score higher on reduction of sound and can perform impaction and extraction. (Figure 2.28)

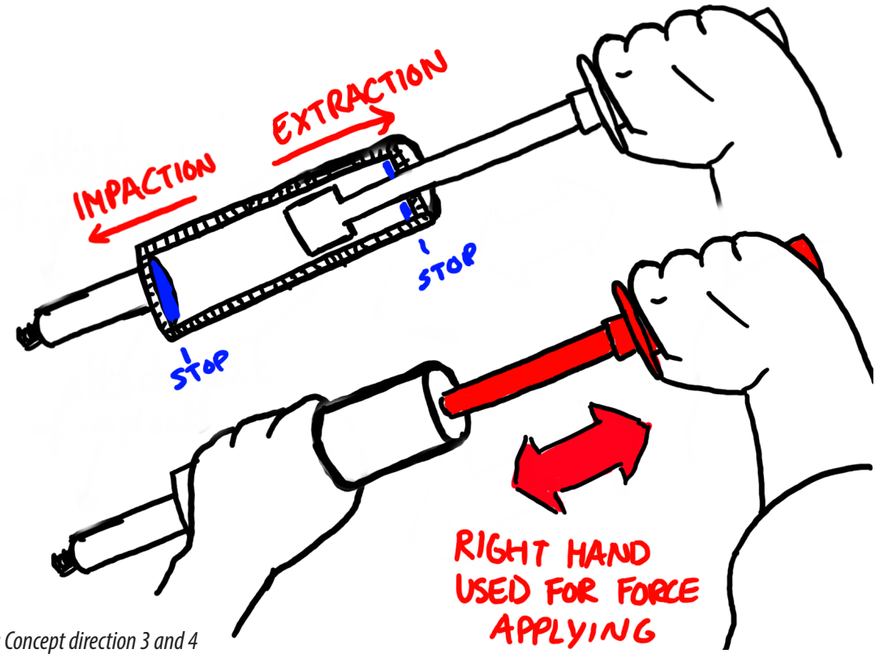
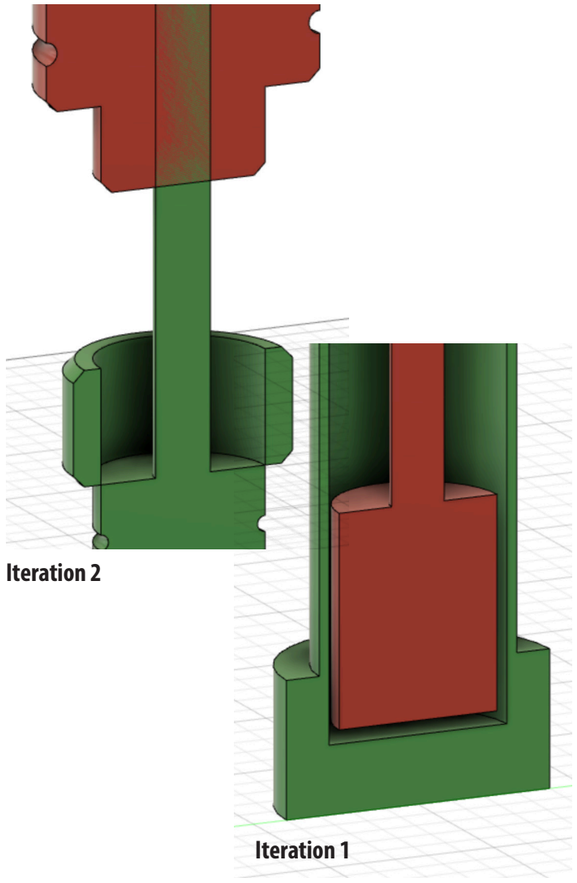


Figure 2.28. Combining Concept direction 3 and 4



2.10 Concept for embodiment

Concept direction 3 came out of the Harrisprofile as best and was developed further before going into the Embodiment phase. (Appendix A.10)

Unique selling points: (Figure 2.30)
- The steering hand for precision is located near the pivot point/implantion location. This makes stabilizing and "aiming" more convenient and easier.
- The hand where force is exerted with delivers lineair strikes, which increase implant stability and less colateral damage to bone tissue.
- The Guiding tube is enclosing the impact sound and functions as a handle. (sound reduction)
- The product can be used on both side of the patients body, thus left and rightside implants. Depending on the implant attachment connected to the product.
- Extraction slide hammers are not necessary anymore, which are present in every THA surgery. Less instruments needed.

Two iterations where made (Figure 2.30) , Iteration 1 was chosen due to its full enclosement of the impact sound (Figure 2.29) , smaller dimensions (and probably weight) and the least risk of pinching your fingers.

Figure 2.29. Iteration 1 and 2 sound enclosement (guides are green/impact material is red)

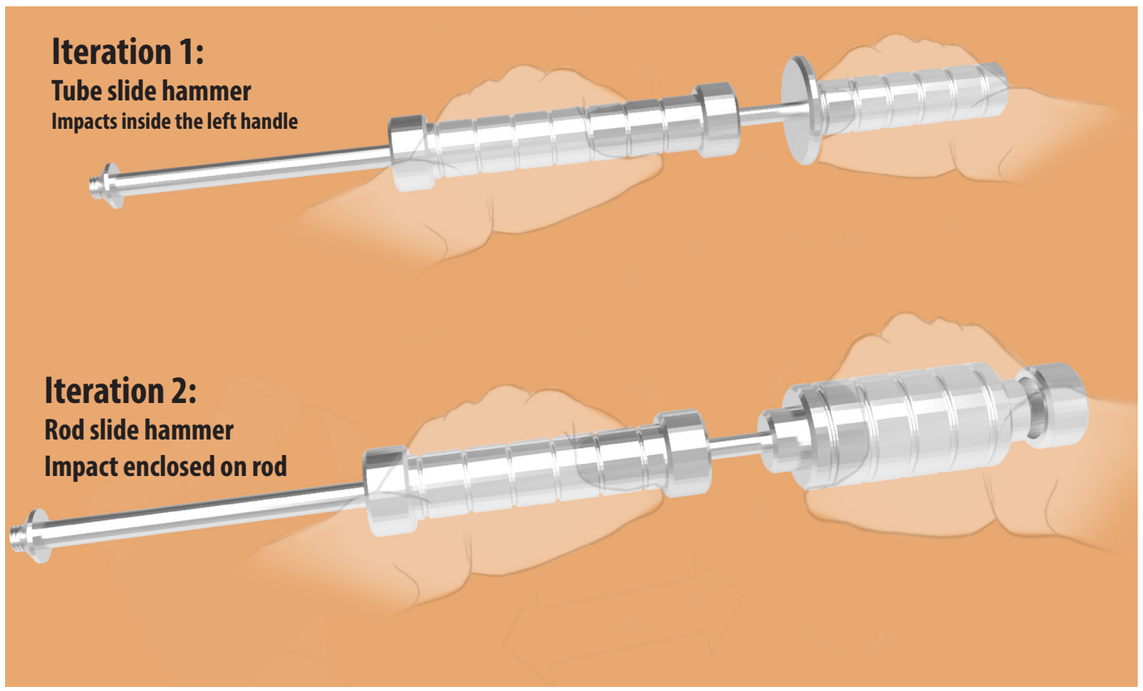


Figure 2.30. Slide hammer: Iteration 1 and 2 with Acetabular Cup Attachment

2.11. Medical device

As the product will be used in a medical enviroment to treat a medical condition it will be seen as a medical device. Medical devices have to comply with medical device rules and regulations. (MDR)

Medical device definition & classification
To requirements that a product should met differ as there are different medical product classifications ranging from class I tot III.

The new impactor/driver will be classified as a Class I medical device. Class Ir, because the device is a reusable surgical instrument. All surgical devices which are reusable surgical instrument and the driver itself is non invasive.

MDR, Annex VIII, point 2.3:
"Reusable surgical instrument" means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out." (MDR Annex VIII, 2019)

So before this medical device can be used in the OR, a CE mark has to be obtained on the product, a detailed technical file has to be made that proves safety and efficacy of cleaning, disinfection and sterilization processes. (Fowler, 2019)

Some regulations for re-usable instruments:
Cleaning, desinfection, sterilization and maintenance are the most important aspects that have to be checked by the manufacturer as these are related to the reuse of the device. Functional testing has to be done and related instructions for use have to be made to ensure safety when using. Coming from Section 2, Article 52 Conformity Assessment MDR (MDR, 2017)

To conclude, the manufacturer of the product has to assess if the product meets the Class I reusable surgical instrument requirements to obtain an CE marking. There is no focus on medical device regulations in this project, but to complete the List of Requirements (Appendix A.8) the device classification can not be forgotten.

2.12. Embodiment Challenges

In the embodiment phase Concept 5 is developed into a product. When the concept is used it should be able to impact and extract hip replacement implants and components (rasps). While using the sound level emitted should be lowered and the risk for MSD decreased.

During a meeting with my Zimmer Biomet coach it was decided to narrow the scope of this project towards designing only the driver system and not the implant attachments/modules. This was done to ensure the current hip replacement products and the connections could stay the same. Furthermore, designing implant attachments was found not feasible during the set graduation period.

Challenges that are to be solved in the embodiment phase:

- Designing a product that reduces the risk of MSD. Taking anthropometry and ergonomics into account.

- To impact implants with the design, research is needed to find out how much force can be applied using this product.

These challenge add up to the list of requirements in Appendix A.8.

3. EMBODIMENT

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3. EMBODIMENT

The chosen concept is a tube slide hammer and impact driver combination, which has the function of retracting and impacting implants and rasps. In this phase I made two prototypes. The first was to validate the force produced and the second evaluated by an orthopedic surgeon through cadaverlab testing. To make things easier from now on concept 5 will be called DriveFit.

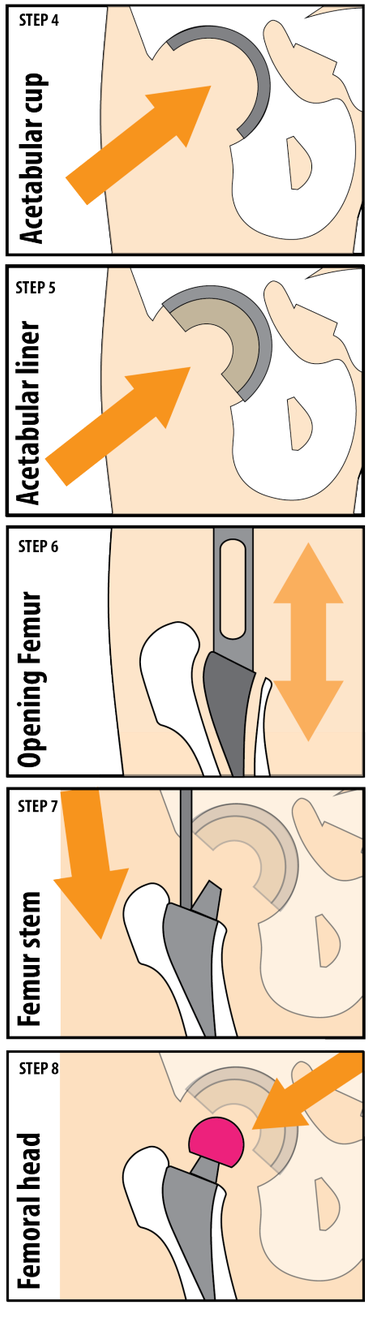


Figure 3.1. Surgical steps for incorporation of DriveFit

3.1. Functions of new design

The currently used surgical mallet was used to implant multiple implants and components, Acetabular cup, liner and Femur stem. Next to impacting parts of the procedure, it was used to extract rasps out of the Femoral canal.

Looking at Figure 3.1 we see the mallet is used in 5 out of 8 total surgical steps and is of great importance in the total hip replacement procedure. Therefore, it is required that the the driver product can be used in all off the same steps and can perform the same actions or more, to fully take the surgical mallet out of the hip replacement procedure.

The DriveFit has to have the following functions:

1. Impaction of implants and/or components/tools
2. Extraction of implants and/or components/tools
3. Modular product to accomodate different implant/tool attachments to suit al surgical steps (Figure 3.1.)

All functions have to be done with minimal noise emittment and improved ergonomics. To see the ***new surgical workflow/scenario***, see Figure 3.2.

Import requirements were taken into account:

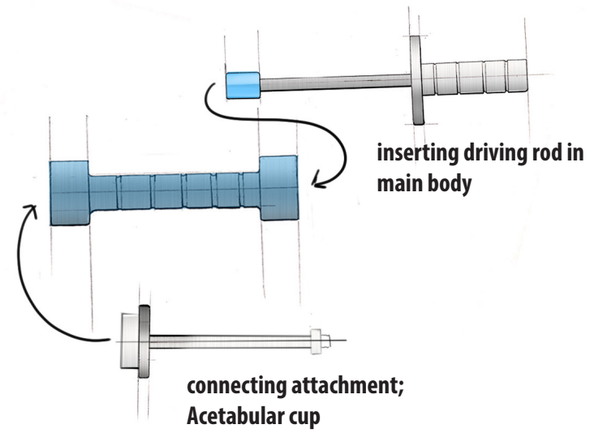
+ DriveFit needs to be taken apart, so it can be cleaned manually. For this reason, cavities need to be avoided as these are hard to clean.

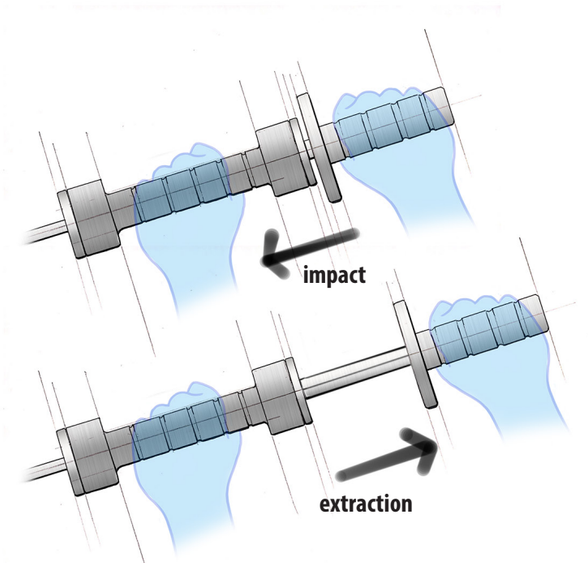
+ DriveFit needs to withstand sterilization processes to be used in a medical environment.
** Materials need to withstand three minutes of water vapor/steam at 134 degrees Celsius (sterilization) (DIN EN 285)**

+ DriveFit needs to convey some sort of instrumental feedback to the surgeon. This will be hard as the product is new and not similar to any previously used products.

1. Assembly before surgery

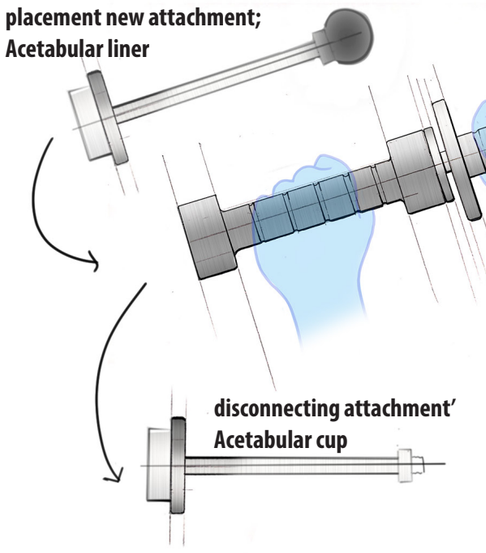
Fully assembled DriveFit plus first modular attachment, Acetabular cup. Done previously to surgery by the instrumental scrub nurse.





2. Use by surgeon

During surgery the product will be used for impaction or extraction of implants/tools. After implantion implant gets disconnected from its attachment all done by orthopedic surgeon.



3. Modularity change

Changing the implant/tool attachment during surgery for next surgical step done by instrumental scrub nurse. Total of 5 different attachments *(Step 2 and 3 repeats to finalize surgery)*

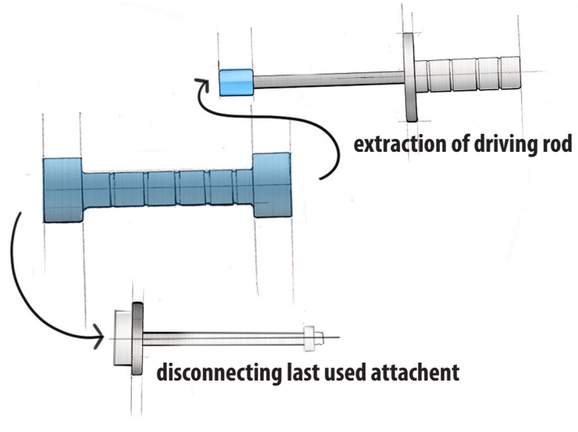


Figure 3.2. New Surgical scenario/workflow with DriveFit

4. Full disassembly

After surgery the product will be fully disassembled for cleaning and sterilization purposes.

Current workflow with mallet

The surgeon switches between different driver/handle types, each driver suitable for a different surgical step concerning implant or tool fit.

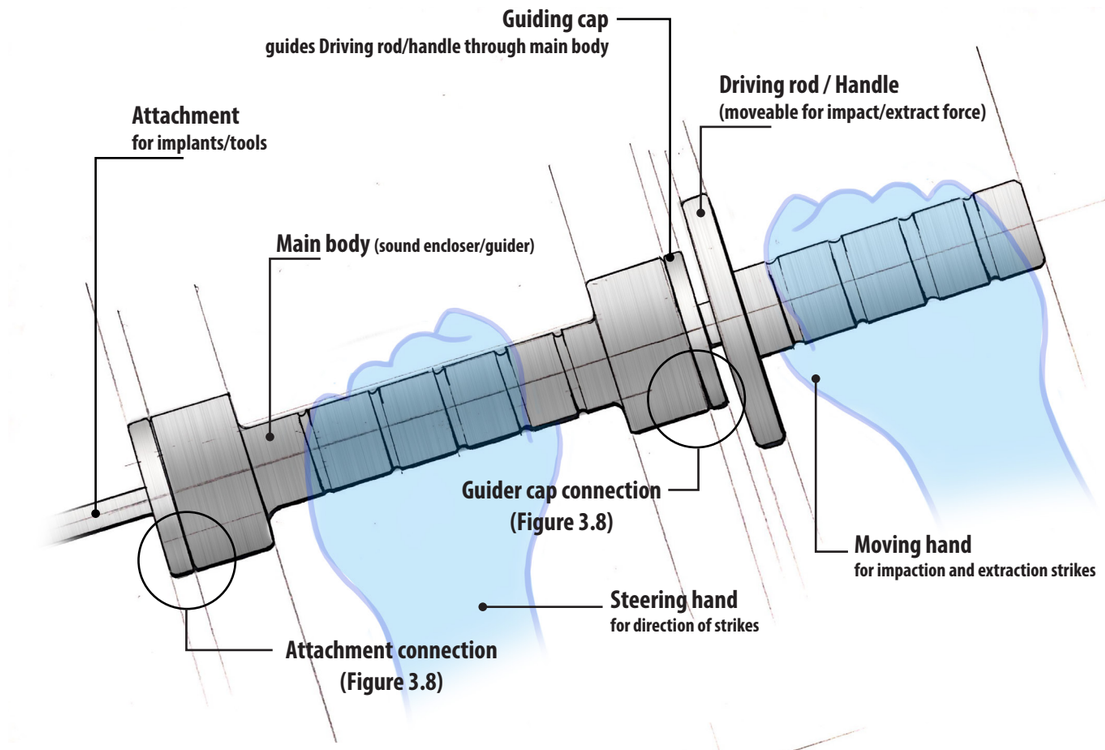


Figure 3.3. DriveFit held in use; schematic

3.2 DriveFit

The DriveFit is an instrument held by two hands, one hand for steering of extraction and impaction of implants. The other hand is the moving hand which pushes/pulls the handle and driving rod resulting in a force for the action needed. (Figure 3.3)

Before coming to this design, multiple option where sketched. (Conceptualization 2.11)) As the product is held by two hands the product can be devided into two main parts, the driving rod/handle and the main body. (Figure 3.4)

The function of the main body:
- Enclosing the sound source; as the impacts for extraction and impaction occur inside this cyllindrical body.
- Accomodates the connection of different types of implant/tool attachments,

The function of the Driving rod /Handle:
- The moving part of the product, which is there the build up the force needed for impacts/extraction strikes.
- Tip of this product (Piston), slides through the main body avoiding metal-on-metal impact, which should reduce the sound level. (Collides with connection in the bottom and top of the main body, to transfer force)

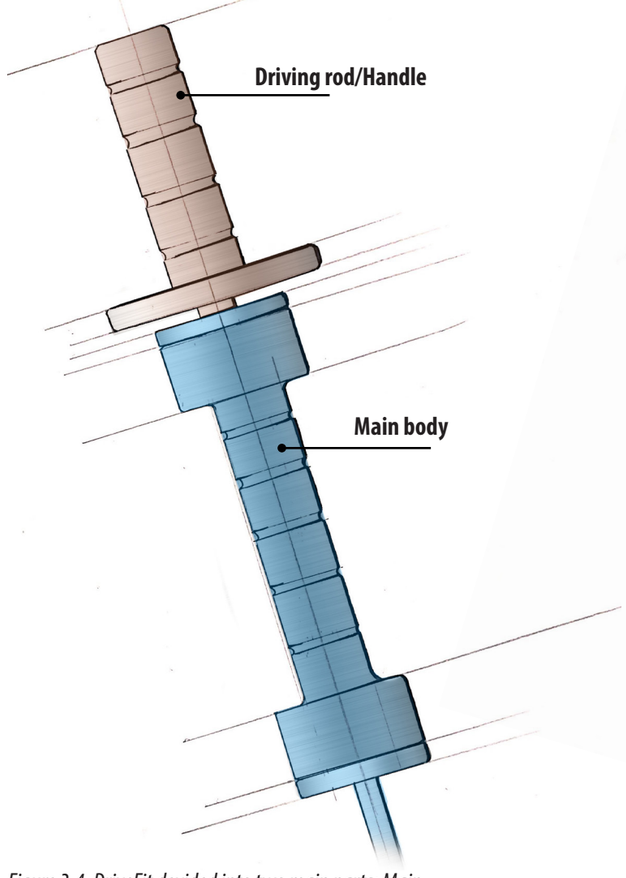


Figure 3.4. DriveFit devided into two main parts; Main body and Driving rod/Handle

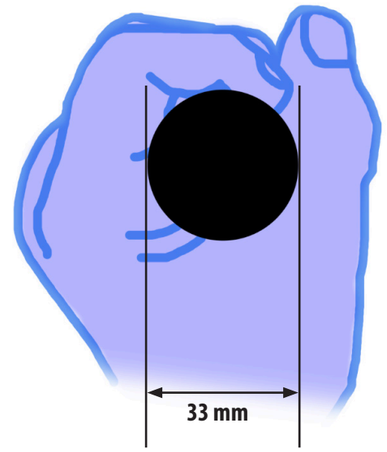


Figure 3.5. Optimal Grip circumference (A) for male/female; Main body (Napier, 1956) (Sancho-Bru, 2003)

Figure 3.6. Main body dimensions

3.3 Main body

The main body of DriveFit is held by one hand and is the part where-in the impacts occurs when impacting and extracting implants and rasps during the surgical procedure. For a firm grip, the main body needs to be designed with anthropometry in mind to ensure suitable handling and holding for the user.

The grip on the product needs to be powerful, in which fingers and thumb are used to clamp to object against the palm. (Figure 3.5) (Napier, 1956) The diameter should allow the thumb to just cover the end of the index and middle fingers. (Drury, 1980) Due to repeated impacts and extractions, the wrap around provides extra stability and gripping force.

An optimal diameter for a cylindrical grip suitable for both males and females was found at 33 mm diameter. This optimal handle design reduces the forces required for gripping the handle and will reduces the risk for repetitive strain injuries because grip forces are at a minimum and awkward postures are avoided. (Sancho-Bru, 2003) Therefore, the diameter is set at 33 mm (A) chosen to accommodate both men and female with an optimum handle diameter. (Figure 3.5)

The length of the main body is derived from the distance (B), which is needed to build up force before impaction, this needs to be tested. (see Prototype 1) Looking at the length of the part we can look at the width of the hand of p95 men (Appendix A.11) (Pheasant, 1996). When the distance, length of main body can be smaller than the hand witdh, p95 men (114 mm, hand breadth "across thumb) broad becomes the minimal length of the part. (Figure 3.6)

To give more security against slipping of the product, pommels (C) (Figure 3.6) where designed on both the top and butt end. In the middle ages, pommels were common on swords to prevent slippage due to momentary relaxation of grip. (Patkin, 2001) Next to prevent slippage of grip, these pommels will be used to accommodate connections to fasten modular instrument attachments needed for the different surgical steps.

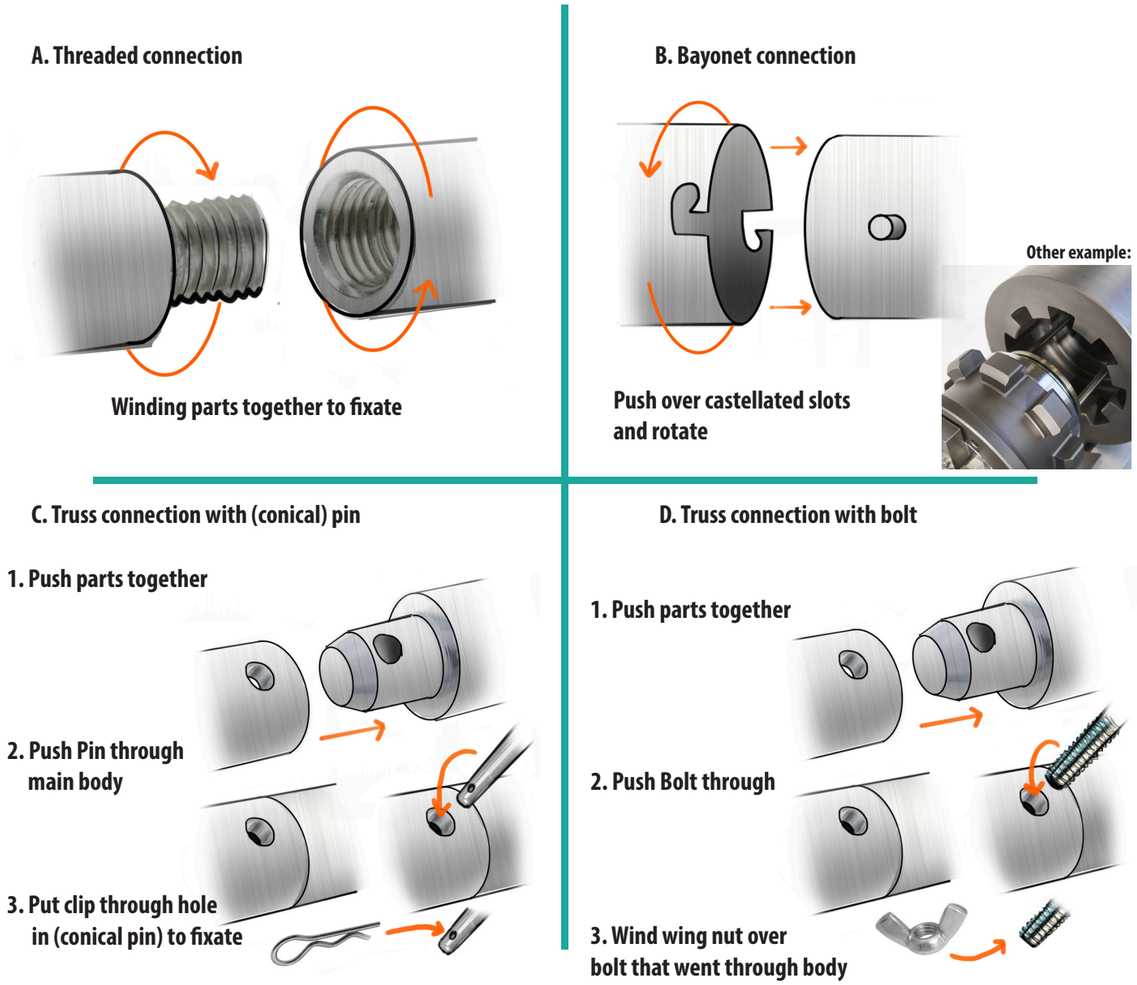


Figure 3.7. Overview of the different connection types

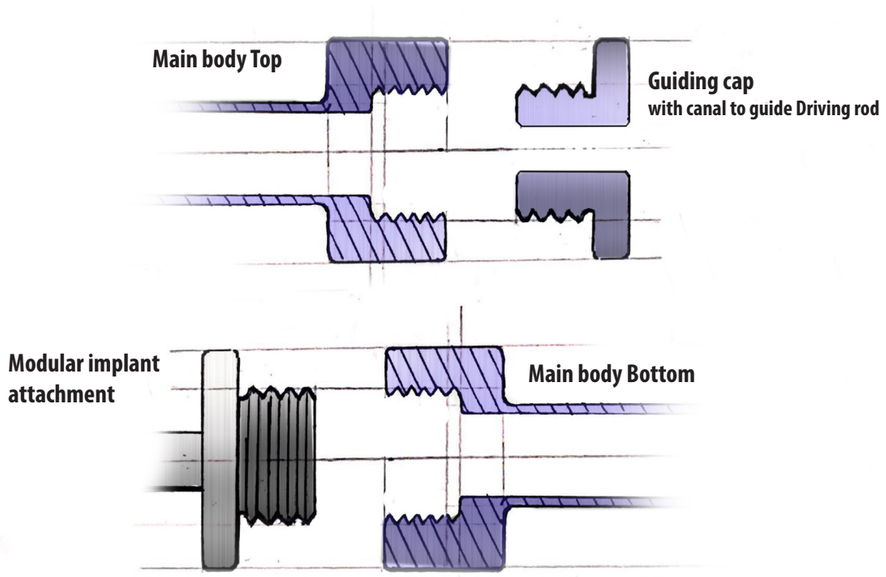


Figure 3.8. The chosen connection for the main body; threaded connection.

Connection type

To connect various implant and component attachments to the main body a connection must be designed. This connection must be designed having to following requirements in mind:

1. The connection needs to be releasable and ensure immobility of the implant attachment fastened to the main body.
2. Needs to withstand forces coming from two directions (impaction and extraction usage)
3. The main body needs to remain hollow when disassembled to ensure for easy cleaning before sterilization
4. Production method and costs

At the left page in Figure 3.7 an overview of the different connection types can be found. To see all options and sketches, see Appendix A.12.

A. Threaded connection

To connect the attachment and guiding cap to the main body, all parts can be wounded into eachother. Most easy example is a nut and bolt.

Plus: Product can be symmetrical.

+ Reliable (strong and durable)
+ Compact in construction (small dimensions)
+ Easily attachable and detachable
+ Cost effective (easy to produce)
+ Self-locking properties in all positions

B. Bayonet connection

The principle of this connection consist of a locking ring with castellated slots and a closure plug with matching set of castellated lugs. When the plug is inserted and rotated, castellations plug and lug engage to ensure fixation.

Plus: Product can be symmetrical.

+ Fast closure, easy to operate
+ Small dimensions and is compact in construction
+/- Locks by twisting (no full turn; <360 degrees), depending on locking-type. Will easily disconnected which could give problems.
- Expensive, harder to produce

C. Truss connection with (conical) pin

Within this connection principle a male and female part get pushed into eachother. A locking pin is pushed through the hole (sometimes conical)after engaging through the hole a clip is used to fixate the connection.

+ Compact in construction
+ Cost effective connection (easy to produce)
+ Lock by pushing in pin
- Extra (small) part for the product
- Hard to disassemble (removing pin costs force)
- Can only be used at the implant attachment side of the main body; no room for Driving rod

D. Truss connection with bolt

The principle of this connection is similar to the truss connection where a pin is used to lock the male and female part into eachother. The difference is that the pin is a bolt and fixates the male and female part of the connection by a wing nut which goes over the bolt.

+ Compact in construction
+ Cost effective connection (easy to produce)
+ Lock by screwing-in pin
- Extra (small) part for the product
- TIme consuming to assemble, threads have to be perfectly alligned.
- Can only be used at the implant attachment side of the main body; no room for driving rod

Conclusion

Looking into the connection types the threaded connection was chosen (A) (Figure 3.8) As it fits with the connection requirements for the design, resulting in a hollow product which makes it easier to clean and is able to withstand forces coming from two directions as it it strong and durable.

Next to that the mainbody becomes a symmetrical product, which ensures that assembly of the product always results in the same functional part. Combining this functionality with the fact that threaded connection does not need extra parts to guarantee immobility of the connected attachment, resulting in a reliable and convenient connection type.

3.4 Driving rod and Handle design

The driving rod/handle is held by one hand during use and is there to transfer the users impact and extraction-forces onto the implant or tools. (Figure 3.10)

The design of the handle started with a hilt (A) (Figure 3.11) , this is a protection for sliding against or onto the main body, which can cause risk of jamming your hand and/or fingers.

For the handle diameter is looked at the most comfortable grip diameter. As this handle is used for fast movements/impacts it can be categorized as a handle used for dexterity and speed. Therefore, the same diameter as the main body grip is used, 33 mm. (B) (Figure 3.11)

As this diameter reduces the amount of muscle activity required to hold the handle and the risk for potential RSI risks. (Sancho-Bru, 2003)

The handle lenght should at least extend across the entire palm breadth. A handle too short can cause unnecessary compression in the middle of the palm (Pheasant, 1998). Therefore, the length of the handle is set at 114 mm, as this is the 95th percentile of hand breadth (across thumb for men). (Appendix A.11)

The weight of this part needs to be reviewed as it needs to be in-line with the weight of the currently used surgical hammer. (see Embodiment, Prototype 1)

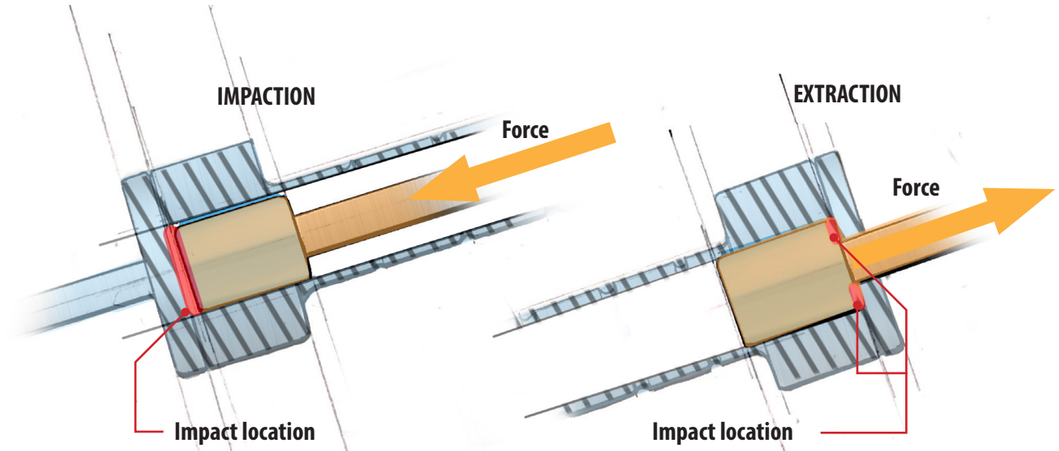


Figure 3.10. DriveFit main body intersection bottom (impact) and top (extract); red is impact location

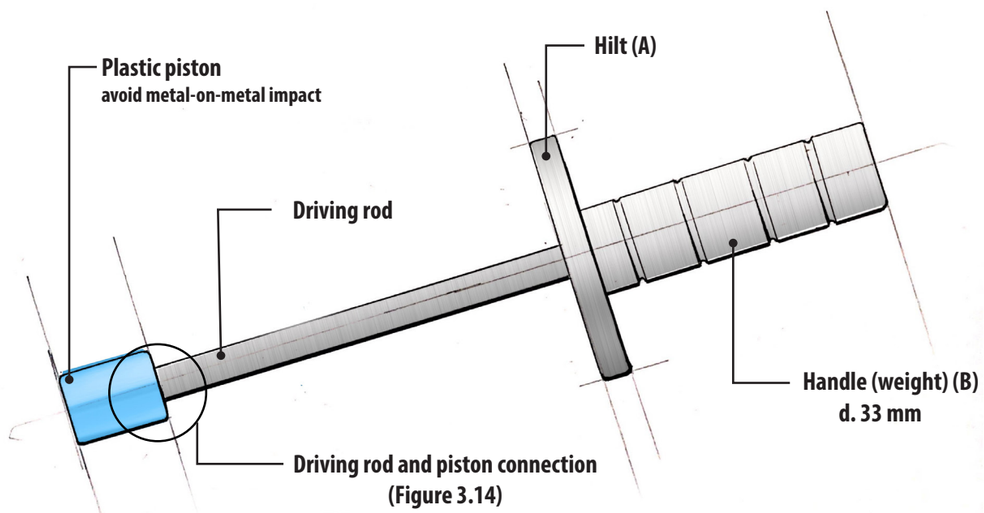


Figure 3.11. DriveFit Driving rod/Handle; parts

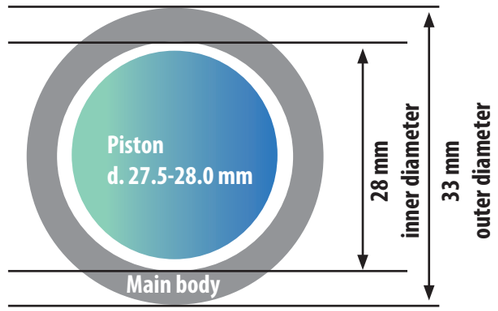


Figure 3.12. Diameter Piston and Main body

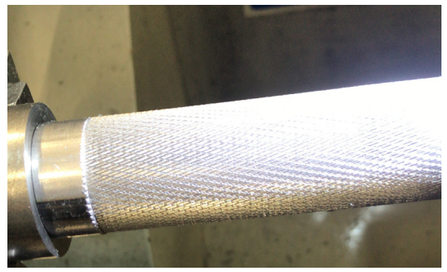


Figure 3.13. Knurling on a products; Prototype 1 (19-12-2019) (Done to get acquinted with prototyping on a Lathe)

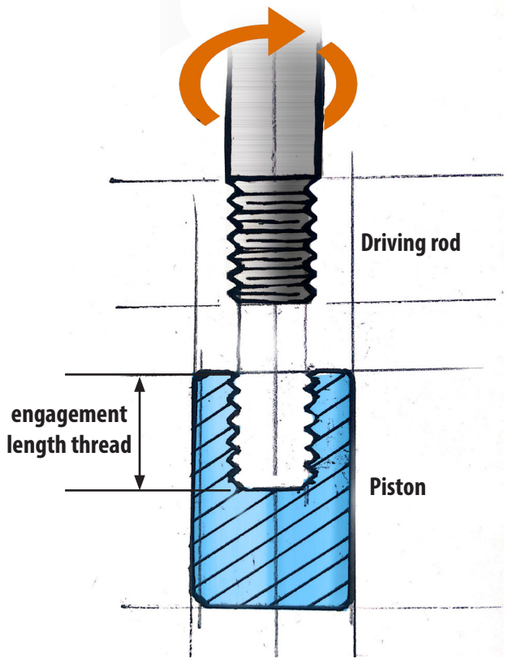


Figure 3.14. Connection between Driving rod and piston; Threaded connection was chosen

3.5 Surface design

The surface of the main body and handle has to give security against slip to its user.

The Piston diameter is set at 27.5-28.0 mm (smaller will give less friction), the reason for this choice is that, the main body (handle) than has a wall-thickness of 2.5 mm (Figure 3.12), which leaves enough room to make gentle grooves or a knurled surfaces (Figure 3.13) on the main body of (0.7-1.0 mm deep) , without decreasing wall-thickness too much making the main body weak. This surface has to make sure to prevent hand from slippage, as the combination of body fluids such as blood and plastic gloves may cause grip slippage problems.

Breaking up large smooth surfaces is necessary to make the product more non-reflective, to avoid surface glare in a brightly-lit working environment such as the operation room. (Patkin, 2001)

Choi, 2017 found that knurled surfaces have significantly higher level of microbacterial contamination. Knurling may increase frictional force on the hand, but it is found difficult to clean, which increases the residual rate of blood or bacteria. (Williams, 2010) Therefore, gentle grooving (0.70-1.0 mm deep) was chosen to adapt the surface to a potential grip slippage over the lenght of the main body handle and Driving rod/handle.

3.6 Driving rod and piston connection

The driving rod needs to be connected to the plastic piston and (dis)assembled. (Figure 3.10)

As the piston has to move through the main body (Figure 3.10) a connection has to be chosen that is compact in construction, as the main body outer diameter is 33 mm, looking at the users grip. (Chapter 3.2). To proceed to the prototyping fase a threaded connection was chosen, as this connection is compact in construction, strong and reliable. Other options were discarded as this option made assembly and functioning best. (other options see Appendix A.13)

Figure 3.15. Prototype 1, being made at PMB. (Fully produced on lathe)

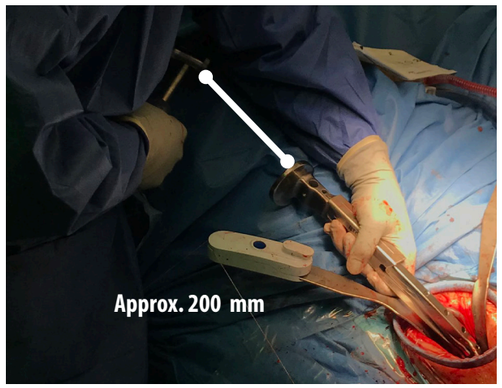


Figure 3.16. Assumed Swinging distance, Femural rasping

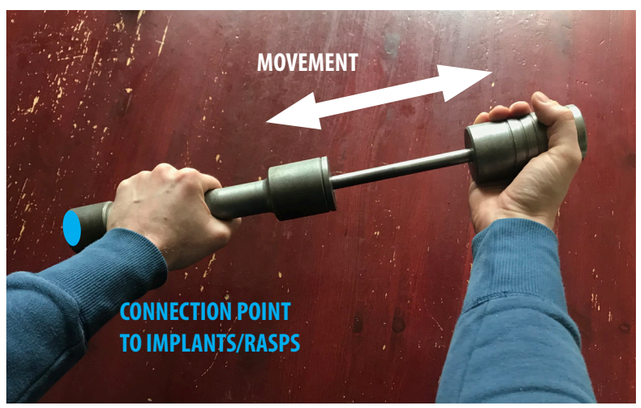


Figure 3.17. Prototype 1

3.7 DriveFit V1

The first prototype was made to see if the force coming from the design is in range with the currently used surgical mallet/hammer. Next to this the sounds level was measured to see if DriveFit's could reduce the sound level.

The entire prototype was constructed in the PMB workshop on a Lathe (Figure 3.15), at the Faculty of Industrial Design. The chosen material for this prototype was steel (Grade 1018), as this has similar machining and material properties (density) with surgical steel, plus it was available at the TU Delft, material shop. For the handle, a mass of fairly similar weight was constructed in comparison to the surgical mallet ((0.802 kg vs. 0.7695 kg).

For the length of the guiding cylinder a length of approximately 200mm was taken, as this is the assumed swinging distance during broaching of Femoral canal during surgery. (Figure 3.16)

For the first prototype simulation of the working principle and sound reduction was the focus, the connection onto DriveFit was neglected in this prototype. See Figure 3.17 for Prototype 1. (Appendix A.14)

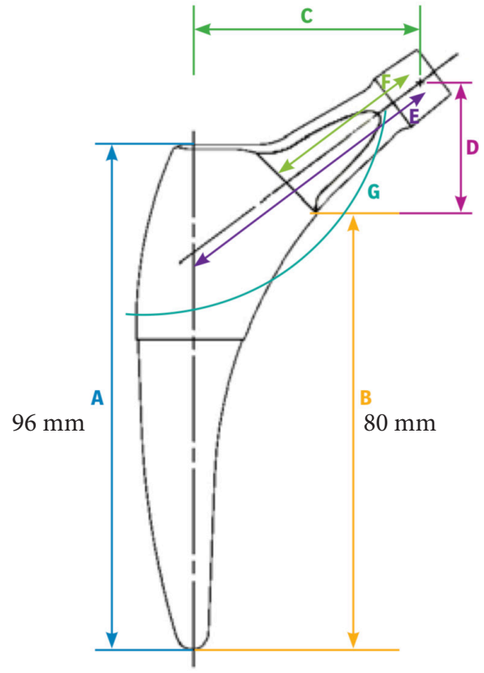


Figure 3.18. C1 Fitmore Hip Stem, C1 sizing (Fitmore Hip Stem, 2019)

Work equals energy / conservation of energy

Work equals

```
> restart;
> m := 1.0; d := 0.004; g := 9.81; h := 0.20; v := 5.1;
```

$$m := 1.0$$
$$d := 0.004$$
$$g := 9.81$$
$$h := 0.20$$
$$v := 5.1$$

```
> W := F · d; Ek := 0.5·m·v^2; Eg := m·g·h; Etot := Eg
      + Ek;
```

$$W := 0.004\,F$$
$$Ek := 13.0050$$
$$Eg := 1.96200$$
$$Etot := 14.96700$$

```
> Force := W = Etot;
```

$$Force := 0.004\,F = 14.96700$$

$$IF := solve(Force, F)$$
$$IF := 3741.750000$$

Impact Force of 3741 Newton

Figure 3.19. Maple 2017, worksheet, calculation of impact force surgical mallet (observations)

Hand calculation

As it is hard to estimate the impact force of a mallet swing. Some assumptions and calculations had to be made to see what impact forces and speeds of a currently used mallet are.

Looking into literature, impact forces during orthopedic surgery differ from values between 2500 - 4500 N for implantation. These are the maximum forces measured, applied by a hammer hitting impactor tools. (Michel, 2016) Approximate mallet velocities in broaching are 5.1 ±0.4 m/s. (Preutenborbeck, 2019)

To get an idea of the impact force (Figure 3.16) of an moving object onto another object, a stop distance or deformation of the object has to be known. As the product press-fits implants, the deformation can be assumed as the distance the implant is drivin' into bone. For this calculation the lenght B, medial calcar (Figure 3.18.) , is used for a C1 size Femoral stem. (Fitmore Hip Stem, 2020) The surgeons in Naarden, approximately used 20 strikes to fully press-fit the Femoral stem into the Femur. (B=80mm) So we assume, the deformation is 80mm/20 strikes = 4 mm per strike.

Parameters

F = range 2500 - 4500 N (Michel, 2016)
m = mass of the weight, Hammerweight, 0.7695 kg
v = velocity of the impact, 5.1 m/s (Preutenborbeck, 2019)
d = deformation distance, 4 mm = 0.004 m
h = swing height, distance appr. 20 cm = 0.2 m

Formulas

To calculate the forces speed of impact, the total amount of energy equals work. (conservation of energy) A downward swing is gravitational energy plus kinectic energy. *Etot = W*, thus *mgh+.5*m*v^2 = F*d*

This formula work (*W=F*d*) equals kinetic energy (*Ek=0.5*m*v^2*) plus gravitational energy (*Eg = mgh*)

Conclusion

With Maple 2017, the hammer force is calculated at 3741 N (FIgure 3.19.) As the DriveFit needs to have similar forces to implant, forces have to be inbetween 2500-4500 Newton. To get a real grip on the impact speed and force that can be exerted with DriveFit, a physical impact force measurement needs to be conducted.

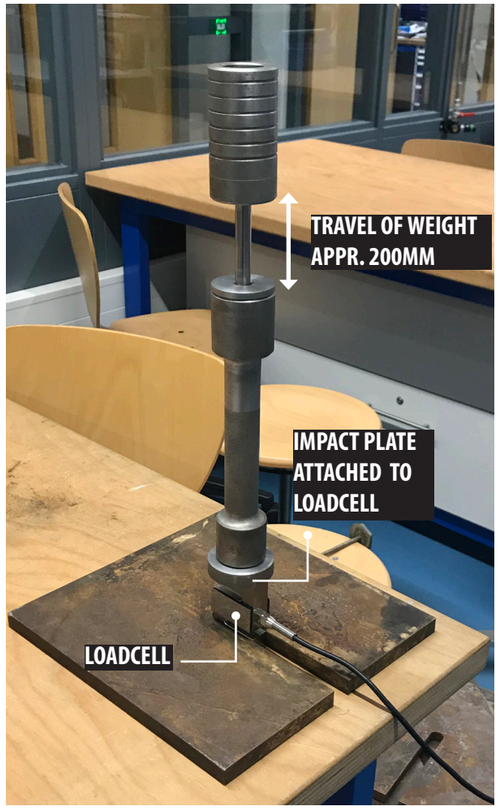


Figure 3.20. Physical force test set-up (impact site)

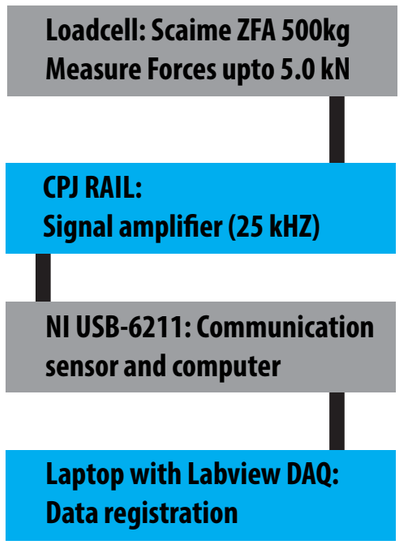


Figure 3.21. Test set-up schematic overview, with load cell.

3.8 Physical Force Testing

To calculate the impact force of a hammer swing a physical test was set-up. This was done to see if Prototype 1 is able to exert similar forces as the currenlty used surgical hammer.

Test-set up

In this set-up a loadcell was hit with the current surgical hammer and Prototype 1. The current hammer was swung down onto the loadcell from a height of approximately 200 mm. The driver system handle got driven down, 200 mm, onto the loadcell. (Figure 3. 20)

A calibarated; Scaime ZFA 500kg, tension and compression load cell (799304), was used in a test set-up. This loadcell was connected to a CPJ rail (signal amplifier) and NI USB-6211 (data acquisition device), which makes sure the computer is able to make registrations of the voltage data in the smallest time intervals possible (25 kHz) via Labview DAQ software. As impact force peaks can only be measured with high sensitivity, due to the short time span of the peak. The data from the NI USB-6211, was put through Labview 2018 and exported to Microsoft Excel.
(Figure 3.21)

Calibration of the SCAIME ZFA, was done by registering the voltage coming from the loadcell, by hanging 50 kg onto it. The results coming from the strikes were exported into Microsoft Excel, giving the measured impact forces.

Further info on the used products, set-up and calibration, see Appendix A.15.

Measurement set	Surgical Mallet Force (N)	Prototype 1 Force (N)
Swing 1	3811	4231
Swing 2	3823	4182
Swing 3	3846	4181
Swing 4	3800	4179
Swing 5	3793	4177
Swing 6	3403*	4214
Swing 7	3698	4169
Swing 8	3734	4173
Swing 9	3746	4172
Mean/Average	3739	4186
%-increase	100%	112% (12% in.)

*Hammer slipped from the hand

Figure 3.22. Impact forces (N) measured during testing

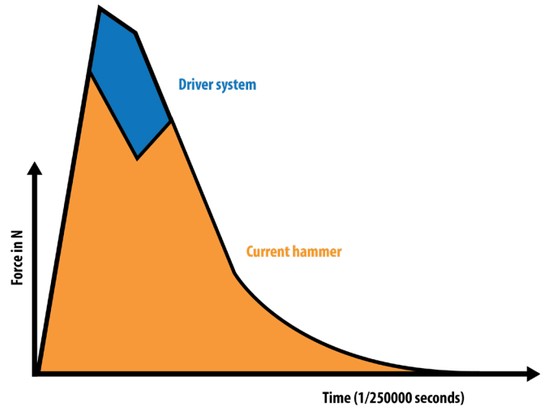


Figure 3.23. Schematic view of impact force over time

Results

The maximum impact forces are shown in Figure 3.22. Both impact products where swung down for 9 different measurements sets of one blow each.

Conclusion

When looking at the impact forces measured (Figure 3.22) we can conclude that the DriveFit can exert forces similar and even of greater magnitude than the currently used hammer.

To say where the difference in force comes from we have to see what the course of the force is over time. As it was not possible to export tables and graphs coming from the results, due to the large amount of data collected. The reason for this is that the maximum impact force could only be measured when the load cell, registered 250 thousand measurements a second. For that reason, an illustrative overview was made that shows the difference in force over time. (Figure 3.23)

To discuss the graph (Figure 3.23), we can see that the current hammer has a small peak after the hit. This peak is imputed to the hit coming after the first blow and can be seen as a hammer rebound. This could mean that a part of the forces gets lost due to vibration of the hammer or transferred to the wrist, hand or arm of the user. Next to that none of the hammer blows are of similar impact, as it is impossible to hit on the same location with every blow.

The reason for larger magnitude forces (12% increase) can probably be allocated to the fact that the blows with the driver system are lineair and hit the same location with everyblow. For the driver system there is no second peak for that reason we could say that there is less rebound or loss of force due to vibration. Next to that the driver system is held against the loadcell, which already loads it. Working with the driver system makes user able to lean-in on the product adding up to the overall load.

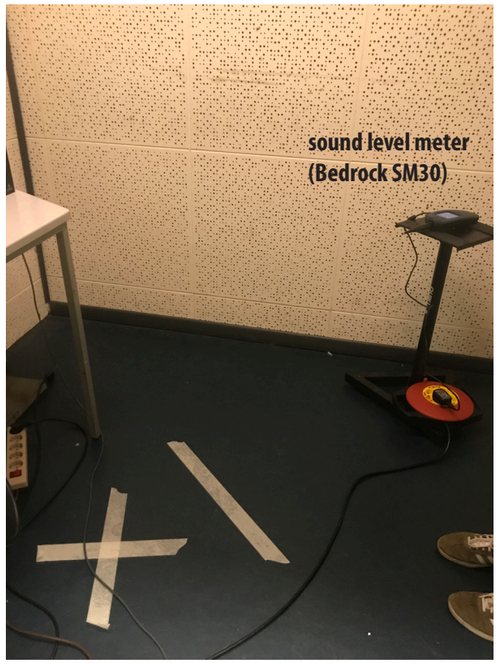


Figure 3.24. Test set-up: Sound source at the cross, Sound level meter on stand at the right

Figure 3.25. Test set-up: Striking broaching handle with surgical mallet

3.9 Soundtesting Prototype 1

To validate the first prototype we have to see if the sound level decreases when comparing the currently used mallet to the first prototype one in a sound studio.

The new instruments is in essence a cylinder with a guided piston/shaft which hits the "enclosed" bottom and transfer force onto an object. The current action in surgery, is striking a metal object with a metal object and in that way. These metal-on-metal impacts cause the sound peaks within the operation room.

Test set-up

To measure sound level of the current mallet and prototype 1, they were both put to the test in a sound-proof room/studio, Sound lab at IDE TU Delft. Used for the measurements, a calibrated Bedrock SM30 class 2 device, was set approx. 1 meter away from the sound source. (Figure 3.24)

For these measurements the surgical instruments were hold in the air and struck 5 times:
- The current used hammer was held up with one hand and struck towards to broach handle, hold in the other hand. (Figure 3.25)
- Prototype 1 was held in two hands, one hand on the Main body and the other one on the handle/weight. (Testing enclosement of sound source)
- Prototype 1 was held in two hands, one hand on the cylinder and the other one on the handle/weight. A piece of plastic (POM) was placed into the Main body (Testing both enclosement of sound source and material dampening)

Results

Figure Fix 3.26 shows the results from the measurements.

Measurement set	Surgical Mallet in dB(LAeq) and dB(Cpeak)	Driver System impaction dB(LAeq)/dB(Cpeak)	Driver System Retraction dB(LAeq)/dB(Cpeak)	Driver System impaction w/ POM dB(LAeq)/dB(Cpeak)
Swing 1	*78.4 / 121.8*	*68.3 / 111.8*	*73.3 / 117.8*	*64.6 / 106.1*
Swing 2	*79.1 / 120.2*	*70.3 / 113.4*	*74.3 / 115.6*	*65.4 / 107.8*
Swing 3	*76.3 / 119.4*	*73.9 / 114.8*	*75.4 / 115.7*	*65.7 / 108.3*
Swing 4	*77.1 / 119.6*	*68.6 / 111.4*	*74.6 / 115.1*	*64.6 / 106.2*
Swing 5	*79.3 / 120.8*	*67.7 / 110.4*	*77.7 / 116.0*	*64.9 / 107.4*

Figure 3.26 Sound level measurements; Prototype 1 vs Surgical Mallet

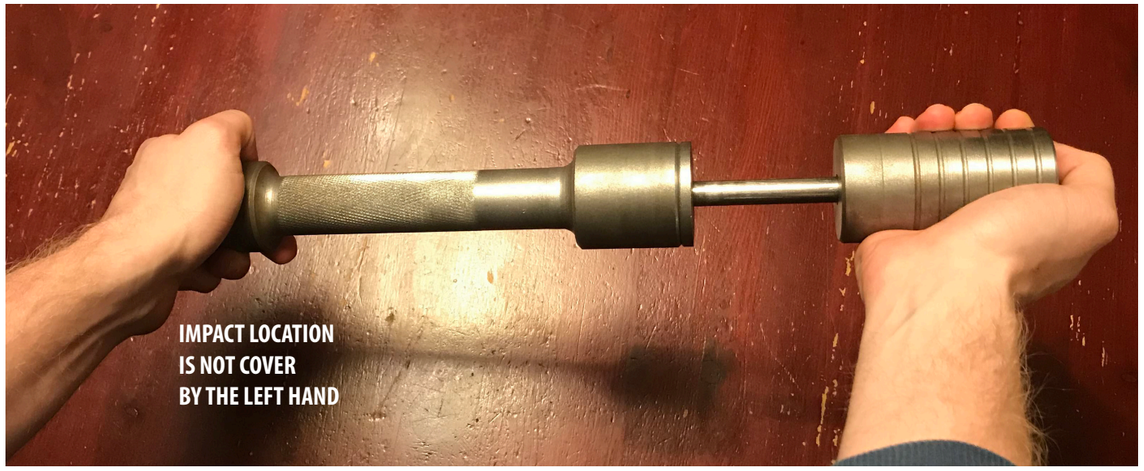


Figure 3.27 Change of grip, during usage (foto taken after testing

Conclusion

As can be seen in the results (Figure 3.26) all the sound levels registered are below the operation room levels. Probably due to the fact that a studio has sound absorbing walls, soundwaves will be not reflected.

Next to that the driver system is a lot quieter than the current hammer and broach handle. Therefore, it is safe to say that enclosing the impact will definitely contribute to making the product quieter.

When adding the plastic (POM) piece to the impact location we see even more decrease in soundlevel. The addition POM cap definitely had impact on the sound level decreasing it with up to 3-5 dB when looking at the peak levels.

When striking backwards the sound level increased this due to the fact that the top has an opening for the drive shaft to be guided through and the piston was made of steel.

For next iterations the piston that guides the weight to the bottom of the cylinder, needs to be made of a non-metal to decrease the sound level.

Noticed within the test, that placing your grip/hand away from the impact site (Figure 3.27), the sound level went up. (Approximately with 1-2 dB(C)) This means that your hand could function as an isolator for sound.

Meeting: 16-01-2019 (Appendix A.16 Extra weight)

In this first meeting (16-01-2019) the driver system, Prototype 1), was shown to the hip product specialist and orthopedic surgeon, both were enthusiastic on the outcomes and looked forward to testing a prototype in Erasmus MC, Skills lab. In this meeting a skills lab test session was arranged for (29-01-2019), it was discussed there placement of Acetabular cups could be done, as the bone marrow of the Femoral canal was already broached in the cadaver. Due to usage of the cadaver in a training previous to this test session. In this meeting the surgeon mentioned that fixation of the Acetabular took most effort, force wise and lineair force may guarantee better implant fit.

In this meeting the surgeon mentioned:

- "Feels already way better on hands and wrist, than the current used mallet."
- "It emits a more comfordable sound than the hammer does."
- "Lineair force can help with the opening of the Femur... it is probably more stable than what we use at the moment"

Evaluation

Due to the fact that the forces of the driver system where way higher than expected, we could change geometry and weight of the handles. Geometry changes will shorten the slide distance and hinder acceleration of the mass and will change the force emitted. As both height/sliding distance contribute to the impact force. (Embodiment 3.6)

3.10 POM-C and 17-4 stainless steel

In this chapter the materialization of the product is detailed. Note that the materialization and production methods are related to each other.

Production technique

It is decided to make use of a medical grade plastic and stainless steel in combination with lathe and milling work as all parts can be produced on these machines. Assumed that a batch size of 100.000 pieces is going to be produced, decided upon in consultation with Zimmer Biomet. Currently used surgical instruments are widely produced with similar techniques and materials. (Figure 3.28)(Van Straaten Medical, 2020) More on production of the product in Embodiment 3.8.

Requirements

Two different materials will be used in the product. The main body and driving rod/handles will get made from one material and the impact-sound reducing piston is made from another. Differentiating in materials to impact with, metal-on-metal impacts will not take place. This will automatically result in a reduction of sound level when using the instrument to impact or strike with.

The materials all should be medically approved and meet regulations concerning medical devices. After and during production the product should be able to be sterilized and packaged ready for surgical use. Looking at the product, the product needs to withstand sterilization to be used in surgery. When sterilization can be performed on the product, the product can be used over-and-over again in a surgical context if it does not fail. The product has a long-lasting end of life and makes the total product a non-disposable. Thus the goal of the material selection is to find materials that do not lose mechanical properties when sterilized, so the product will be a non-disposable.

Figure 3.28. Medical instrument production on Lathe (Van Straaten Medical, 2020)

Main body

For the Main body, Driveshaft and modular handles a surgical steel needs to be selected that suits the products criteria.

When selecting a steel for the design, surgical steel is the go-to-choice. Throughout the medical industry surgical instruments are made from surgical steel. Surgical steel is "Stainless steel" and used because of its good corrosion and, chemical resistance plus it is autoclave sterilization proof. High strength values make the material durable and by heat treatment its hardness can be increased.

There are 3 different kinds of surgical stainless steels that can be used: (CES Edupack, 2019)
- **Austenitic steel 316:** often referred to as marine grade used for implants due to its biomedical compatibility.
- **Martensitic steel 440/420:** high carbon steel alloyed with chromium. Mostly used for cutting and sawing instruments because of its high hardness.
- **17-4 stainless steel:** most common used steel for general surgical tools due to its machinability. The name is derived from its chemical structure, 17% chromium and 4 % nickel. (NAS, 2020)

Criteria for the surgical steel:
1. Materials need to withstand three minutes of water vapor/steam at 134 degrees Celsius form of sterilization and cleaning cycles to be used in surgical context. (DIN EN 285)
2. The material can be machined and welded and has acceptable properties. To ensure the product can be produced. Material can be used in this environment without restrictions and additional techniques or consumables are not needed. (CES Edupack, 2019)
3. Price of the material (EUR/kg) (CES Edupack 2019)

As all materials can withstand autoclave sterilization (DIN EN 285) an overview of properties concerning criteria 2 and 3 are side by side in table (Figure 3.29)

Conclusion

For the material of the main body 17-4 stainless steel was chosen. As the product needs to be produced on a lathe, CNC milled and welded, the processing properties of the material are of high importance. 17-4 stainless steel has no weld line corrosion and scores good on machinable and has excellent welding properties. This means that the product can achieve comparable properties to the parent material after processing. Therefore, 17-4 stainless steel makes for an excellent material choice for the product.

	Austenitic steel 316	Martensitic steel 440/420	17-4 stainless steel
Machining speed	0,345 m/s	0,112 m/s	0,203 m/s
Weldability	Good, preheating is required	Poor	Excellent
Weld line corrosion	Restricted*	Restricted*	Good**
Price (EUR/kg)	0,968	3,11	4,86

*Restricted: risk of sensitization when welded or heat treated due to high content of carbon.
*Good: high alloy austenitic not affected even at high temperatures.

Figure 3.29. Medical grade stainless steels (CES Edupack, 2019)(DIN EN 285)

Plastic Piston

For the plastic piston, that slides/glides through the main body of the instrument and dampens impact sound when using, a material needs to be selected. The Plastics looked into need to avoid Metal-on-Metal impact, which definitely decrease the noise level.

Criteria selection plastic material:
1. Materials need to withstand three minutes of water vapor/steam at 134 degrees Celsius form of sterilization and cleaning cycles to be used in surgical context. (DIN EN 285)
2. The material has acceptable processing properties. To ensure the product can be produced. Material can be used in this environment without restrictions and additional techniques or consumables are not needed. (CES Edupack, 2019)
3. Price of the material (EUR/kg), the plastic piston can be a part that is easily lost or has possibility for failure. (CES Edupack 2019)
4. High impact strength as the plastic piston receives most of the impact forces. To see if the product can withstand these forces and not fail in use. A high impact strength means that a product needs high amount of energy per unit area to break a test sample. (CES Edupack 2019)

Looking at the first criteria the plastic needs to be processed at high temperatures this makes most plastics unsuitable for sterilization by autoclave. Which is the market standard for sterilization as it the safest and cheapest of all sterilization methods.

When combining this criterium with plastics that are being applied in medical industry only three medical grade plastics remain: (Ensinger plastics, 2019)
- **PEEK**, used for segmental reconstruction of joints.
- **PPSU**, tool grips and sterilization trays are made of this material.
- **POM-C** (copolymer), sizing implants are made of this material. Particularly suitable for its sliding/friction properties. There are surgical mallets on the market that already use POM striking surfaces to reduce damage to the "to-strike-surface".
- **PP**, used for (medical) packaging. Mechnical properties not suitable for large forces. Therefore, left out of the decision-making process.

All plastics above have excellent chemical resistance, high strength and can be sterilized. Therefore, some other characteristics are set next to each other. (Figure 3.30) (Ensinger Plastics, 2020)

Conclusion

The chosen material for the piston will be POM-C, because of its low material costs and high impact strength compared to the other materials. The plus point for using POM-C is that it can be re-used because sterilization does not affect its mechanical properties. The downside of re-using this product part is that it discolors after 200 sterilization cycles (Ensinger Plastic, 2020) and therefore could be seen by operation room staff as non-sterile. In my opinion we must look at the environment and therefore see the piston as a re-usable part within DriveFit, as it discolors but will keeps it function. POM-C is available in many different colours, for the final product a blue POM-C will be chosen as this reduces glare when changing view from blood/human tissue compared to a white material.

Medical grade - plastics	PEEK	PPSU	POM-C
Price (EUR/kg) (CES Edupack 2019, level 3)	84,90	17,10	2,18
Processing properties	Excellent	Acceptable	Excellent
Impact strength (23 C) (J/m^2)	5,91e3	3,39e3	7,51e3
Friction and sliding properties	Excellent	Good	Good

Figure 3. 30. Medical grade plastics set next to each other (Ensinger Plastics, 2020)(CES Edupack, 2019)

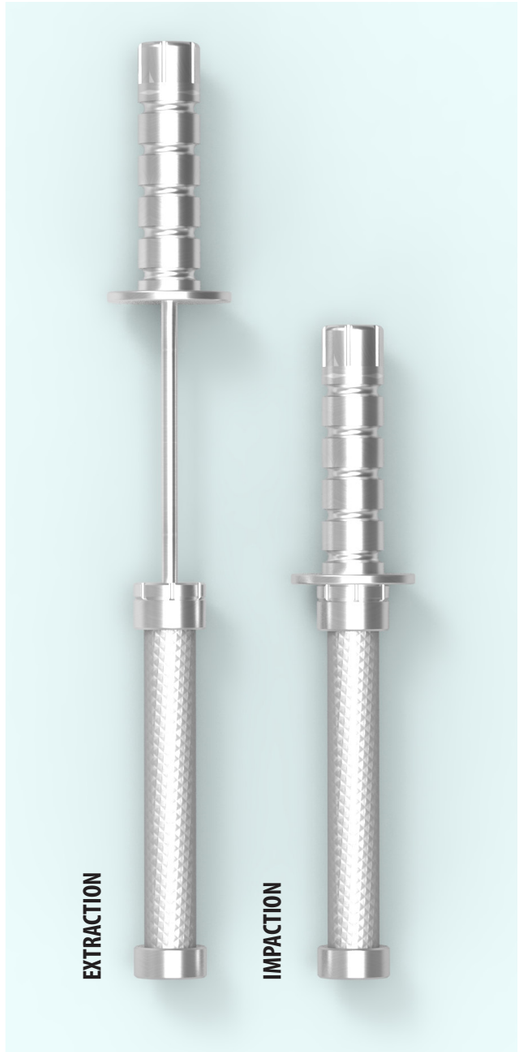


Figure 3. 31. Render DriveFit V1 in extraction and impaction state

3.11 Detailed design: DriveFit V1

After validating the first prototype and determining the material and production techniques, the first fully functioning prototype was made, DriveFit V1 (Figure 3.31. for render). This prototype will be tested in a cadaverlab test implanting Acetabular cups.

Before the manufacturing of this prototype a detailed design has to be made. The main adaption made on this prototype is the function of adding weights at the top end of the handle via a threaded connection. (Figure 3.32) This function results in an extra modular part which allows the surgeon to change the weight and thereby force to his/her operational preference. (Appendix A.16) For this prototype was chosen to add a weight of approx. 1 kg. The idea of adding larger weights is allowing the user to apply less speed and reach similar levels of force all eyeing on his/her preference when using.

Looking at the formula Work equals kinetic energy,

$$Work = .5 * mass * speed^2$$

of the hammer strike, we can state that, speed is of greater importance as it is not changing lineair, but quadratic.

Shifting around with weights therefore is mainly important for the user, as a smaller weight can generate more speed and even increase the force to a greater magnitude.

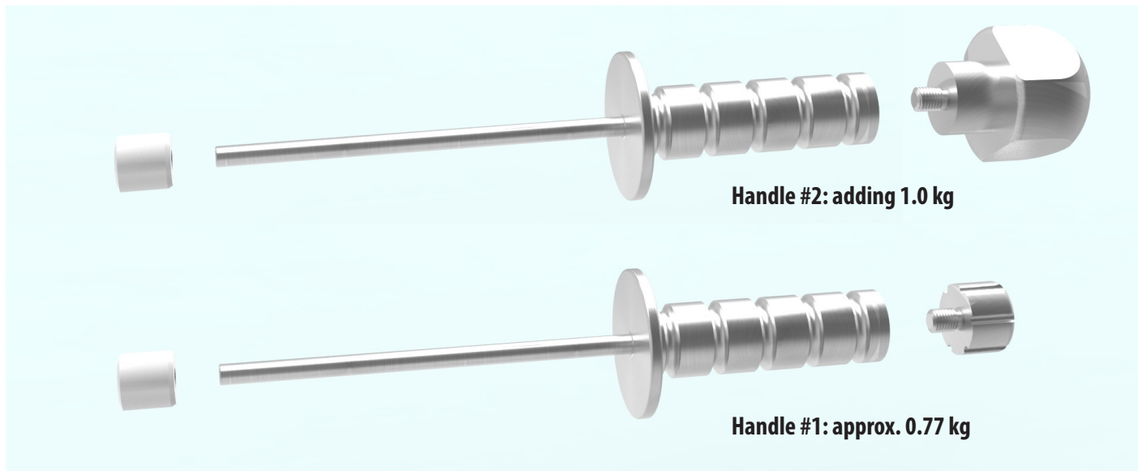


Figure 3.32. Interchangable handle nobs making the handle modular; changing weight

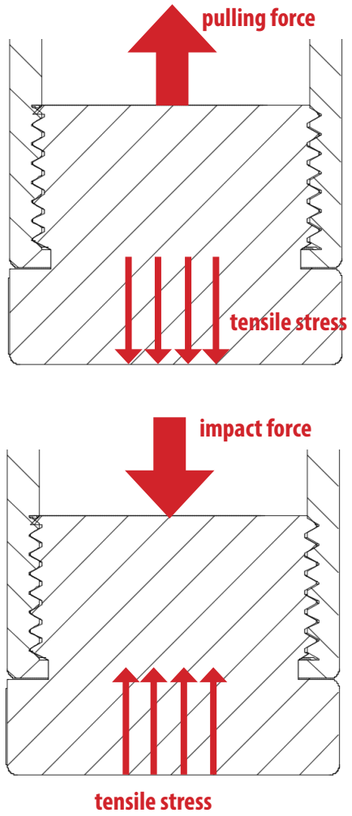


Figure 3. 36. Forces on threaded connections (extraction top; impaction bottom)

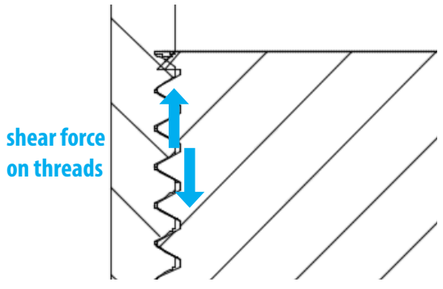


Figure 3. 34. Forces on threads

Figure 3.35. Shearing of threads (Van Beek, 2004)

Concerning the geometry of the threaded connection in the **main body (A)** and the **driving rod + POM-C piston (B)** calculations were made to show that these connections can handle the forces within DriveFit. Next to calculations concerning the connections there is also investigated the **working lenght (C)** of the user , giving the main body dimensions and the possibility of **buckling of the driving rod (D)**. As impact forces during orthopedic surgery differ from 2500 to a maximum of 4500 N. (Michel, 2016) Looking at physical force testing a 12% increase in impact force was measured, combining these values results in an assumed maximum impact force of 5040 N with the DriveFit. Forces coming downwards by impaction and the pulling forces on the threads by extraction will put tensile/compression forces on the bolt. (Figure 3.33) Next to tensile forces on the bolt, the threaded engagements between the winding are put under shear force. (Figure 3.34)

A reliable threaded connection gets designed in such a way the bolt breaks first before the threads will shear off. (Figure 3.35) Therefore, we could look at a few rules of thumb when designing this connection. The engagement lenght of the nut has to be, **Le = 0.8 * d0 (nominal pitch diameter)**, when bolt and nut are of same strength material. Using this standardized formule for nut-lenght the bolt will fail before the threads will shear. (Van Beek, 2004)

If your working with two different materials, where fore example; the nut is of lower strenght than the bolt, the engagement lenght of the nut has to be, **Le=2*(0.8*d0) (nominal pitch diameter)**, controling the shearforce is unnecessary as well, as these formules are standardized and match physical testing. (Van Beek, 2004)For the modular implant/tool attachments on the product we however want the least amount of windings possible, because this will make switching between modules faster. (less turns to fully engage the threads) When looking at standardization for low profile nuts, **Le=0.5*d0 (nominal pitch diameter)**. (Van Beek, 2004) In this case the external thread will shear before the thread will break. Therefore, we have to see if the force coming of the user (5040 N) will stay below the critical shearforce.

For the module caps and main body a fine thread will be used, as this is stronger than a coarse thread. For all other connection coarse threads are used as these are durable and have greater resistance to stripping. As the height of thread is greater making flank engagement greater. (KATO, 2020)(App. A.17)

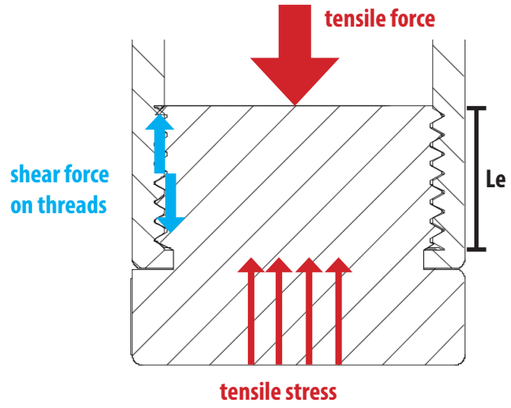


Figure 3. 36. Forces on Main body - cap connection

Stresses on the threads M30x2 :

```
> restart;
> tau := 8.8·10^10 : d2 := 28.701·10^-3 : d3 := 27.546·10^-3 :
  Tm := 1.03·10^9; Force := 5040·2 :
                                  Tm := 1.030000000 10^9
```

Calculation of *nominal threat* diameter :

```
> d0 := (d2 + d3)/2;
                                  d0 := 0.02812350000
```

Calculating tensile stress : Ts = Force / Area

```
> At := (Pi/4)·(d0)^2;
                                  At := 0.0006211959530
> Ts := Force/At;
                                  Ts := 1.622676380 10^7
```

Ts < Tm, product will **not** *fail due* **to** *tensile stresses*

Calculate effective thread length equal strenght materials : Le/d0 = 0.5

```
> Le := d0·0.5;
                                  Le := 0.01406175000
> Lmm := Le·1000;
                                  Lmm := 14.06175000
```

Calculation of thread surface :

```
> Ath := 0.5·Pi·d0·Le;
                                  Ath := 0.0006211959529
```

Calculate max force that threads can withstand :

```
> Fcr := Ath·tau;
                                  Fcr := 5.466524386 10^7
```

Product will **not** *fail due* **to** *shearing · (F < Fcr), so low nut is possible. A low nut will make connecting faster as it has less windings.*

Figure 3. 37. Calculation of tensile stress and Maximum shear stress of M30x2.

A. Main body threaded connection

The connection of the modular implant attachments onto the DriveFit is a threaded connection. The forces coming from the Driving rod onto the threaded connection may cause failure due too high shear stresses. (Figure 3.36) Assumed is:

- Only force on the connection comes from the user downwards or upwards (impact and extraction)

The used thread is M30x2, this was chosen to allow easy access when cleaning and mainly assembling, as the inner diameter of the thread is approximately 28 mm (M30x2). What makes it easier to push in the Piston plus Driving rod. The connection is loaded by impact (compression stress) and extraction (tensile stress). As tensile strenght of the material is smaller than compression strenght. It will break more easily on tensile stresses, therefore only tensile stresses were calculated.

Parameters (Appendix A.18 threads)

Fc = critical shear strength
τ = material shear strength, 8,8e^10 Pa (CES Edupack, 2019)
Ath = cross sectional area of thread material
At = tensile stress area or compressive stress area threads
d0= nominal pitch diameter of thread
d2= flank diameter of thread, M30x2 = 28.701mm (App. A.17)
d3= core diameter of thread, M30x2 = 27.546 mm (App. A.17)
Le = effective length of engagement (thread), in this design; when nut and bolt are of equal strenght (similar material), Le = 0.5*d0. (for low profile nut)(Van Beek, 2004)

Formulas

d0 = (d2+d3)/2
At = π/4 * (d0)^2
Ts = F / At, for compression Tc = Force/At (similar values)
Ath = .5 π * d0 * Le
Fcr = τ * Ath

Shear strength is 8,8e^10 Pa (tau), Tensile strenght is 1.03*10^9 Pa (Tm) and compression strength is 1.01*10^9 Pa (Tc) (CES Edupack, 2019). When tensile stress is above the tensile strenght the connection will break. Furthermore, when the force of the user is above the outcome of this calculation (Fcr) the threaded connection will fail, because of shear stress.

Conclusion (Figure 3.37)

The tensile stress (8.1*10^6 Pa - Ts) stays below the tensile strenght (Ts<Tm) of 17-4 stainless steel and the Maximum shearstress is of greater magnitude than the force applied by the user. Therefore, the connection will not fail in use. The thread should have a effective (engagement) lenght (Lmm) of 15 mm.

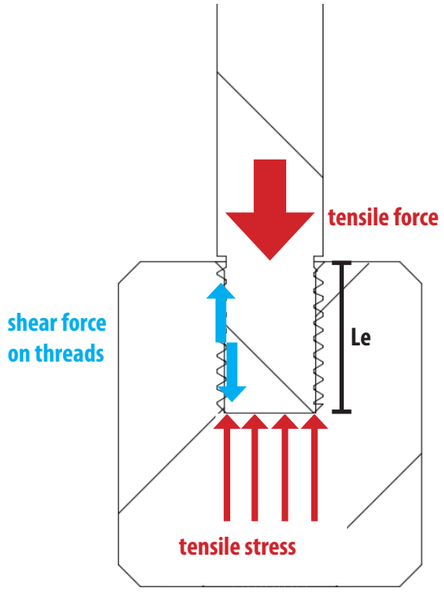


Figure 3. 38. Force on Piston - Driving rod threaded connection

Stresses on the threads M10x1.5 :

```
> restart;
> τ := 9.33·10^8 : d2 := 9.026·10^-3 : d3 := 8.160·10^-3 :
  Tm := 8.96·10^7; Force := 5040 :
                        Tm := 8.960000000 10^7
```

Calculation of nominal thread diameter :

```
> d0 := (d2 + d3)/2;
                        d0 := 0.008593000000
```

Calculating tensile stress : Ts = Force / Area

```
> At := (Pi/4)·(d0)^2;
                        At := 0.00005799352472
> Ts := Force/At;
                        Ts := 8.690625418 10^7
```

> Product does **not fail** due to tensile stress (Ts < Tm)

Calculate effective thread length weaker material : $Le := 2\cdot(.8\cdot d0)$

```
> Le := 2·(0.75·d0);
                        Le := 0.01288950000
> Lmm := Le·1000;
                        Lmm := 12.88950000
```

Calculation of thread surface :

```
> Ath := 0.5·Pi·d0·Le;
                        Ath := 0.0001739805742
```

Calculate max force that threads can withstand :

```
> Fcr := Ath·tau;
                        Fcr := 162323.8757
```

***Conclusion* :** Product will **not fail** due to shearing of the threads

Figure 3.39. Calculation of tensile stress and Maximum shearstress of M10x1.5.

B. POM-C piston connection onto Driving rod

The connection of the piston onto Driving rod is a threaded connection. The forces coming from the Driving rod onto the threaded connection may cause failure due too high shear stresses. (Figure 3.38)
Assumed is:

-Only force on the connection comes from the user downwards or upwards (impact and extraction)

- Due to POM-C impact strength, of 7500 N, the material does not fail when impacted. (Ensingerplastics POM-C MD, 2019)

The used thread is a metric thread M10x1.5 (standard metric) as smaller threads (M8 and smaller) fail due to tensile stress in the connection. (Appendix A.17)

Parameters

Fc = critical shear strength
τ = material shear modulus, 9.33e^8 Pa (CES Edupack, 2019)
Ath = cross sectional area of thread material
d0= pitch diameter thread
d2= flank diameter thread, M10x1.5 = 9.026 mm (App. A.17)
d3= core diameter thread, M10x1.5 = 8.160 mm (App. A.17)
Le = effective length of engagement (thread). When using two different materials (a weaker material combined with a strong material), Le=2*0.8*d0. To keep thread from gilling and stripping. (Van Beek, 2004)

Formulas

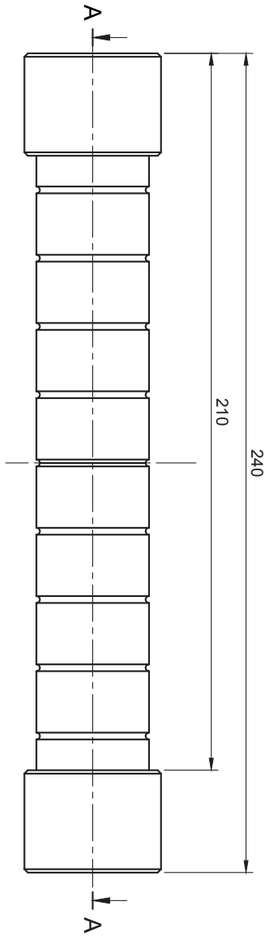
d0 = (d2+d3)/2
At = π/4 * (d0)^2
Ts = F / At, for compression Tc = Force/At (similar values)
Ath = .5 π * d0 * Le
Fct = τ * Ath

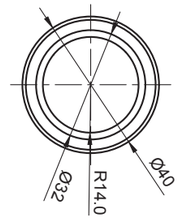
The shear modulus is 9.33e^8 Pa and has a tensile strenght of (CES Edupack, 2019). The Force coming from the user is set at 5040 N (Prototype 1, Chapter 3.4) When the force of the user is above the max. shearstress of the thread or above the t the threaded connection will fail, because of shear stress.

Conclusion

With Maple 2017 (Figure 3.39), the Maximum force which the connection can withstand was calculated. The maximum force stays below the value coming

The tensile stress (8.7*10^7 Pa - Ts) stays below the tensile strenght (Tm) of 17-4 stainless steel and the Maximum shear strenght is of greater magnitude than the force applied by the user. Therefore, the connection will not fail in use. The thread should have a effective (engagement) lenght (Lmm) of 13 mm.





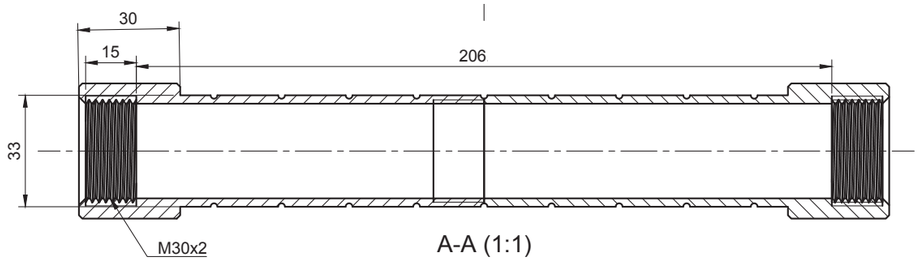


Figure 3.41. Dimensions of the Main body; Prototype 1 (mm) (Autodesk Fusion 360) (section view in Figure Fix)

C. Mainbody Lenght: DriveFit V1

Combining the previous calculations and dimensions a construction for all parts can be decided upon. The Main body dimensions for DriveFit V1, can be found in Figure 3.40).

As the product can deliver 12% more force than the currently used surgical hammer. We can set a working lenght for the main body, if we assume all variables remain the same.

The product of 88% times 200mm (working height taken in physical force testing) gives 17.6 mm as new working lenght. We add 24 mm, as you want to be sure the user is not extracting when, he/she wants to generate speed for impaction. Combing all these values the new working lenght will be 206 mm. Looking at the working lenght and the engagement lenghts of the thread, a total main body length of mm was found. (Figure 3.41)

Looking at the new working lenght, the lenght of the Driving rod can be dimensioned. Adding the index finger thickness of a male (95th percentile, 21 mm) (Appendix A.11) to the lenght of 206 mm results in a lenght of 227 mm. This is done so the risk of finger pinching between the handle hilt and mainbody is decreased.

Note:

To see if with this distance is able generate enough force, the new prototype will be tested implanting Acetabular cups on a cadaver. Orthopedic surgeons informed that press-fit fixaction of Acetabular cups costs them the most amount of force.

Figure 3.40. Working lenght visible in section view: A-A (1:1) Main body; Prototype 1 (mm) (Autodesk Fusion 360)

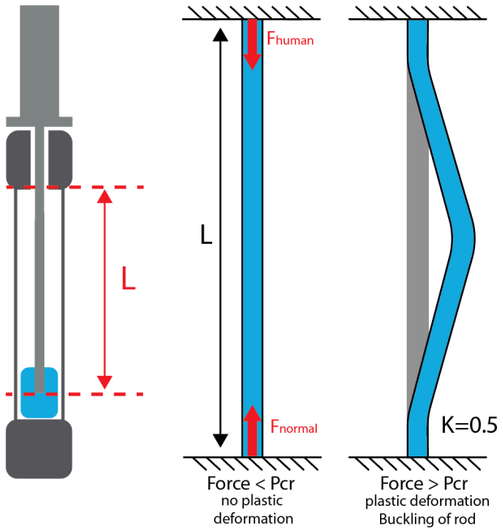


Figure 3. 42. Schematic overview presentation of rod buckling

Calculating potential failure due to yielding or buckling:

```
> restart;
> L := 206·10^-3 : E := 1.97·10^11 : r := 6·10^-3 :
```

Calculate if it yields; Compare stress to yield strenght

```
> A := Pi·r^2; Ys := 8.96·10^8; F := 5040;
```

$$A := \frac{9\,\pi}{250000}$$

$$Ys := 8.960000000\ 10^{8}$$

$$F := 5040$$

```
> Yc := evalf(F/A);
```

$$Yc := 4.456338405\ 10^{7}$$

Assumed buckling constant K=0.5, fixed at both ends.

```
> Ir := Pi·r^4/4; K := .5;
```

$$Ir := \frac{81\,\pi}{250000000000}$$

$$K := 0.5$$

```
> Pbk = evalf((Pi^2·E·Ir)/(K·L)^2)
```

$$Pbk = 186546.1993$$

Figure 3. 43. Calculation of Yieldstress in rod and buckling of the rod.

D. Buckling of the Driving rod

Derived from C. Mainbody lenght, the lenght of the Driving rod is found, to be 227 mm. The part that stays within the main body is 206 mm.
(Figure 3.42) As the forces for impactions may cause buckling of the driving rod. A calculation needs to be done to see if the Driving rod buckles in use.
Assumed is: (Figure 3.42)
-Driving rod is only affected by human force (compression and extension)
-The rod is fixed at both ends, so the buckling constant is K=0.5

As the threaded connection with the POM-C piston sits at the bottom of the Driving rod, a diameter of 10 mm or larger has to be chosen to accomodate the metric threat, M10x1.5. A rod with a diameter of 10mm was chosen, as this is the minimal diameter the rod can have. (see B. POM-C piston connection onto Driving rod, page 82)

Parameters

Pcr = critical buckling force/pressure (Pbk)
E = Young's modulus, 1.97^11 Pa (CES Edupack, 2019)
I = surface moment of inertia
K = constant, in this case 0.5 (Figure 3.)
L = length of the beam/rod, in our design = 206 mm
r = 5 mm (half diameter of 10 mm rod)

Formulas

Area = Pi * r^2
Yield stress = Force/Area (Ys = F/A)
Pbk = π2 * E * I / (K * L)2

First we have to see if the rod does not fail (plastic deformation) due to yield stresses, before we could look if the rod buckles due to the axial load.

The shear modulus is 9.3e^8 Pa and Yield strenght is 8.96*10^8 Pa (CES Edupack, 2019). When the yield stress (Yc) is greater than the Yield strenght the product breaks plus when the force of the user (5040 N) is above the buckling force (Pbk) the rod buckles and thus fails.

Conclusion

With Maple 2017 (Figure 3.43), first was looked at the yield stress in the rod. The yield stress (4.45*10^7 Pa) is below the yield strenght of the material so the stainless steel Driving rod does not break due to yield stresses. To see if the rod buckles, the critical force for buckling was calculated. The maximum force (Pbk) stays below the value coming from the human force (5040 N),the rod will not buckle.

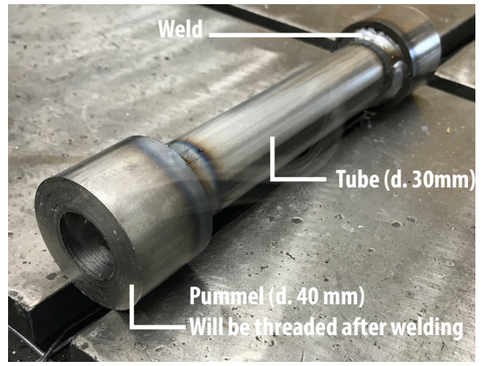


Figure 3.44 Build-up prototype Main body after welding (27-01-2020)

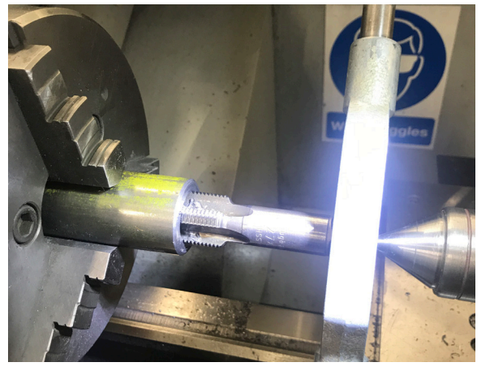


Figure 3.45 Turning thread into the pummels (27-01-2020)

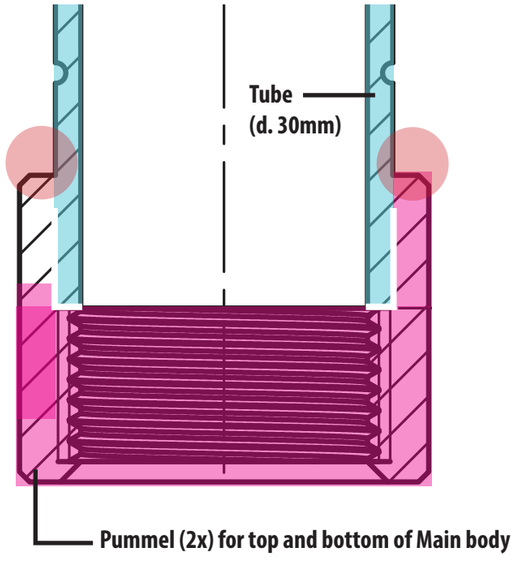


Figure 3.46 Build-up Main body when prototyping; Red circle are the weld locations; White lines are the hard to clean cavities as these parts cannot be welded shut.

E. Prototyping: DriveFit V1

To reduce the amount of scrap material and prototyping costs, the main body was build up from two pummels (within threaded connection will be made) and a metal tube (handle), and not milled from one block of steel. The metal tube used was 30 mm diameter, with a inner diameter of 26 mm. As these dimensions came closest to the wanted geometry. (33 mm diameter inner 28 mm) (Figure 3. 44 and 3. 45)

Two pummels will be made and welded onto the metal tube. In the "real" product, this will not be possible as the inside will have areas that are hard to clean and form spots where debriss and/or bacteria can nestle. (Figure 3.46)

To be able to use the prototype to implant Acetabular cups, a Acetabular cup attachment was replicated from a Zimmer Biomet one and welded onto a module cap. (Appendix A.18) (Figure 3.47)

Figure 3.47 Left Zimmer Biomet's Acetabular cup impactor; Right Acetabular module DriveFit

3.12 Cadavertesting

To simulate the placement of an Acetabular cup, the DriveFit was used on a cadaver. (29-01-2020)

Test set-up

To simulate the placement of a titanium cup into the Acetabular, a cadaver was used. The cadaver was used in THA surgery training before DriveFit was tested. The cadaver is Femur was broached and the cup (in this case a Continuum shell) was removed before testing.

Materials used: (Figure 5. 48)
- DriveFit V1
- DriveFit straight cup inserter attachment (Replica of Acetabular straight inserter)
- Continuum shell/cup (54 mm)

Cadaver information:
- Acetabulum was reamed in a previous (cadaver)training
- The Acetabular cup (Continuum shell) was used in previous training and removed from the same cadaver.

Note: At the start of the testing making photos was not allowed, after left side implantation it was. Making of videos was not allowed at all.

Results

A. (Un)expected use

- Using the DriveFit the surgeon was able to implant a Continuum shell (54 mm) on both the left and right side of the cadaver. (Figure 5.49)

- "Dosing my force when implanting is something I have to get used to, surgical training would be an outcome for this as it is totally new." - Surgeon

- Surgeon noted that via the extracting function the repositioning and reinserting of the cup could be done faster to achieve the desired orientation.

- The surgeon would have liked- a steering handle on the main body of the product, the place the cup in the desired orientation. (Embodiment 3.13)

- Wanting to screw of the implant was hard, due to the large instrument connected to the inserter and Continuum shell. The surgeon said this was solvable by using an Offset Inserter, which have a rotational control of the cup. (Continuum shell surgical technique; Zimmer Biomet, 2019) (Figure 5.50)

- Entering bottom of DriveFit friction was noticed. Probably due the prototype not being straight.

- The product has a tendency to roll, because of its round geometry.

Figure 5.50 Offset Inserter; By turning the black handle (screw driver) the cup can be released from the inserter. (Zimmer Biomet, 2019)

B. Ergonomics of DriveFit

- The product was experienced more quiet than the currently used surgical hammer.

- The orthopedic surgeon was holding the instrument in the intended working position and found the working posture pleasant. (Figure 5.51)

- The large half dome grip was preffered over the cylinder handle grip when implanting and extracting. "Less vibration on the hand than using the long grip." - Surgeon (Figure 5.52)

- More handle option could improve the products capabilities, the surgeon would have preferred a less heavy handle. As he felt he had enough power to implant.

Conclusion

The test validated the working principle of DriveFit, showing implantion and extraction was possible. Most of the results showed that training with this product is necessary as it functioning is different than mallet use and "it is something to get used to."

Changing the geometry (Embodiment 3.13) of the product would offer the surgeon more product capabilities when performing surgery.

Figure 5.48 Used DriveFit V1, main body with Acetabular inserter attachment (29-01-20, Erasmus MC)

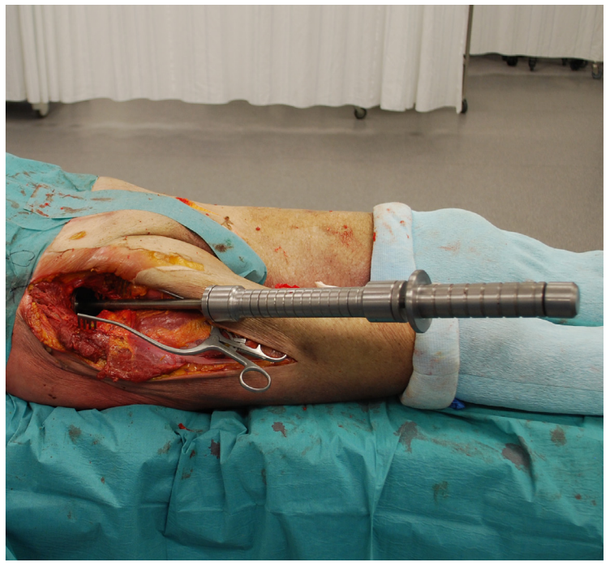


Figure 5.49 Continuum shell/cup succesfully implanted; Right side Acetabulum (29-01-20, Erasmus MC)

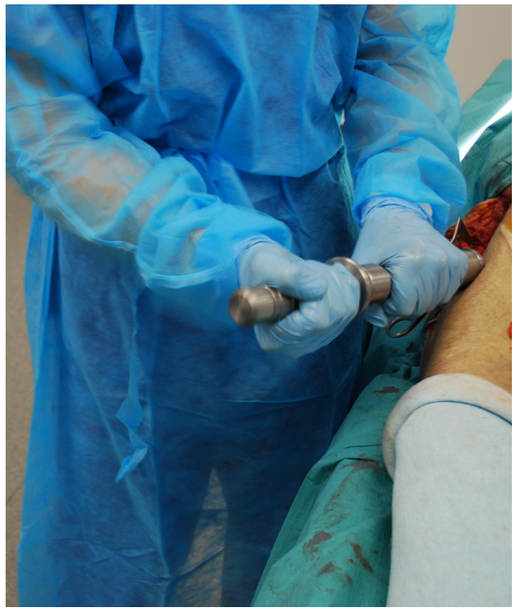


Figure 5.51 Working position surgeon when inserting the Acetabular cup (29-01-20, Erasmus MC)

Figure 5.52 Surgeon indicating the Half sphere shape felt ergonomically better and preffered a steering handle (drawing) (29-01-20, Erasmus MC)

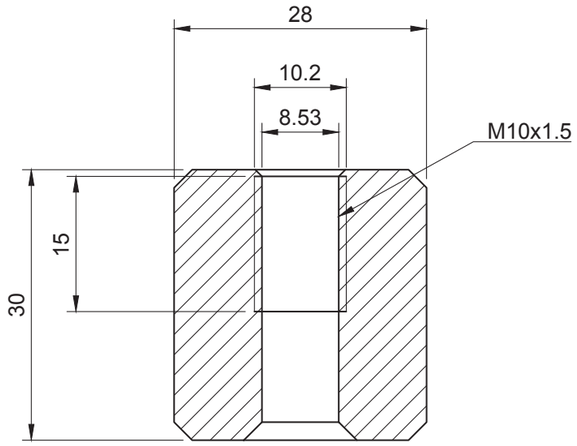


Figure 3.53 Piston with hole throughout its body, making sure it can be cleaned. (mm)

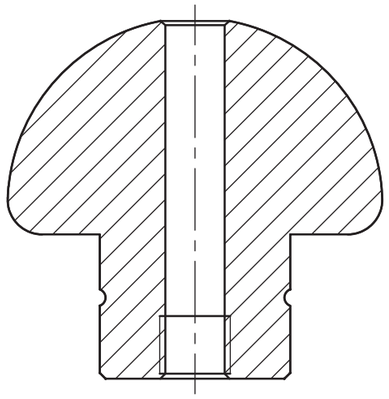


Figure 3.54 New Handle design free of cavities; easier to clean (The Driving rod has the "bolt" part of the connection)(mm)

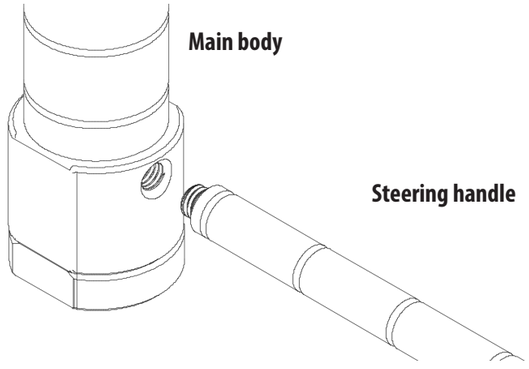


Figure 3.55 Steering handle can be placed into the Main body

3.13 Optimizing the product

After testing and the greenlight meeting the design was optimized.

A. Greenlight meeting: Cavities

Coaches from Zimmer Biomet notifed that the product still had cavities and this is not allowed as this makes it hard to clean before sterilization. In design optimization the product was made free of cavities.

The piston and handle (more on handle #1 next page) were redesigned to make sure cavities were out of the design (Figure 3.53 and 3.54)

B. Friction

During testing the use of the Driveshaft increased in friction when the piston reached the bottom of the guiding cylinder. At first it was assumpted that this was a prototyping fault. This was not the case, it was found that the prototype was straight. Diving into this showed that the friction was due to the build up of air-pressure in the main body, as it felt similar to when you are using a tirepump. As the pressure and volume of a fixed mass of gas (constant temperature) are related as followed: (Fullick, 2001)

Initial pressure x Initial volume
=
Final pressure x Final volume

To release air from the main body holes were made in the pummel on both sides of the main-body, this keeps the product symmetrical and makes sure air can escape when the piston is moved up or down in use. In this case the user will not work against the final pressure he creates when decreasing the final volume of air.

The surgeons ***wish was to include a steering handle perpendicular onto the Main body***. As the holes were made to release air these can serve a second purpose by making them threaded to fixate the steering handle into. By doing this both the surgeons wish and the friction/pressure problem are solved. (Figure 3.55) For the Lenght and diameter of the steering handle 114 mm (hand breadth: p95 men) (Appendix A.12) and 12 mm as diameter were chosen, as this is recommended for a pricision grip. (CCOHS hand tool ergonomics, 2020)

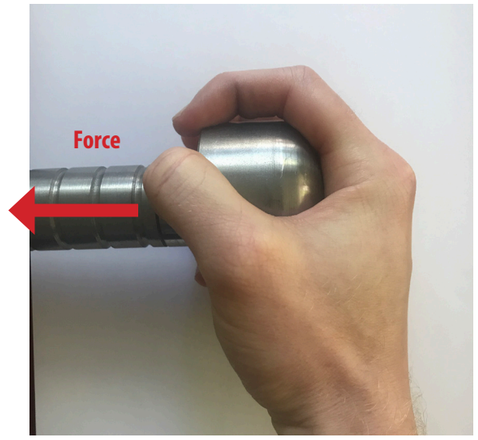


Figure 3.56 Reconstruction of how surgeon held the dome handle

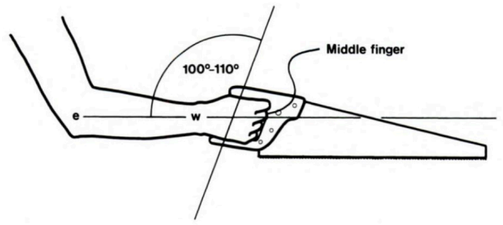


Figure 3.57 Preferred tool wrist angle when working (Pheasant, 1975)

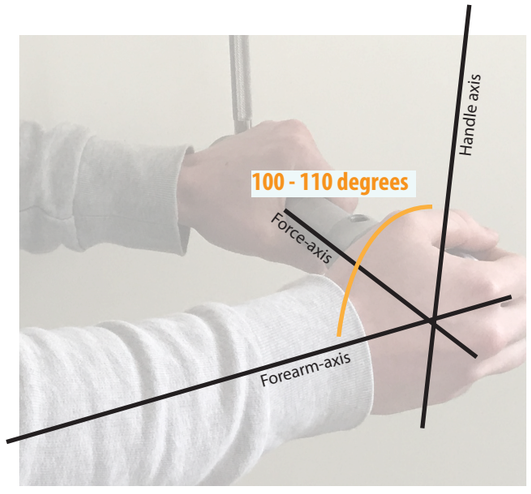


Figure 3.58 Knob/Dome handle on the product to exert thrust/force (Pheasant,2001)

C. Handle shape

During testing in the cadaverlab the surgeon preferred the dome like shape of the 1 kg handle attachment, but found the adding of this weight unnecessary, when applying force. The surgeon held the product on the top half dome. (Figure 3. 56) When holding the dome/half sphere handle the surgeon, experienced less vibration on his hand. (Embodiment 3.12 Cadavertesting) Looking into his comments and handling a new handle was designed.

Wrist position

When the wrist is in a non-neutral position, the load on the tendons in wrist, hand and forearm increase. The increase in load may lead to an increase risk of developing conditions such as carpal tunnel syndrome or other work-related musculoskeletal disorders. Next to that grip strength is highest when the wrist is in its neutral position, because when the wrist is flexed, the finger flexors are shortened and their capacity to generate tension is decreased. (Pheasant, 2001) A surgical mallet and current grip are bad in that sense because these force you to work with you wrist in unnatural positions and mallet impact evenforces your wrist out of its natural/neutral position.

Therefore, a handle in use should allow the wrist remain as close as possible to the neutral position. The neutral position of the wrist is best preserved, when the handle in use makes an angle between 100-110 degrees to the forearm-axis. This reason for this range is due to different carpal bones lengths in your hand-palm. (Figure 3.57) (Pheansant, 1975)

Force

Combing the wrist angle stated above with the handle design principle; It is more effective to exert thrust perpendicular to the axis of a cylinderical handle than along the axis. A knob on the end can give extra purchase in this situation. (Pheasant, 2001) (Figure 3.58) As for this principle, the new handle design is located at the end of the "old" cylinderical handle perpendicular to the force axis and will change the overall geometry of the handle

Next to this, a grip design can create a sense of tool orientation coming from the feel of the grip. (Lehto, 2013) The surgeon already held to dome handle in an orientation towards the impact location. This feeling will now be increased as the knob, gives a feel for force exertion along its axis. This tool orientation will make sure the orthopedic surgeon only has to watch and think about where he is working.

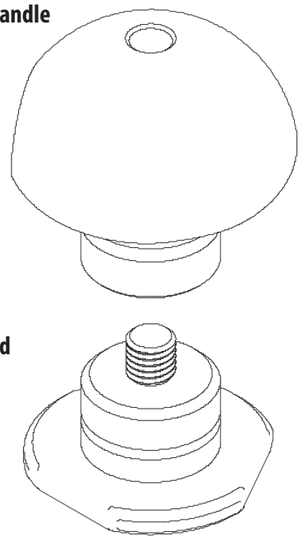


Figure 3.59 Handle can be placed by winding it onto the driving rod

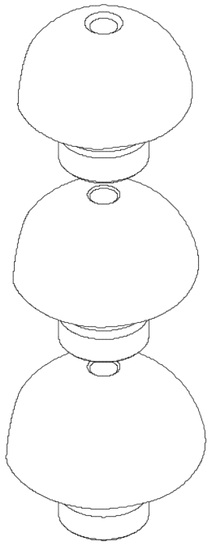


Figure 3.60 All different handles ranging from 65 - 75 mm in diameter.

Handle shape

As the force exerted has to be perpendicular to the cylinder handle axis, a knob shaped handle at the end of the handle set-up was chosen. (Figure 3.58)

For extra functionality three new handles with different dimensions (and weights) where added. By screwing of the handle, a heavier/larger handle can be placed on the product giving the user another modular product feature to fit his/her preference. (Figure 3.59) For the diameter/radius of the dome handles, a diameter of 65, 70 and 75 mm were developed. These sizes were chosen as diameters of 65-70 mm allow for greatest grip force in operation. (Pheasant, 1975) The used sizes are derived from sphere handles, as dome handle are half spheres with similar radius. The different handle diameters account for different weights approximately 0.6, 0.7 and 0.9 kilograms.

Feeling less impact on the hand (Cadavertest 3.12) and wrist is probably due to the fact that a half dome handle has a larger surface area and is able to spread the impact over a larger hand surface resulting in less vibration of impact. Feeling less impact on hand and wrist decreases the risk of MSD plus a natural wrist angle between 100-110 degrees to the forearm axis will add up to that. Lastly force exertion can be done with more efficiency compared to the handle design of DriveFit V1.

D. Flat sides on product body

To stop the product from rolling off a potentially sloping work-surface, product bodies are milled flat.
For the handles, three seperate faces are milled onto the body due to their larger diameter compared to the Main body, which has two flat surfaces. (Figure 3.61) Next to this, flat surfaces make dis)assembling of the Main body caps and Modular handles easier by providing grip.

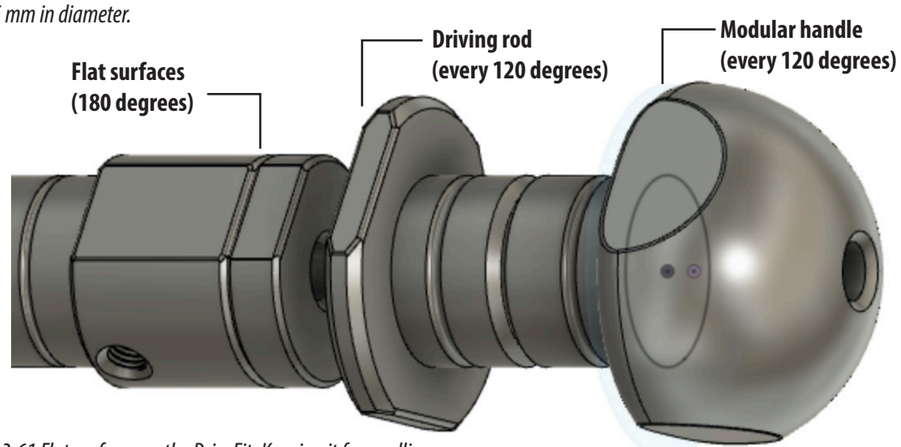


Figure 3.61 Flat surfaces on the DriveFit; Keeping it from rolling

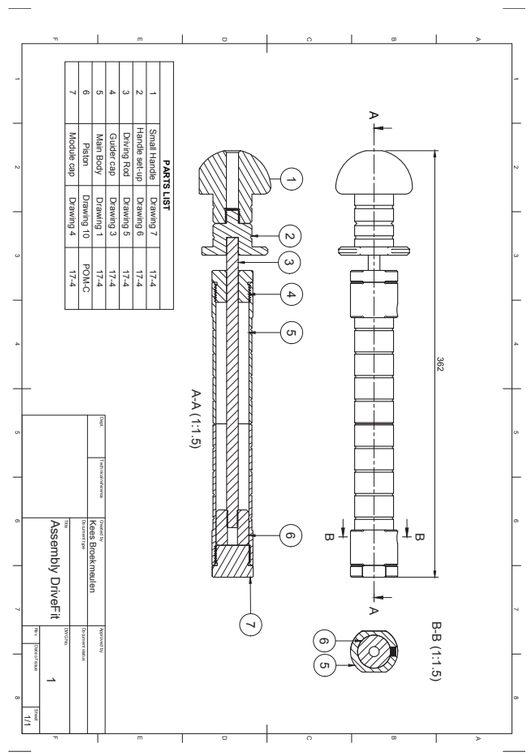


Figure 3.62 Assembly drawing of the Final design (Appendix A.FIX)

3.14 Turning Lathe, CNC milling and welding

As decided on the materials and cadaver testing outcomes prototyping of the final design was done. In this chapter the production of the final design, DriveFit (Figure 3.62), will be showed in production steps.

The photos seen in this chapter are made during the prototyping process and will give insights into the real fabrication process. The production was done in consultation with PMB employees and machining principles (Van Terheijden, 1975). The parts shown below are the components made when prototyping. (Figure 3.63) For all technical drawing of DriveFit see the Appendix A.19.

Guidelines for using lathe and CNC lathe-milling:
- To get a stable product to work with, the material must be clamped into the "3 or 4 claw" for at least half length of the material.
- The horizontal chisel speed may not exceed 0,203 m/s. (CES Edupack, 2019)

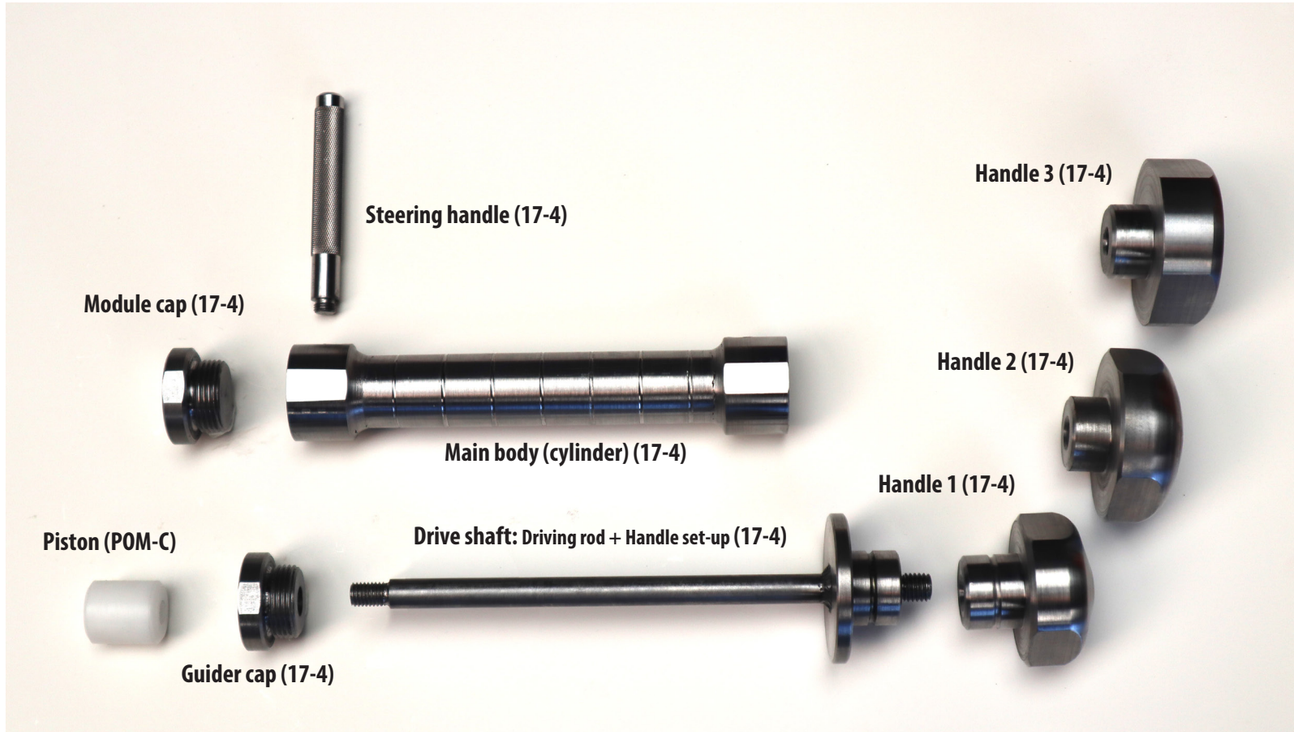


Figure 3.63 Overview of DriveFit components + material

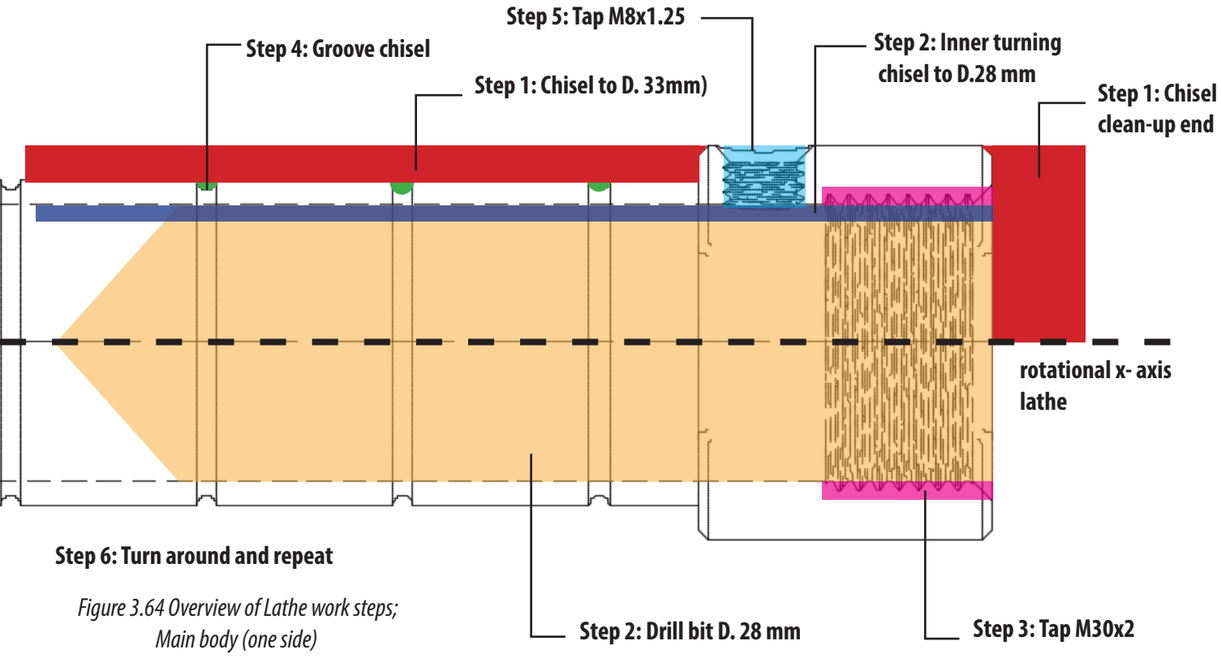


Figure 3.64 Overview of Lathe work steps; Main body (one side)

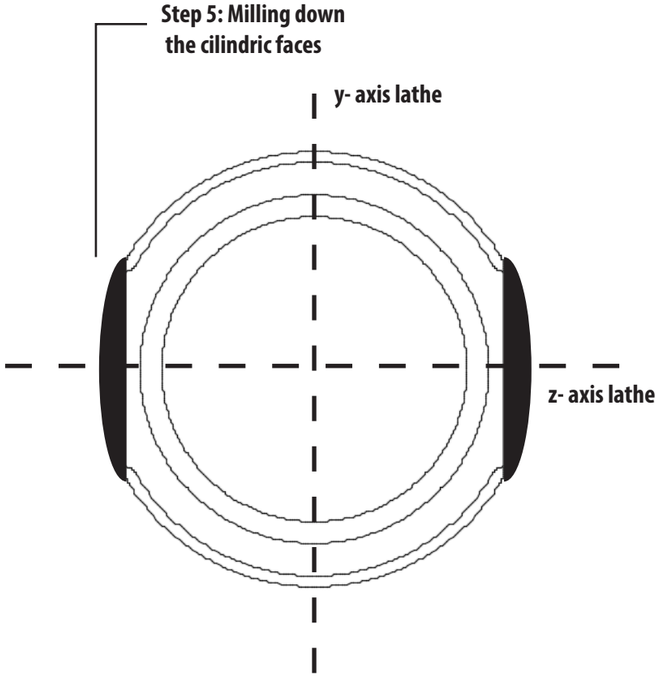
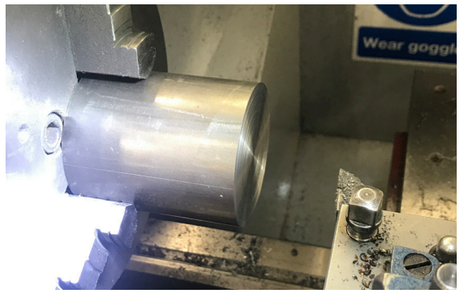
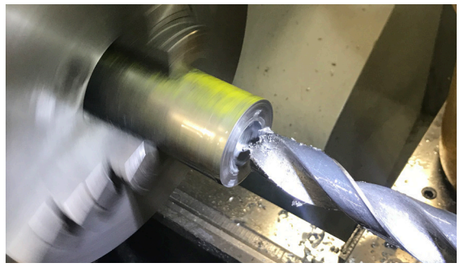


Figure 3.65 Milling step (y-axis)

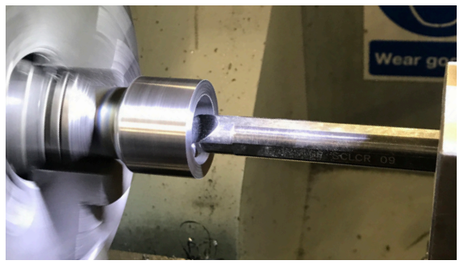
Figure 3.66 Finalized Main body



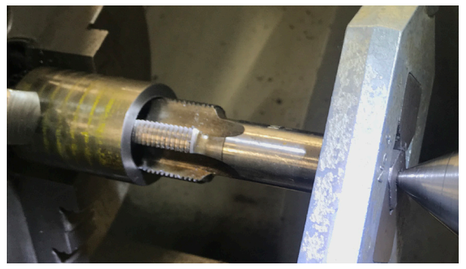
Step 1. Cleaning up rod; raw material



Step 2. Hole is drilled of 26 mm diameter



Step 3. Milling hole to 28 mm, to accomodate M30 tap



Step 3. Milling hole to 28 mm, to accomodate M30 tap

Step 5. Milled flat surface and drilling hole to accomodate tap for steering handle attachment

Stainless steel 17-4

For the prototype machining steel was used as the product's main material as this was the hardest material possible to work with at the PMB, faculty of industrial design engineering and has a similar density as 17-4. (CES, 2019). To illustrate that most the parts of DriveFit can be fabricated out of one piece of 17-4 stainless steel.

Fabrication of the Main body (Figure 3.64)

Step 1: Starting off with a rod with 40 mm diameter of approximately 250 mm. This size is chosen to clean-up the top and bottom (red) of the rod and turn away the rough surface of the cylindric length to 33 mm. (red)

Step 2: To open-up the main body a drill must be used with a diameter of 28 mm. This size is chosen to guide the piston through and give the cylindrical main body a inner diameter of 28 mm. First a center drill is used to create a perfect middle in the rod's end to drill into. After drilling a center, a smaller drill bit can be used to drill into the main body. The next step than is to drill the diameter of 28 mm. (orange)

Step 3: After giving the rod an internal diameter of 28 mm, the hole needs to be smootend using an inside turning tool. After cutting away material to 28 mm. (purple) The canal gets chamfered for centering the tap and for easier attachment of modules when in use. Using a tap (M30x2) the female half of the screw on connection can be cut, M30, which means that the threaded hole will have an outer diameter of 30 mm and as internal diameter 28 mm. (pink)

Step 4. The channels and grooves are made onto the main body, to ensure a more anti-slip surface to hold onto. (green)

Step 5. The sides faces of the main body will be milled flat using the y-axis of the lathe and thread is tapped (M8x1.25) (light blue) into the top surface for attachment of steering handle, also with the y-axis of the CNC lathe. (Figure 3.65) (black)

Step 6: After using the tap the rod must be turned around and the step 1-5 must be repeated so both ends of the product have similar shape and tapped threaded ends.

This will result in the Main body of DriveFit. (Figure 3.66)

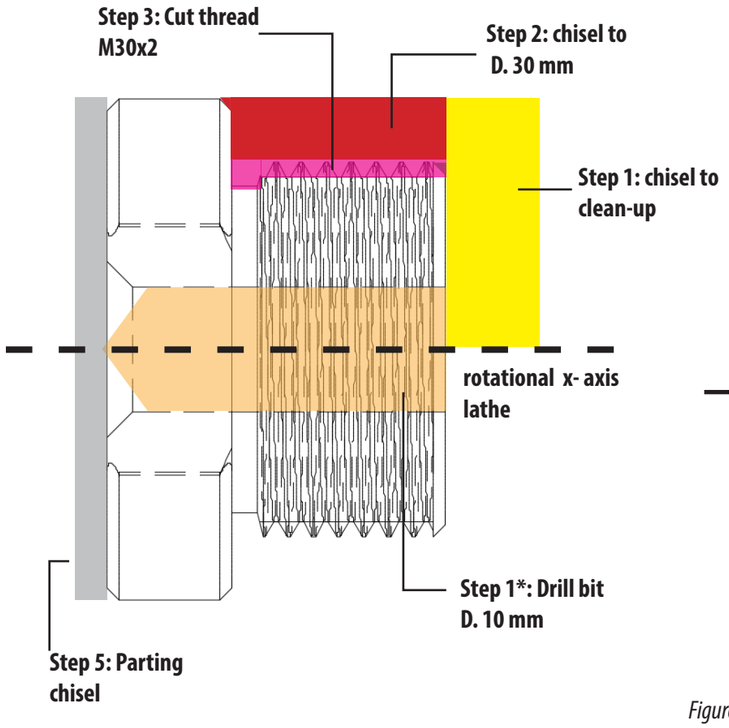


Figure 3.67 Overview of Lathe work steps; Main body caps

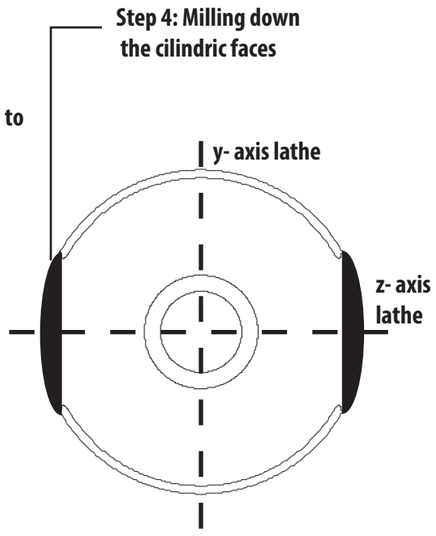


Figure 3.68 Overview of Lathe work steps; Main body caps

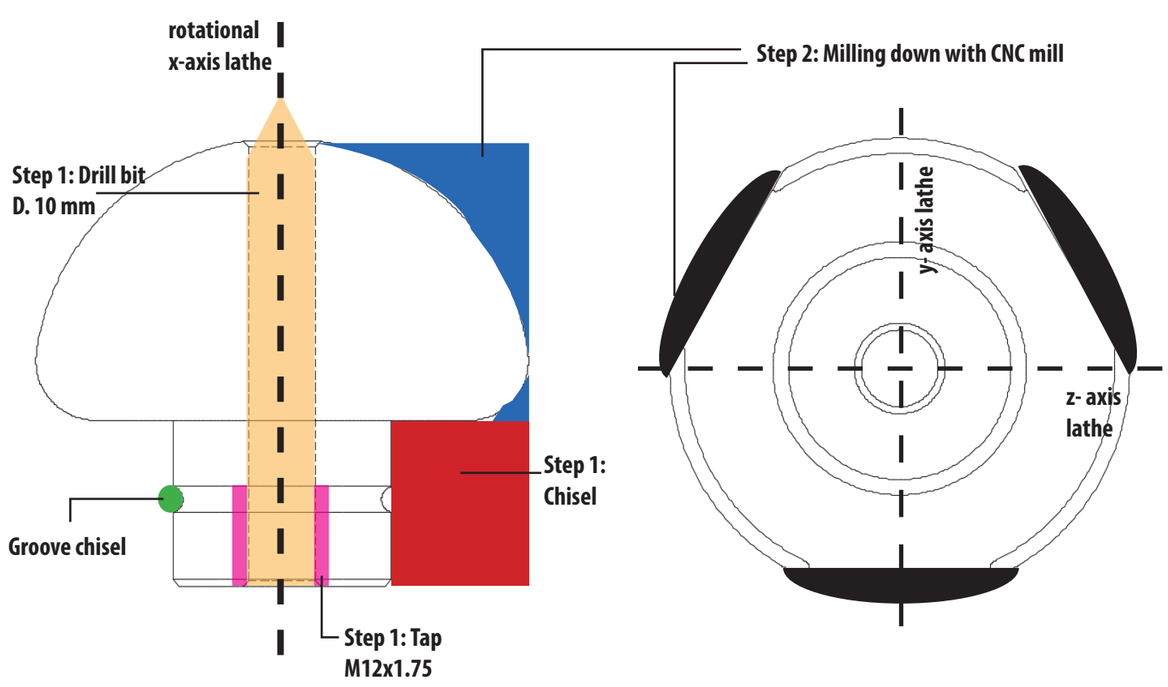
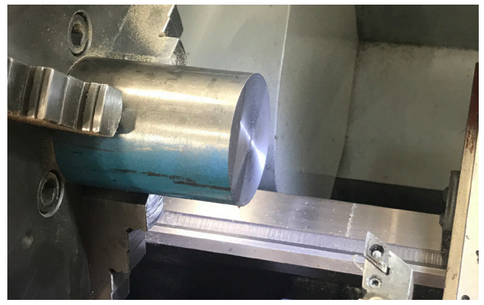
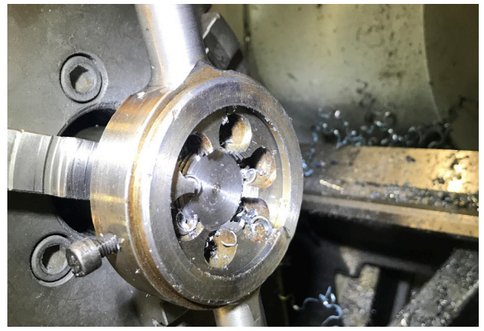


Figure 3.69 Overview of Lathe and milling work steps; Modular Handle

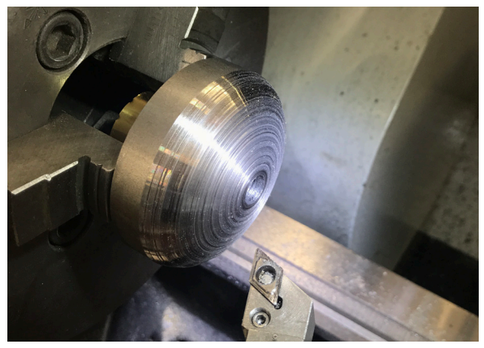


Step 1. Cleaning up rod; raw material

Step 2. Turning diameter to 30mm to fit Thread Cutter; step 1 is done on this part*



Step 3. Thread cutter; Die M30x2 is made



Step 1. Done on Lathe not CNC machine when prototyping; hard to make the half dome shape

Fabrication of the main body caps (Figure 3.67)

The main body is closed off by two caps on either side of the main body, one cap is used to weld the modular attachments onto, which are not designed in this project. The other one has a canal that guides the Driving rod through.

Step 1: A metal rod (diameter 40 mm and around 60mm in length) is used. First step is to clean-up the top, bottom and sides of the material. (yellow)

Step 1*: For the cap with the canal, a hole must be drilled into the material which is large enough for the Driving rod, 10 mm diameter. This is done by using a drill bit of 10 mm after drilling a centric hole, to center the bit. (orange)

Step 2: Turn material off the top side to reach a diameter of 30 mm. (red) This needs to be done to cut thread which fits the M30x2 threaded ends of the main body. (pink) Chamfer the top of the material to make thread cutting possible. This chamfer will help the user with assembling the product as the female and male are easier to connect. Behind the wanted thread length to make sure to create a thread run-out, this ensures a snug fit between the bold and nut part.

Step 3: Use a thread cutter for M30x2 on the material going over the thread runout. To make sure the nut part can be fully pushed over the thread runout.

Step 4: Via the y-axis milling is done, resulting in two flat surfaces on the cap. (black) (Figure 3.68)

Step 5: After having finished the male threaded part, a parting chisel (grey) is used to cut the cap to size.

Fabrication of modular handles (Figure 3.69)

The half dome shape it is hard to make by hand. Therefore, will be done on a CNC lathe. The robot arm chisel (y-axis) then mills away material to get the desired shape. (red)
Step 1: Hole is made (d. 10 mm) through the part and threaded at the bottom end. (orange) (M12x1,75) and part is turned down to 33mm (red). Then the rod is turned around and clamped in on the just turned part.
Step 2: The material gets rounded (blue) and the three flat sides are milled. (red black)

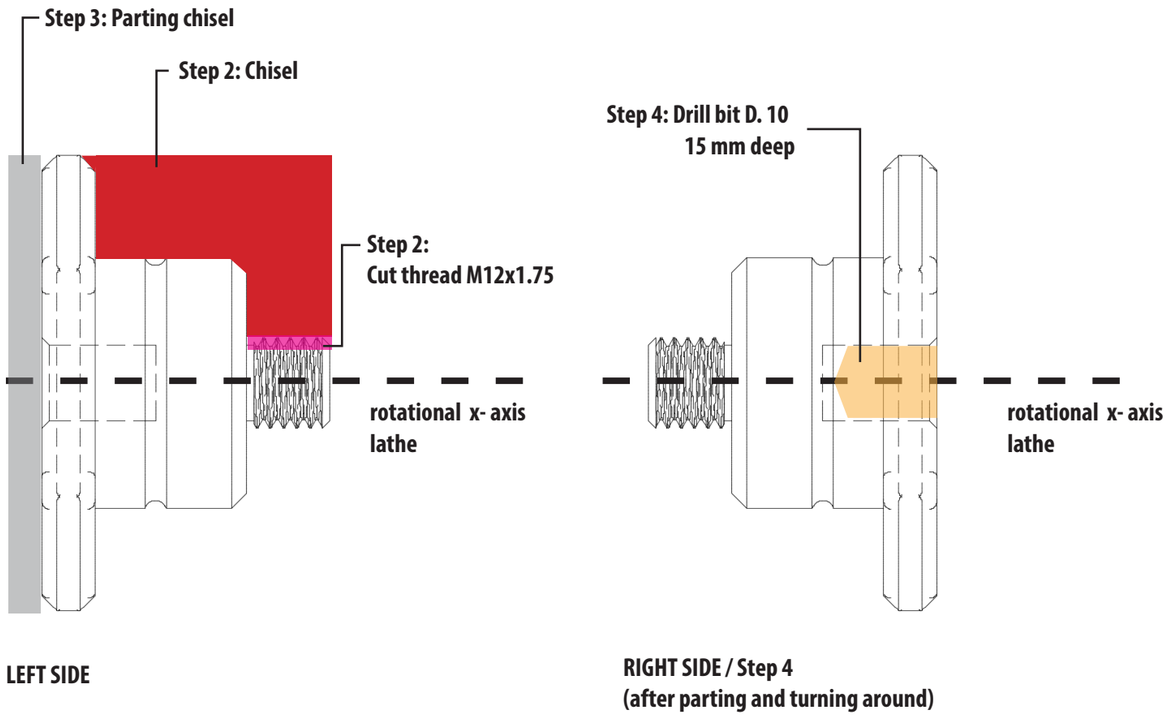


Figure 3.70 Overview of Lathe work steps; Driveshaft

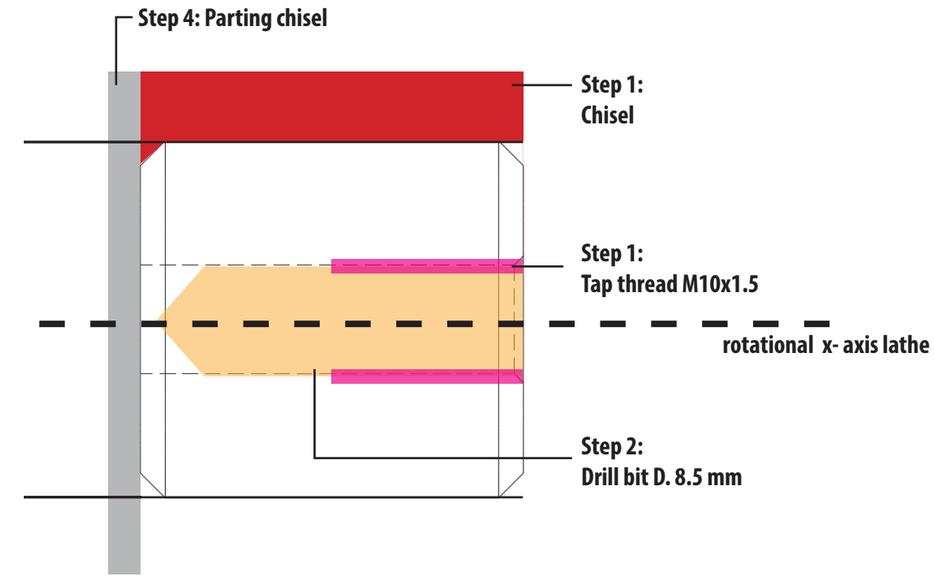
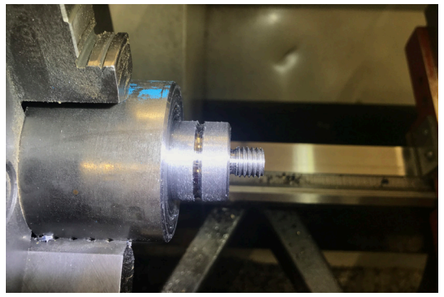
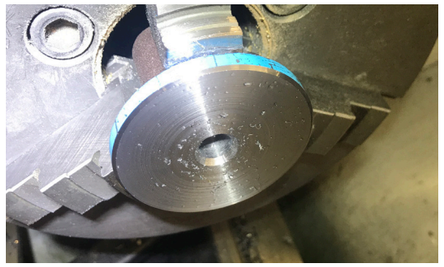


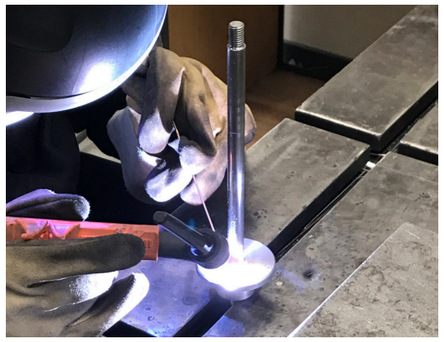
Figure 3.71 Overview of Lathe work steps; POM-C piston



Step 2. Handle set-up and threated end is made



Step 4. Product is turned around; hole is drilled (10mm)



Step 6. Rod is welded into the drilled hole

Figure 3.72. Result fully fabricated Driveshaft with Piston.

Fabrication of the Driveshaft (Figure 3.70)

The Driveshaft consist of a metal rod with a diameter of 12 mm which is welded into the handle set-up part. What makes connection of different handles possible.

Step 1: The metal rod of 10 mm, get threaded (M10x1.5) and a thread run-out is made on one end to fit the POM-C piston. To ensure proper fastning when connecting.
Step 2: The handle set-up is turned to the wanted geometry (red), starting from a 40 mm diameter rod and receives a threaded end. (pink) (M12x1.75)
Step 3: The product is cut a part, using a parting chisel (grey) and turned around (right side)
Step 4: In the other side of the handle set-up a hole (D.10mm) is drilled, 15 mm deep.
Step 5: The Handle set-up get milled flat on three side , similar as in Figure 3.69.
Step 6: The metal rod is TIG welded into the 10mm diameter hole inside of the handle set-up.
Result: in one fabricated Driveshaft part.

POM-C piston (Figure 3.71)

The product only has one POM-C part and this is the piston. In the prototype regular POM (homopolymer) was used. The fabrication of this product was fully done on a lathe, because POM-C is a purchased material which comes in rod shape. (Ensinger plastics, 2020)

Step 1: A rod of 30 mm diameter was clamped into the lathe. Turning the sides clean gives the material to a diameter of approximately 27,90-27,95 mm. This is done to reduce friction and make the piston fit into the main body to guide to forces towards the modular attachments. (red)
Step 2: A center hole is drilled into the top side of the material. After a drill bit of 8,5 mm is used to create a hole through the POM. (orange)
Step 3: M10x1,5 tap is used into the hole of 8,5 mm diameter. To create the nut that will screw the Driveshaft into.
Step 4: Using a parting chisel the POM piston is cut to size. The longer POM-C rod can be pushed out and the next Piston can be produced.

Conclusion

To illustrate how the parts are made the above mentioned production steps are taken. Resulting in a fully fabricated DriveFit (Figure Fix). No problems were encountered during the prototyping process, so fabrication of a product is possible.

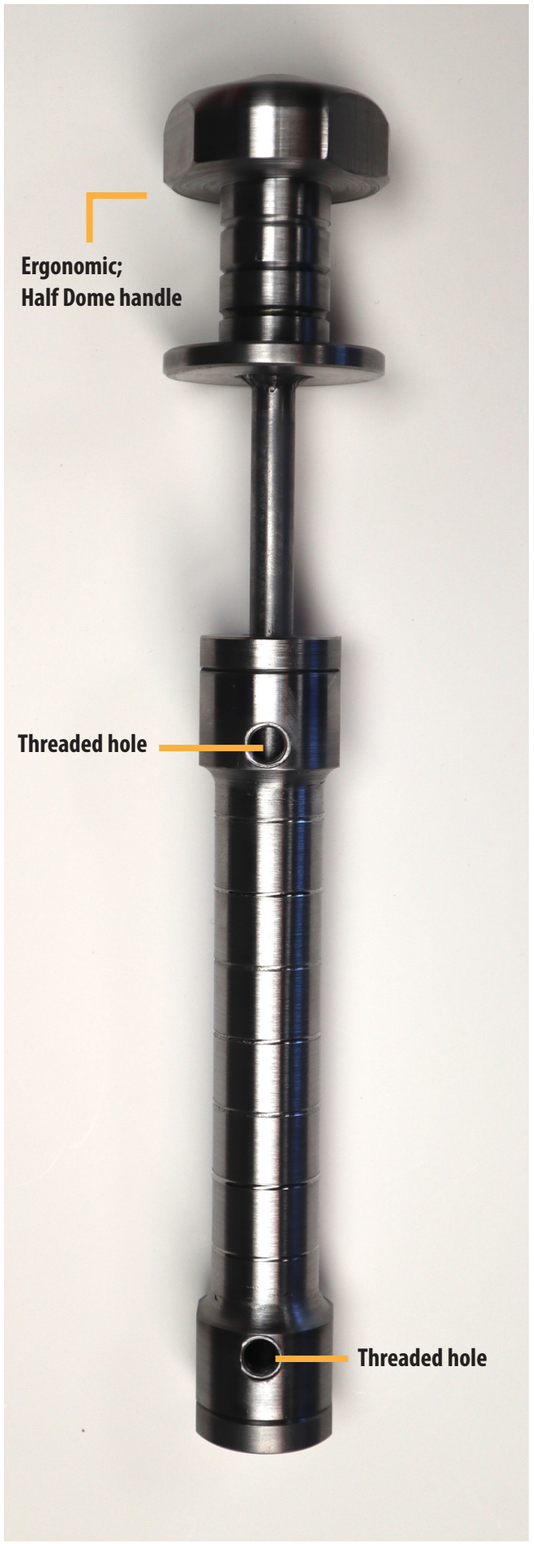


Figure 3.68 Result fully fabricated Driveshaft, with final addaptions.

3.15 Conclusion

The product has one plastic part, POM-C which is chosen to reduce metal-on-metal impact and friction when impacting and extracting actions done with Drive Fit. The other parts are made out of 17-4 stainless steel, to ensure durability of the product. As both chosen materials are medical grade they can be sterilized and are convorm medical device regulations.

After validation testing in the dissectionlab at Erasmus MC, a few changes were made to ensure the DriveFit wil be more ergonomically and fit to the wishes of the surgeon. The main body of the product was altered with a threated hole at each side of the cylinder, this was done to make air escape from the cylinder when using. This results in less friction when using due to the escaping of air. (Figure 3.68 and 3.69)

In the next chapter the final design is showed and eleborated upon. Validation tests in this last chapter will give insights into the future use scenario. Outcomes of these validation test are being translated into recommendations for potential production of the product.

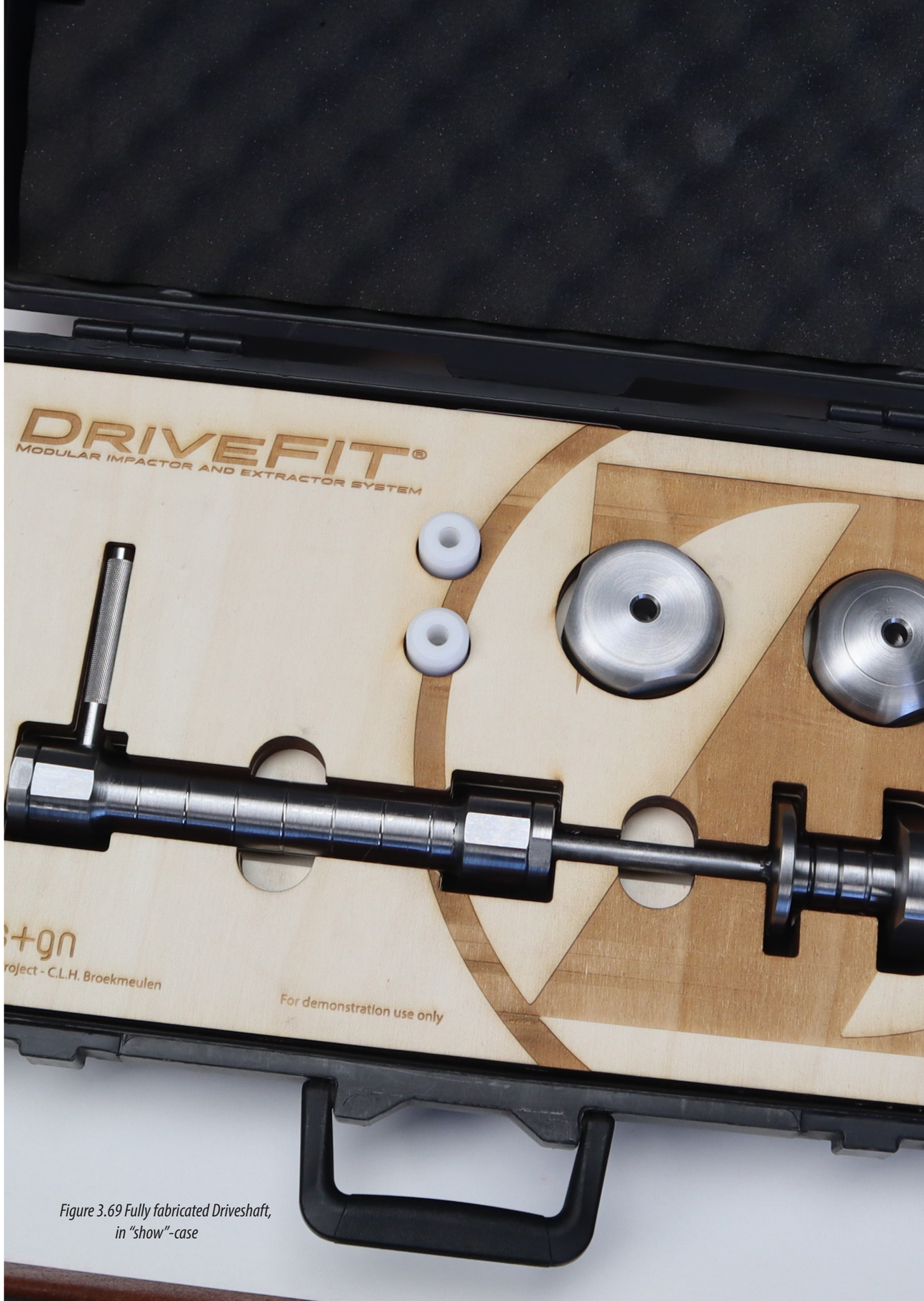


Figure 3.69 Fully fabricated Driveshaft, in "show"-case

4. FINAL DESIGN

DRIVEFIT®
MODULAR IMPACTOR AND EXTRACTOR SYSTEM

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TUDelft
medis+gn

4. FINAL DESIGN

This chapter presents and explains the function of the final design. A new surgical instrument, DriveFit, which can impact and extract various implants and components used to successfully replace the hip joint. Validation tests with the user in context where not possible due to the COVID-19 outbreak, but were creatively solved with previously gathered materials, newly made sound measurements, artificial bones and a fully functioning third prototype. A risk analysis was done to provide insights into dangerous situations and actions that can occur during (unintended) use.

4.1 Introduction

The DriveFit is a re-usable medical instrument, which is specifically designed for THA surgery d. The product can be disassembled to meet sterilization standards and meet the requirements for a class I medical devices. (Fully disassembled: Exploded view Figure 4.3)

The function of this instrument is to Press-fit, impact, (Figure 4.1) implants and components into place (Acetabular cup, Acetabular liner, Femural stem, Femural head). Next to impacting various implants it can function as an extractor for incorrectly placed or infectious implants and extraction of rasps needed to open the Femoral canal. (Figure 4.1) All of this will be done with a reduction of the noise level compared to the currently used mallet. This decrease lowers the sound level to a value below the human pain threshold, decreasing the risk of temporary and long-term noise induced hearing loss.

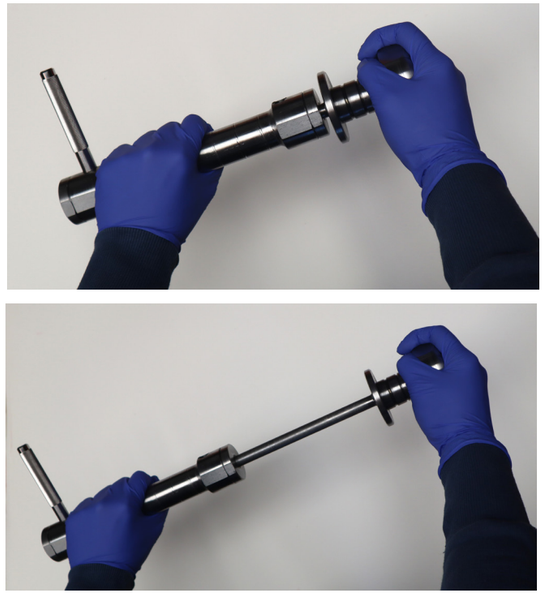


Figure 4.1. DriveFit in impaction and extraction state

The advantages of the DriveFit instrument:

- Decreased sound level compared to current surgical mallet

- Linear movement, impacts in the same direction /location, improving stability and less tissue damage compared to unstable mallet striking (Johnson and Johnson, 2019) (Figure 4.2)

- Better working posture, decreased risk for MSD.
Plus Safer product to work with, less risk of hitting hands and fingers. Resulting in less healthcare institute revenue loss. (Analysis 1.10)

- Can impact and extract various implants/parts
Results in less general instruments needed for surgery. (Other extraction instrument are not needed anymore)

- Modular instrument to fit surgical steps and surgeon's preference.

The main concerns and parts that need more attention. Effects on implants and human tissue (product needs clinical testing) and surgical workflow.

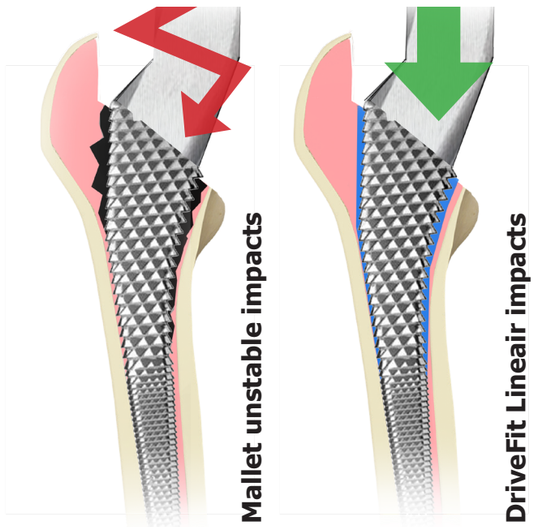


Figure 4.2. More stable lineair forces on the implant

Figure 4.3.Exploded view - disassembly of the product

4.2 Future scenario

Because DriveFit is a new medical instrument for THA surgery, a future working scenario has to be set-out. The paragraph shows the future usage scenario with DriveFit in multiple steps.

Future scenario is the following:

Step 1. Assembling the DriveFit.
*(*assumed the DriveFit is assembled before surgery)*
Step 2. Attaching appropriate implant connector onto the DriveFit, main body
Step 3. Placing the implant/rasp on the implant (component) attachment
Step 4. Impacting and/or extracting the implant
Step 5. Detaching implant connector from DriveFit, for the next surgical step or cleaning after surgery.

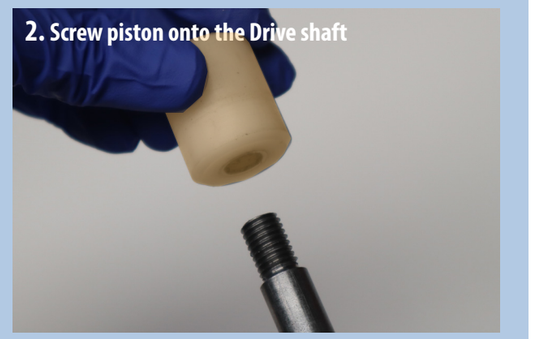
Step 1: Assembling the DriveFit*

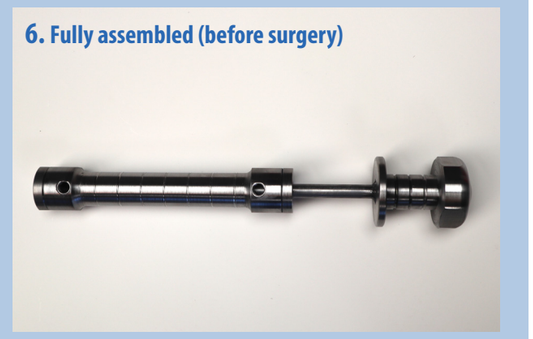
As found in the analyzis phase within this project; the instrumental nurse prepares the instruments before surgery. (Analysis 1.5) Therefore, it is assumed that he/she can assemble the main body, driveshaft with piston and modular handle. This is done so only the modular attachments and handle weights have to be changed. (see Step 1, below)

Step 2 to step 5: Use during surgery

Step 2 to 5 are the scenario steps done during surgery, see the next page for these steps of the future scenario. Steps 3 and 4 are done by the surgeon and the adaptions on the DriveFit are done during or inbetween surgical steps done by either the surgeon but mostly done by the Instrumental nurse. For use scenario with for broaching the Femoral canal (see step 2 to 5, right page) (Analysis 1.4 and 1.5)

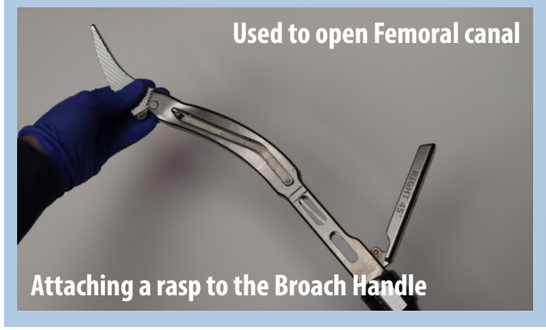
Step 1: Assembling the DriveFit* - Done by instrumental nurse before surgery

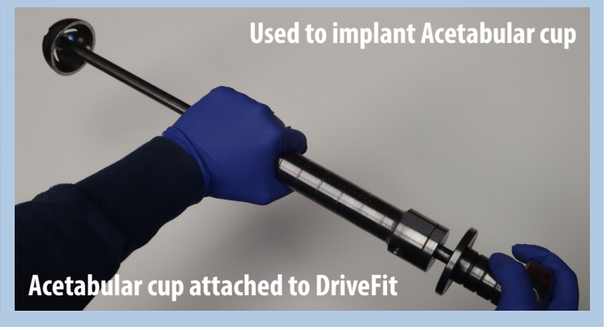




Step 2: Attaching appropriate implant connector onto the DriveFit (*these parts are not designed in the project)

Step 3: Placing the implant or component onto the Attachment (*these parts are not designed in the project)





Step 4: Impact the implant and/or extracting the implant

Step 5: Detaching the implant connector from DriveFit

Figure 4.6. DriveFit main body connection to modular attachments.

Figure 4.6. DriveFit main body with Broach handle attachment

4.3 DriveFit, Main body

The main body of the instrument is the users grip closest to the modular implant attachments and the patients body.

The main body is a re-usable part of the surgical instrument. The function the main body is enclosing the sound source/vibration of the impact and guiding the driveshaft with piston. Furthermore, the main body is the part to attach different implant components to. (Figure 4.6) This makes the main body modular within surgery, as it can be used in different surgical steps. (Figure 4.7 with broach handle connected)

The Main body of the product is an open cylinder (tube) which has some adjustments compared to the previous design and prototype. The cylinder is symmetrical and therefore can be built up to a functioning instrument at both sides, this makes the cylinder a "dummy-proof" component, both ends of the cylinder received a small threaded hole, which functions as the screw-on connection for a steering handle which can be placed perpendicular onto the main body. (Figure 4.7) The threaded holes also serve another purpose, to ensure air can escape from the tube when using the product. When air cannot escape the main body, the user must compress the air in the cylinder as well, which decreases the force emitted and negatively effects the functioning of the product. The sides of the cylinder are milled flat to ensure the product is stable when placed on a table and will not roll.

The diameter and shape of the main body are chosen as it must ensure a powerfull grip for its user, because the tool experiences repeated impact movements. (Figure 4.9) The product is made from stainless steel (17-4, medical grade) and due to its shape, which is circular/turning symmetric, it can be turn milled to the exact dimensions in the fabrication process.

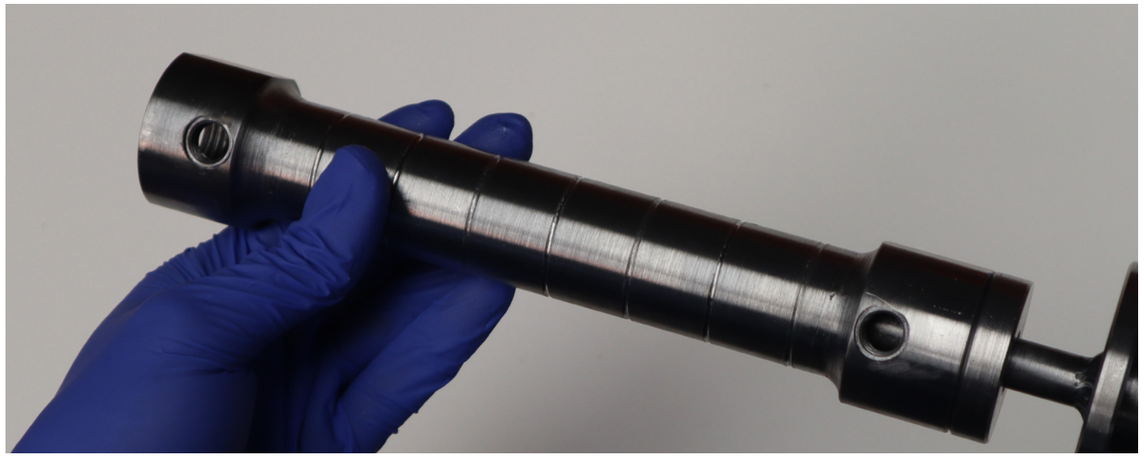


Figure 4.7. DriveFit main body with threaded holes

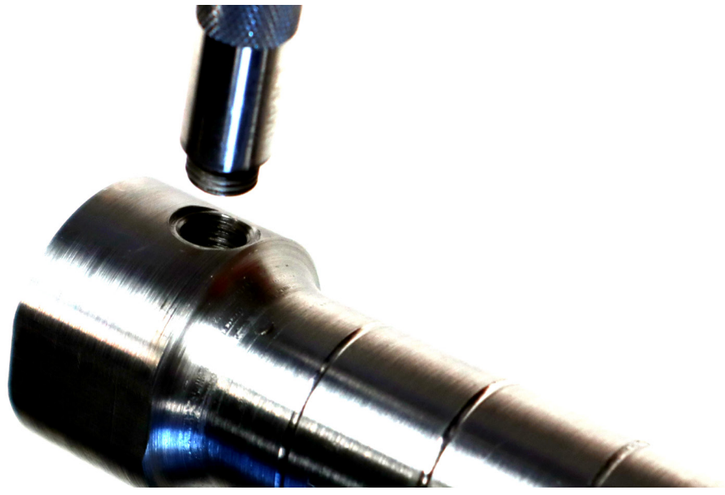


Figure 4.8. Threaded holes allow for connection of steering handle

Figure 4.9. Powergrip onto the mainbody and gripping on the installed steering handle

Figure 4.11. DriveFit Driveshaft, piston and modular handle

4.4 DriveFit, driveshaft and modular handles

The driveshaft is the part that can be moved through the main body to impact and extract implants and components. (Figure 4.10)

The driveshaft and modular handles (Figure 4.11) are made of medical grade stainless steel just as the main body; therefore, these parts are re-usable due to its sterilization capabilities. The piston is made of POM-C, a medical grade plastic that is used to reduce the vibration/sound level and friction within the guiding cylinder when striking. POM-C has superb mechanical properties as it comes to chemical resistance, high strength and toughness. To ensure the product can be cleaned thoroughly before sterilization the POM-C piston and modular handles are free of cavities. (Figure 4.11)

The function of the driveshaft is to convert human forces into impact forces towards the different implant components attached to the bottom of the main body. The driveshaft is a modular part, because different handle shapes and weights can be attached to suit the users' preference. (Figure 4.12)

When looking into the handles I made 3 half dome shapes as they improves ergonomics by changing the grip to a natural position of the hand. The driveshaft has endless possibilities concerning handles a T-handle or straight handles can also be produced to suit orthopedic surgeon preferences worldwide.

Like the main body, the drive shaft and modular handles are bench milled (turning) because of their rotational symmetric configuration. Some parts have been CNC milled as well to ensure they have a flat surface that keeps them from rolling. The advantage of these materials is that the surface hardness prevents bacteria from bonding, their wear resistance when using and "no-loss" of mechanical properties when put through sterilization processes.

Figure 4.10. DriveFit driveshaft and modular handles in hand user

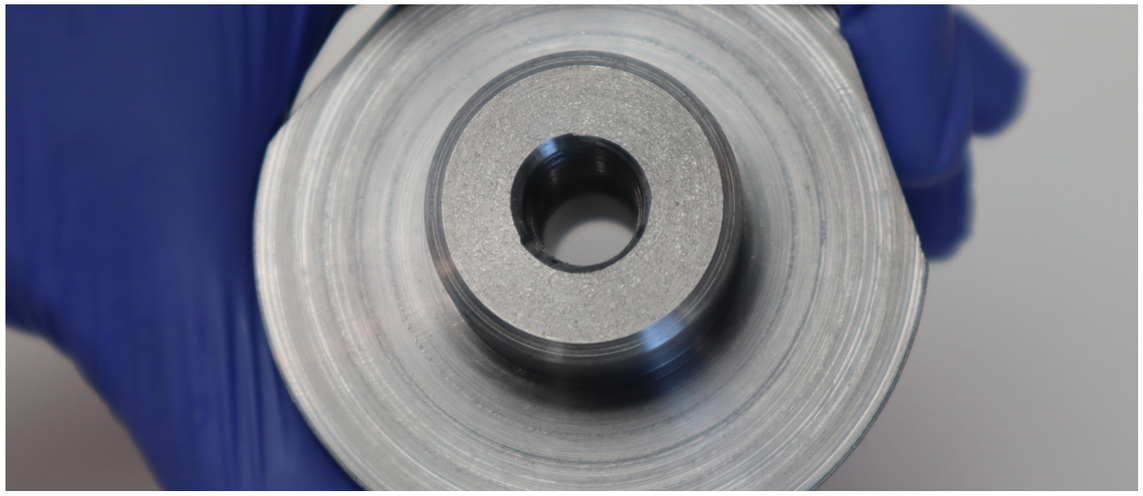


Figure 4.11. DriveFit modular handle free of cavities.

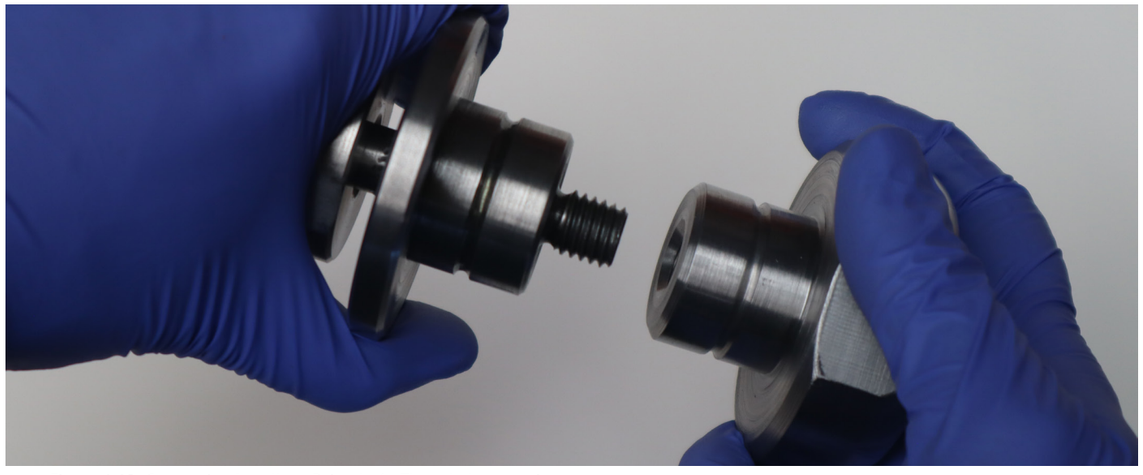


Figure 4.12. Connecting handle to Driveshaft; Threaded connection

4.5. Production cost estimation

The cost price of the DriveFit was estimated by making use of date from Cambridge Engineering Selector (CES 2019) (material price), the final design in Solidworks (mass properties) and "Manufacturing costs build-up" worksheet (Thomassen, Faculty of Industrial Design). This cost estimation provides an indication, note this price is build up out of assumption and therefore not the fixed price.

Batch size

The production cost of the product is depending on the batch size. Nearly 1.4 million hip replacement procedures take place worldwide. (Orthoknow, 2012) As found in the competitor analysis (Appendix A.7), Zimmer Biomet has a market share of 31%. This comes to 434 thousand procedures a year done with Zimmer Biomet implants and instruments. In consultation with the employees from Zimmer Biomet the batch size therefore was estimated at a value around100.000 products.

As found in the CES 2019 (Level 3) the prices for the materials per kg are set below:

- Stainless steel (17-4, medical grade): 4,86 EUR/kg
- POM-C (medical grade): 2,18 EUR/kg

As the DriveFit consists of multiple components with all different weights, an estimations of component weights was found in mass properties option in Autodesk Fusion 360. (Figure 4.14) Since almost all components are made on a lathe and mill, they need to be clamped into the machines and are milled down from a larger piece of raw material. It is estimated that around 50% of the material gets turned into waste in the production process. (Figure 4.15)

Cost-build up

As the material prices are known and the machines used for the production (3.34 Lathe, CNC milling and welding) a cost build-up estimation can be done following the book Industrial Production by Kals, 2007.

Assumpted is that:
- Machines are not an investment anymore, surgical instrument factory already own these machines.
- A batch size of 100.000 products is taken.
- A employee hourly rate is around €10.
- The capacity of the lathe and CNC machine is 4 products an hour operated by 2 persons each.
- Welding is a faster process, approximately 20 pieces can be welded in an hour.
- There are 4 people working on the finishing and polishing of the products. Around 100 products an hour can be finished by them.

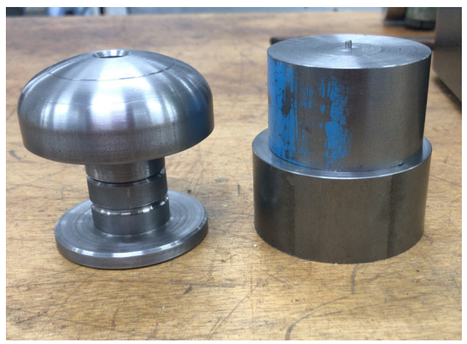


Figure 4.13. The final product vs. Raw material (difference in material is estimated to be around 50%)

Component	Weight in KG	Price in EUR
Cylinder	0,433	2,10
Driving rod	0,308	1,49
Handle weight (3x)	2,4	11,66
Guider cap (2x)	0,18	0,87
Grip	0,058	0,28
POM-C piston	0,02	0,09
Total		€ 16,49
Total (50% waste considered)		€ 32,98

Figure 4.14. Product weight estimation x EUR/kg

Cost build-up of a manufactured part (as by Kals)

Part name	Partname	DriveFit	Production batch	100.000	pcs		per part
Material cost		**gross amount/product**	**unit**	**price/unit**		**amount**	
17-4 Stainless steel	material A	3,379	kg	€ 4,86		€ 16,42	
POM-C	material B	0,02	kg	€ 2,18		€ 0,04	
				total material cost		**16,49 no 50% waste**	**€ 32,93**
Labour cost	**capacity [pieces/h]**	**machine hours**	**machine hourly rate**	**machine-cost**			
CNC machine	4	25000,00	€ 7,00	€ 175.000,00			
Lathe work	4	25000,00	€ 13,00	€ 325.000,00			
Welding	20	5000,00	€ 10,00	€ 50.000,00			
finishing	100	1000,00	€ 1,50	€ 1.500,00			
				total machine cost		**€ 551.500,00**	
machines as above	**man/machine operating ratio**	**working hours**	**man hourly rate**	**man cost**			
CNC machine	2	50.000,00	€ 10,00	€ 500.000,00			
Lathe work	2	50.000,00	€ 10,00	€ 500.000,00			
Welding	2	10.000,00	€ 10,00	€ 100.000,00			
finishing	4	4.000,00	€ 10,00	€ 40.000,00			
				total man cost		**€ 1.140.000,00**	
				total labor cost		**€ 1.691.500,00**	**€ 16,92**
Initial set-up of production	**set-up time [h]**	**hourly rate operator**	**machine hourly rate**	**set-up cost**	**per product**		
	10	€ 24,00	€ 7,00	€ 310,00	**€ 0,00**		**€ 0,00**
General factors							
defects-waste-factor*	1,0%	* defects, ref Kals for %-values				**subtotaal**	**€ 49,85**
overhead factor**	15,0%	** general factor for production facilities					
total	**16,0%**						**€ 7,98**
		C-part for internal calculation			**Production Cost Partname**		**€ 57,83**

Figure 4.15. Material Cost build-up as by Kals, 2007; Worksheet Thomassen, Faculty of Industrial Design)

	Example of retail price calculation based on manufacturing cost (Erik Thomassen).		
K_{Ft}	C Assembled product for internal calculation	**Productname**	**€ 57,83**
F_{OB}	Overhead factor general production cost*	15%	
F_{OV}	Overhead factor sales	5%	
F_W	Profit (unforeseen costs are payed out of profit)	25%	
	Total factor = product of (each of these factors+1) - 1	50,9%	**€ 29,46**
K_V	Outlet price (direct from manufacturing plant)		**€ 87,29**
	Trade margin (eg: importer, wholeseller, supplier, distributor)	30,0%	**€ 26,19**
	Whole sale price		**€ 113,47**
	Retailers margin is very much depending on branch and promotions, varies typically between 25% for a web shop up to 300% for a service oriented retailer on a premium sales location. Strategy and competition define this margin.	100,0%	**€ 113,47**
	Nett retail price (VAT excluded)		**€ 226,95**
	VAT (Value added Tax)	21,0%	**€ 47,66**
	Suggested retail price: regular off-the-shelf price		**€ 274,61**
	*) Before production can even start, many costs have been made. Not just design and engineering but also prototyping in many stages, user testing, market development, compliance cerficiations, patent and so on. If all of these are to be included in the sales price, this adds up to a fair amount.		
	**) high VAT = 21%, low VAT (books, food) = 6%. Also some fees such as waste contribution fee must be incalculated.		

Figure 4.15. Example retail price calculation based on manufacturing cost (Erik Thomassen,IDE) based on Kals, 2007

Conclusion

By making multiple assumptions and filling them into the Material cost worksheet of Thomassen. A production cost price of €57,83 is found. When putting this value into a worksheet to find the example retail price, a price of €274,61 was found.

This is probably a low retail price for a medical product, as margins for consumergoods was used. A medical instrument is not a consumergood and therefore the retail margin is probably higher. A producer of medical products, (service oriented retailer) could set his margin up to 300%, which will change the retail price around 550 euro.

4.6. Evaluation of the final design

Prototype II was tested in the dissection room of Erasmus MC, Rotterdam and proved that the working principle was functioning correctly when implanting and extracting an Acetabular cup. With some minor changes on that prototype, validation testing needs to be conducted, to find problems and potential recommendations for future use.

Future scenario (see 4.2 Future scenario)

1. Assembling the DriveFit
2. Attaching appropriate implant connector onto the DriveFit, main body
3. Placing the implant on the implant (component) connector
4. Impacting and/or extracting the implant
5. Detaching implant connector from the DriveFit
6. Attaching appropriate implant connector for the next surgical step/implant (component)

Goals of validation

A. Sound level measurements of DriveFit compared to current surgical mallet

B. Psychoacoustic listening test, to compare how the current and new sound quality is rated.

C. Opening the Femoral canal, to find potential problems during use in future scenario and to see if the DriveFit can speed up surgery.

D. Fit in the surgical workflow of total hip arthroplasty. Assembly and disassembly was timed to see if instrumental nurses are able to complete the product in-time for surgical use.

E. Ergonomic and risk assessment of DriveFit during use.

*Figure 4.17. Test set-up in sound studio, using current mallet (*studio-door was closed during testing*)*

*Figure 4.17. Testing using DriveFit with steering handle in (*studio-door was closed during testing*)*

A. Sound level measurement

To see what the sound level is of the final concept compared to the currently used surgical mallet and broach handle.

Test set-up

Sound measurements were done in a sound studio (at IDE, TU Delft) using a calibrated Bedrock SM30 class 2 measuring instrument. The Bedrock SM30 was placed on a stand 0.5 meter away from the sound source. (Figure 4.17) In this case the sound source was the impaction and extraction striking of a surgical mallet and broach handle and impaction and extraction movement of DriveFit. During the measurements the Bedrock SM30 registered LAeq (dB-A) and LCpk (dB-C peak) of the sound source.

Note: Testing was done with the steering handle in and out of the main body. (Figure 4.18)

Results

The results of 5 strikes where measured and registered the averages sound pressure levels can be seen in Figure 4.19.

Conclusion

When looking into the measured sound levels we can conclude that the DriveFit has a large noise reduction in all functions, with a maximum decrease of 15.8 dB(C) compared to the currently used products to implant. As the human pain threshold is set around 120 decibels, it can be concluded that the goal of this project is reached by decreasing the sound pressure level to a value below the human pain threshold.

To make sure the product has the same sound reduction during surgery, sound level testing needs to be done during surgery as the acoustics are different in a sound studio than in an operation room.

	Currently used Impact (Old)	DriveFit Impact (New)	Difference Old vs. New	DriveFit without handle impact
LAeq | dB(A)	87.6	70.7	- 16.9	71.3
LCpk | dB(C)	122.5	106.7	- 15.8	108.9

	Currently used Extract (Old)	DriveFit Extract (New)	Difference Old vs. New
LAeq | dB(A)	82.6	71.8	- 10.8
LCpk | dB(C)	116.6	108.7	- 7.9

Figure 4.19. Average results of measurement tests

B. Psychoacoustic analysis

To see how the sound of the new product is perceived a psychoacoustic analysis was done with the current mallet and DriveFit. Twenty-two participants filled in the analysis and rate the sounds. The participants were people working in the Hip department at Zimmer Biomet and Orthopedic surgeons, both have knowledge on the current products used and its sound levels.

Test set-up

At the same time as the sound measurements were done in a sound studio (at IDE, TU Delft) the sound was captured using a digital recorder, Olympus LS-P1. The sound recorder was placed on a stand 0.5 meter away from the sound source. In this case the sound source was the impaction and extraction striking of a surgical mallet on a broach handle and the impaction and extraction movements of DriveFit. The participants did not receive information on which sound they were listening to. All participants had to rate all four sounds.

These sounds were:
- Currently used hammer and broaching handle impaction (sound 1)
- Currently used hammer and broaching handle extraction (sound 2)
- DriveFit impaction action (sound 3)
- DriveFit extraction action (sound4)

Due to the COVID-19 outbreak, this test became an online listening test. Four recorded sounds were set in videos and added to an online form. In this form participants were asked to rate the sounds on a semantic scale, rating 1 to 7. Where a rating of 1 for example corresponds with "not loud" and 7 with "very loud". Participants had to rate sound as they perceived its:

- loud
- sharp
- noisy
- dull
- pleasant
- calm

At the end of the form they were asked to rate the sound on a **sound quality/intensity**, differentiating from faint (around 40 dB) to painfully load (around 120 dB). Questions and full results can be found in Appendix A.20.

Figure 4.20. Test set-up to capture sound (similar to sound measurements done)

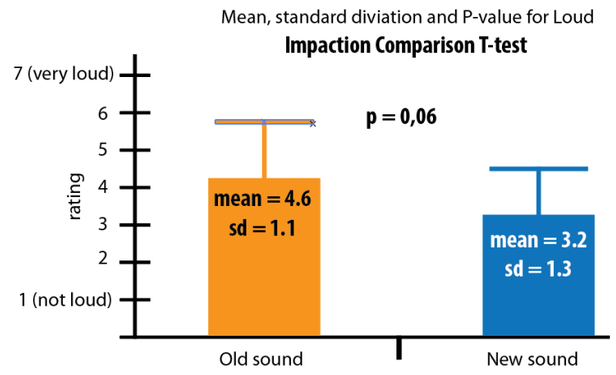


Figure 4.21. Rating loud; Old vs. New Impaction (T-test outcome)

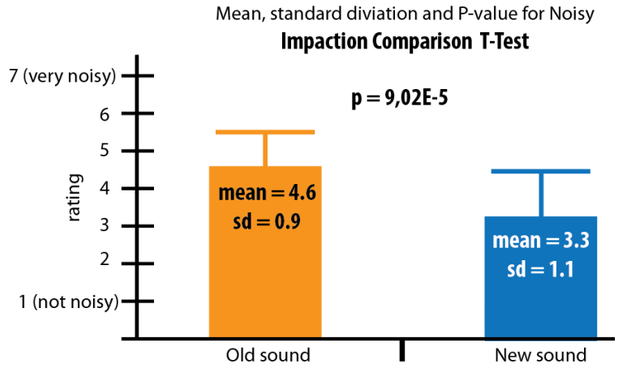


Figure 4.22. Rating noisy; Old vs. New Impaction (T-test outcome)

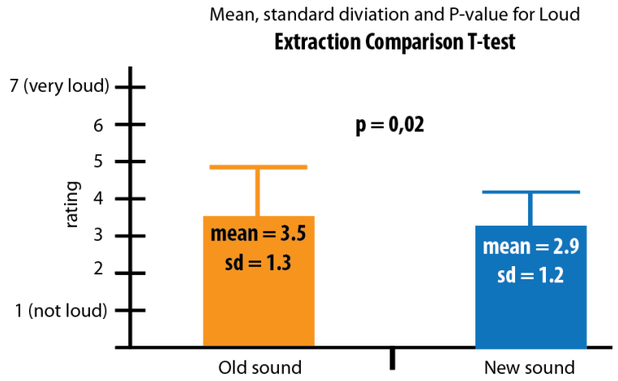


Figure 4.23. Rating loud; Old vs. New Extraction (T-test outcome)

	New impact is an improvement!
Psychoacoustics	Old vs. New impact
loud	0,0006
sharp	1,39E-07
noisy	9,02E-05
dull	0,000293564
pleasant	0,0091
calm	0,0037
sound quality	0,00045

	Only loud is significant
Psychoacoustics	Old vs. New extraction
loud	0,02
sharp	0,25
noisy	0,44
dull	0,1
pleasant	0,46
calm	0,5
sound quality	0,32

Figure 4.24. P-values of both comparision | T-test outcome

Results

To compare the results of the psychoacoustic analysis a T-test was done to see if the sound ratings are significantly different. In this T-test the current impaction was compared to the DriveFit impaction and the current extraction to the DriveFit extraction (old vs. new) As the ratings were participant specific a paired test was chosen. Additionally, a two tailed option was picked as we want to test improvement of a product compared to the existing product. With choosing a two tailed test, we also test for the possibility that DriveFit is rating worse than the currently used surgical mallet. The results of the comparison between impaction sounds "loud" (Figure 4.21), "noisy" (Figure 4.22) and extraction "loud" (Figure 4.23) are put in a graph. All P-values for both comparisons can be found in Figure 4.24. For the rest of the results see Appendix A.20.

A seperate test with only the surgeons was not done, as a T-test can only be performed with more than 10 participants.

Conclusion

As can be derived from the results, a probability value of $p<0.05$ results in a 95% chance that the data set is statistically significant, the new sound therefore is an improvement. For the comparison of impaction all P-values are below 5% (<0.05) so the impaction is rated as a perceived sound improvement overall.

For the extraction, a statistic significance is found for loudness, in all other questions the DriveFit has no significant difference compared to the currently used hammer. This conclusion collides with the results made in the previous (A. sound level measurements), as it was expected that people would perceive the new sounds as a significant improvement. Especially because the sound level went down around 10 decibels and this is perceivable.

Presumably the sound samples do not resemble the usage sounds realistically enough. The reason for this could be that the used microphone to record or the video conversion of the sound samples, flattened the sounds or limited its peaks. A new test where participants use the product could suit this test better as this gives the most realistic sounds and realtime perception.

C. Opening Femoral Canal

To see how the DriveFit functions when preparing the Femoral canal, a Saw bone user-test was done. Also to see if the DriveFit could save time when looking at the current surgical steps.

The Saw bones I used for the test came from Zimmer Biomet and where used in total knee replacement training. Saw bones are seen as replicas of human tissue and widely used for surgical training and product testing. Therefore, can be said that implanting in saw bone needs similar action forces to implant and extract.

Set-up

For this test, 6 Saw bones (SKU: 1145) with a Femur inner diameter of 16 mm. (Sawbones, 2020) where used to implant and extract a rasp. The sawbones where clamped in a vise and hit from the front. (Figure 4.26) Applying force with the left hand and holding (Figure 4.27) the main body of the instrument with the right hand. All participants used their offhand to apply force with, because they were all right-handed.

During testing the amount of impacts were counted for impaction and extraction of the rasp from the bone and the time needed to complete the actions was timed with a Iphone 7 stopwatch function. All participants implanted and extracted on two different saw bones.

Side-note: (Appendix A.21)
- The Sawbones used where left leg human anatomy replicas.
- The broach handle used was a right sided, 45-degree offset, of the patient's body.

Therefore, was chosen to implant the rasp into the knee-side of the Tibia and Femor as this piece of bone would fit the rasp and broach handle orientation was normal. (Figure 4.26)
- Bone was opened up, with hand rasp before started testing. (Appendix A.21) In surgery this is done aswell.
- All 3 participants, had no surgical background.

(Due to the COVID-19 outbreak all participants available were used.)

Figure 4.26. Set-up of bone in the vise; Looking at the Tibia plateau Photo taken after broaching the sawbone

Figure 4.27. Participant impacting rasp into the sawbone

Mallet	Impact strikes	Time in s.
Video 1	18	14
Video 2	22	18
Video 3	20	20
Video 4	22	22
Video 5	20	20
Video 6	18	18
Average	20 strikes	18,6 s

Mallet	Extract strikes	Time in s.
Video 1	6	3
Video 2	7	4
Video 3	8	3
Video 4	5	5
Video 5	6	3
Video 6	7	2
Average	6,5 strikes	3,3 s

Figure 4.27. Impaction and extraction plus timing of current mallet

DriveFit	Impact strikes	Time in s.
Bone 1	24	15
Bone 2	26	19
Bone 3	24	20
Bone 4	27	22
Bone 5	28	21
Bone 6	26	18
Average	26 strikes	19,2 s

DriveFit	Extract strikes	Time in s.
Bone 1	2	1-2
Bone 2	3	1-2
Bone 3	2	1-2
Bone 4	1	1-2
Bone 5	3	1-2
Bone 6	2	1-2
Average	2,2 strikes	1-2 s

Figure 4.28. Impaction and extraction plus timing of DriveFit

Figure 4.29. Impaction with DriveFit changing grip

Results

All participants were able to impact the rasp into the saw bone. The amount of impacts needed to impact the rasp into the bone with the DriveFit was registered, when setting this next to video material shot during observations in hip replacement surgery. We could spot the differences in time and count the impacts needed to implant and extract. See Figure 4.27 for currently used mallet and Figure 4.28 for DriveFit. The 6 videos used where videos of the impaction of one rasp into the marrow and the extraction of one rasp. **Note: Opening-up the Femoral canal for the hip stem takes multiple of impactions and extracting, as a surgeon goes up in size after each broach action (Analyse 1.3 THA procedure)**

Conclusion

This test was improvised with the available participants to see if implanting was possible. All the 3 test participants were able to impact and extract rasps from and into the saw bone. Via this test the implantation and extraction of rasp in and from the femoral canal can be validated. The results show that the amount of impacts is higher than the currently used instrument, this could be due to not having used a starter/the used chisel was to small or impact forces generated are lower than expected. Extraction on the other hand can be done in less actions than using a mallet. By finding this it is possible to state that the usage of DriveFit is similar in surgery speed, because extraction is done with less impacts and time. Impacts of less force and still being able to implant can can also be seen as a plus points. This is said because research from the University of Denver Center for Orthopaedic Biomechanics showed that lower impaction forces may reduce the likelihood of intraoperative calcar (hard bone) fracture. (DePuySynthes, 2019)

During and after testing all participants pointed out that the broach handle adaptor is quite bulky and makes the total instrument long and clumsy. Because of this, participants changed they way of held the product. (Figure 4.29) Therefore, a recommendation for DriveFit will be redesigning the modular adaptors to make the product less long and lumpish. Further testing is advised as the sawbones used did not have to wanted geometry and the broach handle used was for right side only. Plus the participants had no surgical background. If possible, testing should be done in a cadaver lab or with the correct sawbones and attachments by orthopedic surgeons taking dimensions/sizing of bone and tools into account.

D. Fit in surgical workflow

To see if the product fits in the current surgical workflow, a test was set-up were surgical steps where timed. To see if the surgeon and/or instrumental nurse has enough time to assemble, disassemble and use the product.

Set-up

From the materials captured during observations done in hip replacement surgery, the time-slots in-between surgical steps were timed. (Figure 4.30) These where set next to the assembly and disassembly times of DriveFit attachments. Before testing the participants received instruction of how to assemble and disassemble the product. (4.2 Future scenario) Every participant disassembled and assembled the Acetabular cup and broach handle modular attachment 2 times and was timed with a stopwatch.

Assumed is that:

- User has knowledge on the products function, had training or experience with the product. (user is not a layman, but an instrumental nurse with sufficient training and knowledge)
- DriveFit is assembled correctly before surgery by the instrumental nurse and that he/she can do this at ease, this means that only the modular attachments need to be changed in-between surgical steps. (Figure 4.31A)
- Switching between attachment is done with the following assumptions on surgical step 4 to step 8: (Analysis 1.4) (Figure 4.30.B)

+ ***From Acetabular cup impaction to Acetabular liner impaction (step 4 - 5)***= *disassembly of Acetabular to assembly of Acetabular attachment (A)*

+ ***From Acetabular liner placement to Femoral rasping (step 5- 6)*** = *disassembly of Acetabular to assembly of Broach handle attachment (B)*

+ ***From Femoral rasping to Femoral stem impaction (step 6 - 7)*** = disassembly of Broach handle to assembly of Acetabular cup (C) (Figure 4.31B)

+ ***From Femoral stem impaction to Femoral head impaction (step 7- 8)*** = disassembly of Acetabular to assembly of Acetabular attachment (A)

Side-note:

- Changing the plastic piston was done as well. To demonstrate what the time increasement will be when changing the piston if needed.

Results

Three participants assembled and disassembled the product. (Figure 4.32A)The time they needed for the task are set in Figure 4.32B.

Surgical steps (see Analyze phase)	Duration of step (minutes)	Preparation time (seconds)
Step 1. Incision	0:00 - 5:00	Instruments are prepared during incision
Step 2. Oscillating saw	5:00 - 5:30	300
Step 3. Acetabular reamer	7:40 - 9:40	130
Step 4. Acetabular cup	12:00 -12:20	140
Step 5. Acetabular liner	12:20 -12:30	Next instrument is handed over immediately
Step 6. Femoral rasping	17:30 – 19:30	300
Step 7. Femoral stem	22:40 – 23:20	190
Step 8. Femoral head	25:00 – 25:20	100

*Full surgery takes 30 minutes to complete

Figure 4.30. Time-slot inbetween surgical steps

Figure 4.31. How DriveFit will be assembled before surgery with Acetabular cup (Left); Broaching adaptor (right)

Figure 4.31B. Participant assembling Acetabular parts

Attachment and participant	Assembly time (s)		Disassembly time (s)	
P1: Acetabular cup	10	12	8	10
P2: Acetabular cup	12	11	10	9
P3: Acetabular cup	12	10	11	11
P1: Broach change	20	21	23	19
P2: Broach change	21	23	21	20
P3: Broach change	21	23	20	21
P1: Piston change	50*	31	30	31
P2: Piston change	55*	32	32	31
P3: Piston change	37	38	33	30

*Forgot to place guide cap over driveshaft before installing piston

Figure 4.32A. Measurments on assembly and disassembly

Action	Disassembly average time	Assembly average time	Total time needed
(A) Acetabular > Acetabular	9,8	11,2	21 s
(B) Acetabular > Broach	9,8 s	21,5 s	31 s
(C) Broach > Acetabular	20,7 s	11,2 s	32 s

Figure 4.32B. Average time needed to complete surgical steps

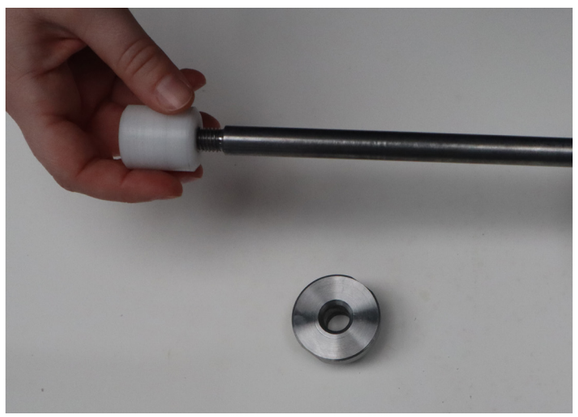


Figure 4.33. Assembling the piston before installing guider cap.

Conclusion

All participants were able to adapt the product to the next surgical step, but timewise the DriveFit loses from the currently used product. When the Acetabular cup is placed the matching liner placement follows immediately, therefore the DriveFit is slower than the currently used product. As the instrument needs to be converted to use for the next surgical step. Currently the surgeon gets handed a different impactor each step and can immediately start with the procedure. Inbetween the other surgical steps the participants had enough time to convert the DriveFit.

When the surgeon or instrumental nurse wants to change the piston the time increasement of this is almost a minute. Due to disassembly and assembly times. When looking at step 7 to 8 this action wont fit the surgical work flow. A problem which was encountered during assembly of the piston, the guiding cap was forgotten by two participants in there first test. In the second test of the same participants this was not done anymore. (Figure 4.33)

The assembly of the off-set broach attachment took more time to assemble and disassemble than the Acetabular cup attachment. In a discussion afterwards the participants concluded that installing this attachment onto the main body was hard and a faster more easy to handle connection has to be designed in the future. A recommendation for this project is redesigning the connection so its faster and easier to install offset pieces.

Due to the COVID-19 outbreak the participants to test with, where the people available and had no background in orthopedic surgery. To see if Drivefit really fits in the current workflow, a test with orthopedic surgeons and instrumental nurses needs to be conducted in context. It is advised to set-up a hip replacement surgery on a cadaver by doing this the usage time can be considered. The results of this test will give a better view on timesaving or a loss of time in THA. This recommended test will give insights in how DriveFit affects surgery time/ workflow, which is an important aspect within surgery.

D. Ergonomic and risk assessment

To see if the working posture and risk level lowered when working with DriveFit, a REBA assessment and risk analysis was done.

Ergonomic assessment

When using a surgical mallet for broaching of the Femur the surgeon had a non-natural, medium risk posture, which means the posture should be further investigated and changed soon. The working posture for the extraction, was seen as very risky, when assessing it with a REBA worksheet. (Fix. Human Factors Engineering) To ensure these postures are improved by using DriveFit, a new REBA assessment needs to be done for both postures. (Hignett, 2000)

Test set-up

During usage of the DriveFit, photos where made of multiple angles of the participant. This was to ensure that an analysis of all the body parts could be done with a good overall view of the Employee. Phots were made of the user:
- *Extracting the femoral rasp with DriveFit (4.32)*
- *Impacting the femoral rasp with DriveFit*

The Load score for the REBA comes from the weight of the product. Coming from Mass properties in Solidworks the weight of DriveFit is estimated at approximately 2,5 kg, which score 0, but due to rapid build up of force and shock a score of +1 needs to be added.

Results can be found in Appendix A.22
New ways of extraction and impaction score Medium Risk.

Conclusion

When looking at the REBA scores, 5 Medium Risk, coming from the worksheet. (Appendix A.22) The lower scores comes from a better neck, trunk and upperarm position (Figure 4. 33) compared to the current working position, which scored 10 as risk value.

Halving the risk value means the DriveFit surely improves the working posture in comparison to the currently used surgical mallet working position. A lower risk means less workrelated injury, because of a better working posture.

Figure 4.32. Extraction with DriveFit

Figure 4.33. Impaction position with DriveFit

Risk assessment

As the healthcare context is a high risk (user) environment a Failure Mode and Effect Analysis (FMEA) was done. Possible risks are identified using the method.

Set-up

This FMEA is done via; Risk Management using FMEA by Stamatis, 2019. Coming from recommendations and problems occured during the previously done validation tests. All potential risk are set out next to eachother. The risks are rated on a scale from one to 10 on three elements, severity (S), frequency of occurence (F) and Likelyhood of detection (D).

- Severity, rated 1 no effect to 10 harzardous without warning
- Frequency of occurence, rated 1 remote - 10 high occurence
- Detection, rated 1 certain - 10 absolute uncertainty

The found number ares then multiplied. The outcome of this is called a "Risk Priority Number (RPN). A value of 1000 is worst and a value of 1 best. For this project I set a action limit at a value of 150. When all values are below this level a new level has to be set and the highest value risks has to be reduced. As a FMEA is not a set approach, but on ongoing process.

Results

The risk values are determined by mulitplying the risk elements resulted in Figure 4.35.

The following potential risks were rated:
1. Hitting your fingers when using DriveFit
2. Outward Sliding of the Driveshaft due to unintended use (used upside down) (Figure 4.37)
3. Placing the piston on before guider cap (Figure 4.31)
4. Dropping the DriveFit at the sterile table
5. Dropping the DriveFit to the ground
6. Failure of the system during insertion
7. Failure of the piston during usage
8. Failure of modular attachment connection

Conclusion

As seen in table 4.36 the RPN of the potential risk is highest for potential risk 2. The rest of the values are below the action limit set at a value of 150. Therefore, it can be said that the potential risk has to be reduced. The recommendation is to adapt the product so this risk is not occuring anymore. After redesigning, the risks have to be assessed again and the action limit lowered to ensure a constant improvement of the product.

Risk	Severity	Frequency	Detection	RPN	Note
1	Low (5)	Unlikely (1)	Low (6)	30	Did not occur in validation testing
2	Hazardous (10)	Repeated (7)	Remote (8)	560	Detection when hit
3	Minor (3)	Occasional (6)	High (3)	54	Will be detected
4	Very Low (4)	Low (3)	Very High (2)	24	Will be detected
5	Minor (3)	Remote (1)	Very High (2)	6	Did not occur in validation testing
6	Minor (3)	Remote (1)	Very High (2)	6	Did not occur in validation testing
7	Minor (3)	Remote (1)	Very High (2)	6	Did not occur in validation testing
8	Minor (3)	Remote (1)	Very High (2)	6	Did not occur in validation testing

Figure 4.35. FMEA results with the potential risks

4.7. Recommendations

From the tests and risk analysis recommendations are set out for the DriveFit surgical instrument.

Functioning of the DriveFit

The function of the DriveFit is to impact, press-fit, and extract implants and matching components during total hip arthroplasty. Impacting and extracting can be done with a reduced noise level and better ergonomics compared to the currently used surgical mallet.

Recommendations

- The user needs training, schooling and instruction manuals of "how to work" with the new instrument as it does not resemble any of the current ways of working. The DriveFit brings a new surgical technique and instrumental feedback into hip replacement surgery. Recommendation in consultation with Orthopedic surgeon (coming from Cadavertesting) and coaches of Zimmer Biomet. The Avenir Hip system gets introduced in the Netherlands in the coming months, this could be the perfect timing of introducing a new instrument as DriveFit, this was told by Zimmer Biomet coaches.

- The functioning of the product was only tested with the placement of the Acetabular cup and the opening of Femoral canal. Other surgical steps where a surgical mallet is used should be tested as well, the surgical steps above where done in consultation with the partnering surgeon and hip department personnel from Zimmer Biomet. Both these also accounted for the highest registered sound levels in hip replacement surgery. (Appendix A.2)

- Placement of the Acetabular cup was validated with one orthopedic surgeon in the cadaver-lab and opening of the Femur with participants with no surgical background. This was impotence due to the COVID-19 outbreak, before production and marketing testing with multiple orthopedic surgeons should be done to ensure proper functioning in hip replacement surgery.

- It should be validated what the effects of the DriveFit are on human tissue. For this reason, clinical testing needs to be done to ensure the product is safe to use on a patient.

-The product will need to comply with Medical Device Regulations (MDR), only then it can get a CE marking and be marketed.

- During this project it was assumed that the current product does not convey sound cues to its user. My focus was on sound level and not on frequency, due to the measurement equipment available. When doing new measurements in the operation room the frequency has to be measured as well. Frequency changes could show different results than the measurements done on sound level. If the frequency changes over the course of the procedural steps, sound cues could be of interest for adapting DriveFit. Therefore, its recommended to do frequency measurements during procedural steps. When frequency sound cues are present, the DriveFit should have a similar efflux in frequency to ensure it conveys sound cues to the surgeon.

- The connection between the main body and modular attachment has to be redesigned or improved to ensure the user an easier and faster way of connecting attachments. A new connection should be designed that is able to withstand forces coming from opposing directions and keep the main body free of cavities. An idea for a connection is a camlock system, this system consists of a female coupler and male adaptor part. When pushing the coupler in the adaptor and closing the cams, a link will be made. With the intergration of the connection the product loses it symmetric design but stays free of cavities. (Figure 4.36)

- To improve its functionality in operation, the modular attachments should be adjusted to ensure that the DriveFit is less bulky and clumsy. By redesigning the modular attachments, it becomes easier to handle and more convenient to operate with.

- Holding the product in a not working position could make the handle and driving rod move outwards, this can result in unnecessary harm or injury for surgeon, staff or patient. To get rid of this problem a stop or lock can be implemented to keep the driving rod from moving out when not holding horizontally or topside up. An idea for this is a magnet as 17-4 stainless steel is magnetic. This magnet can be placed in between the main-body and Drive shaft. (Figure 4.37)

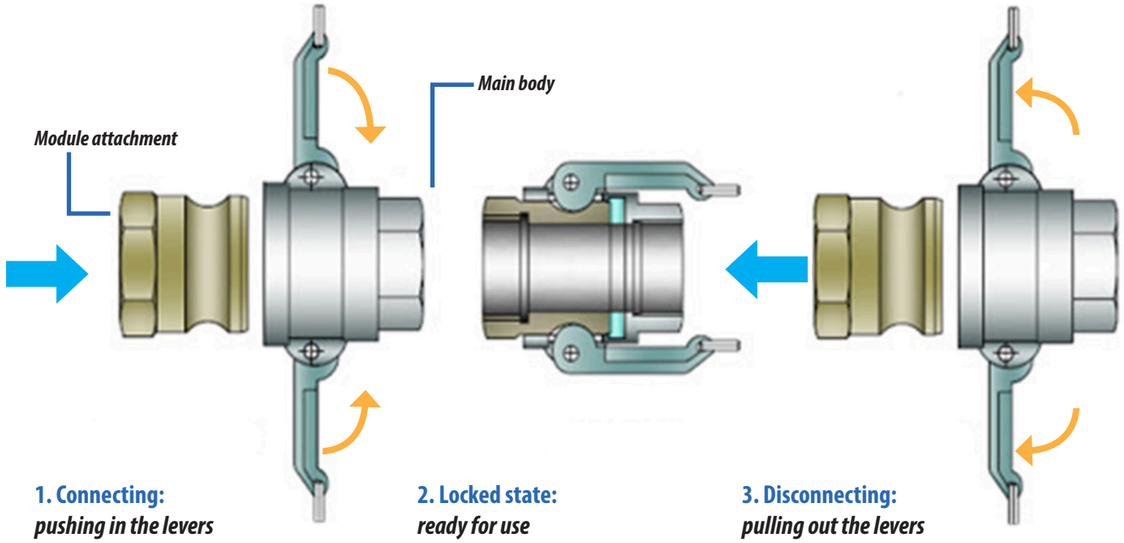


Figure 4.36. Camlock as modular attachment connection

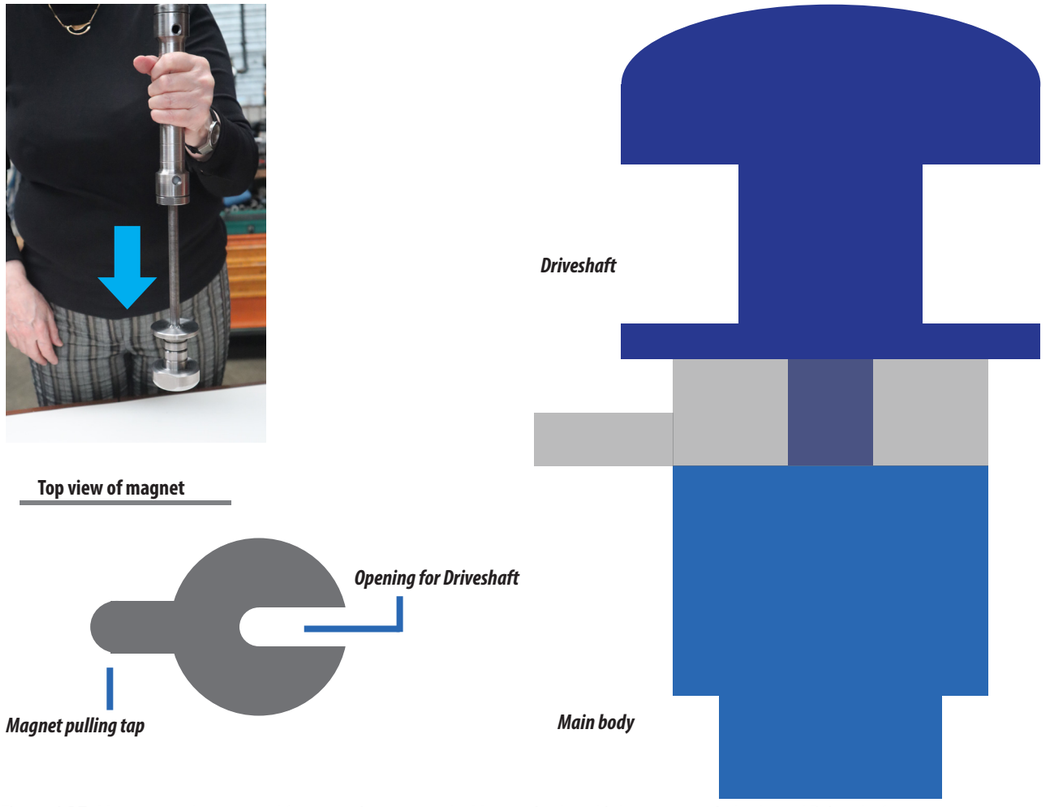


Figure 4.37. Magnet used to stop rod from moving outwards; Magnet is placed inbetween main body and Drive shaft

4.8 Conclusion

The DriveFit is produced out of a medical grade stainless steel main body (17-4) and driveshaft plus POM-C piston. The production cost for a batch size of 100.000 pieces, the production cost is estimated at 57,83 Euro.

From the testing can be concluded that the DriveFit can be used to open the Femoral canal and implant/ extract Acetabular cups, thus it functions as it is intended. It is recommended to change the connection between the main body and implant (component) specific attachments, as this is seen as not that user-friendly. An idea for a new connection is the usage of a camlock, where a lever locks the cam into the edge of a male adaptor. Research into a new connection and its ability to handle impact forces in both directions needs to be done.

New measurements on frequency should be done, to see if the currently used product conveys frequency sound cues to its user. If these sound cues are present in the current used product DriveFit should transfer these in a similar course. If this is not possible surgical training with DriveFit is needed, to get grip and understanding of the new way of working.

Finally, DriveFit needs clinical testing and testing by professionals to see how it functions in an operation room and what is does to human tissue. Next to these future validation actions, the product needs to be checked concerning medical device regulations as it needs to comply with the regulations to receive CE-marking for a class I reusable instrument.

DriveFit presentation case made for graduation ceremony

5. EVALUATION

Assembling the DriveFit, modular impactor and extractor

Contents

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5. EVALUATION

The final concept was validated in Chapter 4. Final Design and the results were translated into recommendations. This final chapter is an evaluation on the project, final design personal reflection and final recommendations.

5.1 Reflection on project

The starting point of this graduation project was the design brief written in consultation with Zimmer Biomet and my graduation team:

"Reduction of harmful noise pollution during hip replacement surgery"

With a set assignment and goal:
"During this project a tool or instrument will be designed that focusses on the reduction of harmful noise exposure in order to limit temporary and long-term noise-induced hearing loss."

As the design brief implied there where some challenges that had to be considered. Probably the most important one was that a new design needed to convey sound cue feedback equal to the current used products. Through dB-measurements and observations was found that sound cues where not used by surgeons. During the greenlight meeting, discussion showed that frequency should have been looked at. To have certainty if sound frequency could be used as sound cue. My focus was on decibels as it was found that hearing problems were mostly coming from an exposure to high sound pressure levels, as said in ARBO legislation. Next to a focus on sound level the measurement device (I was allowed to use) could only measure decibels or frequency and not both at the same time. Further research must be done, to see if frequency changes are found and are used as surgical cues. If frequency changes are present and this is used by surgeons, DriveFit should have similar efflux of frequency.

In the analysis phase it became clear that the scope of this project had to be broadened. Solving the noise level during surgery was one problem, but seeing surgeons work with products that were not safe and ergonomic broadened the problem-solving space. By writing a design vision, which stated in short; "Designing a tool that not only solves the noise problem but will improve safety and ergonomics for its user." Only solving the sound problem would have put a band aid on the project and not solve it entirely. By broadening the scope, the workload of this project increased and the amount of gathered data as well. It was hard to get through these huge amounts of gather date and to extract conclusions from this.

After doing multiple observations in the operating room it can be concluded that getting a good understanding of the procedure and why they use instruments in certain ways is necessary to fully grasp the problems surgeons and OR staff are facing. Total hip replacement surgery observations showed that the workflow of a procedure is important as surgical teams must be one well-oiled machine and the product should fit right in. A take-away from this is that observations had to be done in other operating rooms/hospitals as well and even different surgeries. The available expertise and facilities were important influencers that altered the projects outcome. Having seen more experts could have changed some design decisions, as the observed surgeries were specialized in only performing THA day in day out in the same team.

In consultation, with Zimmer Biomet a decision was made to focus on the replacement of the sound emitter and to not design the modular attachments as these are specifically engineered to fit the implants and matching components. Also designing implant attachments could have been a project on itself as you need understanding and knowledge of human anatomy and the behavior of human tissues.

In the detailed design phase, prototypes were made that could be mass produced. The design did change throughout the embodiment phase. Before production of the prototypes build plans and constructional drawings were discussed with PMB staff. (workshop personnel at faculty of industrial design) Learning to work with machinery was difficult at first and time consuming, but this was something I had not done previously and really wanted to add to my skillset.

In the Final design phase, a prototype was made that was entirely new in terms of surgical technique and functioning. DriveFit was not a surgical mallet as it had different instrumental (tactile) feedback as currently used products. Testing with the final prototype was important in this project, to validate its working principle of being able to extract and impact implants and/or components. During cadaver lab/dissection room testing the product showed its strengths as being a substitute for the mallet, but training was needed to get acquainted with its functioning as it was so different.

Evaluation phase: COVID-19 outbreak

In my eyes outbreak of this virus ruined the last phase of my project, just after my greenlight meeting the country went into quarataine. This meant that testing and evaluating with surgeons and healthcare personnel was not possible anymore. Luckily enough improvising and finding creative solutions to test the final prototype could be done. Just before the closing of the faculty and in the analysis phase I gathered lots of information which was usefull in the end. Looking back on this last phase I am very pleased to have found solutions to perform my final evaluations. In the end, these give a nice overview of the functionality, problems and recommendations for further development of the product.

Conclusion

As I look back on the project, building multiple prototypes was a nice addition, because it makes testing possible. On the otherhand it is really time consuming, therefore I rather had not made the final prototype, because it gave lots of stress and the time it cost could have been spend on other parts of the project.

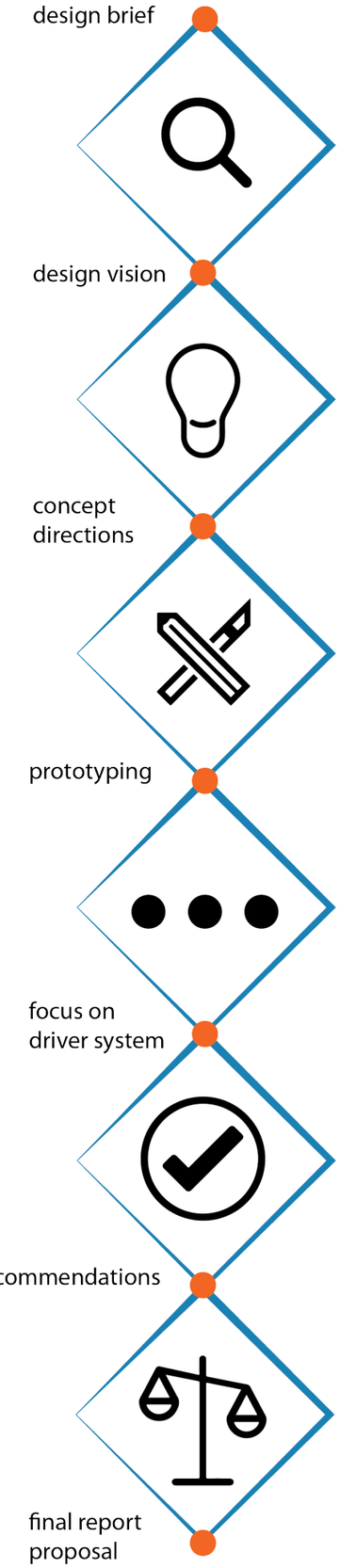


Figure 5.1. Project approach / set-up

5.2 Reflection on the final product

At the start of this project was discovered that sound cues, when interpreting produced sounds, where not used by surgeons to validate surgical goals. So, the product did not have to convey this feedback information to the surgical team, as research showed that sound cues where not necessarily a validation, but tactile feedback was. Current precautions and hearing protections where not used, due to the blockage of necessary communication during surgery.

When doing observations in context it was found that noise levels where not the only problem when looking into total hip replacement surgery. Surgeons complained about bad working postures and pain due to hammer usage on hand, wrists and elbows. This resulted in a design vision where I wanted to reduce the noise level and the risk of musculoskeletal injury. When brainstorming and designing other industry principles became of large interest. The combination of two products seemed interesting and was combined and iterated into DriveFit, a modular surgical instrument for total hip arthroplasty, with multiple functionalities.

When comparing DriveFit against the currently used surgical mallet. It safe to say it has multiple benefits:

Decreased sound level compared to current surgical mallet, to a level below the human pain threshold. Maximum sound level reduction of more than 15 decibels.

Can impact and extract various implants (components). A product with multiple functions that will result in less instruments needed for surgery and thus in OR. (Cheaper surgery)

Linear movement, all impacts are in the same direction and location. No more off axis strikes, when using a hammer. Resulting in more broaching stability, which results in less collateral damage to bone tissue. All in all, improving implant fit.

Better working posture. Resulting in a decreased risk for MSD. Surgeons can work more ergonomically and therefore are less prone to repetitive strain injuries. Resulting in less working days missed by a orthopedic surgeon, decreasing a potential revenue loss; up to 189.000 USD.

Safer product to work with. The user does not have to watch his hands during usage, he can fully focus on the operating field. Due to its extraction function the awkward extraction hammering position gets avoided. Resulting in less risk of hitting hands and fingers.

Modular instrument to fit surgical steps and surgeon's preference. Most currently used instruments do not give surgeons the option to combine product elements into a tool that can is change-able during surgery. A surgeon now can operate with a more tailored tool, set-up to suit his preference.

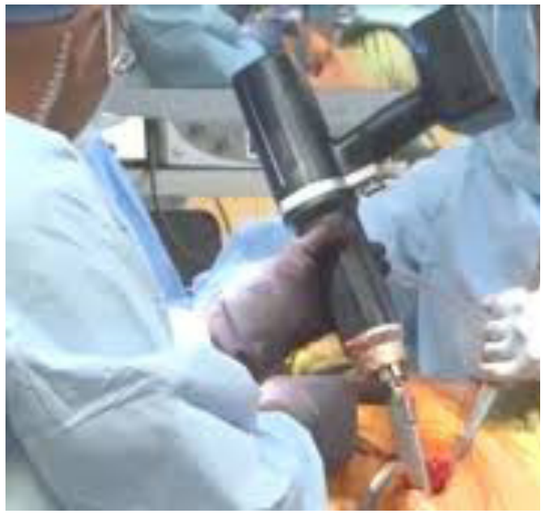


Figure 5.2. KINCISE by DePuy Synthes; used to opening up the Femoral canal (DePuy Synthes Companies Youtube, 2020)

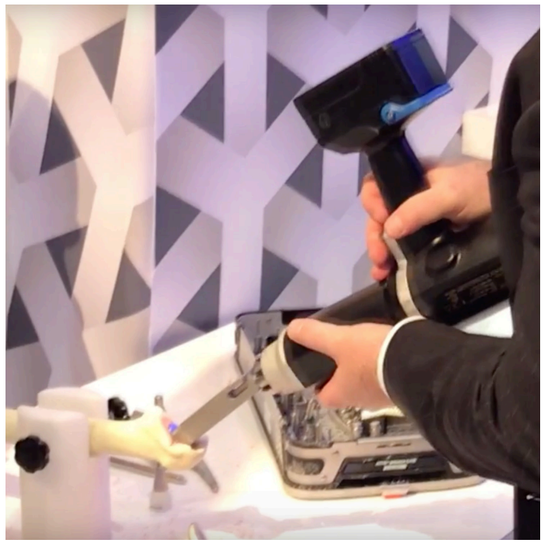


Figure 5.3. Is KINCISE an ergonomic product? (DePuy Synthes Companies Youtube, 2020)

Competition

When looking into other orthopedic companies it can be concluded than none of the competitors designs products with a noise reduction in mind. (Appendix A.7) In my eyes this is strange as the peak levels recorded in orthopedic surgery go beyond the human pain threshold of hearing and will permantly damage your hearing.

Looking at a competitor product, the DriveFit can be put next to the KINCISE, a surgical automated system by DePuy Synthes (Figure 5.2) (Competitor Analysis, Apendix A.7). As they both eliminate handheld mallet use and deliver linear driving force to implant. By replacing the mallet both solutions may reduce potential work-related injuries.

Some points of interest and questions arise when comparing DriveFit to the KINCISE are:

- DriveFit is not electric powered, therefore **not dependent on battery power**.

- KINCISE will decrease the fatigue level of a surgeon, **no manual impaction is needed**.

- The KINCISE seems to be a **non-ergonomically instrument**. Upside down used drill? (Figure 5.3)

- Is an **automated system better** in providing a surgeon with the instrumental feedback they want or use?

- **DriveFit is modular** and capable of being adjusted to surgeons preferance.

- KINCISE is because of its form/design probably **more expensive** than DriveFit?

Conclusion

In my eyes I can say that the outcome of this project could become a real success as it reduces the noise level to a value below the human pain threshold and provides surgeons with a better working posture compared to the currently used products. Next to its application in hip replacement surgery, the product can be used in other operative settings as well. When looking at orthopedic surgery in general, the surgical mallet is commonly used for example in knee arthroplasty. Knowing from a previous project done for Zimmer Biomet on total knee. DriveFit could be implemented in this orthopedic branch as well. Not to mention other industries where mallet/hammer usage is common, such as construction work, automotive body shops or carpentry. The product will need some adaptions, but its general working principle will be accorded its full weight.

During meetings and tests with the people from Zimmer Biomet and surgeons from Bergman Clinics, I received super enthusiastic reactions about the outcome. They told me the product should be implemented in hip replacement surgery or be the foundation of a new product. Their enthusiasm resulted in an embargo on the design and a potential patent pending. Maybe this is not the shape or form surgeons will see in future hip replacement surgery, but DriveFit is a nice foundation for Zimmer Biomet to develop further upon.

Mentionable: For my graduation ceremony a suitcase (Figure 5.4) was made for DriveFit. As my presentation probably will be online, the suitcase does not really fullfil its task and potential.

Figure 5.4. Presentation suitcase for DriveFit.

5.3. Personal reflection

At the start of the project, I set some personal goals mostly on applying knowledge I gathered within my Medisign specialization and Human Factors study abroad. Next to the will of applying knowledge, I wanted to learn more about surgical techniques and sound principles in general as I find these interesting and aim to work in the medical industry after graduation.

When looking back on the project my aim was to deliver a working prototype which could be validated by orthopedic surgeons. Unfortunately, this was not possible in the end, due to covid-19 . With the materials received from Zimmer Biomet and the data gathered before lockdown and some improvising, I managed to test the prototype and find recommendations for it, while not having tested it with healthcare professionals.

During this project an iterative process of prototyping was used. I used these prototypes to validate functioning and different features of the product. When communicating with the supervisory team, company and end user this was of great help. The prototypes made sure problems could be encountered and discussed. The advantage of a prototype, is getting a feel for use, dimensions and potential problems as it gives more information than a drawing or render.

Immediately after the start of the project I found out that the most challenging part of this project was its context and how to validate the product on different levels as replicating medical settings or testing in the medical context is hard to set-up. In the end this worked out good enough, but some of my request where not answered at all. I made two online forms for orthopedic surgeons in general and wanted to set up a brainstorm for the product design, finding solutions for other problems which occur. With the help of enthusiastic Zimmer Biomet product specialists and an enthusiastic surgeon this all worked out in the end.

Personal and project goals achieved:

- Making working surgical prototypes, that can be subjected to near real-life testing.
- Learn new skills and knowledge when it comes to prototyping.
- Learning more about orthopedic surgery and surgical techniques

Looking back at this project I want to notify a few things. As some things I am really pleased with and others I would have done differently.

1. Observations in the operating theatre should have been taken before writing the project brief. This would have resulted in a more defined brief and scope of the project.

2. When looking back I gather lots of information in the first phase, which was not really necessary. Visiting and observing at 13 surgeries took a large amount of time, which could have been put in other parts of the project. In the end, this saved my project as these large amounts of material made me able to do some last validation tests, due to the COVID-19 outbreak.

3. Building fully functioning protypes was one of my learning and project goals. As I wanted to showcase my final prototype in my graduation presentation. Learning to use machinery can be quite time consuming but I would recommend doing this as it is a great addition to your knowledge on fabrication processes and skillset. After all I am happy with the made prototypes but there could have been less and time could be spend on other parts which are not my strenghts, such as writing.

4. A few weeks after my midterm meeting a potential patent and embargo was mentioned. The idea of receiving an embargo on the project, made me nervous and increased the pressure on something that was already well loaded. This resulted in my going into the project even deeper, which was probably not necessary.

5. A brainstorm or discussion with a group of surgeons could have helped, for validation, inspiration and advice. I tried to set-up brainstorm sessions and even send mails to the Nederlandse Orthopaedische Vereniging, but got no responses. After trying a few times I went on with the project without these sessions.

6. During this project weekly updates had to be send to all stakeholders, with short evaluations on the progress and results within the different design phases. I tried update all stakeholders as often as possible by meeting with them or via mail/whatsapp. In the last half of the project, I could have done this more consistent to keep everyone involved.

7. Knowing when to stop; To be really honest, when I get enthousiastic on a project, I keep putting and putting more time into it. This results in eventually having to carry a bigger workload than the idea was at the start. My graduation team noticed this and already gave me more time, between greenlight and delivery. In following project and/or work, I should know when to stop and not keep on going.

6.4. Final Recommendations

As the recommendations on the project and the product are made. The following take-aways are here for Zimmer Biomet and others that maybe continue with this project or start a similar one.

- Clinical testing needs to be done on DriveFit as the effects on human tissue, such as bone and bone marrow are not known.

- Make products more ergonomically, this can be easily done by making product "modular". Modularity is an easy and well-known phenomenon that can be applied into many medical products. This ensures that the user can adapt products to his own preferences and even different operational steps. Taking this approach could lead to reducing risks for surgeons and potential safety hazards during surgery.

- Recommended is setting up a platform where the product portfolio is combined with the procedure workflows. This can be of great help when designing new instruments as it gives a great overview of all tools available. A company as Zimmer Biomet is divided into different specialisms all looking at different types of surgery. This is said because I think the Hip section can get inspiration from other sections instruments such as knee, shoulder and spine.

- Dive into other industries to see their tools and instruments, to learn and get inspired when designing new products.

6.5 Peroration

I look back on this project with a sense of proudness, as I think the outcome of the project can be of large interest within different usage markets. Its not only a product that can be used to impact and extract hip surgery related implants and tools, but can be adapted and serve a purpose in other surgical contexts.

To end, I am happy to have done my final project with Zimmer Biomet. A few years back they sparked my interest in healthcare and orthopedics with a project on Knee arthroplasty. This interest is kept alive by this project and hopefully I can use my enthousiasm, interest and gathered knowledge from these projects in a future career.

Thank you!

Impacting rasps into SAWBONES, using DriveFit as impactor

REFERENCES

Amaro, J., Magalhães, J., Leite, M., Aguiar, B., Ponte, P., Barrocas, J., & Norton, P. (2018). Musculoskeletal injuries and absenteeism among healthcare professionals-ICD-10 characterization. PloS one, 13(12), e0207837. https://doi.org/10.1371/journal.pone.0207837

ARBO. (2019) Artikel 6.8. Maatregelen ter voorkoming of beperking van de blootstelling Retrieved November 9, 2019 from https://wetten.overheid.nl/BWBR0008498/2020-02-1/#Hoofdstuk6_Afdeling3_Paragraaf2_Artikel6.8

ARBO. (2019) Lawaai op Werk. Retrieved on November 25, 2019 from https://www.arboportaal.nl/onderwerpen/geluid

Bergman Clinics. (2016) Kwalliteitsrapportage - Heupklachten. Retrieved November 10, 2019, from https://www.bergmanclinics.nl/files/mediaCategories/kwaliteititems/2016-kwaliteitsrapportage-heupvervanging-25-5-2018.pdf

CCOHS. (2020) Hand Tool Ergonomics - Tool Design. Retrieved on 14 January, 2020 from https://www.ccohs.ca/oshanswers/ergonomics/handtools/tooldesign.html

Choi, J. H., Cho, Y. S., Lee, J. W., Shin, H. B., & Lee, I. K. (2017). Bacterial Contamination and Disinfection Status of Laryngoscopes Stored in Emergency Crash Carts. Journal of preventive medicine and public health = Yebang Uihakhoe chi, 50(3), 158–164. https://doi.org/10.3961/jpmph.17.013

Collins, S. (2016) Zimmer Biomet's Competition in the Hip Implant Market. Yahoo Finance. Retrieved on 20 November 2019 from https://yhoo.it/3eLKJxu

Dailymail. (2016) Having an op soon? DON'T watch this video: Horrific clip shows doctor violently beating metal rod out of patient's bone with a HAMMER. Retrieved on December 1, 2019 from https://www.dailymail.co.uk/health/article-3584553/Having-op-soon-DON-T-watch-video-Horrific-clip-shows-doctor-violently-beating-metal-rod-patient-s-bone-HAMMER.html

Davis, W. T., Sathiyakumar, V., Jahangir, A. A., Obremskey, W. T., & Sethi, M. K. (2013). Occupational injury among orthopaedic surgeons. The Journal of bone and joint surgery. American volume, 95(15), e107. https://doi.org/10.2106/JBJS.L.01427

Davis, W. T., Fletcher, S. A., & Guillamondegui, O. D. (2014). Musculoskeletal occupational injury among surgeons: effects for patients, providers, and institutions. The Journal of surgical research, 189(2), 207–212.e6. https://doi.org/10.1016/j.jss.2014.03.013

DePuy Synthes (2019) Kincise surgical automated system University of Denver study. Retrieved on 6 March 2020 from https://www.jnjmedicaldevices.com/sites/default/files/user_uploaded_assets/pdf_assets/2019-06/KINCISE%20University%20of%20Denver%20Study%20-%20DSUS%202019.pdf

DePuy Synthes (2019) Kincise Automated System Brochure. Retrieved on 6 December 2019 from https://www.jnjmedicaldevices.com/sites/default/files/user_uploaded_assets/pdf_assets/2019-09/108420-190702%20%20KINCISE%20ACTIS%20Surgeon%20Brochure.pdf

Drury, CG (1980) Handles for manual materials handling. Journal for Applied Ergonomics. Volume 11, Issue 1, 35-42. https://doi.org/10.1016/0003-6870(80)90120

Elert, G. "The Nature of Sound – The Physics Hypertextbook". Retrieved October 30, 2019, from https://physics.info/sound/

Encyclopedia Britannica. (2020) Compressed air technology. Retrieved on 2 February, 2020 from https://www.britannica.com/science/compressed-air

Ensinger Plastics. (2020) Kunststof material selectie. Steriliseerbaar en autoclaveerbaar. Retrieved on January, 2020 from https://www.ensingerplastics.com/nl-nl/halffabrikaten/kunststof-materiaal-selectie/steriliseerbar-en-autoclaveerbar

Ensinger Plastics. (2020) POM medical grade. Retrieved on January, 2020 from https://www.ensingerplastics.com/en/shapes/biocompatible-medical-grade/pom-c-acetal

Esser, A. C., Koshy, J. G., & Randle, H. W. (2007). Ergonomics in office-based surgery: a survey-guided observational study. Dermatologic surgery : official publication for American Society for Dermatologic Surgery [et al.], 33(11), 1304–1314. https://doi.org/10.1111/j.1524-4725.2007.33281.x

EUROPEAN PARLIAMENT AND OF THE COUNCIL (2017) MDR Regulation (EU) 2017/745 on medical devices. Retrieved on December 18, 2019 from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&qid=1559821569806&from=EN

Fowler, D. (2019) Preparing for MDR: Don't Forget about Class I Reusable Devices. Retrieved on December 18, 2019 from https://www.medtechintelligence.com/feature_article/preparing-for-mdr-dont-forget-about-class-i-reusable-devices/

Franks, JR. (2016) Preventing occupational hearing loss. A practical guide. (NIOSH) Retrieved on 19 November, 2019 from https://www.cdc.gov/niosh/docs/96-110/pdfs/96-110.pdf

Fritsch, M. H., Chacko, C. E., & Patterson, E. B. (2010). Operating room sound level hazards for patients and physicians. Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology, 31(5), 715–721. https://doi.org/10.1097/MAO.0b013e3181d8d717

Fullick, P. (2001) Physics for AQA. Chapter 9.3 Pressure in liquids and gasses.
p(166 – 169) Oxford, United Kingdom; Heinemann Educational Publishers.

Gloag D. (1980). Noise and health: public and private responsibility. British medical journal, 281(6252), 1404–1406. https://doi.org/10.1136/bmj.281.6252.1404
Guiness world record. (2000) Individual loudest scream. Retrieved on December 3, 2019 from https://www.guinnessworldrecords.com/world-records/67537-loudest-scream-individual?fb_comment_id=733210456788946_889995584443765

Hignett, S., & McAtamney, L. (2000). Rapid entire body assessment (REBA). Applied ergonomics, 31(2), 201–205. https://doi.org/10.1016/s0003-6870(99)00039-3

Hansen, C. (2001) Fundamentals of acoustics. Retrieved October 27, 2019, from https://www.who.int/occupational_health/publications/noise1.pdf

Health and Safety Execu¬tive. (2012) Noise at work: A brief guide to controlling the risks. (PDF) Retrieved on December 6, 2019 from https://www.hse.gov.uk/pubns/indg362.html

Hoffman, Peter J.; Hopewell, Eric S.; Janes, Brian (2015). Precision Machining Technology. Cengage Learning. p. 252. ISBN 9781285444543. Retrieved 3 January 2017.

Innomed. (2019) Hip revision and extraction instruments. Retrieved on November 8, 2020 from http://www.innomed.net/hip_ex_extractors.htm#CupXHipExt

Inspectie SZW. (2019) Basisinspectiemodule; Blootstelling aan geluid, Ministerie van Sociale Zaken en Werkgelegenheid. Retrieved on November 14, 2019 from https://www.inspectieszw.nl/publicaties/richtlijnen/2017/05/09/bim-blootstelling-aan-geluid

IPA. (2019) The Designers, Specifiers and Buyers Handbook of Perforated Metals. Retrieved on November 18, 2019 from http://www.iperf.org/perforating/knowledge-center/designers-specifiers-and-buyers-handbook-perforated-metals/

Johnson and Johnson. (2019) KINCISE™ Surgical Automated System. Retrieved on 12 February, 2020 from https://www.jnjmedicaldevices.com/en-US/product/kincise-surgical-automated-system

Johnson and Johnson Medical Devices. (2019) Kincise video-popup. Retrieved on February 10, 2020 from https://www.jnjmedicaldevices.com/en-US/video-popup/kincise-surgical-automated-system-features-video
Kant, I. J., de Jong, L. C., van Rijssen-Moll, M., & Borm, P. J. (1992). A survey of static and dynamic work postures of operating room staff. International archives of occupational and environmental health, 63(6), 423–428. https://doi.org/10.1007/BF00386939

Kato Fastening Systems, Inc. (2020) Coarse threads vs fine threads. Retrieved on January 8, 2020 from https://www.katofastening.com/article/coarsevsfine.html

Kawase, T., Yamaguchi, K., Ogawa, T., Suzuki, K., Suzuki, M., Itoh, M., Kobayashi, T., & Fujii, T. (2005). Recruitment of fusiform face area associated with listening to degraded speech sounds in auditory-visual speech perception: a PET study. Neuroscience letters, 382(3), 254–258. https://doi.org/10.1016/j.neulet.2005.03.050

Kilbom, s., Armstrong, T., Buckle, P., Fine, L., Hagberg, M., Haring-Sweeney, M., Martin, B., Punnett, L., Silverstein, B., Sjøgaard, G., Theorell, T., & Viikari-Juntura, E. (1996). Musculoskeletal Disorders: Work-related Risk Factors and Prevention. International journal of occupational and environmental health, 2(3), 239–246. https://doi.org/10.1179/oeh.1996.2.3.239

Laffosse J. M. (2016). Removal of well-fixed fixed femoral stems. Orthopaedics & traumatology, surgery & research : OTSR, 102(1 Suppl), S177–S187. https://doi.org/10.1016/j.otsr.2015.06.029

Lehto, M. Landry,S. (2013). Introduction to Human Factors and Ergonomics for Engineers. (2e ed.) Chapter 3. Design of work areas, tools and equipment. Google books, Boca Raton, USA; CRC press.

Love, H. (2003), Noise exposure in the orthopaedic operating theatre: a significant health hazard. ANZ Journal of Surgery, 73: 836-838. doi:10.1046/j.1445-2197.2003.02776.x
Merritt Hawkins and DePuySynthes (2019) AMN Healthcare Company. 2019 Physician inpatient/outpatient revenue survey. 2019. Occupational Injuries and Hazards Faced by orthopedic surgeons. Retrieved on 12 November 2019 from https://www.jnjmedicaldevices.com/sites/default/files/user_uploaded_assets/pdf_assets/2019-11/122660-190906%20Occupational%20Hazards%20Orthopaedics.pdf

Mdc. (2019) Technical documentation for reusable surgical instruments (class Ir) Retrieved on December 18, 2019 from https://www.mdc-ce.de/fileadmin/user_upload/Downloads/mdc-Dokumente/Englisch/3680_001_07_2019_TD_class_Ir.pdf

Michel, A., Bosc, R., Meningaud, J. P., Hernigou, P., & Haiat, G. (2016). Assessing the Acetabular Cup Implant Primary Stability by Impact Analyses: A Cadaveric Study. PloS one, 11(11), e0166778. https://doi.org/10.1371/journal.pone.0166778

Mirbod, S. M., Yoshida, H., Miyamoto, K., Miyashita, K., Inaba, R., & Iwata, H. (1995). Subjective complaints in orthopedists and general surgeons. International archives of occupational and environmental health, 67(3), 179–186. https://doi.org/10.1007/BF00626350

Miskovic, D., Rosenthal, R., Zingg, U., Oertli, D., Metzger, U., & Jancke, L. (2008). Randomized controlled trial investigating the effect of music on the virtual reality laparoscopic learning performance of novice surgeons. Surgical endoscopy, 22(11), 2416–2420. https://doi.org/10.1007/s00464-008-0040-8

National Institutes of Health. (1990) Noise and Hearing Loss. Retrieved on 4 November, 2019 from https://consensus.nih.gov/1990/1990noisehearingloss076html.htm

NAPIER J. R. (1956). The prehensile movements of the human hand. The Journal of bone and joint surgery. British volume, 38-B(4), 902–913. https://doi.org/10.1302/0301-620x.38b4.902

Nave, R. (2005) HyperPhysics: Sound and hearing. Georgia State University, Department of Physics and Astronomy. Retrieved on November 14, 2019 from http://hyperphysics.phy-astr.gsu.edu/hbase/Sound/soucon.html#soucon

North American Stainless. (2020) Long Products Stainless Steel Grade Sheet. 17-4 Grade stainless steel (630). Retrieved on 6 February, 2020 from https://www.northamericanstainless.com/wp-content/uploads/2010/10/Grade-630-17-4.pdf

NIOSH. (2019) Criteria For a Recommended Standard: Occupational Noise Exposure. Retrieved on November 14, 2019 from https://www.cdc.gov/niosh/docs/98-126/default.html

O'Daniel, M. Rosenstein, A. (2008) Chapter 33 Professional Communication and Team Collaboration. Retrieved on 19 November, 2020 from https://www.ncbi.nlm.nih.gov/books/NBK2637/#ch33.r1

OSHA. (2019) OSHA – Occupational noise exposure 1910.95. Retrieved on November 14, 2019 from https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.95

Patkin, M. (2001) A Check-List for Handle Design. Department of Surgery.The Royal Adelaide Hospital, Retrieved on February 13, 2020 from http://ergonomics.uq.edu.au/eaol/handle.pdf

Park, A., Lee, G., Seagull, F. J., Meenaghan, N., & Dexter, D. (2010). Patients benefit while surgeons suffer: an impending epidemic. Journal of the American College of Surgeons, 210(3), 306–313. https://doi.org/10.1016/j.jamcollsurg.2009.10.017

All data retrieved /gathered from Pheasant, comes from the following book:
Pheasant, S. Haslegrave, C. (2005) Bodyspace: Anthropometry, Ergonomics And The Design Of Work. (3e ed.) Google books, Boca Raton, USA; CRC press.

Preutenborbeck, Martin & Reuter, Julian & Ferrari, Elisabetta. (2019). Quantitative characterisation of impaction events during femoral broaching in total hip arthroplasty. Medical Engineering & Physics. 76. 10.1016/j.medengphy.2019.12.004.

Pyroteknc (2019). Sorberscreen ST. high-performance metal perforated sound absorber. Retrieved on November 23, 2019 from https://www.pyroteknc.com/products/sorber/sorberscreen-sta/

Radermacher, K., von Pichler, K. C., Erbse, S., Boeckmann, W., Rau, G., Jakse, G., & Staudte, H. W. (1996). Using human factor analysis and VR simulation techniques for the optimization of the surgical worksystem. Studies in health technology and informatics, 29, 532–541.

Roozenburg, N. F. M., & Eekels, J. (1995). Product design: fundamentals and methods. Chichester, UK; John Wiley & Son Ltd.

Sawbones. (2020) Knee with Three Non-Stretch Ligaments, Full Length. (SKU: 1152) Retrieved on 4 April 2020 from https://www.sawbones.com/knee-large-left-foam-cortical-shell-w-cancellous-w-nylon-ligaments-1145.html

Sancho-Bru, J. L., Vergara, M., Rodríguez-Cervantes, P. J., Giurintano, D. J., & Pérez-González, A. (2008). Scalability of the muscular action in a parametric 3D model of the index finger. Annals of biomedical engineering, 36(1), 102–107. https://doi.org/10.1007/s10439-007-9395-6

Soueid, A., Oudit, D., Thiagarajah, S., & Laitung, G. (2010). The pain of surgery: pain experienced by surgeons while operating. International journal of surgery (London, England), 8(2), 118–120. https://doi.org/10.1016/j.ijsu.2009.11.008
Stamatis, D. (2019) Risk Management Using Failure Mode and Effect Analysis (FMEA). Googlebooks. Milwaukee, Wisconsin; ASQ Quality Press.

Stringer, B., Haines, T. A., & Oudyk, J. D. (2008). Noisiness in operating theatres: nurses' perceptions and potential difficulty communicating. Journal of perioperative practice, 18(9), 384–391. https://doi.org/10.1177/175045890801800903

Thomassen, E. (2015) Excel worksheet Manufacturing Costs Build-up.xlsx. Retrieved via Faculty of Industrial Design, Technical University of Delft. Based on:
- Kals, H. (2007) Industrial productie; Het voortbrengen van technische producten. (4e ed.) Amsterdam, Nederland: Boom.

Trung Le, N., Straatman, L. V., Lea, J., & Westerberg, B. (2017). Current insights in noise-induced hearing loss: a literature review of the underlying mechanism, pathophysiology, asymmetry, and management options. Journal of otolaryngology - head & neck surgery = Le Journal d'oto-rhino-laryngologie et de chirurgie cervico-faciale, 46(1), 41. https://doi.org/10.1186/s40463-017-0219-x

Van Beek. (2004) Ontwerpen op Bedrijfszekerheid. Versie december 2004, Hoofdstuk 1, ontwerpen van schroefverbindingen. Retrieved on 12 Februari, 2020 from https://docplayer.nl/9400178-Ontwerpen-op-bedrijfszekerheid.html

Van Terheijden, C. (1971) Gereedschapswerktuigen 1. (6e ed.) Groningen, The Netherlands; Wolters-Noordhoff

Van Straaten Medical. (2020) Instrumentenmakerij. Retrieved on 6 March, 2020 from https://vanstratenmedical.com/nl/fotos-instrumentmakerij/
Wang, C. Gao, H. Yu,L. Yu, T. Yan,W. Xue, Q. (2016) Portable Low-Frequency Noise Reduction Device for Both Small Open and Closed Spaces. Hindawi. Volume 2016. Article ID 6241935. 11 pages. https://doi.org/10.1155/2016/6241935

Way, J. Long, A. Weihing, J. Ritchie, Jones, R. Bush,M. Shinn, JB. (2013) Effect of Noise on Auditory Processing in the Operating Room. Journal of the American College of Surgeons. p933–938. https://doi.org/10.1016/j.jamcollsurg.2012.12.048

Willett K. M. (1991). Noise-induced hearing loss in orthopaedic staff. The Journal of bone and joint surgery. British volume, 73(1), 113–115.
Williams, D., Dingley, J., Jones, C., & Berry, N. (2010). Contamination of laryngoscope handles. The Journal of hospital infection, 74(2), 123–128. https://doi.org/10.1016/j.jhin.2009.09.015

Wong, W. (2010) The Risk Management of Safety and Dependability
A Guide for Directors, Managers and Engineers. (ed) Chapter 3.5.2. Noise measurement.
, Pages 57-58. Googlebooks, Boca Raton, USA; CRC Press.

Yasobant, S., & Rajkumar, P. (2014). Work-related musculoskeletal disorders among health care professionals: A cross-sectional assessment of risk factors in a tertiary hospital, India. Indian journal of occupational and environmental medicine, 18(2), 75–81. https://doi.org/10.4103/0019-5278.146896

Zimmer Biomet. (2004) Intramedullary Nail Extraction Surgical Techniques. Retrieved on 2 December. 2019 from https://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/000-surgical-techniques/trauma/intramedullary-nail-extraction-surgical-technique.pdf

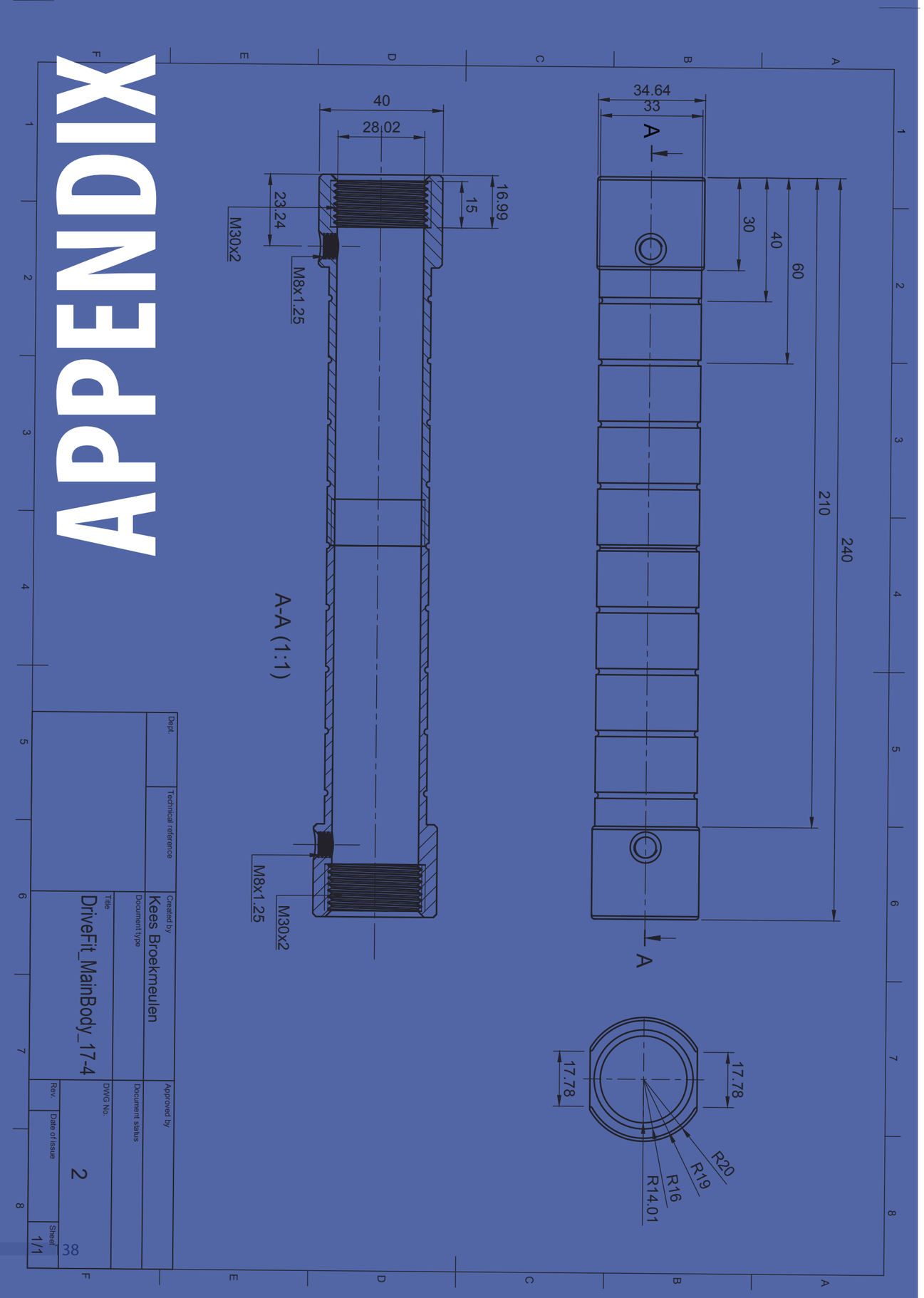
Zimmer Biomet. (2019) Avenir Femoral Hip system. Retrieved on 10 March, 2020 from https://www.zimmerbiomet.com/medical-professionals/hip/product/avenir-total-hip-replacement-implant-system.html

Zimmer Biomet. (2019) Continuum-acetabular-system-surgical-technique. Retrieved on 4 January, 2020 from https://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/000-surgical-techniques/hip/continuum-acetabular-system-surgical-technique.pdf

Zimmer Biomet. (2019) Fitmore® Hip Stem Surgical Technique - Zimmer Biomet. Retrieved on 4 January, 2020 from https://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/000-surgical-techniques/hip/1013.1-GLBL-en%20Fitmore%20Surgical%20Technique%20-%20FINAL.pdf

Zimmer Biomet Holdings Inc. (2018). Annual Report 2018. Retrieved on 2 December, 2019 from https://investor.zimmerbiomet.com/~/media/Files/Z/ZimmerBiomet-IR/documents/annual-reports/2018-annual-report.pdf

APPENDIX



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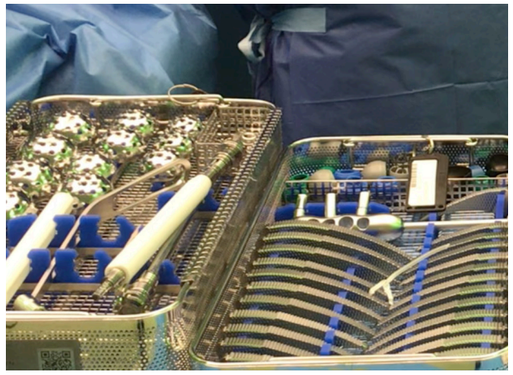
TU Delft medis+gn

BERGMAN CLINICS

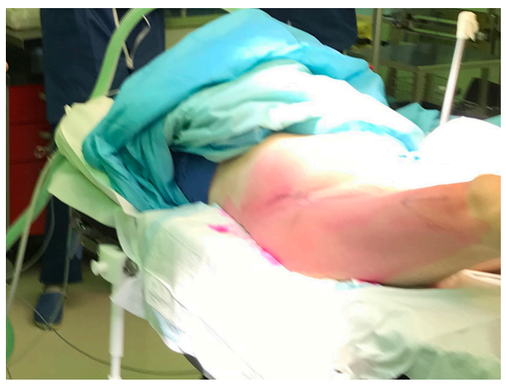
ZIMMER BIOMET

A.1 Observations THA (total hip arthroplasty)



(1.1) Prepared tools

(1.2) Dressing up to be sterile



(1.3) Patient is Anasthetized and incision site gets cleaned

Total Hip Replacement procedure

Date: 21-10-2019 / 01-11-2019 / 14-11-2019
Location: Bergman Clinics, Naarden and Rijswijk/The Hague
Material: Photos and videos shot by iPhone 7 by C.L.H. Broekmeulen

Note: Surgeons and staff signed a consent form, to be able to include information gathered into research, photos and videos. (Appendix A.24)

Observations Total Hip Arthroplasty (Naarden)

Dates: 21-10-19 (Naarden)
Location: Bergman Clinics, Naarden
Total: 9 THA operations (Anterior)

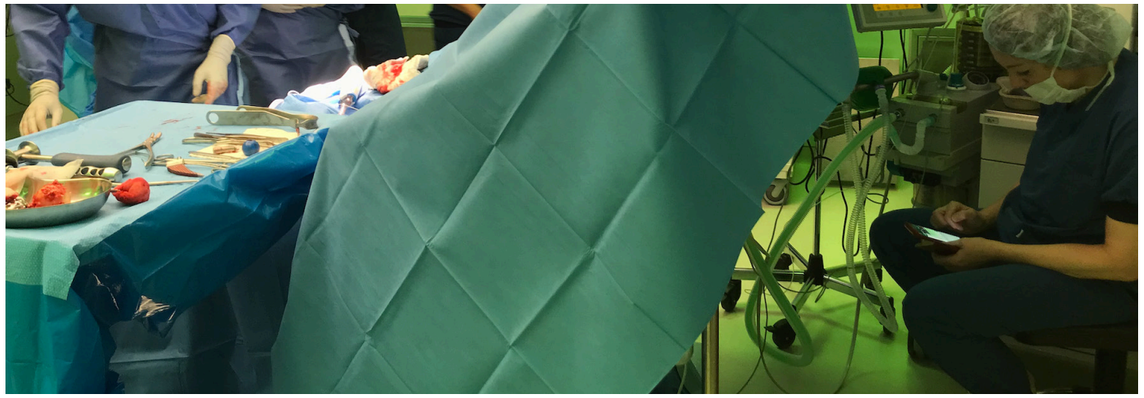
Introduction and goal of observation

At the 21th of October observations were conducted at the Bergman Clinics. Goal of the observations was to learn more on the procedure, context, user and surgical workflow. Orthopedic surgeon, H. Bouma and operation room team performed seven total hip replacement on that day via the anterior approach. The surgeon conducts yearly around 200-250 total hip replacements surgeries. Goal of this observation was focused on the main sound emitters concerning the noise level and the instruments used to perform surgical steps with.

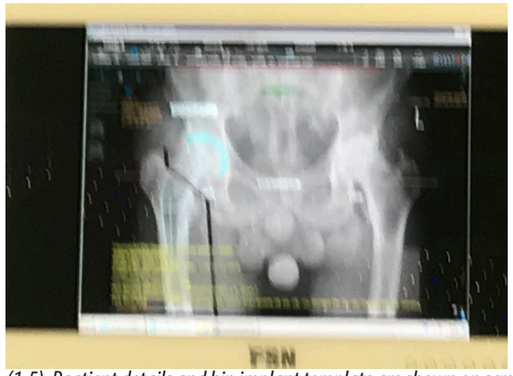
Before surgery

Before the operation the patient is in the waiting room. In the meantime, the operation room is cleaned (made sterile). The surgeon picks the patient up from the waiting room and has a small talk with the patient before the patient is brought to the operation room (OR). The instrumental scrub nurse is preparing tools in the room next to the operation room (1.1), preparation room. When the patient is in the operation room, a team meeting (time-out) gets done. In this meeting the surgeon asks the patient; name, date of birth and "What he/she is here for". After this the anesthetist (assistant) is goes over potential allergic reactions/diseases and patient vitals.

When the 'time-out' is over, the operating surgeon and operating assistant will wash their hands and start putting on their operating jackets, to become part of the sterile team (together with the scrub nurse)(1.2). Meanwhile, the patient gets anesthetized by the anesthetist (assistant) and is fully sedated in about 1 min. (1.3)

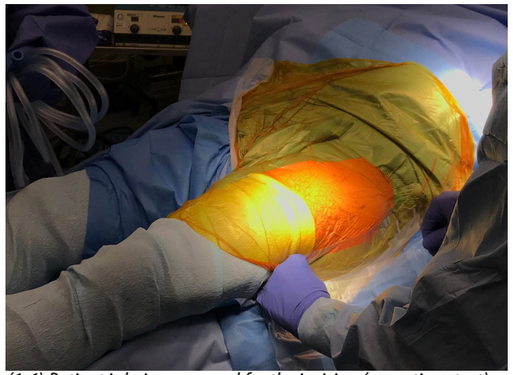


(1.4) Anasthetist is behind the operation site; checking patient vitals



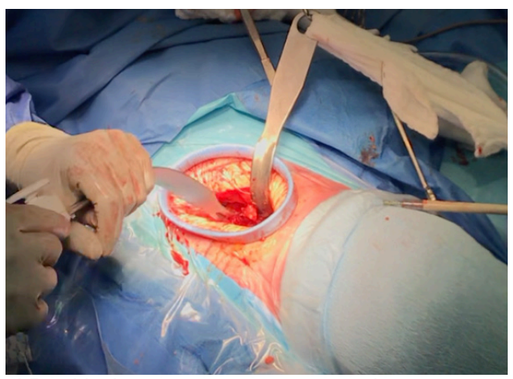
(1.5) Paatient details and hip implant template are shown on screens

When the patient is anesthetized the surgeons goes over information on a computer screen located above the operating site; data is about templating/sizing of the hip, to have an indication of size and model implant; This data comes from x-ray scans done previously to surgery.(1.5) In the meantime, the sterile scrub nurse starts disinfecting the leg/hip with a pink fluid with a sponge. Next step is covering the surgery table and the patient, except for incision site, the anterior side of the patients hip joint.



(1.6) Patient is being prepared for the incision (operation start)

At the top side of the operation bed, behind a cloth hang from two intravenous poles, the anesthetist is taking care of the patient. (1.4)The patient can be conscious (epidural sedation) or sleeping during the surgery (full sedation via intravenous drip). From the 'preparation room' next to the OR two tables with surgical tools and instruments are brought into the OR. All tables are being placed in dark blue square around the operation table, called sterile area. This area is called the sterile area because only staff and surgeon can go into this area when wearing sterile clothing. This is done to reduce the risk of infection for the patient.

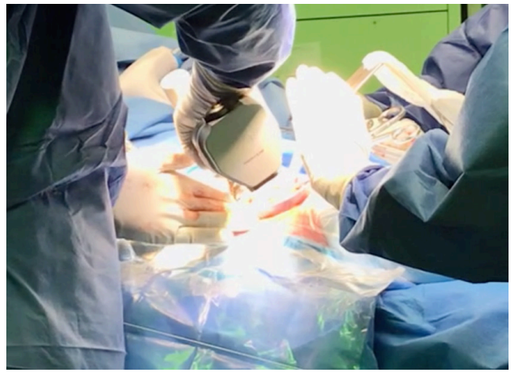


(1.7) Incision is made and muscle are pushed aside to have a clear view of the incision location

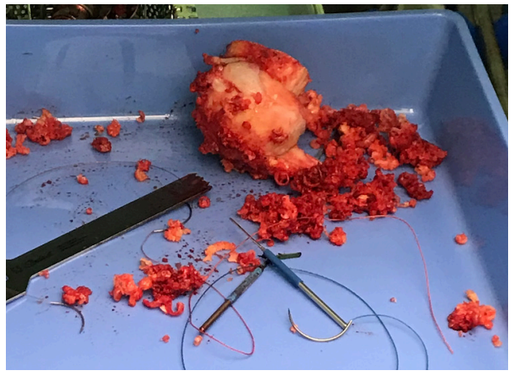
Surgery

When all instruments are in, the surgeon asks permission as a last check if he may start the surgery by making an incision. When the incision is made, sterility is of great important and the operation room doors are closed. After this the surgeon pushes aside muscle and tissue to have a clear view of the hip joint. Using retractors, the surgeons keeps the incision opened up, to have the best view possible. (1.7)

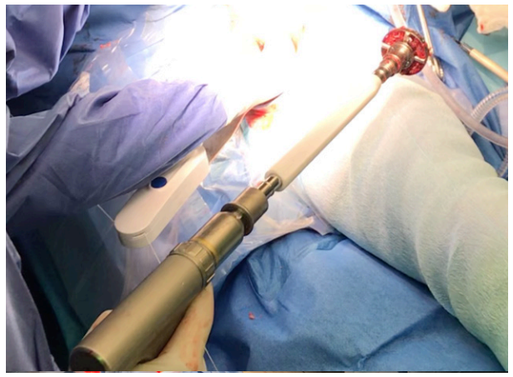
To get a clear overview of the surgery, it was divided into eight steps. ***Step 1 is the incision made above.***



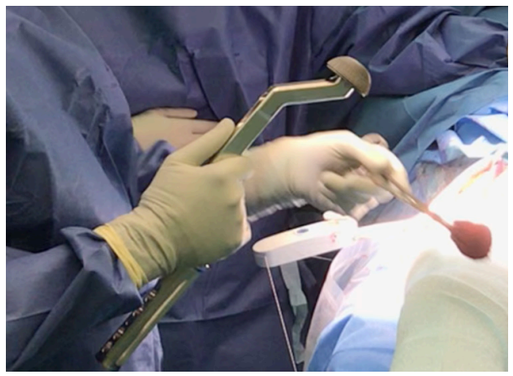
(1.8) The Femoral head gets saw with oscillating saw



(1.9) The arthritic Femoral head after sawing



(1.10) The arthritic Femoral head after sawing



(1.11) The arthritic Femoral head after sawing

Step 2. Cutting the Femoral neck

In the first step after the incision a drill gets used to drill a handle into the Femoral head. When this handle is attached to the Femoral head, the Femur is cut at the Femoral neck, a few centimeters below the Femoral head. The cut is made using oscillating bone saw, powered by an electric motor. After the cut is made the Femoral head and part of the neck gets pulled out of the patient using the handle. (1.8) The head coming out of the patient clearly shows arthritic tissue and has a torpedo like shape, due to wear. (1.9)

Noticed/Perceived:

- This oscillating bone saw make a high frequency sound and it becomes less annoying when it starts cutting into the bone.

Step 3. Reaming the Acetabular (1.10)

Once the arthritic head of the Femur is removed, the worn-out hip socket part of the pelvis bone, the Acetabular gets addressed. Where the handle drill gets converted to a reamer, a dome-shaped grater, is used to scrape away the damaged cartilage and bone. This leaves a smooth, perfectly dome-like surface to accept the new hip replacement for the Acetabular cup.

Noticed/Perceived:

- The surgeon must apply large amount of pressure when reaming. The surgeon leans onto the drill pushing it into the Acetabular.
- Sound level decreases when applying force.
  (perceived)

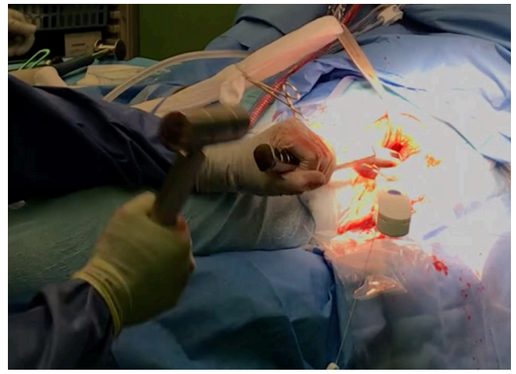
Step 4. Placement of Acetabular cup

The arthritic bone is removed from the Acetabulum, the new Acetabular a titanium cup can be inserted. The titanium cup gets screwed onto an impactor, looks like a large screwdriver, with a tapped end to attach the cup onto. When the cup is attached to the impactor and placed against the Acetabulum (1.11), the impactor gets hammered using a surgical mallet. (1.12) When the cup is fixed into the Acetabulum, the impactor gets screwed loose of the cup.

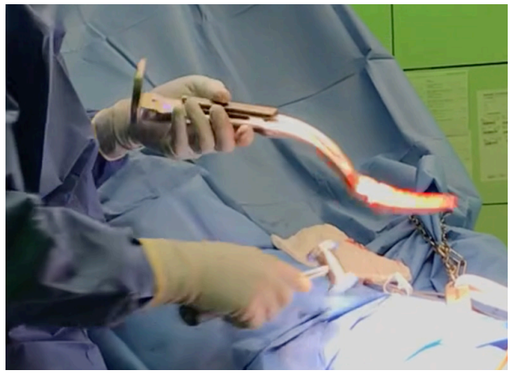
The titanium cup is held tightly in the pelvis, by making the socket slightly smaller than the Acetabular component. (1.12) The cup is wedged into the pelvis/acetabular bone. The cup has a rough outer surface to allow bone to grow into the surface of the implant over time.

Noticed/Perceived:

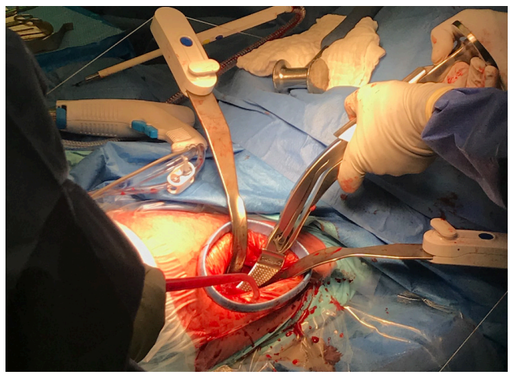
- The mallet strikes hurt my ears; large peak level perceived. (1.12)



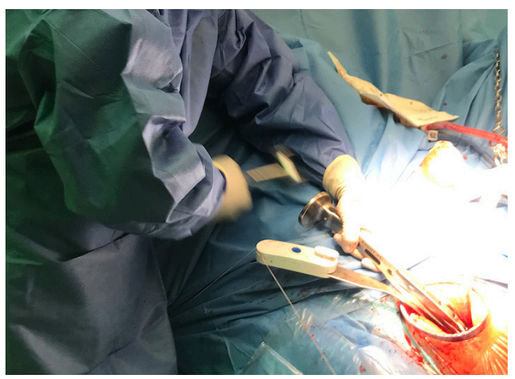
(1.12) The arthritic Femoral head after sawing



(1.13) The broach handle with rasp during surgery



(1.14) Placement of the rasp in the Femur



(1.15) Broaching the femoral canal

- Operation room staff flinches on impact and frown/squint with their eyes, as mouth is not visible due to protective mask.
- Surgeon shouts; That he will start striking = verbal communication stops.

Step 5. Placement of Acetabular cup liner

After placing the titanium cup, the surgeon puts a plastic liner into the previously fixed Acetabular cup. When this is put into the titanium cup, the plastic cup gets hammered using a mallet and impactor. The used impactor has a knob-like end, that fits into the plastic cup.

In this step of the procedure, the Acetabular cup, most of the time made from titanium gets lined with a cup, made from ceramic or polyethylene. The liner is there to reduce wear and facilitate smooth movement within the joint.

Noticed/Perceived:

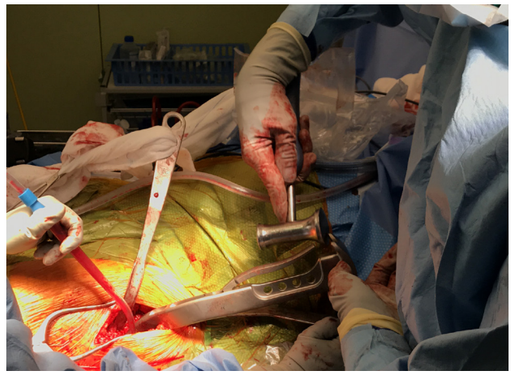
- Usage of the mallet gives large sound peaks.
- Communication stops during hammering actions.

Step 6. Opening the Femoral canal

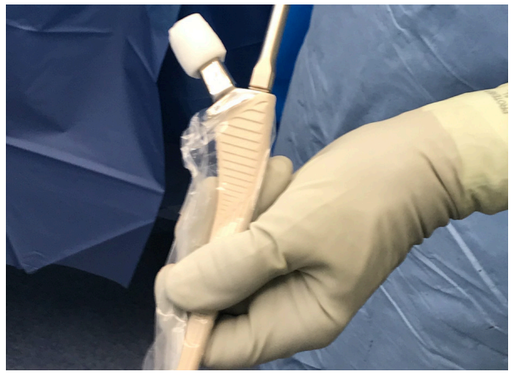
Having replaced one side of the hip joint, Acetabular side, the Femur side (upper leg) needs to be replaced. The sawn-off Femoral head provides a view of the bone marrow inside the Femur, Femoral canal. The Femoral canal needs to get opened to accommodate a Femur stem that fits the new head and completes the replacement procedure.

A broaching handle, a chisel where different rasp sizes can be attached to is used. (1.13) This tool gets hammered using a surgical mallet. By striking this handle, the rasps attached broach their way into the Femoral canal. (1.14-1.15) When the rasp gets stuck it is hammered out of the canal. This done multiple times going up in rasp sizes till the rasp is set firm in the femoral canal, in-between the Femur bone sides.

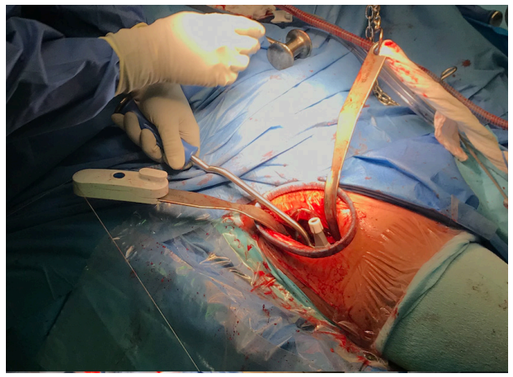
The surgeon uses plastic pilot model attachments on top of the rasp of the implant, to see if the patient's legs are of the same length. When the leg length is not similar, the Canal gets broached again (to accommodate a larger size stem) or a new pilot model gets attached. (to see if the leg length can be solved by femoral head sizes). When the leg length is similar, to surgeon proceeds to the next surgical step.



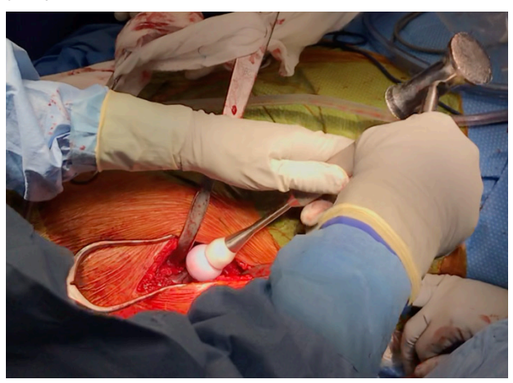
(1.16)Extracting femoral rasp, in weird posture



(1.17) Femoral stem



(1.18) Placement of the Femoral stem



(1.19) The Femoral head impacted onto the stem

Noticed/Perceived:
- Usage of the mallet gives large sound peaks. (Multiple strikes)
- Operation room staff flinches on impact and frown/squint with their eyes.
- Surgeon has a weird/unnatural posture when opening the femoral canal. Surgical mallet is not used in a swinging motion. (multiple strikes needed)
- When extracting the rasps, the surgeon must watch his hand. Posture looks very unsafe, no proper way of holding onto the tool when striking to extract. (1.16)

Step 7. Placement of Femoral stem

When the Femur is fully prepared (opened) for the stem, the stem is wedged into the canal made in the femur, by using a mallet and impactor (with a stem attachment). The impacting of the stem (1.17) into the canal gets called press-fitting, as the fixation of the implant is done by jamming it into the Femoral canal. (1.18)

The Femoral stem is the implant that supports the fixation of the Femoral head. Due to the outer surface of the stem, the implant allows bone to grow into the implant over time.

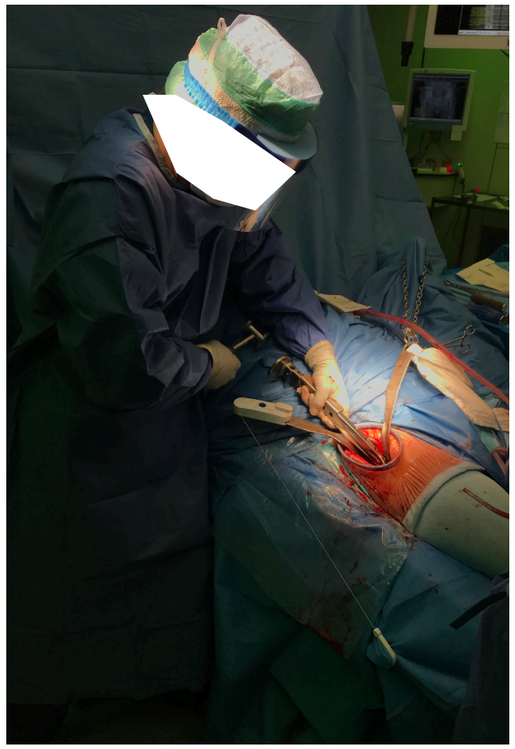
Noticed/Perceived:
- Usage of the mallet gives large sound peaks. (Multiple strikes)
- Surgeon has a weird/unnatural posture when placing the stem. Surgical mallet is not used in a swinging motion.

Step 8. Placement of Femoral head

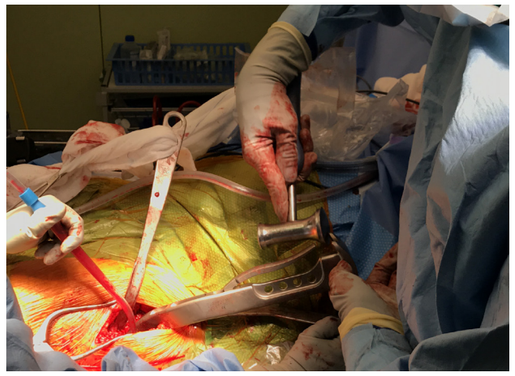
With the stem press-fitted down the center of the Femur, the Femoral Head (ball like shape) is tightly fitted onto the top of the Stem. The fitting is done by putting the plastic, femoral head onto the Femoral stem. When the head is attached onto the stem, the head is struck with an impactor and mallet combination as used in previous surgical steps. The impactor used is placed against the Femoral head and has a bowl-like shape which accommodates the shape of the head. (1.19)

This Femoral head is mostly made of ceramic, plastic or even metal and facilitates the connection and movement between the Acetabular and the Femoral components of a THA.

Noticed/Perceived:
-One or two strikes needed to fixate the Femoral head onto stem.



(1.20) Unnatural postures when using the surgical mallet



(1.21) Unsafe working posture, when extracting rasps.

Noticed perceived during surgery:
- The surgical mallet used emits the largest sound peaks and is used from step 5 – 8. Probably the most malicious product/instrument used in surgery.

- In usage scenarios (Step 6/7) the surgical mallet is used in weird un-natural postures. (1.20)

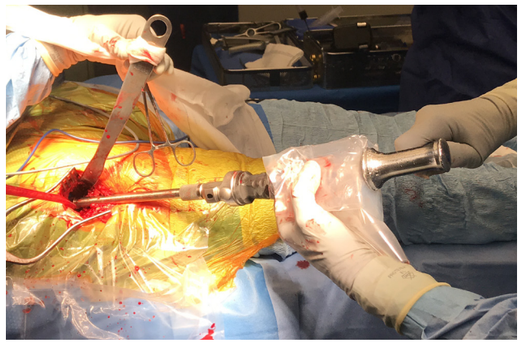
- The broach handle is unsafe to use. Surgeon must watch his hands when striking to extract the product. Applying real force cannot be done, too much risk of hitting hands/fingers. (1.21)

- Surgeon looks at the impact location of his mallet before striking. Must control the instrument he is hitting (impactor and/or broach handle) and hitting with (mallet). (During hammering not looking at the implant location but watching if he hits straight onto the instruments.)

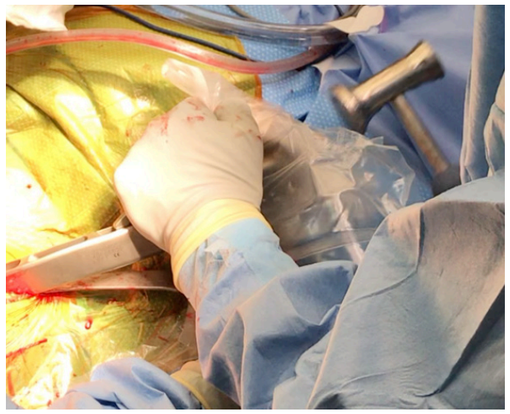
- After using the surgical mallet, the surgeon is out of breath. It takes the surgeon large amounts of force to fixate implants and rasps.

- (Verbal) Communication is only done, when instruments are not used. Staff gets noticed when they start using sound emmitting (powered) tools.

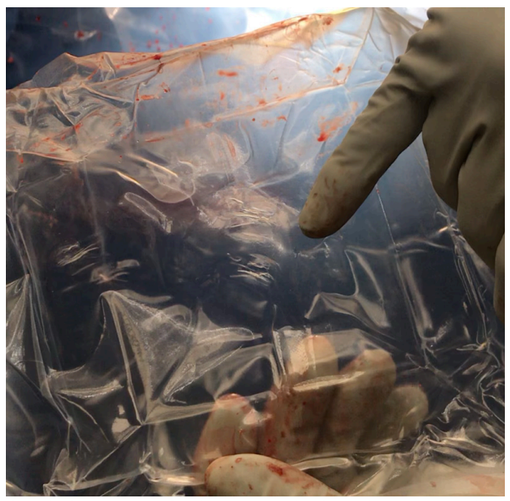
Note: After the first day of observations I had the idea my hearing was effected. Every next time I observed during THA surgery I did wear earplugs, this helped tremendously.



(1.20) Cup impactor wrapped in plastic



(1.21) Broaching handle wrapped in plastic



(1.21) Plastic wrap after hammering/melting the wrap together.

Observations Total Hip Arthroplasty
Date: 14-11-19 (Rijswijk/The Hague)
Location: Bergman Clinics, Rijswijk/The Hague
Total: 5 THA operations (Anterior)
Material: Photos and videos shot by iPhone 7 by C.L.H. Broekmeulen

Introduction and goal of observation
Before the observation day, contact was made with the Surgeon working in this clinic.

This surgeon experienced problems coming from sound and was experimenting with different mallet types and other sound reducing improvisations. The goal was to see what this surgeon did to decrease the noise level. Note: This surgeon did not only work with Zimmer Biomet implants and instruments. He worked with DePuy Synthis.

The surgeon had a POM strike face deadblow hammer in the operation room, see the report what this did to the soundlevel. (Analysis 1.7)

Noticed/Perceived:
- The surgeon used plastic packaging around the impactors and broach handle, impact locations, to reduce the soundlevel. (1.20-1.21):
+ This only worked for the first couple strikes before the plastic wrapping melted. (1.22)
+ Made the posture of handle tools, even more unnatural, as the surgeon also had to held the packaging next to the handle with the same hand.
- Surgeon wanted a different material strike face, resembling the plastic wrapping which could last:
+ Hitting a air-bubble in plastic made the im pact quieter, but when the air was out the LCpk increased again.

+ The surgeon did not wear hearing plugs, as he found that the communication gets affected by wearing hearing plugs. Not everything is understandable which could cause unsafe situations.

+ This surgeon approached the striking differently, seemed like he did not exert strikes as hard as the other surgeon. He used shorter swing distances and more blows.

A.2 Sound measurements

Registered dB(A) - LAeq during surgeries

surgery	#1 / 21.10	#3 / 21.10	#4 / 21.10	#3 / 01.11	#2 / 01.11	#1 / 14.11	#2 / 14.11	range	avg .(log)	set avg.
dB(A)/Laeq										
incision	66,8	65,3	61,1	64,7	67,2	57,3	60,2	57 - 67	64.1	64
osc, Saw	68,4	84,2	74,6	84,7	83,2	79,6	76,4	68 - 85	81.3	81
clean-up/suc	72,2	65,8	64,6	66,6	63,2	62,6	69	63 - 73	67.7	68
reamer (elec)	72,2	70,5	66,1	64,3	67,1	68,2	67,1	64 - 72	68.7	69
pelvis cup tit	85,7	90,8	87,7	94,4	90,3	86,6	80,5	80 - 95	89.7	90
pelvis cup	78,8	83,4	80,6	88,4	86	87	80,3	78 - 89	84.8	85
rasp femur	95,4	94	85,4	97,7	101,4	88,1	88,3	85 - 102	95.9	96
femur stem	79,4	78,3	81,2	83,6	86	81,1	81,4	78 - 86	82.3	82
bal fix	77	68,7	68,9	69,8	66,3	75,6	64	64 - 77	72.3	72

Registered dB(C) - LCpk during surgeries

surgery	#2 / 21.10	#5 / 21.10	#3 / 01.11	#2 / 01.11	#1 / 14.11	#2 / 14.11	range	avg (log)	set avg
dB(C) - LCpk									
incision	82,6	85,5	87,2	92,1	89	84	82 - 92	87,9	88
osc, Saw	100,2	101,4	106,1	105,6	95,7	95	95 - 106	102,5	102,5
clean-up/suc	93,4	88,2	90,6	86,8	94,9	95,1	86 - 95	92.6	92
reamer (elec)	91,7	94,7	88,5	95,2	90,2	91,9	88 - 95	92.7	93
pelvis cup tit	123,4	124	123,6	124,7	124,2	124	123 - 125	124	124
pelvis cup	119,3	123,6	117,4	119	121,7	114,8	114 - 124	120.2	120
rasp femur	121,5	119	125,1	124,9	122,1	121,3	119 - 125	122.8	123
femur stem	116,2	114	122,7	120,6	116,6	118,4	114 - 121	119.1	119
bal fix	97,2	95,2	92,1	98,5	114,5	108,4	92 - 115	107.9	108

Average over entire surgery measured: 01-11-2019

Surgery 1	01-nov	30 min	1800 sec	80 dB(A)	124,7 dB©
Surgery 2	01-nov	29 min	1740 sec	80 dB(A)	124,9 dB©

Used sound level meter-device
Bedrock SM30 class II measurment device

Specifications:
20 - 20.000 Hz frequency range
Dynamic range 24 -124 dB with included BAMT2 microphone.

Measurement location:
0.5-1.0 meter away from the surgery/sound emitting location.

Settings:
Registering LAeq (human hearing equavalent) and LCpk (peak level)

Measurement location (21-10-2019)

A.3 Surgery duration

Surgery 1	01-nov	30 min	1800 sec	80 dB(A)	124,7 dB©
Surgery 2	01-nov	29 min	1740 sec	80 dB(A)	124,9 dB©
TIMING SOUND EMITTING TOOLS/INSTRUMENTS					
	start (s)	ending (s)	total (s)		
Incision (incl. Retracting tissue/suction/handle drill					
Surgery 1	0	315	315		
Surgery 2	0	340	340		
Oscilatting saw, cutting Femoral neck					
Surgery 1	316	328	12		
Surgery 2	340	355	15		
Electric reamer, preparing acetabular for cup					
Surgery 1	471	565	40		
Surgery 2	468	496	28		
Placement of Acetabular cup and Liner (liner follow imediatelly after cup)					
Surgery 1	642	742	21		
Surgery 2	531	731	24		
Opening the Femoral canal (rasping)					
Surgery 1	1046	1168	122		
Surgery 2	1072	1189	117		
Placement of the stem into Femur					
Surgery 1	1379	1402	23		
Surgery 2	1365	1391	26		
Placement of Femoral head onto Stem					
Surgery 1	1515	1523	8		
Surgery 2	1506	1511	7		

A.4 Information flow

Abbreviation	Job Title
S	Orthopedic surgeon (sterile)
A	Anesthetic nurse
IN	Instrumental nurse (sterile)
N	Non-sterile nurse
AN	Assistant Nurse (sterile)

Surgery #2 – 01-11-2019

1740 sec	**Surgical step**	**Information exchange**
Before surgery	*Patient information exchange*	S: To all information on templating of patient / age/ side implant / blood type / allergies etc. A: - IN: - N: - AN: Introduction to operation for patient / Comforting talks
0 – 340	*Incision*	S: Starts operation by incision (calls it out loud) = **10 s** A: Gives intel on patient vitals = **5 s** IN: Preparing instruments and tools N: - AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
341 – 355 s.	*Cutting Femoral neck*	S: Surgeon asks for osc. saw and talks about sizing = **23 s.** A: Gives intel on patient vitals = **5 s** IN: Surgeon asks for osc. saw and talks about sizing N: Template sized implants are gathered from closet in OR – talked about before surgery AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
356 – 496 s.	*Reaming Acetabular*	S: Asks for reaming sizes – talks cup diameters and pelvis arthroses = **50 s** A: Gives intel on patient vitals / Adding muscle reapers surgeon = **15 s** IN: Asks for reaming sizes = **10 s.** N: Instruction which size implant cup to open and look for. = **13 s** AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
497 – 731 s.	*Placement of Acetabular cup*	S: Talking about liner type/material = **24 s** A: - IN: Talking about cup liner type/material with S= 24 s N: Opening of the Acetabular liner package/cleaning = **16 s** AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s**.
497 – 731 s	*Placement of Acetabular liner*	S: Asks A for calling in new patient = **8 s** / Liner inserting asks for instruments = **22 s** A: Gives intel on patient vitals = **5 s** IN: Assembling of the liner insertion instruments = 18 s N: Busy with cleaning / Sitting in the corner of the OR AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
732 – 1189 s.	*Opening of the Femoral canal*	S: Talking about rasps sizing and potential Femur size = **29 s** A: Asks about blood loss to N = **14 s** IN: Talking about rasps sizing and potential Femur size = 19 s N: Checking blood loss of patient to A/S= **8 s.** AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
1190 – 1391 s.	*Placement of the Femur stem*	S: Talking about rasps sizing and potential Femoral head material and size = **20 s.** A: Update on patient vitals / needs to give more anesthetics. = **8 s.** IN: Talking about rasps sizing and potential Femoral head material and size = 30 s. N: Looking for Femoral heads instructed by surgeon = **4 s.** AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
1392 – 1740 s.	*Placement Femoral head and suture*	S: Talking Femoral head material ceramic or plastic = **12 s.** and suturing = **18 s.** A: Talks about reducing anesthetics… patient allowed to wake-up? = **28 s.** IN: Gauge and instrument count with N **30 seconds – 40 seconds.** N: Gauge and instrument count with IN 30 seconds – 40 seconds. AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
Surgery related communication (? / total)		**Surgery related communication is approximately 499 to 1800 (approx. 8.5 min) seconds surgery time, rest is chitchat on all kinds of things ranging from children, gaming, festivals and music and more.**

Noticed:
This team works together for a long time already and are a well organised/ oiled machine some of the communication is not even verbal but a gesture or a hand up in the air is enough to spark an action of OR staff or surgeon himself.

Surgery #1 – 01-11-2019

1800 sec	Surgical step	Information exchange
Before surgery	*Patient information exchange (No sound emitting tools used)*	S: To all information on templating of patient / age/ side implant / blood type / allergies etc. A: - IN: - N: - AN: Introduction to operation for patient / Comforting talks
0 – 315	*Incision*	S: Starts operation by incision (calls it out loud) = **5 s** A: Gives intel on patient vitals = **5 s** IN: Preparing instruments and tools N: - AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
316 – 328 s.	*Cutting Femoral neck*	S: Surgeon asks for osc. saw and talks about sizing = **26 s.** A: Gives intel on patient vitals = **5 s** IN: Surgeon asks for osc. saw and talks about sizing = 16 s N: Template sized implants are gathered from closet in OR – talked about before surgery AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
329 – 565 s.	*Reaming Acetabular*	S: Asks for reaming sizes – talks cup diameters and pelvis arthroses = **40 s** A: Gives intel on patient vitals / Adding muscle reapers surgeon = **15 s** IN: Asks for reaming sizes = **10 s.** N: Instruction which size implant cup to open and look for. = **13 s** AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
566 – 742 s.	*Placement of Acetabular cup*	S: Talking about liner type/material = **24 s** A: Gives intel on patient vitals = **5 s** IN: Talking about cup liner type/material with S= 24 s N: Opening of the Acetabular liner package/cleaning = **16 s** AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s**.
566 – 742 s	*Placement of Acetabular liner*	S: Asks A for calling in new patient = **6 s** / Liner inserting asks for instruments = **18 s** A: Gives intel on patient vitals = **5 s** IN: Assembling of the liner insertion instruments = 18 s N: Busy with cleaning / Sitting in the corner of the OR AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
743 – 1168 s.	*Opening of the Femoral canal*	S: Talking about rasps sizing and potential Femur size = **19 s** A: Asks about blood loss to N = **14 s** IN: Talking about rasps sizing and potential Femur size = 19 s N: Checking blood loss of patient to A/S= **8 s.** AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
1169 – 1402 s.	*Placement of the Femur stem*	S: Talking about rasps sizing and potential Femoral head material and size = **30 s.** A: - IN: Talking about rasps sizing and potential Femoral head material and size = 30 s. N: Looking for Femoral heads instructed by surgeon = **4 s.** AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
1403 – 1800 s.	*Placement Femoral head and Suture*	S: Talking Femoral head material ceramic or plastic = **13 s.** and suturing = **24 s.** A: Talks about reducing anesthetics… patient allowed to wake-up? = **28 s.** IN: Gauge and instrument count with N **30 seconds – 60 seconds.** N: Gauge and instrument count with IN 30 seconds – 60 seconds. AN: Holding and cleaning instruction from surgeon every step. Just words approx. **12 s.**
Surgery related communication (? / total)		**Surgery related communication is approximately 489 to 1800 (approx. 8 min) seconds surgery time, rest is chitchat on all kinds of things ranging from children, gaming, festivals and music and more.**

Noticed:
This team works together for a long time already and are a well organised/ oiled machine some of the communication is not even verbal but a gesture or a hand up in the air is enough to spark an action of OR staff or surgeon himself.

Talk-out Loud protocol – Femoral Broaching 01-11-2019

On 01-11-2019, the orthopedic surgeon was asked to talk-out-loud during the broaching of the Femur. This surgical step was chosen as this step needs multiple rasps to complete the broaching of the Femoral canal. More steps would given more information. This was done the see if the surgeon uses sound as a surgical cue, ensuring propper fixation of implant. During talking-out-loud was noticed that broaching of the Femur gets done with tactile feedback and not sound cues, as the surgeon did not talk about sound at all during the protocol. Only about friction and not having anymore movement when broaching.

Rasp number	**Sound level**	
Starter	123.9 dBC	Let's start rasping the Femur… starter gets used… (hand chisel hit as starter not a starter rasp that hit with mallet)
1	123.8 dBC	The first hit with the broach handle… push… it in Firmly… keep in mind it must be stable
2	124.5 dBC	No comment of surgeon
3	124.4 dBC	Sorry forgot to talk-out-loud …. Next rasp is in as you see… This hammer is nicer… with the blue handle… After few strikes… feels just better on the wrist… okay… it's down this Top of the Femur (neck) is high… hard to go deep into the bone
4	------- dBC	No recorded dBC
5	124.6 dBC	No comment of surgeon
6	124.6 dBC	I feel the friction increasing with every blow… you feel it moving slightly… (after few blows) now it time to go up a size
7	124.9 dBC	I thought this was the final, but still think it can move a bit, so let's try a new rasp to see if this works… otherwise this will be the final rasp used.
8	124.7 dBC	The friction increases and there is no movement anymore in the rasp. I must go up a size to ensure good fixture. There is cortical contact is there so it's ready for the stem…
9	124.7 dBC	When hitting the friction increases when the top of the rasp is level I can stop hammering.
10	124.8 dBC	One blow, now I feel that this is the last size I could use, it stuck… Now I can pick the trail head to see if leg lengths are good.

Surgery #3 (Left side/ Female)

Rasp number	**Sound level**	
Starter	124.9 dBC	So, this was loud…. the starter is hammer is used to reach the canal… In this case broaching will be possible because the rasps are a bit curved
1	121.1 dBC	This is less loud than the previous blow… (I answered yep about a 3-dB decrease) Oh that's something I can perceive…
2	124.6 dBC	The second rasp is used to broach the Femur, it goes in quite smoothly… just a few blows (counted 17 blows)
3	124.6 dBC	Second rasp… let's put some force onto it (adapts his stance) By hitting it goes down into the canal… (few strikes), I think I'm almost there… You see this is sclerotic tissue… goes down way easier than younger male patients…
4	125.1 dBC	With every hit the friction increases, it feels like its stuck, but it can still wiggle to the back a bit. There is no movement anymore… You see what happens…
5	125 dBC	Going a rasp up gives even more friction after a few blows the final one can be put inside the Femur. Guess this is it… snug fit into the canal… (no movement)
6	124.5 dBC	The friction increases with every blow until it is stuck… I don't feel it moving anymore… so know it's time to stop. The rasps top is about level with the

A.5 Interviews

Free flowing interviews with Surgeon and Hip product specialist

Dates: 19-09-19 (Naarden)
Location: Bergman Clinics, Naarden
Interviewed personnel: Orthopedic surgeon

Can you tell me something about the noises in Total hip replacement surgery?
You really have to come by and attend some surgeries next week… because there is more to it than you expect. In short we replace the pelvis socket with an artificial surface and the top of your upper leg bone (Femur) with a new head (ball like shape)… to reach this we have to hammer in the implant, cut and ream away arthritic bone which causes the pain when walking or even sitting. Most of my patients are between 60-70 years old, but sometimes even people younger need a new hip or revision of a hip they have gotten previously.

What is you experience with the sound emitting tools in surgery?
Most malicious is in my eyes the oscillating saw and the usage of the hammer, which is used for almost every implant... (hammer) Every implant in hip replacement is jammed into the bone by striking it with a hammer. Maybe something like a disposable cap is the solution, you will have multiple caps in a surgery, when it breaks just throw it away… in my eyes the best solution at the moment. Please make something like that that would be great.

Is the sound used in surgery or is it just a noise that damages?
Sound is used when implanting… as the loudness of the sound changes when you're hitting in the implants… I definitely use it as a surgical cue to know if where going in the right direction and when to stop hitting for proper fixation of the implant.

Are you wearing earplugs as this could solve the hearing loss problem?
I wear hearing plugs… as I already have tinnitus and don't want my hearing to get worse even more**.**

Does other Operation room staff wear earplugs as well? The rest doesn't want to wear them as they are not willing to
listen… it damages the hearing, but they think the damage is already done… Some colleagues of me here at Bergman Clinics wear hearing plugs as well, but most people working in orthopedics are not wearing any… reasons differ

Hearing plugs are not necessary the solution as they also hinder the communication during surgery. They just dampen the sound too much sometimes… but to be honest I am wearing them now for almost a year and I got used to working with them… The only thing others say is that they think I started to hit harder to still hear the sound cues.

Do you experience more problems coming from working with these instruments? I saw you turning your wrists (exercise?
If you could help me with that that would be awesome… that really an orthopedic surgeon thing… I and most of my colleagues have elbow, hand or wrist problems… definitely coming from the impacts that vibrate through to the hammer to your hand.

Maybe that cap I talked with you about on top of the hammer… if that is softer there is probably less vibration which will help concerning the injuries, we have…

What kind of injuries do you mean by this?
Ohh that ranges from carpal tunnel syndrome to golfers' elbow… That something most surgeons have or had complaints about... Nice that you can solve that as well…

In the end of the interview the surgeon started to mention the solution for his problem again, a strike face /disposable hammer cap, which dampens the sound and when breaks are disposable. Furthermore, it was discussed that 01-11-2019, I could attend surgeries at Bergman Clinics, Naarden.

With having an idea of the problems, a project brief was written. Added to this project brief was some research diving into these problems.
(Appendix A.23)

Free flowing interviews with Surgeon and OR staff

Dates: 21-10-19 (Naarden) / 14-11-19 (The Hague)
Location: Bergman Clinics, Naarden /The Hague
Interviewed personnel: Orthopedic surgeon/ Instrumental nurses/ Assisting scrub nurse / Non-sterile scrub nurses and Anesthetist (assistant)

Note: Surgeons and staff signed a consent form, to be able to include information gathered into research.

Q1. What is the reason your not wearing hearing protectors such as earplugs?

Anesthetist
"I'm already wearing hearing aids and suffer from tinnitus. I think these already dampen loudness and frequency so I will not get more damage."

Anesthetist Assistant
"earplugs are a bad solution for noise problems, as these will also silence calamities alarms or patient vitals. You cannot wear earplugs in the OR – especially I need to hear the equipment and eventual calls for help when a calamity happens"

Anesthetist Assistant
Off course they give you more insurance against hearing damage, but these will definitively give problems…. you just can't hear calamities coming... alarms and commands for example.

(Sterile) Scrub Nurse
"I'm doing this job already for 19 years, started in 2000. To be honest we just don't speak when loud sounds are emitted. Especially when by sawing, but with hammering we can speak in between

(Sterile) Scrub Nurse
Just as my colleague I'm working in this environment already for 34 years but hearing plus don't solve the problem. This is not an appropriate solution for in the OR (OK). Communication is just too important and just can't be silenced.

(Sterile) scrub nurse
I already wear this surgical cap, face mask and eye protection and rubber gloves... wearing more protection will... if I add earplugs- I would feel completely disconnected from my environment.

(Sterile) scrub nurse
I only wear one of the plugs, otherwise I cannot understand/hear the things people tell me – as you cannot read lips because of the masks.

Q2. What is in your eyes the most harmfull or annoying sound?

Anesthesist
I my eyes the hammer strikes are the most harmfull or the oscillating saw... I really hate that sound. If I am really done with it I can put the volume of my hearing aid a bit lower.

Anesthetist Assistant
The hammer blows are really bad.. you already noticed but we all really flinch when the impacts are happening

Anesthetist Assistant
The oscillating saw.. that high pitch sound goes through "merg en been"

(Sterile) Scrub Nurse
The hammer blows are definitely the worst... the oscillating saw isn't that bad when you start cutting with it... but those hammer blows.. there is no other way metal-on-metal is just so loud

(Sterile) Scrub Nurse
Hammer strikes these are so loud... I did not know they were that loud but this is insane.. I have earplugs but never wear them... Now I will this is just stupid.

(Sterile) scrub nurse
When you are too close the hammer blows give me a "beep" in my ear... so loud... some days I have a headache know I know what is the reason for this.. I always thought it was the lighting in the OR

(Sterile) scrub nurse
I really hate the oscillating saw that sound is super annoying that high frequency sound... it gives me goosebumps... but the impact tools are also something else.

Orthopedic surgeon
The hammer is most malicious... you are here for the solution but these sound peaks are high... never expected this.

Free flowing interview with Surgeon

Dates: 19-09-19 (Naarden)
Location: Bergman Clinics, The Hague
Interviewed personnel: Orthopedic surgeon

Note: Free flowing Interview happened during the surgery asking on actions noticed.

What is you experience with the sound emitting tools in surgery?
Heard that you observed surgery in Naarden… in my eyes the hammer is the most damaging to your hearing… the metal-on-metal impacts are loud. No other reason in THA for damaging your hearing… You should change these hammers making them less loud…. I will show you a trick in a few minutes demonstrating that I can dampen the sound of impacts.

- Surgeon used plastic wrapping around his impactor handles, when striking on the plastic wrapping, the sound was decreased. Till the wrapping broke, which increased the sound again.

You should make something like this plastic wrapping, putting it on the strike face… or even on top of the impactor, that would be even better… IN surgery then you would have a set of these caps. When it breaks you unpack a new one and throw away the old one.

Do you use the sound as feedback?
Some surgeons say they use sound as feedback, but the sound is super loud and damages your hearing... It would be weird to take that as a guide to ensure you did a good job or doing a good job. It is just really loud.

So, you mainly work on tactile feedback?
Yep I think tactile feedback is most important… you will feel when you can't impact an implant any further… and next to that there are multiple visible cues where you could look at to see if you did a good job. For example, a stem implant as I am hitting in now has to sink into the canal… making an even surface with the cut femur neck. Now its stick out a bit but this is the proper way of implant… now it stays there.

What is the reason you are not wearing hearing protection?
I tried them… but did not like working with them… as they dampen all sounds... In some cases, you can't miss critical information as this could lead to unsafe situations.

I talked to other orthopedic surgeons and they experienced injuries coming from hammer usage… Do you experience similar problems?
Some tools are just hard to work with… especially extracting the rasp, hammer the broach handle out isn't handy. Most of the instruments you are almost hitting your hand or exerting force is not possible due to weird postures… holding them and striking is something to look at.

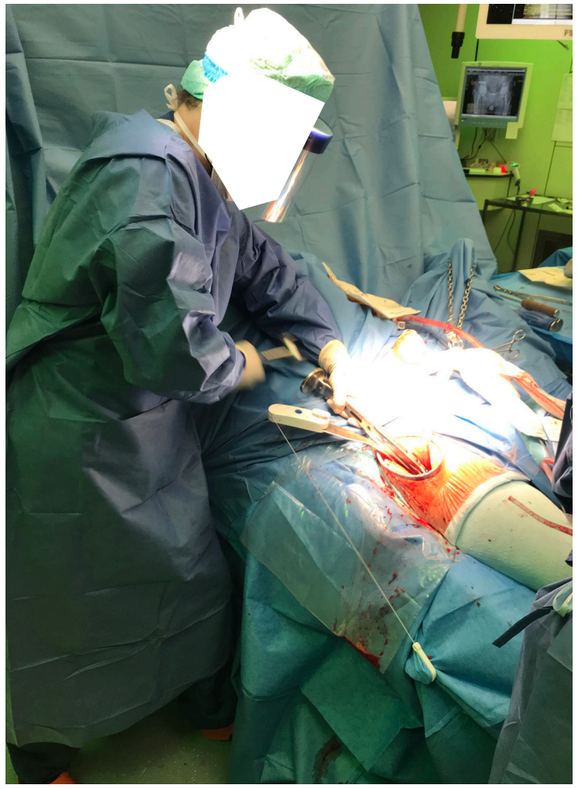
Is the reason for this that you always like to strike with your strong hand?
Not always… but I prefer my right hand as I am much stronger on that side. But to get back… I have an elbow injury coming from doing surgeries on both elbows.

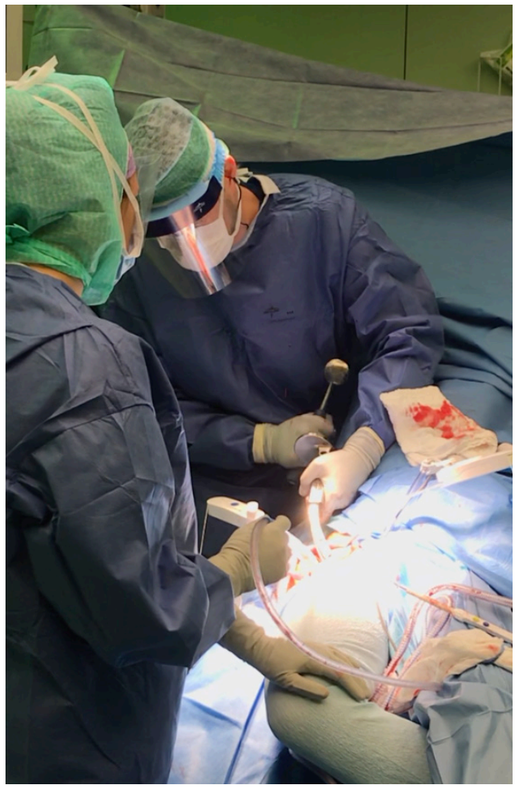
The surgeon found that deadblow hammer could reduce vibration and wanted to try these in surgery, as there are surgical deadblow mallet aswell. Seeing the price of one of those, he mentioned 700€ and found that way too expensive. Therefore, he bought a construction one (non-medical) to try-out at the end of the working day by hitting a broach handle. (Analysis 1.9)

The deadblow mallet did the following:
- When used in a circular motion (swing) it reduced the vibration/recoil of the hammer. No bouncing off the "to-strike" product.
- Using in a non-circular motion, the sand or metal shot inside the mallet head was not doing it's job properly.
- Due to it's Nylon or POM strike faces it was less loud than a metal-on-metal impact.

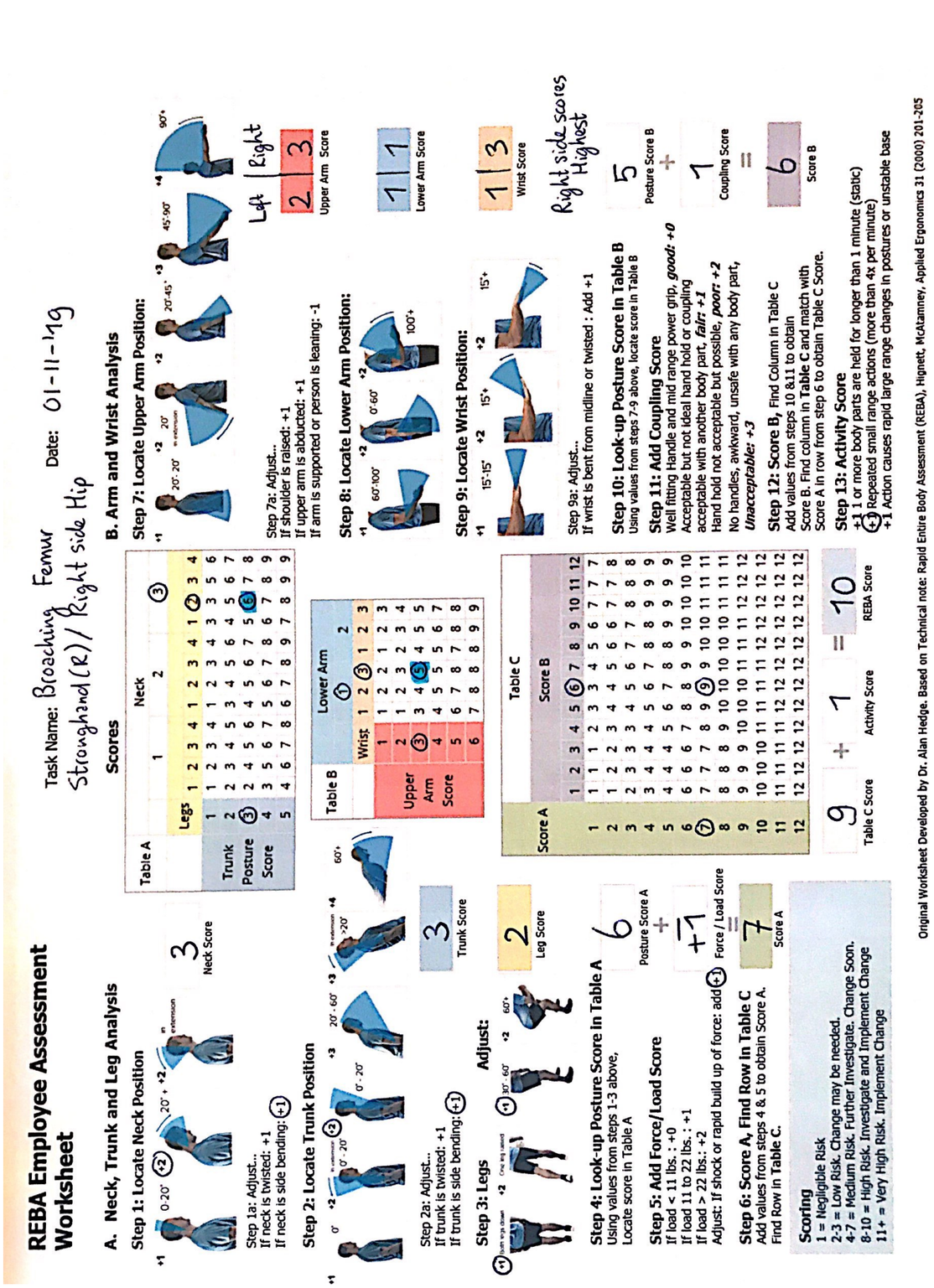
A.6 Posture analysis - observations

A. In observations noticed awkward postures when using strong hand (R) with Femural broaching right side patient





Group A: Neck, Trunk and Leg Analysis	
Trunk score	+3 back flexion between 20-60 degrees
Neck score	+2 flexion 20 degrees | +1 side bend of the neck
Legs score	+1 for straight legs | +1 knees bend 30-60 degrees (standing upright) A score of 2 in total
Table A posture outcome	**Table A gives posture score of 6**
Load/Force	+1, for rapid build-up of force/shock, due to impacting motion/actions
Score A = Posture score A + Force/Load score	7
Group B: Arm and Wrist Analysis (R = right side / L = left side)	
Upper Arm (R)	+3, flexion 45-90 degrees
Upper Arm (L)	+2, flexion 20-45 degrees
Lower Arm (R)	+1, flexion between 60-100 degrees
Lower Arm (L)	+1, flexion between 60-100 degrees
Wrist (R)	+2, extension of more than 15 degrees | +1 wrist bent
Wrist (L)	+1, flexion between 15 degrees
Table B outcome	**R: 5 for L: 1, highest scoring side for rest of score sheet.**
Adding of Coupling score	+1, acceptable but not ideal hand hold/coupling (fair)
Total Arm and Wrist Analysis score	6
Table C outcome	**10, for the right side (arm and wrist)**
Activity score	+1, repeated small range actions (more than 4x per minute)
Reba Score	**11**
Action Level	**High Risk, implement change**

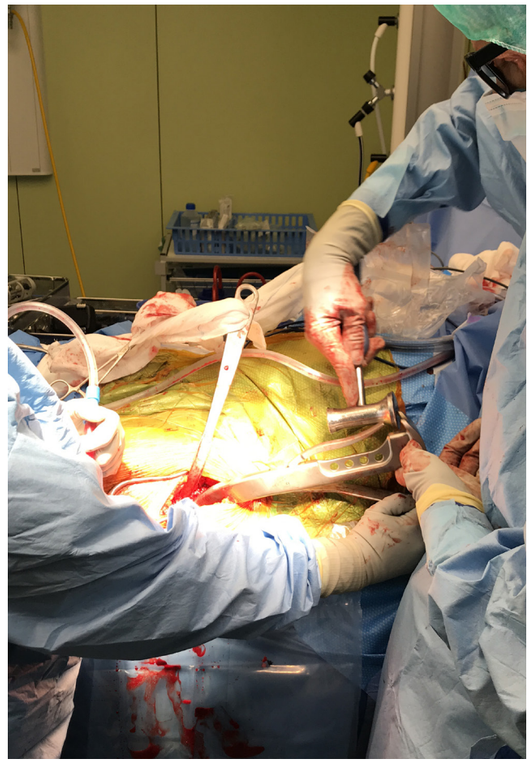


Source for worksheet:

Hedge, A. (2000) REBA Employee Assessment worksheet. Retrieved on 12 November 2019 from https://ergo-plus.com/reba-assessment-tool-guide/

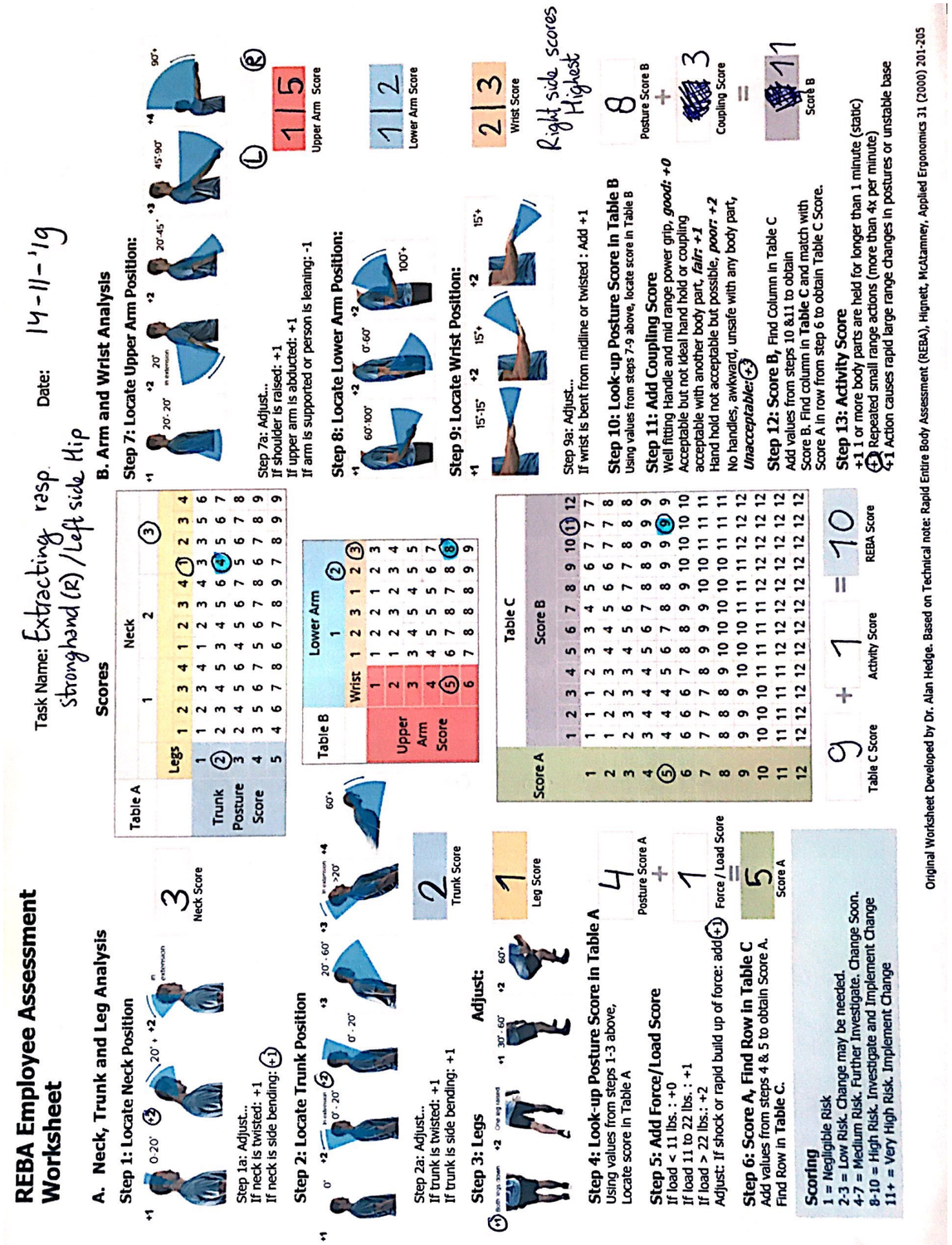
Hignett, S., & McAtamney, L. (2000). Rapid entire body assessment (REBA). Applied ergonomics, 31(2), 201–205. https://doi.org/10.1016/s0003-6870(99)00039-3

B. In observations noticed awkward postures when using strong hand (R) with extracting rasps left side patient



Posture used for standing postures legs (similar as in left picture)

Group A: Neck, Trunk and Leg Analysis	
Trunk score	+2 back flexion between 0-20 degrees
Neck score	+2 flexion 20 degrees | +1 side bend of the neck (observed not clear view in pictures)
Legs score	+1 for straight legs
Table A posture outcome	**Table A gives posture score of 4**
Load/Force	+1, for rapid build-up of force/shock, due to impacting motion/actions
Score A = Posture score A + Force/Load score	5
Group B: Arm and Wrist Analysis (R = right side / L = left side)	
Upper Arm (R)	+3, flexion 45-90 degrees | +1 raised shoulder | +1 abducted upper arm
Upper Arm (L)	+1, resting between 20 flexion and 20 degrees extension
Lower Arm (R)	+2, flexion between 0-60 degrees
Lower Arm (L)	+1, flexion between 60-100 degrees
Wrist (R)	+2, flexion of more than 15 degrees | +1 bent/twist
Wrist (L)	+1, flexion between 15 degrees and extension 15 degrees | +1 bent/twist
Table B outcome	**R: 8 for L: 2, highest scoring side for rest of score sheet.**
Adding of Coupling score	+3, awkward and unsafe handling/coupling (based on safety +3 was chosen)
Total Arm and Wrist Analysis score	11
Table C outcome	**9, for the right side (arm and wrist)**
Activity score	+1, repeated small range actions (more than 4x per minute)
Reba Score	**10**
Action Level	**High Risk, investigate and implement change**



REBA Employee Assessment Worksheet

Task Name: Extracting resp stronghand (R) / Left side Hip Date: 14-11-19

Scores

A. Neck, Trunk and Leg Analysis

Step 1: Locate Neck Position
Step 1a: Adjust...
If neck is twisted: +1
If neck is side bending: +1
Neck Score: 3

Step 2: Locate Trunk Position
Step 2a: Adjust...
If trunk is twisted: +1
If trunk is side bending: +1
Trunk Score: 2

Step 3: Legs
Adjust:
Leg Score: 1

Step 4: Look-up Posture Score in Table A
Using values from steps 1-3 above,
Locate score in Table A
Posture Score A: 4

Step 5: Add Force/Load Score
If load < 11 lbs. : +0
If load 11 to 22 lbs. : +1
If load > 22 lbs.: +2
Adjust: If shock or rapid build up of force: add +1
Force / Load Score: 1

Step 6: Score A, Find Row in Table C
Add values from steps 4 & 5 to obtain Score A.
Find Row in Table C.
Score A: 5

Scoring
1 = Negligible Risk
2-3 = Low Risk. Change may be needed.
4-7 = Medium Risk. Further Investigate. Change Soon.
8-10 = High Risk. Investigate and Implement Change
11+ = Very High Risk. Implement Change

Table A: Neck / Legs / Trunk Posture / Score
Table B: Lower Arm / Wrist / Upper Arm Score
Table C: Score A / Score B

9 + 1 = 10
Table C Score | Activity Score | REBA Score

B. Arm and Wrist Analysis

Step 7: Locate Upper Arm Position:
Step 7a: Adjust...
If shoulder is raised: +1
If upper arm is abducted: +1
If arm is supported or person is leaning: -1
Upper Arm Score: 1 | 5 (L ②)

Step 8: Locate Lower Arm Position:
Lower Arm Score: 1 | 2

Step 9: Locate Wrist Position:
Step 9a: Adjust...
If wrist is bent from midline or twisted : Add +1
Wrist Score: 2 | 3

Right side scores Highest

Step 10: Look-up Posture Score in Table B
Using values from steps 7-9 above, locate score in Table B
Posture Score B: 8

Step 11: Add Coupling Score
Well fitting Handle and mid range power grip, *good: +0*
Acceptable but not ideal hand hold or coupling acceptable with another body part, *fair: +1*
Hand hold not acceptable but possible, *poor: +2*
No handles, awkward, unsafe with any body part, *Unacceptable: +3*
Coupling Score: 3

Step 12: Score B, Find Column in Table C
Add values from steps 10 &11 to obtain Score B. Find column in Table C and match with Score A in row from step 6 to obtain Table C Score.
Score B: 11

Step 13: Activity Score
+1 1 or more body parts are held for longer than 1 minute (static)
+1 Repeated small range actions (more than 4x per minute)
+1 Action causes rapid large range changes in postures or unstable base

Original Worksheet Developed by Dr. Alan Hedge. Based on Technical note: Rapid Entire Body Assessment (REBA), Hignett, McAtamney, Applied Ergonomics 31 (2000) 201-205

Source for worksheet:
Hedge, A. (2000) REBA Employee Assessment worksheet. Retrieved on 12 November 2019 from https://ergo-plus.com/reba-assessment-tool-guide/

Hignett, S., & McAtamney, L. (2000). Rapid entire body assessment (REBA). Applied ergonomics, 31(2), 201–205. https://doi.org/10.1016/s0003-6870(99)00039-3

A.7 Competitor analysis

When looking into the competition concerning the hip market field the largest competitor next to Zimmer Biomet (31%) are DePuy Synthes (31%), a Johnson & Johnson company, Stryker (25%) followed by Smith & Nephew (9%). (Sarah Collins, 2016)

Due to the fact Zimmer acquired Biomet in 2015, their focus was on commercial integration towards a combined company, others gained market share by new and innovative devices. Innovation within this market concerning surgery is mostly gained through the successes of robotic assisting systems, such as the MAKO hip system from Stryker. (Annual Report, 2016) Robotics enable surgeons to plan and place components more accurately than in manual hip replacements. If these robotic assisting procedures emit less noise than manual placement surgeries is not known.

Most big ortho companies are throwing money at robotic surgery technologies for orthopedic procedures. Zimmer Biomet is more cautious and focusses more on its Recovery program, to improve the care process and saving money for the healthcare system. (2) At this moment Zimmer Biomet has a focus innovating in biological fixation, advanced bearing materials and infection diagnosis to offer surgeons and hospitals the ability to meet the various needs of today's patients. (1) Zimmer recently marketed a robot supporting surgeons with total knee replacement, Rosa™, by assisting with bone resections, assessing the state of soft tissue and guide implant positioning intraoperatively (3). If this product is going to be used in hips is not sure, to keep up with the competition within the market I guess they will. (Figure 7.1)

After finding the largest competitors to Zimmer Biomet, I looked into the surgical procedure and technologies they use and tend to market within the hip replacement field.

(1) Zimmer Biomet. (2019) Hip replacement (2019) Retrieved on 11 November 2019 from https://www.zimmerbiomet.com/medical-professionals/hip.html

(2) Cairns, E. (2018) Trickey Europeon Future for Zimmer Biomet (2019)Retrieved on 11 November 2019 from https://www.evaluate.com/vantage/articles/interviews/interview-zimmer-biomet-sees-tricky-european-future

(3) Zimmer Biomet (2019) Rosa Knee. Retrieved on 11 November 2019 from https://www.zimmerbiomet.com/medical-professionals/knee/product/rosa-knee.html

Figure 7.1 Rosa Knee System (Klein G.R., James D., Lonner J.H. (2019) Total Knee Arthroplasty Technique: ROSA® Knee. In: Lonner J. (eds) Robotics in Knee and Hip Arthroplasty. Springer, Cham. First Online: 21 June 2019. DOI https://doi.org/10.1007/978-3-030-16593-2_18)

Figure 7.2 KINCISE System (Johnson and Johnson, 2019)

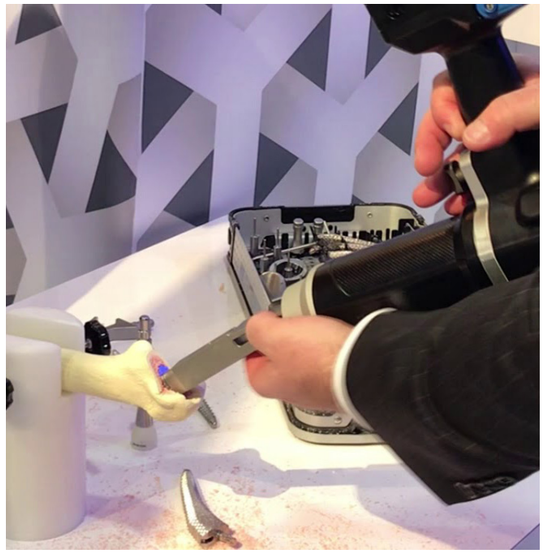


Figure 7.3 KINCISE System (Johnson and Johnson, 2019)

DePuy Synthes, a Johnson and Johnson company

Zimmer Biomet's largest competitor has implants which are in line with the ones Zimmer Biomet produces. DePuy's innovation is on technologies lowering the risk of work-related injury at work and reducing surgical time by digitally templating a patient's hip during surgery.

a. KINCISE™ System

This hammer-drill like system delivers consistent energy, which is there to reduce variabilities experienced with traditional mallets. The system eliminates repetitive mallet swings, which may reduce the risk of work-related injury. (Figure 7.2-7.3) (4) This could be a direct competitor of DriveFit (Final Design Chapter 4 / Evaluation Chapter 5) and therefore the most interesting product to mention.

b. JointPoint™ Hip Navigation System

This system is there to intraoperative analyze the placement of the implants and digitally template the hip of the patient. Focused on analyses of leg length, implant offset and cup position, combined with data-driven decision making. Goal of using this device is reducing surgical time and faster rehabilitation for the patient. (5) (Figure 7.4)

(4) Johnson and Johnson (2019) Kincise surgical automated system Retrieved on 11 November 2019 from https://www.jnjmedicaldevices.com/en-US/product/kincise-surgical-automated-system

(5) Joint Point (2019) Joint Point Hip Navigation System. Retrieved on 11 November 2019 from https://www.jointpoint.com

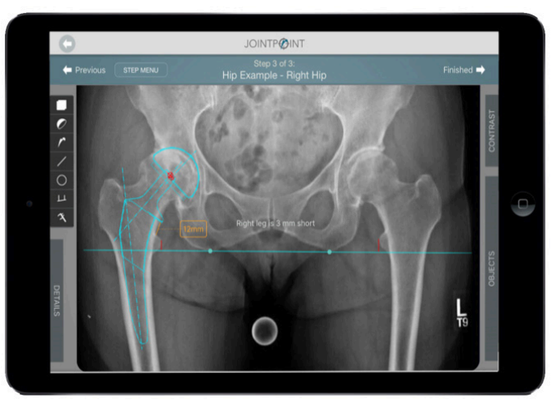


Figure 7.4 Joint Point (Johnson and Johnson, 2019)

Stryker

Stryker was the first company that started integrating surgical assisting robots into their product catalogue. Focused on the best clinical outcome for patient during surgery and on long-term use of the implant.

Mako™ Total hip

Prior to surgery a CT scan is taken in order to generate a 3D model of your hip joint. This model helps the doctor to determine optimal size, placement and positioning of your implant. During surgery the range-of-motion can be assessed continuously providing the surgical team with real-time data. (Figure 7.5) When removing arthritic bone, the robotic arm guides the reamer, where a virtual boundary provides tactile resistance to stay within removal boundaries. Finally, it guides the placement into its final sate, ensuring alignment and placement according to your 3D model. (6) (Figure 7.6)

(6) Stryker (2019) Mako Robotic arm. Retrieved on 11 November 2019 from https://patients.stryker.com/hip-replacement/options/mako-robotic-arm-assisted

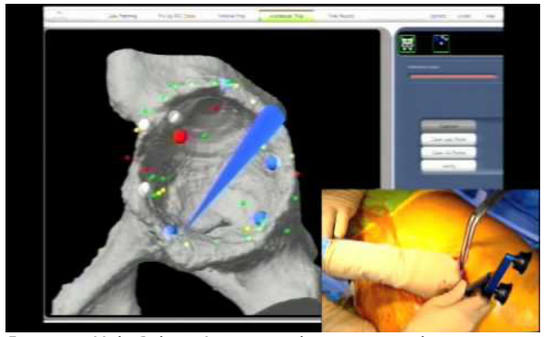


Figure 7.5 Mako Robotic Assistant real time reaming data (Stryker, 2019)

Figure 7.6 Mako Robotic Assistant for reamer (Stryker, 2019)

Smith & Nephew

Most company competitors are slowly going towards software or robotic guided surgery, Smith & Nephew has their own supporting software-guided surgery tool.

Brainlab HIP™

Brainlab software supports orthopedic surgeons to accurately position components, leg length and offset measurements. The software works together with a set of instruments used during the procedure, enabling to precisely and reproducibly align implant components within the replacement surgery. (7) (Figure 7.7)

(7) Brainlab (2019) Orthopedic surgery products, hip navigation app. Retrieved on 11 November 2019 from: https://www.brainlab.com/surgery-products/orthopedic-surgery-products/hip-navigation-application/

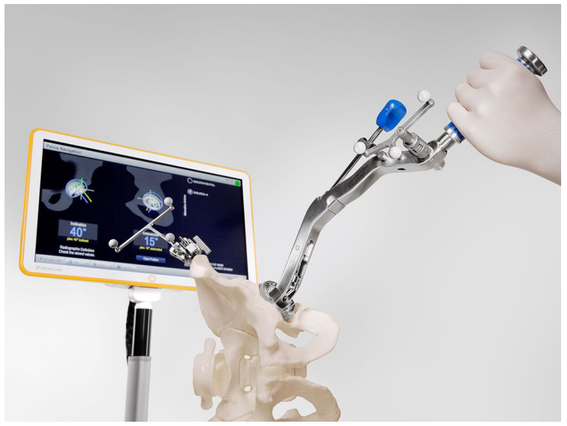


Figure 7.7 Brainlab HIP software + instruments (Smith and Nephew, 2019)

A.8 List of requirements

Performance
1. Reduce the sound level by 10 dB, this means reduction of perceived noise to half its level. So, it is below the human pain threshold of +-120 dB.
2. The product should guarantee safety for user.
3. The new medical device should not affect the current procedure (flow).
4. Used materials can withstand medical device cleaning process and sterilization techniques.
5. The product may not damage current instrumentation and implants when being used within the total hip replacement procedure.
6. Wish: The product should have a production price ranging from €100-150.

Environment
- The product needs to survive in a hospital environment. (21 degrees and dry).

Life in Service
- The product needs to be used within specific time frames during surgery and has to perform the way it's constructed and intended to use. (Fit to the surgical workflow)
- The product should be used 2-5 years, as it is intended to use.

Testing
- The product needs to be tested on FDA and MDR standards to be sure of its stability.
- The product needs to meet CE requirements.
- The product has to meet Class 1 Medical device regulations.
- The product needs to be checked after assembly on function.

Quantity
- About 100.000 units will be produced specific for the hip replacement procedure.

Production Facilities
- The product has to be produced with the current production methods that Zimmer Biomet is familiar with.

Weight
-Product weight should be around 2,5 kg, because the tool will be used away from the body or above the shoulder (CCOHS, 2020)

Materials
- The materials used are qualified to be used in a hospital environment, especially orthopedics. (medical grade)
- The materials used are provided with quality marks, to show they are medically approved.

Product Life Span
- The expectance is the product will get produced for 5-10 years and sold for 15 years.

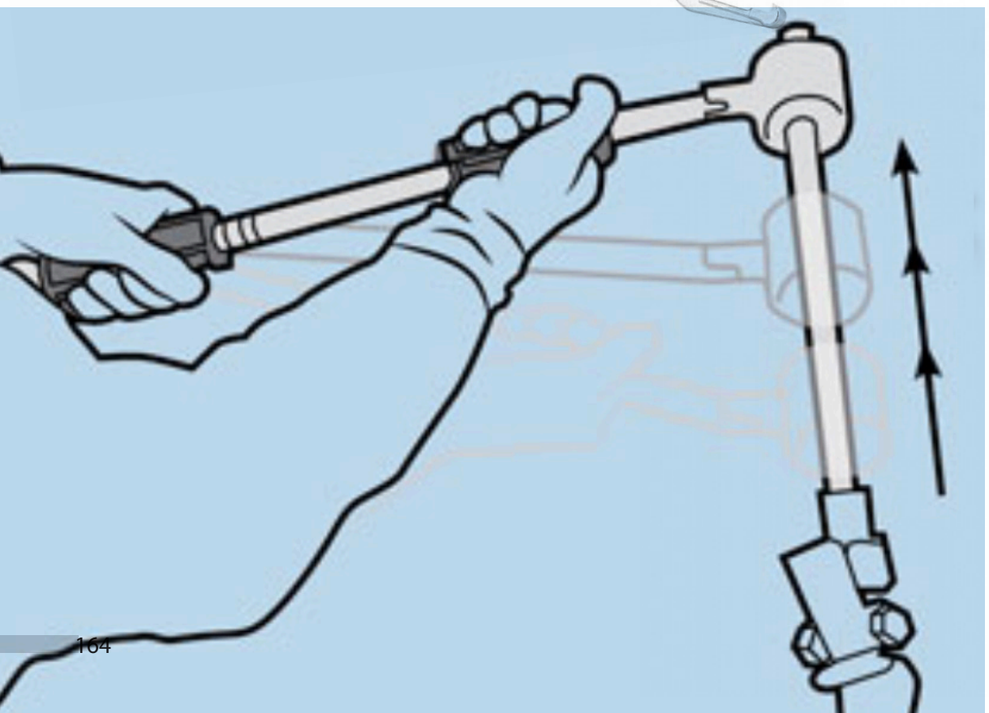
Ergonomics
- Product needs to be comfortably be used by P5 and P95.
- Product needs to lower the risk for musculoskeletal injury, to low risk state.
- When the product is used to apply force with, it should give the similar output as the current used instruments.

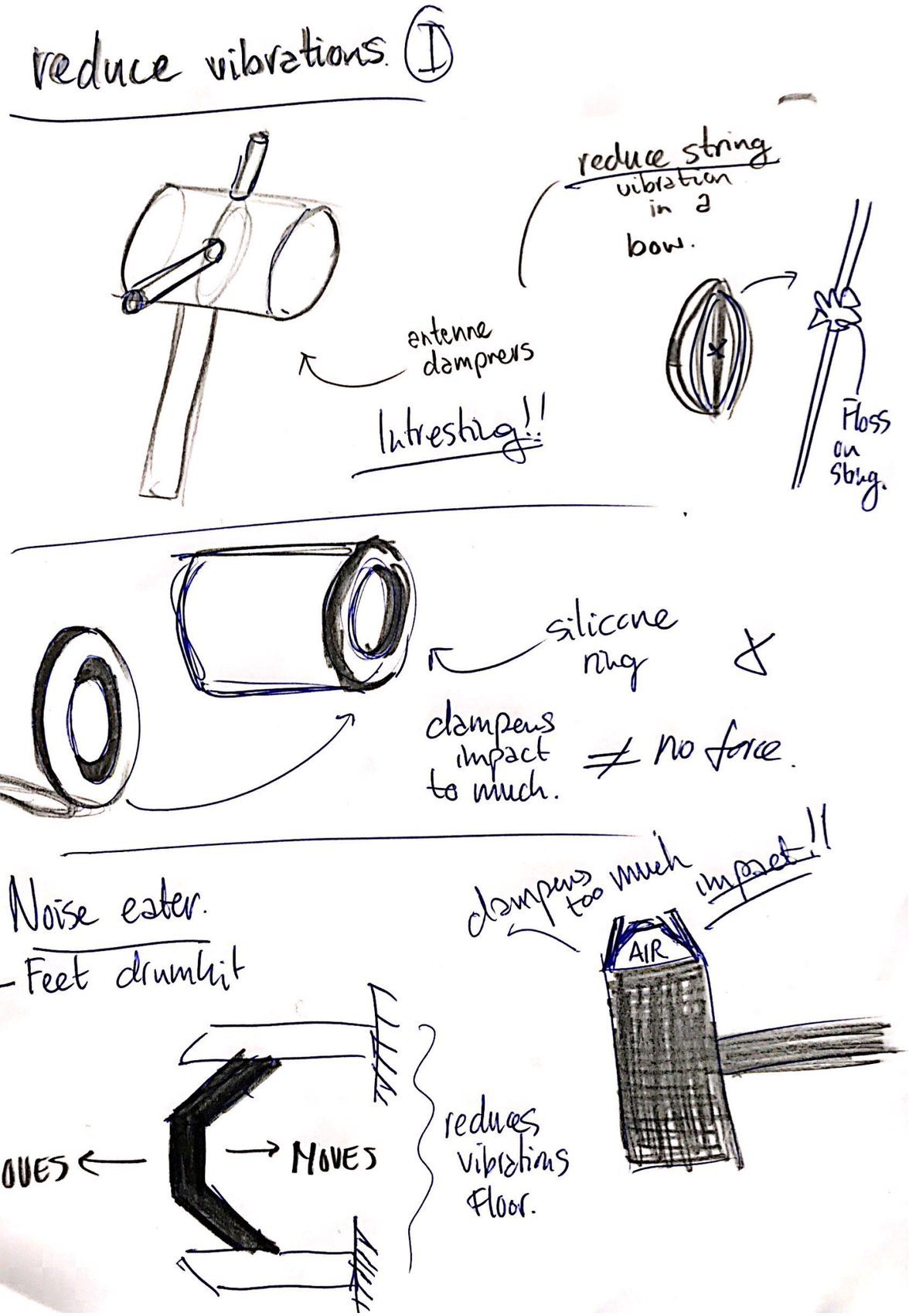
Reliability
- The product cannot simply fail in normal use.
- The product needs to guarantee sterility when cleaned. (Autoclave sterilization)

Safety
- The product should not harm the user in any possible way.
- The product should not damage the implant.
- The product should not damage human tissue (clinical testing needed)

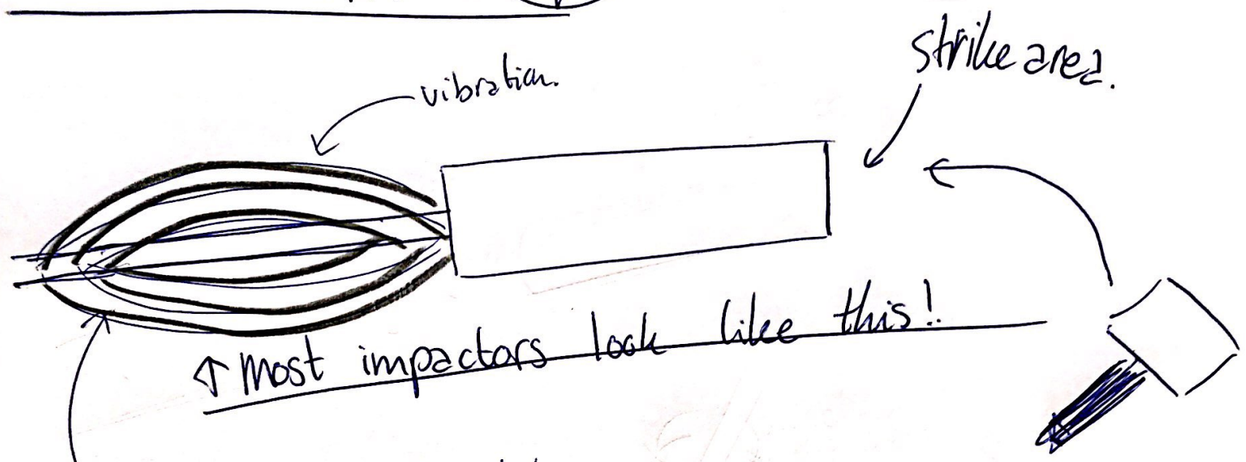
A.9 Ideation: Hammer collage - inspiration

Slide hammers (lineair force) - inspiration

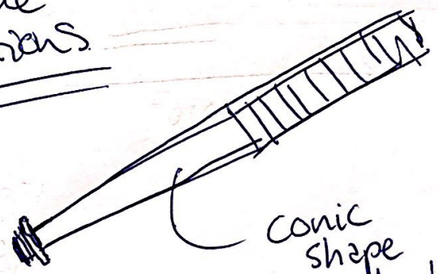




Reduce vibrations (I)

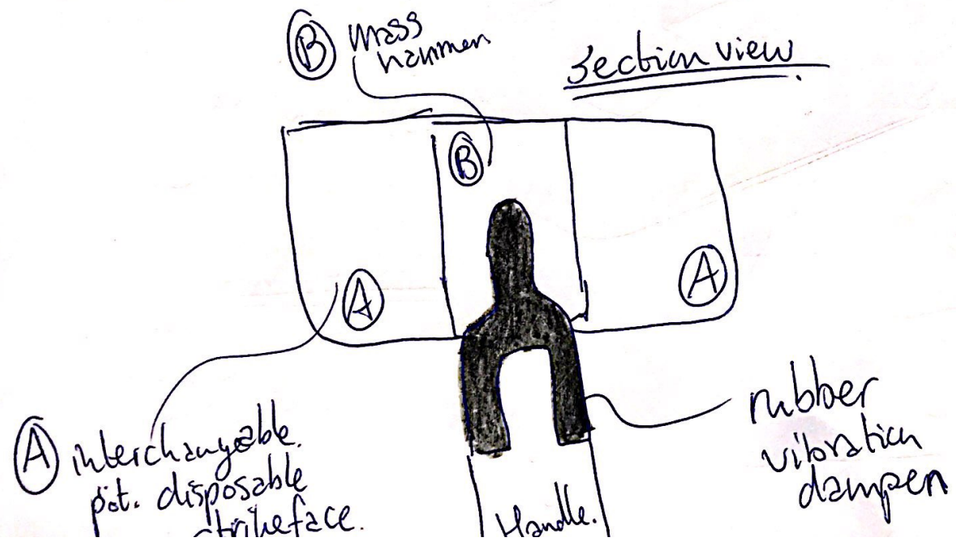


tuning fork like vibrations



conic shape less high freq. sound.

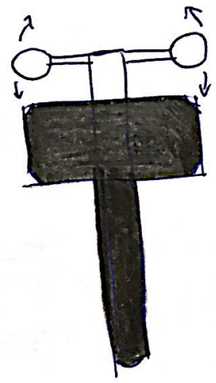
* Antivibration hammer



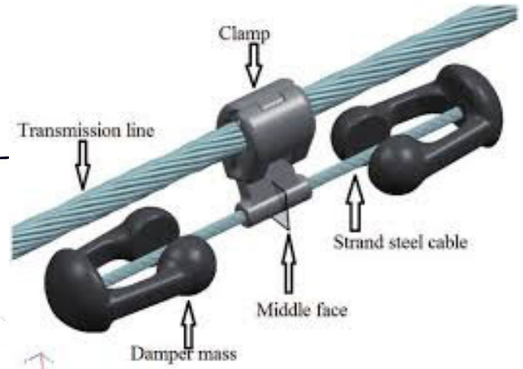
Reduce vibrations (II)

Source:
Wang, Liang & Yisheng, Zhang. (2014). Nonlinear numerical model with contact for Stockbridge vibration damper and experimental validation. Journal of Vibration and Control. 22. 10.1177/1077546314535647

↳ vibration damper.
used in transmission lines.



↳ dampen vibration. many mass on impact.



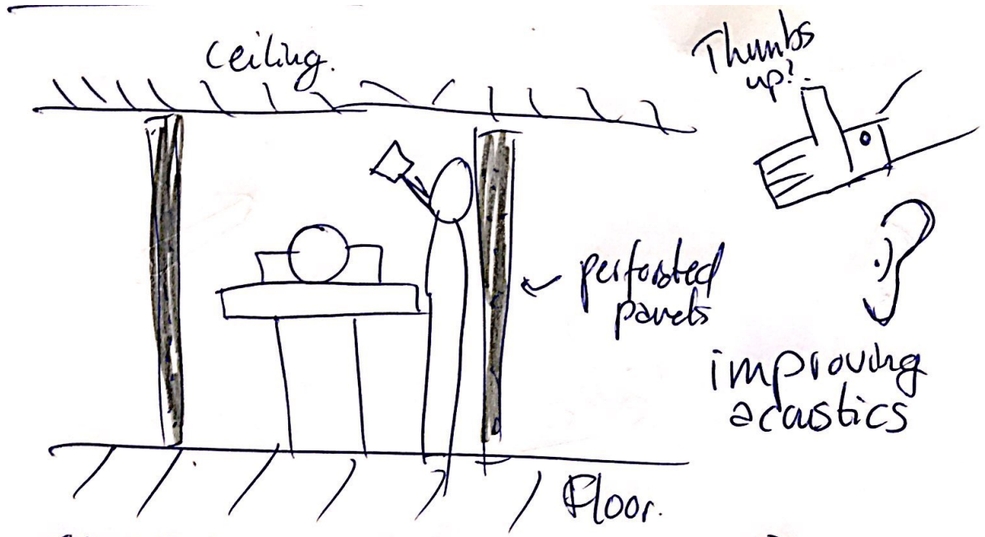
Stockbridge vibration damper (Wang, 2014)

Hammer head wrapped

cloth disposable.

no-metal on-metal impact.

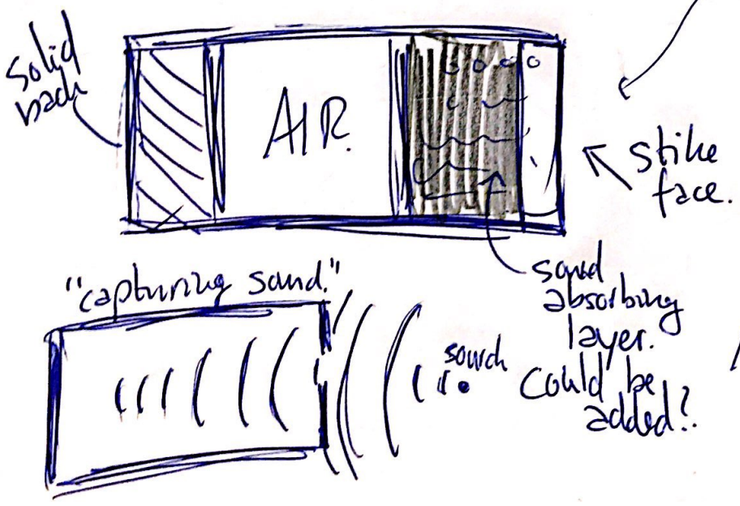
↖ Similar as plastic surgeon uses, DOES NOT MELT/BREAK!



concerns.
- regulations. (cleaning?)
- movability
- not solution posture and MSD.

Hammerheads

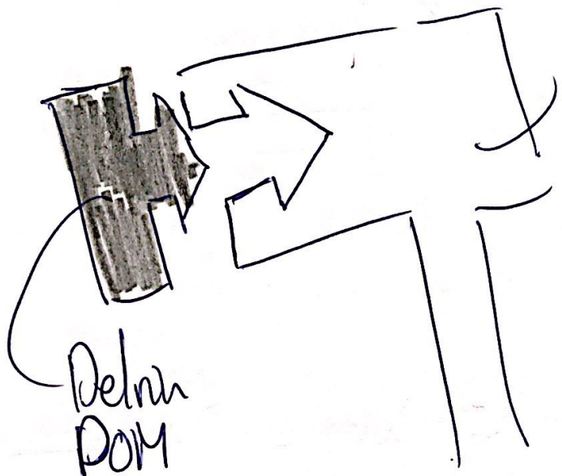
Tuned resonant absorber.



Foam/cloth
disposable.
Medical Grade.
=Polydamp.

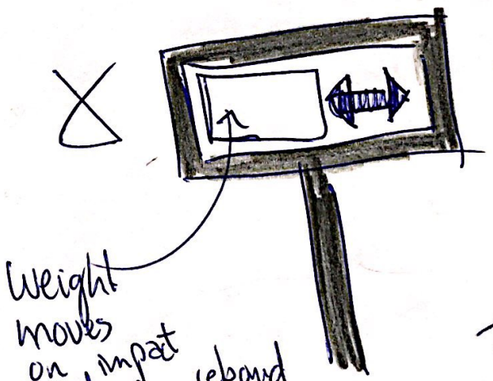
Hammer ideas. (I)

* disposable strikeface.

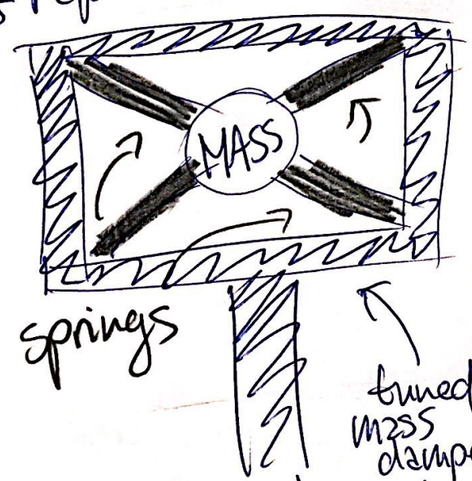


interchangeable dunky surgery.

* dead blow hammer.



* repercusion

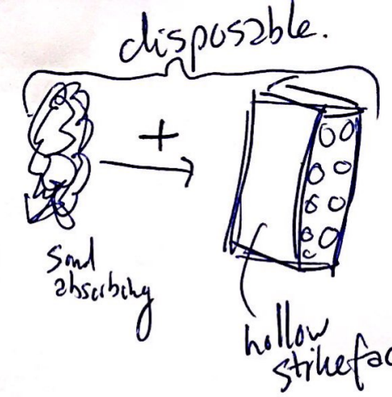


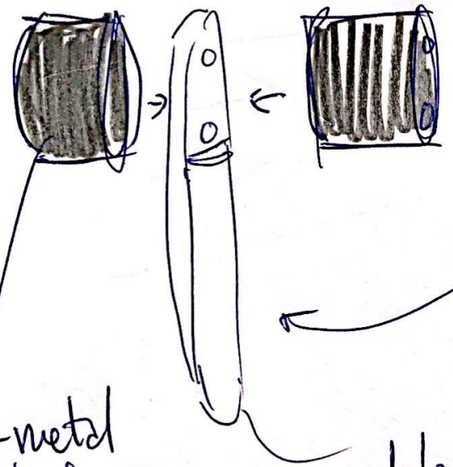
elastic rebound as in skyscrapers

always return to centre of mass

Hammer Ideas (II)

Modular Hammer



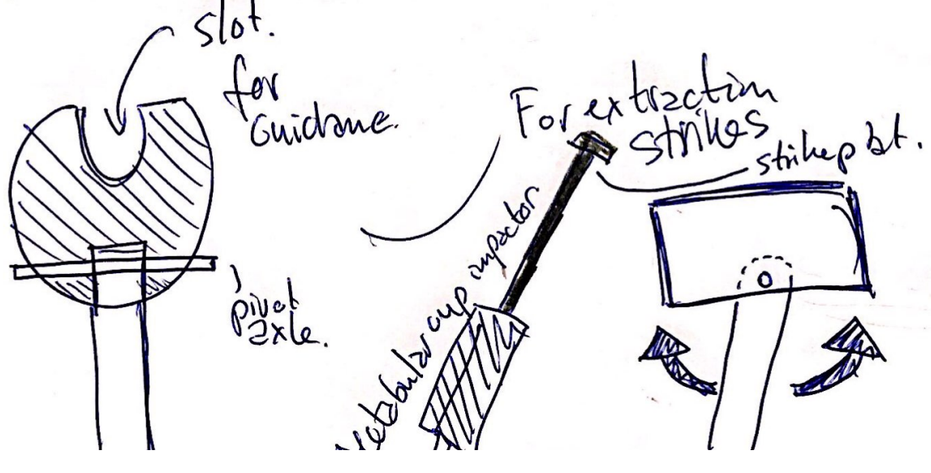


Interchangeable Handles

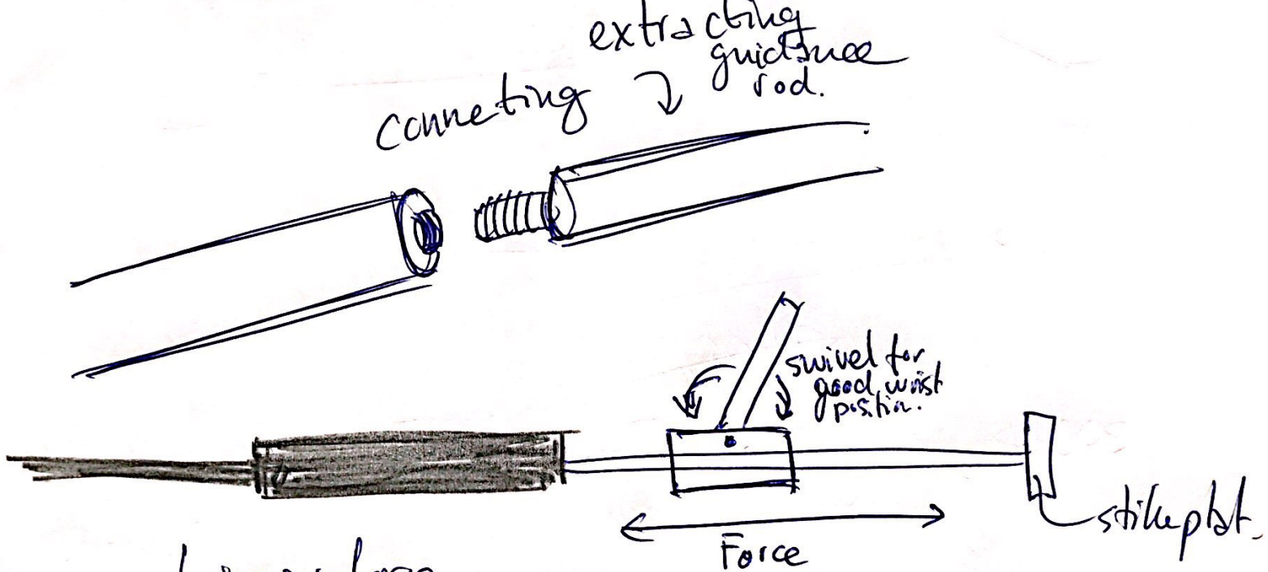
- appropriate for all surgical steps.

Plusses (+)

* weight can be adapted.



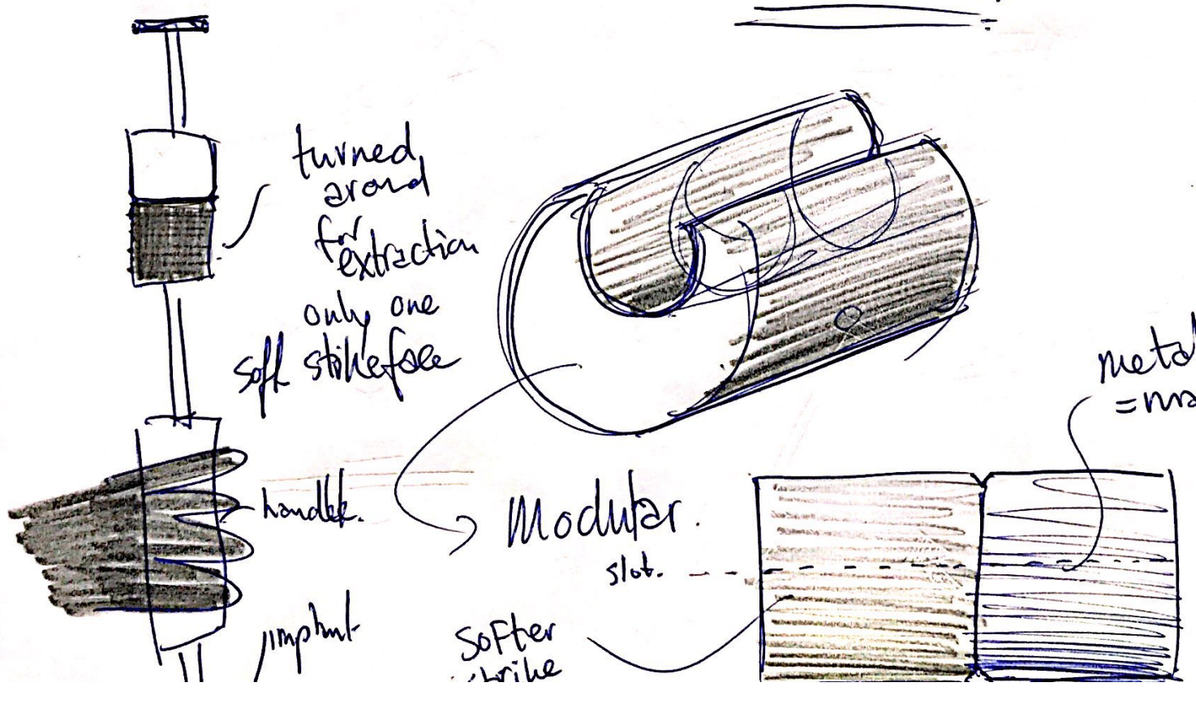
Hammer Ideas (III)



Linear force.

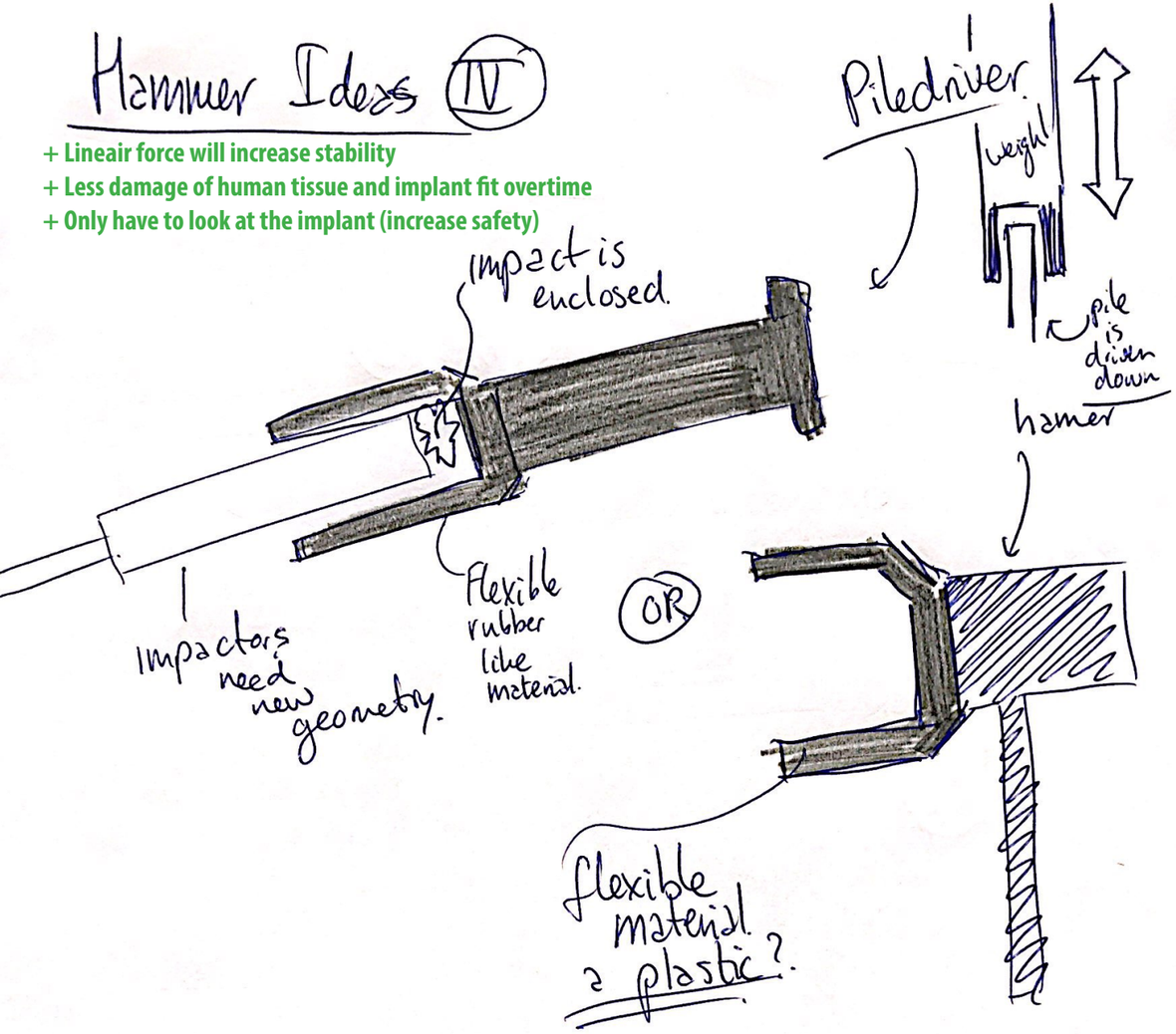
- hit same spot.
- same direction
- better stability

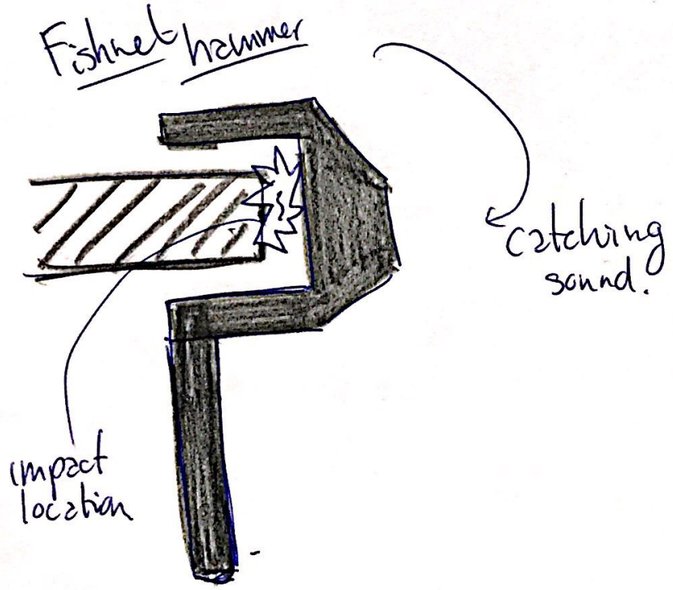
slot hammer



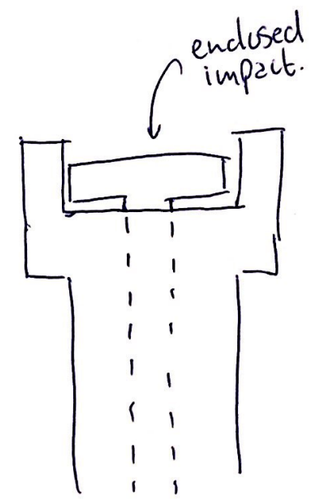
Hammer Ideas IV

+ Lineair force will increase stability
+ Less damage of human tissue and implant fit overtime
+ Only have to look at the implant (increase safety)



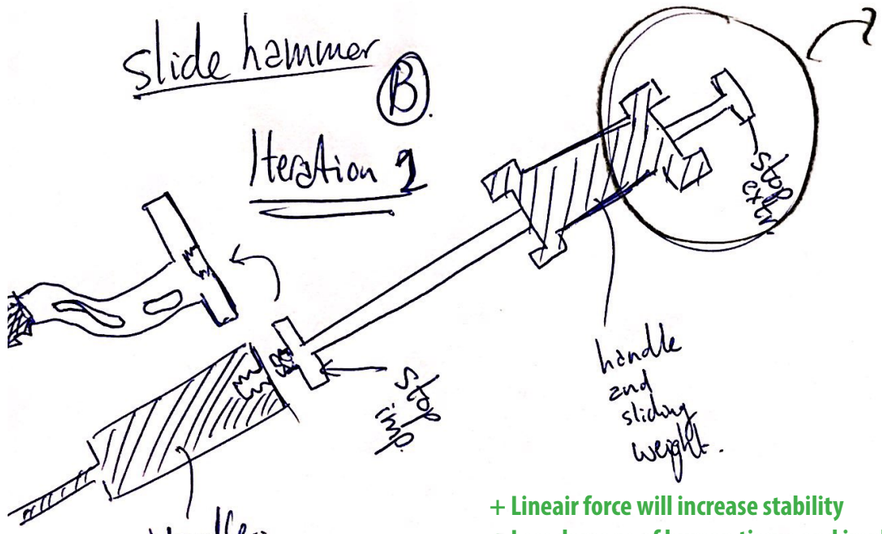


Hammer Ideas V



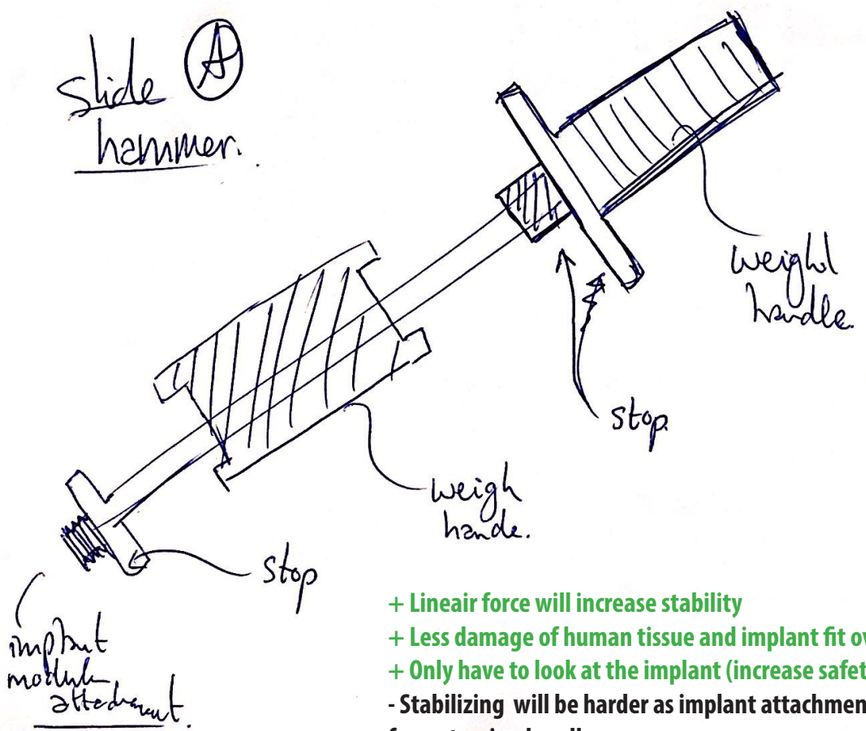
slide hammer B.

Iteration 2



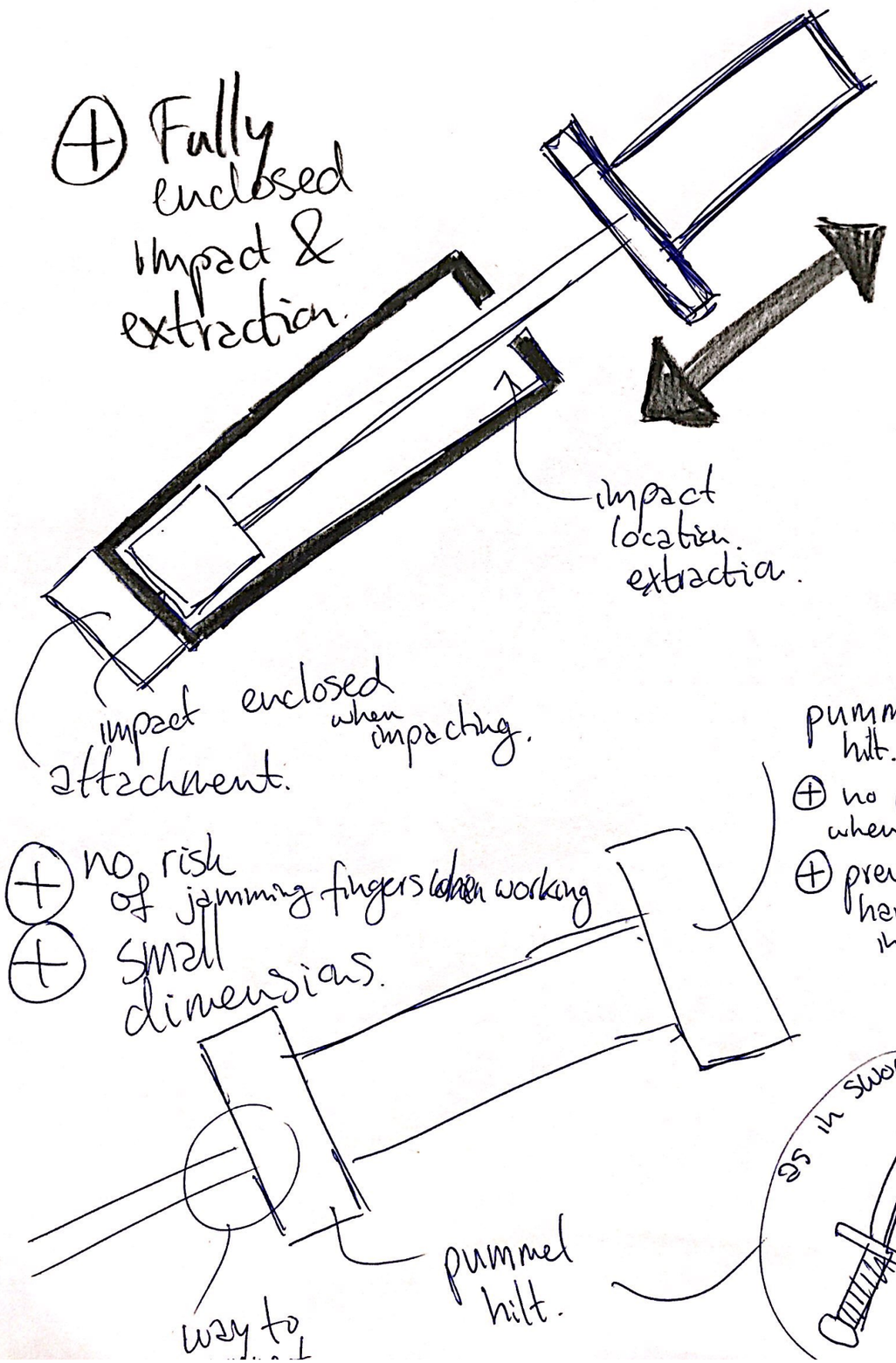
+ Lineair force will increase stability
+ Less damage of human tissue and implant fit overtime
+ Only have to look at the implant (increase safety)

slide hammer. A

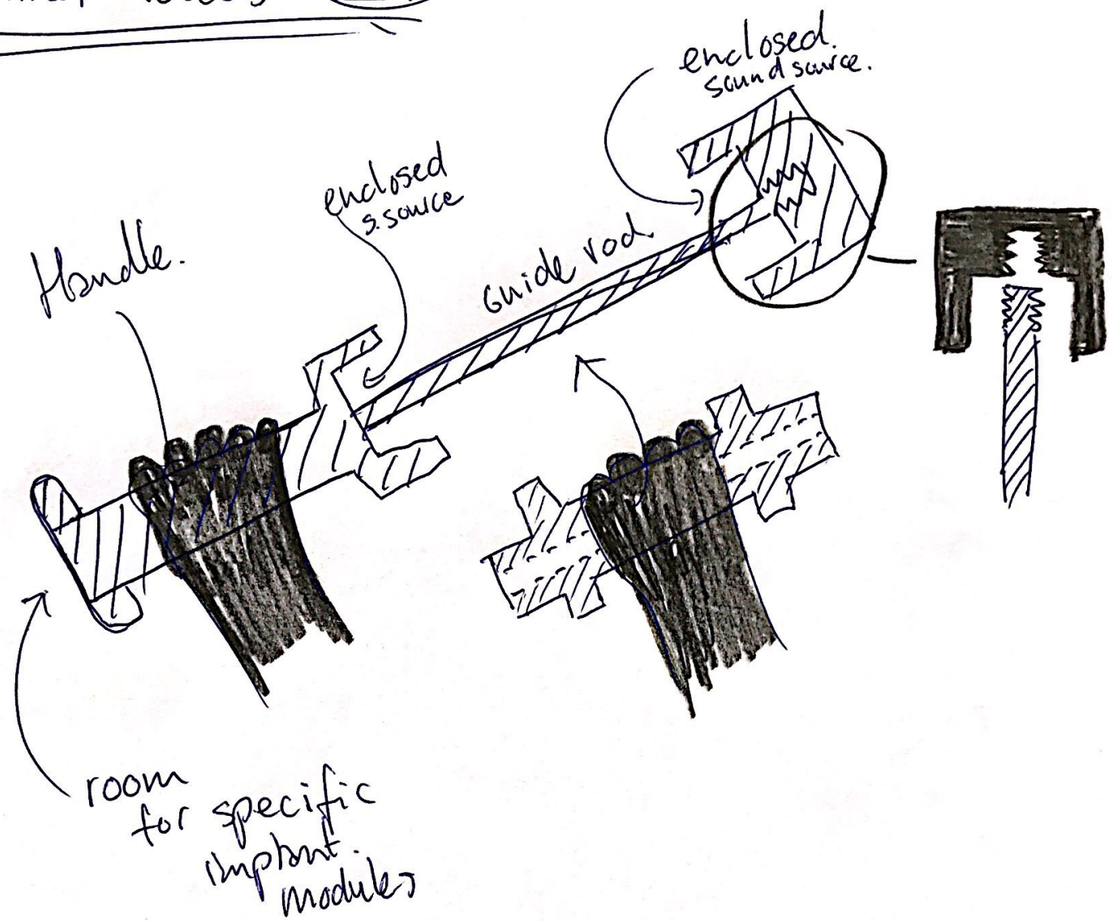


+ Lineair force will increase stability
+ Less damage of human tissue and implant fit overtime
+ Only have to look at the implant (increase safety)
- Stabilizing will be harder as implant attachment is located further away from steering handle

Hammer Ideas VI



Hammer Ideas VII



For Hammer Idea VI and VII, developed after Harris profile

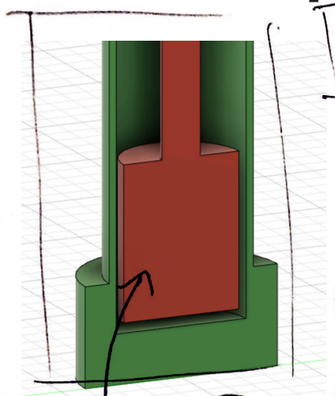
+ Lineair force will increase stability

+ Less damage of human tissue and implant fit overtime

+ Only have to look at the implant (increase safety)

A.10 Concept for Embodiment

Iteration 1



Hand can function as isa. aswell.

sound isolating.

handle for Force exertion.

Hilt (protects hand).

Handle.

Piston collides in tube.

* Top = extraction.
* Bottom = impaction.

these parts will not hit.

impact only inside of tube.

Impact in tube.

handle grip (stability & steering).

pummels safety when losing grip.

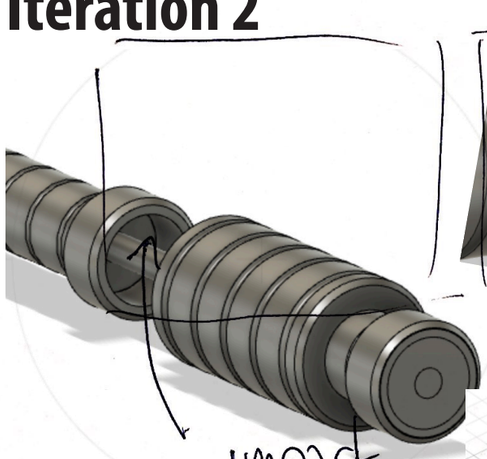
Tube needs to be opened for cleaning

Ways to attach implant have to be decided upon!

Part that will move out.

compact dimensions

Iteration 2



Stop at top when extracting.

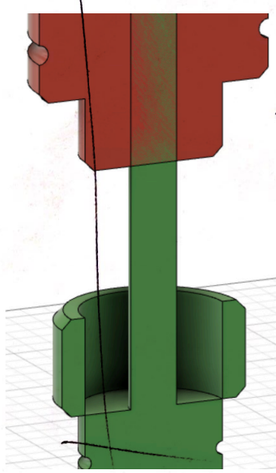
impact is semi enclosed. (reduces sound level!)

grip.

Addeption!

enclosed grip.

Hilts.



weight impact into cavity

Handle.

no use exept grip. increases dimensions

not necessary.

Screwed off - for bigger cleaning!

GIVE LARGER dimensions

A.11 Anthropometry

Hand dimensions (mm) of British adults (Pheasant, 1996); see Figure 14.11. Dimensions of Americans should be similar.

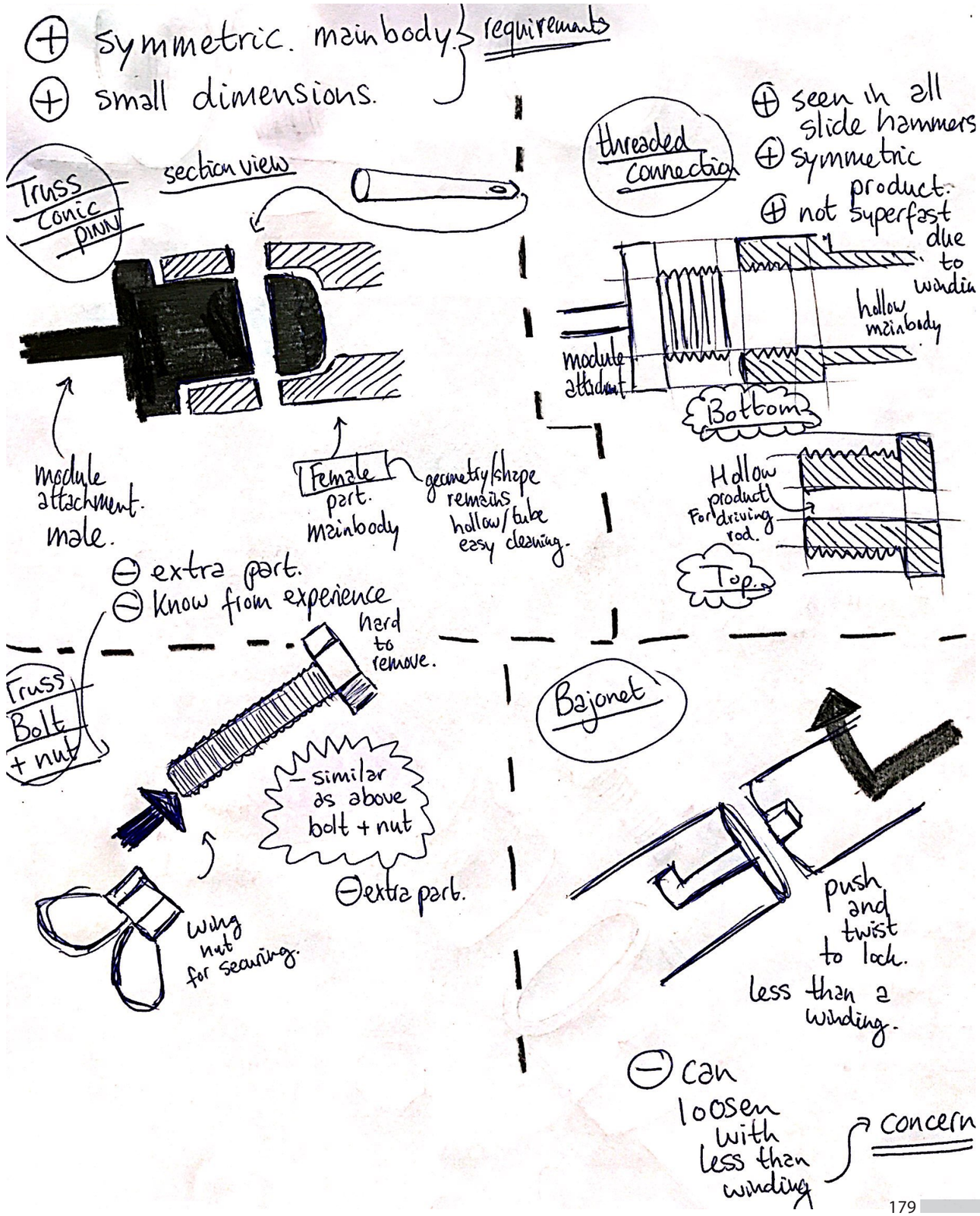
	MEN				WOMEN			
Dimension	5th %ile	50th %ile	95th %ile	SD	5th %ile	50th %ile	95th %ile	SD
1. Hand length	173	189	205	10	159	174	189	9
2. Palm length	98	107	116	6	89	97	105	5
3. Thumb length	44	51	58	4	40	47	53	4
4. Index finger length	64	72	79	5	60	67	74	4
5. Middle finger length	76	83	90	5	69	77	84	5
6. Ring finger length	65	72	80	4	59	66	73	4
7. Little finger length	48	55	63	4	43	50	57	4
8. Thumb breadth (IPJ)[a]	20	23	26	2	17	19	21	2
9. Thumb thickness (IPJ)	19	22	24	2	15	18	20	2
10. Index finger breadth (PIPJ)[b]	19	21	23	1	16	18	20	1
11. Index finger thickness (PIPJ)	17	19	21	1	14	16	18	1
12. Hand breadth (metacarpal)	78	87	95	5	69	76	83	4
13. Hand breadth (across thumb)	97	105	114	5	84	92	99	5
14. Hand breadth (minimum)[c]	71	81	91	6	63	71	79	5
15. Hand thickness (metacarpal)	27	33	38	3	24	28	33	3
16. Hand thickness (including thumb)	44	51	58	4	40	45	50	3
17. Maximum grip diameter[d]	45	52	59	4	43	48	53	3
18. Maximum spread	178	206	234	17	165	190	215	15
19. Maximum functional spread[e]	122	142	162	12	109	127	145	11
20. Minimum square access[f]	56	66	76	6	50	58	67	5

[a] IPJ is the interphalangeal joint, i.e., the articulations between the two segments of the thumb;
[b] PIPJ is the proximal interphalangeal joint, i.e., the finger articulation nearest to the hand;
[c] as for dimension 12, except that the palm is contracted to make it as narrow as possible;
[d] measured by sliding the hand down a graduated cone until the thumb and middle fingers only just touch;
[e] measured by gripping a flat wooden wedge with the tip end segments of the thumb and ring fingers;

Source:

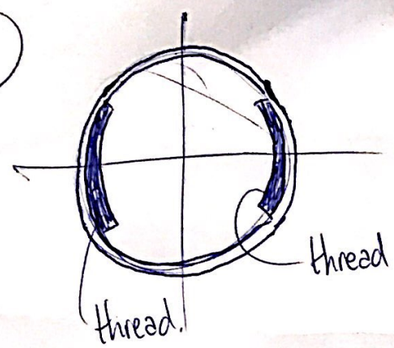
Pheasant, S. Haslegrave, C. (2005) Bodyspace: Anthropometry, Ergonomics And The Design Of Work. (3e ed.) Google books, Boca Raton, USA; CRC press.

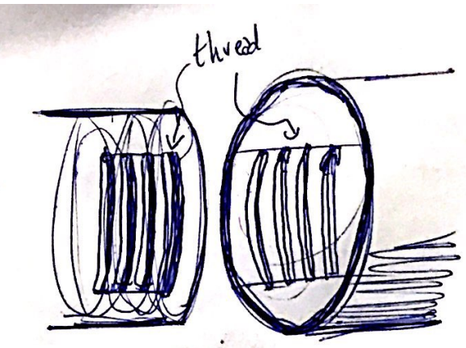
A.12 Connections



~~Half thread~~ connection.

(springy, seen in plastics)





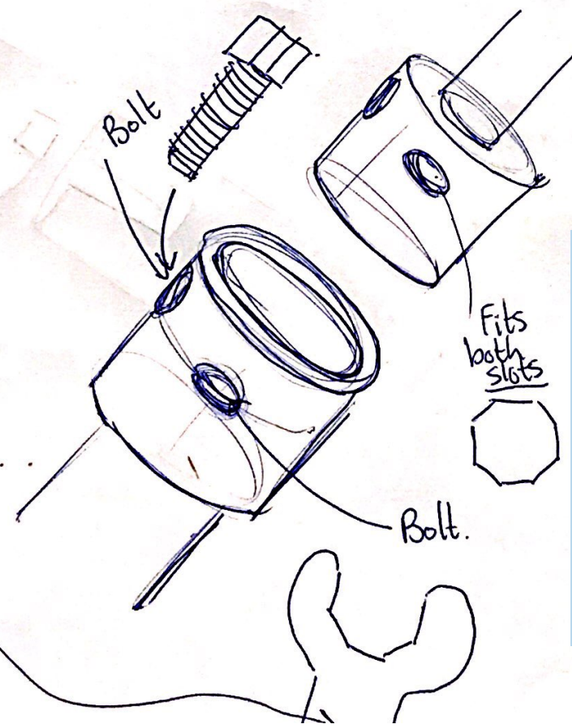
⊖ not strong enough.
⊖ not reliable.

push & twist (90°)

GK connection - gardenhose

⊖ rubber needed For proper closure.
⊖ Hard to dissasemble.
⊕ remains hollow (mainbody).

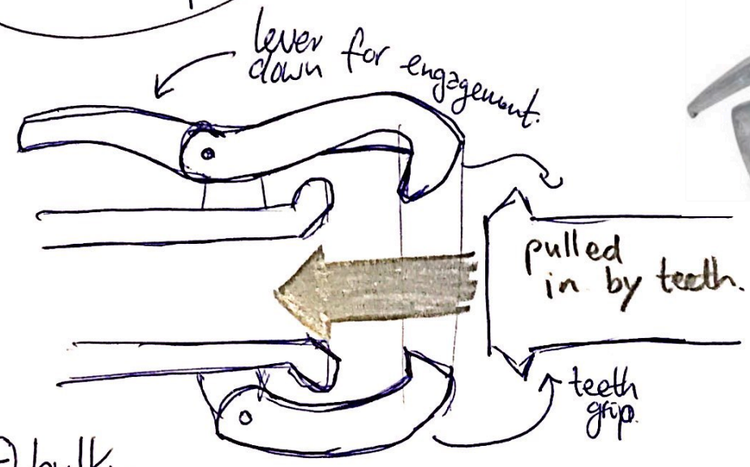
Dubble bolt fixture.



⊖ extra tools needed.
⊖ too slow
⊖ hard to desn.

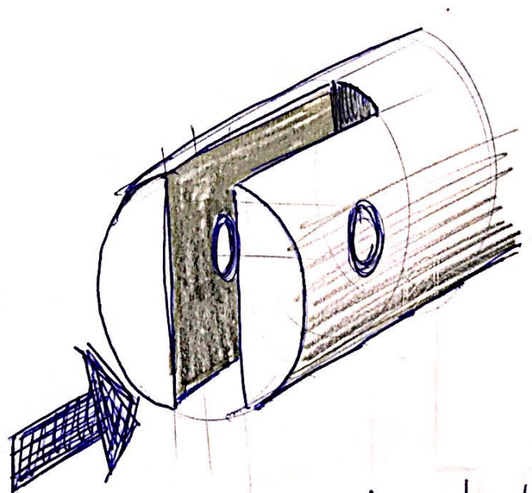
seen in innomed. products

Hose clamp

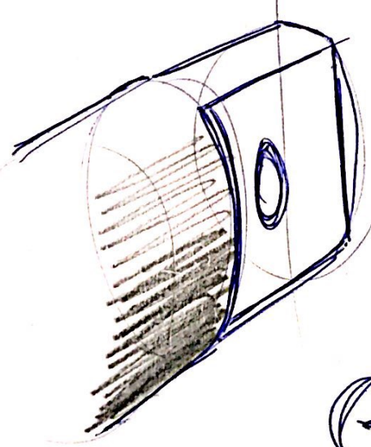


⊖ bulky
⊖ not, clean look + sharp. shape.

NON ROUND Linking. (slot).



✗ NO GO!!

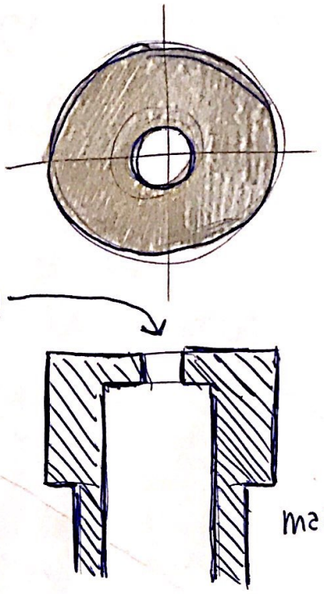


- can be locked with pin or bolt.

⊖ NON HOLLOW PRODUCT.

A.13 Piston Connections

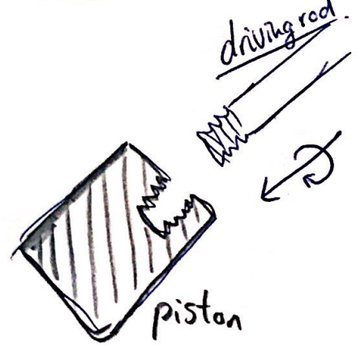
Piston connections



small dimensions.
– HAS TO FIT THROUGH TOP.
AS GUIDE(cap)
+ SO PART HAS TO FIT WITHIN TUBE

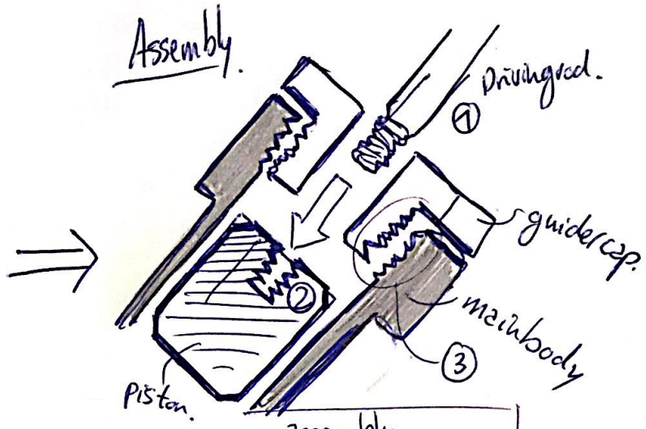
* HOLE HAS TO BE ROUND TO improve sliding
—holes with edge can make rod/hole jamming

Screw Threaded connection.



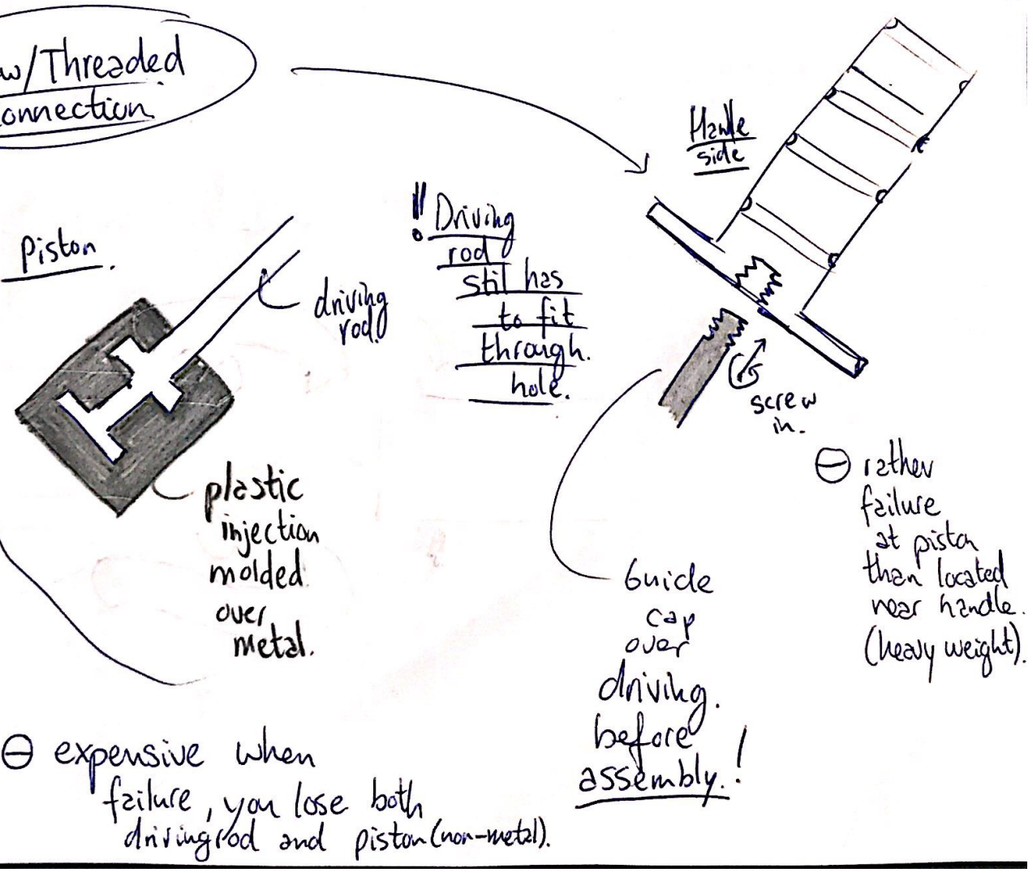
⊕ replacement part only Piston
"relative cheap" plastic.
⊕ reliable. & strong.

Assembly.



Assembly.
① push guiding cap over drivingrod
② screw on piston to drivingrod.
③ push into mainbody & screw onto mainbody.

Screw/Threaded connection



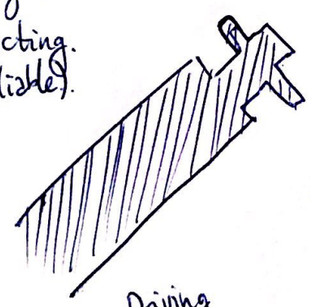
⊖ rather failure at piston than located near handle. (heavy weight).

⊖ expensive when failure, you lose both drivingrod and piston(non-metal).

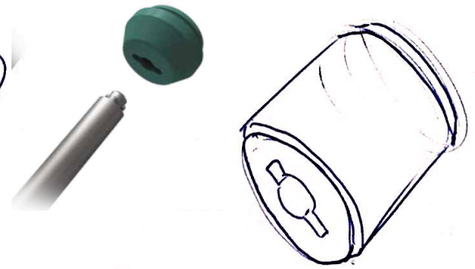
Bayonet closure.

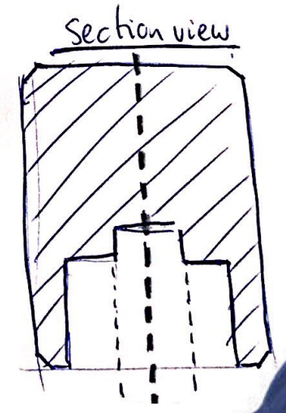
? strong enough when retracting. (pos. unreliable).

? can it be loaded in two directions.



push-in twist. 90°

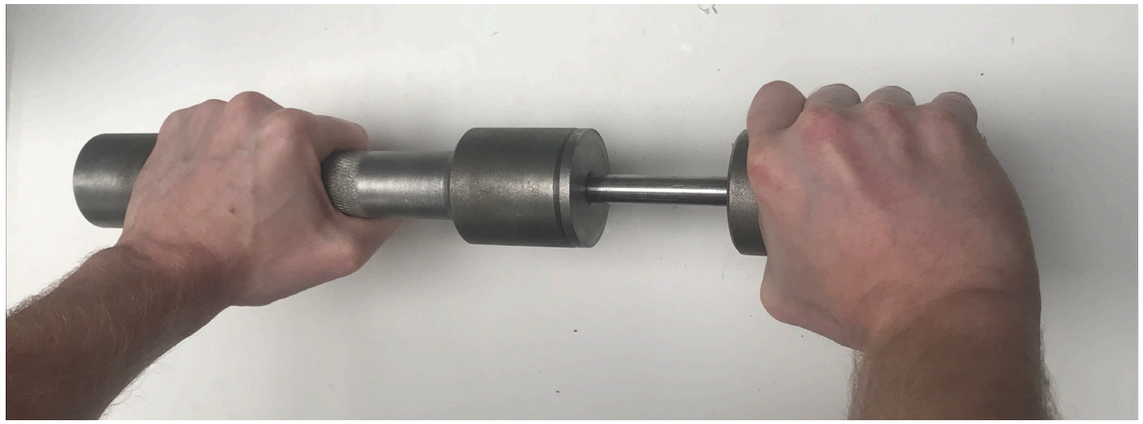




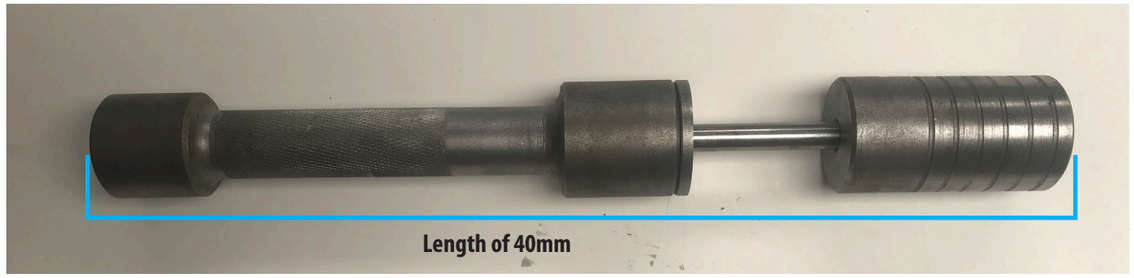
Note: Do not impact the liner insertion instrument. This is indicated on the instrument using the following symbol.

Source: Zimmer Biomet. (2019) Continuum-acetabular-system-surgical-technique. Retrieved on 4 January, 2020 from https://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/000-surgical-techniques/hip/continuum-acetabular-system-surgical-technique.pdf

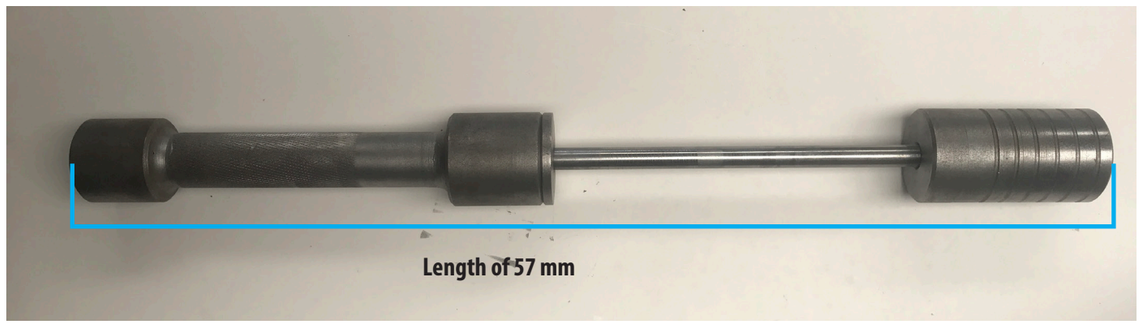
A.14 Prototype 1



(14.1) Prototype 1, held in working position



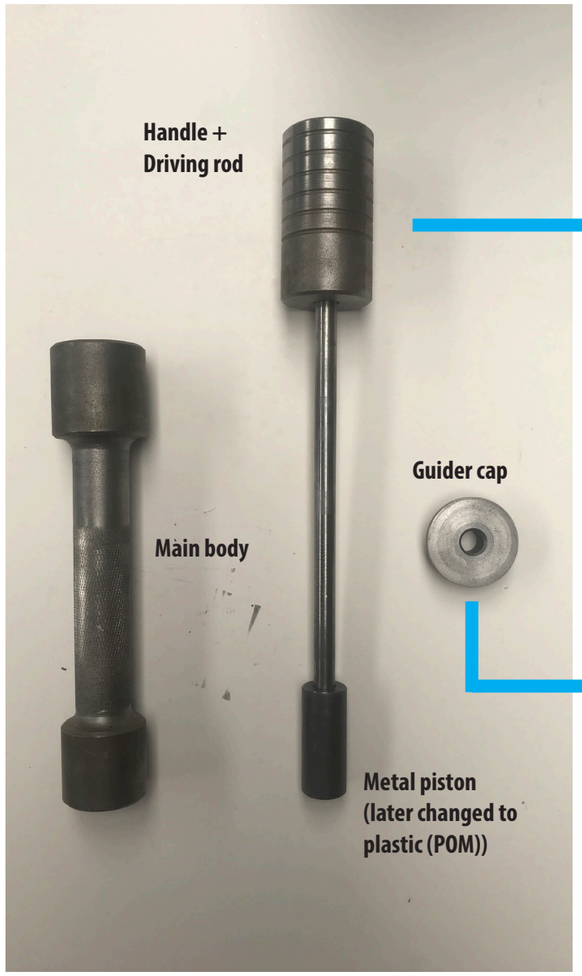
(14.2) Impact state of Prototype 1



(14.3) Extraction state of Prototype 1

(14.4) Powergrip on the Main body

(14.5) Threaded connection on top of main body and guider cap (M30x2)



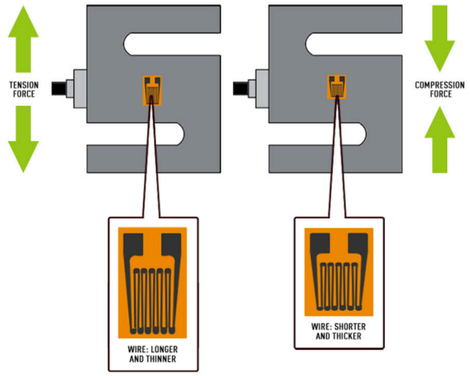
(14.6) All parts of the first prototype

(14.7) Hollow handle as weight reduction (otherwise it was too heavy)

(14.7) Guider cap with hole for driving rod; connected to the top of the main body

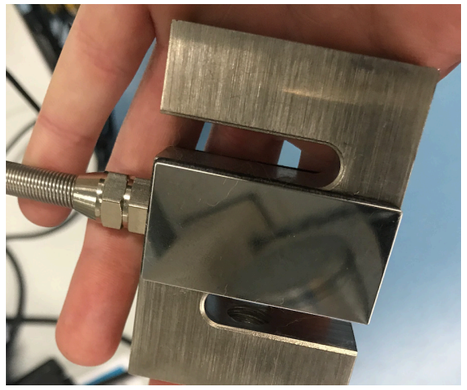
A.15 Loadcell testing - Physical force

By hitting the load cell, in this case a strain gauge made from stainless steel, the spring element in the loadcell deforms slightly and returns to original shape after. When spring like element (copper wire) inside deforms, the gauge changes shape. The result of this is a change in measured voltage, as the resistance changes with the shape. As the force applied is proportional to the change in voltage, the force can be calculated by the strain gauge loadcell's output. (15.1)



(15.1) Stain guage working principle

Scaime ZFA 500 kg (15.2)
Input/output resistance = 385 ±10 / 350 ±5 Ω
Measured Input .384 kilo Ohms with Multimeter (Fluke 117)
Measured Output .351 kilo Ohms with Multimeter (Fluke 117)
This means the loadcell is balanced, thus not broken.



(15.2) Scaime ZFA 500 kg Loadcell (Force to 5000N)

Wiring the set-up (15.3)

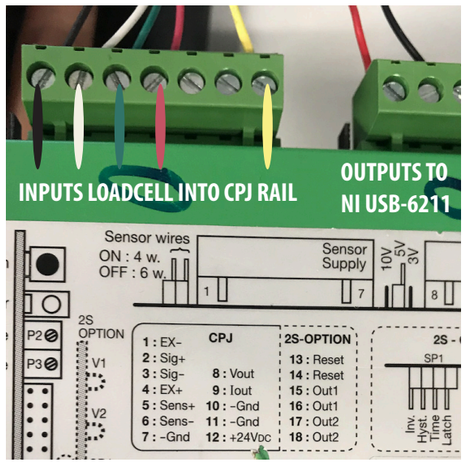
There are 5 wires coming from the Scaime ZFA 500 (loadcell):
• Green and white wire = signal leads (Output)
• Black and red wire = input leads (Input).
• Yellow wire = earth wire (shield)

To the input of the Scaime CPJ rail, sensor inputs:
• Green to Sig- (Port 3), and white wire to Sig+ (Port 2)
• Black to EX- (Port 1), and red to EX+ (port 4)
• Yellow wire to -Gnd, ground/earth shield (Port 7)

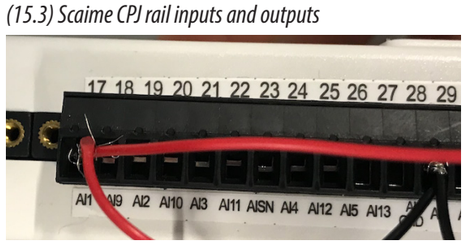
From CPJ rail (outputs) to NI USB-6211: (15.4)
• Red wire from Vout (Port 8), and black wire from I-out (Port 9)

To the input of NI USB-6211:
• Red wire to Port 17 (AI1) Analog Input 1
• Black wire to Port 28 (AI 6 = AI 2-) Analog Input 6

NI USB-6211 is connected to laptop with USB and Labview DAQ.



(15.3) Scaime CPJ rail inputs and outputs



(15.4) CPJ rail out to input NI USB-6211

Calibration Loadcell (15.2)

Calibration in strain by hanging plates of 10 kg on the loadcell, to a total of 50 kg. Measured of the outputs with a Fluke 117 Multimeter, over the green and white wires coming from the Scaime ZFA 500.

Calibration results

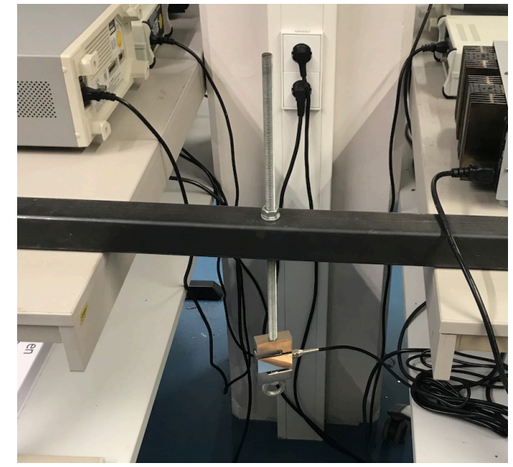
Pressure KG	Unit Data mVdc
0.250 (mass of weight attachment)	-0.005
10.250	-0.205
20.250	-0.404
30.250	-0.605
40.250	-0.803
50.250	-1.007

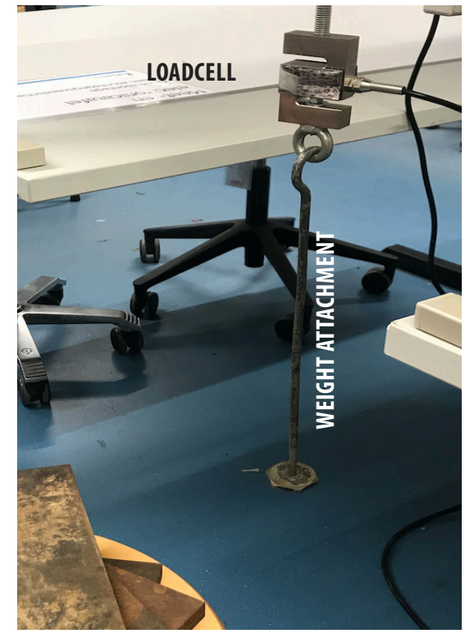
Software DAQ setup

The Labview DAQ 2018 Software was set up with Loadcell "Force" testing settings. As input of the Analog signal, AI1 port was chosen. For the calibration settings the calibration results were used coming from the Fluke 117 Multimeter. This was done by the Measurement Lab personel at Mechanical Engineering TU Delft. All these setting generated a Labview DAQ block diagram, making able to gather data coming from the Analog signal of the Loadcell. (see next page, 15.6)

Test

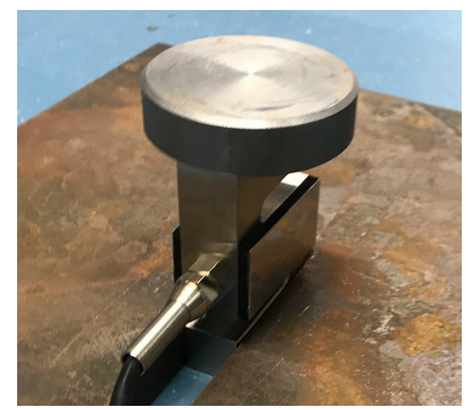
Participant swings 9 times onto a strike plate (15.3-15.4) fabricated specifically for this loadcell with maximum effort with Driversystem Prototype and 9 times with the currently used surgical mallet.





(15.2) Scaime ZFA 500 kg Loadcell loaded in tension to calibrate with weight attachment (Left cornor plates of 10 kg are used as weight)

(15.4) Scaime ZFA 500 kg with strikeplate on top



(15.3) Scaime ZFA 500 kg with strikeplate on top

Results

On the right in 15.5 you find the measured results of 9 swings with prototype 1 and the surgical mallet on the gauge strain loadcell. Forces show that the Scaime ZFA 500, Loadcell was able to measure the forces (below 5000N)

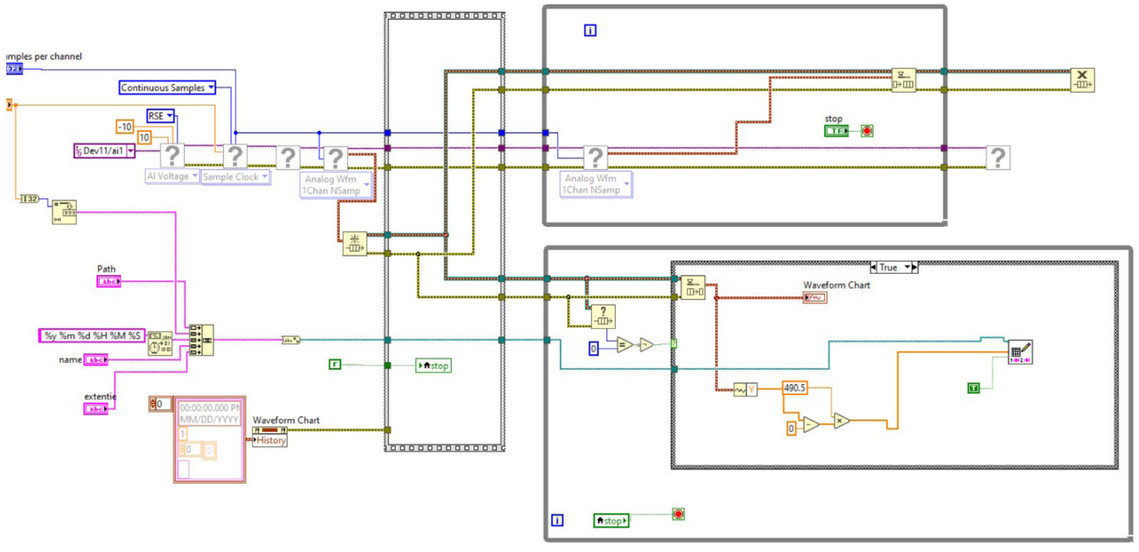
Conclusion

The Driver, Prototype 1, registered larger force maxima. This will probably be due to less impact rebound/vibration and pushing of the driver onto the loadcell before impaction.

Measurement set	Surgical Mallet Force (N)	Prototype 1 Force (N)
Swing 1	3811	4231
Swing 2	3823	4182
Swing 3	3846	4181
Swing 4	3800 *	4179
Swing 5	3793	4177
Swing 6	3403	4214
Swing 7	3698	4169
Swing 8	3734	4173
Swing 9	3746	4172
Mean/Average	3739	4186
%-increase	100%	112% (12% in.)

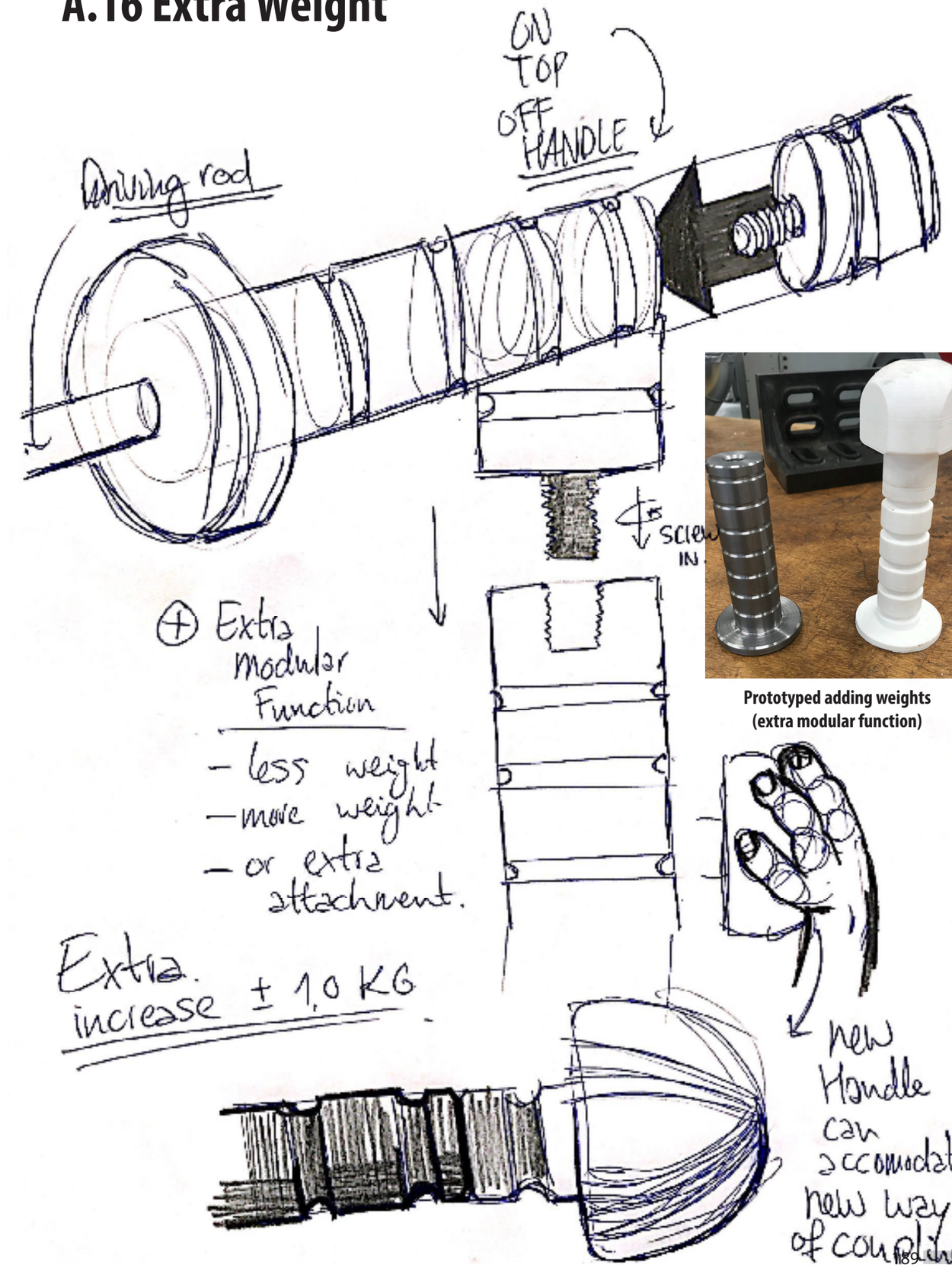
*Hammer slipped from the hand

(15.5) Results of the force measurments



(15.6) Analog Input Reader - Block diagram in Labview DAQ 2018

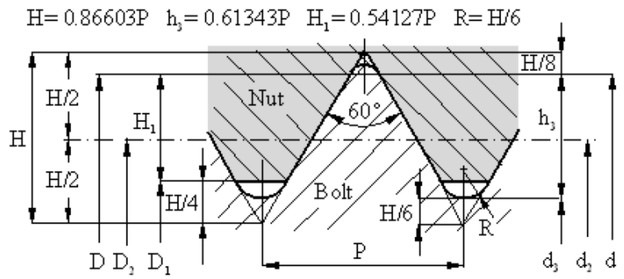
A.16 Extra Weight



Prototyped adding weights (extra modular function)

A.17 Threaded connections

Thread information



Metric screw threads ISO 724 (DIN 13 T1)								
Nominal diameter	**Pitch**	**root radius**	**pitch diameter**	**minor diameter**		**thread height**		**drill diameter**
d=D	**P**	**r**	**d2=D2**	**d3**	**D1**	**h3**	**H1**	**mm**
M8	1.25	0.180	7.188	6.466	6.647	0.767	0.677	6.80
M10	1.5	0.217	9.026	8.160	8.376	0.920	0.812	8.50
M12	1.75	0.253	10.863	9.853	10.106	1.074	0.947	10.20

Metric fine screw threads ISO 724 (DIN 13 T1)								
Nominal diameter	**Pitch**	**root radius**	**pitch diameter**	**minor diameter**		**thread height**		**drill diameter**
d=D	**P**	**r**	**d2=D2**	**d3**	**D1**	**h3**	**H1**	**mm**
M30x2.0	2.00	0.289	28.701	27.546	27.835	1.227	1.083	28.00

Source: Tribology ABC. Unknown. Metric Screw Dimensions ISO Fasteners. Retrieved on January 8, 2020 from https://www.tribology-abc.com/calculators/metric-iso.htm

Failure of M8x1.5

Stresses on the threads M8x1.25 :

```
> restart;
> τ := 9.33·10^8; d2 := 7.188·10^-3; d3 := 6.466·10^-3; Tm := 8.96·10^7; Force := 5040;
                                  τ := 9.330000000 10^8
                                  d2 := 0.007188000000
                                  d3 := 0.006466000000
                                  Tm := 8.960000000 10^7
                                  Force := 5040
```

Calculation of nominal thread diameter :

```
> d0 := (d2 + d3)/2;
                                  d0 := 0.006827000000
```

Calculating tensile stress : Ts = Force / Area

```
> At := (Pi/4)·(d0)^2;
                                  At := 0.00003660578185
> Ts := Force/At;
                                  Ts := 1.376831677 10^8
>
```

Ts > Tm, product will fail due to tensile stresses

Calculate effective thread length weaker material : $Le := 2\cdot(.8\cdot d0)$

```
> Le := 2·(0.8·d0);
                                  Le := 0.01092320000
> Lmm := Le·1000;
                                  Lmm := 10.92320000
```

Calculation of thread surface :

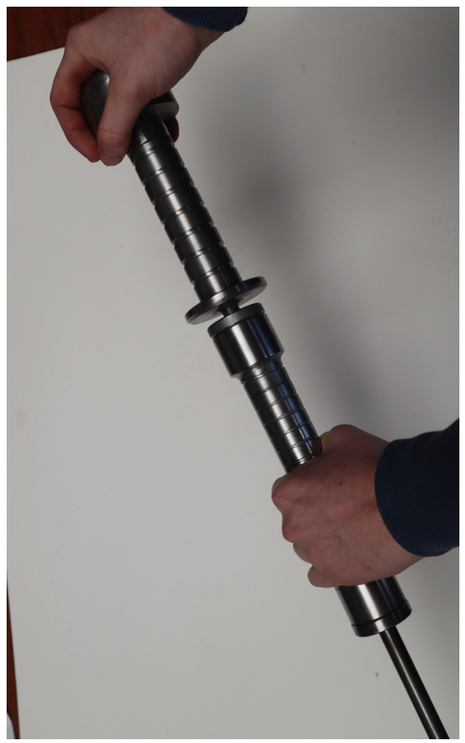
```
> Ath := 0.5·Pi·d0·Le;
                                  Ath := 0.0001171385018
```

Calculate max force that threads can withstand :

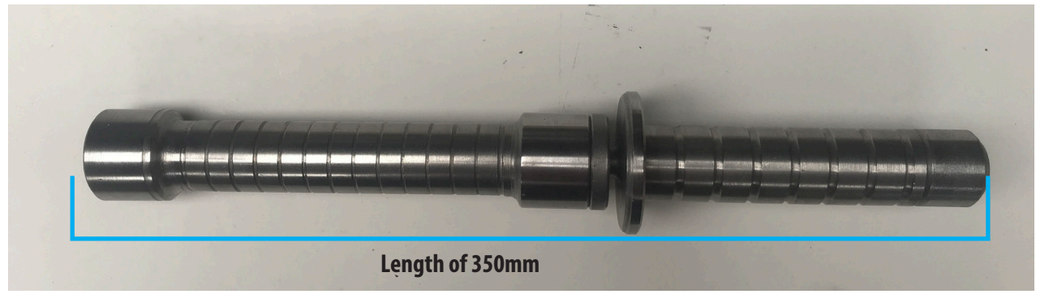
```
> Fcr := Ath·tau;
                                  Fcr := 109290.2222
```


A.18 Prototype V1

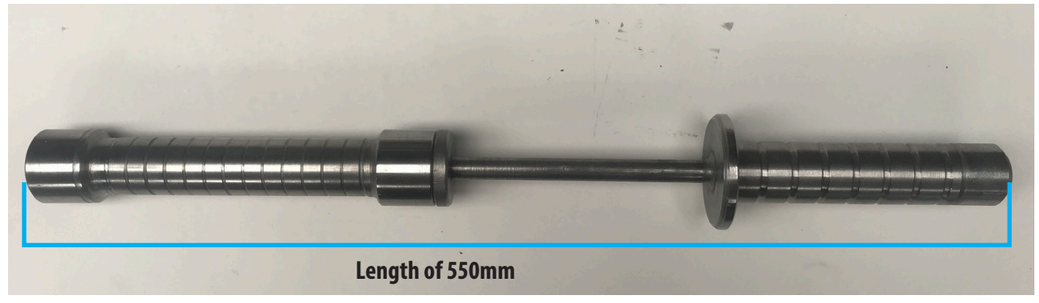
(18.1) DriveFit V1 with normal handle



(18.2) DriveFit V1, with extra weight handle



(18.3) DriveFit V1 in impact state



(18.4) DriveFit V1 in extraction state

Assembling DriveFit V1

Step 1: Guidercap over Driving rod

Step 2: Piston onto Driving rod

Step 3: Full assembled handle + Driving rod

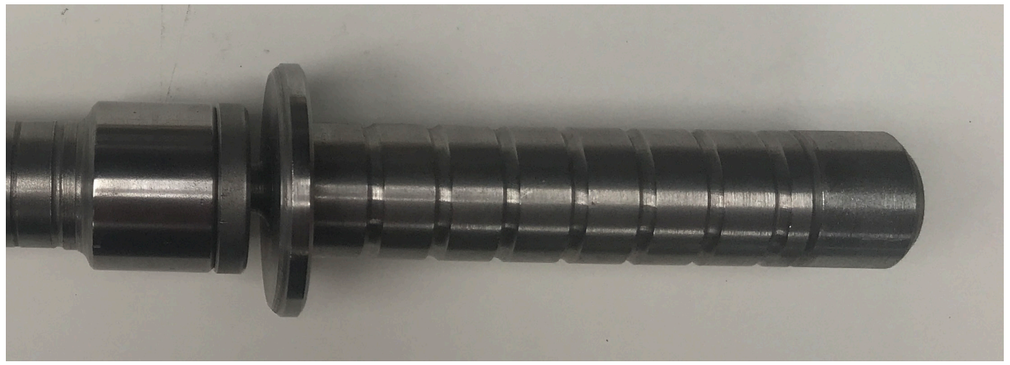
Step 4: Pushing driving rod into main body

Step 5: Screwing guider cap onto Main body

Step 6: Screwing modular attachment onto the DriveFit main body

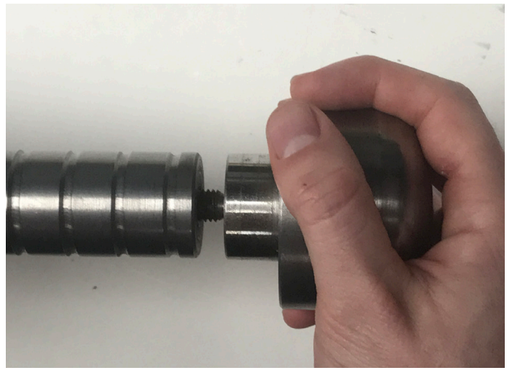
Step 7: Fully assembled DriveFit V1 + Acetabular cup impactor attached (ready for use)

Modular Handle DriveFit V1

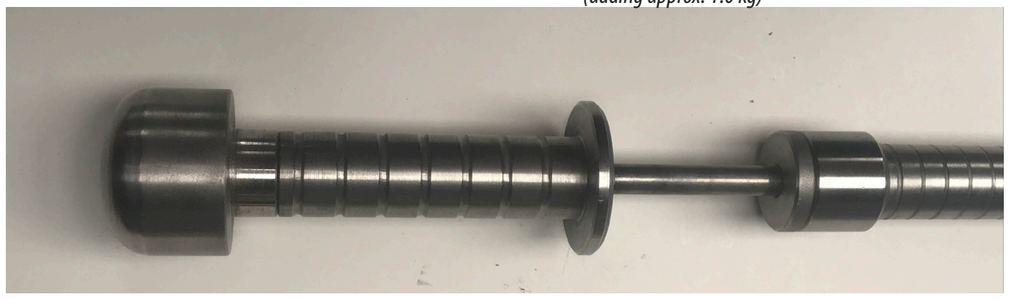


(18.5) DriveFit V1 Handle with small stock weight

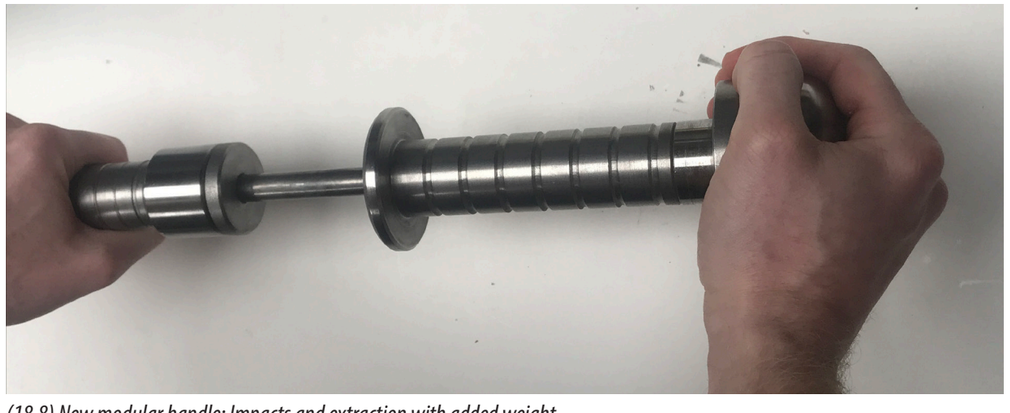
(18.5) Taking of the small weight handle stock



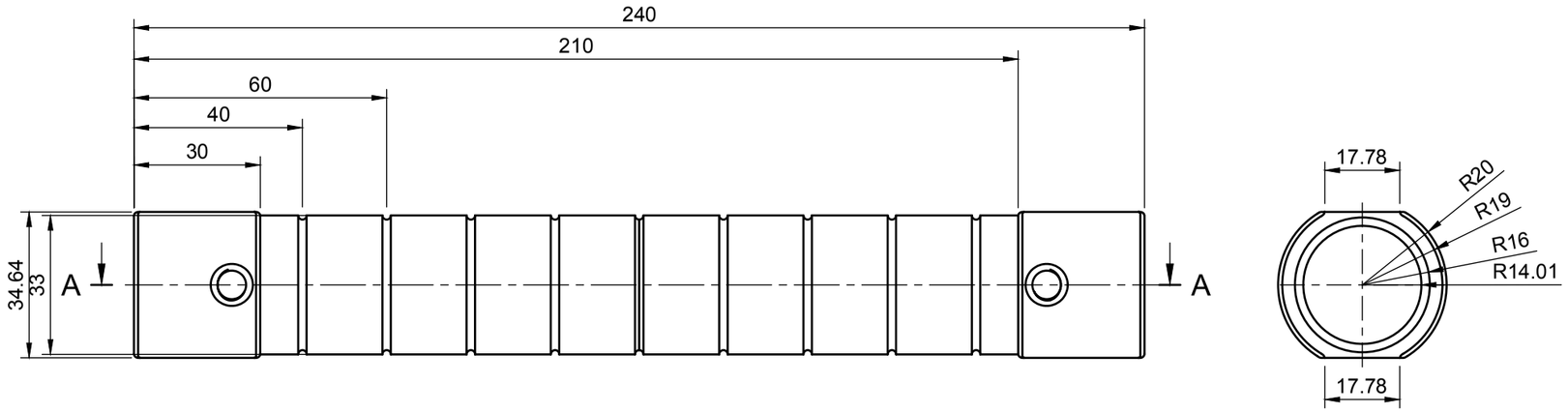
(18.6) Screwing other weight handle onto the Handle (adding approx. 1.0 kg)

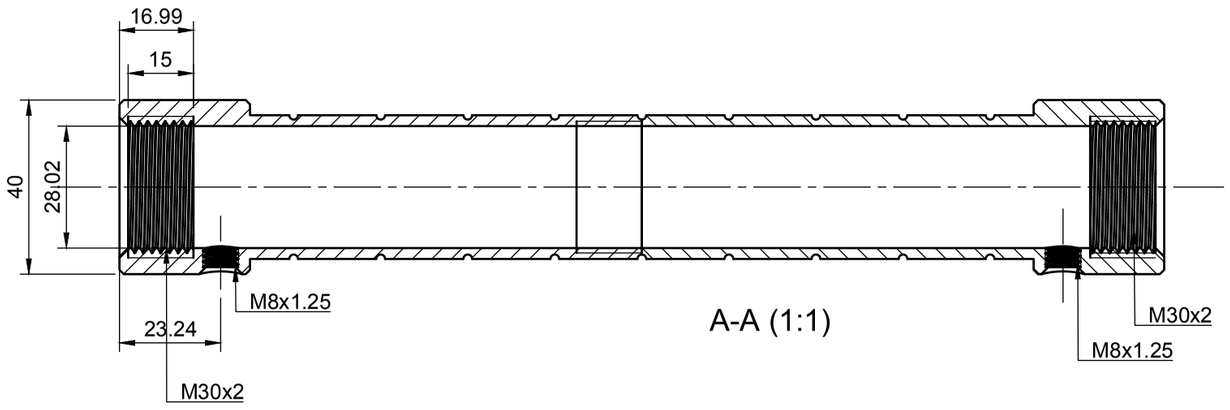


(18.7) Handle with Large weight attached can offer new way of coupling



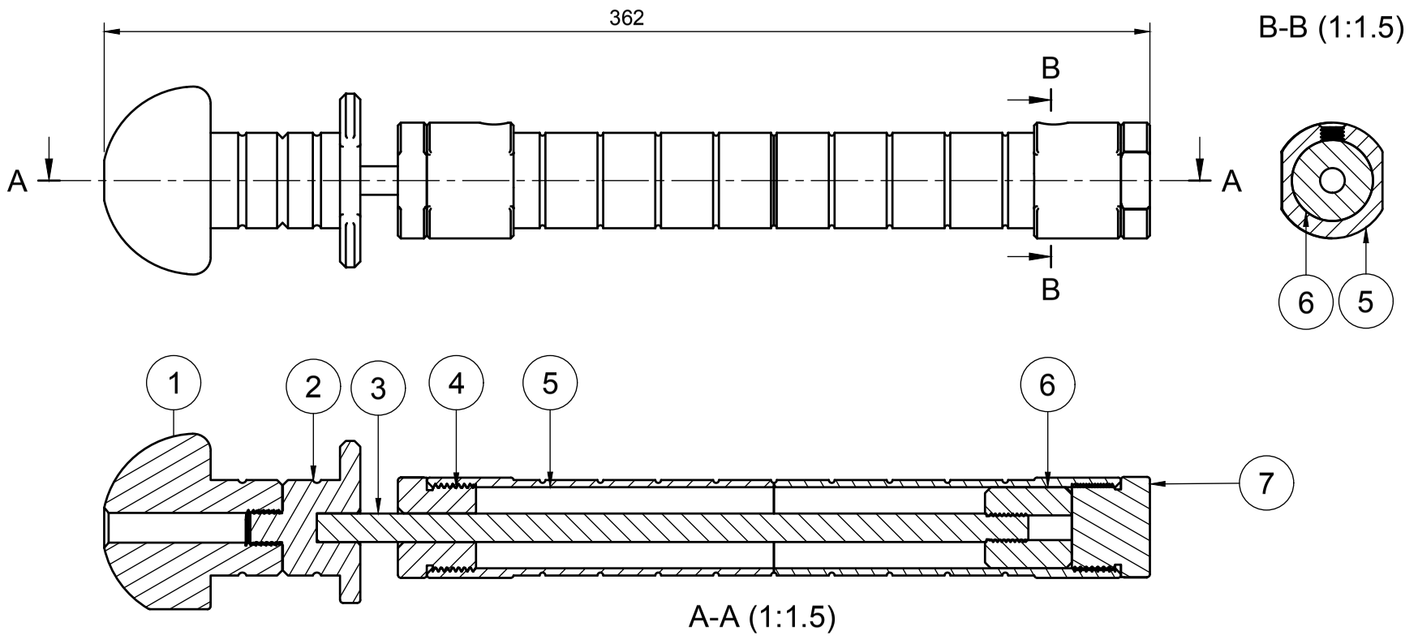
(18.8) New modular handle; Impacts and extraction with added weight





A-A (1:1)

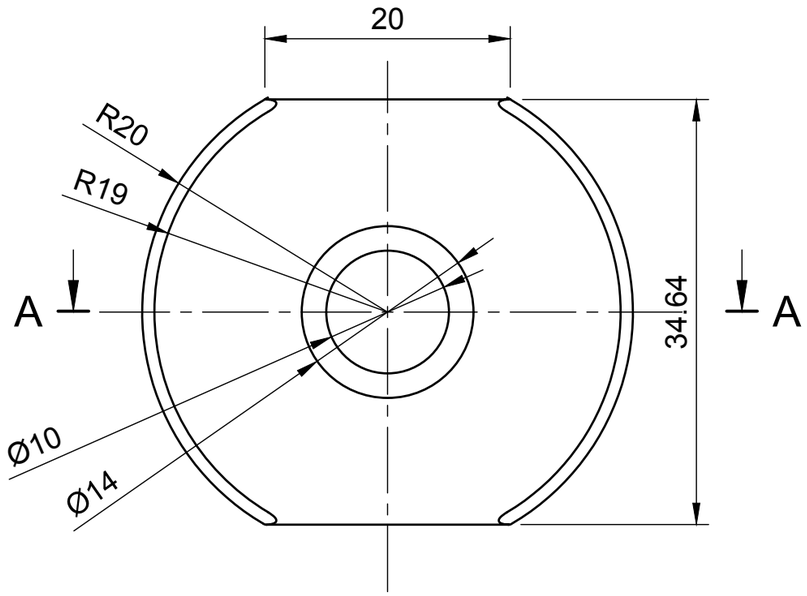
Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
17-4 stainless steel 0.433 kg		Document type	Document status
		Title: DriveFit_MainBody_17-4	DWG No.: 2
			Rev. / Date of issue / Sheet: 1/1



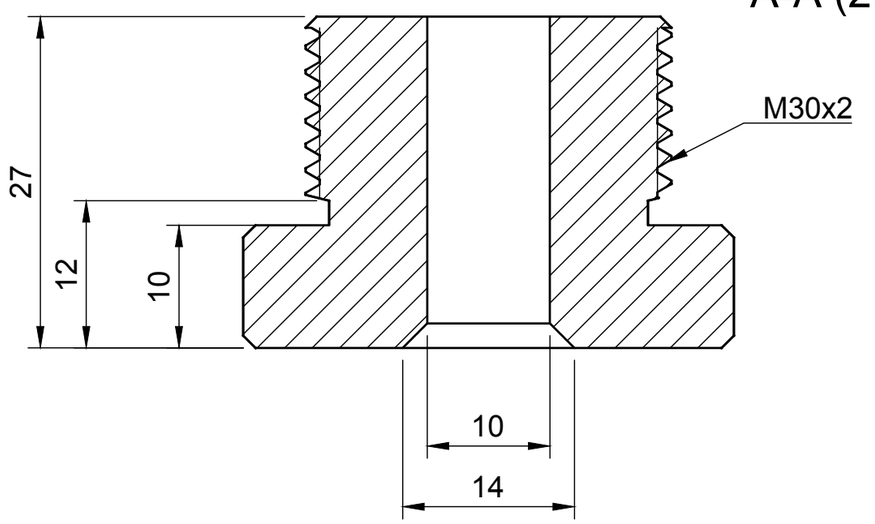
A-A (1:1.5)

PARTS LIST			
1	Small Handle	Drawing 7	17-4
2	Handle set-up	Drawing 6	17-4
3	Driving Rod	Drawing 5	17-4
4	Guider cap	Drawing 3	17-4
5	Main Body	Drawing 1	17-4
6	Piston	Drawing 10	POM-C
7	Module cap	Drawing 4	17-4

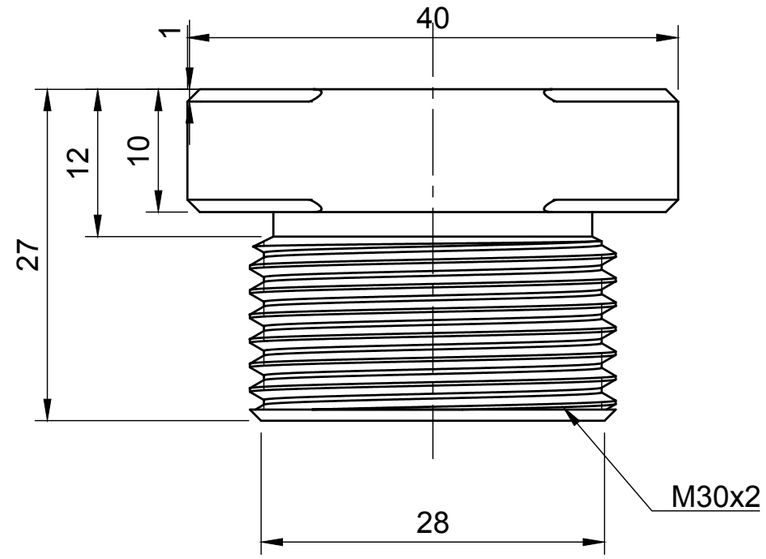
Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
		Document type	Document status
		Title: Assembly DriveFit	DWG No.: 1
			Rev. / Date of issue / Sheet: 1/1

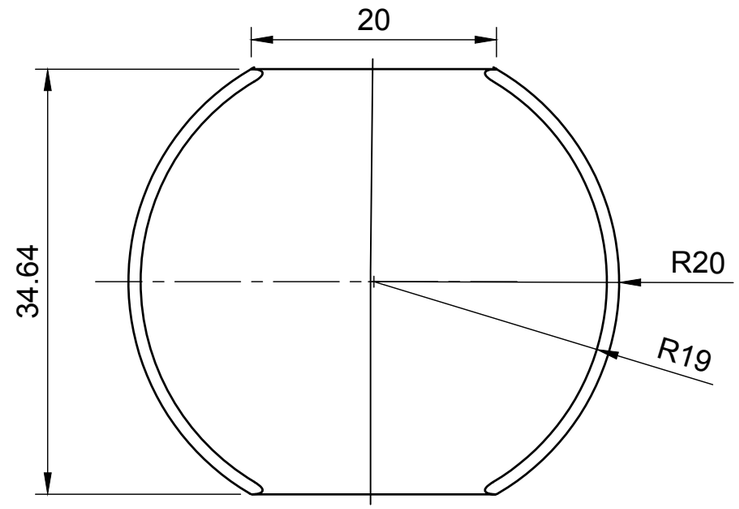


A-A (2:1)

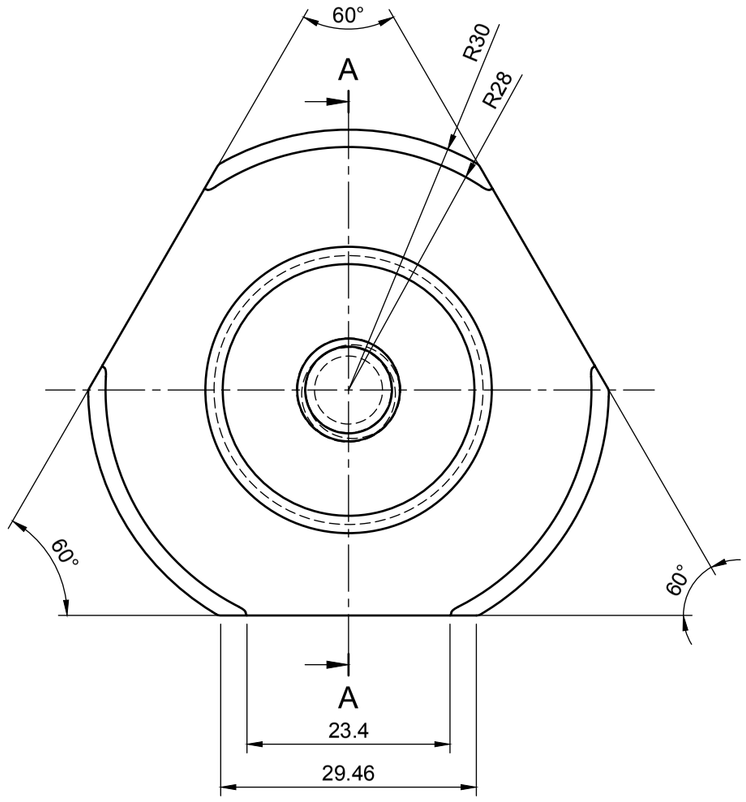


Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
17-4 stainless steel 0.18 kg		Document type	Document status
		Title DriveFit - Guider cap	DWG No. 3
		Rev. / Date of issue	Sheet 1/1

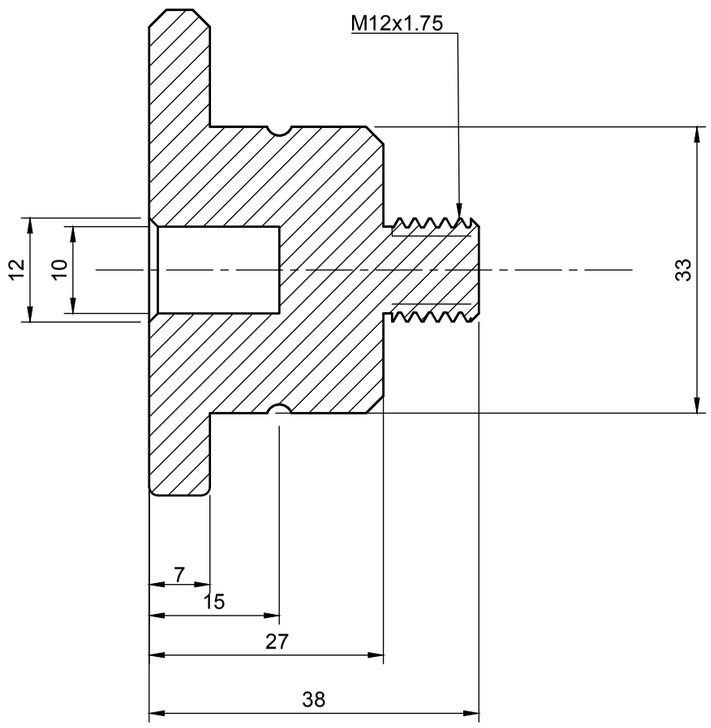


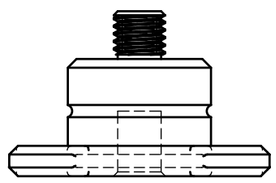


Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
17-4 stainless steel 0.18 kg		Document type	Document status
		Title DriveFit - Module cap	DWG No. 4
		Rev. / Date of issue	Sheet 1/1



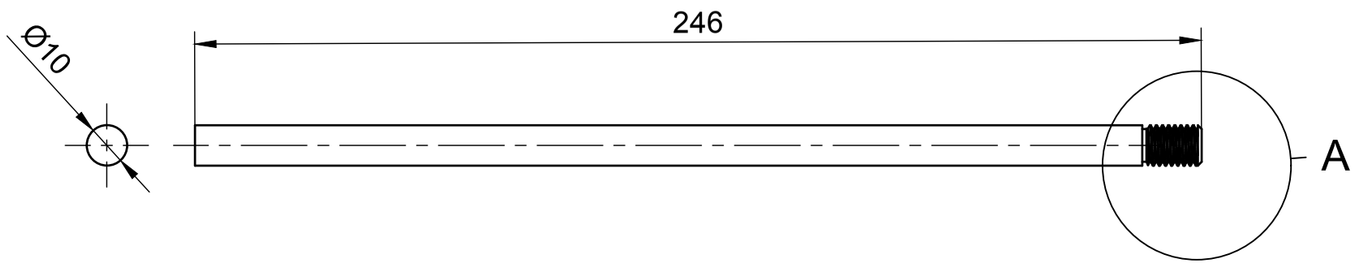
A-A (2:1)

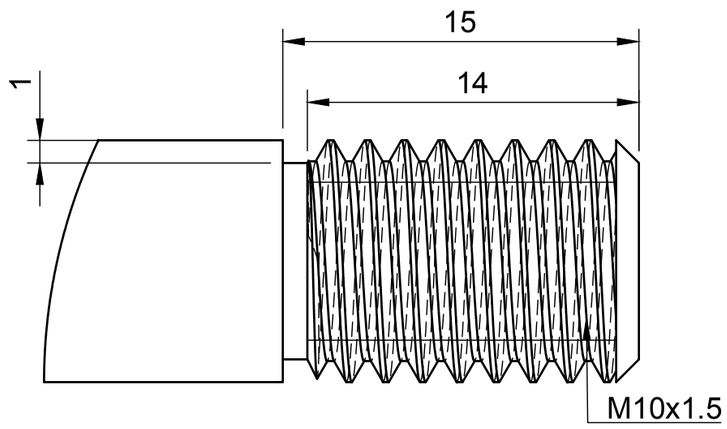




driving rod will get welded into this hole

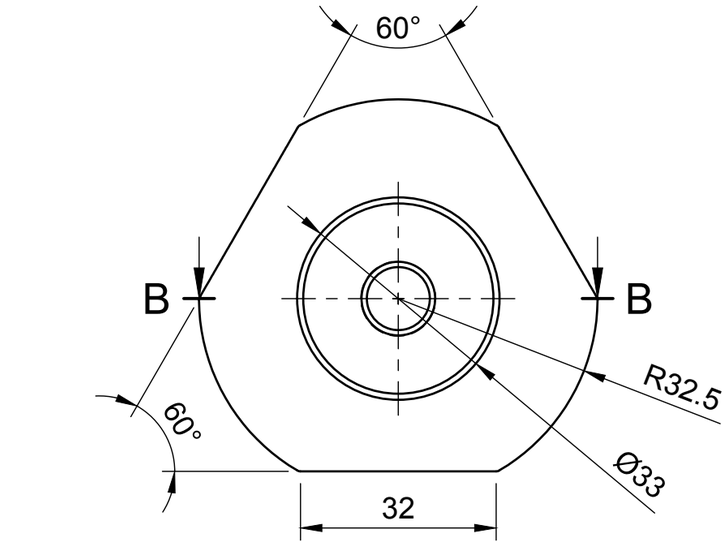
Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
17-4 stainless steel 0.26 kg		Document type	Document status
		Title DriveFit - Handle adaptor	DWG No. 6
			Rev. / Date of issue / Sheet 1/1

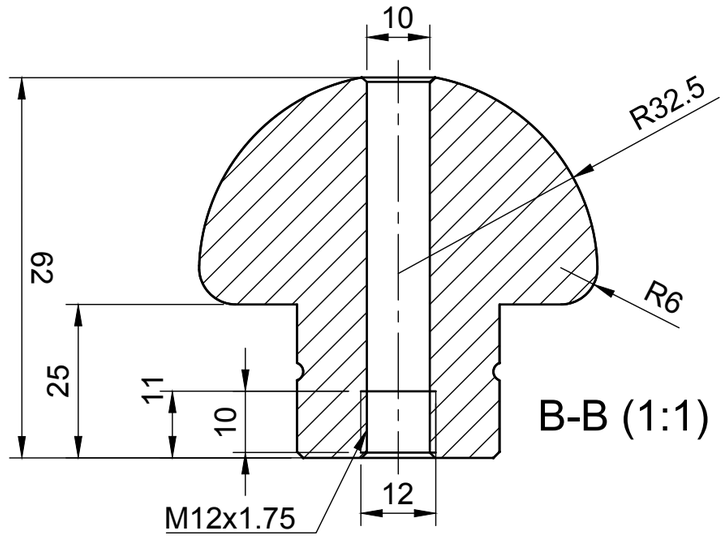




A (4:1)

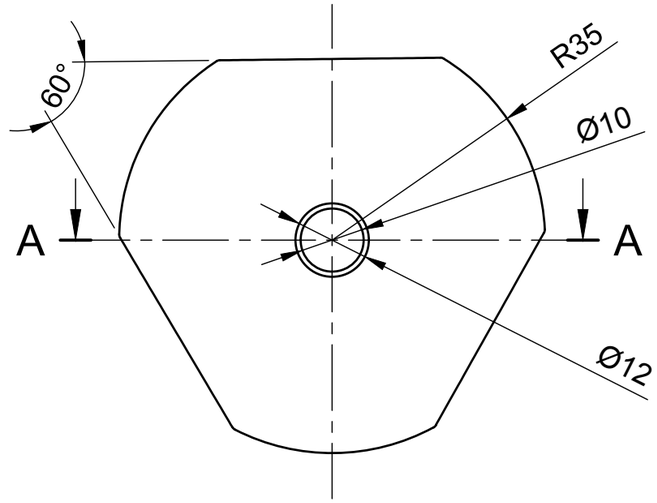
Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
17-4 stainless steel 0.14 kg		Document type	Document status
		Title DriveFit Driving Rod	DWG No. 5
			Rev. / Date of issue / Sheet 1/1

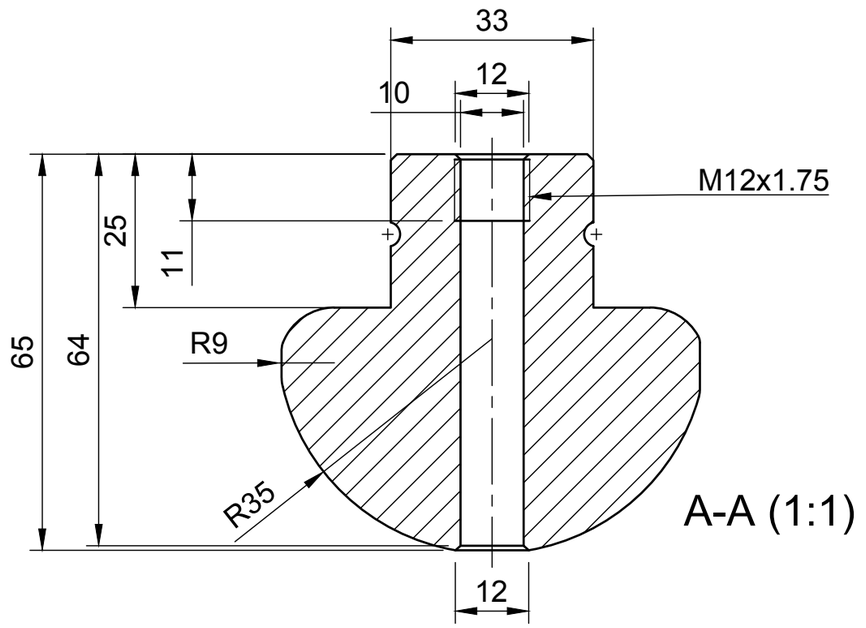




B-B (1:1)

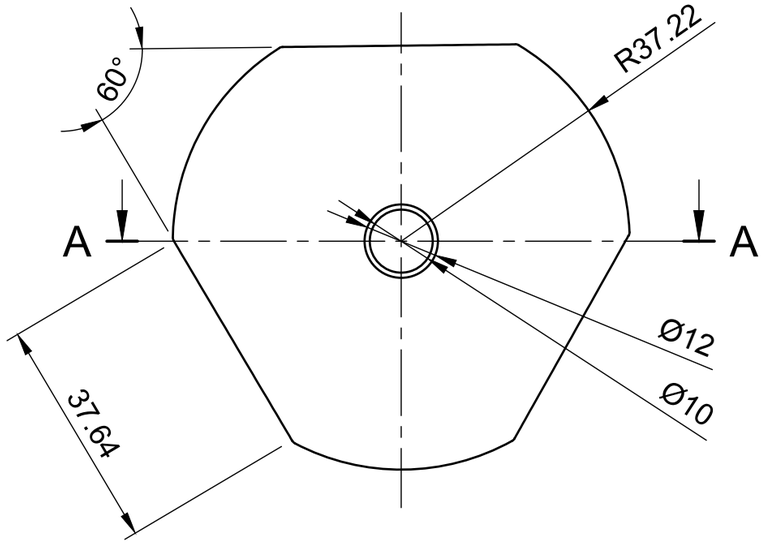
Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen 1	
Weight: 0.58 kg 17-4 stainless steel		Document type	Document status
		Title: Handle Small	DWG No.: 7
			Rev. / Date of issue / Sheet: 1/1

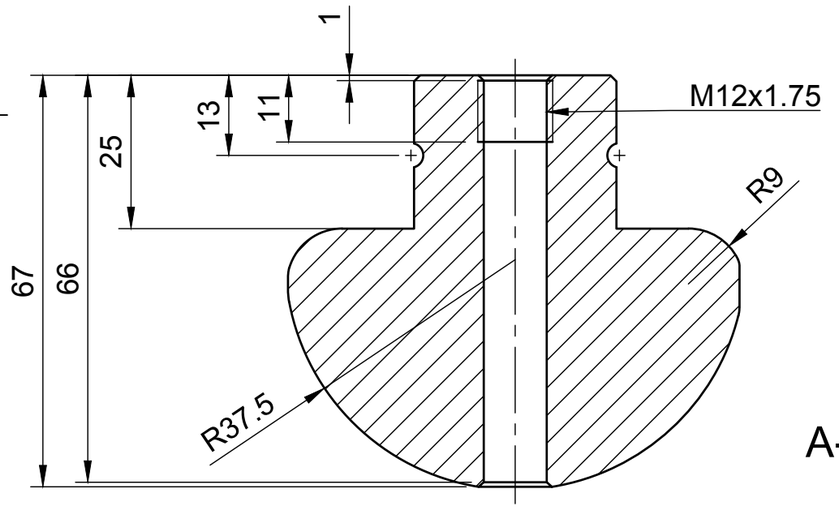




A-A (1:1)

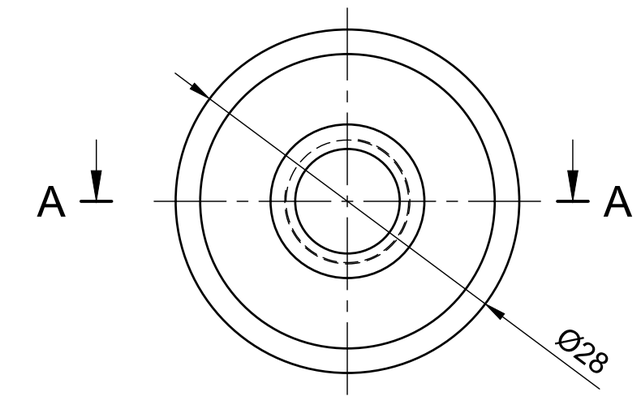
Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
17-4 stainless steel 0.7 kg		Document type	Document status
		Title: Handle Middle	DWG No.: 8
			Rev. / Date of issue / Sheet: 1/1

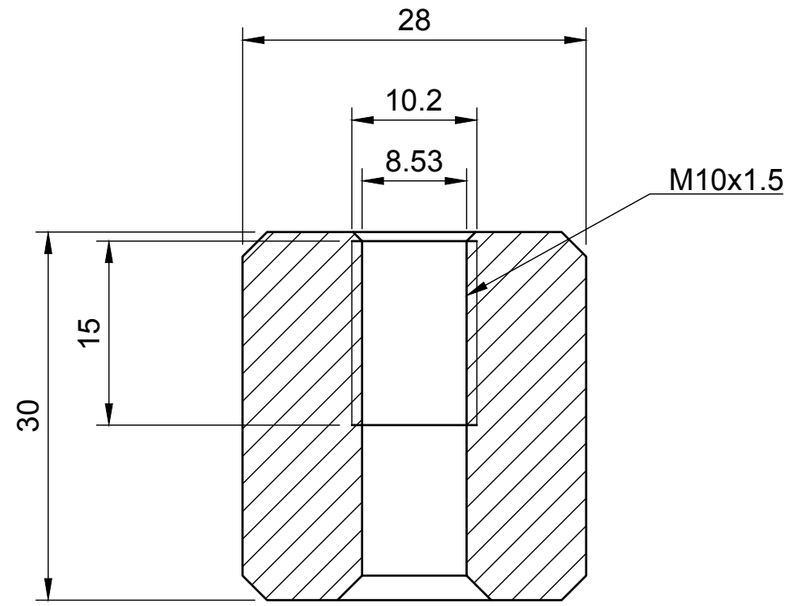




A-A (1:1)

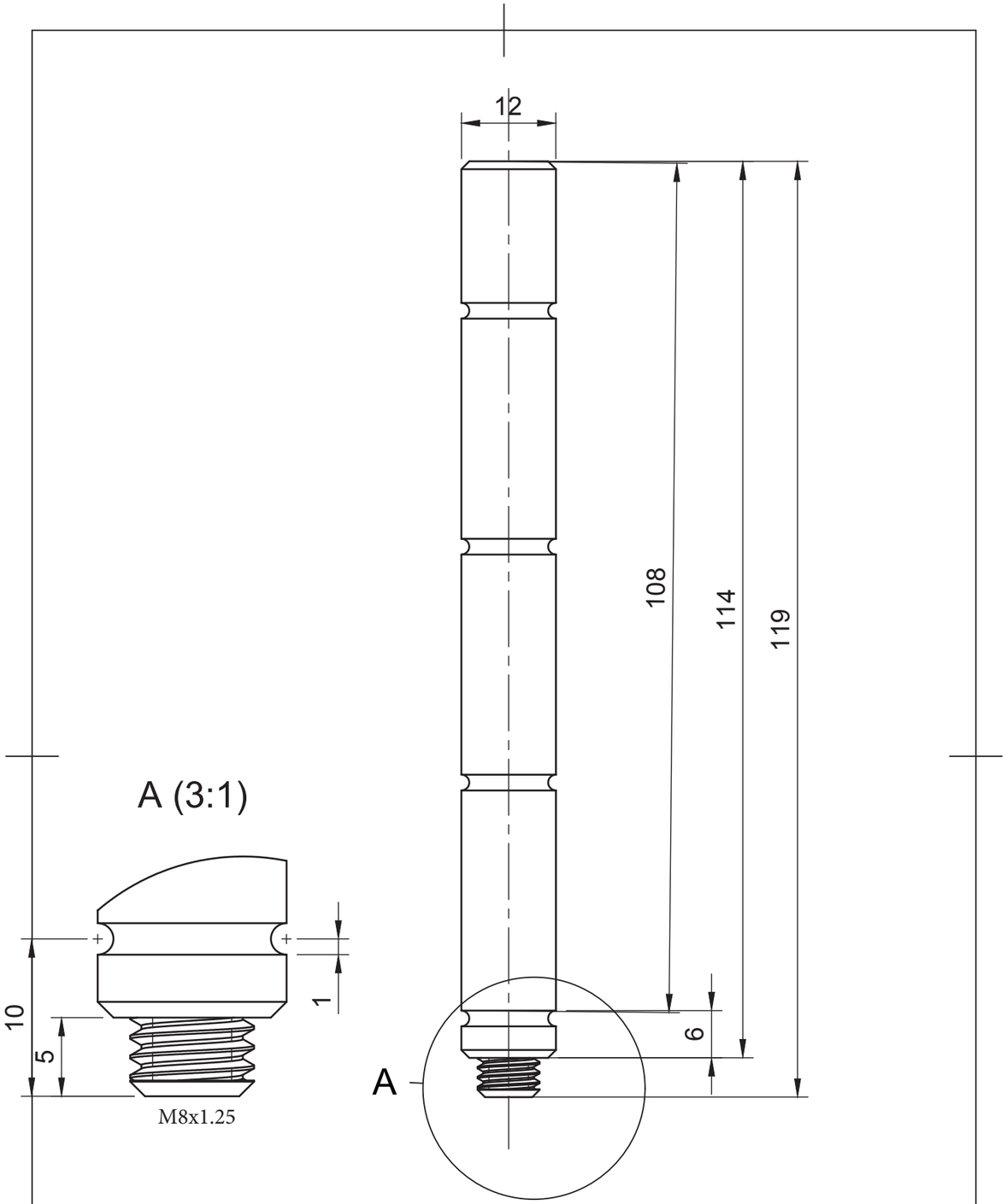
Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
17-4 stainless steel 0.9 kg		Document type	Document status
		Title Handle Big	DWG No. 9
			Rev. / Date of issue / Sheet: 1/1





A-A (2:1)

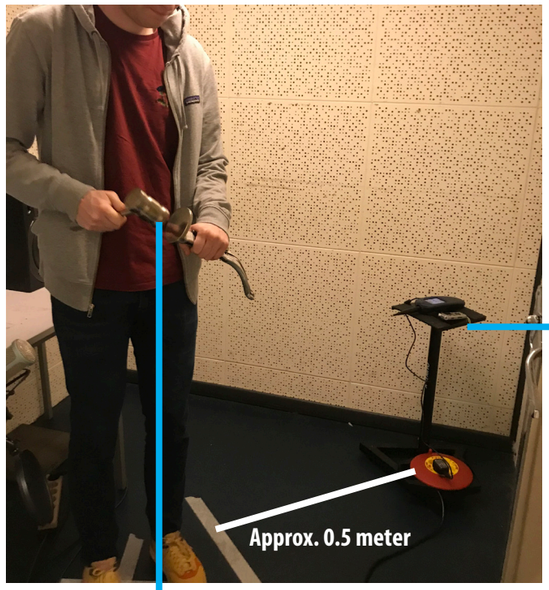
Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
Weight: 0.02 kg POM-C (MD)		Document type	Document status
		Title Piston	DWG No. 10
			Rev. / Date of issue / Sheet: 1/1



Dept.	Technical reference	Created by	Approved by
		Kees Broekmeulen	
17-4 stainless steel 0.1 kg		Document type	Document status
		Title Steering Handle	DWG No. 11
			Rev. / Date of issue / Sheet 1/1

A.20 Psychoacoustic analysis

1. Test set-up



Sound capturing device

Olympus LS-P1
Microphone system:
120 dB max. soundlevel
/60-20.000 Hz

All sound were captured
as PCM (WAV):
96 KHz/24 bits

Striking with maximal effort for 4 sounds:
- Impaction surgical mallet - broach handle
- Impaction DriveFit
- Extraction surgical mallet - broach handle
- Extraction DrivFit

2. Google form

Introduction to the Google form for the psychoacoustic analysis participants. The questions where divided into 4 sections, a section for every sound. After answering all 7 questions concerning one sound the participant could proceed to the next "sound" section. The sound could be played (as much as the participant needed), by clicking a youtube-video embedded in the form.

Psychoacoustic analysis

Hello sir/madam,

In this listening test, you are asked to rate four different sounds resulting from the usage of a surgical mallet.
In the following questions you have to rate the quality of the sound on a semantic scale. Please listen to every sound before answering the questions. You can listen to it as many times as you need.

Attention:
- Only participate in this test, if you have NO hearing problems.
- Listen to all sounds on the same volume level and HD settings (preferably with ear- or head-phones)

If you agree to participate in the study, and give your consent to use the listening test results in my graduation report, please insert your email address below.

Thanks in advance!

E-mailadres *

Geldig e-mailadres

Question 1

How loud is this sound? *

- 1 (not loud)
- 2
- 3
- 4
- 5
- 6
- 7 (very loud)

Question 2

How sharp is this sound? (sharp = schel) *

- 1 (not sharp)
- 2
- 3
- 4
- 5
- 6
- 7 (very sharp)

Question 3

How noisy is this sound? *

- 1 (not noisy)
- 2
- 3
- 4
- 5
- 6
- 7 (very noisy)

Question 4

How dull is this sound? (dull = dof) *

- 1 (not dull)
- 2
- 3
- 4
- 5
- 6
- 7 (very dull)

Question 5

How pleasant is this sound? *

- 1 (not pleasant)
- 2
- 3
- 4
- 5
- 6
- 7 (very pleasant)

Question 6

How calm is this sound? *

- 1 (not calm)
- 2
- 3
- 4
- 5
- 6
- 7 (very calm)

Question 7

How would you rate the quality of this sound? *

- Faint (around 40 dB / Refrigerator)
- Moderate to quiet (around 60 dB / normal conversation)
- Loud (around 70 dB / Traffic)
- Very loud (around 80 dB / Truck)
- Extremely loud (around 100 dB / Trombone)
- Discomfortable loud (around 110 dB / Siren Police)
- Painfully loud (around 120 dB and over / Fireworks)

All questions and the way they looked on the Googleform (see above); 22 particpants filled in the form.
All participants have knowledge and know-how of the total hip replacement procedure, as most of them are working as hip product specialist at Zimmer Biomet. From the 22 participants, 5 of were orthopedic surgeons.

3. Results

Via Microsoft Excel (2010) a t-test was done on the test results, to compare if people perceived the new product as an improvement or not. To set-up the t-test the results where paired, to see a participants specific relation to the old vs new sound. This was done by the formula: **fx:=T.Test(Matrix1, Matrix2, Sides, Types)**, this resulst in a p-value. (P-value <0.05, means there is a significant difference) For the formule the **Matrix 1**- Old sound data column / **Matrix 2** - New sound data column / **Side** = 2, as we want to know if it is better or worse (2 sided) / **Types = 1,** paired t-test.

CALM impac	OLD	NEW
participant	SOUND 1	SOUND 3
P1	2	3
P2	2	2
P3	4	4
P4	5	4
P5	1	4
P6	2	3
P7	2	3
P8	2	3
P9	4	4
P10	3	3
P11	1	3
P12	3	2
P13	1	3
P14	1	4
P15	3	3
P16	5	3
P17	3	4
P18	3	5
P19	4	6
P20	1	3
P21	1	2
P22	4	6
mean	2,6	3,5
standard dev	1,302415	1,076611
P-value	0,003700296	

CALM Extrac	OLD	NEW
participant	SOUND 2	SOUND 4
P1	5	5
P2	2	4
P3	4	4
P4	3	4
P5	2	4
P6	4	4
P7	3	3
P8	4	3
P9	5	3
P10	5	3
P11	5	2
P12	4	5
P13	3	4
P14	1	4
P15	3	4
P16	4	3
P17	5	4
P18	5	5
P19	4	5
P20	2	5
P21	5	5
P22	5	5
mean	3,8	4
standard dev	1,203486	0,852803
P-value	0,003700296	

^RESULTS CALM IMPACT AND EXTRACT^

	old impact m	sd (standard	new impact	sd (standard
loud	4,6	1,1	3,2	1,3
calm	2,6	1,3	3,5	1,1
sharp	5,3	0,9	2,9	1,1
dull	2,2	1,3	3,5	1,1
noisy	4,6	0,9	3,3	1,1
pleasant	2,5	1,1	3,5	1,1
quality	4	1,4	2,8	0,8

^MEAN; SD for impaction ^

	old extract m	sd (standard	new extract	sd (standard
loud	3,5	1,3	2,9	1,2
calm	3,8	1,2	4	0,9
sharp	3,5	1,2	3	1,3
dull	3,1	1,4	3,6	1,3
noisy	3,2	0,9	3,2	0,9
pleasant	3,7	1	3,8	1
quality	2,8	1,1	2,7	1

^MEAN; SD for extraction ^

LOUD impact	OLD	NEW
participant	SOUND 1	SOUND 3
P1	4	2
P2	4	5
P3	6	5
P4	4	4
P5	6	4
P6	4	1
P7	6	5
P8	4	1
P9	4	3
P10	6	3
P11	5	2
P12	4	2
P13	5	3
P14	6	3
P15	3	5
P16	6	3
P17	4	3
P18	5	2
P19	3	4
P20	3	3
P21	4	5
P22	5	3
mean	4,6	3,2
standard dev.	1,054	1,2699
P-value	0,00061552	

LOUD Extract	OLD	NEW
participant	SOUND 2	SOUND 4
P1	3	1
P2	4	3
P3	4	4
P4	3	4
P5	3	3
P6	1	1
P7	7	5
P8	2	2
P9	3	5
P10	5	3
P11	2	2
P12	2	3
P13	3	2
P14	4	3
P15	4	5
P16	4	2
P17	3	3
P18	3	2
P19	4	2
P20	4	2
P21	5	4
P22	4	2
mean	3,5	2,9
standard dev.	1,263	1,21
P-value	0,02298769	

^RESULTS LOUD IMPACT AND EXTRACT^

NOISY impac	OLD	NEW
participant	SOUND 1	SOUND 3
P1	5	3
P2	5	5
P3	5	4
P4	3	4
P5	6	5
P6	4	1
P7	6	4
P8	4	3
P9	4	3
P10	5	3
P11	3	2
P12	3	3
P13	5	3
P14	5	2
P15	4	5
P16	6	3
P17	5	4
P18	5	2
P19	4	3
P20	4	3
P21	5	5
P22	4	3
mean	4,6	3,3
standard dev	0,890796	1,061154
P-value	9,02E-05	

NOISY Extrac	OLD	NEW
participant	SOUND 2	SOUND 4
P1	3	2
P2	4	3
P3	4	4
P4	3	4
P5	3	4
P6	2	3
P7	6	5
P8	2	3
P9	3	4
P10	3	3
P11	2	2
P12	2	3
P13	4	2
P14	3	3
P15	4	5
P16	4	3
P17	3	3
P18	3	2
P19	4	2
P20	4	2
P21	3	4
P22	4	3
mean	3,2	3,2
standard dev	0,924074	0,919357
P-value	0,445605471	

^RESULTS NOISY IMPACT AND EXTRACT^

PLEASANT im	OLD	NEW
participant	SOUND 1	SOUND 3
P1	3	4
P2	3	2
P3	2	4
P4	3	4
P5	3	5
P6	4	4
P7	1	3
P8	2	3
P9	3	3
P10	3	3
P11	1	2
P12	3	3
P13	1	3
P14	1	4
P15	2	3
P16	5	3
P17	2	4
P18	2	5
P19	2	5
P20	5	4
P21	3	1
P22	2	5
mean	2,5	3,5
standard dev	1,11715	1,033529

PLEASANT Ex	OLD	NEW
participant	SOUND 2	SOUND 4
P1	4	5
P2	2	4
P3	4	4
P4	4	3
P5	5	4
P6	3	4
P7	1	3
P8	4	3
P9	5	3
P10	4	4
P11	5	2
P12	3	5
P13	3	4
P14	3	3
P15	4	4
P16	4	3
P17	4	4
P18	4	6
P19	4	5
P20	3	5
P21	5	4
P22	4	5
mean	3,7	3,8
standard dev	0,962108	0,928767

^RESULTS PLEASANT IMPACT AND EXTRACT^

Quality impa	OLD	NEW
participant	SOUND 1	SOUND 3
P1	3	2
P2	3	3
P3	5	4
P4	2	2
P5	6	3
P6	2	2
P7	6	4
P8	3	3
P9	4	3
P10	3	2
P11	3	2
P12	3	3
P13	5	3
P14	4	2
P15	2	4
P16	4	2
P17	4	3
P18	5	2
P19	5	3
P20	3	3
P21	5	4
P22	7	2
mean	4	2,8
standard dev	1,364427	0,734363
P-value	0,000452052	

Quality Extra	OLD	NEW
participant	SOUND 2	SOUND 4
P1	2	1
P2	3	3
P3	3	4
P4	2	2
P5	3	3
P6	1	2
P7	7	5
P8	2	2
P9	3	4
P10	2	3
P11	2	2
P12	2	2
P13	3	3
P14	3	3
P15	3	5
P16	3	2
P17	3	3
P18	3	2
P19	3	2
P20	3	2
P21	3	3
P22	3	2
mean	2,8	2,7
standard dev	1,071809	1,008247
P-value	0,324094996	

^RESULTS QUALITY IMPACT AND EXTRACT^

SHARP impact	OLD	NEW
participant	SOUND 1	SOUND 3
P1	5	2
P2	5	4
P3	5	3
P4	4	4
P5	6	4
P6	5	1
P7	6	2
P8	5	2
P9	5	4
P10	7	3
P11	5	2
P12	3	2
P13	5	3
P14	7	2
P15	4	4
P16	6	3
P17	5	3
P18	6	2
P19	5	2
P20	5	3
P21	6	6
P22	6	3
mean	5,3	2,9
standard dev.	0,91364275	1,0833085
P-value	1,39E-07	

SHARP Extract	OLD	NEW
participant	SOUND 2	SOUND 4
P1	2	1
P2	4	3
P3	4	3
P4	2	4
P5	3	4
P6	3	3
P7	4	4
P8	2	2
P9	3	5
P10	5	5
P11	2	2
P12	2	4
P13	3	2
P14	3	3
P15	4	5
P16	5	4
P17	2	2
P18	4	2
P19	5	2
P20	6	1
P21	4	4
P22	4	2
mean	3,5	3
standard dev.	1,15712264	1,22393779
P-value	0,258497104	

^RESULTS SHARP IMPACT AND EXTRACT^

DULL impact	OLD	NEW
participant	SOUND 1	SOUND 3
P1	3	5
P2	1	2
P3	2	5
P4	4	3
P5	2	3
P6	1	1
P7	2	4
P8	2	2
P9	2	4
P10	3	4
P11	1	3
P12	1	4
P13	2	3
P14	1	4
P15	1	3
P16	6	3
P17	3	4
P18	2	4
P19	4	5
P20	1	4
P21	1	2
P22	3	5
mean	2,2	3,5
standard dev	1,266223	1,076611
P-value	0,000293564	

DULL Extract	OLD	NEW
participant	SOUND 2	SOUND 4
P1	2	6
P2	2	3
P3	5	5
P4	3	3
P5	4	3
P6	1	2
P7	3	3
P8	2	2
P9	5	3
P10	3	3
P11	1	3
P12	4	5
P13	4	2
P14	2	3
P15	2	3
P16	4	3
P17	4	4
P18	3	4
P19	5	6
P20	1	5
P21	3	3
P22	5	6
mean	3,1	3,6
standard dev	1,311111	1,262972
P-value	0,10352893	

^RESULTS DULL IMPACT AND EXTRACT^

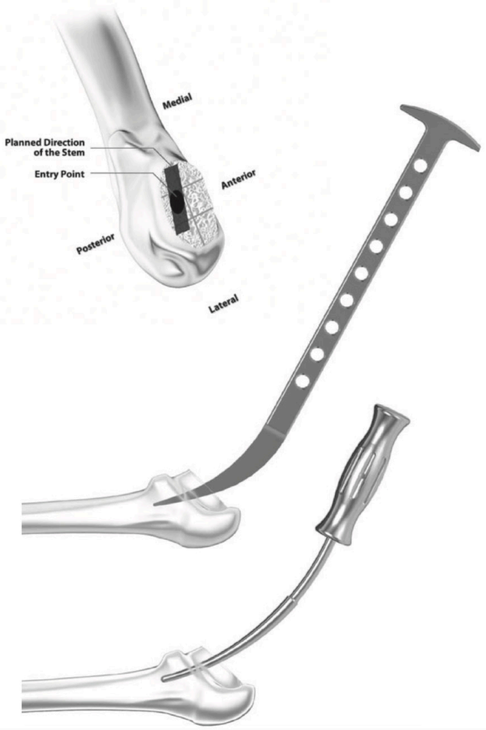
A.21 Femoral broaching - test

Test set-up of sawbone
- The Sawbones used where left leg human anatomy replicas. (21.1) (SKU:1145) (inner diameter of 16 mm) (Sawbones, 2020)
- The broach handle used was a right sided, 45-degree offset. Was fabricated to fit DriveFit. (21.2)

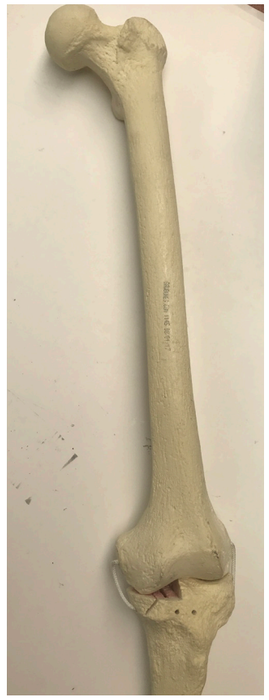
Therefore, was chosen to implant the rasp into the knee-side of the Femur/Tibia as this piece of bone would fit the rasp, plus the orientation made it possible to implant (21.3-5) (Next page

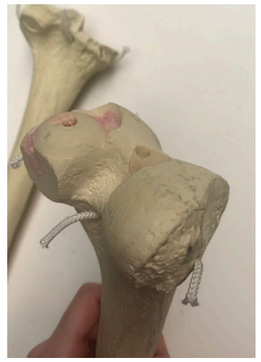
- Bone was opened up, with hand rasp before started testing. In surgery this is done aswell with first a hand rasp and then a starter rasp. (Fitmore surgical technique Zimmer Biomet, 2019) (21.3)
Stating:
"The femoral canal is entered by opening the medullary canal with a starter instrument (eather a curved chisel or curved hand rasp) which enters into the resection surace on the posterior side, in the middle third, and should be in line with the axis of the femur" (Fitmore surgical technique Zimmer, 2019)

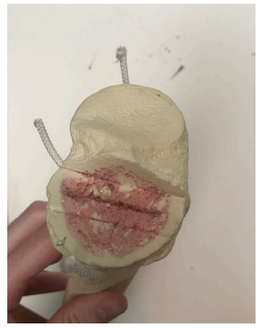
****See next page for fotos of testing****



(18.4) DriveFit V1 in extraction state (Zimmer Biomet, 2019)







(21.1) Left leg human replica sawbone (Left); Rightside top is Femur knee side and below Tiba knee side, used for impaction.

(21.2) Offsett handle 45 degrees - Right side

(21.3) Saw of bone structure to get view of marrow

(21.4) Bone in vice + sawn off part of Femur; Knee side

(21.5) Opening up the bone with a chisel as done in THA surgery

Test photos

(21.6) Inserting rasp into chiseled hole

(21.7) Impacting rasp into sawbone (front view)

(21.8) impacting rasp into sawbone (front view)

(21.9) Impacting rasp into the sawbone (side view)

(21.10) Extracton of rasp from bone (side view)

A.22 Ergonomics assessment - DriveFit

A. Using off- hand (L) with extracting rasps right side patient (similated in sawbone use)

Group A: Neck, Trunk and Leg Analysis	
Trunk score	+2 back flexion between 0-20 degrees
Neck score	+1 flexion 0-20 degrees | +1 twist of the neck
Legs score	+1 for straight legs
Table A posture outcome	**Table A gives posture score of 3**
Load/Force	+1, for rapid build-up of force/shock, due to impacting motion/actions
Score A = Posture score A + Force/Load score	4
Group B: Arm and Wrist Analysis (R = right side / L = left side)	
Upper Arm (R)	+2, flexion 20-45 degrees
Upper Arm (L)	+2, between 20-45 degrees | +1 abducted upper arm
Lower Arm (R)	+1, flexion between 60-100 degrees
Lower Arm (L)	+1, flexion between 60-100 degrees
Wrist (R)	+1, flexion between 15 degrees and extension 15 degrees
Wrist (L)	+1, flexion between 15 degrees and extension 15 degrees +1 bent/twist
Table B outcome	**R: 8 for L: 2, highest scoring side for rest of score sheet.**
Adding of Coupling score	+0, power grip / well fitted handle; No coupling score added
Total Arm and Wrist Analysis score	4
Table C outcome	**4, for the right side (arm and wrist)**
Activity score	+1, repeated small range actions (more than 4x per minute)
Reba Score	**5**
Action Level	**Medium Risk, further investigate and change soon**

Extraction/Impaction. Date: 02-04-2020
Task Name: With DriveFit

REBA Employee Assessment Worksheet

Original Worksheet Developed by Dr. Alan Hedge. Based on Technical note: Rapid Entire Body Assessment (REBA), Hignett, McAtamney, Applied Ergonomics 31 (2000) 201-205

Source for worksheet:
Hedge, A. (2000) REBA Employee Assessment worksheet. Retrieved on 12 November 2019 from https://ergo-plus.com/reba-assessment-tool-guide/

Hignett, S., & McAtamney, L. (2000). Rapid entire body assessment (REBA). Applied ergonomics, 31(2), 201–205. https://doi.org/10.1016/s0003-6870(99)00039-3

B. Using off- hand (L) with broaching the femoral canal at right side patient (similated in sawbone use)

Group A: Neck, Trunk and Leg Analysis	
Trunk score	+2 back flexion between 0-20 degrees
Neck score	+1 flexion 0-20 degrees | +1 twist of the neck
Legs score	+1 for straight legs
Table A posture outcome	**Table A gives posture score of 3**
Load/Force	+1, for rapid build-up of force/shock, due to impacting motion/actions
Score A = Posture score A + Force/Load score	4
Group B: Arm and Wrist Analysis (R = right side / L = left side)	
Upper Arm (R)	+2, flexion 20-45 degrees
Upper Arm (L)	+2, between 20-45 degrees | +1 abducted upper arm
Lower Arm (R)	+1, flexion between 60-100 degrees
Lower Arm (L)	+1, flexion between 60-100 degrees
Wrist (R)	+1, flexion between 15 degrees and extension 15 degrees
Wrist (L)	+1, flexion between 15 degrees and extension 15 degrees +1 bent/twist
Table B outcome	**R: 8 for L: 2, highest scoring side for rest of score sheet.**
Adding of Coupling score	+0, power grip / well fitted handle; No coupling score added
Total Arm and Wrist Analysis score	4
Table C outcome	**4, for the right side (arm and wrist)**
Activity score	+1, repeated small range actions (more than 4x per minute)
Reba Score	**5**
Action Level	**Medium Risk, further investigate and change soon**

A.23 Project brief

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME
Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name	Broekmeulen
initials	C.L.H. given name Kees
student number	4296265
street & no.	Jacoba van Beierenlaan 71
zipcode & city	2613JB
country	The Netherlands
phone	+31 6 81 88 50 04
email	broekmeulenk@gmail.com

Your master programme (only select the options that apply to you):

IDE master(s): ★ IPD ☐ Dfl ☐ SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: ☐ Honours Programme Master
specialisation / annotation: ★ Medisign ☐ Tech. in Sustainable Design ☐ Entrepeneurship

SUPERVISORY TEAM **
Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair	Elif Ozcan Vieira	dept. / section:	DA (Critical Alarms
** mentor	Sonja Paus-Buzink	dept. / section:	AED (Medesign)
2nd mentor	Hilbrand Bodewes		
	organisation: Zimmer Biomet		
	city: Dordrecht	country:	The Netherlands
comments (optional)			

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

Procedural Checks - IDE Master Graduation

TU Delft

APPROVAL PROJECT BRIEF
To be filled in by the chair of the supervisory team.

chair Elif Ozcan Vieira date 21 - 10 - 2019 signature

CHECK STUDY PROGRESS
To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: EC

Of which, taking the conditional requirements into account, can be part of the exam programme EC

List of electives obtained before the third semester without approval of the BoE

YES all 1st year master courses passed

NO missing 1st year master courses are:

name date signature

FORMAL APPROVAL GRADUATION PROJECT
To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **.
Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED NOT APPROVED

Procedure: APPROVED NOT APPROVED

comments

name date signature

Personal Project Brief - IDE Master Graduation

TU Delft

Reduction of harmful noise during hip replacement surgery — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 11 - 10 - 2019 17 - 03 - 2020 end date

INTRODUCTION **
Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

A hip replacment surgery is a major surgery and usually takes around 60-90 minutes to be completed. Due to the use of powered and manual instruments (e.g., drills, saws, hammers) the orthopedic surgeon, support staff and patient get exposed to significant levels of noise pollution. Noise levels experienced during this procedure carry a risk of noise-induced hearing loss. In addition, it constitutes to a higher possibility of adverse events due to a loss of communication and dexterity among personnel. Prolonged exposure to potentially damaging noise levels in the workplace has become a subject of interest in recent years. In our faculty the Critical Alarms Lab is fighting against excessive noise in medical enviornments through well-design products/systems/services. Therefore, my graduation project is needed and timely.

In this project, the operation room could be described as a sonic environment, where sound(scape) is defined by acoustics (dB) and human sensation of sound (e.g. quiet, noisy). Perception of these sounds can differ for listeners, therefore we should consider multiple types of listeners and the way they interact with this information within the context. A differentiation can be made for three types of listeners: sound users that are required to interact with sound (surgeons), active listeners that voluntarily interact with sound (operation room staff) and passive listeners that are exposed to sound by force (patients). (Fig. 1)

During the procedure (powered) instruments generate sound levels as high as 131 dB. The different listeners are exposed to the sound levels at varying distances on site. Many (powered) instruments use generated noise levels greater than the threshold for hearing loss under health and safety legislation. These instrument emmisions eventually become hazardous within the length of an average surgical procedure. (Fritsch MH, 2010). When looking at the procedure the main used surgical tools can be described using four steps. (Fig. 1)
1. Incision is made when the patients is anesthesized.
2. Oscillating saw used to remove the upper part of femur.
3. Surgical Reamer used to hollow out the pelvis and upper part of the femur.
4. Using a mallet to fixate the cup into the pelvis hollow and the stem, into the hollow femur top.

Orthopedic surgeons and operation room staff want to reduce the risk for noise-induced hearing loss and improve operation room communication during hip replacement. By the reduction of noise, communication and dexterity will improve and the risk of surgery related complications will decrease. Zimmer Biomet wants to develop instruments with lower noise emmissions. By doing this, protective equipment and instrument sounds will not interfere with the normal communication between surgeons and staff. This will all be in favour of the patient, whom will not be exposed to harmful noise levels and most likely will have no adverse events during his/her procedure.

The major challenges of this project are: 1) Surgeons (sound users) have learned to interpret the currently produced sounds as an indicator for achieving surgical goals, such as proper fixation of the implant. Therefore, the solution to be developed needs to convey this feedback information or present this essential information to the surgical team in a different way. 2) The current precaution is to wear hearing protection, but this can block the necessary feedback and subsequently results in a loss of communication. Additionally, hospital masks and sterile operating suits already negatively affect verbal communication.

space available for images / figures on next page

introduction (continued): space for images

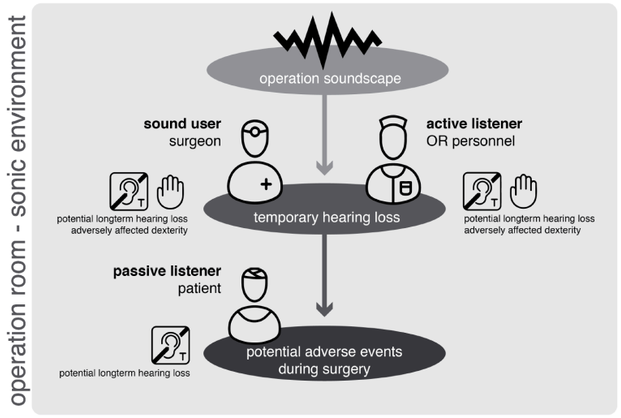


image / figure 1: Overview of the effected listeners in the sonic environment

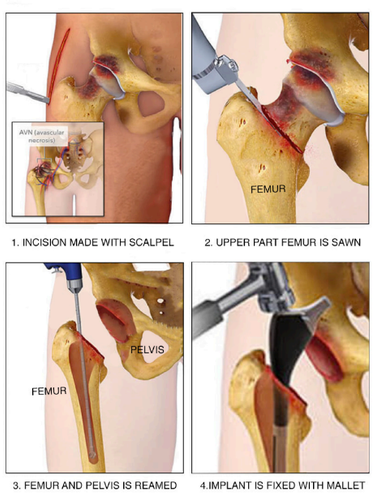


image / figure 2: Overview of surgical tools with high dB emission

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

During the hip replacement procedure, the problems arise when surgeons and/or personnel start using (powered) instruments. The noise produced is considered as a major conributing factor for temporary and potentially longterm hearing loss for all people in the operation room. Therefore, finding a solution againts hearing loss during hip replacement surgery was chosen as the focus for this project.

Noise-induced hearing loss may be temporary during surgery, but could become permanent, resulting in requiring hearing aid and may be accompanied by tinnitus. In research, it is found that 50% of orthopedic personnel with longterm exposure to power instruments showed early signs of hearing loss (Willet K.M, 1991).

__Strategy__
At first, a basic analysis of the hip replacement procedure in relation to the produced sound levels (dB) need to be conducted. Such context and acoustic analysis will be the foundation of the project and is required in order to identify key problem areas and opportunities within hip replacement surgery and the noise exposure. After having an overall feel for the essence of the complete procedure and noise producers, the focal point can be shifted towards finding optimal solutions to main issues and challenges. To specify the research, the information-flow between people and devices within the OR and during surgery will be investigated. Further, knowing more about the used sounds and the current flow of information between personnel. Additionally, research should be done into the projects challenges such as surgical sound cues, instrument feedback and current hearing loss precautions. Questions which arise are: How does the surgeon handle surgical sound cues during the procedure? Is it only sound that gives the surgeon feedback? Are there alternative ways to get this feedback?

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

During this project a tool or instrument will be designed that focuses on the (perceived) reduction of harmful noise in order to prevent temporary and longterm noise-induced hearing loss.

The solution that I aim to deliver is a product prototype, which proves a working principle that significally lowers the perceived noise levels during hip replacement surgery. The goal of the final prototype is demonstrating the working principle during my final presentation and to prove the feasibility and fit within the use environment and the surgeons' workflow.

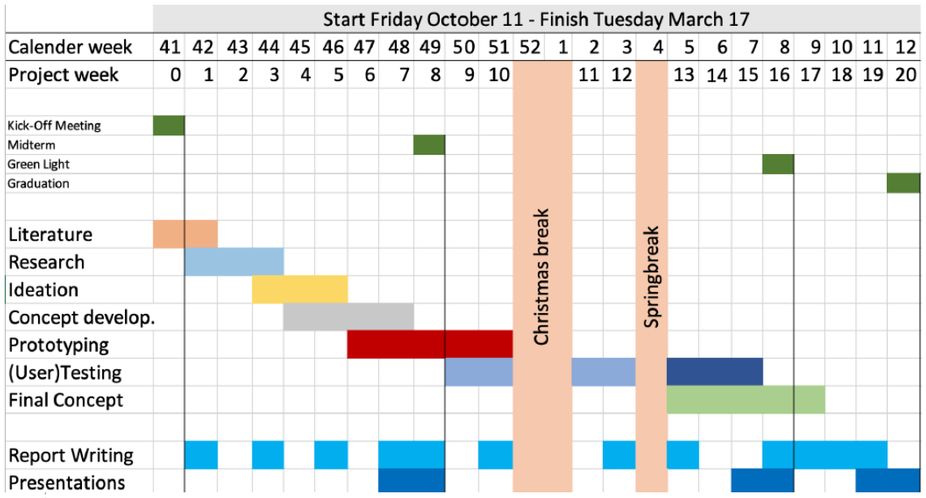
The working principle of the design will be validated in the first phase of usability tests through at least three prototypes that vary in levels of maturity. When assessing the prototypes, their strenghts and weakness will come foward, after the most promising prototype will be further developed. The design will go through another round of user test, but first the product will be risk evaluated concerning medical devices and is looked into ergonomics.

The goal is to have at least one orthopedic surgeon to test the prototype, but a test panel of three orthopedic surgeons is preferred. In the final user test, the fit of the prototype in the surgery workflow will be assesed. After this last testing is done, the prototype will be finilized and subsequently the working principle could be demonstrated during the graduation presentation. Acoustic analysis of the sonic environment at every user test as well as the product in lab conditions will be conducted in addition to the listening tests with sound users (surgeon), active and passive listeners in the field and in the lab.

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 11 - 10 - 2019 17 - 3 - 2020 end date



As can be seen in the Gantt chart above, my plan has a focus on prototyping and usertesting. Both of these phases are fairly time consuming, but very important steps within my "user-centered" project. My learning goals are a good pick to broaden my knowledge in lign with Medesign courses. Additionaly, I planned meetings with my chair and company coach once every 3 weeks and my coach every 2 weeks. If this is not possible due to busy schedules, I want to update my graduation team by sending concise e-mails, which will state my progress and points of discussion. Preferably all meetings will be held in person, because discussing will ensure an in-depth approach within the project and will help by finding feasible solutions.

I plan to start off with a literature-review, which is needed to understand the background of the sound problem and the surgical techniques. Followed by the research phase, during which the problem will be assessed within the operating room, by attending surgeries at Bergmanclinics. Subsequently, ideation process will start by solving the problem by creative sessions, such as brainstorming, how-to's and focussing on a quantity of ideas. This is followed by the development of concepts, during which focusses on the idea quality coming from the ideation process.

The concepts will be evaluated by interviewing the focus group to determine, which aspects need to be optimised and to understand how intended users/stakeholders value the concepts. Thereupon, at least three prototypes will be created of different maturities. These prototypes will be usertested by 5-7 people with a healthcare background. After the first phase of usertesting, the best performing prototype according to performance and the produced / perceived sound levels will be optimised. The final prototype will

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

As an IPD student with a great interest for the medical industry and healthcare in general, I consider this project challenging, but inspiring at the same time. Inspiring because the healthcare sector is rapidly changing and is in need of innovation. A challenge because of its habits, hierachy, rules and regulations have to be taken into account. I have set up this project, because of my interest for surgery/medicine and the the possibility to help two levels of users, in this case the surgeon and the patients who eventually benefit. Additionally, a previous project during my studies that I was assigned to, in collaboration with Zimmer Bioment, has sparked a keen interest for orthophedic surgery.

During the research phase, I will start by applying my knowledge of ergonomics and will research all the problems that arise with sound due to noise pollution. Eventually, I want to look into the user-interaction (tool and user) and learn more about what sound can do in a healtcare environment. Therefore, the knowledge that I have obtained from ACD/AED combined with the expertise from my coach and supervisor will be of great support to my research in finding the right approaches.

The skills I gained from my medesign courses will be a great addition during this project as I need to deliver a design ready for the healtcare industry. Capita Selecta gave me a broader view on finding solutions within this industry. Additionally, rules and regulations concerning medical devices give me a good platform to analyse risks and see if the design will be up to medical device standards. During my exchange period at Loughborough University, I have worked with healthcare professionals that specialised in human function. This will form one of the foundations to aid my research into finding ergonomically better ways of handling tools during surgery that do not harm the enviornment. Having understood the importance of ergonomics in my design, I aim to take the right decisions inspired by the anatomy of the human body and considering surgical techniques as taught in my medesign electives at Erasmus Medical Centre. A combination of the above-mentioned electives has given me a rather broad view, because of this I would like to put more emphasis on surgical techniques, rules & regulations and ergonomics to extend my knowledge on these matters before graduating.

Finally, I want to evolve on a personal level by focussing on project managing, meeting requirements, communication between team members, making decisions and presenting. I believe these skills all together will ensure the succes of this project and help me to become a better designer. In addition, I think this project will provide me with the opportunity to gain experience in a relatively conservative sector, in which I as a designer with a multi-disciplinary approach could introduce innovation.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

A.24 Consent forms - interviewed/observed

Research on Noise Levels in OR

This research concerns the noise levels occuring during hip-replacement surgeries in operation rooms and how it influences the performance and health of persons performing and participating the surgery. The hip-replacement-surgeries will be recorded in order to identify critical areas of sound exposure during the process of a hip-replacement surgery. The information gathered during this research will be used to analyse the critical context and to gain insight about the possibilities to improve future orthopaedic surgery environments including the utilised tools.

In this form we ask for your permission to make audio recordings and to capture the observations on photo and video, so we can evaluate the sound situation. Your face/name will be presented unrecognizably for everyone other than our project team.

Contact information:
Kees Broekmeulen (and Zoe Luck)
broekmeulenk@gmail.com; z.a.luck@student.tudelft.nl
06-81 88 50 04

Consent Form: Research on Noise Levels in OR

Please tick the appropriate boxes

Participating in this test

-I have read and understood the study information dated [01/11/2019]. I have been able to ask questions about the study and my questions have been answered to my satisfaction. (Yes) No

-I consent voluntarily to be a participant in this research and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason. (Yes) No

-I understand that taking part in the research involves recording and asking questions about the current sound situation.

Capturing this test

- I give permission for using what I said during the oberservation and to quote me anonymised in the report. (Yes) No

- I give permission for making audio and video recordings, as well as photos. I understand my face will be presented unrecognizably for everyone other than our project team. (Yes) No

M Parziale

Signatures

Name of Participant	Signature	Date
M. Parziale	M Parziale	14/11/19

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Researcher Name	Signature	Date
Kees Broekmeulen		14/11

Research on Noise Levels in OR

This research concerns the noise levels occuring during hip-replacement surgeries in operation rooms and how it influences the performance and health of persons performing and participating the surgery. The hip-replacement-surgeries will be recorded in order to identify critical areas of sound exposure during the process of a hip-replacement surgery. The information gathered during this research will be used to analyse the critical context and to gain insight about the possibilities to improve future orthopaedic surgery environments including the utilised tools.

In this form we ask for your permission to make audio recordings and to capture the observations on photo and video, so we can evaluate the sound situation. Your face/name will be presented unrecognizably for everyone other than our project team.

Contact information:
Kees Broekmeulen (and Zoe Luck)
broekmeulenk@gmail.com; z.a.luck@student.tudelft.nl
06-81 88 50 04

Consent Form: Research on Noise Levels in OR

Please tick the appropriate boxes Yes / No

Participating in this test

-I have read and understood the study information dated [01/11/2019]. I have been able to ask questions about the study and my questions have been answered to my satisfaction. Yes / No

-I consent voluntarily to be a participant in this research and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason. Yes / No

-I understand that taking part in the research involves recording and asking questions about the current sound situation.

Capturing this test

- I give permission for using what I said during the oberservation and to quote me anonymised in the report. Yes / No

- I give permission for making audio and video recordings, as well as photos. I understand my face will be presented unrecognizably for everyone other than our project team. Yes / No

Signatures

Name of Participant	Signature	Date
C.P. Essen		14-11-19

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Researcher Name	Signature	Date
Kees Broekmeulen		14-11

This research concerns the noise levels occuring during hip-replacement surgeries in operation rooms and how it influences the performance and health of persons performing and participating the surgery. The hip-replacement-surgeries will be recorded in order to identify critical areas of sound exposure during the process of a hip-replacement surgery. The information gathered during this research will be used to analyse the critical context and to gain insight about the possibilities to improve future orthopaedic surgery environments including the utilised tools.

In this form we ask for your permission to make audio recordings and to capture the observations on photo and video, so we can evaluate the sound situation. Your face/name will be presented unrecognizably for everyone other than our project team.

Contact information:
Kees Broekmeulen (and Zoe Luck)
broekmeulenk@gmail.com; z.a.luck@student.tudelft.nl
06-81 88 50 04

Consent Form: Research on Noise Levels in OR

Please tick the appropriate boxes

Yes No

Participating in this test

-I have read and understood the study information dated [01/11/2019]. I have been able to ask questions about the study and my questions have been answered to my satisfaction. Yes No

-I consent voluntarily to be a participant in this research and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason. Yes No

-I understand that taking part in the research involves recording and asking questions about the current sound situation.

Capturing this test

- I give permission for using what I said during the oberservation and to quote me anonymised in the report. Yes No

- I give permission for making audio and video recordings, as well as photos. I understand my face will be presented unrecognizably for everyone other than our project team. Yes No

Signatures

Ger Vedder		1-11-2019
Name of Participant	Signature	Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Kees Broekmeulen		1-11-'19.
Researcher Name	Signature	Date

Research on Noise Levels in OR

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Contact information:
Kees Broekmeulen (and Zoe Luck)
broekmeulenk@gmail.com; z.a.luck@student.tudelft.nl
06-81 88 50 04

Consent Form: Research on Noise Levels in OR

Please tick the appropriate boxes (Yes) No

Participating in this test

-I have read and understood the study information dated [01/11/2019]. I have been able to ask questions about the study and my questions have been answered to my satisfaction. (Yes) No

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Capturing this test

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Signatures

Name of Participant	Signature	Date
Arjen van Riet		1-11-19

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Researcher Name	Signature	Date
Kees Broekmeulen		1-11-19

Scanned with CamScanner

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Researcher Name	Signature	Date
Kees Broekmeulen		14/11

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Signatures

J.m. Spoon-te Brinke — [signature] — 01-11-2019

Name of Participant — Signature — Date

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Kees Broekmeulen — [signature] — 14-11-19

Researcher Name — Signature — Date

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Name of Participant	Signature	Date
		1/11/19

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Researcher Name	Signature	Date
Kees Broekmeulen		1/11/19
S. Castelein		9-11-19.

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J.v. Leersum-Kraaij		14/11/19

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Kees Broekmeulen		14/11/19

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TOM HOGERVORST _____ 14.11.19

Name of Participant Signature Date

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Kees Broekmeulen _____ 14-11

Researcher Name Signature Date

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Monfils — Name of Participant

Signature

14-11 — Date

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Kees Broekmeulen — Researcher Name

Signature

14-11 — Date

Graduationproject - Integrated Product Design

C.L.H. Broekmeulen | 2020

TU Delft

medis+gn

ZIMMER BIOMET