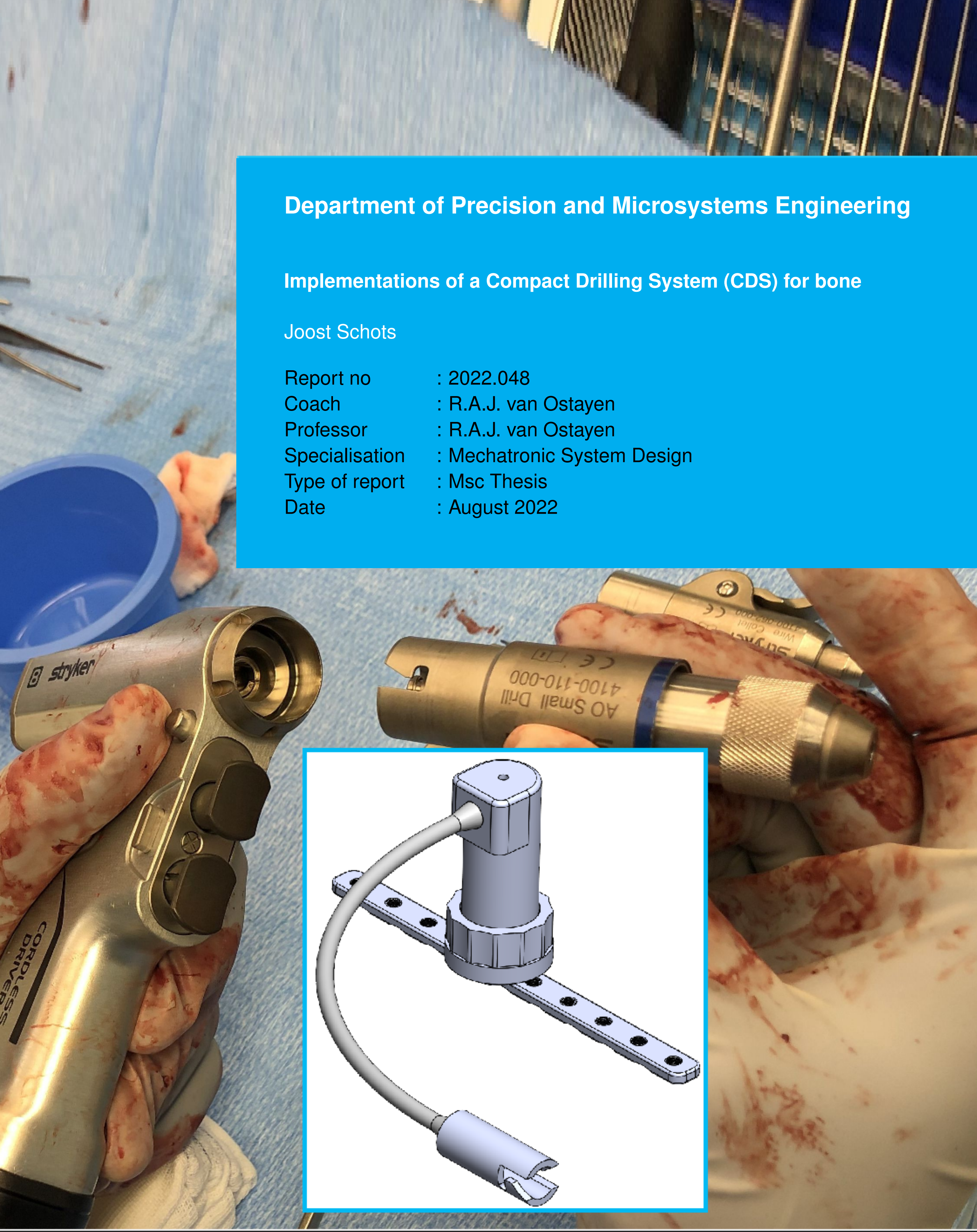

Department of Precision and Microsystems Engineering

Implementations of a Compact Drilling System (CDS) for bone

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TU Delft Delft University of Technology

Precision and Microsystems Engineering

Challenge the future

Implementations of a Compact Drilling System (CDS) for bone

by

J.F.A. Schots

to obtain the degree of Master of Science
at the Delft University of Technology,
to be defended publicly on august 29 2022.

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This thesis is confidential and cannot be made public until 29-09-2023.

Preface

The research presented in this thesis is towards designing a Compact Drilling System, to improve surgical outcome by creating a smaller device then currently available. It is a continuation of projects done by Laurens Krijgsman and Jorik van der Laan, to whom I owe my graditude for introducing me to this topic. I feel that with this latest addition to the project, the goal of an improved drilling device has come closer.

This part of my report is the final one to be written, and with that it finalizes my time as a student in Delft. I look back on a challenging but interesting part of my education. As a result of a global pandemic that started as I had just started my research, a lot of plans had to be postponed or adjusted. Nevertheless I have learned a lot during this time.

I would like to thank everyone who has been there to support and motivate me, both in person and remotely. Friends, family and roommates have been crucial to keep me going, either by sharing words of encouragement or by allowing me to take my mind off things.

I especially want to express my thanks to Jo Spronck, who through his feedback and support was always able to help me progress. This project would not have been successful without his continued support. Also the help of Ron van Ostayen supervising my masters thesis was very much appreciated.

J.F.A. Schots
Delft, August 2022

Summary

The goal of this master thesis research has been to improve on the design of a drill, as used for drilling human bone. Current industry standard is to use a fairly large drill, which makes it harder to reach certain places and is prone to human error due to its dimensions. For that reason a new Compact Drilling System (CDS) is proposed. The goal is to design a device that, due to its reduced size, is easier and safer to use in hard-to-reach drilling sites in the body.

The CDS includes the first implementation of a novel self-feeding mechanism first proposed by Van der Laan [1]. This mechanism combines the translational and rotational motion of the drill, but had not yet been used in a full system. The current iteration of the CDS is a module, to be used in combination with existing drills. This serves as an intermediate step towards a fully redesigned system. If it can be shown that this module is indeed useful in surgical applications, it follows that further research in this direction is worthwhile.

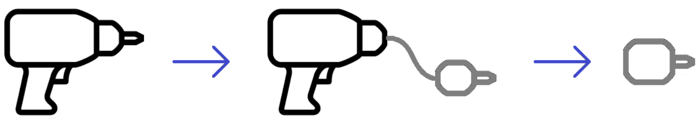


Figure 1: Schematic representation of the foreseen evolution of the current drill (left), via a disconnected module (middle), to a fully redesigned compact drilling system (right). The CDS as pictured on the right is the envisioned end goal of the extended project, the middle is the subject of this particular thesis.

There are various ways to implement the aforementioned self-feeding mechanism in a Compact Drilling System. These ways, and the corresponding advantages and disadvantages, are discussed. Different interfaces between the drill, module and patient are identified and considered separately. This makes it easier to differentiate between the numerous design variables of the Compact Drilling System. The most important interfaces are A (between the drill and the module) and B (between the module and the bone), as seen in the figure below.

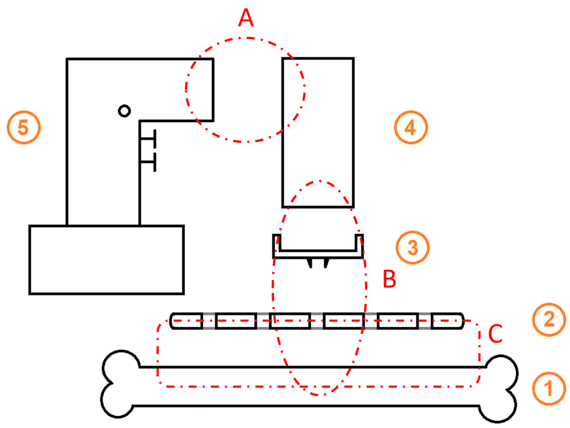


Figure 2: Schematic overview of components and interfaces

One full design has been worked out in more detail, to serve as an example of the potential of such a system. Other applications or scenarios may require a different implementation, which can be found in future research.

In this example design the module is connected to the plate to ensure the drilling orientation is correct. The power comes from the drill by means of a flexible coupling. This makes the module suitable for a variety of cases. It also disconnects the movement of the drill and the module, which can result in drilling errors.

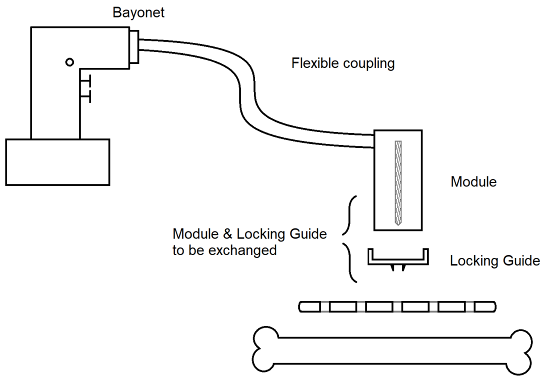


Figure 3: Schematic overview of the system proposal. A flexible coupling transfers the power from the drill to the module. A locking guide is used to connect the module to the plate during drilling

A locking guide mechanism is proposed, to be featured in this particular design implementation. The locking mechanism makes use of a swivel cap connection to easily connect and disconnect the module. Through the use of Finite Element Analysis a design has been validated in terms of strength. The results of this analysis inspired an adapted version, also discussed.

In conclusion it is possible to implement the self-feeding mechanism in a Compact Drilling System. A possible combination of design choices is shown in more detail to serve as an example of the potential of the system.

The module as designed in this research is just one of numerous possible implementations. Multiple other design options have been discussed . In future research these other options, for specific applications, can be worked out into their respective modules as well. A fully modular system is also possible, in which a standardized module can be combined with various attachments. This way it is possible to create the ideal configuration for the task at hand.

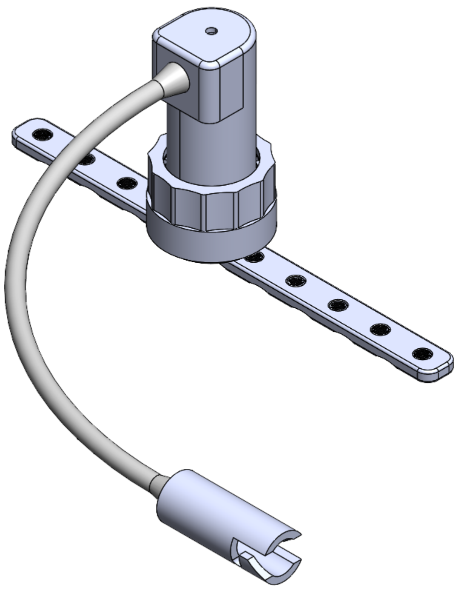


Figure 4: A CAD 3D model of the Compact Drilling System as proposed

Contents

1

Bone Drilling

1.1. Context/ relevance

Broken bones are a common medical condition, often caused by a high force impact or a medical condition weakening the strength of the bone. In the Netherlands alone, the Dutch Association for Trauma Surgery estimates that 175.000 bone fractures occur each year[2]. The number of bone fractures is expected to increase in the foreseeable future, as a result of the aging demographic in the Netherlands. Elderly people tend to have weaker bones due to osteoporosis [3, 4].

About half of these fractures require surgical intervention [2]. Less severe fractures can be healed by applying a cast for example. The serious cases need to be fixated, either internally or externally [5]. Internal fixation is accomplished by means of a plate (usually metal) that is screwed to the bone on both sides of the fracture. This locks the bone in the correct orientation to heal. An example of this is shown in figure 1.1.

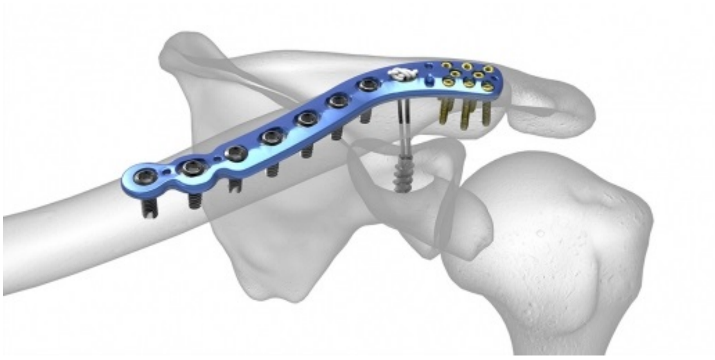


Figure 1.1: A visualization of internal fixation by means of a plate, in this case of a clavicle bone. Screws are used to fasten the plate to pre-drilled holes in the bone. Source: `www.acumed.net`

The screws attaching the plate to the bone require a hole to be pre-drilled in the bone. This research thesis focuses on improving the way these holes are drilled. Currently, the device used is a fairly large drill, quite similar to a conventional drill used outside the medical field. The current general approach to fixating bones is described in section 1.1.1.

Bone consists of multiple layers of different densities [6, 7]. Simply put, the cortical layer on the outside is dense, and the cancellous bone in the middle is soft, as seen in figure 1.2. To ensure maximum stiffness in the fixated bone, the screw is placed through both the front and back cortical layer, and the cancellous bone in between. It is important however not to overshoot the second layer of cortical bone, because that would result in damage to the tissue behind.

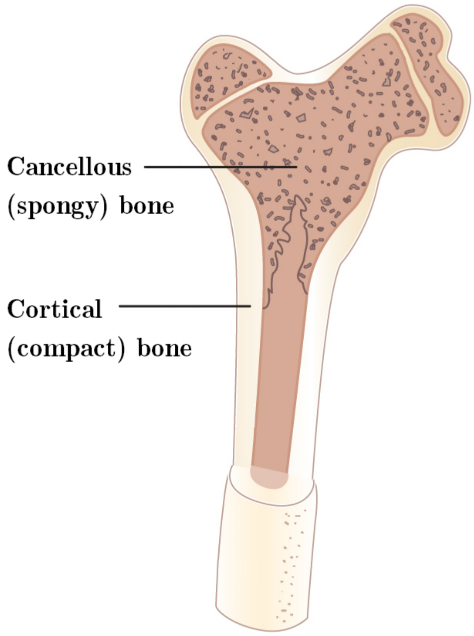


Figure 1.2: A visualization of two main types of bone tissue. Cortical bone is more dense, cancellous bone is more spongy. Adapted from [8].

1.1.1. State of the Art: Current procedure

The following is a description of an internal fixation procedure, as introduced in section 1.1. This description is based on both literature research and own observations. A number of surgeries were attended at *Reinier de Graaf Gasthuis*, a dutch hospital. The photographs in the following section were taken at these occasions, unless specified otherwise.

1. Incision is made and the tissue in front of the bone is pulled aside using retractors and spreaders.

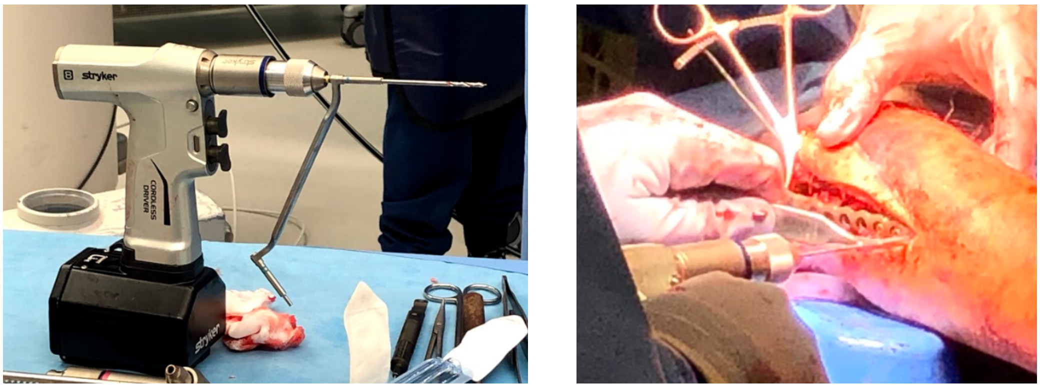
2. The plate that will be used is selected. There are many options, varying in size and layout. This plate is fixed in place using a plate holding forceps (figure 1.3).

Figure 1.3: A plate holding forceps. Source: Kax Instruments

3. A hole is drilled through the bone and one of the plate holes, as deep as possible. This means through the cortical bone, the cancellous bone and again the cortical bone on the opposite side. This depth is based on the experience of the surgeon, who feels and hears the difference in hardness of the different layers of bone.

A drill guide (figure 1.4) can be used to ensure straight drilling. This is a sleeve that the drill passes through, during which it can be held by the surgeon (figure 1.5).

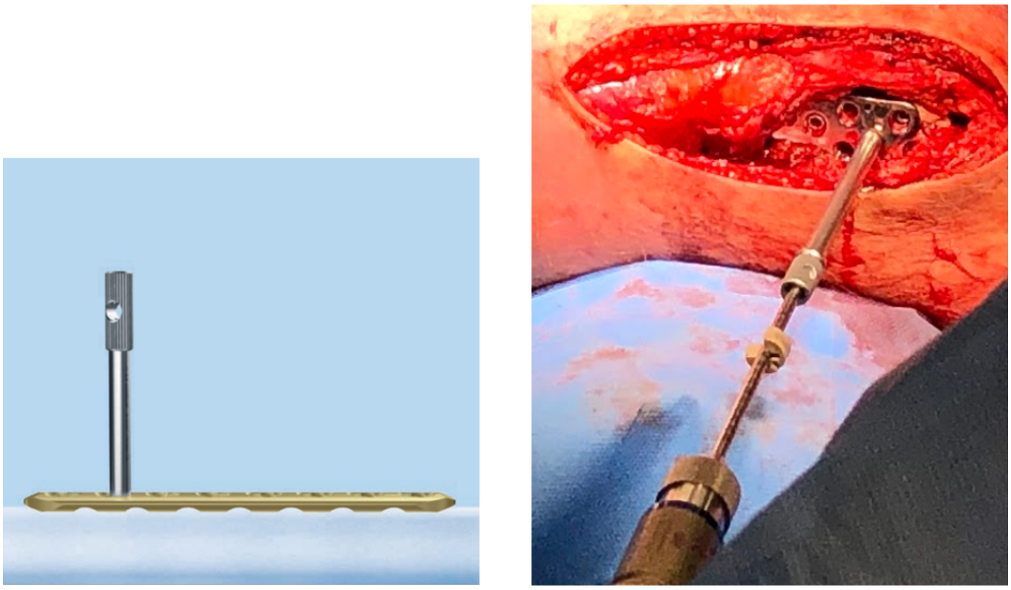
Figure 1.4: Double drill guide. Source: https://www.orthomed.co.uk/product/double-drill-guide/



(a) (b)

Figure 1.5: A Double drill guide as used in combination with Stryker drill

If the hole in the plate is a locking hole (meaning it is threaded on the inside), a special guide can be used. This threaded guide is a sleeve that is twisted onto the hole to guide the drill bit straight through it (figure 1.6).



(a) (b)

Figure 1.6: A threaded drill guide. a: taken from [9]. b: A threaded drill guide in use

4. The depth of the hole is measured using a depth gauge. This depth determines the length of the screw that is used.

Figure 1.7: A depth gauge. Source of left picture: `https://www.orthomed.co.uk/product/depth-gauge/`

5. A self-tapping screw is manually inserted through the plate and the bone. It is possible to use a self-locking screw (figure 1.8) which ensures that the screw is entering the plate perpendicular to it. Conventional screws are also an option.

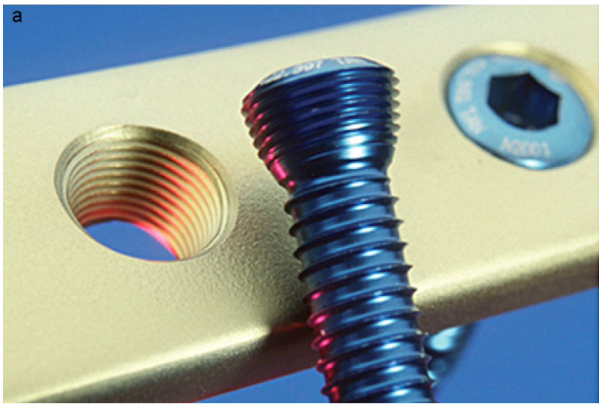


Figure 1.8: a self-locking screw and plate combination. Source: [10]

6. X-ray pictures are used to verify that the screw is indeed placed correctly. Many of the tools used are radiopaque, i.e. they are visible in an x-ray image. This means they first have to be moved away to make a useful image because otherwise it would block the vision.

Figure 1.9: X-ray image of a plate fixated to bone using screws.

7. Steps 3 through 6 are repeated for the other holes. Once the plate and the bone are sufficiently fixated, the procedure is finished. The plate holding forceps can be removed and the incision can be closed again.

1.2. Goals

The existing surgical procedure, as described in section 1.1.1, requires working space over and around the fracture. There is no problem when ample space is available, such as in fractures in the arm or leg.

It is a different case if one needs to drill a bone that is not as easily approachable. For that reason the initiative was taken at Delft University of Technology to design a compact, automatic drilling device. A device that can be placed at the correct location by the surgeon and with the click of a button a hole would be drilled. More on this vision is highlighted in section 1.2.1. The goal of designing a new, compact, drilling system is to improve on the surgeon's ability do drill holes in cases where limited space is available.

Earlier work, by Krijgsman [11] and Van der Laan [1], laid the foundation for a novel Compact Drilling system. The work of Krijgsman can be seen as an introduction to this topic, and introduces some functional requirements and a first concept. In this concept the drill head it separated from the power source to save space. In this design the only part to enter the body would be the drill head, which would be powered by a flexible coupling. The drill head is attached to a handle via a ball joint to allow for varying orientations. The drill bit is on a linearly moving stage which can be pulled down using a trigger in the handle. This very rudimentary concept, shown in figure 1.10 was an initial step towards a compact bone-drilling device.

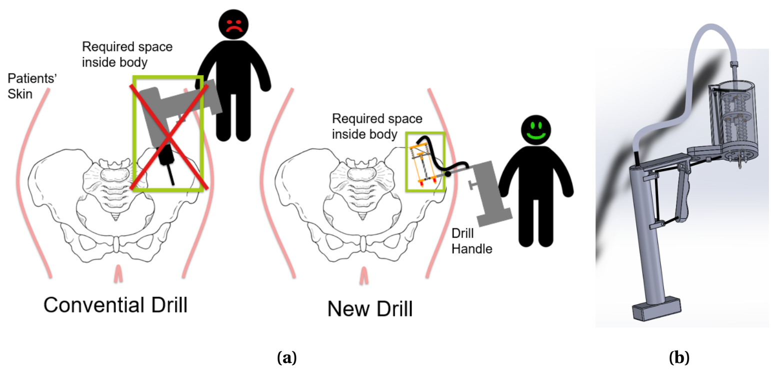


Figure 1.10: 1.10a: A schematic representation of the concept by Krijgsman [11]. By only putting the drill head inside the body, the amount of required space is reduced. The power source remains outside of the patient. 1.10b: The design by Krijgsman. Both images from [11]

In continuation of this project, Van der Laan [1] has worked on a mechanism which combines the translational and rotational motion needed for drilling. This mechanism is explained in more detailed in section 2.1.2, as it is carried over to the current iteration of the Compact Drilling System.

The envisioned Compact Drilling System is a completely reworked device. Both the previous and the current iterations however are still to be used in combination with a separate surgical drill. The foreseen evolution of the device is visualized in figure 1.11. On the left, a large drill as is currently used. This drill is then combined with a small module to reduce the required volume in the body (middle). In the future (right), the vision is to have a completely separate Compact Drilling System. This automatic device provides its own power and does no longer require a conventional drill.

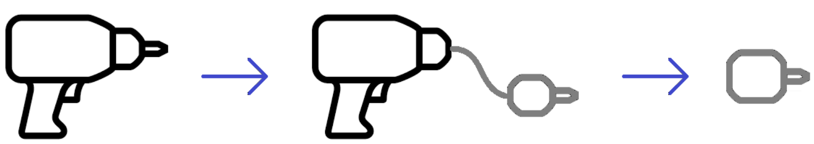


Figure 1.11: Schematic representation of the foreseen evolution of the current drill (left), via a disconnected module (middle), to a fully redesigned Compact Drilling System (right). The CDS as pictured on the right is the envisioned end goal of the extended project, the middle is the subject of this particular thesis.

The vision for a CDS such as the right of figure 1.11 represents is given in section 1.2.1. The current iteration, the subject of this thesis, is represented in the middle of said figure. The goal is to present possible implementations of the mechanism that Van der Laan introduced and give a proof of principle of a compact drilling system. Future steps can then be taken to continue the evolution towards the envisioned end-goal of a fully automated compact drilling system.

1.2.1. Vision: Intended surgical procedure

The goal of this thesis was stated in section 1.2 but it also good to expand a bit on the envisioned evolution of the device in the future. The device and procedure that act as the 'vision' of this research is a big step forward. A small device is to be placed on the bone, and drills a hole automatically.

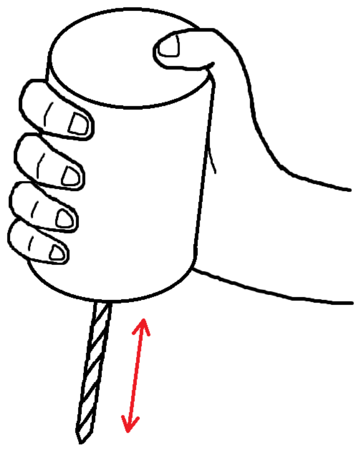


Figure 1.12: Visual representation of a future version of a Compact Drilling System, a hand held drill.

The device can be held in one hand, which means the surgeon's other hand is free. Due to the small size it is possible to reach every required bone site inside the body. When placed in the correct location, a push of a button starts the drilling. The device can detect breakthrough to prevent overshoot into the surrounding tissue. The generated heat is monitored to prevent thermal damage to the bone. The depth of the hole that is drilled is measured at the same time, and is communicated to the surgeon. This means they already know which length screw is needed. One hole after the other can be drilled, and the device can indicate when the drill bit gets too worn down to use. The drill bit can be exchanged easily, to replace dull bits and allow for different drill bit diameters to be used.

The device can be used handheld, or combined with a selection of guiding stands to help with alignment. For example, a guide to help drill through a fixation plate if needed. Or a stand that can be fixed to the bone to assure the surgeon there is no unwanted movement between drill and bone.

Example Process

The following is how the use of a handheld CDS is envisioned.

1. Incision is made and the tissue in front of the bone is pulled aside using retractors and spreaders. *

2. The plate that will be used is selected. There are many options, varying in size and layout. This plate is fixed in place using a plate holding forceps (see figure 1.3). *

3. The correct drilling depth and drill bit size is selected. The Compact Drilling System is prepared with these surgical choices.

4. The CDS is placed in the correct place, either using some sort of guide or stand, or freely in hand. †

5. The hole is drilled with a push of a button. The drill bit is expelled from the device and retracts after the correct depth is reached. ‡

6. A self-tapping screw is selected based on the depth of the hole and inserted though the plate and the bone. *

7. Steps 4-6 are repeated as necessary.

8. X-ray pictures are used to verify that the screws are placed correctly. If so, the procedure is finished. The plate holding forceps can be removed and the incision can be closed again. *

Notes on the Example process

- * Steps equal or similar to current procedure
- † Due to the device being small and handheld, hard-to-reach locations can be reached easier. Also it can be used with one hand instead of two
- ‡ Previously an extra step was required to measure the depth of the hole

1.3. Functional requirements

Bone drilling requires certain characteristics in terms of drilling speed, force et cetera. These need to be sufficient to penetrate the bone without causing collateral damage. One major contributing factor is excessive heat generation. The cause of this heat is the friction between the drill bit and the bone. Drilling speed, drilling duration and applied force are some of the main contributing factors. The damage caused by this heat is called thermonecrosis and is irreversible [12].

The threshold for this type of damage to occur is a temperature of 47 °C during one minute [13]. In his research, Krijgsman conducted experiments to find essential parameters to avoid thermonecrosis [11]:

Requirement	**Value**
Thrust Force	20 N
Drill Torque	0.2 Nm
Rotational Speed	1500 rpm

The aim is to design a small device, the maximum dimension of which may differ between cases and application. Based on conversations with a surgeon, Van der laan chose maximum dimensions of 80x40x40 mm to fit most procedures [1]. These maximum dimensions are also used in this research.

2
Conceptual Design

In this chapter design options are discussed, and a selection of options is then used in chapter 3 in one full example. For ease of understanding, a distinction has been made between components and interfaces.

The components that are used in this research but not specifically redesigned are discussed in section 2.1. The challenge is to figure out how to best combine these components and that is discussed in section 2.2. Two main interfaces are distinguished and treated separately.

2.1. Compact Drilling System layout; based on existing components

The implementation in this research takes some components as is. These components, namely the drill and the self-feeding mechanism, are to be used in the Compact Drilling Device and are introduced in this section.

The current version of the Compact Drilling Device is to be based around these components, to serve as a bridging step between the current state of the art and a completely redesigned system. This can serve as a "proof of concepts" of sorts to introduce surgeons to the idea of allowing a new device into their work field. The first iteration is a module to be used in combination with tools they are already familiar with, which can help easy the adaptation.

2.1.1. Drill

The module is to be used in combination with a standard medical drill. These drills are widely used in surgery, and allow for various different supplementary parts to be used in combination with the drill.

In preparation for this research, a number of surgeries were observed at Dutch hospital *Reinier de Graaf Gasthuis*. During these surgeries the Stryker 8 drill was used, and for that reason it has served as the example drill in this research.

Multiple other manufacturers produce medical drills though, and the functionality is mostly the same. Whatever design is chosen needs to be adapted to fit with one or multiple of these brands.

Figure 2.1: The Stryker 8 drill with a drill chuck and drill bit attached. The black part below is the cover in which a removable battery is kept, to allow for cleaning afterwards. Source: `www.stryker.com`

2.1.2. Self-feeding mechanism

One of the components that this version of the Compact Drilling Device is based on is the module containing the self-feeding mechanism as proposed by Van der Laan[1]. The goal of this mechanism is to convert an incoming rotation into the rotation and translation that is needed for drilling. While this mechanism is promising and has potential, there is still room for improvement in its realization. For that reason the mechanism will be explained here, as well as reflected upon. First the working principle of the design is explained. Next, some drawbacks of the mechanism are considered. Afterwards the advantages of the self-feeding mechanism are highlighted and the way it will still be used in the Compact Drilling Device.

The Mechanism Explained

The effect of using the mechanism as described by Van der Laan is twofold: Firstly the amount of space that is required inside the body is reduced by moving the power generation (in the drill) away from the drilling site through an angled connection. The drill can remain outside the body where more space is available. Secondly, because the mechanism provides its own feed, the device itself does not need to move during drilling. The drill bit is pushed out of the device, which can remain stationary. In the conventional drilling method the entire drill needs to be moved in the drilling direction.

The mechanism introduced by Van der Laan is an application of a lead screw, pictured in figure 2.2. This is a mechanism where a lug translates along a threaded axle by rotating it. When the nut does not rotate and the axle does, the nut slides along the axle. The relation between the translational speed (the feed rate) and the rotational speed is set by the lead of the thread (the distance along the axle covered in one full rotation).

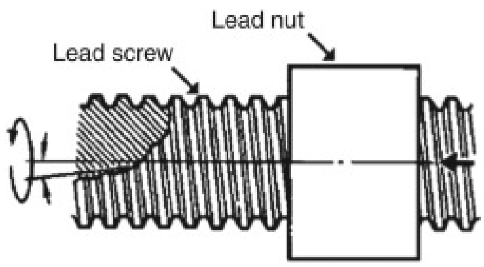


Figure 2.2: Lead screw mechanism. Indicated are the screw and the nut. The nut can translate by rotating the screw while blocking the rotation of the nut. Source: [14]

The required drilling speed and feed rate in this particular application would require an impossibly small lead of 60 μm. Van der Laan used a differential thread mechanism to obtain the required motion without needing such a small thread lead. Instead of locking the rotation of the nut, both nut and axle rotate. There is a difference in the rotational speed however, which results in the feed rate. By having both the main elements rotate, a high drilling speed can be achieved while keeping the feed rate low. The mechanism is visualized in figure 2.3 below. The drive gear on the left powers both the lead gear and the lag gear. Due to the lag gear having one tooth more, it rotates at a slightly lower rotational speed. This allows the green part with threading on it to move with respect to the blue part. A slot allows the green part to slide in the direction of the drilling.

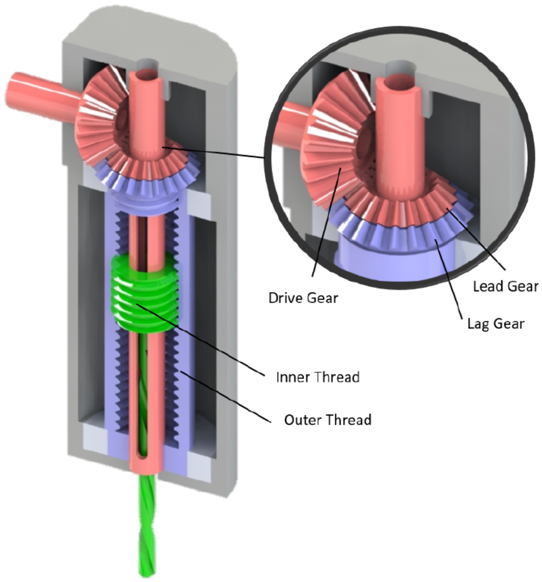


Figure 2.3: Section view of the lead screw- and differential thread mechanisms[1]. The incoming rotation (Drive gear in red on the left) is transferred to a lead gear and a lag gear, which have a different number of teeth. This results in a rotational speed difference between the inner thread on the nut (green) and outer thread (blue). This makes the green part, with the drill bit attached, translate along the drilling axis.

The relation between the number of teeth in the lead gear (N_{lead}) and lag gear (N_{lag}), the drilling speed (ω_{drill}), feed rate (v) and the thread lead (L) is as follows:

$$\frac{N_{lag}}{N_{lag} - N_{lead}} = \frac{\omega_{drill}}{2\pi v} L \tag{2.1}$$

This equation was solved for the required drilling speed and feed rate, leading to 28 teeth on the lead gear and 29 teeth on the lag gear. The drive gear has 25 teeth. The teeth of the lag gear are not as wide, to maintain the same distance between the teeth compared to the lead gear. They are after all driven by the same drive gear and jams due to a tighter fit need to be prevented.

Drawbacks of the mechanism

The mechanism as explained above has advantages, but also disadvantages. Some of these will be highlighted below.

Frictional losses and heat generation

As is always the case when introducing gears and threads, frictional losses decrease the efficiency of the mechanism. Friction energy will heat up parts that rub together. Heat accumulation can be a problem when drilling for a long amount of time. In the case of the Compact Drilling System the drilling takes place for short periods of time because the depth of the bone is quite limited. Damage to the bone due to heat generated in the drill bit is already a limiting factor for the drilling speed and time. Therefore heat generation in the mechanism itself is not expected to be problematic. Van der Laan cites an efficiency of 83% in the bevel gear assembly, based on the static friction coefficient. The thread efficiency is calculated to be 18%. This is a measure of how much of the incoming torque is converted to linear motion. The efficiency of the slotted tube, which is a measure of how much of the torque in the tube gets converted to thrust, is stated as 55%.

Limitations of the direction of incoming rotation

In the current design the incoming rotation is transposed 90 degrees by means of bevel gears. This is a fixed angle chosen beforehand. For a device which is to be used in a number of different cases it is preferred to have some flexibility in the incoming angle.

Not yet used in bone

A demonstrator has been fabricated to prove the functionality of the mechanism, but this has not been used to actually drill into bone. A wooden substitute was used. Preferably, a full test in bone is done as well.

Reusability

Any device used in a surgical setting needs to be sterile to prevent contaminating the patient. This can be achieved by cleaning the tools or by using disposable items. Complex shapes make sterilizing difficult. In this particular case, due to there being a hole that the drill bit comes out of, the inside of the device can get contaminated. It would not be feasible to sterilize the inside because of all the different parts and features such as threads. This means the entire module would have to be discarded after each use. Reusable parts are preferred by surgeons and hospitals in an effort to reduce the amount of waste material used in each procedure.

Varying drill bit size

The drill bit is directly connected to the threaded nut (green in the previous figure). Therefore it is not possible to replace the drill bit without replacing the entire mechanism. A drill bit may get blunt or damaged, or a different size can be required. In the current design each new drill bit would also mean using a new module. A replaceable drill bit would make it possible to only use one module per surgery.

Indirect feedback to the surgeon

This drawback is more of a general feature of an automatic drilling device. Currently the surgeon relies on feedback to know when to stop drilling. They feel how much force they are exerting and how far they have moved the drill, hear how fast the drill is spinning, et cetera. This is taken away by having the Compact Drilling System do more of the work. A surgeon needs to have enough trust in the reliability of the system to give away some of the responsibility. If there is some more feedback from the device this could help in understanding exactly what is happening during the drilling process and allowing the surgeon to intervene should something go wrong. One could for example use sensory feedback to provide data on the drilling torque as an indication of the density of the bone that is being drilled.

Feed rate and drilling speed directly related

There is no possibility for the surgeon to change the drilling speed (the rotational speed of the drill bit) without changing the feed rate (how fast the drill bit is entering the bone). There is no option to go into the bone slowly with a higher rpm, for example when the tissue is more dense than expected. This can also be an advantage because the number of rotations is directly linked with the distance travelled by the drill. In other words if you know how many rotations you have put in, you also know how deep you have drilled. This is beneficial for a fully automatic system because it allows for direct knowledge of drilling depth.

Advantages and using the Self-feeding Mechanism in the Compact Drilling System

Although the mechanism is not perfect, as described in the previous section, it is a promising mechanism to be used in a Compact Drilling System. The small dimensions allow for drilling in hard to reach locations with other organs and tissue present. By combining the drilling rotation and the translational feed, the module that encloses the mechanism does not need to be moved once placed in the correct location. This also means that, even if the angle that the surgeon reaches in from is quite awkward, once the module is locked in place there is no need to apply a lot of drilling force.

The Compact Drilling Device, using a self-feeding mechanism, is a big step towards a new way of drilling bone in hard to reach locations in the body. The transition from the current state of the art towards a fully redesigned device that can be placed in the correct location and drills the holes automatically is a big transition. The potential of such a device can be made clear to surgeons by showing the advantages of a module with the self-feeding mechanism as an intermediate design. This shows that it can be achieved to place only a small (part of the) device inside the patient, while still keeping the surgeon directly in control via a drill that they are familiar with.

As explained earlier, the aforementioned self-feeding mechanism is not perfect and further improvements need to be made before it is ready to be used in a Compact Drilling System. An important conclusion to be drawn however is that it is indeed possible to provide the drilling motion from a small device. The exact way of doing so needs to be improved upon but it can be done.

The Compact Drilling Device will use the self-feeding mechanism as currently proposed as a reference for dimensions and functionality. The actual internal mechanics however are outside the scope of this particular research however. The location of the incoming rotation is fixed, as well as the location where a drill bit exits the module. What happens in between is seen as a black box mechanism to be specified in a later stage.

2.2. Challenges: interfacing existing components

In the previous section the components were discussed that are used as is. The challenge is to figure out how to combine these components into a new Compact Drilling Device. To give some structure two main interfaces are defined: Interfaces A and B. The following figure contains a schematic representation of the different components (some of which as discussed in the previous section) and interfaces.

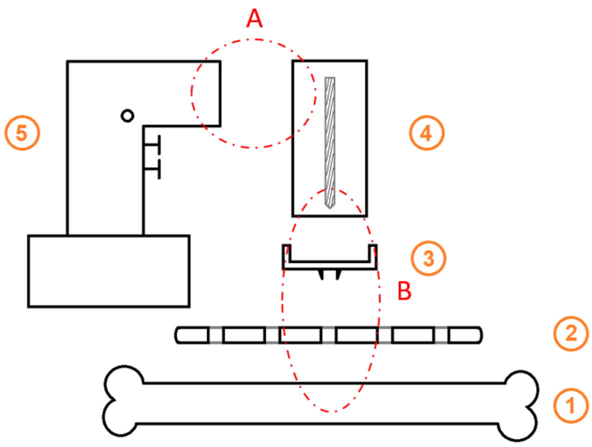


Figure 2.4: Schematic representation of the different components and interfaces in the Compact Drilling System. 1: Bone; 2: Plate; 3: Guide; 4: Module; 5: Drill. Interfaces A and B are indicated in red.

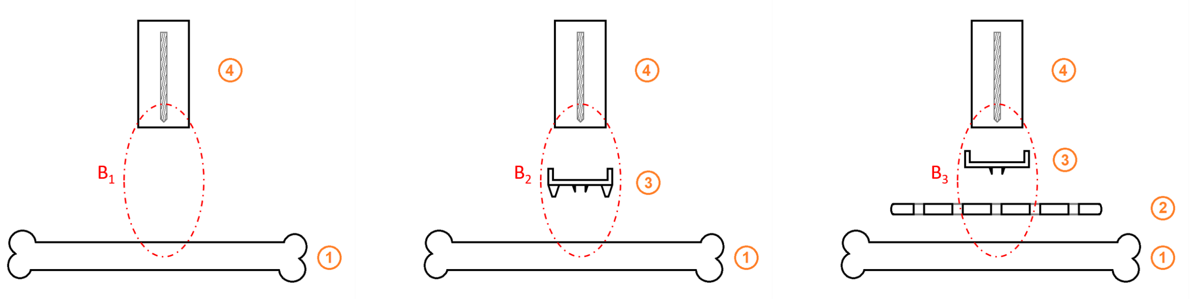
In red, the main interfaces to be discussed and designed next are marked.

Interface A is the connection between the drill and the module. The main function of this interface is to transfer the rotational motion of the drill axis to the module. The module needs to be easily attached and detached, possibly with a bayonet mount. This is the way various attachments can be attached to a Stryker drill.

Figure 2.5: Keyless drill chuck (source: `aamedicalstore.com`)

Another important functionality of interface is to shield the rotating axis from the outside world. This is needed to ensure no objects or human tissue can get stuck in the moving parts. Interface A is further expanded upon in section 2.3.

Interface B is the interface between the module and the bone. The main function is to ensure there is a connection to the bone so the drill bit can enter in the correct location and orientation. Interface B is subdivided in different cases, pictured and listed below:



(a) B1 **(b)** B2 **(c)** B3

Figure 2.6: three cases

- **Case B_1**: The module is in direct contact with the bone, without additional means of fixation (figure 2.6a)
- **Case B_2**: A guide or stand is connected to the module (figure 2.6b)
- **Case B_3**: A guide is connected to the module, and used in combination with a plate. (figure 2.6c) There are two main cases to be discerned here:
  - **Case $B_{3.1}$**: The hole is a conventional hole. In this case a guide can be slid into the hole, thus centering the module over it. this way the translation in the plane of the plate is fixed, and the other degrees of freedom are not.
  - **Case $B_{3.2}$**: The hole is a locking hole. In this case the locking mechanism, which is present to fixate the screws in the plate, can be used to attach a guide. This would lock all degrees of freedom between the plate and the guide.

(a) **(b)**

Figure 2.7: Two different types of holes in the fixation plate. (a) is a conventional hole (Case $B_{3.1}$), (b) is a locking hole (Case $B_{3.2}$)

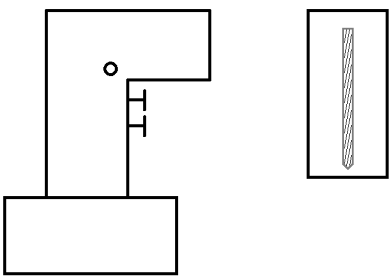
2.3. Design interface A: drill to module

Interface A is the interface between the drill and the module. The main function of this interface is to transfer the rotational motion of the drill, while shielding the axis from the outside world. The drill already has a standardized mounting point, used to attach various types of drill heads. For example, pictured in figure 2.8 is the Stryker 8 system. Attachments, such as the chuck on the right, can be coupled to the drill, pictured left. The connection is made through a bayonet mount and can be released by pressing a button (also visible, on the left next to the thumb).

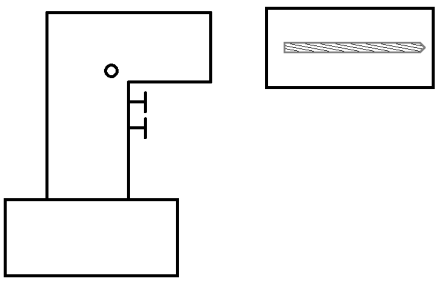
Figure 2.8: Stryker 8 drill and chuck

This way, the system can be disassembled and the attachments can be cleaned separately for later use. The possibility to clean and reuse surgical tools and materials is preferred, because there is a growing trend to reduce the amount of waste materials coming from hospitals.

There are multiple ways to connect the module to the drill. An important aspect to take into account is the orientation between these two components, visualised schematically in figure 2.9. Both of these orientations can be beneficial in their own right, depending on the preference of the surgeon. One bone fracture may require a different setup than another, due to the surrounding tissue, organs etcetera.



(a) 90 degrees



(b) in-line

Figure 2.9: Two ways of orienting the module with respect to the drill: (a): 90 degrees angle and (b) in-line

The first iteration of the self-feeding mechanism as designed by Van der Laan [1] already has a 90 degree angle between the input rotational axis and the drilling direction. This can be seen in figure 2.10. The most straightforward implementation is therefore to keep this design feature, resulting in a 90 degree angle between drill and module (visualised left in figure 2.9).

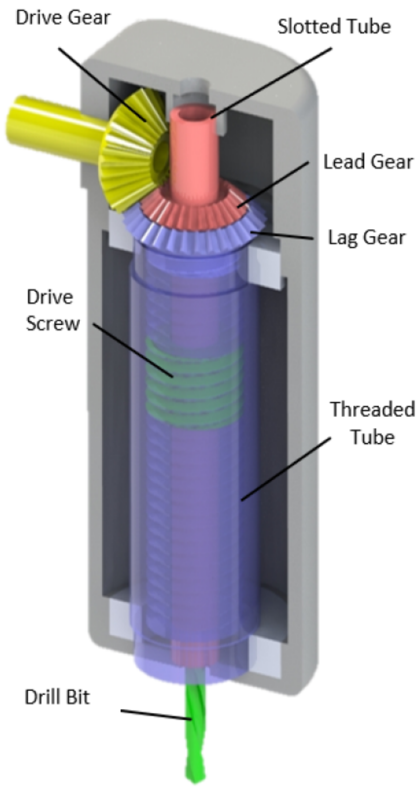


Figure 2.10: Section view of the design by Van der Laan [1] with critical components highlighted

It is also possible the required drilling direction is in line with the input axis (figure 2.9b). To achieve this, either the existing mechanism would need to be redesigned or the connection bridging interface A would need to take into account the extra angle. The latter of these solutions is not preferred, because one of the goals is to minimize the size of the system. Having a somewhat redundant transmission would not benefit that goal. A redesign of the self-feeding mechanism to make it use an input in line with the drilling action would be a more sensible solution.

In the end, the intention is to deliver a system that can be adapted to the needs of the surgeon. In cases where there is little space above the fracture, one may prefer approaching the drill site from the side. In other cases one may prefer drilling in-line. This method also most closely resembles the current drilling method, where there generally is no angle shift between the drill and the drill bit. It is worth noting that drilling attachments that allow drilling from the side do exist. An example of this is a right angle drive as pictured in figure 2.11.

Figure 2.11: Stryker 4100-355 Radiolucent Right Angle Drive (Source: `aamedicalstore.com`)

This device is powered from the right (note the universal bayonet mount that attaches to the drill), and drills downward. An added feature of this particular device is that it is radiolucent. This means that it does not show up on x-ray photography, easing the process of verifying if the drill direction is correct.

There is a distinction to be made when comparing conventional right angle drives such as the one pictured above and the compact drilling module. While both make it easier to approach a drilling location with limited available space above it, the Compact Drilling System also limits the necessary movement. When a conventional drill and right angle drive are used, the entire system of drill and drive needs to be moved in order to drill.

The Compact Drilling System consists of a module which provides the drilling motion. For that reason it only needs to be placed in the correct location, there is no need to move the entire system as the drill bit moves. Of course, it is necessary to provide enough counter-force to the module. Otherwise the drill bit would push the module back instead of drilling into the bone as required.

Three types of connections are discussed next: a rigid connection with a fixed angle, a connection with a variable angle, and a flexible connection. The variable angle and flexible connection can also be imagined as a semi-rigid connection. Advantages and disadvantaged of these types of connections are listed below. Note that these angles refer to the in-plane orientation as pictured below. Adjustment of the orientation along the axis of the drill is also an option, regardless of the approach chosen.

Rigid, fixed angle

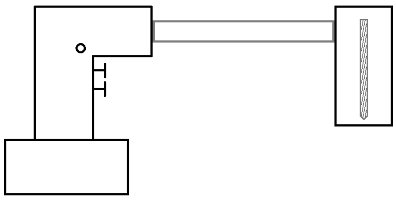


Figure 2.12: Rigid, fixed angle

Note: As stated before, the angle at which the module is fixed is to be determined. The orientation as visualized above is the most straightforward one, because the module in its current design has the input rotation on the side. Other orientations, such as having the drilling direction in line with the rotation of the drill, would require a redesign.

Advantages:

- least complex option, both in design and manufacturing. This makes it more suitable as first demonstrator
- Component would also be easier to clean and reuse compared to more complex solutions

Disadvantages:

- more limiting in surgery due to the rigidity of the system
- smaller improvement compared to state of the art (result is still a bulky assembly)
- Rigid connection allows for unwanted forces to be transferred from drill to module

Variable angle†

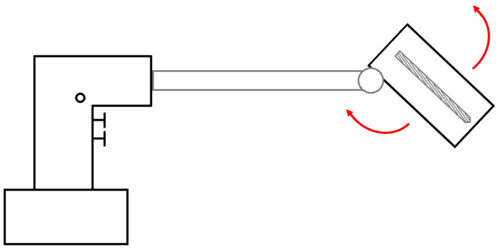


Figure 2.13: Variable angle

Advantages:

- More flexibility than a fixed connection, makes it suitable for more cases

Disadvantages:

- Increased complexity in design and manufacturing
- Needs additional mechanism to lock the orientation in place (in case of semi-rigid implementation (†))
- Rigid connection allows for unwanted forces to be transferred from drill to module (in case of semi-rigid implementation (†))

Flexible†

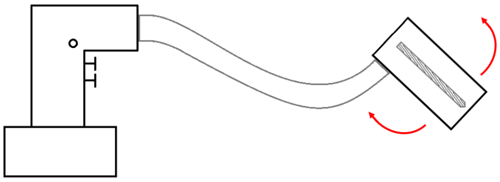


Figure 2.14: Flexible

Advantages:

- less intrusive so suitable in more cases
- Disconnects the drill bit from the drill, so in case of accidental movement this is not transferred to patient
- Manoeuvrability in all degrees of motion

Disadvantages:

- increased complexity in design and manufacturing
- more difficult to sterilize
- Additional losses due to friction likely

Notes

† Both the *Variable Angle* and the *Flexible* options that are discussed above can be imagined as either a nonrigid or semi-rigid option:

Nonrigid A connection that is not stiff during drilling. In the case of the variable angle, it can be imagined as a joint that allows the angle to vary. A flexible option is a bendy drive shaft that allows for flexibility during the drilling.

Semi-rigid This is a connection which can be placed in the correct orientation and locked. So the angle can be varied, but during the drilling procedure the system is rigid. In the case of the flexible coupling, a shell mechanism that is locked into a stiff orientation.

2.4. Design interface B: module to bone

Interface B is the interface between the module and the bone. The main function is to provide for a connection between the module and the bone. The drill bit needs to enter the bone in the correct location and orientation.

This interface is subdivided in three different cases (B1, B2 and B3), which will be discussed in the next section. These are different types of stands to put between the module and the bone, or the choice can be made not to put anything in between.

2.4.1. Different cases

Case B1: no guide/stand

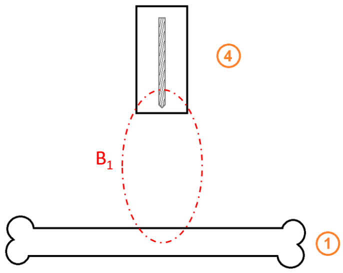


Figure 2.15: Interface option B1: no guide or stand

This method would be the simplest because no additional guide needs to be designed. A big disadvantage however is that there is nothing to help the surgeon obtain the correct orientation of the module. The module needs to be held into place just by holding the module itself. The module would therefore need to allow for sufficient grip, for instance by a coarse finishing, knurled surface or a ledge.

The drill bit is enclosed in the module, and only comes out during the drilling procedure. For that reason it is not possible to use the tip of the drill to find the correct location. The module needs to have a way to easily discern where the exact location of the drill bit is. For instance a lip around the perimeter of the drilling hole on the module.

In the case of a rigid connection between drill and module (see interface A), it would be possible to hold only the drill. This would be problematic because the forces are applied far away from the contact point with the bone, thus risking large human errors due to the moment arm. Using both hands, one on the module and one on the drill, would be better in this case.

Case B2: A guide/stand

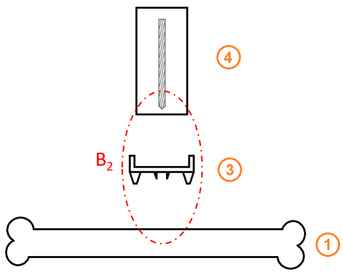


Figure 2.16: Interface option B2: A guide or stand

In this case a guide or stand is connected to the module. This would help fixate the module in the correct location. The guide is removable, is it can be cleaned separately.

Different guides can be designed for different applications or bone types, and chosen by the surgeon. This would require some sort of universal connection between the module and the guide, which can be easily swapped. The bone-facing end of the guide could be designed in a way that matches the shape of the bone that needs to be drilled. For instance, a guide that specifically matches the general shape of a clavicle or a pelvic bone.

A rather recent development in the surgical field is the use of patient-specific instrumentation[15, 16]. Using imaging techniques such as Computed Tomography (CT), a 3D scan of the affected bone is created. Based on that scan, patient-specific tools such as implants [17, 18, 19, 20] or guides [21, 22, 23, 24] are made using rapid prototyping. It would be possible to 3D-print a guide for the Compact Drilling System that is specifically designed for the patient.

Another possibility is to create a stand which would have some level of adaptability to the shape of the bone. For instance a series of pins or a deformable 'cushion' that can be formed in the required orientation.

Case B3: A guide/stand combined with plate

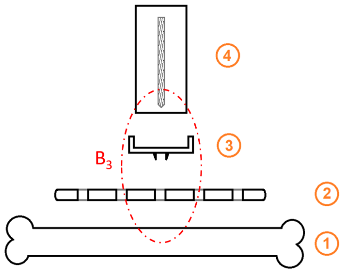
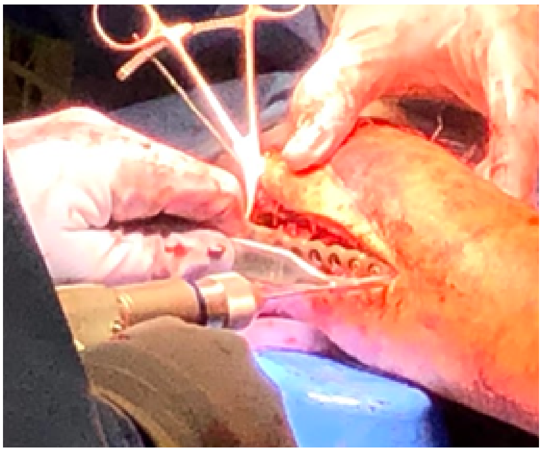


Figure 2.17: Interface option B3: A guide/stand combined with plate

This case is similar to B2 but, instead of connecting to the bone directly, a plate is used. This can help by limiting the sideways movement of the drill bit. Drill guides are already in use in surgery. They consist of a small tube, that the drill bit fits through, and a handle. This helps the surgeon exert force close to the point of contact of the drill.

(a)



(b)

Figure 2.18: Double drill guide (`https://www.orthomed.co.uk/product/double-drill-guide/`), (b): drill guide in use during surgery

As can be seen in figure 2.19 the combination of drill guide and drill can take up a lot of space. This is not a problem when the bone is easily approachable, but it can be in tighter situations. When the guide is connected to the module the required space is a lot smaller. After all, the drill bit is already in the module. This reduction in required space above the drilling site is already a key feature of this new Compact Drilling System, but even more so when the added length of a guide is to be taken into account.

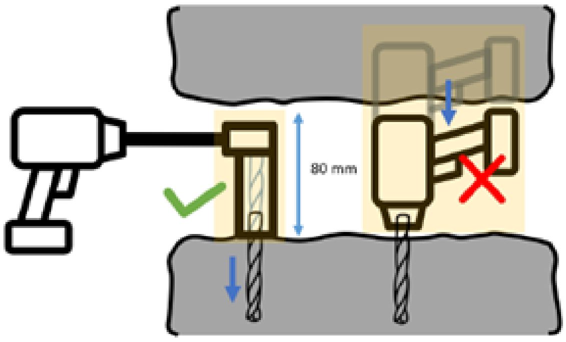


Figure 2.19: Schematic comparison between required space, from [1]. Using a module (out of which the drill bit comes) takes less space above the surgical site than using the entire conventional drill.

Consideration between the three cases

The three cases B1, B2 and B3 as discussed are all valid implementations of the module in a Compact Drilling System. Solely using the outside of the module to orientate it (case B1) is very easy but also potentially inaccurate and rather trivial for the purpose of this thesis.

Both case B2 and B3 make use of a stand or guide and are quite similar. In this particular research case B3 (a guide combined with the plate) is expanded on further and used in the design in chapter 3.

The types of guide that are combined with a plate can be further specified. A particularly interesting implementation of such a guide is the locking guide. This is the type of guide that is used in the remaining of this thesis. Locking guides, as a subsection of drill guides are introduced in the following section.

2.4.2. Locking Guides

An interesting subsection of drill guides is that of locking drill guides. To understand what these are, it is important to first discuss locking plates and screws.

Types of locking mechanisms

A conventional compression plate is, simply put, a metal plate through which a screw is drilled. The compression between the plate and bone keeps the bone in place to allow it to heal. The plate is pressed onto the bone when using this technique, which is not without its disadvantages. The compressive force between bone and plate can limit the circulation of blood in this area [25], damaging the bone. To limit this, plates are designed with minimal contact area [26]. Undercuts are used to limit the contact, as can be seen in figure 2.20. Further reduction of compressive forces can be achieved by using angular-stable screws. This way, the plate does not need to be in direct contact with the bone to achieve stability. A visualization of this principle is shown in figure 2.21.

Figure 2.20: Side view of a Synthes Locking Compression Plate, from [9]. On the bottom, the undercuts are visible that reduce the contact area with the bone.

There are multiple ways to create a fixed connection between the screw and the plate. Different plate manufacturers use different techniques. A division can be made between systems where the screw head is locked into place by a threaded locknut, and systems where the screw head is threaded itself. The threads on the screw head are used to attach it to the plate. A number of locking plate systems are discussed in appendix A.1. For purposes of using existing plate systems to provide guiding and orientation to a new to design drilling module, the threaded locking plate are the most relevant. These are not as manufacturer-specific and do not require additional components to fasten the guide, such as separate locknuts. For that reason only that general mechanism is explored further.

Figure 2.21: Visualization of the advantage of locking screws by Cronier et al [10]. Figure (A) With a locking screw, the assembly is stable. (B) With an untightened common screw, the assembly is unstable. (C) Compression is necessary against the plate. From [10]

The plate systems that use a threaded screw head and plate combination to lock the plate work as follows; When a locking screw is inserted though the plate and the bone, the threading on the screw head and locking hole ensure that both bone, plate and screw are connected. This is visualized in figure 2.22

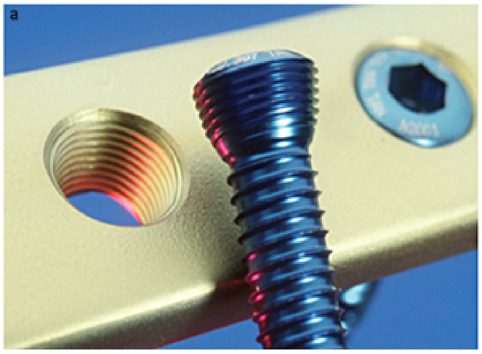
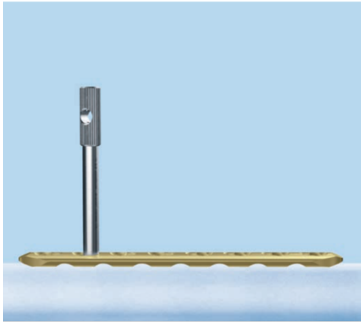


Figure 2.22: A Locking screw and plate combination by AO (Synthes). The screw head is threaded and locks in the plate. [10]

This system requires a hole to be predrilled though the bone in line with the locking hole of the plate. To help the surgeon achieve this, guides exist which can be twisted onto that same hole. The hole that results from drilling though this guide is in the correct orientation with respect to the plate. This can be seen in figure 2.23.



(a)

(b)

Figure 2.23: Locking guide screwed onto one of the locking plate holes. a: Depiction from [9], b: in surgical use

In this case, a lot of space is required above the drilling site. The guide has some length to sufficiently stabilize the drill bit, which also needs to be long to fit through it all. The drill itself is even further away from the bone.

The auto-feed mechanism that is used in the module of the Compact Drilling System already has a linear guide in place. This means only the part that twists onto the plate is required, limiting the amount of space required to use a locking hole guide. If the module can be rigidly attached to the plate by means of the threaded hole, the hole will be drilled in the correct direction.

The module and the guide need to be connected and disconnected easily and quickly, because this needs to happen for each hole that is drilled. The guide is to be twisted onto the plate separately, to prevent the need of the entire system of drill and module to be twisted around (step one in the following figure). The module is then connected to the guide by means of a bayonet mount or a similar technique which requires minimal movement from the module (step 2). After the hole is drilled (step 3), the module is disconnected from the guide (step 4). The guide can now be twisted off the first hole (step 5) and twisted on the next hole (step 6). This process repeats for each hole.

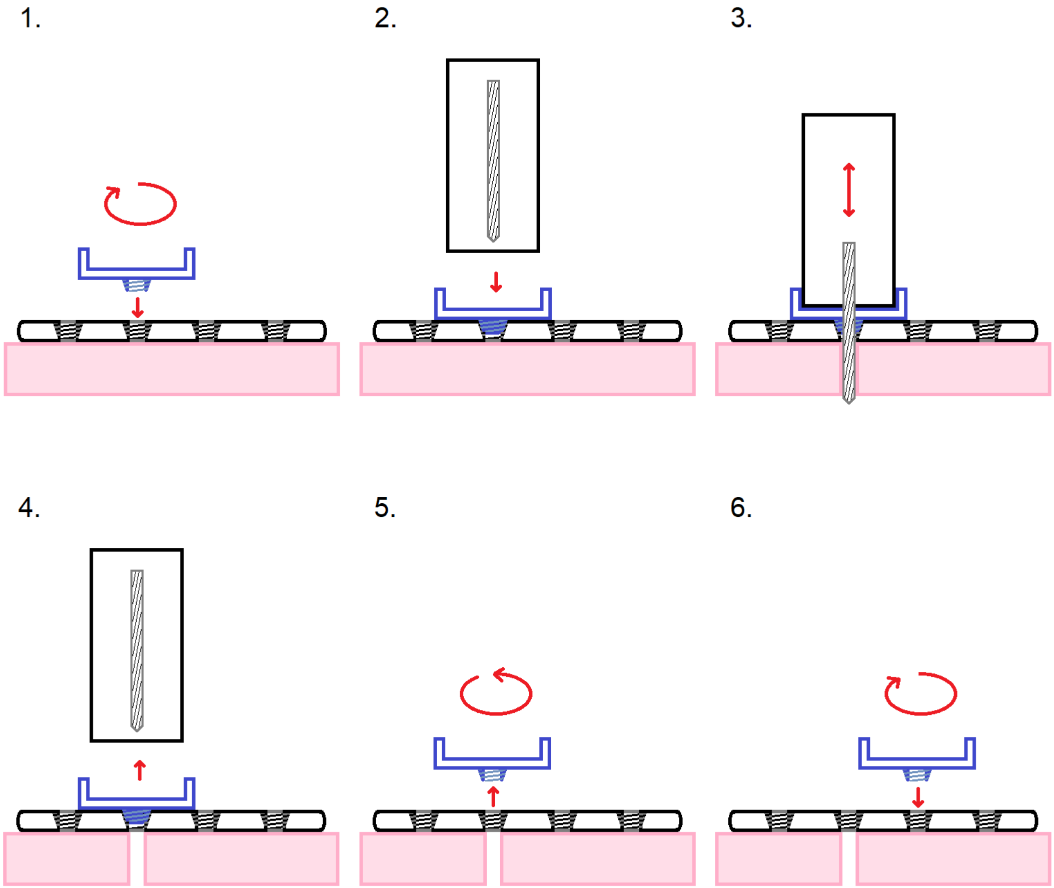


Figure 2.24: A schematic representation of the different steps taken when transferring the locking guide between holes. 1) guide twisted on first hole; 2) module attached to guide; 3) Drilling; 4) module released from guide; 5) guide twisted off first hole; 6) guide twisted on second hole,

Using the geometry of the plate

A different approach to locking the module in the correct orientation is to use the geometry of the plate itself. This means using the specific shape or surface of the plate to align the module to each of the holes. A proposal of such a mechanism is described below.

The module is attached to a 'gripper' which clamps onto the plate in the correct orientation. The shape of the gripper matches with the shape of the plate to ensure this. The claws of the gripper open and close by using a mechanism actuated by the surgeon, by means of a button. This way it can easily be transferred between different holes of the plate. The attachment to the module can remain in place between holes.

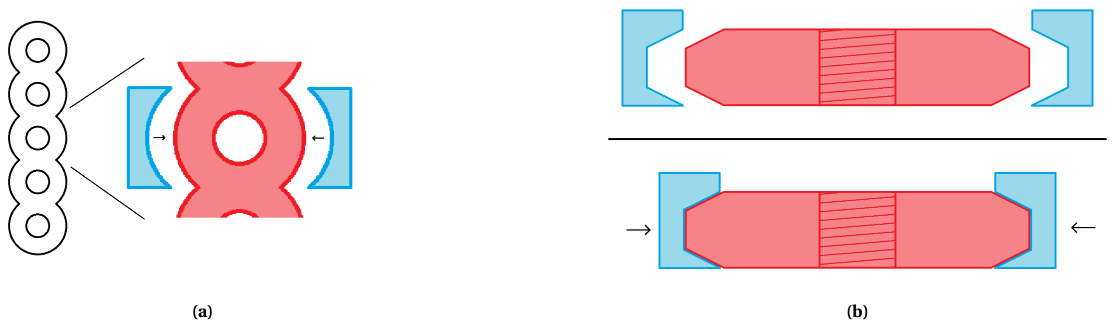


Figure 2.25: A schematic representation of a clamping mechanism using the geometry of the plate to fasten the module. Claws match the shape of the specifically designed plate (a) and tighten around the shape (b).

The main advantage such a system has when compared to the threaded locking holes is that it has a potential of increased speed. There is no need to remove the guide after each hole. Clamping and releasing needs to be redone for each hole, but the connection between module and gripper can remain.

There are also downsides to implementing such a system. A newly designed plate is needed, as current plates are not specifically designed for this purpose.

Comparing the threaded locking hole to plate geometry

The two techniques discussed in the previous section have their own advantages and disadvantages. Both would potentially reduce the amount of space required to properly align the drill bit, compared to using a separate drill guide and drill. The main advantage of using a gripper to clamp onto the plate is the increase in speed. Making the process fast and easy for the surgeon is important because it will make the transition to a new method easier to justify.

Another aspect that makes transition easier is the amount of innovation that is introduced in the prototype. By having the system relate closely to the current state of the art, the potential benefits can be shown without introducing a daunting new system. Surgeons have a procedure already that works for them and it is important to have them on board when introducing new innovations. Using familiar techniques and principles can help in this.

Adapting currently available techniques also allows for easier prototyping and developing. Using a plate clamping technique would require a new design of not only the compact drilling device, but the plate as well. For that reason it was decided that this iteration of the compact drilling device will make use of threaded locking holes to align the module.

It is worth remembering that the goal of the module is to have multiple attachments to be used for different use cases. This design with the threaded locking hole will serve as an example of the potential of the system. Different, faster, applications such as the plate gripper can always be designed if the system is deemed worthwhile.

Connection between the guide and the module

Regardless of whether a regular guide or a locking guide is used, it needs to be connected to the module. This needs to happen quickly and easily to ensure it is not a hindering factor in terms of operating time. A locking guide needs to be connected and removed for each hole that is drilled, making it even more important it can happen fast.

Important functional requirements that the connection needs to meet are:

Fast

The guide needs to be connected to and removed from the module numerous times during a surgery, and for that reason it can not take up too much time. Ideally one would want a system that can simply be put into place and locked with the push of a button. After the hole is drilled the guide is released and the surgeon can move on to the next hole.

Easy

Related to the speed, the complexity of the connection needs to be limited. Placing the guide should be a minor step in the drilling process, without requiring too much attention. This also means additional tools and techniques are not favoured. If for example a screwdriver is needed this adds to the number of tools to keep track of during the surgery. Should the device require a specific new handling technique to use it, the surgeons need to be educated first. This is not the intention, as the goal is a new device that fits easily in the current 'toolbox' at the surgeon's disposal.

Secure (clicking into place)

The guide needs to be connected securely. Discrete mechanisms that 'click' into place are preferred because it is immediately clear to the user that the connection is made. More continuous mechanism such as tightening a bolt to keep something in place do not provide such direct feedback.

Resisting the drilling force and moment

The main function of the device is of course to drill, and the connection between module and guide should allow for that. The guide would come loose if the resisting force along the drilling axis exceeds that of the guide connection. Instead of pushing the drill into the bone, the guide is pushed off the module. Similarly the moment along the same axis must be resisted. Otherwise the module would rotate in the guide instead of drilling into the bone.

Cleanable or disposable

The guide will need to be sterile when it is used in surgery. To achieve this it needs to be either sterilizable after each use, or discarded. For a tool to be sterilizable its geometry needs to be suitable. Complex shapes, hollow parts and long tubes can not be cleaned sufficiently. For that reason a design is preferred which is reasonably simple in shape.

Manufacturable

Related to the previous point, the guide needs to be manufacturable. A lot is possible using modern day manufacturing tools, but everything has its limits. If the part ends up to be disposable due to the design, the cost of manufacturing can not be high to keep it economically viable.

3
Selected overall design

In chapter 2 the various possible implementations of a Compact Drilling System have been discussed. In this chapter one overall design is selected to serve as an example of an implementation. CAD models have been made to visualize the new components.

3.1. Implementation of selected interfaces

Figure 3.1 shows the selected implementation of options. For interface A, a flexible coupling is used. This allows for a transfer of power from the drill to the module while providing flexibility to the surgeon. Also, unwanted motion (i.e. a translational movement) from the drill is not transferred to the module.

Interface B is based on a locking guide. The guide is attached to the plate, providing the correct drilling orientation.

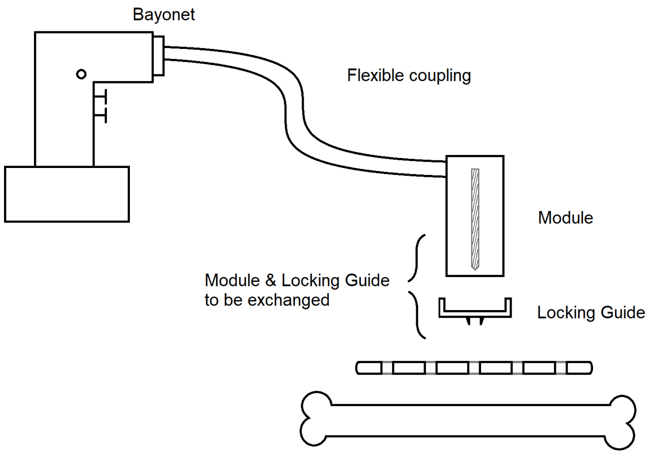
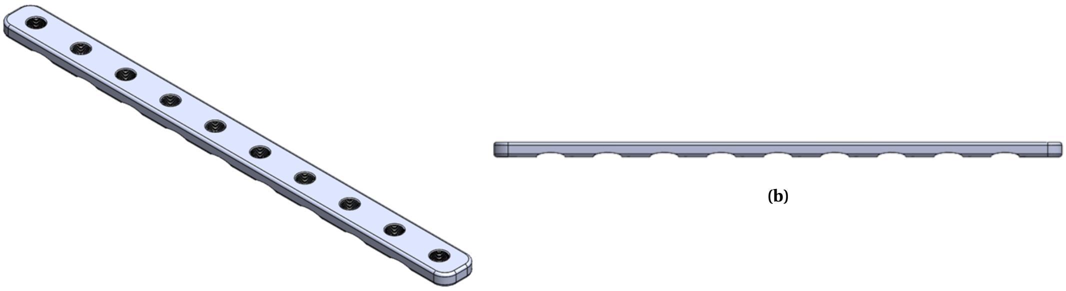


Figure 3.1: The overall system proposal. A selection of possible implementations from chapter 2 has been made. A flexible coupling transfers the power from the drill to the module. A locking guide is used to connect the module to the plate during drilling.



(a) (b)

Figure 3.2: A locking internal fixation plate.a: isometric view, b: side view. The bottom of the plate has indentations to limit the contact pressure between bone and plate.

3.1.1. Plate

In figure 3.2 a 3D model of a fixation plate is shown. Precise dimensions of the plate depend on the manufacturer and the application, as can be read in section 2.4 and appendix A.1. The bottom of the plate is ridged to minimize contact pressure between the bone and the plate, which can cause damage. Important to note is the threaded hole, which allows for the locking guide to be used. This is shown more closely in figure 3.3. In reality, plates often also consist of conventional (non-locking) holes and appear in various shapes. For instance, curved shapes that match the general shape of specific bones.

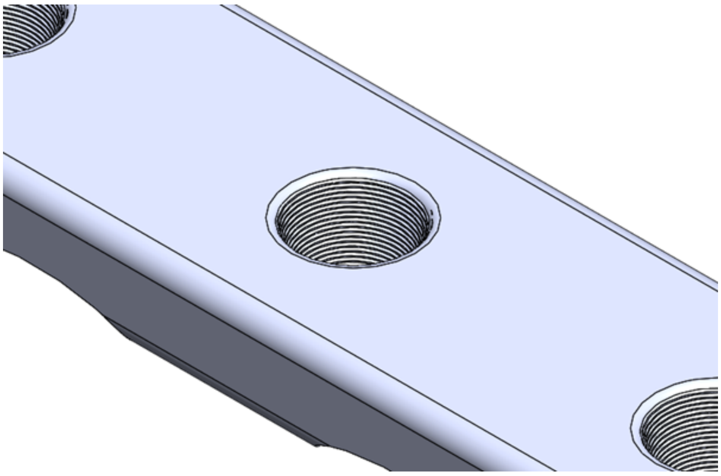


Figure 3.3: A closeup of the locking plate, showing the threaded hole. This threaded hole allows for locking screws to be used in combination with this plate, as well as locking guides.

3.1.2. Drill connection

As discussed in section 2.1, the connection to the drill is made using a bayonet coupling. In this particular research the Stryker 8 was used as a reference. Different manufacturers have different but similar techniques to exchange the accessories to be used in combination with the drill.

A central, square, shaft is agitated by the drill and the outside world is shielded from the spinning center. Drill chucks already exist that use this particular design principle. The drill connection and reference can be seen in figures 3.4 and 3.5, respectively.

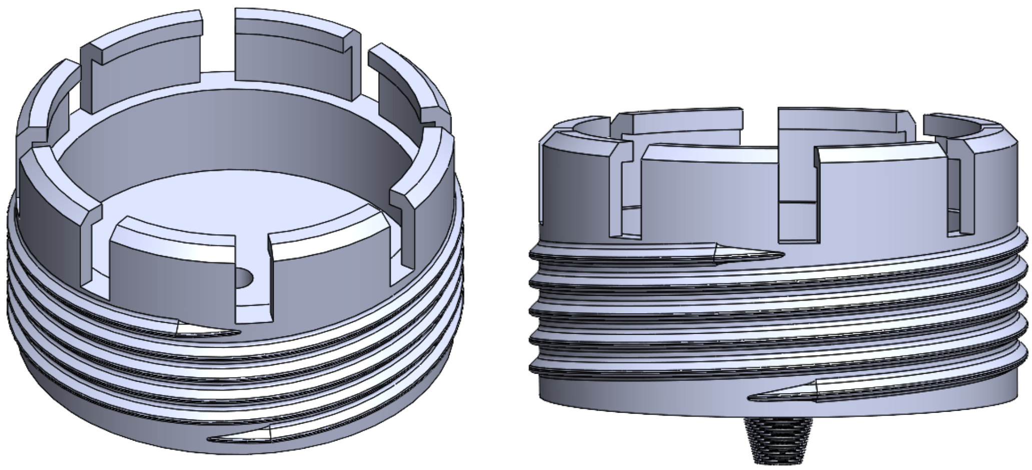
Figure 3.4: Connection to the drill

Figure 3.5: Reference: Stryker keyless drill chuck (source: `aamedicalstore.com`)

3.1.3. Locking Guide mechanism

The plate discussed in section 3.1.1 allows for a locking guide to be twisted onto the hole. A new design of such a guide, to be used in combination with the module, is pictured in figure 3.6. The basis of the design is that of a swivel connector. This type of connection is used in various applications, for instance as a quick fastener in plumbing.

A swivel connector consists of a tubular shape onto which a cap can be twisted. By twisting the cap on, the connection is tightened. The radius of one of the parts declines, causing the assembly to be 'squeezed' together.

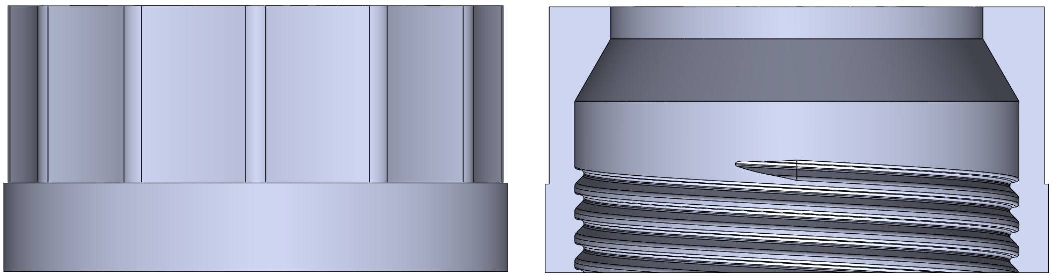


(a) **(b)**

Figure 3.6: The locking guide to be used in the Compact Drilling System. a: isometric view, b: rotated to show the tip. This tip can be twisted onto a threaded hole in a locking plate, such as the one pictured in figure 3.3.

The guide is designed to match the dimensions of the module. The module can be slid into the guide. A cap (figure 3.7) is twisted onto the guide. This bends the fins of the guide inwards, clamping the module into place.

In order to allow the cap to be twisted onto the guide, threading is used. An outside thread is present on the locking guide, and the inside of the cap is threaded. This is best visible in figure 3.8.



(a) (b)

Figure 3.8: A side view (a) of the swivel cap, and a section view of the mid-plane (b) of the cap. The threads that are visible in subfigure 3.8b match the threading on the outside of the guide (figure 3.6).

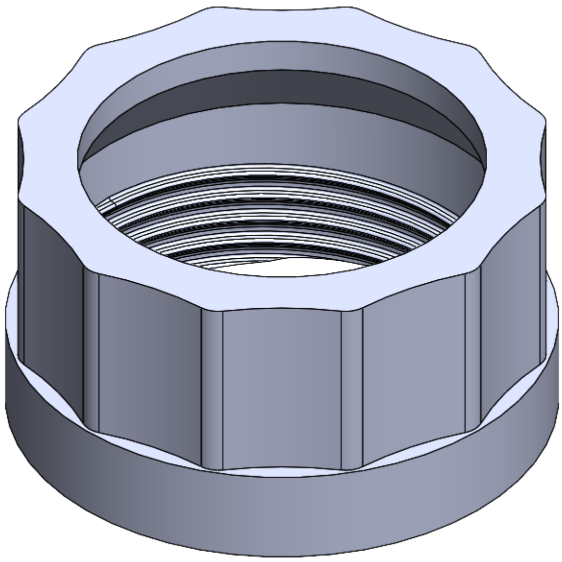
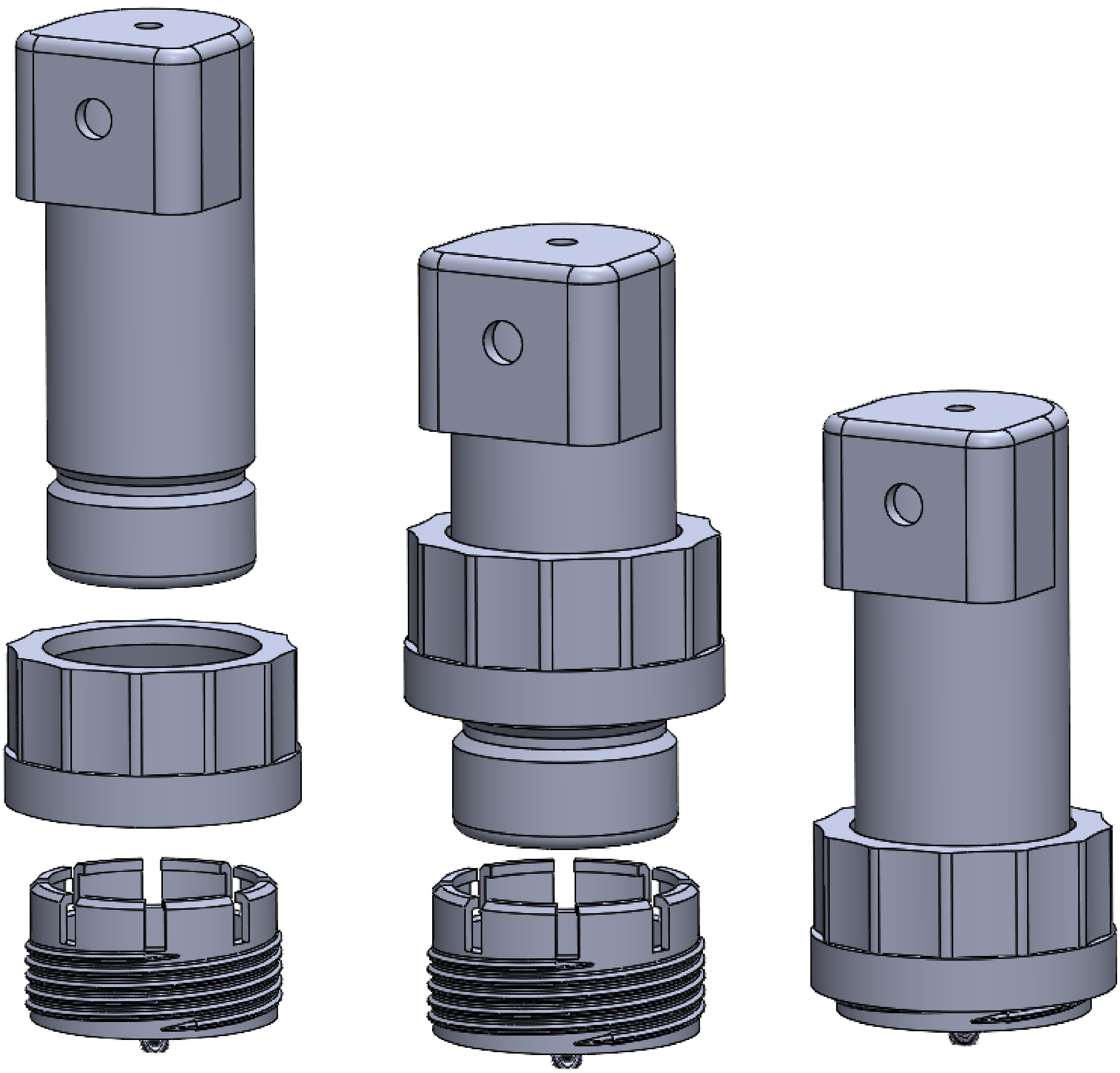


Figure 3.7: Isometric view of the swivel cap. It can be twisted onto the locking guide (figure 3.6) to lock the module into place. A side view and section view are shown in figure 3.8.

The dimensions of the module have been taken from the previous work of Van der Laan [1]. A ridge is added to the outside shell. This matches the hooks of the locking guide visible in figure 3.6. When the hooks bend inwards, they serve as an extra lock to the module. That way, the module is not only held into place by the friction caused by squeezing the sides but also hooked by the ledge. Due to manufacturing constraints on the 3D-printed demonstrator, a chamfer was added to the ridge to avoid a straight angle. Ideally this would be a straight angle to allow for a proper lock into place.

The combination of module, locking guide and swivel cap is shown in figure 3.9. In figure 3.9a an exploded view shows the three parts on top of each other. Figure 3.9c shows the locked position, where the swivel cap is twisted onto the guide.

It is possible to place the swivel cap on the guide without twisting it further, or at most twisting it a little, and slide the module into place afterwards. Twisting the cap further now locks the module into place. As can be seen in figure 3.9b, the swivel cap can also be slid on the module before connecting to the locking guide. This means less vertical space is required, since the module does not need to be higher than the combined height of the locking guide and swivel cap.



(a) (b) (c)

Figure 3.9: The module and locking guide mechanism. (a): exploded view of the three components; (b): The swivel cap is slid on the module; (c): The swivel cap is twisted on the locking guide. The module is fixated in place.

3.1.4. Complete Model

A 3D model of the full Compact Drilling System is shown in figure 3.10.

This is a combination of the models presented in the previous sections. A representation of a flexible coupling connects the module and the drill attachment.

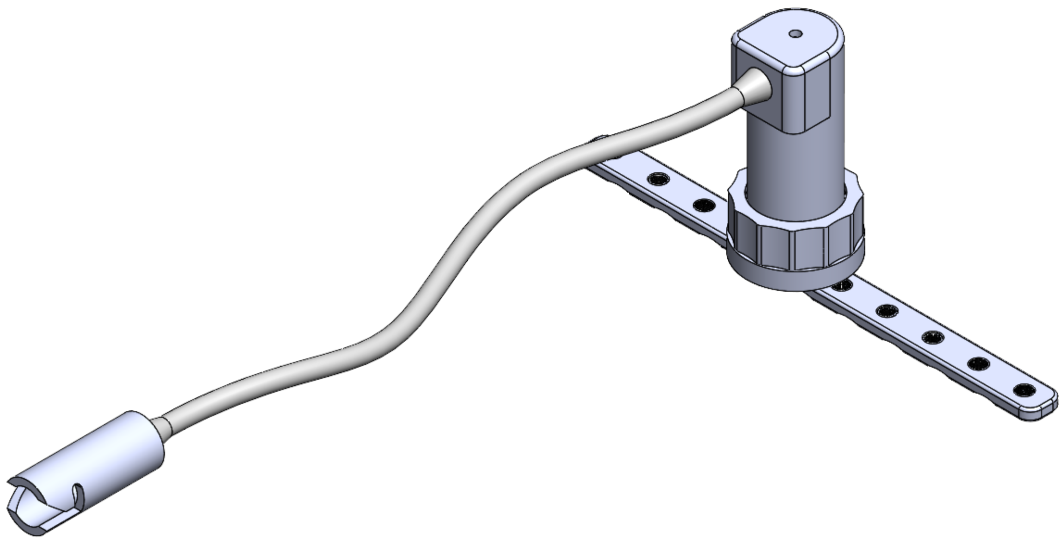


Figure 3.10: A CAD 3D model of the Compact Drilling System as proposed. On the left, the attachment to the drill. A flexible coupling transfers the drilling power to the module. The module is attached to the plate by means of a locking guide, as shown in section 3.1.3.

In figure 3.11 the same model is shown, only now the swivel cap is not yet tightened. It has been slid upwards to show the locking guide below better. If the swivel cap is slid down and twisted, the module is locked to the guide as discussed in section 3.1.3.

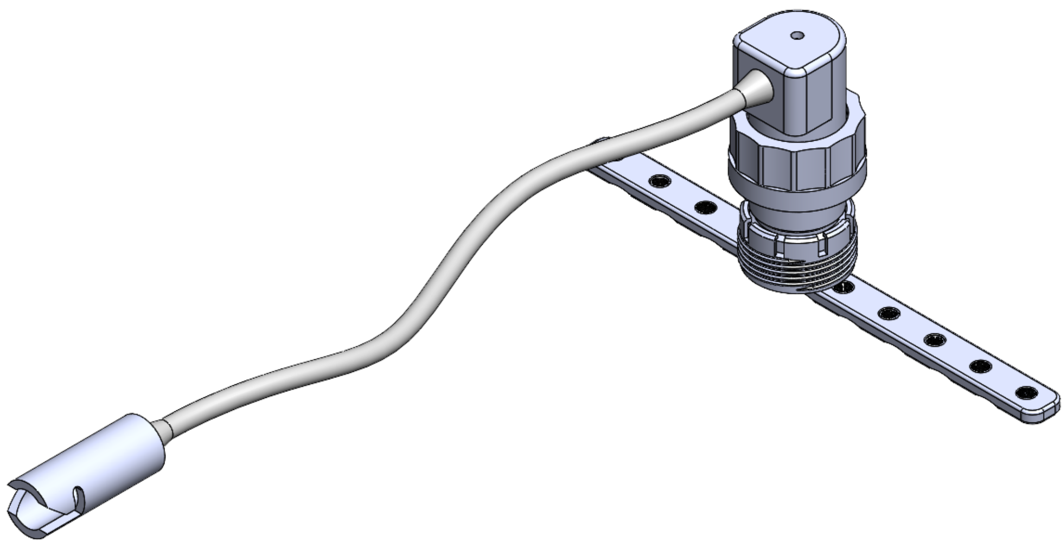


Figure 3.11: The same model as figure 3.10, but with the swivel cap not tightened, and slid upwards. This to show the locking guide that was otherwise obstructed from view. Sliding the swivel cap down and twisting it would lock the module to the guide, resulting in the situation of figure 3.10

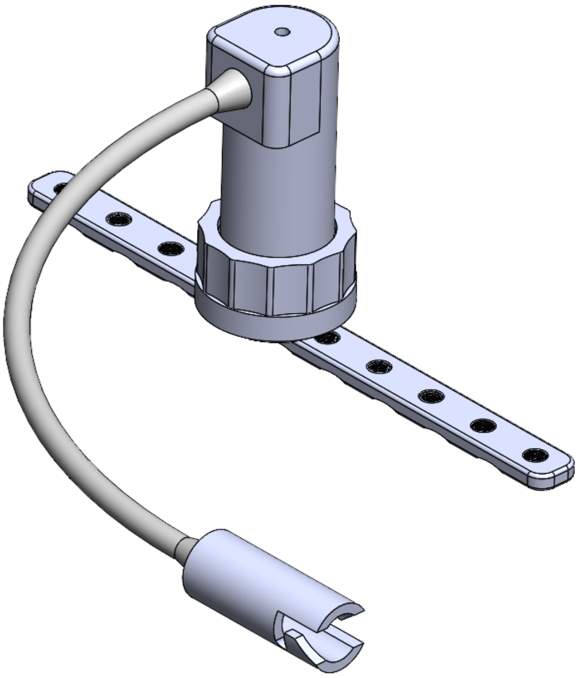


Figure 3.12: A CAD 3D model of the Compact Drilling System as proposed.

Figures 3.10 and 3.11 show the flexible coupling in a rather trivial way, as such a linear orientation would not warrant the need for a flexible connection. The advantage of such a flexible connection is shown in figure 3.12, were the bend is forward. If the space on the left is not available, the bending coupling allows for the module to be powered from another direction.

A section view of plate, locking mechanism and module is shown in figure 3.13. Please note that the internal mechanics of the module are not shown here.

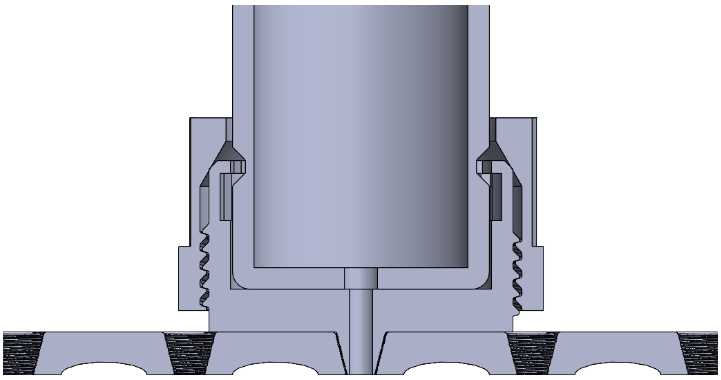


Figure 3.13: A section view of the tightened locking guide on the plate. Note that the internal mechanism of the module is not shown here.

3.1.5. 3D-print of locking mechanism

A 3D printer was used to manufacture mock ups of the locking mechanism. The parts that were made are the module (just the shell, not the interior mechanism), the locking guide and the swivel cap. The goal of this print is to provide a hands-on example of what such a mechanism would work like, and get a sense of the scale.

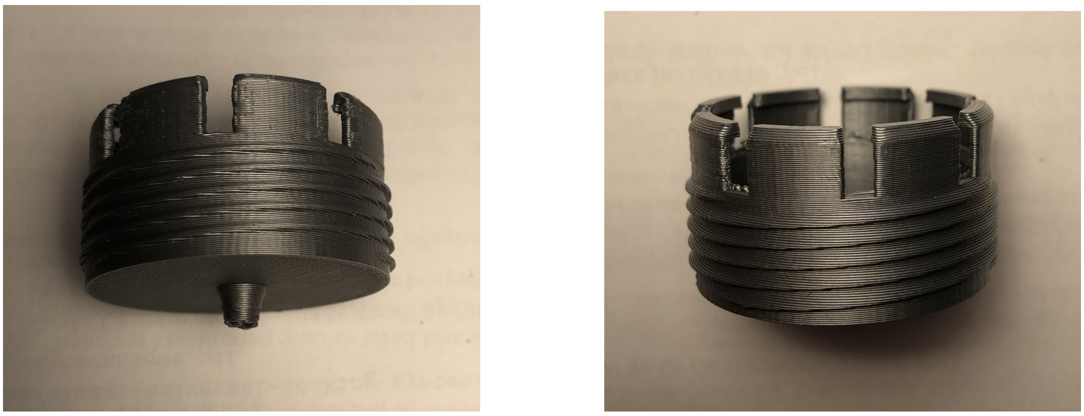
These parts were printed in-house using a Prusa MK3S+ 3D printer. The printing material was Polylactic Acid (PLA), and the resolution was set as indicated in table 3.1.

Dimension	Resolution
XY-plane	0.01 mm
Z-axis	0.2 mm

Table 3.1: 3D printing resolutions used

The manufactured parts were used for a hands-on demonstration of what the locking mechanism would look like in reality. It also provided a feel for the size of the parts involved. Pictures of these prints are shown in figures 3.14 and 3.15.

The material properties of the PLA and the limitations of this particular rapid prototyping technique proved not to be advisable for this application. The material is quite brittle and does not allow for flexible deformation of the components. The locking mechanism relies on some flexibility to allow for the 'fins' of the guide to bend inwards and clamp around the module. In practice the fins barely bent inwards and were easily broken off. This was further caused by separation between the layers of the 3D print. Due to the fabrication technique, in which subsequent layers of material are disposed on top of each other, the tensile strength in that direction is limited. Delamination occurs easily, but this is also influenced by the printing parameters. A finer printing resolution may prove beneficial for this cause.



(a) (b)

Figure 3.14: Pictures of 3D-printed parts of the locking guide

(a) (b) (c)

Figure 3.15: 3D-printed demonstrator of the module and locking guide mechanism. a: exploded view of the three components; b: The swivel cap is slid on the module; c: The swivel cap is twisted on the locking guide. The module is fixated in place. Fabricated in PLA using a Prusa MK3S+ 3D printer.

3.2. Finite Element Analysis

introduction to FEM

The Finite Element Method (FEM) is a method to find an approximate solution to complex modelling problems.

The method is based on solving differential equations for a very large (but finite) number of elements, that the original problem is subdivided in. In the case of mechanical strength analysis, such as in this research, the model is subdivided in many small parts.

This division in small parts is called the meshing. The mesh of the model is a discrete approximation of the original shape. To illustrate this principle, we consider a beam as example. The dimensions of this beam are as shown in figure 3.16. The beam is fixed on the left, and a force of 100N is applied to the top surface on the right, as seen in figure 3.17.

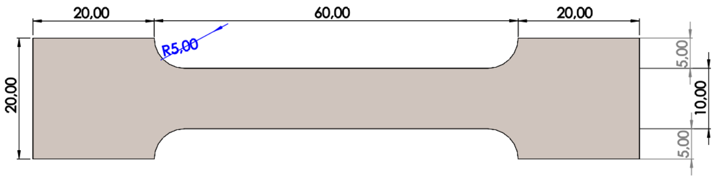


Figure 3.16: The dimensions of the beam used in the example to introduce the Finite Element Method. The out of plane width is 20mm.

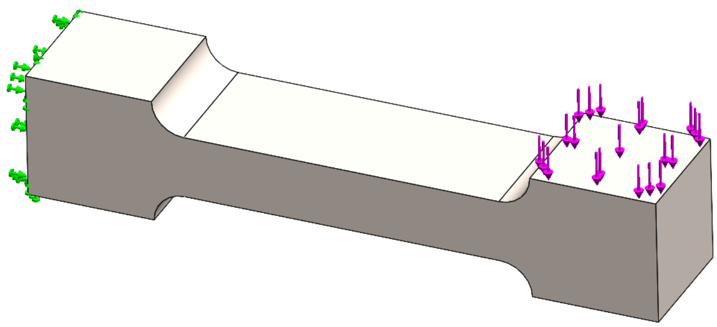


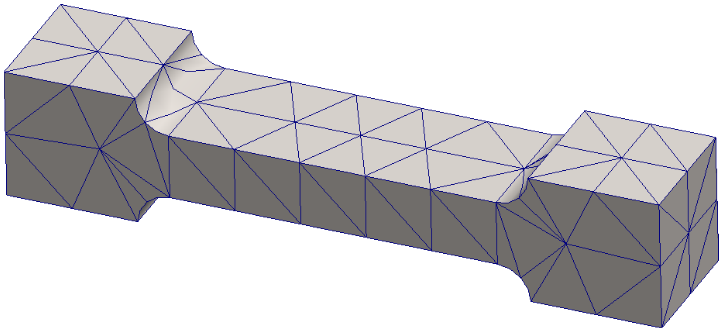
Figure 3.17: The boundary condition applied to the example beam. On the left, indicated in green, is the surface that is considered fixed. The purple arrows on the right indicate the location and direction of the applied force.

An important factor when meshing a model is the dimension of said mesh. A crude mesh consisting of few, large elements is easy to solve. The number of degrees of freedom (DOF) is limited. The drawback is that the results are not quite accurate.

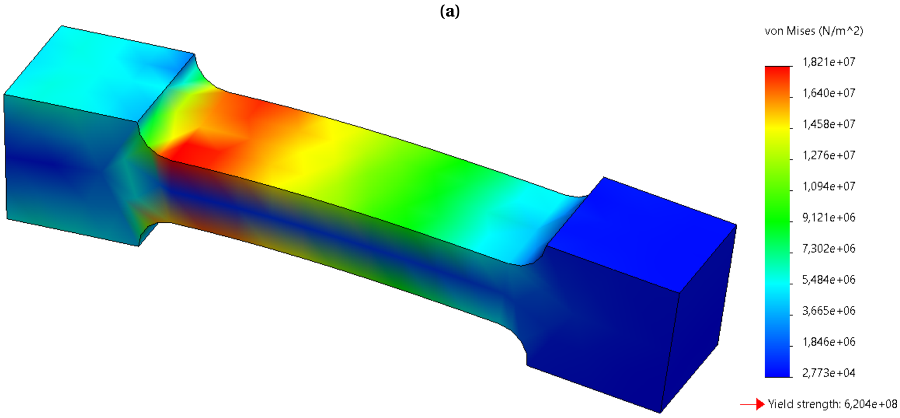
By decreasing the mesh size, and by doing so increasing the number of DOF, the accuracy increases. This comes at the cost of an increased computational complexity. In other words, there is a trade-off between the accuracy and solving time of the FEM analyses (Finite Element Analysis of FEA for short).

An example of a large mesh is shown in figure 3.18. In 3.18a a coarse mesh is shown, with a maximum dimension of 10mm. As a result, the narrow part in the middle is only covered by 1 element in height, and 2 in the width. The resulting von Mises stress as shown in figure 3.18b is not distributed as smoothly as one would expect.

The result can be improved by reducing the mesh size. As a comparison, figure 3.19 the the results of the same analysis when a maximum mesh size of 1mm is used. This is significantly more complex to solve, resulting in a longer computation time. The increased number of elements is clearly visible in figure 3.19a, or rather the entire surface appears shaded due to the tight mesh. The stress distribution (figure 3.19b) is more accurate.

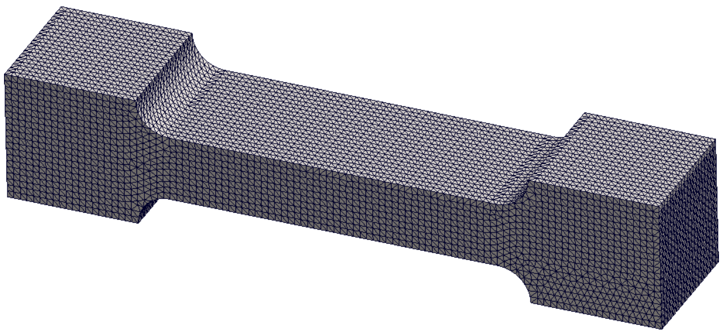


(a)

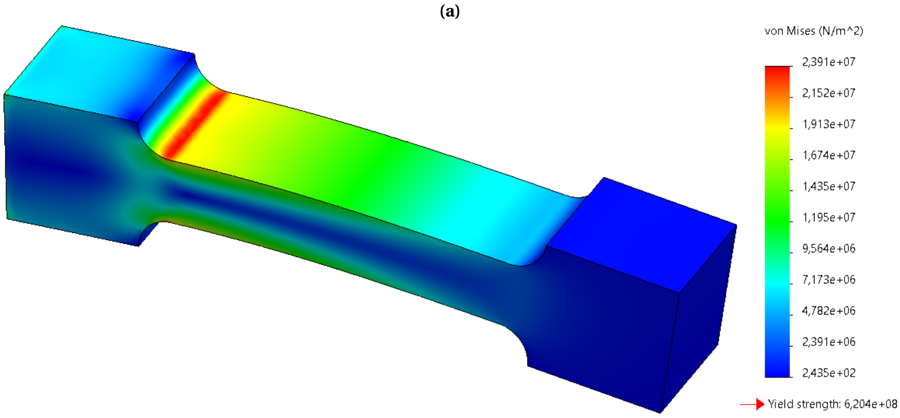


(b)

Figure 3.18: Finite Element Analyis of the example beam from figure 3.16. In subfigure 3.18a the mesh is shown, with an element size of 10mm. The resulting von Mises stress is plotted in subfigure 3.18b.



(a)



(b)

Figure 3.19: Finite Element Analyis of the example beam from figure 3.16. In subfigure 3.19a the mesh is shown, with an element size of 1mm. The resulting von Mises stress is plotted in subfigure 3.19b.

As stated before, there is a trade-off between the mesh size and the resulting accuracy. To illustrate this, the previous analysis is performed for a larger number of mesh sizes. The goal is to check that the calculations converge to the correct solution, without using a mesh that is needlessly small.

In table 3.2 the results of such a mesh analysis are shown. The mesh size is varied from 20mm (coarse) to 0.625mm (fine).

Mesh size (mm)	20	15	10	7.5	5	2.5	1.25	1	0.625
Nodes	269	422	519	1,075	3,282	19,633	123,853	259,355	835,036
DOF	780	1,203	1,482	3,102	9,603	58,032	368,292	773,022	2,492,433
Max Stress (MPa)	18.13	17.72	18.21	18.89	20.87	22.93	23.86	23.91	24.2

Table 3.2: number of nodes, number of Degrees of Freedom and maximum stress when using various mesh sizes.

The number of nodes and degrees of freedom (DOF) that are present for each mesh size are shown, as well as the maximum von Mises stress that occurs in the model. For the coarse meshes, the maximum stress is significantly lower than the value of around 24 MPa we see for the finer meshes. When we compare the stress in the 2.5mm mesh (22.93MPa) and 0.625mm mesh (24.2 MPa), we see a difference of 5.5%. The number DOFs at the same time has skyrocketed: from a little under 60 thousand to nearly 2.5 million. This is a significant increase in computation time.

These results are also plotted in figure 3.20. The maximum stress is shown against the number of degrees of freedom in the simulation.

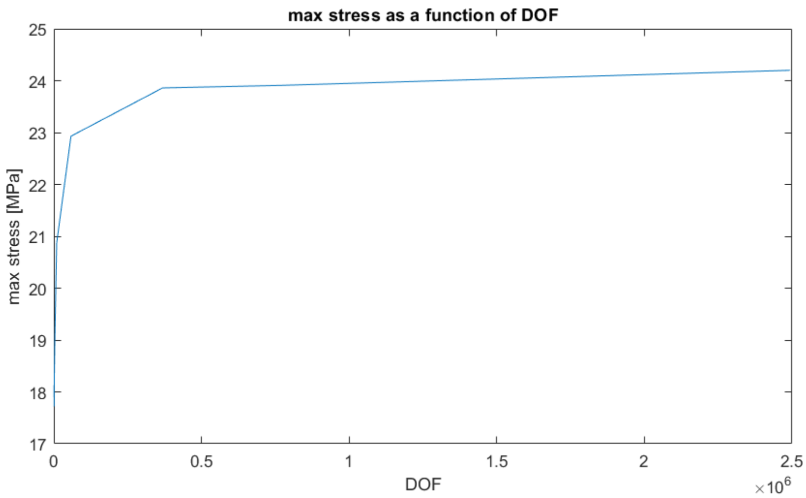


Figure 3.20: the maximum von Mises stress as a function of the number of degress of freedom in the simulation.

Controlling the mesh

There is not really any reason to have a very fine mesh around the regions where the stress gradient is small. All these extra elements add to the complexity of the simulation without improving the outcome much. For that reason it is beneficial to adapt the mesh density to the geometry of the model. As seen in the previous figures, the maximum stress occurs at the fillet on the left. In this region we would like a high accuracy (fine mesh), and in other reason we can settle for a more coarse mesh.

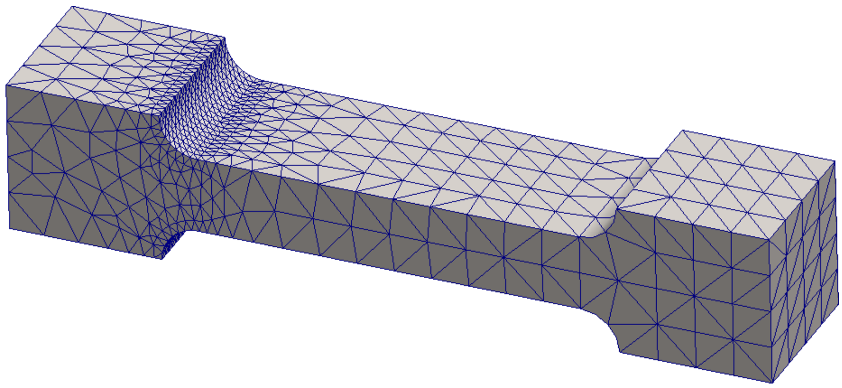


Figure 3.21: Varying mesh densities: On the fillet the mesh size is 1mm, the rest of the model is meshed at 5mm.

Mesh size (mm)	5
Mesh size fillet (mm)	1
Nodes	14,904
DOF	44,469
Max Stress (MPa)	24.13

Table 3.3

In figure 3.21 such a varying mesh is shown. The left fillet has a mesh size of 1mm, the rest of the model 5 mm. The results are shown in table 3.3. The total number of degrees of freedom is now 44.469. For comparison, when the entire model was meshed with a 1mm mesh size the number of DOFs was 773,022 (see table 3.2).

Over 16 times as many degrees of freedom need to be calculated when using a fine mesh throughout the model, with a result that is close to the result of the varying mesh. This shows the value of selecting a mesh that is suitable for the application: fine where it is needed, coarse where it not required.

Compression of the Guide flaps

As seen in section 3.1.5, the flaps on the guide are a critical point of the design. The flaps need to bend inwards to lock the module in place, and this bending causes stress in the material.

A FEM analysis is performed on a CAD model of this part. The displacement of the flaps is dictated to be specified towards the center, as indicated by the arrows in figure 3.22. This surface is free to move in other directions, such as up or down.

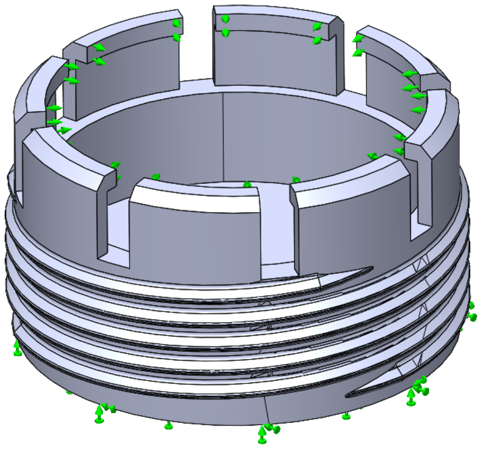


Figure 3.22: The displacement, indicated with green arrows, that is applied in the finite element analysis of the inwards compression of the flaps. The bottom of the model is fixed.

When a displacement of 1.5mm is applied, the resulting stress is as shown in figure 3.23. The stress clearly exceeds the yield strength of the material. In this case PMMA was used as a reference material, which has a yield strength is of 70 MPa[27].

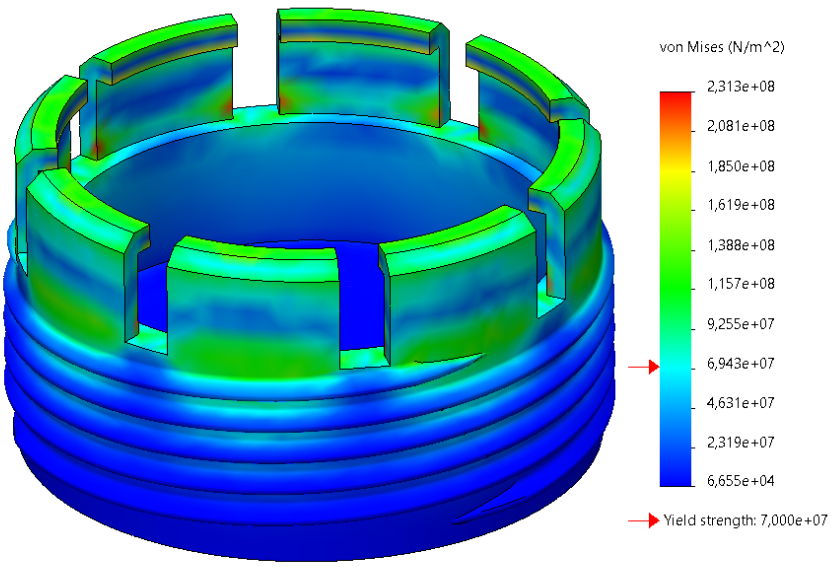


Figure 3.23: Von Mises stress distribution as a result of the displacement applied as shown in figure 3.22.

Adaptations in the design are required to make sure the stress concentrations do not exceed the yield strength. Both the dimensions of the flaps and the amount of bending influence the peak stresses that occur. A longer flap would have more distance to distribute the stress, and a smaller displacement at the tip would likewise decrease the stress.

The FEM analysis is performed for multiple values of the inwards displacement *d*, to find a balance between this displacement and the resulting stress. A smaller displacement would require a more tight fit of all the components. This displacement parameter *d* is being varied from 0.1mm to 1.5mm in steps of 0.1mm, and for all these configurations the peak stress in the model is calculated. The resulting maximum stresses are shown in table 3.4. With an increasing value of d, the stress increases linearly. This is more clearly visible when the values are plotted in a graph such as figure 3.25. In that graph a horizontal line is also added, which represents the yield strength of 70 MPa.

d (mm)	Max. Stress (MPa)
0.1	15.32
0.2	30.64
0.3	45.97
0.4	61.29
0.5	76.61
0.6	91.93
0.7	107.25
0.8	122.57
0.9	137.90
1	153.22
1.1	168.54
1.2	183.86
1.3	199.18
1.4	214.50
1.5	229.83

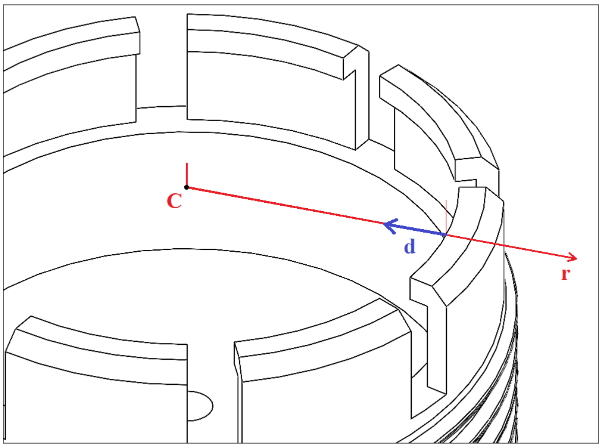


Table 3.4: Maximum von mises stress in the model, as a result of the given flap displacement d. On the right a figure showing the direction of d

The linear relation between d and maximum stress σ_{max} can be explained by simplifying each flap to a cantilever beam (figure 3.24). For such a beam the deflection is known to be as follows [28]:

$$\delta = \frac{FL^2}{3EI} \tag{3.1}$$

Here force F, length L and deflection δ are as shown in figure 3.24, and E (elastic modulus) and I (area moment of inertia) are constant mechanical properties of the beam shape and material. There is a linear relation between displacement δ and force F, when the other factors are kept constant.

The bending stress, which is the main contributor to the maximum stress found in the FEM analysis, in turn is defined by the following equation:

$$\sigma_{bend,max} = \frac{Mc}{I} \tag{3.2}$$

c is the largest distance from the fiber, and bending moment M is linearly related to the aforementioned applied force F. In short, there is a linear relation between the deflection and the bending stress.

The flaps are not exactly the same as such the simple beam: there is a curve which affects the stiffness, and the displacement is radial instead of purely linear. By approximation however the results follow the same linear relation between displacement and peak stress.

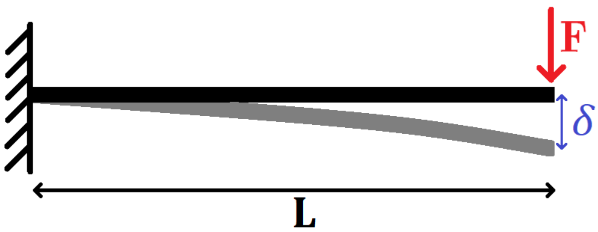


Figure 3.24: Simple cantilever beam with applied force. Also indicated are the displacement δ and length L

With this small flap length the maximum stress easily exceeds the yield strength, visualised as a horizontal red line in figure 3.25. For the adapted design that will be discussed further in section 3.3, this length will be increased. A reduced displacement of 0.5mm will be used. That is a displacement that results in a stress close to the yield strength in the current design, and when combined with longer flaps is expected to result in an allowable stress level.

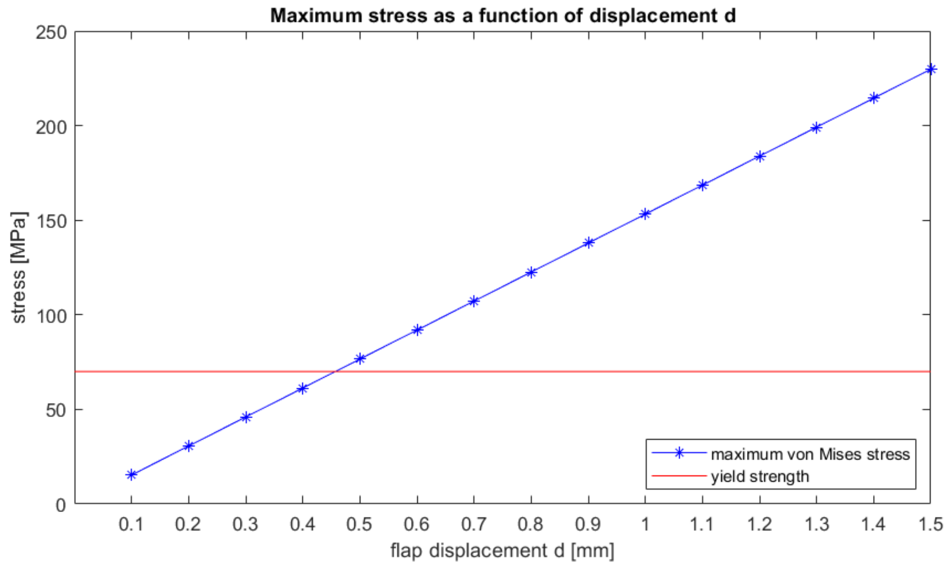


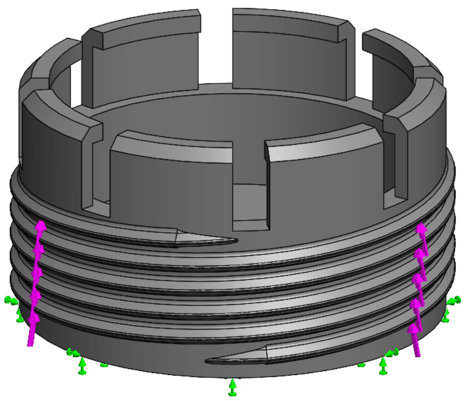
Figure 3.25: Maximum von Mises stress in the model as a function of displacement *d*, as taken from table 3.4.

Swivel cap and Guide

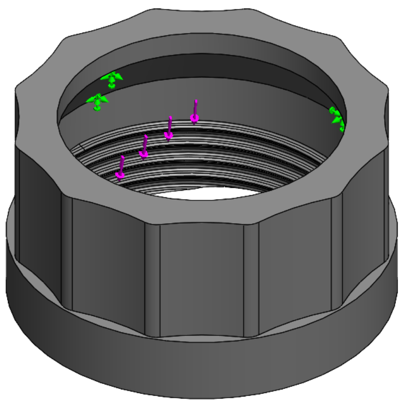
Another FEM analysis is performed to verify that the threaded connection of the guide and swivel cap can withstand the applied forces. A multi-body analysis is more complex, because the interaction between the different parts need to be specified.

As a first verification, a separate analysis of the two parts is performed, where a distributed force is applied along the top or bottom face of the threading. This is visible in figure 3.26. For this analysis 40N of force is applied, which is twice the required drilling thrust force.

By manually placing a force on the expected contact faces, and performing separate finite element analyses, a reference is found for a multi-body analysis. The results of a such a complex calculation are expected to be similar to that of the separate problems. If the results match, this is an indication that the interaction between the models is set up correctly.



(a)



(b)

Figure 3.26: Applied forces to the two separate parts (a the guide, b the cap). Purple arrows indicate the applied force, green arrows indicate the fixed geometry.

After meshing the models and doing the finite element analysis, the stress distribution looks as shown in figure 3.27.

The von Mises stress distribution shows that at no point in the model the stress exceeds the yield strength of 70 MPa for PMMA. An exaggerated visualization of the deformation of the model can be seen in subfigures

3.27b and 3.27d. The deformation is scaled with a factor large factor (around 2000 and 1000, respectively), to show the deformation more clearly. In reality the deformation is minimal. This exaggeration also helps as an extra verification step to notice if results are not as expected: If for instance a force is applied in the opposite direction or a fixed geometry is not placed correctly, the deformation does not match the expected, 'intuitive' shape; A first sign that something is not set up right.

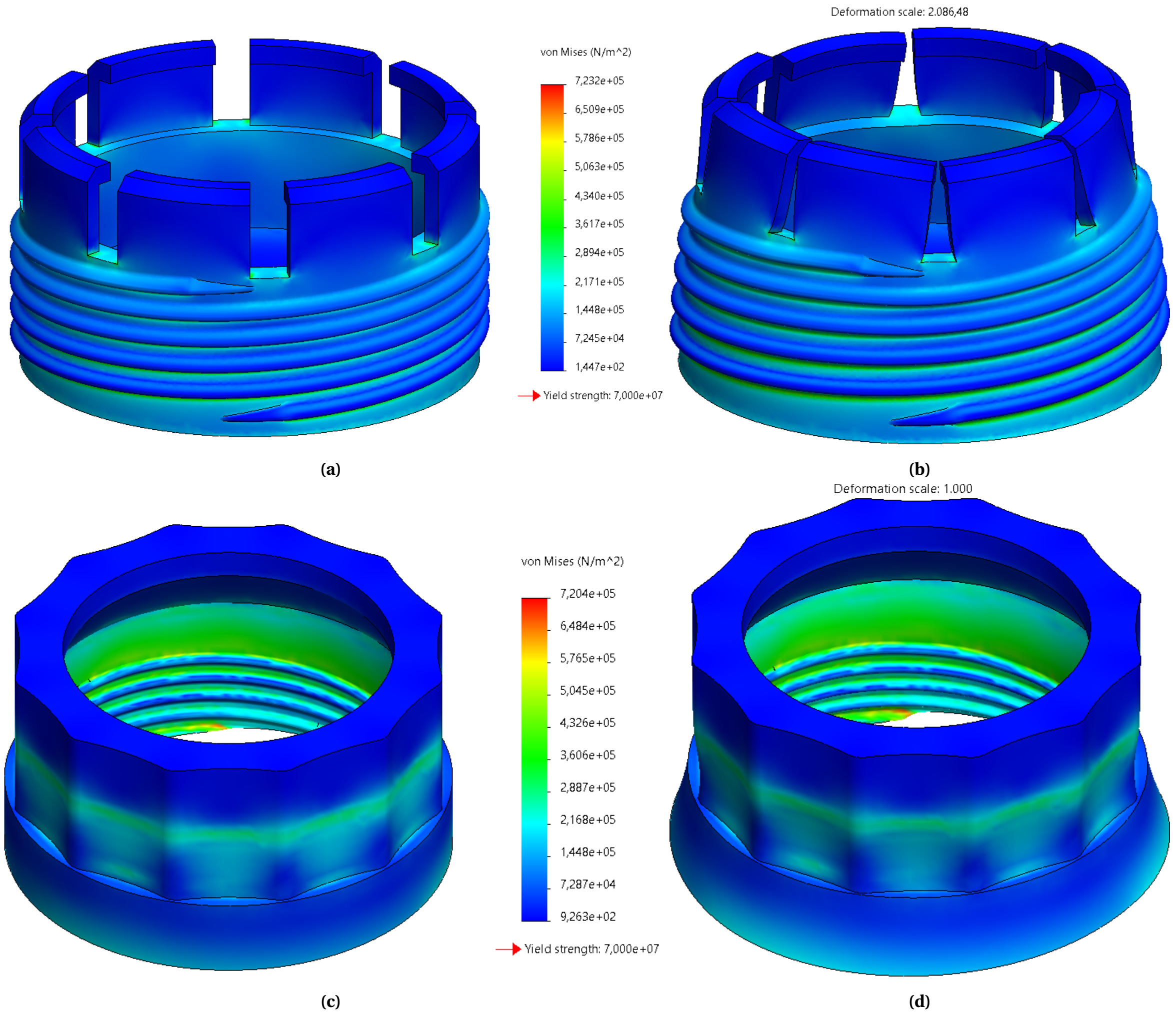


Figure 3.27: Resulting von Mises stress obtained using FEA. (a): locking guide, (b): guide deformed, (c): Cap, (d): cap deformed. Forces applied as shown in figure 3.26.

Guide and cap combined

To show the interaction between the two components as previously discussed, an assembly is analysed. This is a more complex and computationally demanding task due to the contacts and interactions between separate parts. In and of itself the FEM software does not know where certain parts interact. Direct contact is relatively straightforward to simulate, because the software can assume that the parts are supposed to be stuck together. This is called a bonded contact, where the meshes of the two parts are continuous.

The components are not in direct contact practically, as the design allows for a small clearance between the parts. If this clearance was not present, the parts would not realistically fit together in a real world application. It would require an impossibly perfect manufacturing process. As a result of this clearance the software (in this case Solidworks Simulation) does not know that these parts need to interact on certain interfaces. An applied force or translation on one part does not transfer to the other. The software fails to find a correct solution.

It is possible to define an automatically calculated contact set based on the clearance of the parts. The parts are initially oriented such that the faces almost touch as they would in practice. A contact set of non-touching faces can now be defined by calculating all the faces that are within a user-defined minimum and maximum clearance of each other. This is a computationally intensive operation, which would add significant time and effort to each simulation that needs to be performed.

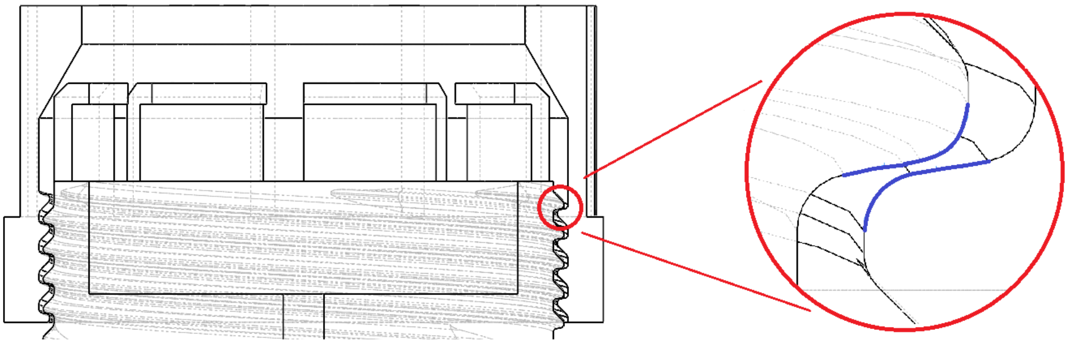


Figure 3.28: Manually selected contact sets. In blue the contacting faces are indicated.

For that reason a manually defined contact set was used in this research. The faces that are going to make contact are individually selected once, resulting in a contact calculation that requires mere seconds. In this case the bottom faces of the threading on the guide and the top faces of the swivel cap were all selected, as seen in figure 3.28.

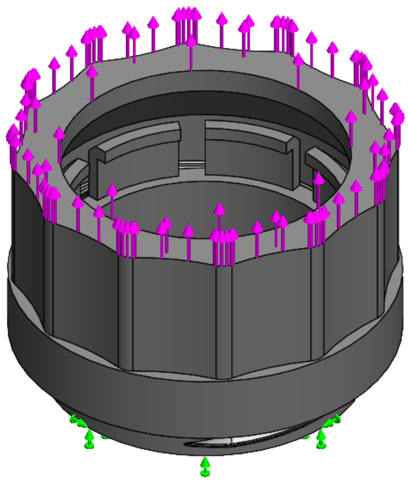
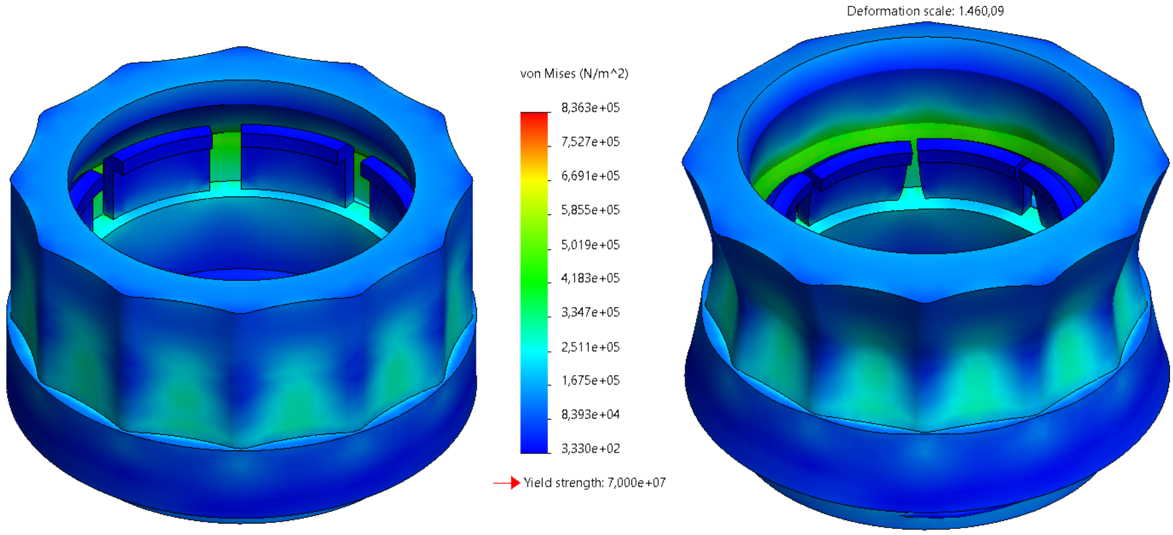


Figure 3.29: Applied force (purple) and fixed geometry (green) of the assembly

A pulling force is applied to the top face of the swivel cap, while it is placed on the locking guide (figure 3.29. The guide is locked in place at the bottom, indicated in green. Contact sets have been specified manually, as stated before. The goal is to see the force being transferred through the contact in the threads to the guide. If done correctly, a deformation and stress distribution similar to that of the previous separate analyses is expected. A highly different result would indicate that the contact does not work as intended. The von Mises stress and deformation are plotted in figure 3.30.

For clarity a sectioned view is also included, see figure 3.31 . The highest stress can be found in the contact between the threads, and in the more narrow parts of the swivel cap. In neither of these parts does the von Mises stress exceed the yield strength.



(a) (b)

Figure 3.30: Von Mises stress in the assembly (a) and exceggarated deformation (b

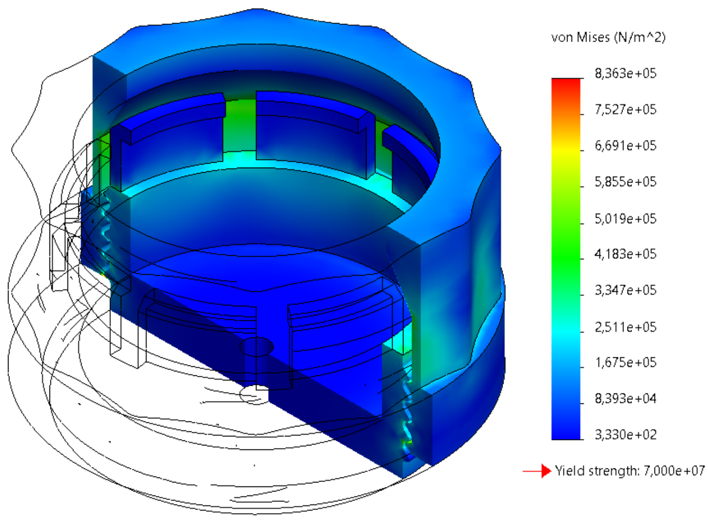


Figure 3.31: section view of the stress plot from figure 3.30

The two parts obstruct the vision of each other, so in the following few plots only one of the two is shown. It is however the same finite element analysis that consists of both parts. When these results are compared to those of the analyses of the separate parts (figure 3.27), they match up.

The resulting stresses are not exactly equal but the distribution is similar. The order of magnitude also matches. This shows that the FEM analysis of these two parts is functioning correctly, and the contact points are indeed where forces are transmitted.

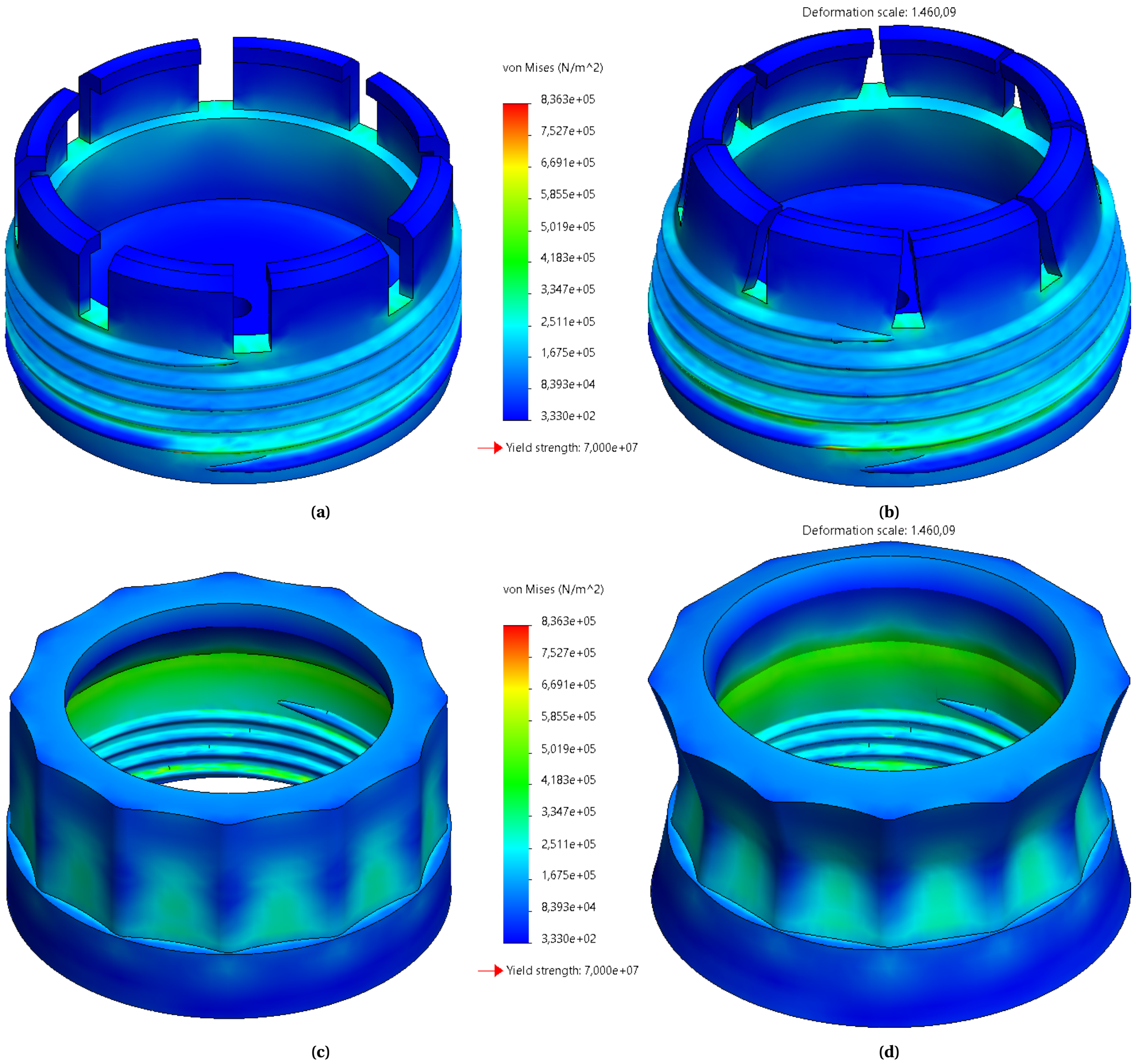


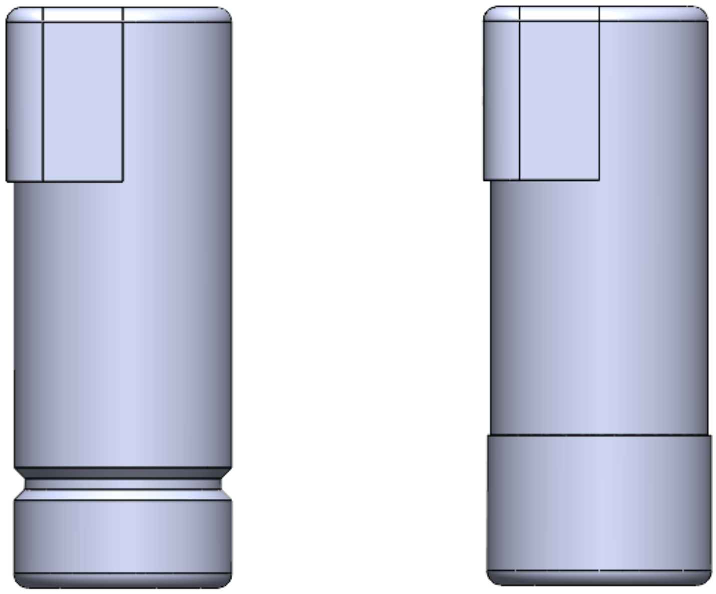
Figure 3.32: Resulting von Mises stress obtained using FEA, with the two components isolated. The analysis is performed on the interaction of both components, but for visibility only one is shown at a time. (a): locking guide, (b): guide deformed, (c): Cap, (d): cap deformed. Forces applied as shown in figure 3.29.

It can be concluded that this version of the design is strong enough to withstand the forces that are expected to be applied to it. The strength of the flaps however is insufficient, as stated in the beginning of this section. For that reason an adapted design was made, which is discussed in section 3.3.

3.3. Adapted Locking Guide Mechanism

This version of the locking mechanism uses a widened base instead of a ridge cut out of the casing (figure 3.33). This ensures the structural integrity of the case design by Van der Laan [1] is not impaired.

A reduced squeeze distance *d* of 0.5mm is used, based on the results of the initial FEM analysis. The result is a slightly widened guide and cap, compared to the previous iteration.



(a) **(b)**

Figure 3.33: Previous (a) and adapted (b) case design. The latter has a slightly widened base, instead of the ridge that is cut out from the existing case.

As stated in section 3.2, the length of the flaps have been increased to limit the resulting stresses in the model. The supporting analysis follows. A zoomed in section view is shown in figure 3.34. When compared to figure 3.13 is is visible that various dimensions have changed. A little less obvious is an adaptation in the design of the flaps.

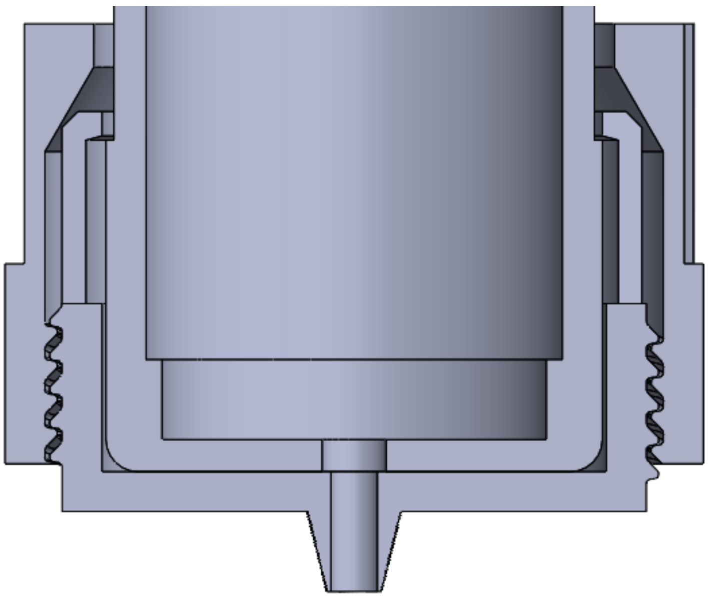


Figure 3.34: Section view of the bottom part of the new assembly

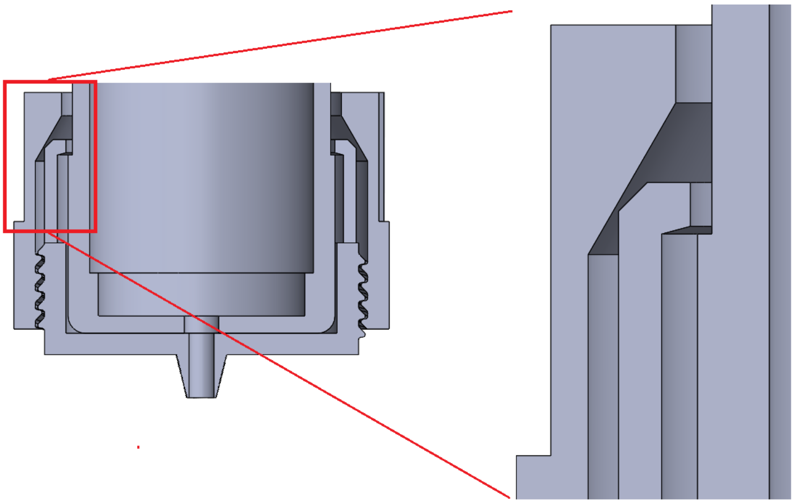


Figure 3.35: Highlighted part of the section view: the flap has been adapted to include an angled face.

The lower face of the flap has been adapted to include an angle. As a result of this, when the case is not fully slid downwards the flap can push it down some more. This helps place the case horizontally on the guide.

Secondly, this angled face helps if the flap does not bend back fully. Due to the high stresses that are present in the material when the cap is tightened, creep can occur [29]. When the tightening force is released (i.e. when the cap is removed), the strain in a viscoelastic material such as a polymer does not jump back to zero as quickly. In other words, the flaps would stay slightly bent and return to their original shape only after some time has passed. The angled face on the flap allows for the module to be removed even if the flap is not bent back fully; pulling the module out helps bend the flaps outward. A horizontal face would not have this benefit.

Optimizing flap height

A parametric sweep design study is performed to find a suitable length for the flaps. The longer the flaps are, the lower the peak stress in the material is. Lower flaps are preferred however, since one of the goals is to minimize the required space. Longer flaps mean the module needs to be lifted higher to slide into the guide.

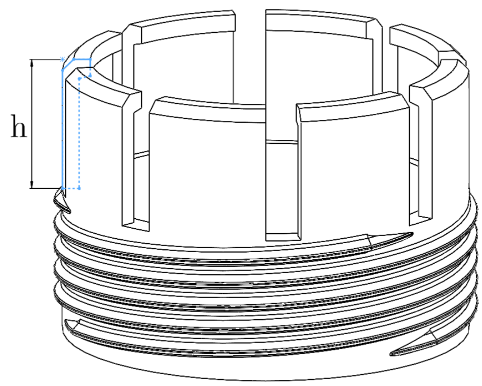


Figure 3.36: definition of flap height h that is used in the design study

A parameter h is defined in the model, so that it can be automatically varied in an optimization study. The displacement distance d is taken to be 0.5mm. For each value of h, the model is meshed, and the flap displacement study from section 3.2 is repeated.

Flap height h (mm)	**Maximum stress (MPa)**
6	110.4
7	88.03
8	81.39
9	74.97
10	61.77
11	56.25
12	50.44
13	45.69
14	40
15	36.34
16	32.73
17	30.19
18	27.09

Table 3.5: Maximum von mises stress in the model, as a result of the given flap height h.

As expected, the higher the flap height is, the lower the maximum stress. A line plot of these result is shown in figure 3.38. Any value of h lower than 10mm results in a stress that exceeds the yield strength of 70 MPa. A value of 12mm is chosen, which gives a stress of around 80% of the yield strength. This is quite high but to reduce the stress further the flaps would need to be higher, negating the compact functionality.

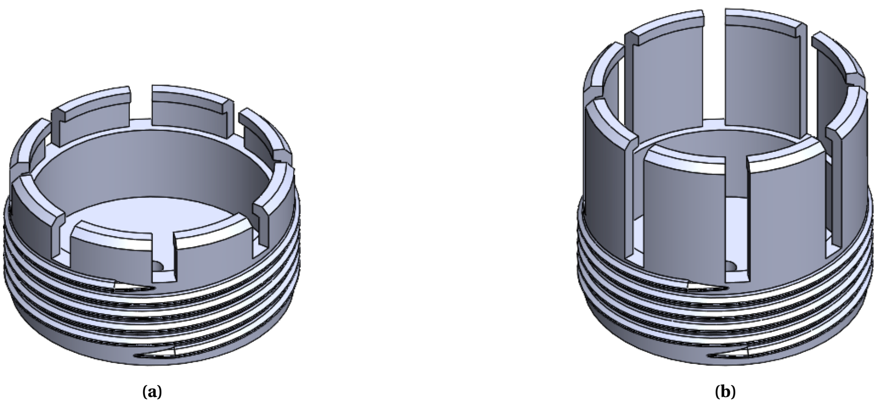


Figure 3.37: Outer limits of the optimization study. (a): h= 6mm, (b): h=12mm

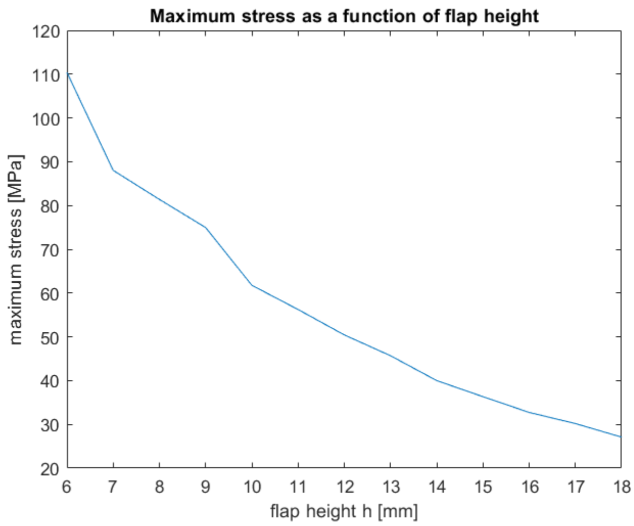


Figure 3.38: The relation between maximum stress and flap height h, also tabulated in table 3.5.

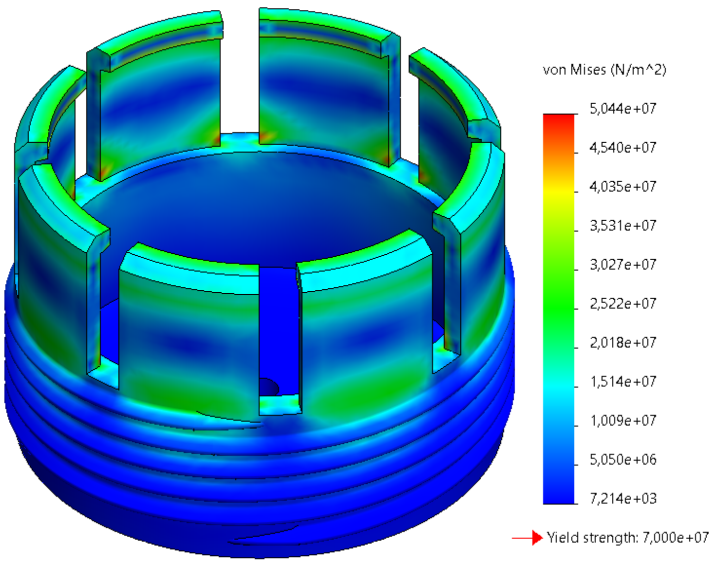


Figure 3.39: Von Mises stress distribution as a result of the displacement applied as shown in figure 3.22. In this case, flap height h is 12mm

Stresses through the assembly
The previous version of the design was able to withstand the forces applied to it, and the adapted design is expected to do the same. To be certain, the FEM analysis is repeated for the adapted design.

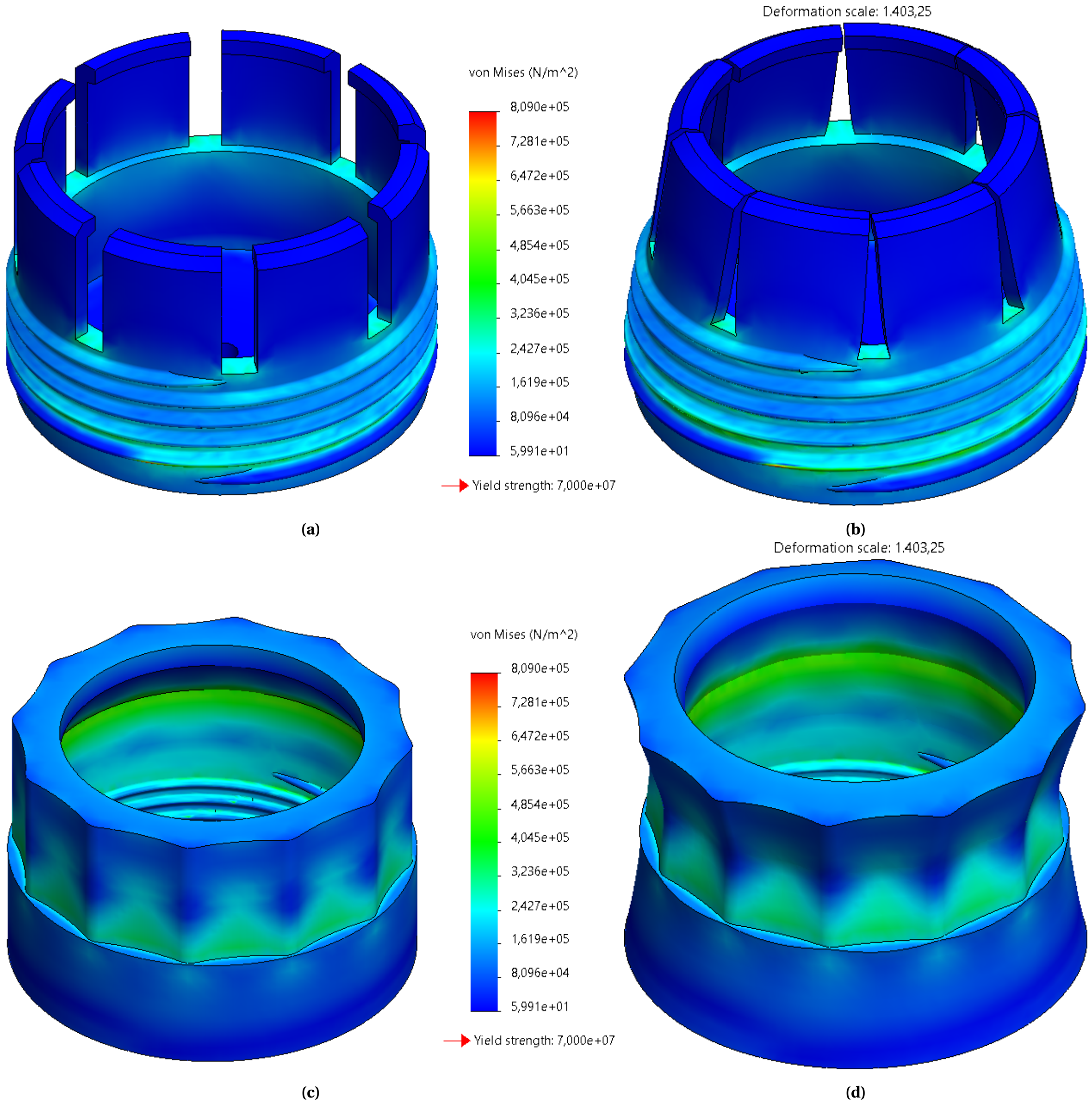


Figure 3.40: Resulting von Mises stress obtained using FEA, with the two components isolated. The analysis is performed on the interaction of both components, but for visibility only one is shown at a time. (a): locking guide, (b): guide deformed, (c): Cap, (d): cap deformed. Forces applied as shown in figure 3.29.

Figure 3.40 shows the four plots of the stresses in the isolated parts, similar to figure 3.32. This is once again the simulation that was performed on the assembly, so both parts interact to transfer the forces as applied (figure 3.29). The two parts are shown individually for clarity. On the right the exaggerated deformation is plotted.

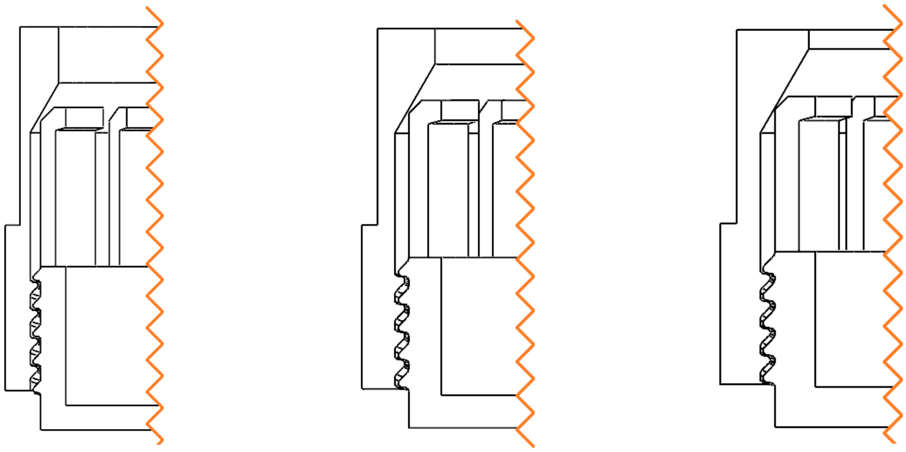
The values remain well below the yield strength, which is to be expected in a design that is only marginally larger. The main difference between the versions is the flap height discussed before.

Size verification

A smaller and larger version of the design were analyse using FEM, to validate a correct order of size.

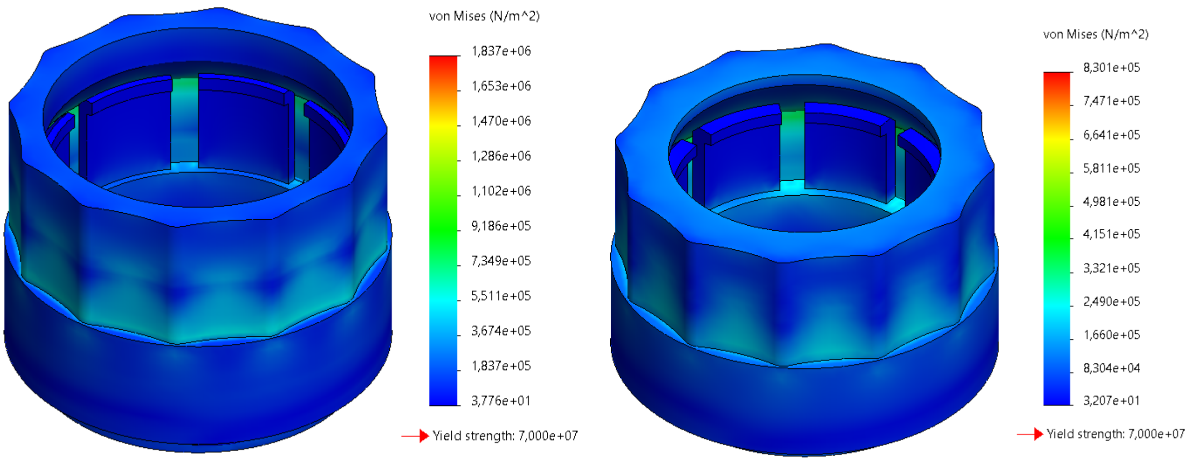
A scaled down version has all wall thicknesses and flap thickness 25% smaller than the original. The larger version has those dimension scaled up 25%.

In figure 3.41 the difference between these sizes is shown, for a small section of a section of the model. The resulting stress plots of the larger and the smaller versions are shown in figure 3.42.



(a) (b) (c)

Figure 3.41: Three variations of wall thicknesses: 3.41a: 25% smaller, 2.24: original, 3.41c: 25% larger



(a) (b)

Figure 3.42: The stress distribution in the model if it was smaller (subfigure 3.42a) and larger (subfigure 3.42b). The thickness of the walls and flaps is 25 % smaller and 25 % larger, respectively.

The new stress plots show that in the case of the smaller design, with thinner features, the stress is slightly higher than the main design (figures 3.40 and 3.42a). It is however still within the boundaries of the yield strength.

The larger design results in slightly lower stresses. This is at the cost of increased material usage and size.

It can be concluded that the design is well within safe boundaries in terms of thickness. While it could be made thinner without reaching yield strength, the added benefit would be minimal. The height of the locking mechanism is more important, in terms of stress development and required space in surgery.

3.4. Surgical procedure for this application

For each type of implementation, and each application a different surgical procedure can be envisioned. In this section an example is given of what a procedure would look like when the design choices are taken as in the previous section. A list of steps, to be read from top to bottom, is shown in figure 3.43. The steps that are taken outside the body are in a separate column from the steps that are taken inside the body. This highlights a difference compared to the current state of the art. Currently, everything has to happen inside the body except preparing the drill.

Outside body	Inside body
Prepare tools: • Connect connector to module • Slide swivel cap on module • (connect drill to connector) *	
	Place plate and clamp
	Twist guide on one of the holes of the plate
	Place module in guide and twist swivel cap to lock
(connect drill to connector) *	
Drill & reverse	
(disconnect drill from connector) *	
	Twist swivel cap to unlock module from guide
	Twist guide off the plate
	Place screw through the plate and drilled hole
	Twist guide on the next hole
	Place module in guide and twist swivel cap to lock
(connect drill to connector) *	
Drill & reverse	
(disconnect drill from connector) *	
	Twist swivel cap to unlock module from guide
	Twist guide off the plate
Repeated steps	Place screw through the plate and drilled hole

Figure 3.43: The process when using the design choices for the Compact Drilling System as separate module. To be read from top to bottom. The actions that take place outside and inside the body are in separate columns. Indicated in the dashed box are the repeated steps when drilling multiple holes. Steps indicated with an (*) are either performed once during preparation, or after every hole.

A dotted box indicates the steps that are repeated when multiple holes need to be drilled. The amount of additional required steps is a clear downside of this particular locking mechanism. Due to the repeated locking and unlocking, and parts that are connected and disconnected, the required time is increased. This was also discussed in section 2.4.2.

Steps that are indicated with an asterisk (*) in figure 3.43 are steps that can take place in one of two places: Either the connection is made once and remains intact throughout the surgery, or the connection is made several times. That would mean fewer steps to be taken but on the other hand the connection may hamper the connection and disconnection of the module to the guide.

The drilling and reversing of the drill bit is shown in the left column because this is something that happens outside of the body. That is to say, the surgeon uses a drill externally and the module inside the body does the drilling. The drill bit comes out of the module, so there is no need to move the entire drill through the hole.

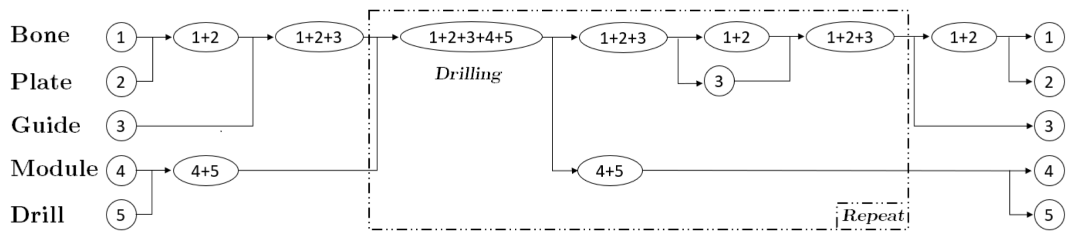


Figure 3.44: An assembly flowchart of the different components in the drilling process. Components are numbered on the left.

Figure 3.44 shows how different components are assembled during the drilling process. In this case the module and drill are connected once, in the step indicated with an asterisk in figure 3.43.

Different application, different procedure

The process as described in figure 3.43 is a particular process for an implementation of components as described earlier. For each way of implementing a Compact Drilling System there is a different process that would be followed.

A balance needs to be struck between the number of possible applications and the complexity of the process that is introduced. If a device is built that can be used for every situation imaginable, but it is too complex to (dis)assemble every time, it is not a true improvement on the status quo. The increased complexity or required time would render it unusable in practice. On the other hand if the device is kept too simple, as not to hinder the surgeon or introduce extra steps, the possible application may be too narrow. If the device is not flexible enough to be used in multiple scenarios or requires a very specific use case, it is too 'niche' to be a worthwhile area of research.

The ideal is somewhere in the middle of these two extremes: A system that can be easily modified to match the surgical requirements without needing a large number of tools or additional steps. A toolkit to mix and match the components that best fit the current surgical challenge.

3.5. Material

As mentioned in section 3.1.5 a mock up of the locking mechanism was manufactured using a 3D printer. This already proved not to be an optimal solution. Although 3D-printing is a useful technique to manufacture custom components with relative ease, it has its limitations. A commercially viable version of the Compact Drilling System needs to be produced in a different fashion. Or with different materials. The advantage of 3D-printing is its easy and possibility to customize tools, but for a mass production more conventional means of production are advisable. Material selection is also important, the material that is used needs to be applicable in a surgical setting. Such materials that can be used inside the human body are called biomaterials. Some of these materials are discussed next. These and more materials are also listed in table 3.6.

Polymers

The PLA that was used is not sufficiently flexible to allow for the required deformations. The mechanism needs to deform a bit to lock the module in the guide. Instead of bending inwards, the little fins on the guide broke off easily, due to the brittle nature of the material. Also the 3D printing technique results in a laminated product, as a result of the layer-by-layer deposit of new material. The tensile strength normal to these laminations is limited.

It needs to be concluded that a different manufacturing technique is required to produce the locking mechanism of the Compact Drilling System. Components that use a similar locking technique, such as pipes used in plumbing, are often fabricated in polyvinyl chloride (PVC). It is possible to use PVC in biomedical applications [30], although it is commonly used in a more flexible composition. Tubing and blood bags specifically are made of PVC [31]. Due to the use of plasticizers, which can leach out of the material, these soft materials are used in short-term applications.

A more dense polymeric biomaterial is polyethylene (PE). This is a material that can be obtained in different grades, varying in density. Ultra High Molercular Weight polyethylene (UHMWPE) is used for joint replacements, for example [30, 32]. Lower density PE is not suitable for applications such as the Compact Drilling System because it lacks stiffness and can not withstand sterilization temperatures [31].

Polymethyl Methacrylate (PMMA) is mainly used as a bone cement and lenses [31, 30]. Main advantages are that it is hard and biostable. It is the most widely used polyacrilate, even though it is more brittle than other polymers [33, 34].

Metals

Many of the tools currently used in surgery are made of metal, particularly stainless steel and titanium (or titanium-containing alloys). Stainless steel is commonly used for surgical instruments and fixation devices. Titanium is used for (fracture) fixation as well, and also joint replacements [35, 36] and surgical tools [37]. These metals are strong enough to withstand significant force, making them suitable for these load-bearing functions. It also makes them suitable for withstanding the forces involved when drilling, given that the elasticity is sufficient to lock the mechanism. Metals can be sterilized which makes them reusable for multiple surgeries.

A downside of using metal compared to a polymer such as the aforementioned materials is that metal is radiopaque. This means the material is visible in X-ray photography. It would be advantageous to have a radiolucent device, because that would allow for pictures to be taken without needing to remove the device from the drilling site. If the surgeon wants to verify that the hole is drilled correctly, or that a screw has penetrated deep enough, they depend on these X-ray pictures.

Material	**Abbr.**	**Type**	**Common Applications**
Polyethylene (low density)	PE	Polymer	Flexible containers, foils, packaging
Polyethylene (high density)	PE	Polymer	Tubing (drains and catheters), prostethic joints
Polylactic Acid	PLA	Polymer	Implants, drug carriers, tools and equipment
Polymethyl Methacrylate	PMMA	Polymer	Bone cement, lenses
Polypropylene	PP	Polymer	Non-degradable sutures, hernia repair
Polyvinyl Chloride	PVC	Polymer	Tubing, blood storage bags
Stainless Steel		Metal	Surgical instruments, orthopedic fixation devices, stents
Titanium		Metal	Fracture fixation, pacemaker encapsulation, joint replacement
Alumina		Ceramic	Joint replacement, dental implants, orthopedic prostheses
Carbon		Ceramic	Heart valves, biocompatible coatings, electrodes

Table 3.6: A selection of biomaterials. Sources: [30, 31, 32, 35, 36, 37, 38, 39, 33]

Ceramics

A third subsection of materials commonly used in medical applications is that of ceramics. They are used because of their high compressive strength and biological inertness, among others [35]. A disadvantage however is that ceramics are generally brittle [30].

Alumina is the common name of aluminium oxide (Al_2O_3). It is a material commonly used for joint replacements and dental implants due to its high hardness and low friction and wear. Another advantage for its use in a medical setting is that it is relatively bio-inert [30].

Another common biomaterial is carbon. This is a group of ceramic materials, the structure of which determines the properties and application of the material. Graphite for instance consists of planar hexagonal arrays, whereas isotropic carbon has no preferred crystal orientation [40]. These different variations of carbon offer various applications, such as coatings for implants and electrodes[35]. Carbon and carbon-based materials are inert, which makes it suitable for coating implants. It is however not commonly used to construct tools and instruments, such as the Compact Drilling Device.

Conclusion

In conclusion, a 3D-printed polymer device would be easiest to fabricate on site at low cost. For an adaptable design, a hospital can fabricate the necessary equipment at the relatively low cost of a 3D printer and the raw material. The locking guide as presented earlier was designed to be sufficiently strong when fabricated from pmma. A different manufacturing technique, such as injection moulding, may be required to prevent delamination of the material. An increased printing resolution would also improve on this.

For repeated use and ease of sterilization, a metal device would be advised. This is closest to the current common practice in surgical instruments. Stainless steel is commonly used, and can be sterilized. Fabrication of such devices would not be possible on site, so a standard design is to be made and ordered at the hospital's need.

Ceramic materials are not (yet) suitable for this type of application. And if they were it does not make economic sense to choose this material over stainless steel.

4

Conclusions and Future Work

4.1. Conclusions

This master thesis research involves a design of a device to drill bone, and the process in which to use it. Certain components have been taken as a given, as discussed in section 2.1. The new self-feeding mechanism (section 2.1.2) offers the required drilling motion within a very limited volume. It is applied in combination with a common medical drill. The goal has been to find viable ways of implementing these components into a compact drilling system, working towards a fully redesigned compact drilling device.

It can be concluded that there are many different ways of implementing the components as discussed into a new, compact, device. The different options have been discussed in chapter 2, and it shows that due to there being numerous potential applications of this device, there are also numerous valid design options.

For that reason it is concluded that it is worthwhile to implement the self-feeding mechanism into a Compact Drilling Device. A modular system, where for multiple different applications a different specific device can be created is desired. For instance, a clamp that has been selected to match the shape of the bone. More on future work can be read in section 4.2.

In the previous chapter a single design was shown as an example. While this is a valid implementation of the mechanism, it is not the only possibility. It serves as an illustration of the potential of such a system.

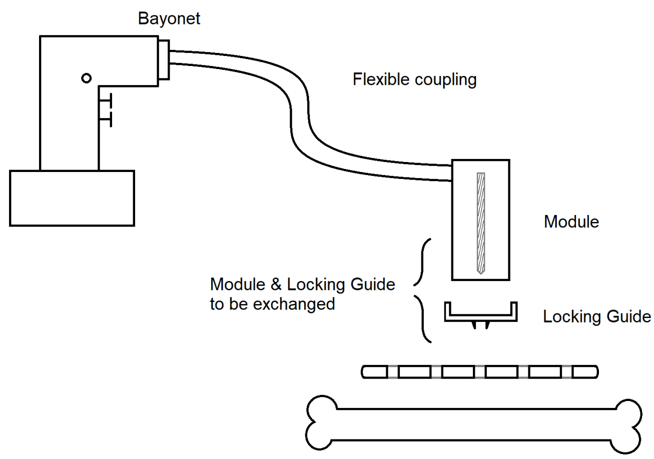


Figure 4.1: Schematic representation of the overall system proposal

This particular implementation of the mechanism includes a locking mechanism which fastens the module to the plate. This way the correct drilling orientation is provided. The locking happens by means of a threaded hole, something that is already quite common in fixation plates. The module is attached to the locking guide using a swivel cap. The power is transferred from the drill by means of a flexible coupling. This enables the surgeon to manoeuvre the Compact Drilling System around, independent of the drill. Unintentional movement of the drill, which remains outside of the body, is not transferred to the Compact Drilling System.

Analysis using the finite element method was used to verify the functionality of the locking mechanism design. Not all features proved to be able to withstand the expected applied forces. For that reason an adapted design was presented as well, to take into account those design challenges.

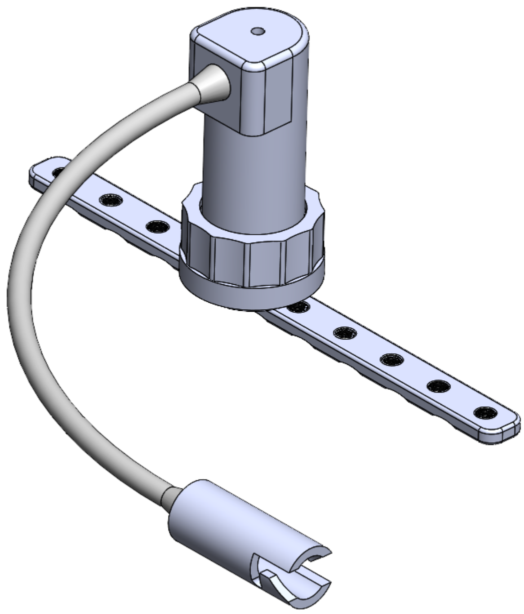


Figure 4.2: A CAD 3D model of the Compact Drilling System as proposed.

It is worth stressing that this research has been intended to be a bridging step between the current state of the art, and a completely rethought device and surgical approach. The current state of the art, although it involves a large drill and has limited options in hard to reach locations, is what surgeons currently are familiar with. It is important to not loose the interest of surgeons, those who are actually expected to use the new device, by alienating them with a device that is too far out of their comfort zone.

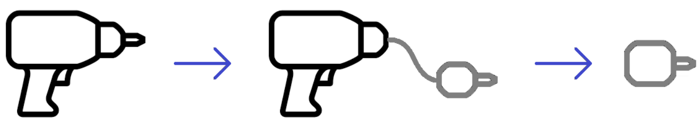


Figure 4.3: Schematic representation of the evolution of the current drill (left), via a disconnected module (middle), to a fully redesigned compact drilling system (right)

4.2. Future work

As stated before, and visualized in figure 4.3, this design is merely a step towards a completely new device. And, indeed, a new approach to drilling into bone. Many possible ways of implementing the given self-feeding mechanism were touched upon.

There are still some key aspects that need to be sufficiently addressed or resolved, before the Compact Drilling System can be implemented as proposed. Aspects that ended up outside of the scope of this particular research, either for reasons of time limitations or personal setbacks hindering the anticipated process. Listed below are some key aspects that are identified in this thesis as in need of further research:

- **Practical testing** A working demonstrator needs to be fabricated in order to properly asses the feasibility of the design. By drilling into bone (or a substitute of bone) the self-feeding mechanism and its implementation in a Compact Drilling system can be put to the test. All its advantages, and disadvantages can be understood in more detail. A demonstrator of the self-feeding mechanism has been made, but not a full device.

- **Drill bit replacement** The current system does not take into account the use of multiple drill bits, of varying size. It must be possible to switch out the drill bit in the module when it is worn down or when another size is needed. In the current design, the entire module needs to be discarded which is very wasteful.

- **Limitations of the self-feeding mechanism** As discussed in section 2.1.2, the self-feeding mechanism is not perfect. A future iteration may take away some of the downsides as discussed earlier. Combining the translation and rotation has made it possible to downsize the module significantly, but better ways to achieve this are likely to exist. Further research into other transmissions or gear types is advised.

- **Separated actuation** The step to separate the drill from the module (i.e. powering the module from outside the body) is quite a big step. It must be assessed if using a conventional drill to power a novel module that actually does the drilling is workable for a surgeon. Due to the absence of direct (force) feedback, it is an entirely new skill to reliably drill into the bone. It is possible that this way of powering the module is both too much out of the hand of the surgeon to trust it, and not automated enough that the device itself can guarantee save drilling.

In this research possible implementations were identified, and one specific combination was shown in more detail. Future work could provide detailed designs of many more specific combinations of design choices, each with their own potential for a specific application. A modular system would be a great advantage. If multiple end effectors or drill connections can be selected and used for a standardized central module, the surgeon's "toolkit" would expand significantly.

∗ Easily approachable fracture in the arm? The standard drill will do.

∗ Tight space inside the body? The small module in combination with a flexible coupling is the way to do it.

∗ Complex fracture? We can design a patient-specific support to match the bone and manufacture it.

A wide selection of combinations need to be expanded on in close collaboration with surgical specialists. A list of essential and useful functionalities can be made in cooperation with experts in the surgical field. This would be the basis for a new catalogue of instruments, specifically designed to improve bone drilling in hard to reach locations.

Alternatively it is strongly advised to consider making the jump to a completely new system such as the one illustrated in the right of figure 4.3. A small, handheld device which can drill automatically once placed in the correct location. The current iteration of the Compact Drilling System as described in this research depends on a conventional medical drill to provide the drilling power. It is scaled down to work inside the body by disconnecting the power generation from the drilling. What if the complete drilling motion can be generated in a small, handheld module? This would make the conventional drill outside of the body, and the connection to it, obsolete. Everything can be done inside the body, possibly freeing one of the surgeon's hands. A sketch of such a handheld device is shown in figure 4.4.

There are caveats of doing it in such a manner, some of which are listed here:

- **Size limitations:** The current drilling module can be kept small by not using the limited volume of the design for power generation. The self-feeding mechanism further keeps the dimensions small. If the drilling power needs to be generated within the module, that would require a larger device. The main design challenge would be to find a way to generate enough power to drill through bone without needing such a large volume that it defeats the purpose of a Compact Drilling System.

- **Heat generation:** Motors generate heat, how can that be dealt with? Outside of the body heat generation is barely a problem, since the drill can cool down in the air of the operating room. Inside of the body cooling the device is not as easy. Using a line of water or a refrigerant to cool down the device adds its own challenges, and again requires a connection to outside the body.

- **Sensors and feedback:** If the drilling occurs automatically, there is a need for sensory data and some system to analyze the data coming in. For instance, breakthrough detection to prevent the device from drilling all the way through bone into the tissue behind it. If drilling is not automatic but still in direct control of the surgeon, they need to have some sort of feedback to tell them what is happening. Is sound alone enough to indicate to the surgeon when the hole is deep enough? Currently they control precisely how much force is exerted on the bone, based on what they feel combined with experience. If some of this feedback is taken away without replacing it with other relevant information, there is not enough to reliably control the drilling.

  The development of smart sensing drilling devices is something that already came up during talks with a surgeon in preparation for this research. They indicated that it would be beneficial if the drill could indicate how much wear a drill bit has already attained, for example.

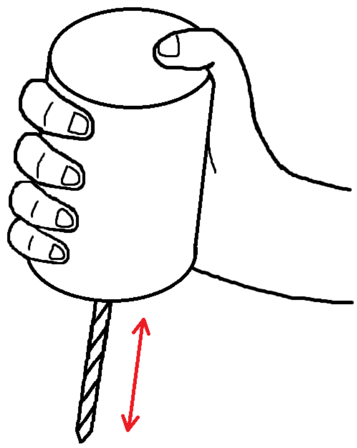


Figure 4.4: Sketch of a possible future version of a Compact Drilling System. A small device only needs to be placed in the correct location and drills automatically. The device contains actuators and sensors to achieve this.

If these challenges can indeed be met, a new device would be added to the ever increasing arsenal of medical instruments. In this research, a concept was proposed as a proof of principle for a quick implementation. A bridging step towards a completely revolutionized drilling device, a candidate for further research. Hopefully this research will have been a step towards providing surgeons with a device which can improve surgical outcome.

A

Appendix

A.1. Locking Plate mechanisms

There are two main mechanism used to lock the screw in the plate:

A.1.1. Fixed Angle

Locking the screw head in its chamber by a threaded locknut

- Surfix®: screw (1995)

Figure A.1: Surfix locking mechanism using a threaded locknut, from [10]

A locknut is screwed into the chamber above the screw. This locks the screw to the plate.

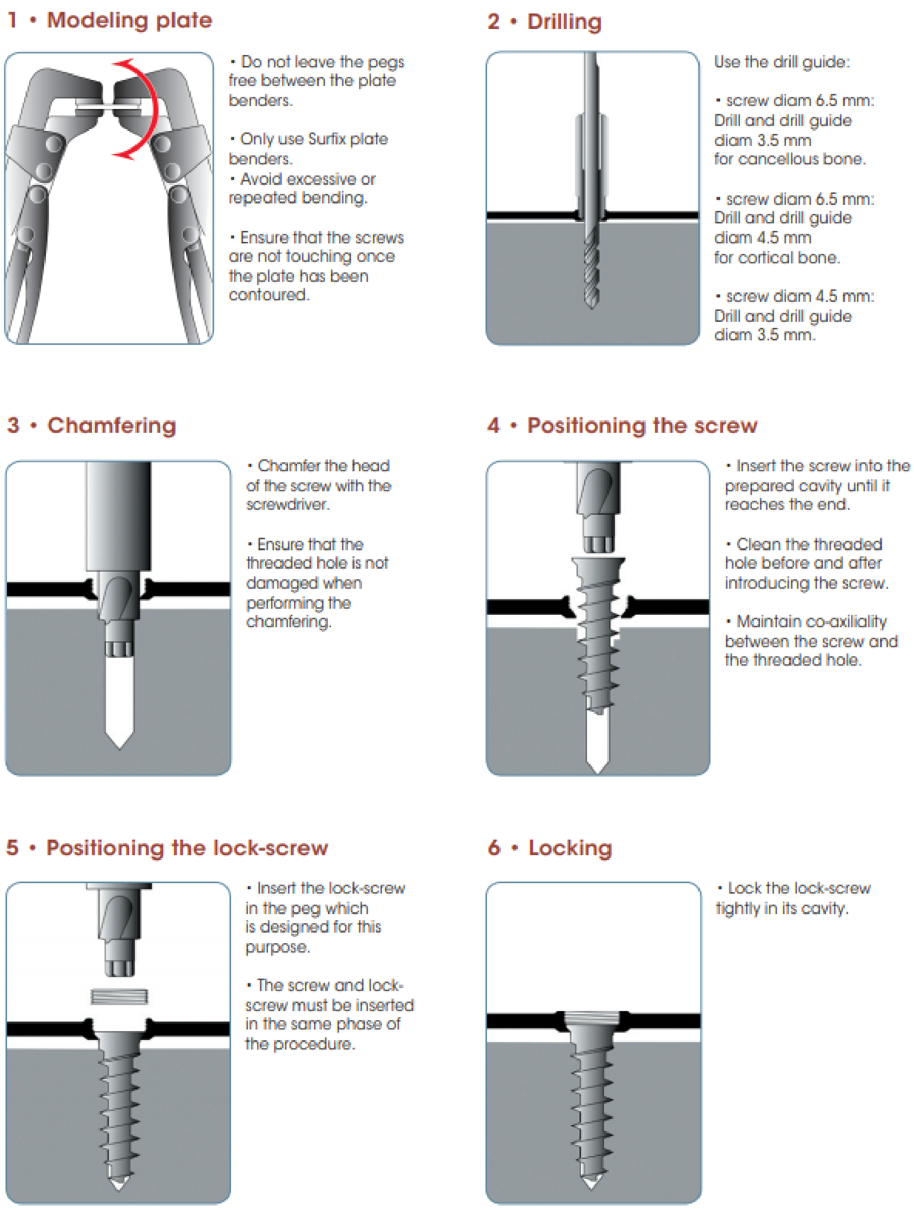


Figure A.2: Surgical technique of the Surfix locking mechanism, from [41]

- Tornier®: Locking insert from biocompatible material (Patent US20150351816A1)

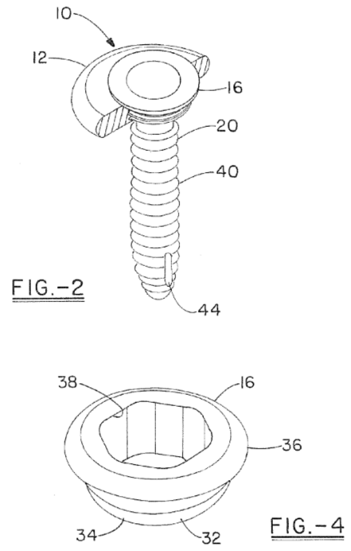


Figure A.3: Mechanism used by Tornier, from [42]

The locking insert is made from a biocompatible material such as PEEK polymer (i.e., polyether ether ketone) or other suitable biocompatible polymer, that is softer than the screw so that when the screw head is screwed into the locking insert, the external threads will cause the surface of the internal opening **38** to flow or deform to form threads in the locking insert, causing the screw to lock into position relative to the plate in the locking insert

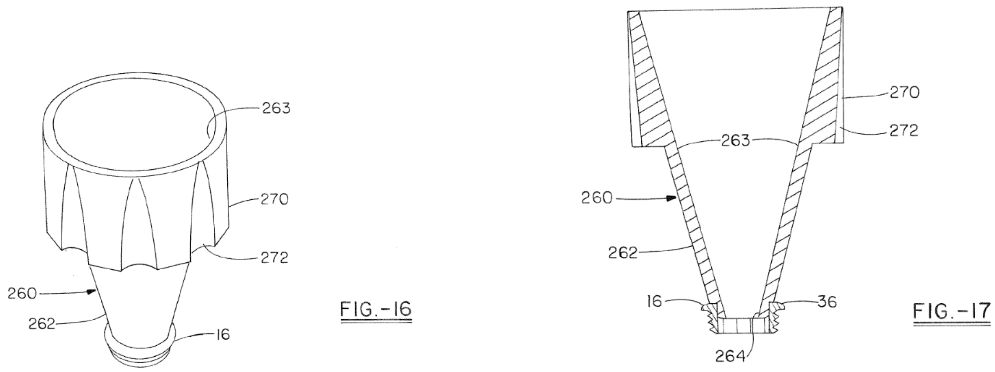


Figure A.4: Mechanism used by Tornier, from [42]

FIGS. 16-20 illustrate a second embodiment of the locking insert driver **260** of the present invention. In this embodiment, the driver **260** is also useful as a poly-axial drill guide. Specifically, the driver has a conical shaped body portion **262**, which functions both as a handle, and also provides a internal opening **263** that has conical shape that defines the limits that the variable locking screw can achieve in the plate. The internal opening **263** ends in a circular opening **264** through which the drill extends during use. On the external wall surrounding the opening **264** there is a tip **265** having friction fit with the locking insert **16**

(...)

At the top end of the body portion **262** of the conical drill guide **260**, the drill guide includes turn means **270** which allow a surgeon to thread the locking insert into the threaded screw hole of a plate using his or her fingers. It is preferred that the turn means **270** include a suitable configuration for this use, such as a polygonal shape, scallops as shown **272**, or knurling, or cross-hatching.

- Stryker AxSOS®: A locking insert is placed in the plate

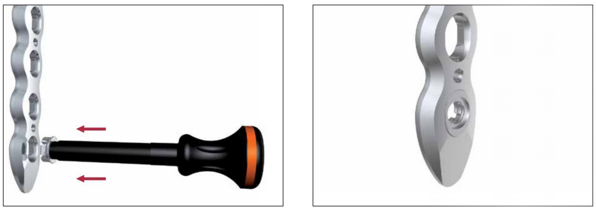


Figure A.5: The StrykerAxSOS mechanism, from [43]

Threaded screw head screws into the plate or into an adapted lip

- AO/Synthes®: Conical screw head with screw thread locks within threaded hole.

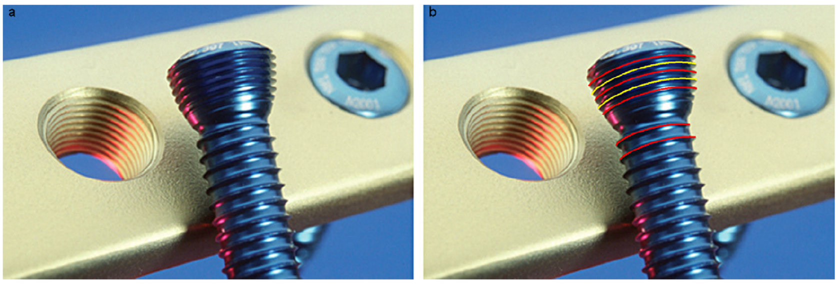
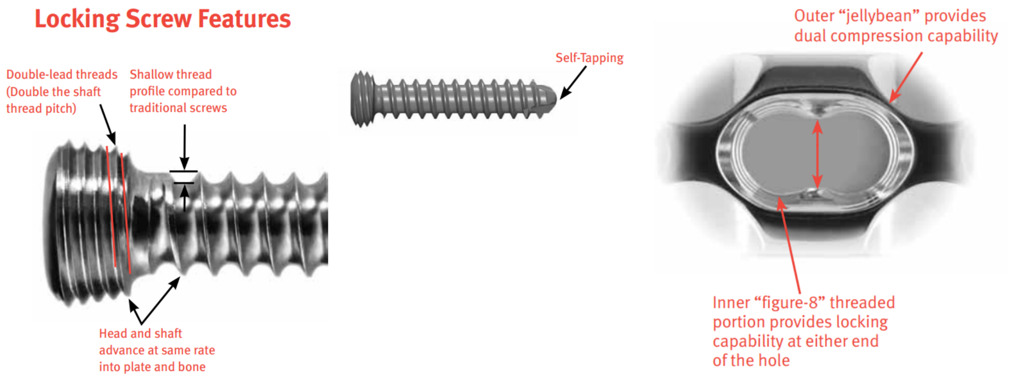


Figure A.6: AO interlocking system. Left: the threaded screw head and screws into the plate. Right: The head has a double thread, with constant pitch. From [10]

Combi-hole allows for using either a locking screw or a standard screw (figure).

Figure A.7: LCP combi-hole. Either a locking screw or a standard screw can be used. From [9]

- Zimmer®: Uses a very similar technique, with their own design of holes in the plate.



(a) (b)

Figure A.8: Mechanism used by Zimmer, from [44]. Figure a shows the features of the locking screw, in b the hole is shown.

A.1.2. Variable Angle

- Newclip®: Expansion ring locks the screw head in the cone (up to 10 degrees)

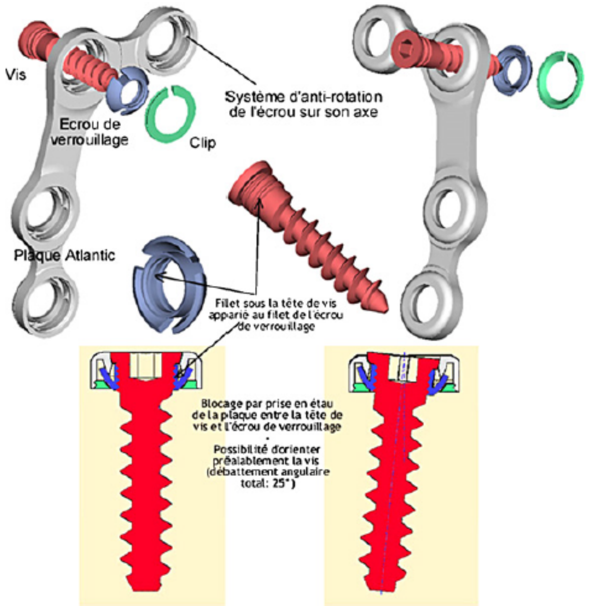


Figure A.9: The Newclip locking system uses an expansion ring. From [10]

- Stryker® VariAx:

  Locking screws have threaded heads. They can be inserted into the holes at an angle of up to 15 degrees. Non-locking screws can be used as well.

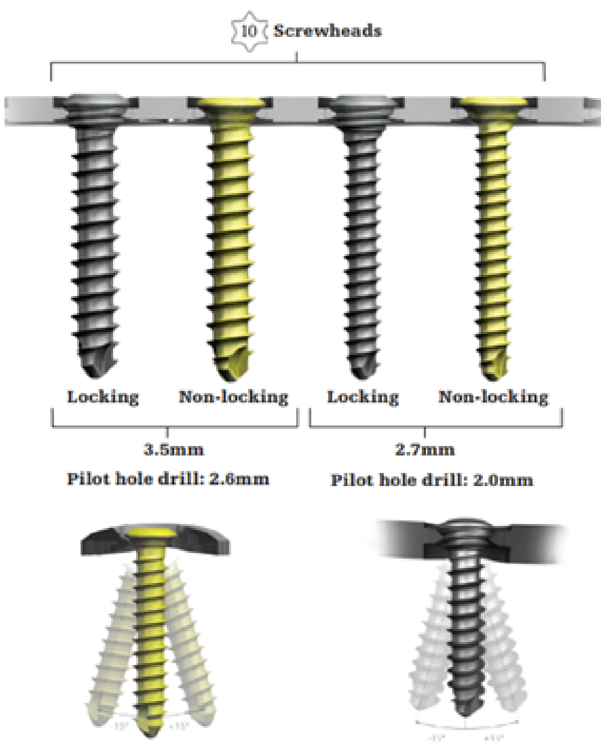


Figure A.10: Stryker VariAx screws, from [45].

- Biotech®: polyaryletherketones (PEEK) inserts

Figure A.11: Biotech system. The screw is inserted in a PEEK insert. From [10]

- Zimmer®: A locknut covers a spherical screw head

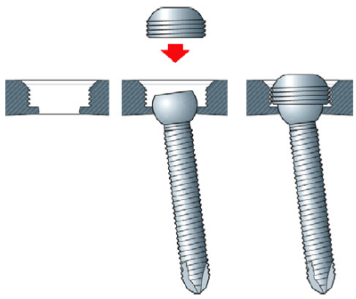
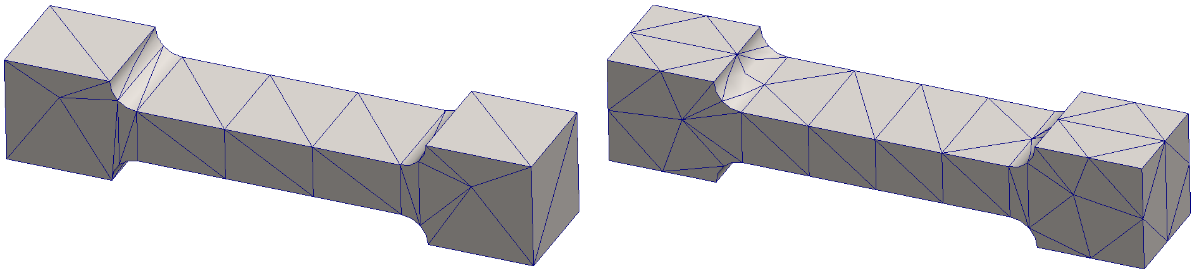


Figure A.12: Zimmer system. A locknut is placed on top of a spherical head. From [10]

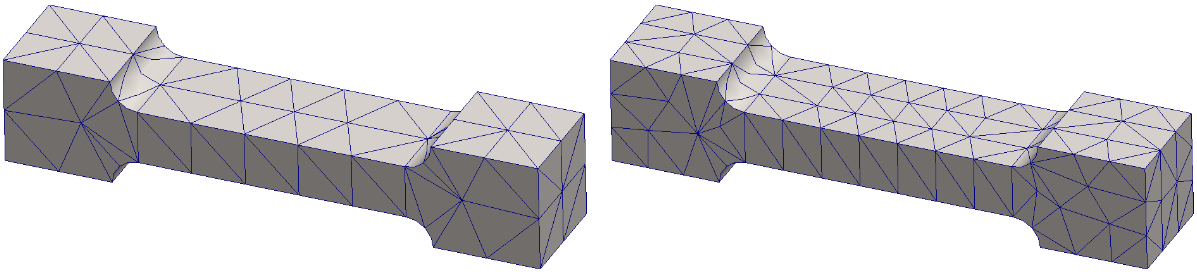
- AO/Synthes®: Similar to their fixed-angle technique, but the screw head is spherical

A.2. various mesh densities of the example beam



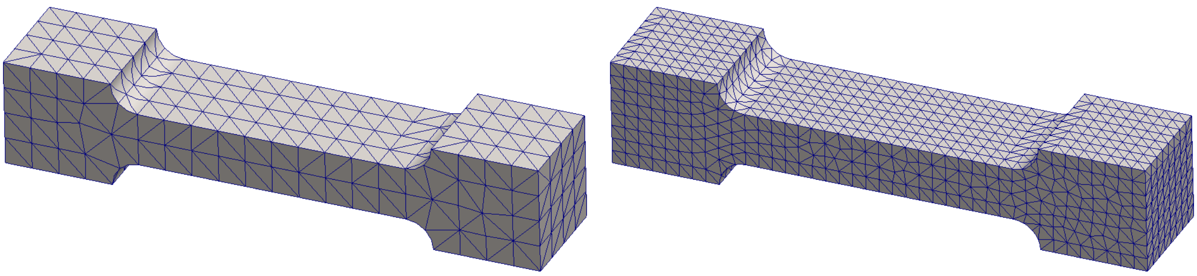
(a) 20mm **(b)** 15mm

Figure A.13



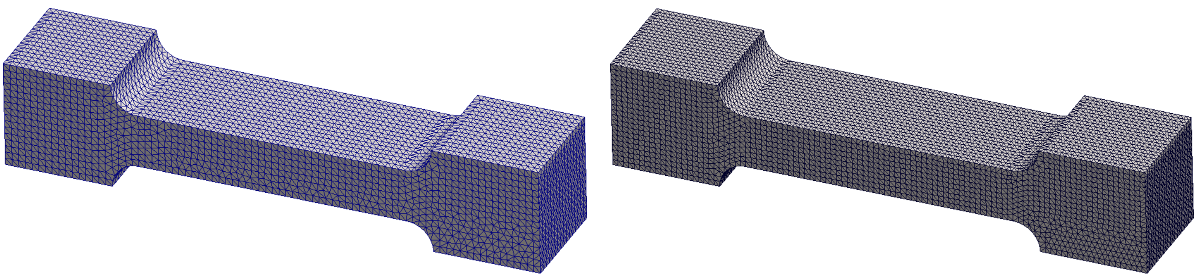
(a) 10mm **(b)** 7.5mm

Figure A.14



(a) 5mm **(b)** 2.5mm

Figure A.15



(a) 1.25mm **(b)** 1mm

Figure A.16

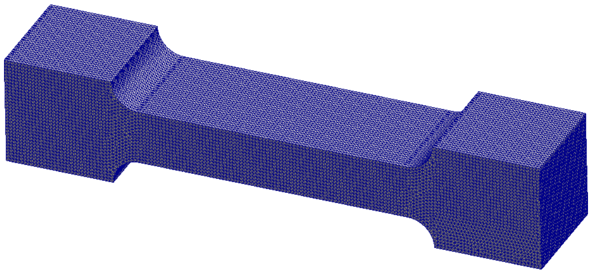


Figure A.17: 0.625mm

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