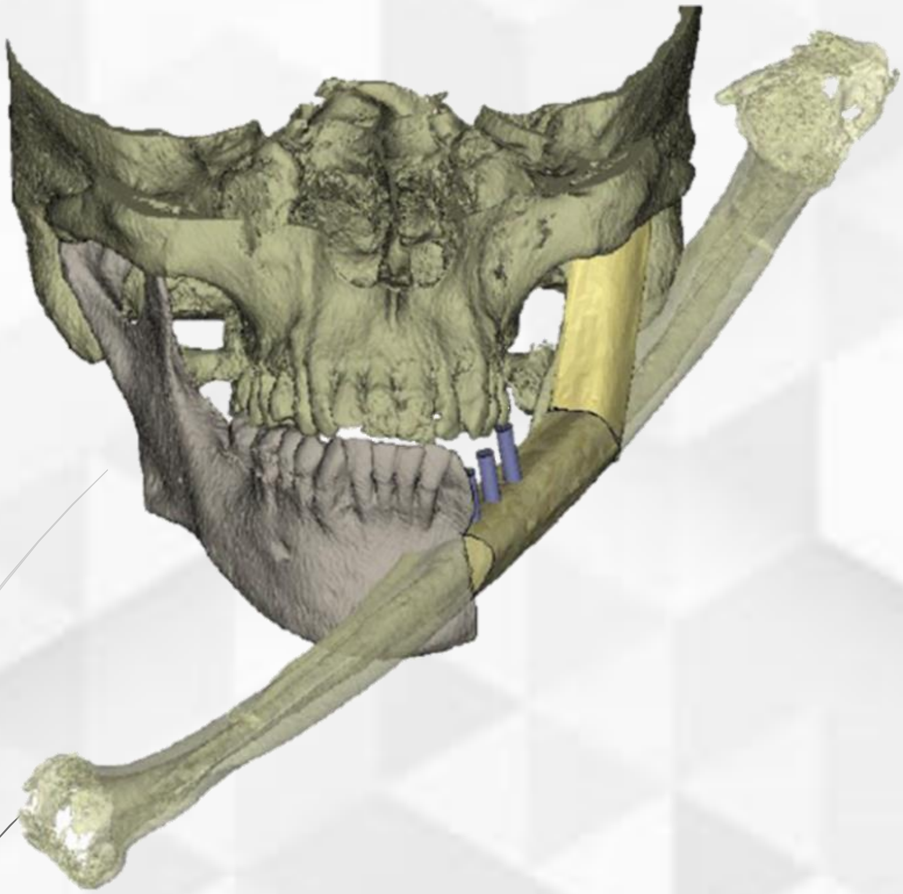
Renewed Mandibular Reconstruction Process

The Development of a universal fibula cutting guide and evaluation of a semi-automatic mandible reconstruction planning software

1-12-2020



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MASTER THESIS TECHNICAL MEDICINE

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Summary

The gold standard treatment for tumors that have invaded the mandible bone is surgical resection of the bone and reconstruction with free vascularized fibula grafts. Beforehand, a pre-operative plan is manually created and patient-specific three-dimensional (3D) printed cutting guides for both the fibula and mandible are developed. These guides allow accurate conversion of the plan to the surgical procedure. However, the process of developing a virtual plan and the patient specific guides is costly and time-consuming. In addition, the fixed plan and guides do not allow for adjustments intraoperatively. Both the lengthy time interval between planning and surgery and the inability to adjust the plan intraoperatively influences the surgical result negatively. To take on this problem, a new mandible resection process is proposed. Four things are needed: an automatic planning software, a universal fibula cutting guide, a universal mandible cutting guide, and universal reconstruction plates. A solution to the latter two was introduced already in previous works. In this study, solutions to the first two aspects are proposed.

In this study, a universal fibula cutting guide is designed and developed. This guide enables adjustment of angle and length measurements intraoperatively. Although still a prototype, a phantom study was executed. The novel guide reached a mean (standard deviation (SD)) yaw and roll angle deviation of 1.1 (0.7)° and 0.9 (0.4)° respectively which was not inferior to the current guides that had a mean (SD) yaw and roll angle deviation of 2.2 (1.7)° and 1.0 (1.0)° respectively. The mean segment length deviations (SD) of the universal guide was 0.9 (0.3) mm and was significantly worse than the length deviations of the current cutting guides, 0.5 (0.2) mm. However, there is still a lot to improve on the guide, which could among other things improve the length accuracy.

In addition, a first version of a semi-automatic planning software was submitted to us for evaluation. Comparison of 7 identically based manually made and automatically generated plans revealed the current version of the software does not reach acceptable plans yet. As judged by three head and neck surgeons, all manual plans were superior. Aside from a subjective evaluation, an objective evaluation method was introduced. Objective methods can be very useful in the development software to obtain the best possible plan. This evaluation method consisted of separate evaluations that could analyze the most important aspects of a plan. The bottom border, fibula surface coverage and mandibular angle positioning could be analyzed this way. The evaluation method of the outer border should be adjusted. However, by optimizing these evaluation methods and combining all aspects of evaluation into a rating system an overall conclusion about the acceptance of a plan may be reached.

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Chapter 1: Introduction

Oral cavity cancers (OCC) belong to the most common cancers among head and neck malignancies. [1] OCC has a tendency to infiltrate surrounding soft tissues and the mandible bone. [2] Tumor invasion of the mandible poses huge consequences for the patient. Surgical removal is the primary treatment for these tumors where often a complete segment of the mandible is resected to achieve sufficient surgical margins. [3] This leaves the patient with a huge defect which can be reconstructed using a free vascularized fibula graft with a skin island. [4] Nowadays, many clinical centers apply computer aided design (CAD) and computer aided manufacturing (CAM) techniques to plan the reconstructive surgery. [5–8] A pre-operative plan is manually made in which the location and orientation of the osteotomies on both the mandible and fibula are indicated. For accurate translation of this plan to the operating room, personalized cutting guides are designed and 3D-printed. This way of planning however, has some important shortcomings such as inflexibility of the plan and lengthy preparation time. Given these shortcomings, this study aims to develop a new, faster and more flexible method by developing a universal cutting method for the fibula and also evaluate software that would replace the current human planners by generating automatic plans for mandible reconstructions.

This paragraph is followed by a short introduction that discusses the relevant anatomy of both the fibula and mandible for mandible reconstructions. In addition, the origin and diagnosis of the tumors that most frequently invade the mandible bone are discussed and further elaboration is provided on the treatment it requires and the shortcomings it possesses.

1.2 Clinical Background

1.2.1 Anatomy and function

The fibula

The fibula bone lies laterally in the leg and forms together with the tibia bone the skeleton of the lower leg (figure 1). In contrast to the tibia, the fibula is a non-weight bearing bone and is therefore much thinner. Its main function is to provide attachment for several muscles, ligaments and fascial septa and provide stability to the ankle joint. The fibula is usually triangular shaped in cross-section with a medial, posterior and lateral side. The fibula shaft enlarges into the fibula head proximally and prolongs into the lateral malleolus distally (figure 1). [9,10]

The origin of the fibula blood supply comes from the popliteal artery which gives off a branch called the anterior tibia artery after which it carries the name, tibia-fibula trunk. This then bifurcates into the posterior tibia artery and the peroneal artery (figure 2). Blood supply to the epiphysis and the head of

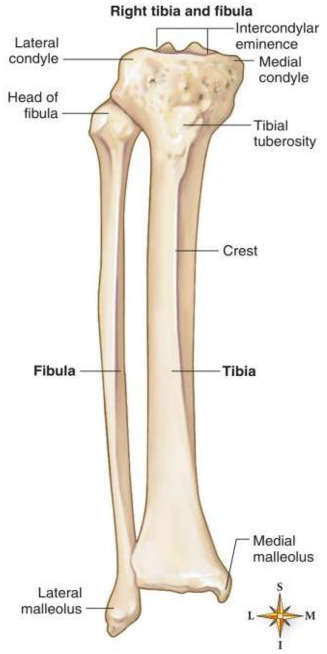


Figure 1: Fibula anatomy of right lower leg (front view) [60]

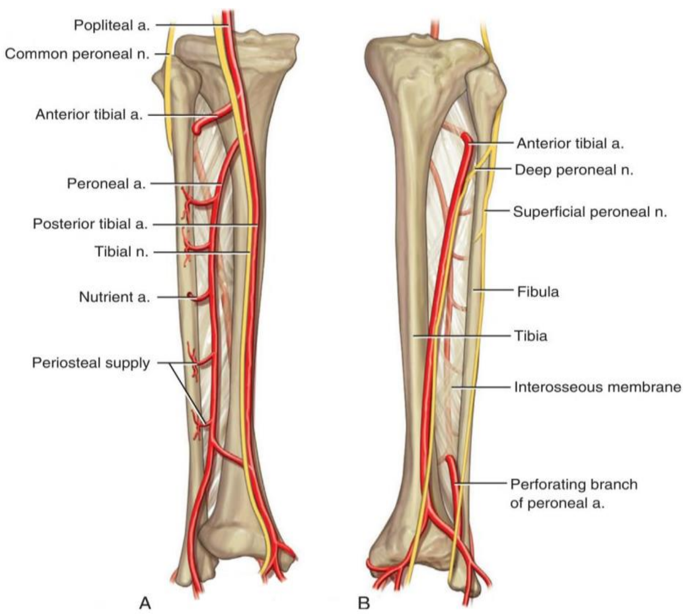


Figure 2: Fibula blood supply of left lower leg. A) rear view, B) front view [61]

the fibula comes from the anterior tibia artery. The peroneal artery supplies the shaft of the fibula usually via a single nutrient artery that enters the bone at the middle which then divides in an ascending and a descending branch. It also offers numerous branches to supply the periosteum which in turn supplies the bone also. Furthermore, it provides some fascial vessels that supply the skin territory lateral to the fibula. The peroneal artery is accompanied by two venae. [9,10] The peroneal blood vessesls in particular are very important for the graft survival if used for mandibular reconstruction.

The oral cavity and mandible

The oral cavity consists of the lips, the gingivae (including the alveolar ridge), gingivobuccal sulcus, buccal mucosa, hard palate, the floor of the mouth, retromolar trigone, and the anterior two-thirds of the tongue (figure 3). [11,12] The mandible or lower jaw lies in close proximity to the oral cavity structures lining the caudal and partly lateral borders. It is the largest, strongest and by far the most mobile bone in the human face. It holds the lower set of teeth and provides for a normal facial contour, normal chewing, swallowing and speech. [13]

The mandible consists of a horseshoe-shaped body anteriorly and posteriorly on either side ramus that project upward and divide into two processes each: the posterior condyloid process which forms the temporomandibular joint with the skull, and the anterior coronoid process. The body itself consists of a superior alveolar part, which holds the lower set of teeth and a lower base part. The body and the rami connect on either side at the mandibular angle (figure 4). [13,14]

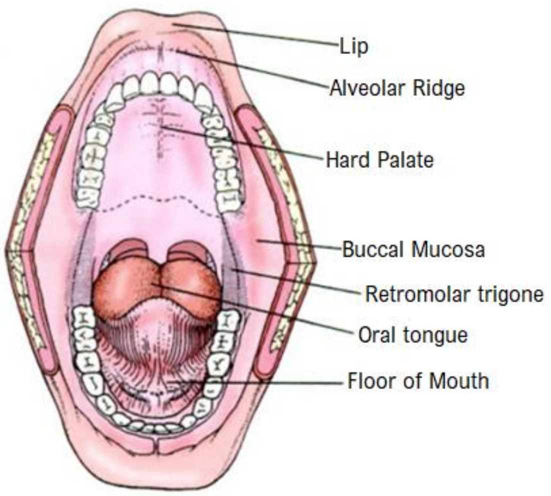


Figure 3: Oral cavity anatomy [12]

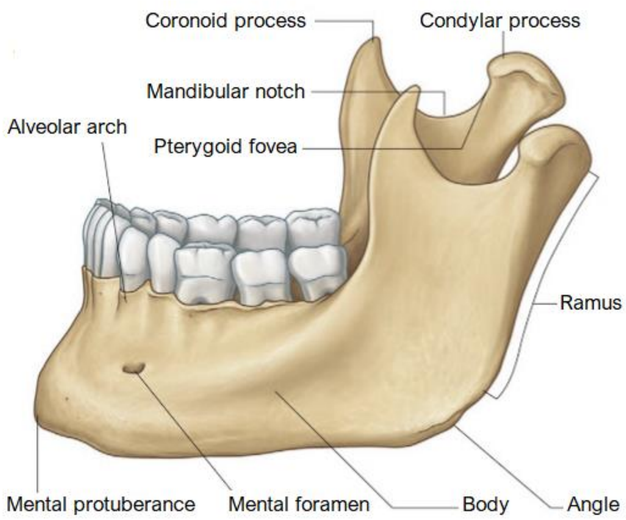


Figure 4: Mandible anatomy [62]

1.2.2 Mandibular cancer

Epidemiology

Primary tumors of the mandible are rare. The most prevalent way for tumors to invade the bony structure is from the oral cavity. In 2019 the incidence rate of OCC was 1000, accounting for one third of all head and neck cancers in the Netherlands that year. [1] In 12-56% of these cases, invasion to the mandible occurs. [15] Primary tumors of the mandible originating from the connective tissue and also metastases from other tumors in the human body, in particular the breast and lungs are two other origins of mandible tumors. These two origins are however much less prevalent. [16–19] The latter accounting for only 1% of all oral cancers. [16,17] Two of the greatest risk factors for developing OCC include the (excessive) use of alcohol and smoking. [20–22] The risk increases even further when there is a combined use. [23]

Diagnostics

Early symptoms of oral cancer are small lumps, sores or white or red spots. [24] Oftentimes however, these symptoms are not readily spotted by patients themselves. Symptoms representing in a later stage when the tumors have grown larger are pain, difficulty chewing, swallowing and speaking. [25] When invaded in the mandible the most common symptoms are swelling and pain and depending on the location of the tumor loosening of teeth and paresthesia may be experienced. [26]

Gaining knowledge off these symptoms, the patient's background and the performance of physical examination are the first steps in diagnosis of OCC. If these result in suspicious findings, a surgical biopsy can further prove the presence of a tumor. Furthermore, a CT and/or MRI scan is performed to evaluate which structures are involved. In addition, an orthopantomogram or a PET/CT scan is performed in case of suspicion for mandibular invasion or metastases, respectively. [27,28] It should be noted that despite these techniques, it remains difficult to distinguish medullary, cortical or no mandibular invasion which have huge consequences for the choice of treatment. [3]

Treatment

Advanced tumors of the oral cavity are treated most often by surgical resection and postoperative radiation therapy. Surgical resection is recommended in particular for tumors that have invaded the mandible because these tumors tend to show a poor response to radiation therapy. Depending on the extent of mandibular invasion, periosteal stripping (no invasion), marginal mandibulectomy (cortical invasion) or segmental mandibulectomy (cortical invasion and/or medullary invasion) is performed. [2,3,29] With a marginal mandibulectomy the base of the mandible remains in place which preserves the continuity of the mandible and hence its function. [30] With segmental mandibulectomy this continuity is lost as a complete segment of the mandibular bone is removed. Since it is difficult to distinguish the extent of mandibular invasion, a segmental mandibulectomy is often performed to be sure to remove all of the tumor when in doubt. Depending on the location of this segment, the patient may develop functional deficits in mastication, deglutition and speech. Therefore, the resected mandible is often reconstructed. [4,31]

Reconstruction

Nowadays, the method of choice for reconstruction are vascularized osteocutaneous flaps, due to their high bone union rates and fast recovery time (2-3 months). Free flaps from several donor sites are suitable for reconstruction, such as the radial forearm, iliac crest, scapula, and fibula. The fibula osteocutaneous free flap however, has become the workhorse of mandibular reconstruction. The main advantages are the possibility of performing multiple osteotomies due to a segmental and intraosseous blood supply to the fibula bone, the length and diameter of the peroneal vessels, the length of dense cortical bone that can be obtained, the possibility for osseointegrated implants, the possibility of simultaneous two site surgery, and minimal donor site morbidity. [4,31–33] The main disadvantage is that the perfusion to the skin island may be unreliable. However, survival of the skin flap may be maximized through surgical experience. [4]

Mandibular reconstruction surgery is planned pre-operatively using computer aided design (CAD) and computer aided manufacturing (CAM) techniques. [5–8] Planning starts by acquiring both a high-resolution CT scan and an MRI scan. Both are necessary for an accurate planning. The MRI scan is used to visualize the soft tissues and the tumor while the CT scan is used to visualize the bony anatomy accurately. From the bony structures of the mandible and the donor site a 3D virtual bone model is created. On the 3D mandible model, resection planes with proper tumor margins can be planned (figure 5 A). Subsequently, the mandibular defect is virtually filled by optimally fitting one or more fibula bone segments in the defect (figure 5 B and figure 5 C). Using this planning, unique personalized surgical resection guides are produced for both the mandible and fibula such that the virtual planning can be translated accurately to the surgical procedure (figure 5 D and figure 5 E). Lastly, titanium reconstruction plates are manufactured based on the planned mandibular reconstruction to hold the fibula bone in the mandibular defect in place (figure 5 F).

1.3 Technical Medicine Problem

Compared to the old free-hand approach, virtual surgical planning with the use of CAD and CAM techniques has proved to be beneficial by offering improved planning options, improved accuracy of reconstruction and reduced surgery times. [34–37] However, by using personalized 3D printed surgical devices, the current technique has become highly inflexible, costly and preparatory time-consuming. [37] These drawbacks can have serious consequences. The time between the planning CT and the surgery should not take more than two weeks and preferably even less, especially in patients with rapidly growing tumors or acute trauma. [38] Currently however, preparation time may take as long as four weeks due to external parties that are needed to create the surgical devices and to create a virtual

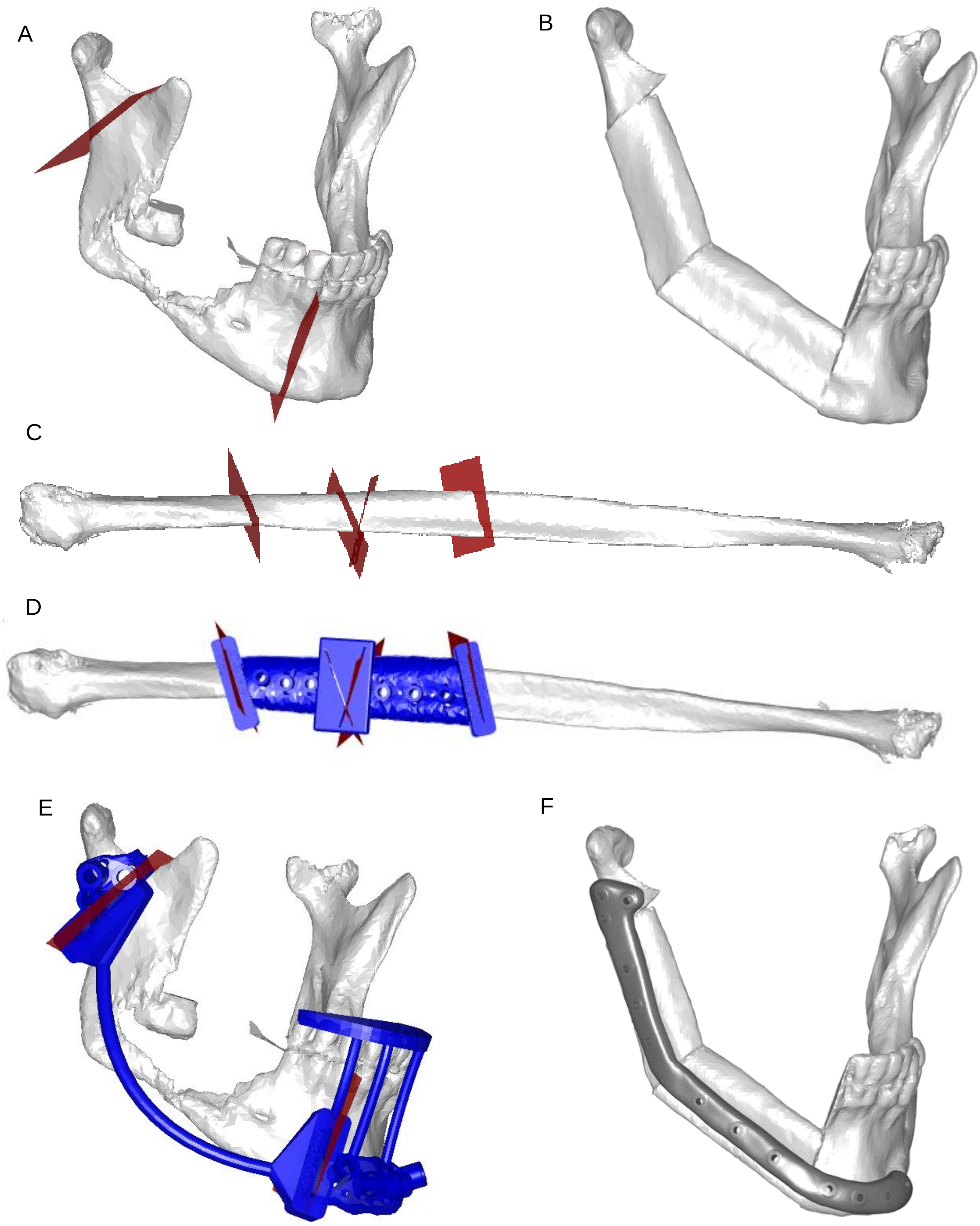


Figure 5: 3D virtual bone model of mandible and fibula showing resection planes and resection guides. 5A) Mandible with two resection planes at marginal distance from tumorous defect. 5B) Reconstruction plan. 5C) Fibula with cutting planes for obtaining segments for reconstruction. 5D) Showing cutting guide for fibula. 5E) Showing cutting guide for mandible. 5F) Mandible reconstruction plan with reconstruction plate.

reconstruction plan which is too complex to be done by the surgeon himself. By the time the surgery can take place, the tumor may have changed considerably, and the proposed resection margins will have to be extended (or reduced) rendering the inflexible reconstruction plan and personalized surgical devices useless.

A possible solution to this problem may be to develop universally applicable surgical devices that can be set to any planned osteotomy imaginable. With this alone, the preparation time will be greatly reduced as no personalized surgical devices need to be developed before each surgery. However, to enable intraoperative adjustments, a planning software should be developed as well such that unexpected intraoperative findings will be manageable by instantly generating a new plan automatically. With an automatic planning software, the external party can be omitted entirely.

To provide an overview, four things are needed to make this solution truly successful. Firstly, a universal mandible cutting guide is required and secondly, a universal fibula cutting guide is necessary. Both should be able to translate any plan to the patient's surgical procedure. In addition, they should be capable to adjust if intraoperatively alteration of the plan is required. Thirdly, universal reconstruction plates are necessary that are able to support any mandible reconstruction. And lastly, an automatic fibula planning software is needed that can instantly produce and alter the planning intraoperatively in both the mandible and fibula. Each innovation on its own will help to speed up the process by a small amount. However, the combined merit of all four innovations is immense: an instant planning that can be translated to the operation room in minutes by the use of adjustable surgical devices and universal reconstruction plates.

Universal reconstruction plates can come in two forms: mini reconstruction plates or long reconstruction plates that follow a general mandibular contour. Both have potential and are ready to be used. A mandibular cutting guide (the 'Bladerunner') based on electromagnetic (EM) tracking has already been developed in the recent past as well. Aside from its benefits to the mandibular reconstruction process, the Bladerunner was also able to achieve a higher accuracy than the currently used personalized cutting guides. [39,40] An in-house study showed that positioning with the current guides differed 1.2 ± 1.0 mm for anterior osteotomies and 2.2 ± 0.9 mm for posterior osteotomies while the Bladerunner produced osteotomies that differed 1.06 ± 0.56 mm (mean of anterior and posterior osteotomies). The angle deviations ranged between 2.6° and 9.5° with the current cutting guides, while the Bladerunner again was capable of more accurate osteotomies with mean roll and yaw angle deviations of 1.63 ± 1.33° and 1.83 ± 1.41° respectively. These findings show that universal cutting guides would not only speed up the process, but in addition enable more accurate osteotomies and hence more accurate reconstructions. Two out of four pieces of the puzzle are thus already been taken care of. The third piece, an automatic mandible reconstruction plan is being developed as well and a first version that is able to generate semi-automatic plans will be evaluated in this study. The main aim of this study however will be to develop the final piece of the puzzle: a quick to access universal fibula cutting guide that can be adjusted intraoperatively. Since there is no in-house information on the accuracy of the current fibula cutting guides, a comparison will be executed between the new universal cutting guide and the current cutting guides to evaluate its potential.

1.4 Thesis Outline

In this thesis a universal fibula cutting guide is developed as an alternative for 3D printed cutting guides. In addition, the first version of the automatic mandible reconstruction planning software is evaluated. First, in chapter 2 a design for a new universal fibula cutting guide is developed and proposed. In chapter 3, the functionalism and accuracy of the proposed cutting guide is tested using phantoms. Thereafter, a first evaluation of the mandible reconstruction planning software is described in chapter 4. Lastly, an overall conclusion and a view on future perspectives are given in chapter 5 and 6, respectively.

Chapter 2: Design of fibula cutting guide

2.1 Design Method

A universal cutting guide is needed to replace the current personalized 3D-printed cutting guides to allow flexibility of the reconstruction plan and to shorten the planning period. For development of this product 8 basic steps were taken:

Paragraph 2.2 – step 1: Problem clarification and problem statement
Paragraph 2.3 – step 2: Investigate concept solutions in literature
Paragraph 2.4 – step 3: Define stakeholders and their implications for the project
Paragraph 2.5 – step 4: Define product requirements
Paragraph 2.6 – step 5: Ideation process. Take on the product's functionality requirements stepwise, starting with the main function and going down to sub functions
Paragraph 2.7 – step 6: Create prototype and find out shortcomings
Paragraph 2.8 – step 7: Improve prototype and repeat step 6
Paragraph 2.9 – step 8: Improve prototype and create a final product design. Product is ready for phantom testing

2.2 Problem definition

The main problem has already been discussed at great length in section 1.3 'Technical Medicine Problem'. In short, the current technique given to surgeons to establish mandibular reconstruction is too time-consuming preparatory-wise and cannot be adjusted intraoperatively if necessary. If the tumor has transformed excessively in the time preparing for the surgery, the 3D printed cutting guides and the preoperative reconstruction plan cannot be used during the surgery. Instead the conventional free hand approach is performed resulting in a significant longer operation time and inferior result. [41,42] To solve the problems of the currently used technique four things are needed: an automatic planning software, universal reconstruction plates, a universal mandible cutting guide, and a universal fibula cutting guide. The first three things are (being) taken care of. The last piece is the fibula cutting guide. The main function of this guide is the ability to translate the osteotomy angles and segments lengths from the planning to the actual bone. In conclusion, the problem statement reads: surgeons need a quick to access method to cut the patient's fibula bone accurately with predefined angle and length measurements which may change during the procedure, such that patients can have surgery quickly and the predefined angle and length measurements can be cut accordingly leading to a successful fibula harvest.

2.3 Concept solutions in literature

Several research groups have come up with alternatives for the 3D printed fibula cutting guides. They each used different methods to reach their goals. Some research groups have designed a universal guide for a full anterior mandibular reconstruction. [43–45] These universal guides have fixed osteotomy angles and fixed segment lengths based on average mandible data. In oncology however, these guides are unpopular since it is undesired to resect more of the mandible than absolutely necessary. The study group of Weitz et al. (2018) [45] made their guide semi-adjustable by implementing a sliding feature at the end. This way, the segment length of the segments positioned laterally in the mandible could be adjusted. However, the adjustment remains very limited leaving larger than necessary resections inevitable. A study of Meyer et al. (2019) [46] took on this problem by creating a truly universal guide, the 'multiuse cutting jig' (MUC-jig) that is adjustable in both segment length and osteotomy angles for each segment. This means all kind of mandibular defects can be reconstructed. In figure 6 the MUC-jig is shown fixed onto a phantom fibula. It can slide along the fibula over the ruler to depict the segment length and it can rotate along both orthogonal axes with respect to the fibula long axis. To use it, the first step is to fixate the MUC-jig onto the fibula, and after that all the osteotomy locations need to be marked. The MUC-jig can then for each cut be correctly angled and lined up with the previously set osteotomy markings onto the fibula. This is done by placing a metal plate along the guide to physically see where the cutting plane will reach the bone. Each segment is sawn only halfway through, such that the fibula is not destabilized. When all cuts have been made, the MUC-jig can be removed, and the fibula can be sawn through completely. Obviously, it is not yet the most practical cutting guide having to

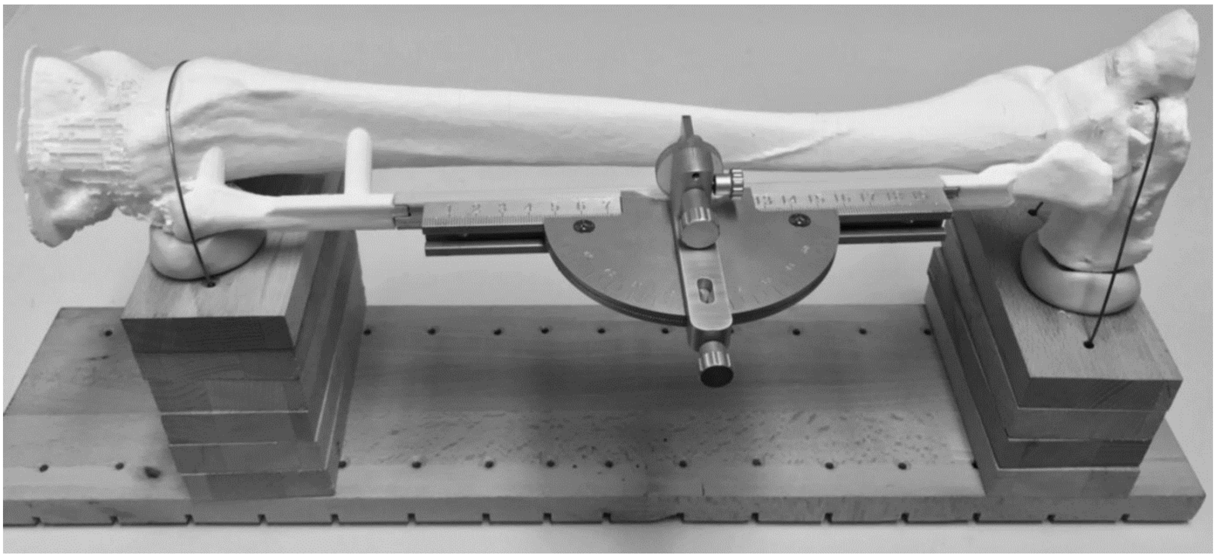


Figure 6: The MUC-jig fixed onto the lateral side of a 3D-printed fibula [46]

mark all osteotomy locations onto the bone, applying a metal plate to line up the guide with these markings and not being able to saw through all at once. However, using the MUC-jig, the authors claimed to have reached an accuracy for both length and angular conversion that is not inferior to the currently used cutting templates. The mean absolute deviation from the original planning was 0.81 mm with a standard deviation (SD) of 0.78 mm in length and 2.22° with a SD of 2.33 for the angles. They did however note that the larger the angle became, the less accurate it became.

Other research groups have tried a different approach, namely navigation. Image guided surgery (IGS) is growing in popularity among oral and maxillofacial surgeons. Remarkably only two research groups have used IGS as an application for harvesting a free fibula flap for mandibular reconstruction. Both navigate the surgical saw by an optical tracking system. The first research group of Li et al. (2016) [47] registers by matching surface data intraoperatively using a laser scanner with the preoperative CT scan. The reference frame is fixed distally onto the lower leg using a headband. With this, they reach a registration accuracy of below 2 mm. The second study of Pietruski et al. (2019) [48] evaluates two methods. A hybrid matching method in which the skin surface data obtained by an optical scanner is matched to the skin data from the preoperative CT by point-pair registration based on 4 surface point-pairs. And a point-pair method, in which adhesive skin markers are used for registration. The reference frame was attached proximally to the anterior border of the tibia using a transcutaneous approach. The point-pair method was found to be best applicable reaching a mean fiducial registration error of 1.82 ± 0.96 mm and a target registration error (TRE) of 2.00 ± 0.67 mm. The mean angular deviations and mean positional deviations were 3.66 ± 3.60 degrees and 1.85 ± 0.99 mm respectively when comparing the planned and actual osteotomy trajectories. Although the TRE is kept below 2.00 mm in both studies, the accuracy of the osteotomies seems to be inferior to the one obtained by the adjustable cutting guide of Meyer et al. [46] In addition, additional (surface) scans and/or fiducial markers are needed for it to work.

Lastly one research group of Zhu et al. (2016) [49] took a first step to implement robotics into the surgical workflow of mandibular reconstruction. However, the developed robot cannot realize the osteotomies yet. It is currently focused to bring the fibula implant to the mandibular defect according to plan and hold it rigidly in position while the surgeon fixates it. To register the images to the patient seven titanium screws were inserted in the maxillofacial region. Registration of the navigation system to the robot was also executed by the point-based method. Their position was then tracked by a reference frame attached to the patient and the robot. Another four titanium screws were implanted in the fibula implant to register the implant to the navigation by probe pointing. With this method, Zhu et al. obtained a mean deviation of the fibula implant of 1.2 mm on phantoms and 1.8 mm on an animal. They argue that further development is needed for it to be able to perform the osteotomies of the fibula taking into account the vulnerable region it is in. In addition, the use of screws is not ideal to use for registration as this is an invasive measure for the patient. Non-invasive methods such as surface matching should be further developed which are simpler and also applicable in emergencies.

From these literature studies, it is evident that several research groups are searching for alternative ways to cut the fibula. However, not all qualify as a solution to our problem and none of the proposed methods have reached clinical use yet. Especially the navigational and the robotic methods seem to need quite some further developments in the ways of realizing a simple, practical, accurate and non-invasive registration method and in addition for the robotic use, a safe way to use the robot for performing the osteotomies in a vulnerable area. Concerning the universal guides, the MUG-jig shows the greatest potential for solving our problem, however this too shows weaknesses in particular concerning the accuracy of cutting larger angles and in its practical use as previously mentioned. Therefore, this project focusses onto a new design of our own with the aim to solve our problem and meet all of our requirements.

2.4 Stakeholders

In Table 1 the stakeholders for this project are listed. For every stakeholder the characteristics, the expectations and the resulting implications & conclusions for the project are defined. The latter will be used to set up some of the product's requirements.

Table 1: Stakeholders and their implication for the project

Stakeholders	Characteristics	Expectations	Implications & conclusions for the project
Patients	Undergoing the mandibular reconstruction surgery.	A successful mandibular reconstruction.	Solution needs to produce accurate osteotomies for a successful mandibular reconstruction.
Surgeons	Operating patients, high efficiency	Accurate, easy and fast to use solution	Solution needs to contain all of the listed expectations. Through conservativeness of surgeons, it won't be accepted otherwise.
Industry	Interested in innovative products at low production cost	Making profit	Cost-efficient solution
Instrument caretakers (operation assistant, sterilization caretakers)	Take the instruments apart, sterilize them, and build them back up	Solution that is easy to take apart and to sterilize. Few parts	Solution needs to be simple, have few parts and be sterilizable.
Insurance	Provides optimal care at low cost. Conservative towards new, unproven and more expensive developments.	Cheap solution (overall surgery costs do not go up), widely usable	Cost-efficient solution
Notified body	Controls the quality and safety of the product	A method that complies to the standard	Gives permission for placement on the market

2.5 Requirements

Following from sections 1.3 'Technical Medicine Problem' and 2.2 'Problem definition' our goal is to develop a universal fibula cutting guide. To be able to develop a successful product a list of requirements is made (Table 2). These requirements will guide the ideation phase; the product should satisfy all of these requirements to achieve the goal of this project.

Table 2: Product requirements

No.	Use Requirements	Importance (1=highest, 3 = lowest)	Value	Unit
1.1.	Enables cutting a fibula segment with a given roll rotation (figure 7 and 8)	1	[-55, +55]	Degree (°)
1.2.	Enables cutting a fibula segment with a given yaw rotation (figure 7 and 8)	1	[-55, +55]	Degree (°)
1.3.	Enables cutting a fibula segment with a certain length (figure 8)	1	>2	Cm
1.4.	Can alter the settings (angle and length) during surgery	1	Yes	None
1.5.	Can be used for every fibula	2	Yes	None
1.6.	Has the same or better accuracy than the currently used fibula cutting guides	1	Yes	None
1.7.	Does not hinder the surgeon	3	Yes	None
1.8.	Is easy to use	3	5	1 (No) – 5 (Yes)
1.9.	Product is applicable with current surgical saws	3	Yes	None
	Safety Requirements			
2.1.	Does not damage surrounding tissues	2	Yes	None
2.2.	Does not trigger adverse reactions to the bone or surrounding tissue	2	Yes	None
2.3.	Complies with medical regulations	1	Yes	None
	Durability Requirements			
3.1.	Is durable	2	Yes	None
3.2.	Is sterilizable	1	Yes	None
3.3.	Product has few components	3	<10	None
3.4.	Product is strong enough to withstand saw forces	1	Yes	None
	Time and Cost Requirements			
4.1.	Duration of use	3	< 30	Minutes
4.2.	Costs	3	< 3	1 (Low) – 3 (High)
4.3.	Ready for use	3	< 2	Years

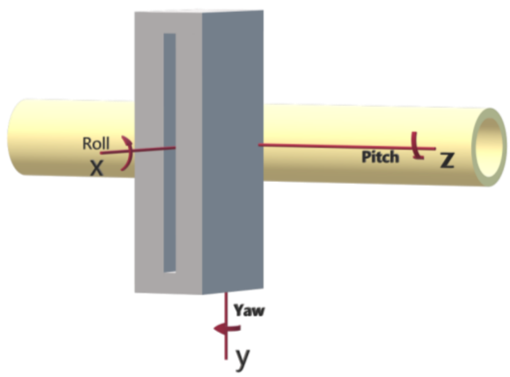


Figure 7: Rotation axes of the guide with respect to the fibula bone.

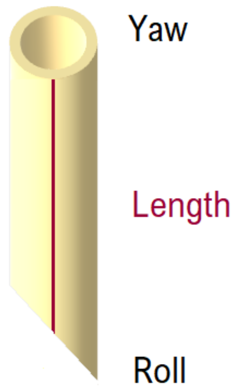


Figure 8: Example of roll angle in lower osteotomy and yaw angle in upper osteotomy. The segment length is illustrated in red.

2.6 Ideation

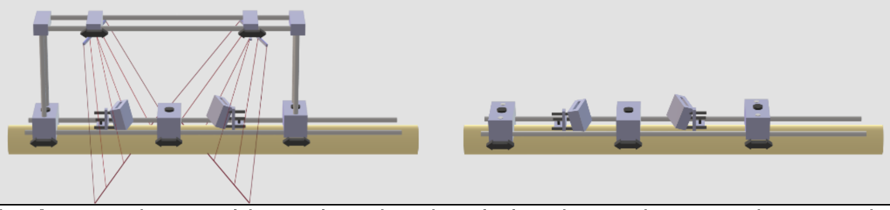
Having defined the problem, stakeholders and requirements for our product, the ideation phase can start. During this phase ideas were generated by a group brainstorm and using word/person/picture/principle stimuli cards. The brainstorm session was set up using principles from the 'Creative Platform' which is a method for a process for creative creation in groups developed at Aalborg University in Denmark. [50] After this brainstorm session, the most promising ideas for solving the most important function (how to cut the bone with specific angles and length) were selected and developed further into working concepts. Next, the best concept was chosen based on the previously defined requirements and the input of the surgeons. After this first round (ideation 1) where the concept had gotten its basic form and principle, the ideation phase for the remaining sub functions continued by following these steps (ideation 2):

1. Define main (remaining) function of the product
2. Create a morphological matrix with principles/concepts to accomplish this function
3. Choose a concept by weighing it to the requirements list and surgeons' opinion
4. Repeat

2.6.1 Ideation 1

The main function for our product is the ability to translate the osteotomy angles and segment lengths from the planning to the actual bone. The brainstorm session was meant to discover any method that would be able to do this. The most promising ideas were then selected and developed further into working concepts. Table 3 shows these concepts and the surgeons' preference. A more elaborate description of these concepts can be found in appendix A. In Table 4 the concepts are rated to the relevant requirements by a Technical Medicine student. The weigh factors are obtained by dividing one by the importance of a requirement (Table 2), such that the most important requirements (1) get a weigh factor of 1, the second most important requirements (2) get a weigh factor of 0.5, and the least important requirements (3) get a weigh factor of 0.33. Using both tables, the most promising concept could be selected.

Table 3: Concepts of techniques and the ranking of them according to the surgeons' preference

No.	Technique	Surgeons' rating (1 = best)
1.	**Self-guiding saw:** the saw is the guide. This can be realized by navigation or by instrument accessories. With the first concept, although guided, the surgeon would still saw in free air. The saw would be aligned by the surgeon with a virtual plane and the bone will be sawn. With the second concept, the saw is able to guide itself by instrument accessories. The saw for example contains a mechanism that holds the saw orthogonal to the bone after which certain yaw and roll angles can be accomplished by a bendable and rotatable saw tip. It may however be difficult to realize an orthogonal positioning due to the irregular surface of a fibula.	6
2.	**Standard guides with fixed angles:** For example, if an osteotomy with a roll of 5° and a yaw of 15° is to be made, a guide that supports these angles is taken. The guide can then be fixated onto the bone and be sawn through by a standard saw. A huge drawback is the numerous guides that are needed to enable cutting many different angle combinations.	4
3.	**Projection by laser or beamer:** the roll and yaw angles are projected onto the bone by a laser suspending from a framework that is attached to the bone. Two separate guides are matched to the lasers and fixed to the bone also. The upper framework can then be detached to make room to saw. By sawing through the guide slots, the correct osteotomies can be ensured. 	3
4.	**Robotics:** a robot would translate the virtual planning to the operating room by accomplishing the planned osteotomies. Although robotics may be the future of operating, huge drawbacks are foreseen in costs, safety and time until clinical implementation.	5
5.	**Navigation:** In this concept not the bone is registered but the guide itself as an exact location of the osteotomy plane on the fibula bone is not necessary. Only the segment length and osteotomy angles are to be translated accurately.	2

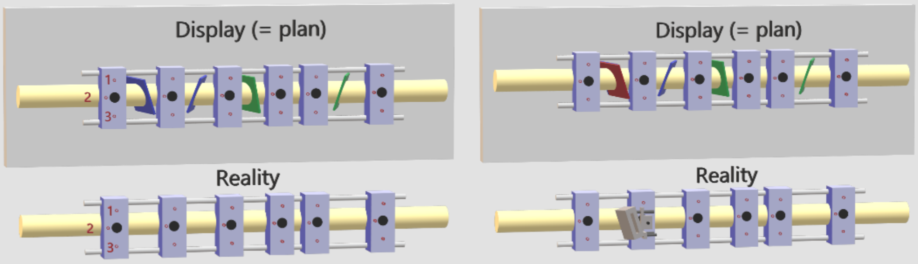
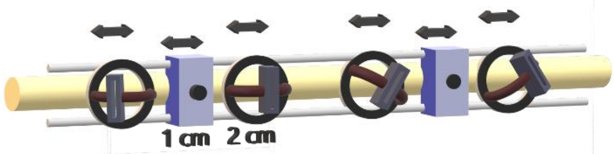
	Therefore, a special register guide is introduced. This guide is added to the preoperative planning. During the surgery, the actual register guide is set onto the fibula in the same way as was done in the planning (left figure). The guide is registered to the planning using a point match registration of the red fiducials on the guides. By EM sensors both on the register guide and onto a separate fibula cutting guide, the orientation of the cutting guide relative to the register guide (bone) is known. Using software that visualizes the cutting plane of the fibula cutting guide, the cutting guide can be matched to the cutting planes on the planning (right figure). 	
6.	**Manually adjustable frame/instrument:** an instrument that is fixated onto the fibula bone and contains cutting guides that can be slid over a rails to obey a certain segment length and be adjusted to accomplish given roll and yaw angles. 	1

Table 4: Rating of concepts to relevant requirements (all) on a scale from 1 (= very bad) to 5 (= very good)

Relevant requirements	Weigh factor	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
1.1	1.0	5	3	5	5	5	5
1.2	1.0	5	3	5	5	5	5
1.3	1.0	5	5	5	5	5	5
1.4	1.0	5	5	5	5	5	5
1.5	0.5	5	5	5	5	5	5
1.6	1.0	2	4	2	4	4	4
1.7	0.33	5	5	2	2	4	4
1.8	0.33	3	4	2	3	3	4
1.9	0.33	1	5	5	1	5	5
2.1	0.5	4	4	3	3	3	3
2.2	0.5	5	5	5	5	5	5
2.3	1.0						
3.1	0.5	5	5	5	5	5	5
3.2	1.0	5	5	3	4	4	5
3.3	0.33	5	1	3	2	3	4
3.4	1.0	5	5	5	5	5	5
4.1	0.33	4	5	2	4	3	4
4.2	0.33	4	2	2	1	4	5
4.3	0.33	3	5	2	1	3	5
Total weighted		49.83	48.50	45.00	46.67	50.33	53.33
Ranking		3	4	6	5	2	**1**

In both tables, concept 6 ranks first. Therefore, based on the surgeons' preference and the potential to fulfill all requirements best, the concept of a manually adjustable frame/instrument is chosen.

2.6.2 Ideation 2

While having chosen a manually adjustable frame/instrument as the principle technique, many options are available to fulfill the main function. The main function was previously denoted as the ability to translate the osteotomy angles and segment lengths from the planning to the actual bone. However, due to the choice of the adjustable frame another crucial function is added in this ideation phase, namely fixation of the instrument to the bone. By breaking down the first function into two, there are three functions for which ideation will take place:

- Fixation of the instrument to the bone
- Movement of the instrument/guide along the bone to accomplish the segment length
- Rotation of the instrument/guide to accomplish yaw and roll cuts

These functions are merely technical and therefore a choice is made based on the list of relevant requirements only. The best choice was then demonstrated to the surgeons who could offer a last say in the form of approval or rejection. If rejected, the second best concept was demonstrated to the surgeons.

Fixation of the instrument to the bone

Table 5 shows the concepts for the fixation of the instrument to the fibula bone. And Table 6 shows the rating of the concepts to the relevant requirements.

Table 5: Fixation technique concepts for the manually adjustable frame

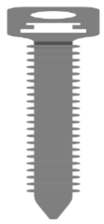
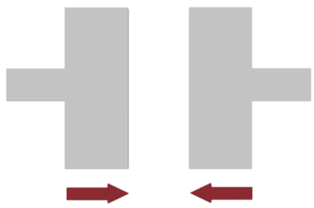
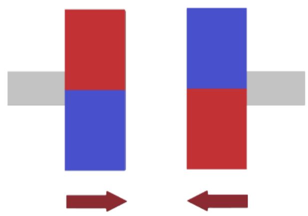
	1.Screws	2. Clamps	3. Magnets
Fixation technique - Concepts			

Table 6: Rating of concepts to relevant requirements on a scale from 1 (= very bad) to 5 (= very good)

Relevant requirements	Weigh factor	Concept 1	Concept 2	Concept 3
1.5	0.5	5	5	5
1.7	0.33	5	3	2
1.8	0.33	4	4	4
2.1	0.5	3	1	1
2.2	0.5	4	4	4
3.1	0.5	1	3	5
3.3	0.33	2	5	5
3.4	1.0	5	4	3
4.1	0.33	4	5	5
4.2	0.33	3	5	5
4.3	0.33	5	4	4
Total weighted		19.09	19.08	18,75
Ranking		**1**	2	3
Surgeon		**Approved**		

Based on Table 6 screws were chosen to fixate the instrument to the bone. This is also the technique that is currently used to fixate the 3D printed cutting guides to the bone. It offers great fixation without damaging surrounding tissues. While operating, the fibula bone offers only one side that is free of tissue. Therefore, clamps or magnets (also functioning as clamps) would damage the surrounding tissue too much as they operate on two sides. The surgeons were therefore in accordance with the ranking.

Movement of the instrument/guide along the bone

Table 7 shows concepts for the movement of the guide along the fibula bone and Table 8 shows the rating of the concepts to the relevant requirements.

Table 7: Movement technique concepts for the manually adjustable frame

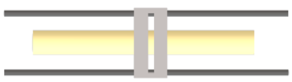
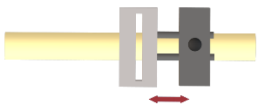
Movement along the bone technique - Concepts	1.Slide over any kind of rails	2. Fix at one point, but have an outward sliding mechanism (similar to the guide designed by the study group of Weitz et al. (2018) [45]	3. Don't slide, but place on different locations each time
			

Table 8: Rating of concepts to relevant requirements on a scale from 1 (= very bad) to 5 (=very good)

Relevant requirements	Weigh factor	Concept 1	Concept 2	Concept 3
1.3	1.0	5	3	5
1.4	1.0	5	4	5
1.5	0.5	4	4	4
1.7	0.33	3	3	3
1.8	0.33	5	4	4
3.1	0.5	4	4	4
4.1	0.33	5	4	5
4.2	0.33	5	5	5
4.3	0.33	5	5	5
Total weighted		21.59	17.93	21.26
Ranking		**1**	3	2
Surgeon		**Approved**		

Based on Table 8 the concept of sliding over any kind of rails to move along the bone is the best choice. The surgeons approved this concept. The second concept would not offer enough freedom of movability and the third concept was thought to be less practical in use than the first.

Rotation of the instrument/guide to accomplish yaw and roll cuts

Lastly, table 9 shows concepts for the rotation of the guide and Table 10 shows the rating of the concepts to the relevant requirements.

Table 9: Rotation technique concepts for the manually adjustable frame

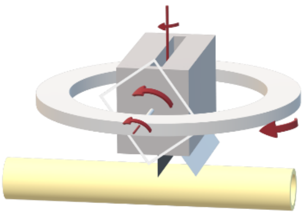
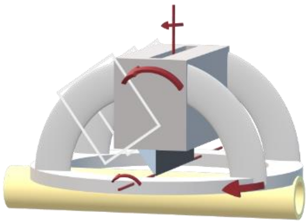
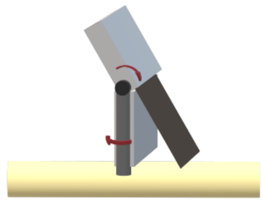
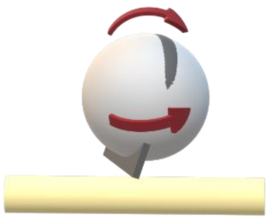
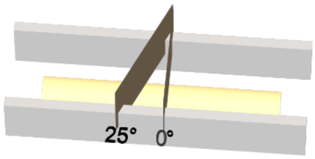
Rotation technique - Concepts	1.Rotation around its own axes for roll and yaw angles	2. Rotation around its own axis for roll angle and around an axis positioned on the fibula surface for yaw angle	3. Hinges for roll and yaw angle. Rotation around the hinges' axes
			
	4. Use a ball	5. Place between grooves	
			

Table 10: Rating of concepts to relevant requirements on a scale from 1 (=very bad) to 5 (=very good)

Relevant requirements	Weigh factor	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
1.1	1.0	5	5	5	5	2
1.2	1.0	5	5	5	5	2
1.3	1.0	2	5	2	2	2
1.4	1.0	4	5	4	4	3
1.5	0.5	4	4	4	4	4
1.7	0.33	4	4	4	3	3
1.8	0.33	3	5	3	3	3
1.9	0.33	5	5	5	5	5
3.1	0.5	4	4	4	4	4
3.4	1.0	4	4	4	4	4
4.1	0.33	3	5	3	3	3
4.2	0.33	5	5	5	5	5
4.3	0.33	5	5	5	5	5
Total weighted		32.25	37.57	32.25	31.92	24.92
Ranking		2	**1**	2	3	4
Surgeon			**Approved**			

Based on Table 10 the concept of rotation around the guide's own axis for the roll angle and around an axis positioned on the fibula surface for the yaw angle, is the best choice. Requirement 1.3 'Enables cutting a fibula segment with a certain length' is maximally fulfilled with concept 2 only. This has a huge influence on the total amount of points, since this is a crucial function for the product to have. The surgeons were also aware of this crucial ability. Therefore, concept 2 got their approval.

2.7 Prototype 1

With the most important functions secured with valid concepts, a first prototype was made using the Formlabs stereolithography (SLA) Form 3 3D printer and the Formlabs Grey Pro Resin. The prototype is shown in figure 9. Every component is 3D printed except for the two metal rods, the ruler and all the screws. The guidance element moves over the two rods, with at each end a stop block (figure 9 A and 9 B). These blocks keep the rods at equal distance to each other and prevent detachment of the guidance element. Furthermore, the rods contain several small blocks (fixation blocks) in between which can slide along the rods and have the function to fixate the instrument to the bone. This can be done by applying screws through the blocks into the bone. By fixating the fixation blocks at strategic locations on the bone, i.e. one fixation block before each cut and one fixation block after each cut, it is possible to saw the bone through without destabilizing the instrument or the bone. In addition to the fixation blocks, the guidance element can slide along the rods as well. By use of a sickle shaped sliding concept for both the fixation blocks and the base block and by using a larger block dimension for the latter, both components can slide past each other (figure 9 C). This ensures that the fixation blocks never hinder the surgeon and the guide can be set to cut at any arbitrary location on the bone. Fixation of the base block is done by screws pressing at the side of the rods (figure 9 C). Onto the base block there is a ring attached. This ring can rotate around a midpoint axis, ensuring the roll rotation. Onto the ring there are two arches holding the guide. By sliding the guide over the arches the yaw rotation is ensured. Note that the arches are part of two imaginary circles with their midpoint at the height of the fibula surface. Therefore, by sliding the guide to any yaw rotation angle the contact point of the saw onto the fibula surface does not change (figure 10). This is very important for determining the length of the segments. By this concept, the saw location is always in the middle of the guidance element, enabling the use of a ruler attached alongside the rods to measure the length. Lastly, the guide slot is only 0.5 cm deep. While this lessens the ability to guide the saw due to less stability, it is necessary to fulfill requirement 1.9 ‘Product is applicable with current surgical saws’, as the current surgical saws have limited blade length.

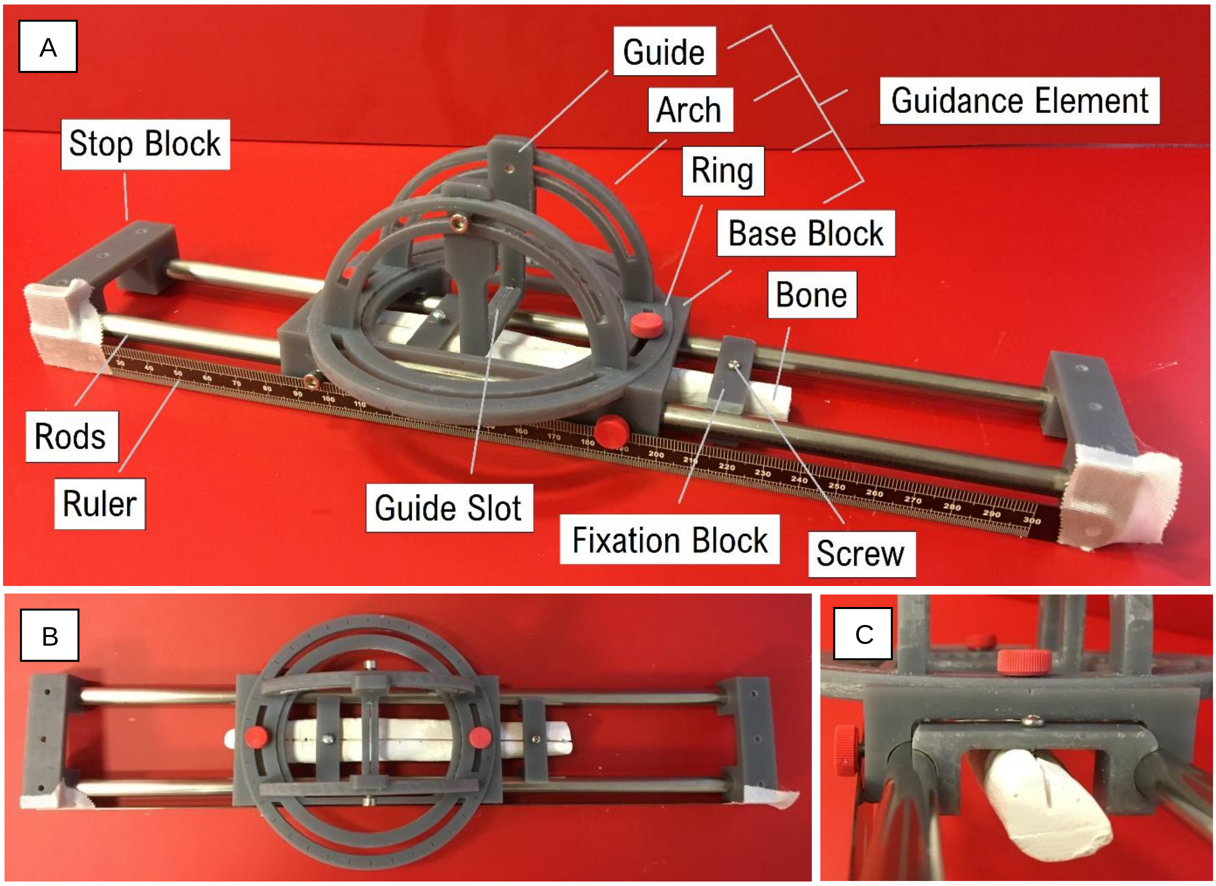


Figure 9: Prototype 1. A) Overview of prototype 1 including names of components. B) Top view of prototype 1. C) Zoomed image of sickle shaped sliding concept and base block fixation.

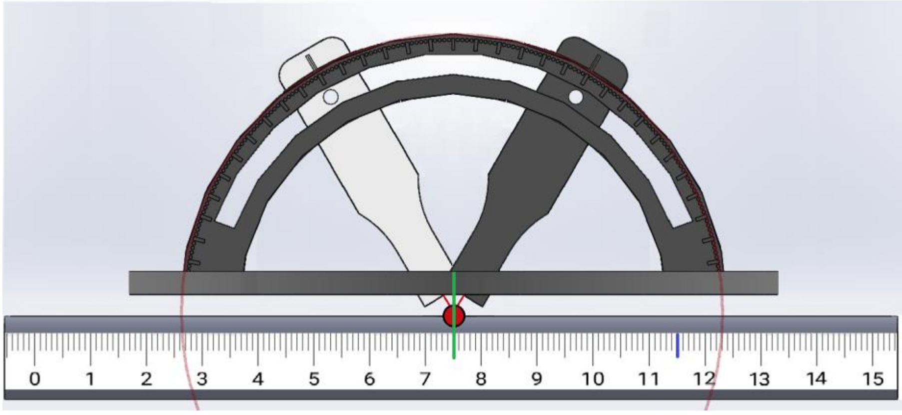


Figure 10: Schematic side view showing the principle of the yaw rotation. The arch is part of an imaginary circle with its midpoint at the surface of the bone. By sliding the guide over the arches and thus adjusting the yaw angle, the cutting position remains fixed and can be read from the ruler.

2.7.1 Findings prototype 1

Although the prototype could eventually be assembled, it took a lot of work to accomplish this. The 3D printed components from the Formlabs Form 3 with the Grey Pro Resin were not accurate enough. The dimensions did not comply with the design drawings and the shapes were not correct. Based on these findings, it was decided to print a second prototype using a corporation 3D printer that uses the selective laser sintering (SLS) technology. The corporation material polyamide 12 powder (PA12) was chosen for the 3D print.

2.8 Prototype 2

Prototype 2 had exactly the same design as the first prototype except for two changes, namely:

A) The guide supporting arms were widened, such that it would have more surface contact with the arches and hence more stability when moving (figure 11 A).
B) The base block was lengthened to allow replacement of the fixation screws from the side to the top. This provided the space needed for the ruler to be properly aligned (figure 11 A, and B).

The complete prototype 2 is shown in figure 12.

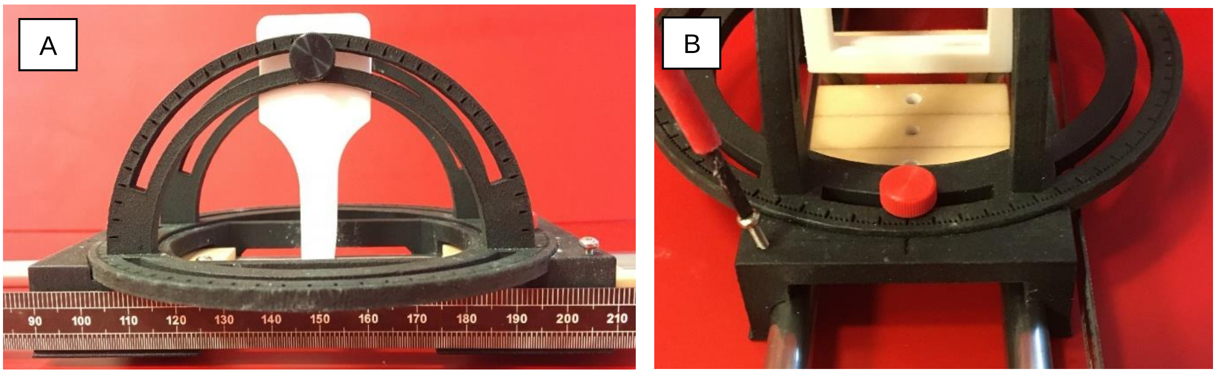


Figure 11: Prototype 2 upgrades. A) widened supporting arms of the guide and lengthening of base block to allow both replacement of fixation screws from side to top and proper aligning of the ruler. B) lengthening of base block to allow replacement of fixation screws from side to top.

2.8.1 Findings prototype 2

The 3D printed components of the second prototype printed from PA12 powder using a corporation SLS 3D printer were accurate and could be assembled into a working prototype easily. This allowed a more extensive assessment of the cutting guide. Everything could move without effort or faltering. The upgrade to use widened supporting arms of the guide was a success as this gave more stability and allowed a smooth sliding movement along the arches. The upgrade to lengthen the base block to allow the fixation screws to be placed in a diagonal way from the top to the bottom instead of horizontally on the side, showed to be ineffective. It did allow room for the ruler to be properly placed, however by

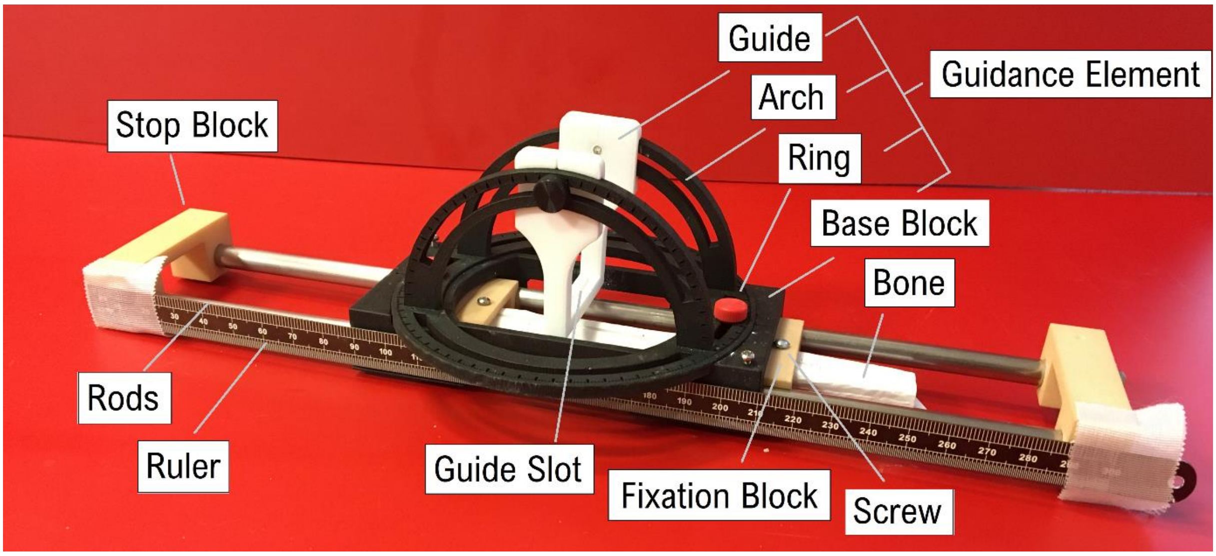


Figure 12: Overview of prototype 2 including names of components

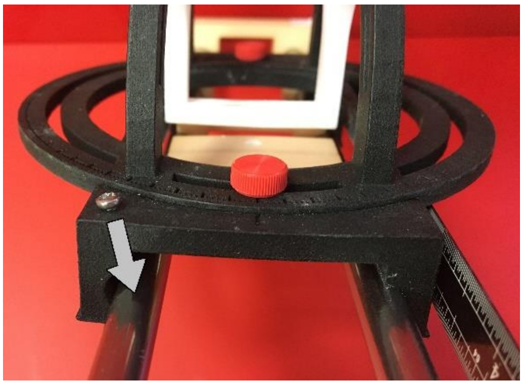


Figure 13: The base block fixation screw pushes the rod inwards.

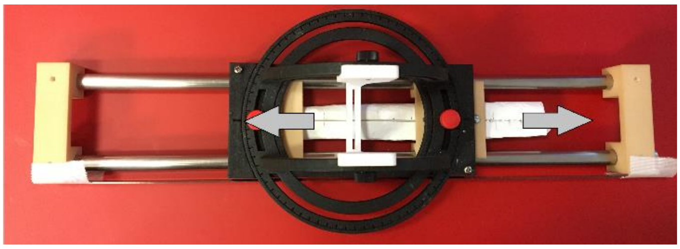


Figure 14: The fixation blocks can freely move with respect to the guidance element. The fixation blocks have no ability to be fixed at a particular location on the rods. Hence these blocks with the bone fixated to it can freely slide along the rods.

placing the fixation screws this way, instead of fixating the base block onto the rods, the screws pushed the rods inwards (figure 13). In addition to this fixation problem, another fixation problem was encountered. The fibula is fixated to the small fixation blocks, however the fixation blocks themselves are not fixated to the rods and can therefore still freely move with respect to the guidance element (figure 14). This severely affects the cutting precision in particular the segment length. This was not encountered in the previous prototype as in that prototype all movement was hard to achieve. These two fixation problems needed to be fixed before the guide's precision could be assessed.

Looking ahead it was also noticed that the measurement scale on the arches was not visible if the fixation screw was present (see also figure 11 A). In addition, no marker place was yet designed to read of the length measurement of the ruler. And the ruler itself could be poorly fixed along the rods using tape. Furthermore, when trying to cut a few things, we stumbled on the fact that the guide was resting on the ground/table. To be able to saw through a fibula you'd cut into the ground/table. Therefore, it was decided to heighten the two outer stop blocks, such that there is room to saw through the object without touching the ground. In addition, the space between the rods was to be increased to create more room to saw at the side of the fibula as well. Lastly, it was decided to improve the ability to cut a segment with a particular length by enabling horizontal movement of the guidance element over the fibula. This movement is necessary when curved fibulas are to be cut. The explanation is illustrated in figure 15. First consider a straight fibula. Suppose the planner decided to fill a defect as seen in a 2D representation in figure A2. The segment is originated from the fibula seen in figure A1. The length of the segment is defined as the segment's central axis placed on the surface of the segment. The segment length is thus independent from the segment angles and will not change upon angle deviations. While this is a 2D representation, this holds in 3D too. Translation of this length to the fibula guide is straightforward. The fibula is fixated to the guide with the central axis of the fibula positioned along the central axis of the guide (figure B1). The latter is also the axis over which the guidance slot moves. These two axes coincide and so the segment length can be copied effortlessly (figure B2). Now suppose a situation for which the fibula is slightly curved. The defect is filled as shown in fig C2. The planning is illustrated in figure C1. The central axis runs from the starting point of the fibula at the top to the endpoint of the fibula at the bottom. Because the fibula is curved, the central axis deviates in the middle part from the midpoint of the fibula at that location. The green line represents the length of the fibula as measured from the midpoints in the defect. It is however very difficult to translate this length to the guide, as the guide can only measure along its central axis. To align the fibula segment axis to the central axis would be very difficult. In addition, if multiple segments were to be cut, the fibula should be aligned separately each time. This is not time efficient or accurate. Therefore, instead of the length measured from midpoint to midpoint along the fibula's segment axis, a length measured from midpoint to midpoint along the central axis is used (the red dashed line in figure C1). This can then be translated in a straightforward manner to the guide as seen in figure D1. The positioning of the guidance slot is measured the same way as in B1. However, before the actual cut is made, now the slot is moved horizontally over the fibula to be positioned over the fibula's midpoint at that location. This ensures the correct segment length. Important with this concept are the start- and endpoints of the planned fibula, as these are the fixation points in the guide. Only when the location of these points are duplicated and the central axis of the planning and guide coincide, the segments can be exactly mimicked, i.e. the central axis along the fibula in C1 should be the same as in D1. To accomplish this, the start- and endpoints of the planned fibula may be specifically defined. For example the starting point may be 5 cm from the ankle joint and the endpoint 5 cm from the knee joint. What happens if despite the correct start- and endpoints, a positional cutting deviation occurs? This is illustrated in figure E. The same segment is now cut from a location lower on the fibula. Because not the actual length (green line) is used, but the length along the central axis, a small deviation will occur depending on how much the fibula orientation deviates at this location. If the orientation is similar, as is the case in this example, this deviation is negligible as can be seen in figure E2. If we were to omit the horizontal movement of the guide and take the length at the central axis, the deviation will be much larger. This is illustrated in figure F. Being able to align the guide over the center of the fibula before cutting is thus important.

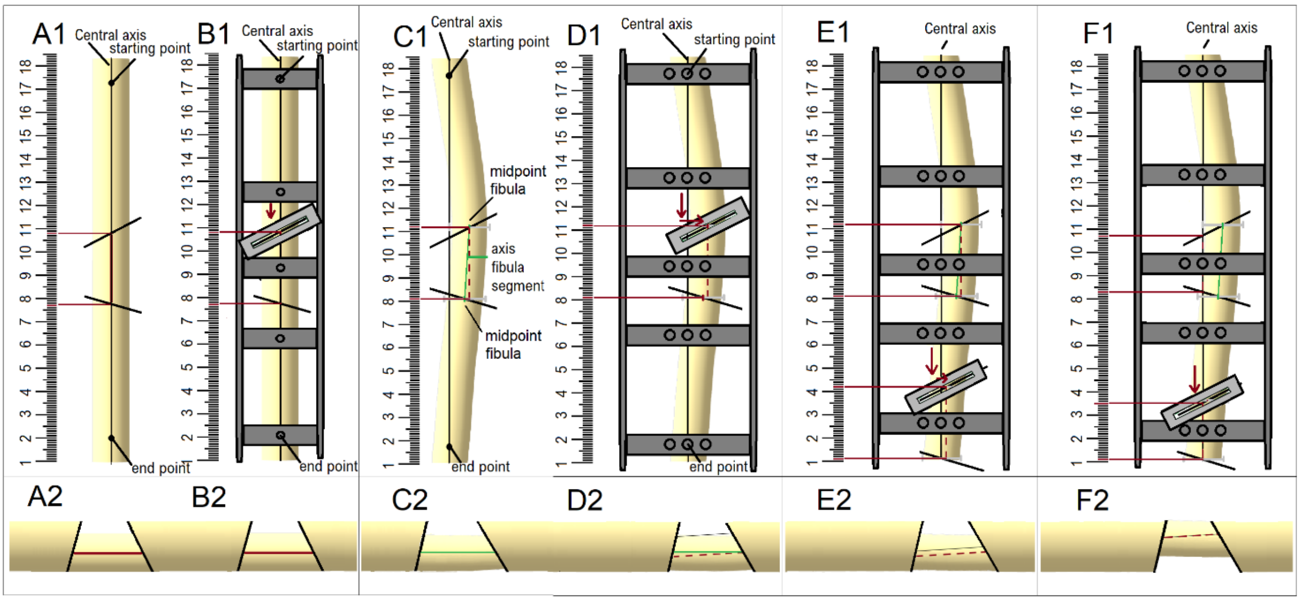


Figure 15: Segment length definition. A1 shows a segment planning in a straight fibula. A2 shows the segment planning in the defect. B1 shows the segment planning translated to the fibula guide. B2 shows the segment of B1 in the defect. C1, C2, D1, D2 show the same as A1, A2, B1, B2 respectively except a curved fibula is used instead of a straight fibula. Green line represents the segment length as measured from the midpoints in the defect in C2. The dashed red line is the length used for segment planning. It runs from the same midpoints as the green measured length, but runs along the central axis of the fibula as positioned in C1. This length is used for translation to the guide. E1 shows the way a planned segment in the middle can be cut at a different location with the segment length defined as in C1. E2. Shows the result of the segment cut at the lower portion of E1. F1 shows the way a planned segment in the middle can be cut at a different location with the segment length defined as the length along the midline axis. F2 shows the result of the segment cut at the lower portion of F1.

2.9 Final product design

Following the previous remarks, the final product design had a few upgrades compared to prototype 2. Figure 16 A-E display the upgrades I-VI.

- I Fixation clips were designed along the rods on the stop blocks and the base block, such that the ruler could be properly applied on the side of the guide (fig. 16A).
- II A marker was placed on the base block to read off the length measurement of the ruler (fig.16B).
- III The two outer stop blocks were heightened, such that cutting through an object was facilitated without touching a ground surface (fig. 16A).
- IV All blocks were widened, allowing the rods to lay further apart from each other (fig. 16C).
- V To tackle the two fixation problems, a few changes were made, including customization of the rods:
  - i. The base block got an upgrade in the way it slides along the rods. Instead of using a sickle shaped concept in which both the base block and the fixation blocks got 50% coverage of the rod, the base block was now given a 80% coverage of the rod. This prevents the rods from shifting inwards when trying to fixate the base block onto the rods by pushing screws onto them. By taking this concept the fixation can be easily done from above by screws pushing against the rods (fig. 16D).
  - ii. By giving the base block 80% coverage of the rod, the small fixation blocks now only have a 20% coverage of the rod left. This is insufficient for sliding the fixation blocks along the rods and keeping its position. Therefore, it was decided to use the 20% coverage to let the fixation blocks slide inside the rods. The rods were given a groove in which the fixation blocks could slide (fig. 16D). In addition, a few holes were drilled into the rods, such that the fixation blocks could be fixated to the rods by drilling screws from the side onto the surface of the fixation block inside the rods (fig. 16E).
- VI The ring was redesigned to allow horizontal movement with respect to its base block (fig.16C).
- VII A measurement device to measure the center of the surface ('Middefiner') was designed to be able to properly set the guide over the center of a curved fibula through the horizontal movement. The principle of this device is discussed in the next paragraph.

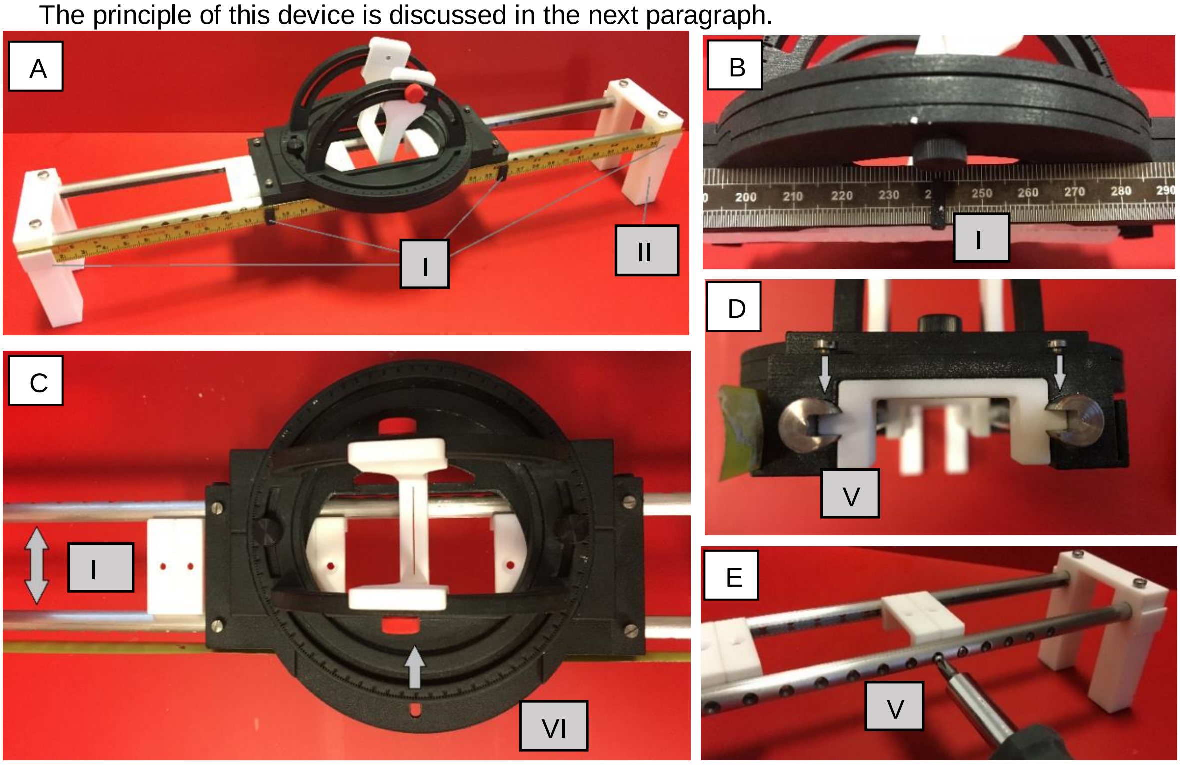


Figure 16: Overview of the upgrades in the final product design. A) Upgrade I shows the fixation clips. Upgrade III shows the heightening of the stop blocks. B) Upgrade II shows a marker to read off the length measurements. C) Upgrade IV shows the widening of all blocks. Upgrade VI shows the horizontal movement of the ring. D) Upgrade V shows the upgraded sliding mechanism and the fixation of the base block to the rods by screws pushing against the rods from above. E) Upgrade V shows the adjusted rods to enable fixation of the fixation

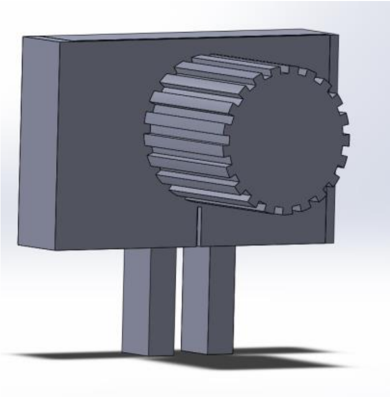


Figure 17: The 'Middefiner' (outside)

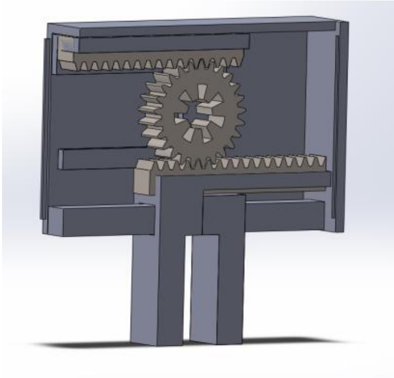


Figure 18: The 'Middefiner' (inside)

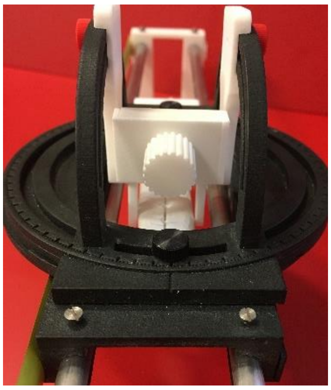


Figure 19: The 'Middefiner' is able to grab the bone with both bars, and thus centering itself and the guide over the bone.

The 'Middefiner'

The 'Middefiner' consists of a box containing the gears, two small bars that allow 'grabbing' the irregular object and a turning knob with which the two bars can be moved outwards or inwards (figure 17). The working mechanism consists of one spur gear and two rack spurs, which are each fixated to a bar (figure 18). By turning the knob the spur gear turns and the two rack spurs in turn start sliding to the left and right. This ensures synchronous movement of the two bars, allowing the device to be always centered over the 'grabbed' object. By applying this 'Middefiner' onto the guide, it is possible to center the guide over the irregular surface. This is shown in figure 19. The ring has moved slightly horizontally allowing the 'Middefiner' to 'grab' the bone with both bars, and thus centering itself and the guide over the middle of the bone.

Photos to clarify the use of the final product design including the 'Middefiner' can be found in appendix B. Blueprints of the guide can be found in appendix C.

2.9.1 Findings Final product design

The second prototype from the SLS 3D printer was again accurate and could be well assembled into a working prototype. The new sliding mechanism and fixation concept of the base block and the fixation blocks were successful. Everything could move very well and fixation gave no problems. Also the horizontal movement was a success, and the 'Middefiner' could define the center well. In addition, the fixation clips and marker for the ruler fulfilled their purpose and also the adjustment of the wideness of the blocks and height of the stop blocks turned out very well.

Despite the good efforts, one design error was noticed however. The rotation axis of the two arches did no longer lay on the surface of the to be sawn object. The new development which enabled the guide to make the horizontal movement relative to the base block, caused the ring and arches to lay slightly higher up on the base block, namely 9.9 mm. It was simply overlooked to reposition the rotation axis of the arches back onto the surface of the to be sawn object. This error causes the guide to not be able to saw the planned segment length. A certain yaw angle would cause the cut to be misaligned from the prospected cut location (figure 20). For now, it is possible however to calculate the prospected deviation by using Pythagoras, but this is far from practical. Fortunately, the error is easily solvable in the next prototype.

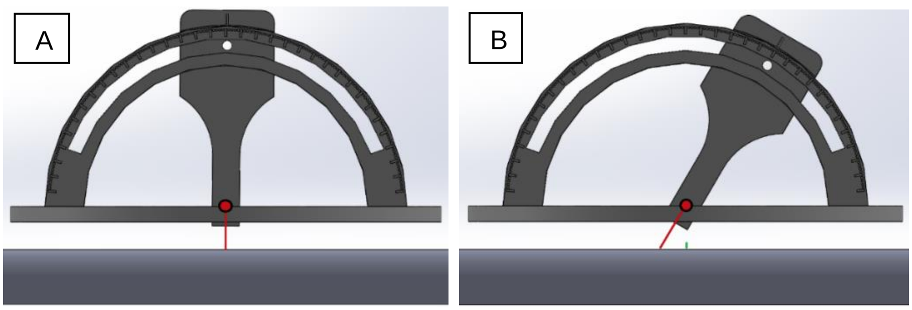


Figure 20: Yaw rotation causing a different cutting location on the phantom due to a wrongly placed rotation point. Knowing the height and angle of rotation, this displacement can be calculated.

Requirement fulfillment with final product design

Table 11 shows the requirement fulfillment with this final concept. It should be noted that this product is not yet finished. For each requirement a short explanation is given on how the requirement is fulfilled and if not, whether the requirement is still thought to be achievable or not.

Table 11: Prototype requirement check

No.	Use Requirements	Importance (1=highest, 3 = lowest)	Value	Unit	Requirement fulfilled?
1.1.	Enables cutting a fibula segment with a certain roll rotation (figure 7 and 8)	1	[-55, +55]	Degree (°)	Yes
1.2.	Enables cutting a fibula segment with a certain yaw rotation (figure 7 and 8)	1	[-55, +55]	Degree (°)	Yes
1.3.	Enables cutting a fibula segment with a certain length (figure 8)	1	>2	Cm	Not fully
1.4.	Can alter the settings (angle and length) during surgery	1	Yes	None	Yes
1.5.	Can be used for every fibula	2	Yes	None	Yes
1.6.	Has the same or better accuracy than the currently used fibula cutting guides	1	Yes	None	Not enough information yet
1.7.	Does not hinder the surgeon	3	Yes	None	Not enough information yet
1.8.	Is easy to use	3	5	1 (No) – 5 (Yes)	3
1.9.	Product is applicable with current surgical saws	3	Yes	None	Yes
	Safety Requirements				
2.1.	Does not damage surrounding tissues	2	Yes	None	Not enough information yet
2.2.	Does not trigger adverse reactions to the bone or surrounding tissue	2	Yes	None	Not expected
2.3.	Complies with medical regulations	1	Yes	None	Not enough information yet
	Durability Requirements				
3.1.	Is durable	2	Yes	None	Not enough information yet
3.2.	Is sterilizable (can be taken apart)	1	Yes	None	Not enough information yet
3.3.	Product has few components	3	<10	None	Yes
3.4.	Product is strong enough to withstand saw forces	1	Yes	None	Yes
	Time and Cost Requirements				
4.1.	Operational use	3	< 30	Minutes	Not enough information yet
4.2.	Costs	3	< 3	1 (Low) – 3 (High)	Yes
4.3.	Ready for use	3	< 2	Years	Yes

1.1 The ring enables 360° roll rotation of the guide
1.2 The arches enable sufficient yaw rotation of the guide
1.3 By repositioning the rotation point of the arches, accurate segment length determination will again be possible. The osteotomy position will then not move when changing yaw rotation.
1.4 The guide is fully adjustable. Roll and yaw rotation can be adjusted and by moving the guide along the rails, the segment length can be determined.
1.5 Any kind of bone (fibula or other bones) that is fairly straight can be fixated to the guide.
1.6 This will be evaluated in the next chapter

1.7 Although it is expected the instrument will not hinder the surgeon while doing surgery, it has not yet been properly investigated since only phantoms have been used to test the instrument (next chapter).
1.8 By optimizing the fixation knobs and scale readability, the practical handling is expected to become better.
1.9 The surgical saws have limited blade length. By creating a guide that is only 0.5 cm deep, the guide is applicable with the currently used surgical blades.
2.1 Although this has not yet been properly investigated, it is thought the instrument will not damage surrounding tissues. The basis of fixating the instrument to the bone is very similar to the fixation of the currently used cutting guides to the bone, hence no difficulties are expected.
2.2 This has not been investigated yet. For now it is 3D printed from PA12. However, for a final design other materials will be used to create the instrument. It will be made sure these materials are biocompatible.
2.3 This is not yet evaluated, as the product is not yet finished. It is expected however that the finished product will be able to comply with medical regulations.
3.1 This is not yet evaluated, as the product is not yet finished. For now it is 3D printed which results in a product that is not very durable, however a future design could be made with more durable materials.
3.2 For now, all parts can be easily taken apart and it is thought to be sterilizable. However, this is not yet investigated as the product is not yet finished.
3.3 The product has two rods, two stop blocks, a variable amount of fixation blocks, two base components, and one guide. Depending on the amount of fixation blocks used, the product meets the requirement of less than 10 components.
3.4 This is not yet evaluated, as the product is not yet finished. If durable and more stronger materials are used in the future design, it is expected to be strong enough to withstand the forces the vibrating surgical saw produces. For now, the product is strong enough to withstand the forces of a small hand saw.
4.1 Operational use is not yet evaluated. However, using the guide on phantoms the segment was obtained in 5-10 minutes. In surgical setting this time may be longer due to caretaking of surrounding tissues and limited space. Nevertheless, the handling time is expected to stay within 30 minutes. In addition, the current prototype is kept simple focusing more on the working principle instead of its practical use. Every fixation needs to be executed by fastening screws. This takes time. A ratchet principle for the angle and length adjustments or the use of clips onto the guide could speed up the adjustment preparation. These more advanced fixation principles are however not yet applied.
4.2: Costs are expected to be relatively low. The purchase of it may be high depending on the materials used and the advanced fixations mechanisms that may still be added. However, this expense is only needed once.
4.3: The guide shows great potential already, and is easy to develop further. In addition, because of the lack of technology it may be introduced to the clinical setting fairly fast.

2.10 Future improvements

Although the product is not yet fully tested (which will be done in the next chapter) there are already a few things that come to light when working with the product. These aspects, concerning the product's design, should be improved in the next version.

First of all, the fixation blocks on which the object is fixated could be altered. These blocks have a straight surface and are evidently all at the same height. Fibula's however do not have a straight surface. In fact, they could be crooked. For example, the middle part could be thicker than the start or end part. When trying to fixate a crooked fibula on straight blocks at the same height, the thinner end parts will be pulled up, while the thick middle part cannot move along with them. This part is already stuck at the surface. The upwards pulling of the end parts will exert a large force on the middle part leading to possible fractures. Giving the blocks a fixed shape is not an option, as the fibula surfaces vary extensively. However, appliance of cushions under the fixation blocks could solve this problem. At locations for which the fibula is thicker, the cushions will be suppressed more, and at locations at which the fibula is thinner, the cushions will be suppressed less, leaving the fibula in equilibrium.

In addition, it is difficult to read off the scales and setting the guide to the appropriate angles and length measurements. It was noted that the angle scale on the arches to adjust the yaw rotation was covered up by the screw when fixating the guide at a particular angle. Therefore, if the guide moves when trying to fixate at the appropriate angle, this movement is missed leaving a deviation in angle set up. This can be easily solved by widening the arches, such that the fixation screw is not covering up the scale. However, even then setting up the guide to the angles and length measurement could be inaccurate. Multiple scales, one for larger angle steps and one for smaller angle steps could help the accuracy. Making the scales digital and hence the adjustments digital could improve the accuracy even more. Another approach could be to make the angle adjustments by a ratchet mechanism. This way, there is limited freedom in between degrees and millimeter settings and the adjustment of the guide to the particular orientation can be carried out faster.

Furthermore, the Middefiner is still a separate measurement device. This makes its use far less practical and maybe less accurate as well than when it would be implicated in the fibula guide itself.

Moreover, use of harder materials could improve the accuracy of the fibula guide. Using the PA12 as material, it was noted that the small saw could widen the sawing slot in the guide by sawing through the material, leaving more room for the saw to move. In addition, pressing the saw against a side of the guidance slot could bend the guidance slot slightly, again leaving more room for the saw to move. Creating a guide from metal, would solve both these problems.

Lastly, some surgeons mentioned it would be practical to create a slot at the bottom of the base block through which a small plate could be inserted. This plate would come to lay between the bottom of the fibula and the vascular pedicle. This protects the pedicle from accidental sawing through when cutting the fibula bone.

Although these changes, could make the cutting guide function better, it was decided to test its accuracy first. The results of the phantom test can be read in the next chapter.

Chapter 3: Analysis of the universal fibula guide

3.1 Introduction

In this chapter, the newly designed universal fibula cutting guide is assessed on angle and segment length conversion accuracy using phantoms and compared to the current 3D printed fibula cutting guides.

3.1.2 Cutting guide design notion

Notion must be made that due to a design error, the rotation axis of the yaw rotation was misplaced. The rotation axis should lay on the phantom's surface to ensure positional accuracy, but instead it laid 9.9 mm higher. Although this has no consequences for the yaw angle itself, rotating the guide to a different angle will cause the saw to end up at a different location on the phantom and hence introduce segment length deviations (figure 21). To get useful data on the segment lengths the deviation was calculated by the following formula:

$$\text{positional deviation [mm]} = 9.9 \tan(yaw\ angle)\ \ [mm] \tag{1}$$

To obtain the expected segment length the calculated deviation was added or subtracted from the initial planned segment length depending on the direction of the angle.

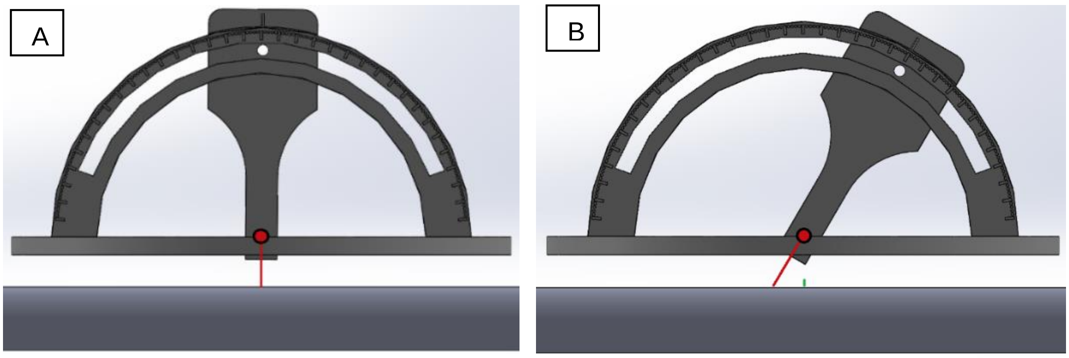


Figure 21: Yaw rotation causing a different cutting location on the phantom due to a wrongly placed rotation axis. Knowing the height and angle of rotation, this displacement can be calculated.

3.2 Methods

In this study two phantom tests are executed. The first one is executed on 15 cm long plaster cylinders of 14 mm in diameter. The goal of this first test was to evaluate the cutting guide's accuracy in the most ideal setting possible. The second test is executed on 15 cm long plaster fibulas. The goal of this test was to approach the clinical setting and evaluate its accuracy in this setting. The cutting on actual fibula phantoms also enabled a comparison in accuracy between the new cutting guide and the currently used cutting guides.

3.2.1 Phantoms

The first step in obtaining a plaster fibula phantom was to acquire a segmented fibula in a CT image. Next, the resulting 3D mesh of the fibula was loaded in MATLAB R2019b (The MathWorks Inc., Natick, USA) and reoriented by aligning it to the z-axis. Subsequently, this reoriented fibula segmentation was loaded into Meshmixer (Autodesk, Inc., http://meshmixer.com), where the lower 7 cm was removed. In addition, a certain length from the top was removed to make the fibula 15 cm long. Lastly, the now shortened fibula was loaded into SolidWorks in which the fibula was given a vertical groove of 0.8 mm wide, which due to the former reorientation lies parallel to the z-axis. This groove will be of severe importance during analysis of the segments. Finally, a rectangular mold was designed around the fibula. The mold was then printed on the Formlabs SLA Form 2 3D printer using the Formlabs Flexible Resin. Due to the dimensions of this printer, the fibula mold could be no longer than approximately 15 cm. The final step in obtaining the plaster fibula's was to pour plaster into the mold and letting it harden for 2 hours. With this mold 11 fibula's were created.

The plaster cylinders were obtained in a similar way. SolidWorks was used to design the cylinder which had a length of 15 cm, a diameter of 14 mm and a vertical groove right over the mid-axis of the cylinder of 0.8 mm wide and 6 mm deep. A rectangular mold was designed around the cylinder and 3D printed the same way as was done for the fibula mold. Plaster was poured into the mold and after letting it harden for 2 hours, a cylinder was obtained. With this mold 10 cylinders were created.

3.2.2 3D model planning

From each plaster phantom a 3D scan was made using the 3Shape TRIOS 3 Basic intraoral scanner. To aid the 3D scanner with shape and surface recognition lines were carved into the surfaces of the plaster objects and signs were drawn onto it.

Reorientation

Each 3D scan was loaded as STL file into MATLAB after which the 3D model of the cylinder/fibula was reoriented first. Reorientation is important for correct angle and length analysis later on. The angles are defined by its rotation with respect to the x-, y-, and z-axes (Euler angles). The object's orientation in its coordinate system is therefore of utmost importance. The orientation should be similar to how the object is sawn using the fibula guide. Only then the angles can be compared.

In the guide, the object is fixated by applying screws along the groove. The object is thus parallel to the guide, with its groove pointing upwards. To accomplish this orientation in the 3D mesh models, the objects are oriented along the z-axis with their groove pointing 'upwards' (groove centered on x-axis at negative y). Figure 22 shows the correct orientation of the object in the coordinate system. It can be seen that this orientation and the definition of the angles (roll around y-axis, yaw around x-axis) is comparable to the orientation of the object in the fibula guide where the roll and yaw angles have similar axes of rotation (figure 16).

Technically, to obtain this orientation the following steps are executed:

Step 1: Normal vectors were found at the bottom of the object. The object was rotated to align the average of these normals to the negative z-axis. This gave the object an initial alignment to the z-axis.

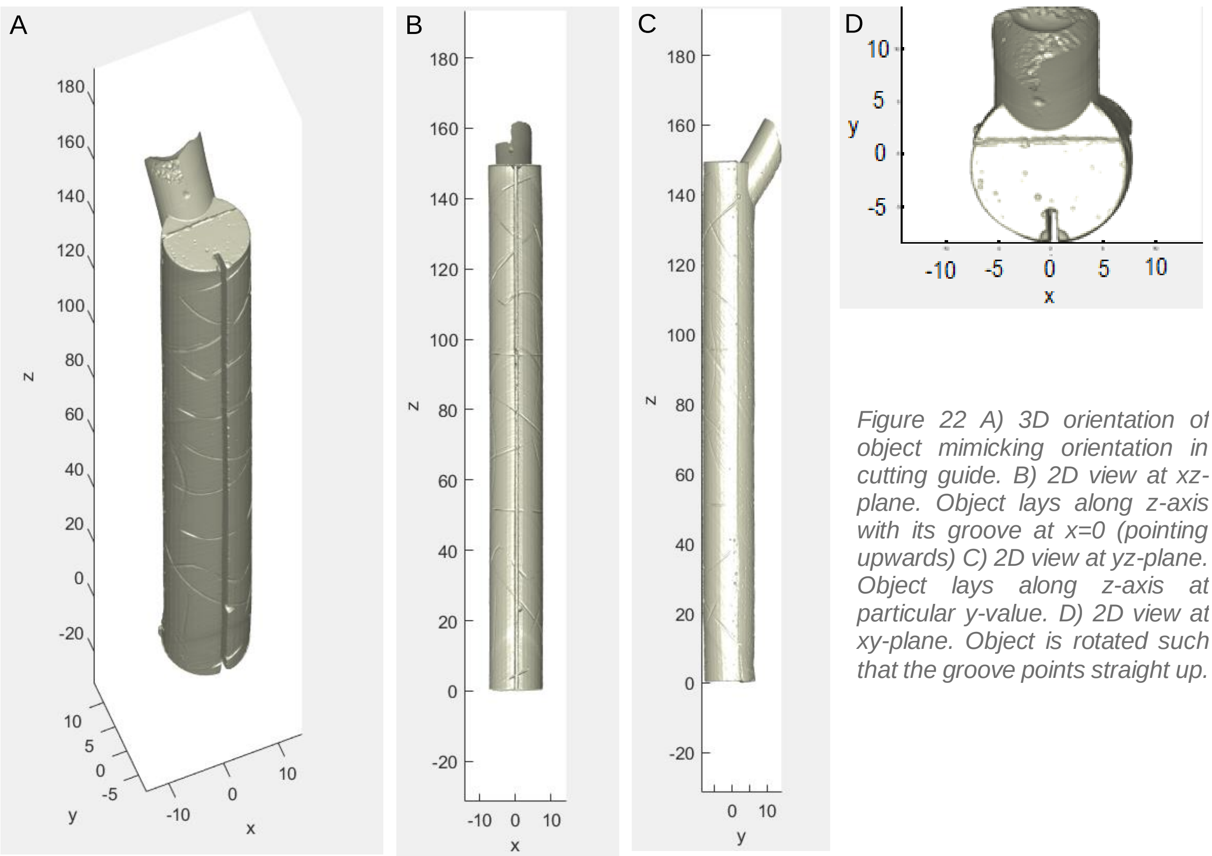


Figure 22 A) 3D orientation of object mimicking orientation in cutting guide. B) 2D view at xz-plane. Object lays along z-axis with its groove at x=0 (pointing upwards) C) 2D view at yz-plane. Object lays along z-axis at particular y-value. D) 2D view at xy-plane. Object is rotated such that the groove points straight up.

Step 2: Normal vectors were found on the left side of the groove. The object was rotated to align the average of these normals along the positive x-axis. This gave the object the correct rotation. Note that the normals on the right side of the groove could have been taken as well to align to the negative x-axis.

Step 3: The position of the two outer fixation blocks on the bone in the guide is measured along the groove. These locations are copied to the 3D mesh model and placed at the center of the groove at the height of the bone's surface (minimum y). This results in a top coordinate and a bottom coordinate from the locations of the top fixation block and the bottom fixation block in the guide.

Step 4: The object is rotated around the y-axis such that the found fixation coordinates (top coordinate and bottom coordinate) are at x=0, i.e. the groove from its fixation points onwards lays in one straight line along the z-axis at x=0.

Step 5: The object is rotated around the x-axis such that both fixation coordinates reach the same y-value. This ensures the correct tilt once fixated to the fixation blocks at both sides as can be seen clearly in figure 22 C.

Preoperative plans

For creation of the plans, two planes were appended to the correctly oriented object in MATLAB. The planes were set in the preferred angles (Euler angles) and at the preferred location such that one segment could be obtained. The segment length was defined by the length between each cut at the object's surface midpoint. This is the only way to guarantee that the segment length can be reproduced by the cutting guide. For the new cutting guide, in contrast to the personalized 3D printed cutting guides, the creation of this plan is all that is needed to saw, as one only needs to know the cutting angles, the segment length and the location on the object. For usage of the personalized 3D printed cutting guides, the plans had to be send to an experienced planner for development of the guides.

In total 10 plans were made for the cylinders, which were divided in two groups. The first group contained 5 identical plans to be able to assess the reproducibility of the guide (Group Cyl identical). The second group contained 5 plans that each differed from each other and contained variable angles (Group Cyl variable). In addition, 11 plans were made for the fibulas, which were also divided in two groups. 6 plans were destined to be cut with the new fibula guide (Group Fib identical new guide), while the other 5 were meant to be sawn by the current cutting guides (Group Fib identical current guides). All 11 plans for the fibula were identical to each other and the same to the plans for 'Group Cyl identical'. Table 12 offers an overview of the planned osteotomies.

Table 12: Overview of planned osteotomies for each phantom group. Both cylinder groups and the 'Group Fib identical new guide' are planned to be sawn by the new fibula cutting guide. 'Group Fib identical current guides' is planned to be sawn by the current cutting guides. The first number in the column 'segment length' is the initial planned segment length, the second number is the expected segment length after correction of the positional deviation.

	Plane 1		Plane 2		Segment length (mm)
	Roll (°)	Yaw (°)	Roll (°)	Yaw (°)	
Group Cyl identical: All 5 cylinders the same	10	0	0	10	50 → 48.2
Group Cyl variable:					
Cylinder 1	0	0	5	0	50 → 49.1
Cylinder 2	5	5	0	5	50 → 50.0
Cylinder 3	10	10	30	0	50 → 51.8
Cylinder 4	0	30	30	30	55 → 55.0
Cylinder 5	5	20	15	20	50 → 50.0
Group Fib identical new guide: All 6 fibulas the same	10	0	0	10	50 → 48.2
Group Fib identical current guides: All 5 fibulas the same	10	0	0	10	50

3.2.3 Data analysis

A 3D scan was made of each cut phantom segment with the 3Shape TRIOS 3 Basic intraoral scanner. The 3D scans were loaded in MATLAB R2019b to obtain the yaw and roll angles and segment length. It does this in two steps:

Step 1: Reorienting the segment the same way the full phantom was oriented when defining the planning angles.
Segment phantom reorientation was done by a rigid registration onto the previously obtained oriented full object. To increase the chance of registration success, the segment phantom was oriented roughly to the right orientation first. This was done in 4 steps which is partly repeating the 5 steps for orienting the full object explained in paragraph 3.2.3:

1. Normal vectors were obtained on the left side of the groove. The object was rotated to align the average of these normals along the positive x-axis. This gave the object the correct rotation.
2. An initial rough rigid registration was done to obtain roughly the tilt around the x-axis.
3. The most top and bottom coordinates are found inside the segment's groove. The segment is then rotated around the y-axis such that the top and bottom coordinates are at x=0, i.e. the groove from its fixation points onwards lays in one straight line along the z-axis at x=0.
4. The segment was shifted to its cutting location along the full object.

After this, registration was performed.

Step 2: Obtaining the roll and yaw angles and segment length
Once oriented correctly, each cut surface is selected and a mean normal vector is projected onto it. Due to the unique orientation the segment is in, one can calculate the angle of the normal vector with respect to the z-axis and convert this to Euler Angles. Firstly, the dot product of the mean normal vector onto the plane and the z-axis is calculated which gives a single angle between these two vectors. Secondly, the cross product of the two vectors gives a third vector that is orthogonal to both vectors. This vector is used as the axis of rotation. Next using the intrinsic MATLAB function 'axang2rotm', a rotation matrix is obtained that describes the angle between the two vectors using the axis of rotation. Lastly, the intrinsic MATLAB function 'rotm2eul' is used which converts this 3D rotation matrix to Euler Angles. The Euler Angles are specified by the intrinsic axis rotation sequence 'ZYX'. The segment length was defined by the length between each cut at the segment's surface midpoint (figure 8 and 15).

3.2.4 Statistical Analysis

Given the small sample size and the fact that the data consists of absolute errors, it is considered that the data is not normally distributed. Hence the Mann-Whitney U test was performed to test whether there was a significant difference between the roll and yaw angle errors of the fibulas cut with the new guide and the fibulas cut with the current cutting guides. The same was done to determine a significant difference of the length deviations between the two groups.

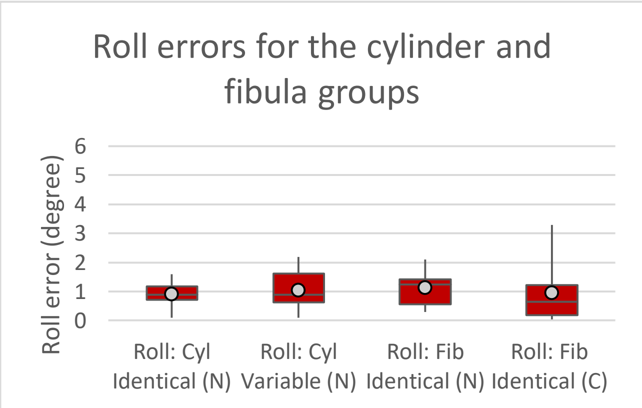
3.3 Results

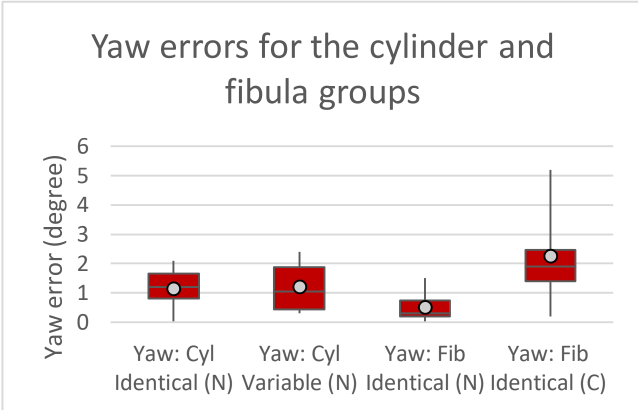
Table 13 Differences in yaw and roll between the planned osteotomy and performed osteotomy. Abbreviations: Med: median, Q1: first quartile, Q3: third quartile, min: minimum, max: maximum, std: standard deviation, N: new fibula guide, C: current fibula guides

Phantom	Roll (degrees)						Yaw (degrees)					
	Med.	Q1	Q3	Min	Max	Mean (std)	Med.	Q1	Q3	Min	Max	Mean (std)
Cyl Group Identical (N)	0.9	0.7	1.2	0.1	1.6	0.9 (0.4)	1.2	0.8	1.7	0	2.1	1.1 (0.7)
Cyl Group Variable (N)	0.9	0.6	1.6	0.1	2.2	1.0 (0.7)	1.1	0.4	1.9	0.3	2.4	1.2 (0.8)
Fib Group Identical (N)	1.3	0.6	1.4	0.3	2.1	1.1 (0.6)	0.3	0.2	0.8	0	1.5	0.5 (0.5)
Fib Group Identical (C)	0.7	0.2	1.2	0	3.3	1.0 (1.0)	1.9	1.4	2.5	0.2	5.2	2.2 (1.7)

Table 14: Deviations in segment length between the planned segments and actual obtained segments. Abbreviations: Med: median, Q1: first quartile, Q3: third quartile, min: minimum, max: maximum, std: standard deviation, N: new fibula guide, C: current fibula guides

Phantom	Length (mm)					
	Med.	Q1	Q3	Min	Max	Mean (std)
Cyl Group Identical (N)	0.8	0.7	1.1	0.6	1.4	0.9 (0.3)
Cyl Group Variable (N)	1.2	0.6	1.5	0.3	2.2	1.2 (0.8)
Fib Group Identical (N)	1.5	1.2	2.1	0.9	3.2	1.8 (0.8)
Fib Group Identical (C)	0.4	0.4	0.4	0.3	0.8	0.5 (0.2)





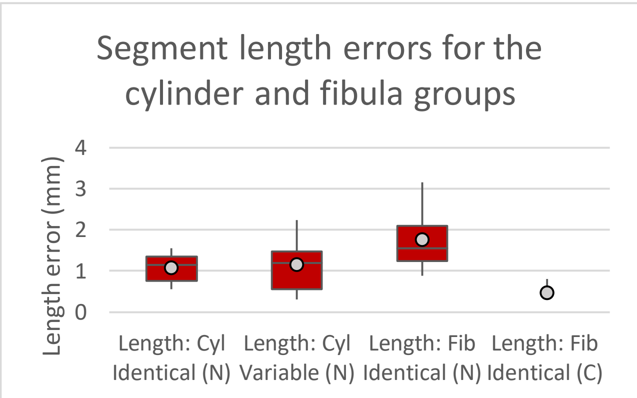


Figure 23: Boxplots showing the roll, yaw and segment length errors for Cyl Group Identical (N), Cyl Group Variable (N), Fib Group Identical (N), Fib Group Identical (C). The bars denote the median, boxes show interquartile range, upper whiskers show third quartile and maximum, lower whiskers show first quartile and minimum. The grey dot represents the mean error. Abbreviations: N: cut with new fibula guide, C: cut with current fibula guides.

A total of 20 osteotomies were performed on cylinders (10 cylinders) and 22 osteotomies on fibulas (11 fibulas). The data illustrating the absolute angle errors for the roll (|roll|) and yaw (|yaw|) are presented in table 13. Absolute segment length deviations are given in table 14. Figure 23 summarizes the data of all errors for all groups in three boxplots. The full data for each osteotomy (planned vs cut) can be found in appendix D.

The Mann Whitney U test revealed a significant difference for the absolute length errors and absolute yaw errors between the two fibula groups ($p = 0.004$ and $p = 0.003$ respectively). No significant difference was found for the absolute roll errors between the two groups ($p = 0.314$).

3.4 Discussion

The currently used 3D printed cutting guides have proven to be a clear improvement on planning options, accuracy of reconstruction and surgery times when compared to the old traditional freehand method. [34–37] However, these cutting guides have become expensive, preparatory time-consuming and highly inflexible during surgery. [51] These shortcomings may mean that the surgeon needs to switch back to the freehand method during surgery after all while high expenses have been made for planning resources. To be able to reduce the preparatory time from weeks to minutes and to prevent having to switch back to the freehand method, four things are needed: universal cutting guides for the mandible and fibula that can be adjusted during surgery at all times, automatic planning software to generate altered plans instantly and universal reconstruction plates. In this chapter one piece of this puzzle is tackled. A novel universal fibula cutting guide is introduced and its accuracy is evaluated.

Osteotomies performed with the new fibula cutting guide should preferably achieve better accuracies, but should in any case not be inferior to the currently used 3D printed cutting guides. Comparing Fib group identical (N) with Fib group identical (C) the yaw angle differed significantly (p=0.003) using the Mann Whitney U test; the novel fibula guide produced more accurate cuts than the currently used guides. The roll angle did not differ significantly between the two groups (p = 0.314). As for the length errors, the Mann Whitney U test revealed a significant difference (p=0.004) in favor of the current cutting guides. It must be noted though, that the data from Fib group identical (N) are not trustworthy due to imperfections in the experimental set-up. As explained in the methods section, the segment angles are analyzed by orienting the segment a unique way such that it resembles the orientation it was cut in in the fibula guide. Only then the Euler angles which are based on rotation around the x-, y-, and z-axis, can be compared. While this worked great for the cylinders, the fibulas turned significantly away from this orientation due to their irregular surfaces when fixated to the novel fibula guide (figure 24 A,B vs C,D). Due to this mismatch in orientation, the analyzed angles are not the angles that were sawn and the measured segment lengths are not the segment lengths obtained. This is illustrated in figure 25. It should be noted though that clinically this rotation is irrelevant. If the fibula turns as in figure 24 C, this has no effect on the actual osteotomy angles. On both planes, the angles are cut in this rotated fashion. Other than the fact that the eventual fibula segment will be slightly rotated around its own axis in the mandible, the angles will be correct, as will be the segment length. They just do not resemble the virtual orientation and thus cannot be accurately analyzed this way. Fib group identical (C) did not show this problem as the personalized guides were created in the virtual orientation of the fibula. The virtual and real orientation do therefore exactly match. To be able to make a comparison, it was therefore decided to compare Cyl group identical (N) with Fib group identical (C). Both are cut with the same angles, and both have trustworthy results.

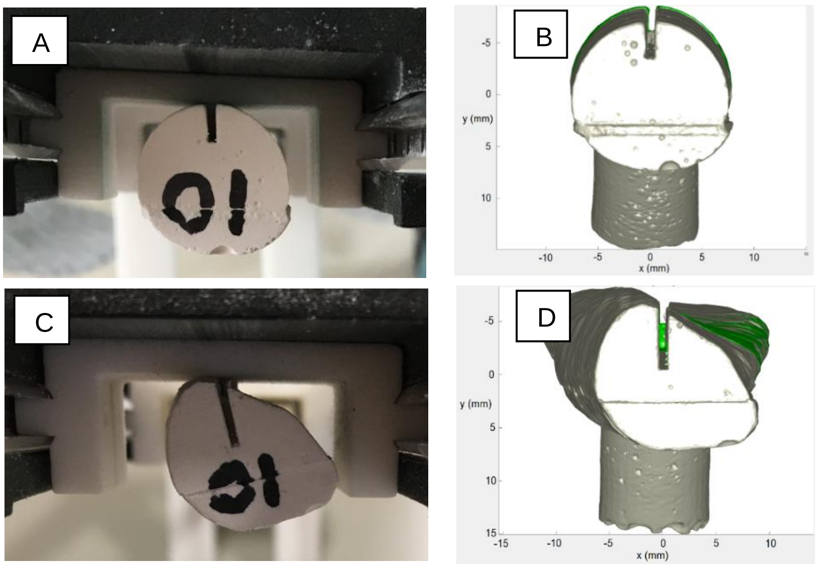


Figure 24: Phantom orientation in fibula guide vs virtual orientation during analysis. A) Cylinder orientation in fibula guide. B) virtual cylinder orientation. C) Fibula orientation in fibula guide. D) virtual fibula orientation. The cylinders are oriented similarly (A,B). The fibulas are oriented differently (C,D).

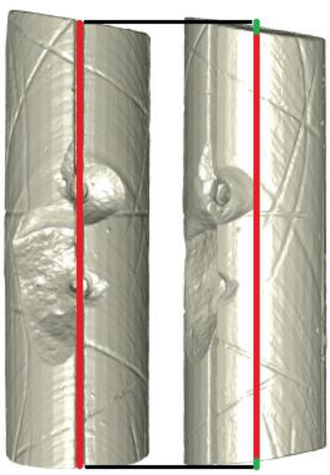


Figure 25: Example of angle and segment length deviation due to rotation. In red the segment length. In green the segment length deviation due to the rotation.

Carrying out the Mann Whitney U test between Cyl group identical (N) with Fib group identical (C), the test showed no significant differences for both roll and yaw angles, p = 0.481 and p = 0.089 respectively. The absolute mean errors (SD) for the roll do indeed show a negligible difference of 0.9 (0.4)° in the cylinder group and 1.0 (1.0)° in the fibula group. The absolute mean errors (SD) for the yaw angle however shows a small difference between the cylinder group 1.1 (0.7)° and the fibula group 2.2 (1.7)°. The fact that no significant difference is found, may be purely because of the small sample size. A power analysis reveals 38 osteotomies should be performed per group to derive whether the absolute mean differences between the two groups are significantly different. With an amount of only 10 osteotomies per guide, this is nowhere the amount that is needed. A difference in the yaw angle would be expected as the slots of the current guides usually offer more space than necessary for the surgical saws. This results in a lot of freedom to move about, especially for the yaw angle. The roll angle is more limited by the side borders of the guide. With the new guide, the slots that guide the saw are very narrow and offer no freedom of movement whatsoever. This results in a more accurate and reproducible angle as can be seen by the lower mean error and smaller standard deviations obtained with the new guide. In any case, judging from these results it can be said the new guide offers at least the same accuracy than the current guides concerning the angles. The Mann Whitney U test further showed a significant difference for the absolute segment length errors between the two groups, p=0.032. The absolute mean error (SD) for the length deviation for the cylinder group was 0.9 (0.3) mm. while the fibula group came out at 0.5 (0.2) mm. Although the current guides seem to perform explicitly well concerning the length accuracy, it must be noted that because of the way the yaw rotation influences the positional deviation in this version of the new fibula guide (equation (1)), the length errors may very well be smaller than illustrated here. The positional deviation in equation 1 is calculated using the planned yaw angle however, due to deviations in the actually cut yaw angles the real positional deviation will differ slightly from the calculated positional deviation. The segment length error obtained is therefore an error of the segment length due to dispositioning of the guide and an extra positional deviation obtained from errors in the yaw angle. The pure segment length error due to dispositioning of the guide along the ruler may therefore be smaller.

Looking further at the errors obtained by sawing the cylinders with the new guide, it can also be deduced there is no difference between the two cylinder groups. The absolute mean error (standard deviation) for the roll and yaw angles for Cyl group identical (N) is 0.9° (0.4°) and 1.1° (0.7°) respectively, and for Cyl group variable 1.0° (0.7°) and 1.2° (0.8°). The small standard deviations suggest that the novel cutting guide can saw any angle with great reproducibility.

Comparing the results of the fibula guide evaluated in this study with the results from the MUC-jig from a study of Meyer et al. (2019) [46], shows the fibula guide evaluated here is more accurate and reproducible concerning the angles and performs similarly for the segment lengths. The MUC-jig offers an absolute mean error of 2.22° with a SD of 2.33° (for roll and yaw taken together) and an absolute mean length deviation of 0.8 mm with a SD of 0.8 mm. Taking the roll and yaw together from all cylinders, the guide evaluated here has an absolute mean error of 1.08° with a SD of 0.67° and an absolute mean length deviation of 1.1 mm with a SD of 0.6 mm. Again it is noted that the segment length accuracy for our fibula guide may still improve in a next prototype by eliminating the yaw influence on the positional deviation.

Although the fibula guide provides good accuracy on osteotomy angles and segment length, errors do arise. Apart from the yaw influence on the length errors, errors originate from three different sources: the analysis, the fixation and the cutting guide. As previously mentioned, during the analysis it is utmost important that the real orientation in which the phantom was fixated to the fibula guide and the virtual orientation are the same. The groove helps with this orientation and from figure 24 A and B, it can be seen that this coincides fairly good. However, minor deviations from each other's orientation could result in angle and length errors. The same holds for the registration of the segment to the phantom in the virtual setting. The registration should be perfect to adopt the (correct) virtual orientation, and although these registrations could be performed really well (figure 24 B and D), the registration error is never zero. The second origin of errors lie in fixation. The fixation blocks in between the two osteotomies hold the phantom in place when having cut one of the two planes. Because the phantoms were made of plaster, in some cases the tightening of the screws caused the plaster to crumble and in turn caused loosening of the screws. This meant that in some cases the phantom could slightly move after the first osteotomy had been made. The second osteotomy could therefore have some errors due to change of orientation. This was seen especially in the fibula group cut with the new guide due to the irregular surface of the fibulas and the straight fixation blocks of the guide. Hence, this has almost no effect on the comparison between the cylinders and fibula group cut with the current guides. It is important however that a future prototype can fixate the fibulas well. Therefore, the fixation blocks should be redesigned by adding cushions underneath it. This way irregular surfaces can be handled better. The last origin of errors comes from the cutting guide itself. The angle is read from a scale on the arches for the yaw and on the ring for the roll. In addition, the angles are set manually. The same is done for the segment length. A ruler on the side defines the location on the phantom and the guide is shifted to this location manually. With both actions errors can occur. Especially the reading off of the degree scales showed to be hard. The scale only contains lines per 5 degrees, and dots for each degree in between. There are no numbers on the scale, so one should count from the zero point. During the phantom study it was noted it was hard to define that zero point, especially when the guide was rotated. In the end, it is suspected that in 5 out of 40 angle settings the count was 5 degrees off. Due to the strong suspicion, the note made during the setting and the overall low angle errors, it was decided to correct these errors with 5 degrees. Also a negative 10 degrees instead of a positive 10 degrees was corrected for as this is purely an error of rotating to the opposite side. A clear definition to turn right or left for positive or negative angles had not been made. A future prototype should clear up the scales either by denoting the zero point clearly or adding numbers. The turning side for positive angles or negative angles should be cleared up as well.

One major limitation of this study is the evaluation of the segment lengths. To accurately establish a specific segment length, one needs to design the guide a special way. Important is the yaw rotation of the guide. If the rotation axis of the yaw rotation is not on the surface of the phantom, rotating the guide to a different angle will cause the saw to end up at a different location on the phantom (figure 21). Only when the rotation axis is on the phantom, rotating the yaw angle will not change the cutting position on the phantom which enables accurate segment length determination. Although the guide was proposedly designed in this way, a design error caused the rotation axis to lay 9.9 mm above the phantom surface. Therefore, depending on how large the set yaw angle was, the segment length differed significantly from the planned segment lengths. In order to get useful data on the segment lengths it was decided to calculate the proposed cutting position on the phantom given the height of the rotation axis and planned proposed yaw angle. Although this gives a good approximation, extra errors are inevitably introduced as the yaw angle itself has some error as well, leaving the data on segment lengths less reliable. In a next prototype, this rotation point should therefore be placed back on the fibula surface and a (phantom) test should be executed to evaluate the accuracy of the segment length properly. In addition, a preferably larger sample size should be taken to evaluate the accuracies of both the segment length and the angles and the guide should incorporate the previously mentioned improvements to further asses the accuracy.

3.5 Conclusion

The novel fibula cutting guide shows great potential for replacing the currently used 3D printed cutting guides and hence for contributing its piece in vastly improving the mandibular reconstruction process. The yaw and roll angle accuracy with the novel cutting guide are not inferior to the currently used cutting guides and the yaw angle accuracy even seems to be better with the novel guide. The smaller standard deviations also suggest the novel fibula cutting guide performs osteotomies with a higher reproducibility. The segment length accuracy with the novel guide did however differ significantly from the current guides, with the latter coming out on top. It is expected though that by improving the guide this accuracy will improve. Future tests will contain the improvements of the guide mentioned and include a more reliable determination of segment length accuracy.

Chapter 4: Automatic Mandible Reconstruction Plans

4.1 Introduction

In this chapter, the first step to solve the last piece of the puzzle is taken: introducing software for creating (semi-)automatic mandible reconstruction plans.

A couple of research groups have undertaken the task to automatize the fibula planning already. Some aim for a semi-automatic approach that still requires some user input while others take a first step at realizing a fully automatic system. Different techniques are used. Aso et al. (2015) [52] introduced a system that is based on optimization problems which minimizes the shape error between the surfaces of the fibula segments and the patient's original mandible. Two other study groups introduced a system that is based on optimization problems which minimizes the error between defined contour curves of the desired reconstruction and the fibula [53,54]. There is even a study group that created a system that makes use of a large training set of previously made reconstruction plans. Based on the input mandible and specific feature points on this, the system can then choose the best adaptable reconstruction plan. [55]. However, maybe even more important than the technique to use for the software is whether to create a software that generates a fully automatically generated reconstruction plan or a semi-automatically generated plan. It has become evident from studies of Kwasaki et al. (2016) [55] and Nakao et al. (2017) [56] that fully automatic systems are very hard to achieve. These studies have only implemented the first steps yet but are very complicated systems already. For these systems to become clinically deployable years will have passed. Therefore, another group of research groups have taken a step back and chose a semi-automatic approach where the surgeon himself determines aspects such as the number of segments to use, the minimum or maximum segment length that can be used, the position of the segments on the harvesting sites, the anterior or posterior placement in the mandible etc. There are even systems that lets the surgeon alter the semi-automatically generated reconstruction plans to improve the plans according to the surgeon's vision. By enabling user specified parameters, the system may be simplified drastically, speeding up the generation of reconstruction plans and, above all, the implementation into the clinic as the surgeon has the ability to steer the reconstruction into the right direction and alter it.

Due to these reasons, it was decided to develop software that allows input and end-alteration by surgeons to generate semi-automatically mandible reconstruction plans. A first version of such a 3D planning software was developed by Technical Medical Solutions BV., a Dutch Technical Medical (TechMed) company and submitted to us for evaluation. The by the software generated plans were evaluated by head and neck surgeons by comparing the generated mandible reconstruction plans to the manually created plans. Although subjective analysis by the surgeon is the current way to evaluate a plan, an objective evaluation method would be very useful too. Such methods could be used in the software to obtain the best possible plan. Therefore, in this chapter aside from a comparison between the two plans by head and neck surgeons to evaluate the software, a comparison was also made objectively by introducing evaluation methods that could analyze specific aspects of the plan. The usefulness of these objective methods was investigated by comparing the results to the conclusions of the surgeons.

4.2 Methods

4.2.1 Mandible reconstruction plan

Mandible reconstruction plans are currently developed manually. The planner receives a CT of the mandible and fibula from the surgeon along with the description of where the resection planes should be placed on the mandible. In addition, the surgeon instructs the planner which fibula should be used (lateral or contralateral), how many segments they think would be best (1,2 or 3) and how the fibula should be oriented in the mandible (knee side placed anteriorly or posteriorly in the mandible). The latter is important for the surgeon to prepare for the vessel connection of the fibula graft to the vessels in the neck. With this data the planner goes to work. First the mandible and fibula are segmented from the CT data using an intensity-based threshold after which the data is converted to 3D surface meshes in a stereolithographic file (STL) (steps 1 and 2 in figure 26). Using specific software two resection planes are then placed onto the 3D surface mesh of the mandible (step 3 in figure 26). After this the fibula segments are manually placed in between these resection planes to reconstruct the mandible. Key

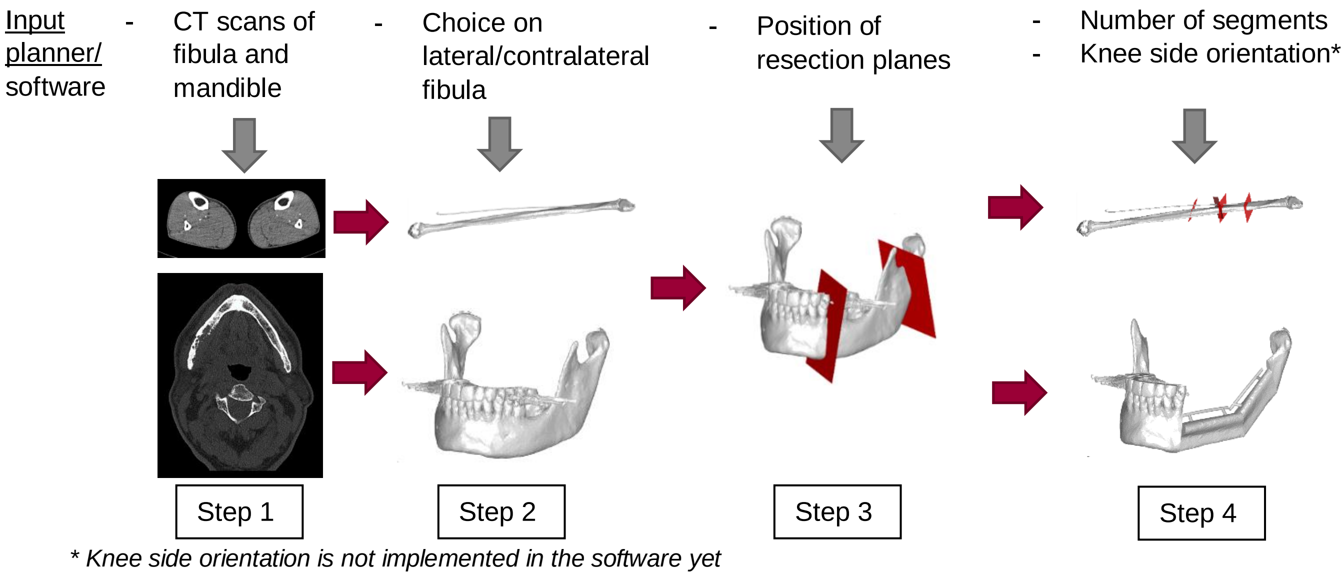


Figure 26: Overview of the steps to develop a reconstruction plan. The input for the planner by the surgeon is denoted in the top row. Step 1) Segmentation of fibula and mandible from CT. Step 2) converting the segmented data to 3D surface meshes in a STL file. Step 3) Placing the resection planes on the 3D surface mesh of the mandible. Step 4) Creating the mandible reconstruction plan.

points for placing the fibula segments in the defect are the resemblance of the bottom and outer border and the optimization of the contact surfaces of the fibula with the mandible. In addition, the fibula segments are always oriented such that their vessel lies on the inside. This offers space on the outside for fixation of the reconstruction plates. Moreover, the planner follows the instructions of the surgeon to place the knee side of the fibula anteriorly or posteriorly. The software tracks which pieces of the fibula are being used and how these are oriented and cut to fit the mandible defect (step 4 in figure 26). After the reconstruction is finished as shown in figure 26, the fibula and mandible cutting guides are developed.

To generate a semi-automatic mandible reconstruction plan the same package of information that is normally given to the human planner should be inserted in the software as well after which the same steps can be taken to develop a plan (figure 26). To make a comparison possible between the two plans, identical information was inserted. The 3D surface meshes of fibula and mandible were the same, the defect was the same and even the number of segments was the same. The only difference between the plans is how the number of segments are positioned in the defect and where the segments originate from on the fibula (step 4 in figure 26). This step is executed automatically by the software. To judge the ability of the software to develop plans automatically, no end-alteration by surgeons was allowed. The first version of the software is focused on obtaining optimal angles between the fibula segments and the orientation of the fibula segments. This is achieved by fitting the lower and outer border of the fibula parts with the bottom and outer border of the mandible. It should be noted however that the current version of the software did not yet consider the rotation of the fibula parts around their own axis and the orientation of the knee side of the fibula (anteriorly or posteriorly faced) in the mandible. Figure 27 illustrates a manual plan and a semi-automatic plan. It can be seen that both have exactly the same defect to fill with the same number of fibula segments. How the two defects are reconstructed is, however, different for both and will be evaluated.

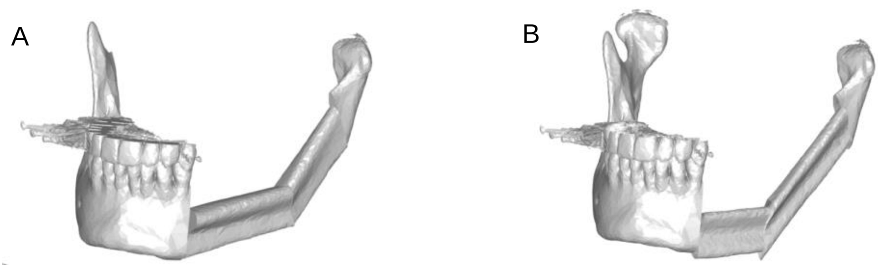


Figure 27: Mandible reconstruction plans. A) Manual mandible reconstruction plan. B) Automatically generated mandible reconstruction plan

4.2.2 Patient's data

Retrospectively, data of 7 patients was acquired which included the STL files of the pre-operative mandible and fibula and the by professional planners created mandible reconstruction plan. The automatic mandible reconstruction plans were generated by the software as discussed in the previous paragraph. Among the 7 patients, different types of mandible defects exist, which are presented in table 15 according to the HCL classification system. In this system 'H' represents lateral defects with condylar involvement, 'L' represents lateral defects without condylar involvement, and 'C' represents central defects including both canines. [57]

Table 15: HCL classification of included patients

Reconstruction Plan	Reconstruction Class
Patient 1	L
Patient 2	H
Patient 3	LC
Patient 4	LC
Patient 5	L
Patient 6	LC
Patient 7	L

4.2.3 Objective analysis

Objective evaluation methods should focus on key aspects of a reconstruction plan. Aspects that are of high importance for reconstruction of the mandible are its shape resemblance and bone to bone surface overlap. A good shape resemblance defines a facial reconstruction with good esthetics. This can be achieved by following the bottom and outer borders of the mandible (figure 28 A and B). The bottom border is defined as the bottom line of the mandible. The outer border is defined by multiple 2D contour lines of intersections at different heights throughout the mandible. In the following these lines will therefore be referred to as outer contour lines. Both the lower border and the outer contour lines serve as boundaries when making a reconstruction plan with fibula segments. Crossing the boundaries would cause protrusions of the fibula segments which are likely to die due to insufficient blood supply. Moreover, following the lower border and thus placing the segments as low as possible in the mandible defect enables the highest bone surface overlap between fibula and mandible as the lower part of the mandible is the thickest. Optimal surface overlap between the graft and the mandible surface is crucial. Only then optimal bone union occurs. The lower part of the mandible also provides a good area for plate fixation using screws as this part consists of a thick dense cortical layer and only a small inner portion of cancellous bone. [13] This composition stabilizes the fixation. [58] Furthermore, following the lower border best as possible ensures the reconstruction of the anatomical mandibular angle at the correct place. This is highly important to reach good symmetry. Besides the shape resemblance and bone to bone surface overlap, if dental implants are to be implanted it is crucial that these can be positioned well under the upper teeth such that good occlusion is possible. For this the segment should be positioned under the upper teeth as illustrated in red in figure 29.

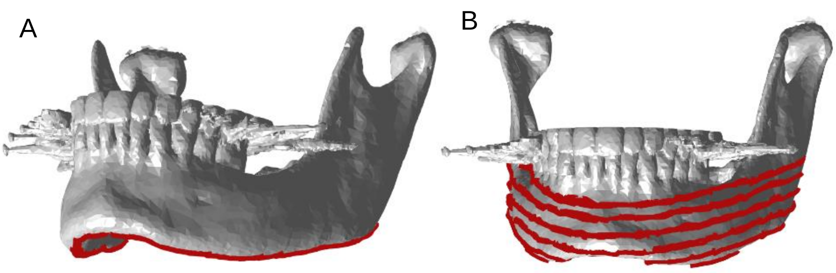


Figure 28: Representation of bottom and outer border. A) Lower border. B) Outer border (multiple contour lines)

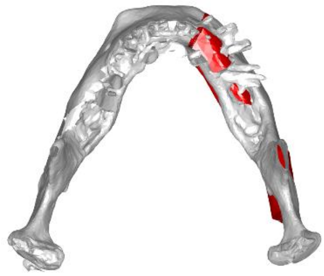


Figure 29: Fibula segment (red) positioned under the teeth row ensuring good occlusion if implants are to be implanted.

With knowledge of these important aspects for realizing an acceptable reconstruction, four methods for quality assessment were developed:

- Outer border analysis (whole and teeth area only): important for reaching proper facial contour. Evaluation of the teeth area only may be important for good occlusion if dental implants are implanted.
- Bottom border analysis: important for reaching proper facial contour and improves surface overlap and plate fixation.
- Distance to mandibular angle: important for reaching proper facial contour
- Surface overlap: important for bone union.

All evaluation methods are implemented using MATLAB. Data consists of the 3D surface meshes of the pre-operative mandible and the reconstruction plans developed on them. The 3D surface meshes consist of vertices and triangular faces. To enable proper evaluation of the reconstruction plans, the mandibles and accompanying plans are first reoriented. This way, the posture of the patient during acquirement of the CT scan does not affect the evaluation.

Reorientation

The 3D surface mesh of the mandible is reoriented such that it rests on a ground plane. The z-axis is the normal vector of this ground plane, with the ground plane set at z=0 (figure 30). The y-axis extends from the front to the back of the mandible, and the x-axis extends from the left to the right of the mandible. The y- and x-axis cross each other in the origin, which is the center of gravity of the mandible placed at z=0.

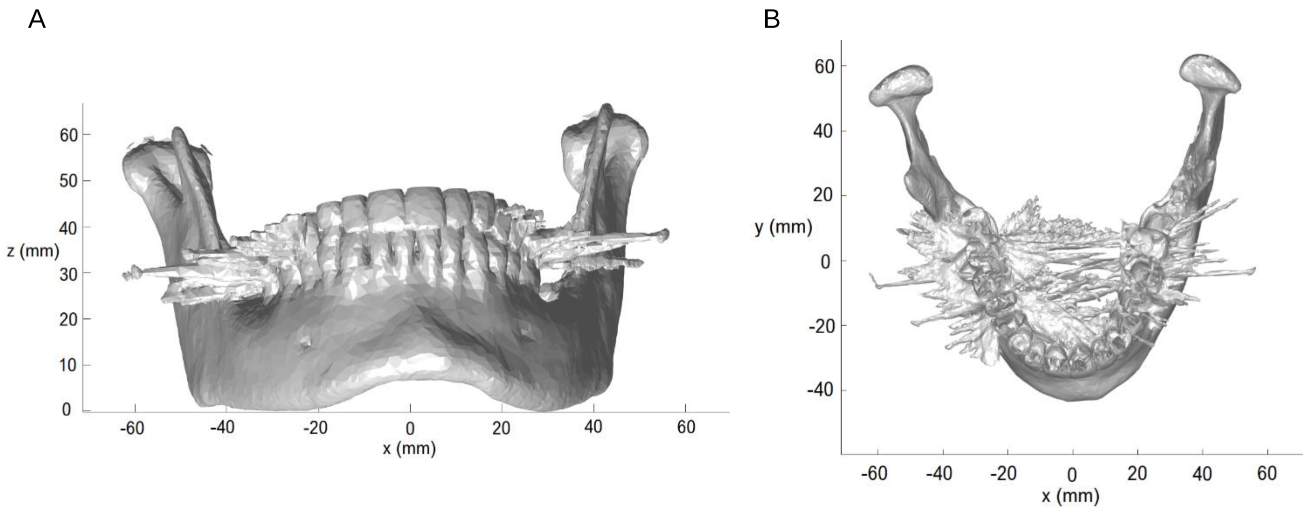


Figure 30: Mandibular coordinate system. A) Mandible viewed in xz-plane. B) Mandible viewed in xy-plane.

Outer border

The method for analyzing differences between the outer border of the mandible and the reconstruction plan is largely derived from a study of Nakao et al. (2017) [56]. It obtains for xy-slice of the mandible the distance between the outer contour of the mandible and the reconstruction plans. The following steps describe the computation algorithm:

- Step1: Obtaining the outer border of the mandible.
  To obtain the outer border of the mandible, multiple contour lines need to be obtained. First, the 3D mandible surface mesh is intersected by an xy-plane at a certain height z. By this, a 2D cross-section of the mandible is obtained. This is done for each z from minimum z to maximum z with steps of 1. A representation of some of those planar intersections is given in figure 31. For each cross-section the outer points are obtained to construct the outer contour. This operation is split in two steps: obtaining the outer contour points of the sides of the mandible, and obtaining the outer contour points of the front of the mandible. The outer points of the side are obtained by scanning the cross-section from minimum y to maximum y. For each y, the minimum x is obtained to find the outer point of the right mandible side and the maximum x is

obtained to find the outer contour of the left mandible side (see figure 32, red points). The outer points of the front are obtained by scanning the cross-section from minimum x to maximum x, and for each x, the minimum y is obtained (see figure 32, blue points). The collection of all the outer points at one cross-section represents one outer contour. The collection of all outer contours at each cross-section represents the outer border.

- Step 2: Create extended contour and resample contour points.
  To prepare for the next step, a second extended contour is created. By projection of 2D-normals of the vertices of the outer contour on the mandible a second wider contour can be obtained. This is illustrated in figure 33, which shows a part of the 3D surface mesh of the mandible and its contour points in blue at a specific cross-section as explained in step 1. The red arrows represent the 2D normal projections of the vertices in blue. Through this a second contour is obtained (burgundy red points in figure 33). These new contour points are resampled, such that they each are an equal distance apart. Corresponding normals are interpolated.
- Step 3: Obtaining the distance between the outer contour of the mandible and the reconstruction plan.
  Figure 34 shows part of the mandible (white) and reconstruction plan (in red). The re-sampled outer contour points are visualized in red along with some of the accompanying normals in black. For each extended contour point, the normal is back projected and the mandibular object and the reconstruction plan are scanned for a point of intersection. This intersection point will be somewhere in a face of the 3D surface mesh. If for a back projection an intersection is found for the mandible and the reconstruction plan (shown as green and cyan points respectively in the zoomed in images in figure 34 B and C), the Euclidean distance between these points is

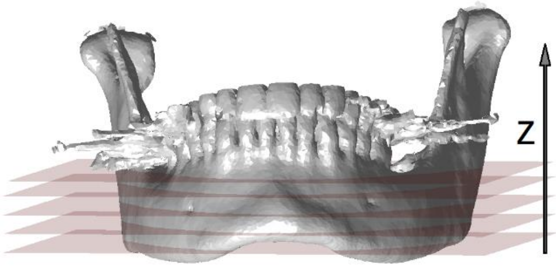


Figure 31: Illustration of the planar intersections to obtain xy-cross sections of the mandible

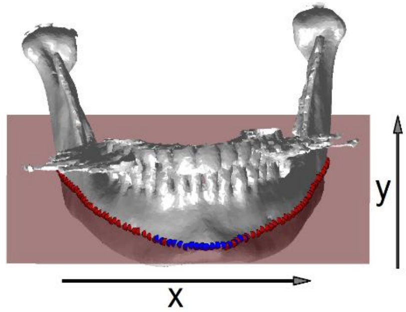


Figure 32: Illustration of a single outer contour of the mandible at a certain height z of the mandible. The height is illustrated by the xy-plane in red. The outer contour points are visualized in red (sides) and blue (front)

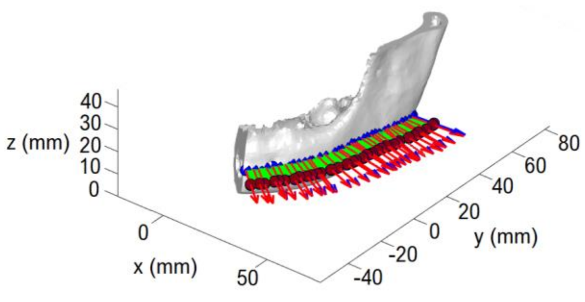


Figure 33: Visualization of the extended outer contour on a part of the mandible. The outer contour obtained in step 1 is illustrated in blue. The red arrows represent the 2D normals of these outer contour points. Extending the outer contour points outward by these normals gives the burgundy red extended outer contour.

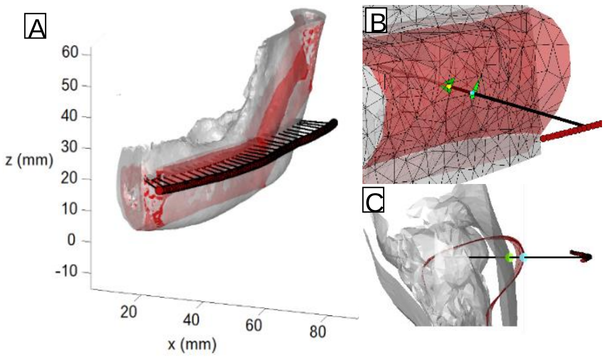


Figure 34: Distance point pairs of the outer contour. A) The burgundy red points represent the extended outer contour. The black lines represent a couple of the back projected normals from this extended outer contour. B) A zoomed in image of A, where a single back projected normal is visualized. The normal intersects the reconstruction plan in red at the face colored blue and the mandible in white at the face colored green. The distance between these two intersection points, is the distance between the outer border of the mandible and the reconstruction plan at that location. C) a xz-cross section view of B.

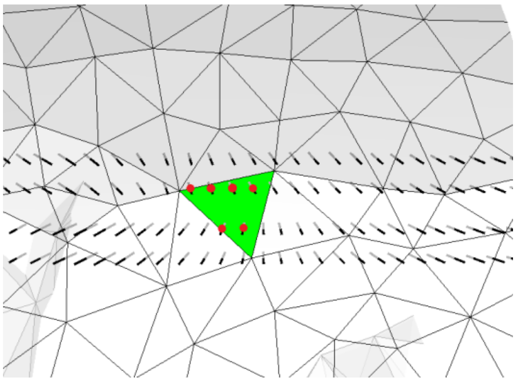


Figure 35: Normal intersection points in the 3D surface mesh of the mandible. Back projected normals of 4 contour lines are visualized in a zoomed in image of the mandible surface. A single face (green) contains multiple intersections of back projected normals (red dots)

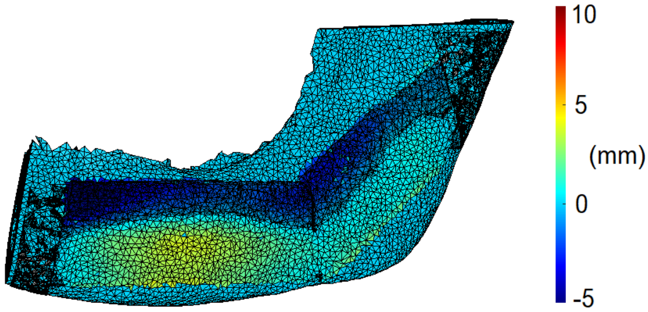


Figure 36: Mandible distance map. Each face of the mandible is colored according to its distance data. A negative value (dark blue) means the reconstruction plan reaches outside the mandible. A positive value (dark red) means the reconstruction plan remains within the outer border of the mandible.

calculated. By seeking which intersection came first it could be defined whether a distance was positive or negative, i.e. whether the reconstruction plan laid on the inside or the outside of the mandible. The calculated distance is stored along with the data of the faces the intersection applies to. By calculating the distances between the mandible and reconstruction plan this way for each point on each extended contour line, a distance map of the mandible can be obtained for which each face contains distance data. For one face, multiple intersections will be obtained, and thus data of multiple distances are present as illustrated in figure 35, where the intersection points of the normals of four contour lines are shown on the faces of the 3D surface mesh of the mandible. To obtain a single distance that can be coupled to the face, the mean of the distances is taken.

- Step 4: Visualize the obtained distances.
  Each face of the mandible contains a single distance after averaging. By grading the distances to colors, a colored distance map can be obtained in which each colored face resembles the distance between the outer border of the mandible and the reconstruction plan at that location. The result is shown in figure 36.

The outer border deviation is both analyzed for the whole reconstruction plan as in figure 36 and for the teeth area only. The latter is to be compared with the visual analysis to determine whether placement of dental implants is possible with good resulting occlusion. The visual analysis was done by a Technical Medicine student by determining whether the fibula segment is positioned under the teeth row as in figure 29 is the case.

Bottom border

The differences between the bottom border of the mandible and the reconstruction plan are obtained in two steps:

- Step 1: Obtaining the bottom border of the mandible and of the reconstruction plan.
  The mandible is scanned from minimum y to maximum y, and for each y, the minimum z value is obtained (see the white points in figure 37). These are vertices of the 3D surface mesh. If the front is involved, the mandible is scanned in the x-direction also, and for each x, the minimum z value is obtained. The same steps are executed to obtain the bottom border of the reconstruction plan (see the red points in figure 37).
- Step 2: Pairing the bottom border vertices of the mandible and the reconstruction plan.
  For each segment of the reconstruction plan, the average normal of the bottom border vertices is calculated. The bottom border vertices of the reconstruction plan are then projected towards the mandible bottom border samples along this normal. Subsequently, by finding the closest point, a pair is created (represented by the blue lines in figure 37). The distance in z between the two vertices is taken. A negative value suggests the bottom border of the reconstruction plan lies higher than the bottom border of the mandible, and a positive value suggests the reconstruction plan bottom border lies lower than the mandible bottom border.

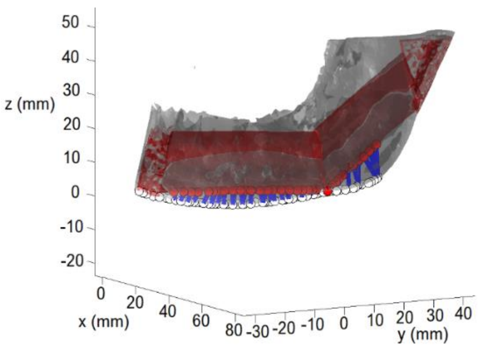


Figure 37: Bottom border evaluation. In grey a part of the mandible and in red the mandible reconstruction plan. The bottom border points are illustrated in white for the mandible and red for the reconstruction plan. The blue lines connect the point pairs.

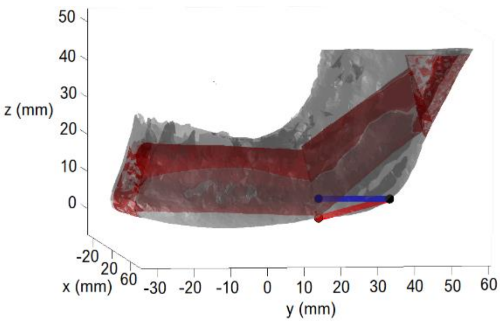


Figure 38: Distance to the mandibular angle. In grey a part of the mandible and in red the mandible reconstruction plan. The black point is positioned on the mandible on the rotation axis of the mandibular angle and the red point on the reconstruction plan on the rotation axis of the reconstructed mandibular angle. The red line represents the 3D Euclidean distance between the two points. The blue line represents the 2D Euclidean distance between the black point and the blue point (=red point positioned at the height of the black point).

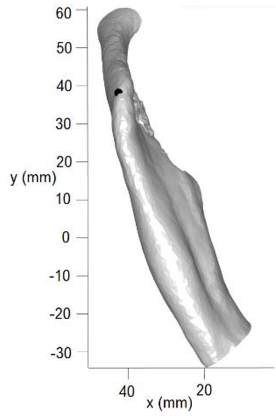


Figure 39: View from below visualizing the center positioning of the point on the anatomical mandibular angle (black).

Distance to mandibular angle

The distance between the anatomical mandibular angle (figure 4) and the reconstructed mandibular angle is calculated by manually placing two points. One on the rotation axis of the mandibular angle of the mandible and one on the rotation axis of the reconstructed mandibular angle in the reconstruction plan (black and red points in figure 38, respectively). Both points on the rotation axis are placed in the center of the mandible or reconstruction plan (middle x) (figure 39). The Euclidean distance between these points is defined as the positional deviation of the mandibular angle. This distance is calculated both in 2D and 3D. The 3D deviation measures the actual positional deviation from point to point (red line in figure 38). The 2D deviation omits the z distance and only takes into account the deviation in the xy-plane. This is illustrated in figure 38 by the blue line. This neglects the deviation due to lower or higher positioning of the segments and thus focuses purely on the positional deviation of the angle vertex in the same plane.

Surface coverage

The percentage of fibula coverage by the mandible is obtained in 2 steps:

- Step 1: Obtaining the fibula and mandibular 2D surfaces at their surface of contact.
  First, the average normal vector is obtained at the fibula surface as illustrated in red in figure 39 A. Next an xy-plane is set a z=0 after which the object is rotated to align the average normal to the normal of the xy-plane as shown in figure 39 B. Due to the representation of the mandible as a 3D surface mesh, only vertices of the outer surface of the mandible (and some inner bodies) are present in the 3D object. Therefore, the surfaces of the mandible and fibula can be obtained by finding all vertices just above the xy-plane ($0.1<z<1$) and just under this plane ($-1<z<-0.1$), respectively (figure 39 C).
- Step 2: Reconstructing the vertices to 2D surfaces.
  The vertices found in step 1 are compressed onto a 2D plane (figure 40 A). Next the points can be connected to construct a 2D surface. This is illustrated in figure 40 B, where in red, the mandibular surface is visualized, in green the fibula surface and in blue the overlap the fibula surface has with the mandible.

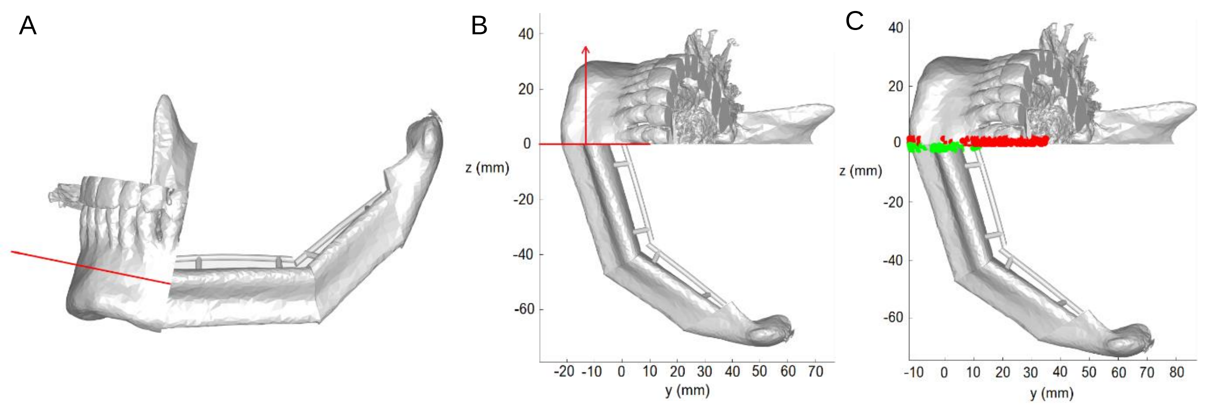


Figure 39: Overview of step 1 for obtaining the fibula surface coverage. A) In red the normal of the fibula surface. B) Reorientation of the mandible by aligning the normal of the fibula surface to the normal of the xy-plane at z=0 (red arrow). C) The vertices representing the surfaces of the mandible (red) and fibula (green) are found by finding all vertices in a small area above the xy-plane (0.1<z<1) and just under this plane (-1<z<-0.1), respectively.

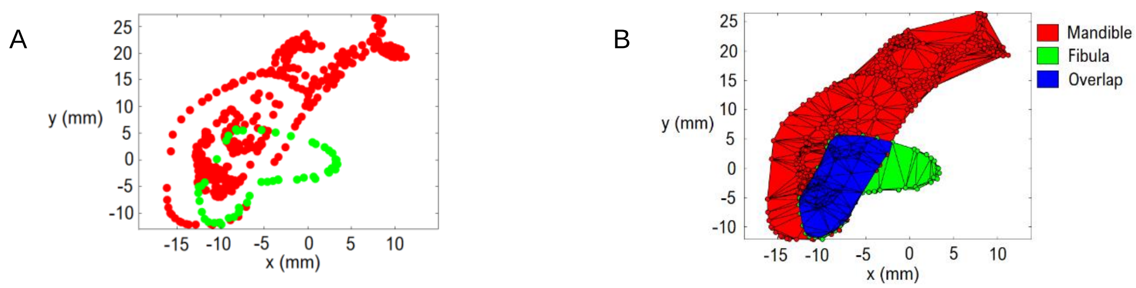


Figure 40: Overview of step 2 for obtaining the fibula surface coverage. A) Mandible (red) and fibula (green) vertices obtained in step 1, compressed to a 2D plane. B) All red points are connected to construct the mandible surface and all green points are connected to construct the fibula surface. The blue area is the area of the fibula that is covered by the mandible.

- Step 3: The area of overlap for the fibula surface onto the mandible surface is calculated by the following formula:

$$Fibula\ surface\ coverage\ [\%] = \frac{Area\ of\ overlap\ \ [mm^2]}{Total\ area\ of\ fibula\ surface\ [mm^2]} 100\ [\%] \qquad (2)$$

4.2.4 Subjective analysis

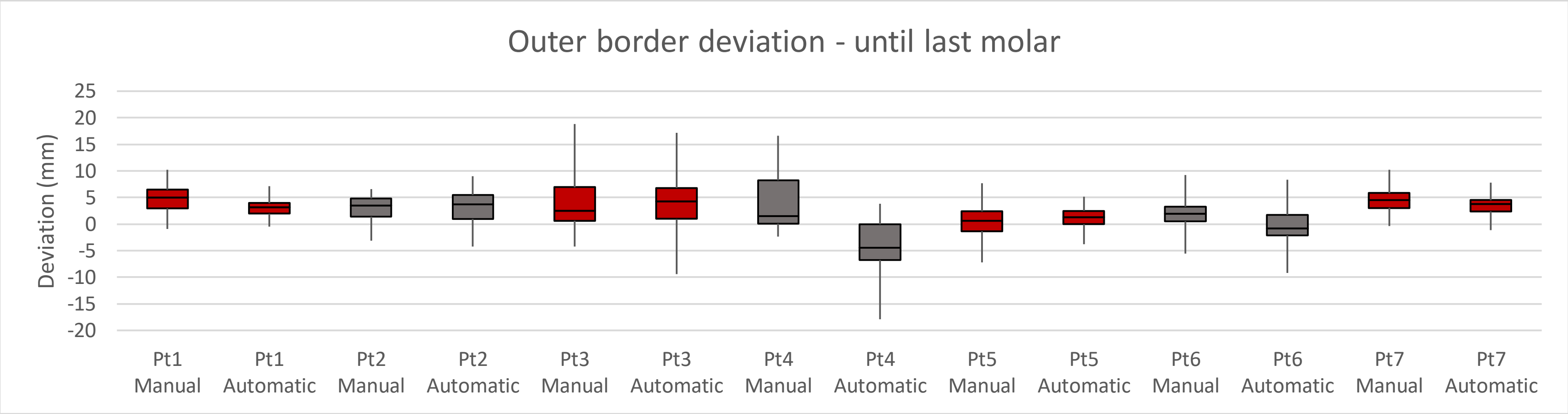
Next to the objective analysis, a subjective analysis was executed by three head and neck surgeons. The subjective analysis was carried out as follows. For each patient the two plans (manual vs automatic) were illustrated in 6 views. These plans were in random order, the surgeons did not know beforehand which plan was generated by the software or which plan was created manually. For each patient the surgeon was asked which of the two plans was best in their opinion supported by a short explanation.

4.2.5 Statistical analysis

The results of the outer and lower border differences from the objective analysis were statistically compared for each patient separately. Due to different plans for each patient it is not possible to compare all manual plans to all automatic plans. A patient that has a reconstruction including the front will be different from a patient that has a reconstruction without the front side involved. Kolmogorov Smirnov tests on the data of the outer contour and bottom contour revealed the data was not normally distributed. Hence Mann Whitney U tests were performed on each dataset of the outer and lower border to test whether the distances obtained between the mandible and manually developed reconstruction plan were significantly different to the distances obtained between the mandible and the automatically generated reconstruction plan.

4.3 Results

4.3.1 Objective analysis



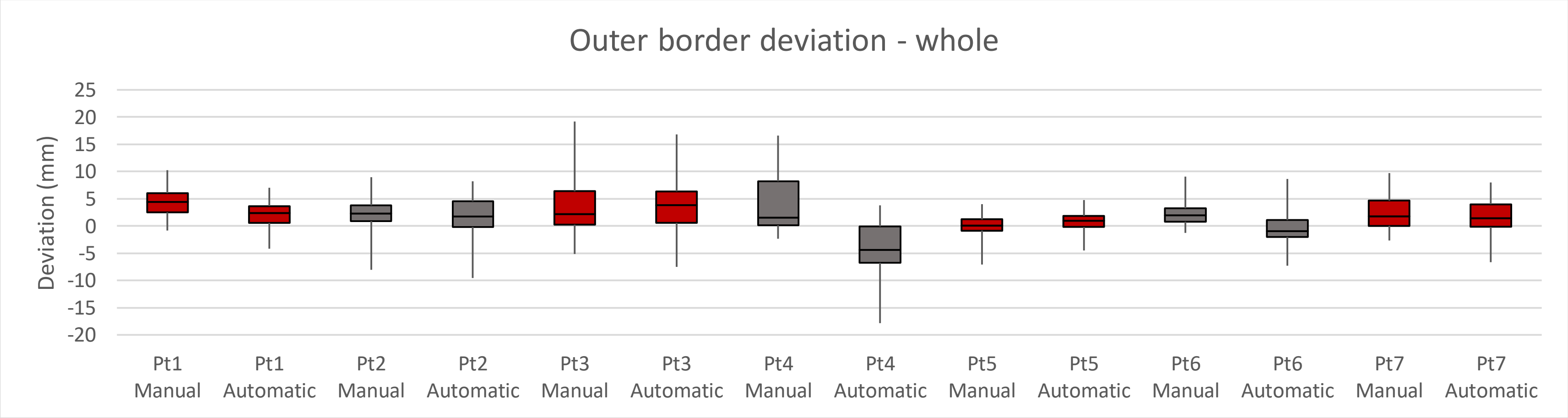


Figure 41: Boxplots showing the distances between the mandible and the reconstruction plans concerning the outer border for each patient. The upper boxplot presents the deviation measured from the front until the last molar. The lower boxplot presents the deviation measured for the entire reconstruction plan. A positive deviation indicates the reconstruction plan lies on the inside of the mandible border. A negative deviation indicates the reconstruction plan reaches outside of the mandible border. The bars denote the median, boxes show interquartile range, upper whiskers show third quartile and maximum, lower whiskers show first quartile and minimum.

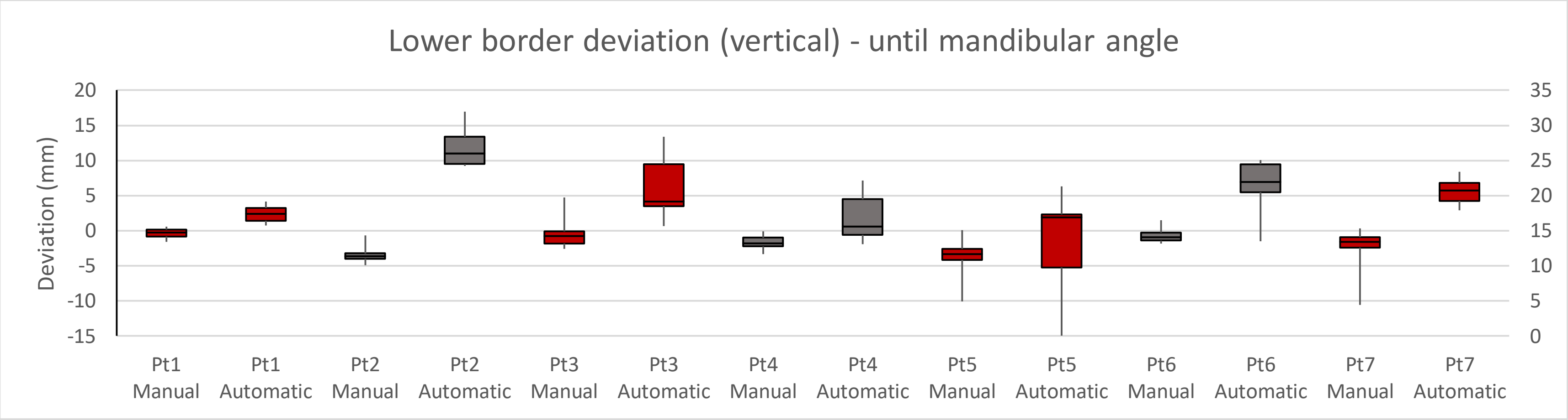


Figure 42: Boxplot showing the distances between the mandible and the reconstruction plans concerning the bottom border for each patient. A positive deviation indicates the reconstruction plan lies under the mandible bottom border. A negative deviation indicates the reconstruction plan lies above the mandible bottom border. The bars denote the median, boxes show interquartile range, upper whiskers show third quartile and maximum, lower whiskers show first quartile and minimum.

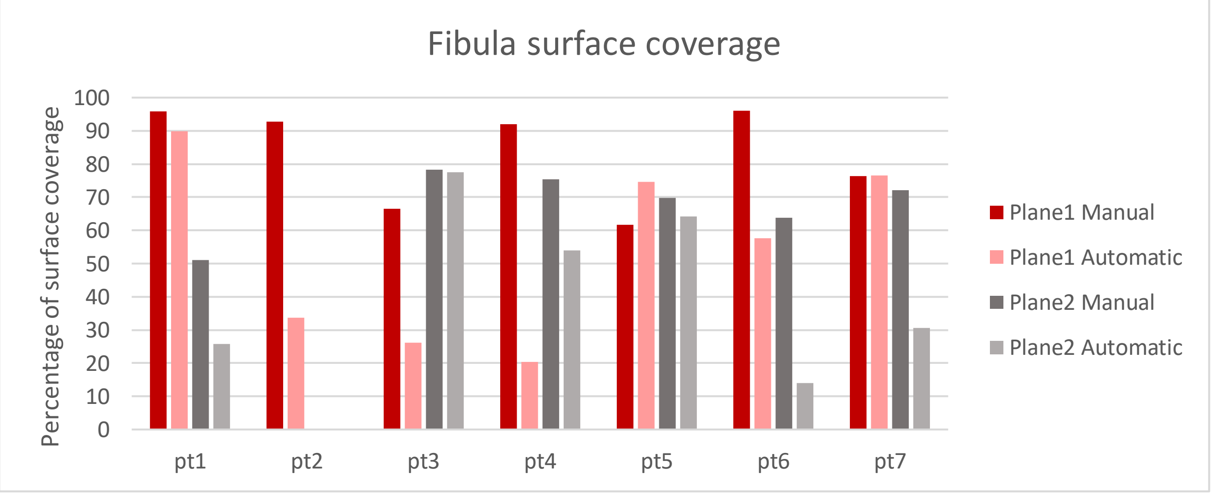


Figure 43: Histogram illustrating the percentage of fibula surface coverage for each patient for the manually created plans and the automatically generated plans. Plane 1 represents the mandible to fibula contact plane furthest to the front of the mandible. Plane 2 represents the mandible to fibula contact plane furthest to the back of the mandible.

Figure 41 presents the results of the outer border deviations between the manually created reconstruction plan and the mandible vs the deviations between the automatically generated reconstruction plan and the mandible. The Mann Whitney U test revealed a significant difference for all patients (p = 0.000) for both the outer border measured until the end and until the last molar. Only patient 2 showed no significant difference for the outer border (p = 0.012) until the last molar. Looking closer, the manually developed plans have smaller deviations (median closer to zero) for patients 2, 3, 4, and 5 measuring up and until the last molar and for patients 3, 4 and 5 taking the whole reconstruction plan into consideration.

The lower border deviations between the manually created reconstruction plan and the mandible vs the deviations between the automatically generated reconstruction plan and the mandible is presented in figure 42. The Mann Whitney U test revealed a significant difference for all patients (p = 0.000). Furthermore, patients 1, 2, 3, 6 and 7 measure a smaller deviation (median closer to zero) in the manually developed plans.

The percentage of fibula surface coverage for each plan and both planes (front and back) is illustrated in figure 43. Patient 2 had no contact point of its fibula segment to the mandible at the back. Hence no data is available for plane 2 in patient 2. For the histogram it can be seen that in nearly all cases the manual plans achieve a higher fibula surface coverage for planes 1 and 2. Plane 1 in patient 5 poses the only exception.

The distance between the locations of the anatomical mandibular angle in the mandible and the reconstructed mandibular angle in the reconstruction plan, denoted by two manually placed points, could be measured in two patients, patient 2 and 5. These were the only two patients for which the reconstruction plan involved the mandibular angle. The results can be found in table 16. Both distances measured in 2D and 3D are smaller for the manually created reconstruction plans.

Table 16: Positional deviation of reconstructed mandibular angle

	Deviation 3D (mm) Manual	Deviation 3D (mm) Automatic	Deviation 2D (mm) Manual	Deviation 2D (mm) Automatic
Patient 2	4.2	19.3	2.7	5.5
Patient 5	19.7	42.5	19.0	40.1

The conclusions on whether or not a good occlusion is expected, inspecting the positioning of the segments under the teeth of the upper jaw, are presented in table 17. In 5 out of 7 patients the fibula segments in the reconstruction plan are positioned well to offer a good occlusion when dental implants are placed. For the automatically generated plans, 4 plans had segments that were properly positioned under the upper teeth row. However, the segments were positioned too low in the mandible for dental implants to achieve a proper occlusion.

Table 17: Visual evaluation of the occlusion in the reconstruction plans

	Manual	Automatic
Patient 1	Yes	No, it is positioned well under the teeth, but the segment is positioned too low
Patient 2	No	No
Patient 3	Yes	No
Patient 4	Yes	No, it is positioned under the upper teeth, but the segment is positioned too low
Patient 5	No	No
Patient 6	Yes	No, it is positioned under the upper teeth, but the segment is positioned too low
Patient 7	Yes	No, it is positioned under the upper teeth, but the segment is positioned too low

4.3.2 Subjective analysis

All three surgeons evaluated each plan and concluded for each patient that the manual plan was preferred. Remarks for the plans were largely similar. For all plans with exception of plan 5, the manual plan was found to have a better bottom and outer border and better surface contact between the fibula and mandible. In addition, automated plans 4 and 6 were found infeasible due to the very bad contact surfaces and a very badly shaped front segment that contained sharp protrusions in plan 4. Plan 5 was judged insufficient for both methods by one surgeon. However, the manual plan showed segments with better length measurements and a better positioning of the mandibular angle.

4.4 Discussion

To unlock the full potential of the universal mandible and universal fibula guides, a (semi-) automatic mandible reconstruction planning software is necessary. Only then deviations from the original plan can be safely made intraoperatively without having to switch back to the freehand method. In addition, (semi-) automatic planning software could mean that professional planners become otiose as surgeons themselves will be able to develop preoperative plans. In this chapter, the first step in solving this last piece of the puzzle was taken by introducing software that could semi-automatically generate plans. The semi-automatically generated plans by the software were compared to manually developed plans. The comparison was executed by surgeons and by objective measurement methods.

For all patients, all three surgeons chose the manually developed reconstruction plan over the automatically generated plan by the software. Remarks for rating the manual plans over the automated plans were largely based on insufficient contact surfaces, and inferior outer and lower borders for the automated plans. Judging from the plans it seems that the software has great difficulty placing the segments at a proper position on the mandible contact surface such that it does not protrude outwards, both to the side and the bottom. It seems that the midaxis of the fibula segment is placed on the outer border of the contact surface of the mandible instead of placing border on border. It is expected that by solving this error, the automated plans will be majorly improved. In addition, the angles and contact surfaces between fibula segments in two or more segment reconstruction plans need to be improved. The angles need to be more similar such that the contact surfaces increase. Lastly, especially in patient 5, the reconstructed mandibular angle was placed insufficiently close to the original mandibular angle. It seems that the software does not take this into account as much as it should. When these issues are solved for the software generated plans, a second evaluation should be executed to optimize the plans further. In the following, the results of each objective evaluation method are compared for both plans and discussed whether the evaluation method can be applied to rate a plan.

Fibula segments should follow the bottom border as best as possible. According to the surgeons, the fibula segments in the automated plans were positioned too low in each plan. The objective analysis for the lower border evaluation showed a significant difference between the two plans for each patient. For each patient the fibula segments from the automatically generated plans were positioned lower than the segments from the manually developed plans. A lower positioning does, however, not result in a higher deviation in all cases. In patient 4 and 5 the automated plans showed a smaller deviation (closer to zero) than the manual plans. This difference is minimal. However, the boxplot distribution is far wider with the automated plans. The wide distribution suggests that the multiple segments are not all following the bottom border properly. One segment may lie above the original border and the other segment may lie under the original border. The median value then results in a deviation close to zero, but the bottom border is not mimicked correctly. It is therefore important to look not only at the median deviation but also at the boxplot distributions, which should be narrow as is the case for all manual plans. In addition, it can be seen that for plans 2 and 5, the deviation of the manual plans is larger than the other manual plans. These plans include the condyles and hence the reconstruction of the mandibular angle. A larger deviation means a larger dispositioning of the rotation axis of the mandibular angle. The more the rotation axis is placed to the front, the larger the bottom border deviation will be after this point (figure 37). To conclude, the bottom border evaluation can be used to evaluate a plan. Judging from the deviations, it seems that a good plan should have a median deviation between 0 and -2 mm if the condyles are not involved and between 0 and -4 mm if the condyles are involved. The segments should thus lie onto the bottom border or just above it. The distribution of data should be narrow to ensure all segments follow the bottom border equally.

Fibula segments should follow the outer border as best as possible. According to the surgeons the fibula segments in the automated plans were positioned worse concerning the outer border in each, plan except for patient 5. The distances between the outer border of the mandible and the reconstruction plans showed a significant difference between the two plans for each patient considering the whole plan using the objective method. This difference is not one sided. Patients 3, 4, and 5 of the manual plans lie closer to the outer border of the original mandible than the automated plans, while in patients 1, 2, 6 and 7, the opposite is true. The surgeons however judged the outer border of all patients (except for patient 5) to be better in the manual plans. It thus seems that the objective outer border evaluation method is not serving its purpose. An inferior outer border by the objective method does not imply an inferior outer border judged by the surgeons. Taking knowledge of the mandible border, this can be explained. The mandible is horseshoe-shaped, while the fibula segments can be considered straight. When a segment is optimally placed at the start and end planes of the mandible defect, the outer border deviation will be larger due to the convex shaped outer mandible than when the segment is placed suboptimally to these planes (more to the outside). This can be seen in figure 44 which illustrates the mandible and reconstruction plans for patient 1. Red represents the manual reconstruction plan, while blue represents the automatic reconstruction plan. The latter plan has the fibula segment placed suboptimally at the rear. Segment placement like this causes protrusions and should be avoided at any cost. However, due to this positioning, the segment lies closer to the outer border of the convex shaped mandible. Therefore, for this patient, the outer border deviation is closer to zero for the automated plan, which would assume the plan is better (2.3 mm vs. 4.4 mm deviation). Automated reconstruction plans of patients 2, 6 and 7, all more than one segment plans, have a lower outer border deviation due to the same reason and thus a false conclusion is given. Given the reason for these false conclusions it would be more useful to use the outer border deviation analysis locally at the start and end planes to place the segment properly at both planes such that no protrusions would arise. In addition, in more than one segment plans, the outer border evaluation could be useful to help find the best position of the angle placement between the first and second segment. The position can then be chosen such that the lowest outer border deviation is found for each segment. In summary, the outer border deviation as a whole, is not a good measure to evaluate a preferred outer border of the reconstruction plan. The outer border evaluation method is, however, a useful tool to help position the segments without protrusions both in one segment plans and in two or three segment plans. It should then be used locally. The outer border deviation may be due to this reason relatively large, up to 4.4 mm. Only in two or more segment plans can the evaluation of the full outer border be useful for determining at which location the multiple segments should make an angle.

The fibula surface coverage should be as high as possible to reach proper bone union. The surgeons judged the surface coverage to be better for the manual plans. This is largely due to the lower and more outward positioning of the segments in the automated plans. The front plane in patient 5 was the only exception. Here the segment had a protrusion in the manual plan, and less in the automated plan. The fibula surface coverage analysis agreed with the surgeons' conclusions and acquired a higher coverage for all manual mandible reconstruction plans except for the front plane of patient 5. The analysis can thus be used to evaluate the surface coverage of the fibula segments.

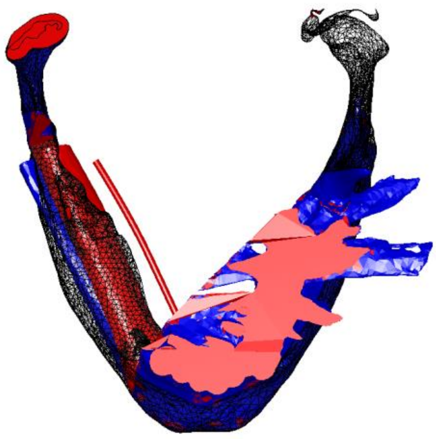


Figure 44: Mandible reconstruction plans. In grey the mandible. In red the manually created reconstruction plan. In blue the automatically generated reconstruction plan.

The reconstructed mandibular angle should be positioned as close as possible to the original mandibular angle. For patients 2 and 5, the reconstruction plans reached until after the anatomical mandibular angle which allowed evaluation of the mandibular angle reconstruction. The surgeons judged both manual plans to have better positioned mandibular angles than the automated plans. The objective evaluation method agreed with the surgeons' outcome, both in 2D and 3D measurements. In both patients the software placed the rotation axis of the reconstructed angle more to the front. The 2D and 3D measurements hardly differed for the manual plans, however for the automated plans due to the lower positioning of the segments the 3D measurements were much higher than the 2D measurements in the automated plans. A large difference between the 2D and 3D measurements therefore also indicates a worse positioning on the bottom border. It seems the software does not value a correctly placed mandibular angle enough. However, the manual plans do not reach a deviation of zero either. In fact, in patient 5 a rather large deviation of 19 mm is present. It should be noted that in some cases, it is not possible to fulfil the wish of proper angle reconstruction. The segments should be able to have sufficient bone to bone contact with both each other and with the mandible. Good surface contact is more important than excellent mandibular angle placement. In conclusion, the objective measurement can indicate the positional deviation well, however the surface contact should be weighed in to reach a decision. Angle positioning deviation should be as low as possible but deviations up to 19 mm may be acceptable as well.

Visual analysis concluded that if dental implants were to be placed a good occlusion would be possible in patients 1, 3, 4, 6 and 7 of the manual reconstruction plans. For the other three patients, the fibula segment laid too much to outer the border such that the positioning of the teeth did not match with the position of the fibula segment. In the automated plans, 4 of those 5 plans were judged to have a potential good occlusion looking at the positioning in the xy-plane solely, patients 1, 4, 6 and 7. Taking the height into account as well, the fibula segments were positioned too low in the mandible and were therefore judged to reach no proper occlusion. Dental implants would not be able to reach that high. Evaluation of the outer border until the last molar showed that the manually developed plans had smaller deviations (median closer to zero) for patients 2, 3, 4, and 5. These results do only partly agree with the visual analysis. The outer border is therefore found incapable to serve as a method to analyze this aspect. The reason for this can be found in the mandible shape. In many cases the mandible is a fraction wider than the fibula segments due to the convex shape. The teeth row, however, are not at the outer convex space, but more to the inside. Positioning the fibula segments as close as possible to the outer border therefore misjudges the plans on proper dental implant placement and correct occlusion. A better way would be to evaluate the mandible inner border at this region. Placing a segment closer to the inner border would allow for dental implants better. This, however, largely contradicts one of the base rules to follow the outer border of the mandible to reach the best mandible symmetry and esthetics. It should be noted that not every patient wants or needs dental implants. A reconstruction plan could therefore aim for the best esthetics following the outer border while in other cases it aims for best occlusion after dental implants placing the segments more to the inside. To create a good plan, the decision on dental implants should be known beforehand.

To summarize, the evaluation methods of the bottom border, the fibula surface coverage, and the positioning of the mandibular angle are able to rate the plan concerning that specific aspect. The outer border should be used locally to position the segments well against the mandible and only used over the whole reconstruction plan in more than one segment plans to decide on the best angle placement between two segments. The outer border evaluated in the teeth area is incapable to predict a good occlusion. The inner border may be of more use. To use these methods to get an objective conclusion on the applicability of a plan, the following is suggested. Establish for each aspect the largest deviation it may have and divide this range into good, medium, and poor result. Good may be rated as 3, medium as 2 and poor as 1. Deviations above the maximum would be considered unacceptable. In addition, a weigh factor may be given to each aspect, as not all aspects are equally important. As mentioned before for example a high surface coverage is more important than a perfectly placed mandibular angle. By adding all ratings, an overall conclusion about the acceptance of a plan can be achieved.

A limitation of this study is the evaluation of the suspected occlusion. The suspected occlusion is an important aspect in mandible reconstruction planning. However, in this study the aspect was evaluated by a Technical Medicine student. Evaluation by head and neck surgeons themselves would add more reliability to the results. In addition, just 7 patients were evaluated. To establish maximum deviations a plan could have, more manual plans should have been analyzed. Only then reliable objective ratings can be calculated.

4.5 Conclusion

The automated plans generated by the current version of the software are still unsatisfactory as is concluded from the performed evaluation. Furthermore, the introduced objective evaluation methods of the bottom border, fibula surface coverage and mandibular angle positioning are capable of analyzing aspects of the plan. The outer border evaluation should be adjusted and only used locally to reach optimal segment placement against the mandible defect planes. Only in more than one segment plans may the outer border evaluation be used in whole to establish the optimal angle positioning between fibula segments. Outer border evaluation in the teeth area was incapable to reach a conclusion on suspected occlusion. Inner border evaluation might be more adequate. Combining all aspects of evaluation into a rating system may reach an overall conclusion about the acceptance of a plan.

Chapter 5: Overall Conclusion

The current process of mandibular reconstruction is too time-consuming preparatory-wise and does not allow for adjustment intraoperatively if necessary. If intraoperative adjustments are required, the plan and cutting guides become unusable and the surgeons need to apply the classical free hand method. This often results in an inferior outcome while both time and money have been wasted. Four things are needed to fully solve this problem: a universal mandible guide, a universal fibula guide, a (semi-) automatic planning software, and universal reconstruction plates. Universal reconstruction plates and a universal mandible guide are already available. The aim of this study was to take on the last two pieces. The development of a universal fibula guide and the evaluation of a (semi-)automatic planning software.

The universal fibula guide enables adjustment of angle and length measurements intraoperatively. Although still a prototype, a phantom study was executed in which the novel guide reached a yaw and roll angle accuracy that was not inferior to the currently used cutting guides. The segment length accuracy was significantly worse than the current cutting guides. However, there is still a lot to improve on the guide, which could among other things improve the length accuracy significantly.

A first version of a semi-automatic planning software was evaluated too. Comparing 7 plans, it could be concluded the current version does not reach acceptable plans yet, as all automated plans were inferior to the manual plans as judged by three head and neck surgeons. Aside from a subjective evaluation, a start was made to develop an objective evaluation method. The developed objective evaluation methods of the bottom border, surface overlap and mandibular angle positioning are capable of analyzing aspects of the plan. The evaluation method of the outer border should be adjusted. However, by optimizing these evaluation methods and combining all aspects of evaluation into a rating system an overall conclusion about the acceptance of a plan may be reached.

Chapter 6: Future Perspectives

The novel fibula guide has shown great potential for replacing the current 3D-printed cutting guides. However, the new guide has still room for improvement in for e.g. the fixation blocks, the yaw rotation, and the readability of the scales. In addition, the separate Middefiner is not practical to work with and should be incorporated into the guide. After optimization of the fibula cutting guide, another phantom study should be executed to evaluate these adjustments and their effect. In particular the effect on the length accuracy.

Moreover, the mandibular reconstruction planning software should be optimized further by improving the positioning of the fibula segments. In addition, some of the objective evaluation methods should be adjusted after which these can be incorporated into a rating system. To define the ratings, a large number of manually created plans should be evaluated first.

If both are optimized, the next step is combining them with each other and with the recently developed mandible cutting guide, the Bladerunner. The planning software should generate an acceptable plan along with the information of the cutting planes both for the mandible and fibula.

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Appendix A: Worked out concepts ideation 1

1. A manually adjustable frame/instrument

The main advantages are:

- ease of use: surgeon can adjust the cutting guide by merely turning some knobs and reading the length/degree measurements from the instrument
- simplicity: the instrument consists of moving and rotating parts in assembly. No technology is needed
- the surgeon has full control

The main disadvantage/problem:

- difficult to create a compact instrument that offers both ease of use and good readability of the length and degree measurements on the adjustment knobs.

Concept:

The adjustable cutting guide consists of several one cm long fixation blocks that are connected by a rails. In between the fixation blocks are the cutting guides (figure 45). All components can be slid over the rails such that it can be assured every possible segment can be cut. In addition, the fixation blocks can fit any fibula which makes the cutting guide universally applicable. This can be realized by a shape similar to half a cylinder that slightly curves around the bone, as was done with the universal applicable fibula cutting guide, the 'L1® Mandible ReconGuide'. [59]. By screwing the fixation blocks onto the fibula it can be assured that the guide is fixed and lies parallel to the fibula bone. Rotational movement of the cutting guide around the y-axis (yaw) is assured by a ring that is connected to the rails. The ring can turn 360°. The degrees can be read from the ring. The rotation over the x-axis (roll) is assured by an arch that runs over the ring and is attached to the outsides of it. The cutting guide can slide over this arch from which the rotational degrees can be read. By creating the arch such that the center point lies exactly on the surface of the fibula bone, it is realized that whichever way the cutting guide is rotated it will always result in a cut that crosses this center point. This omits the use of a metal plate as was needed with the design of the MUG-jig. [46] By a sliding mechanism the rotational rings can by moved over the rails in between the fixation blocks. This way the length of the segments can be adjusted.

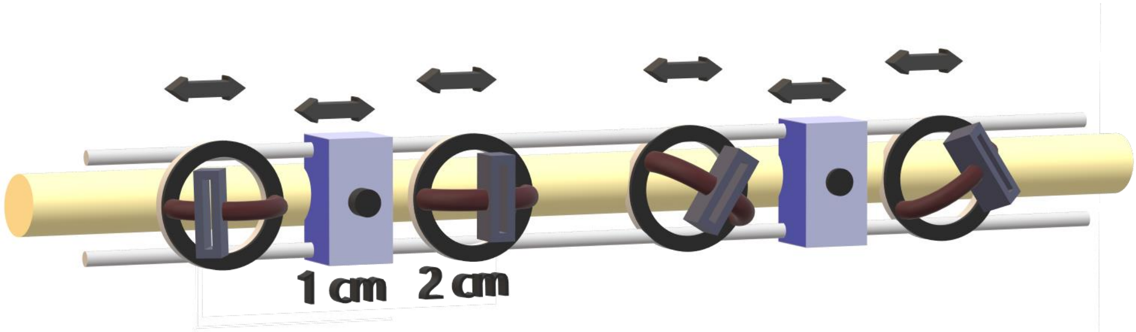


Figure 45: Concept for an adjustable cutting guide. In blue the fixation blocks. Apart from the fixation blocks 4 guidance elements are visualized.

2. Navigation

Looking at the literature it became clear that registration of the fibula bone to the images is difficult. Oftentimes invasive markers are needed or extra scans have to be made. While a full anatomic registration would provide beneficial insight in the location of perforators and nerves at the start of the surgery, it is not needed for the fibula osteotomies. The fibula bone is fairly straight and thus can be considered the same over a short length. It is therefore thought to be enough to estimate the location of a cutting plane as close as possible. The one thing that does need precise translation from the planning to the operation room is the length of the segment and the angles of the cutting planes and hence the orientation of the fibula bone relative to the preoperative CT on which the planning is made. Keeping this in mind, a concept was thought of in which not the bone was registered, but the guide itself.

The main advantages of using navigation:

- Compactness of the fibula cutting guide: no need for large length and degree display plates.

The main disadvantages/problems:

- During surgery an EM or optical tracking system is needed
- Takes time to register properly
- Extra error from tracking system

Concept:

A cutting guide that is navigated. Navigation is realized using an EM tracking system. Instead of registering the bone and surrounding anatomy, the guide itself is registered using a special register guide. On the preoperative planning (figure 46 step 1) a register guide, consisting of a rails and several fixation blocks, is placed over the cutting planes (figure 46 step 2). This can be done manually or automatically. The guide should be placed such that a cutting plane is always surrounded by two fixation blocks. If a segment is relatively long two fixation blocks can be placed next to each other for extra support. By the sliding mechanism of these fixation blocks the register guide is applicable in every situation whilst ensuring a tight fixation. During the surgery, the actual register guide is set to the same situation as in the planning and placed onto the fibula (figure 46 step 3). Registration can be realized using a point match registration. All fixation blocks contain fiducials (red dots in figure 46). By matching the fiducials of the planning to the fiducials in the operation room, the orientation of the registration guides and thus the fibula bone can be matched (figure 46 step 4). In addition, a 6DOF EM sensor is placed onto both the register guide (built in) and onto the actual fibula cutting guide (built in). This way the orientation of the cutting guide relative to the register guide (bone) is known. The registration is now complete. The EM tracking system can track the fibula cutting guide relative to the planning. Using software that visualizes the cutting plane of the fibula cutting guide, one can easily match the cutting guide with the cutting planes on the planning (figure 46 steps 5 and 6).

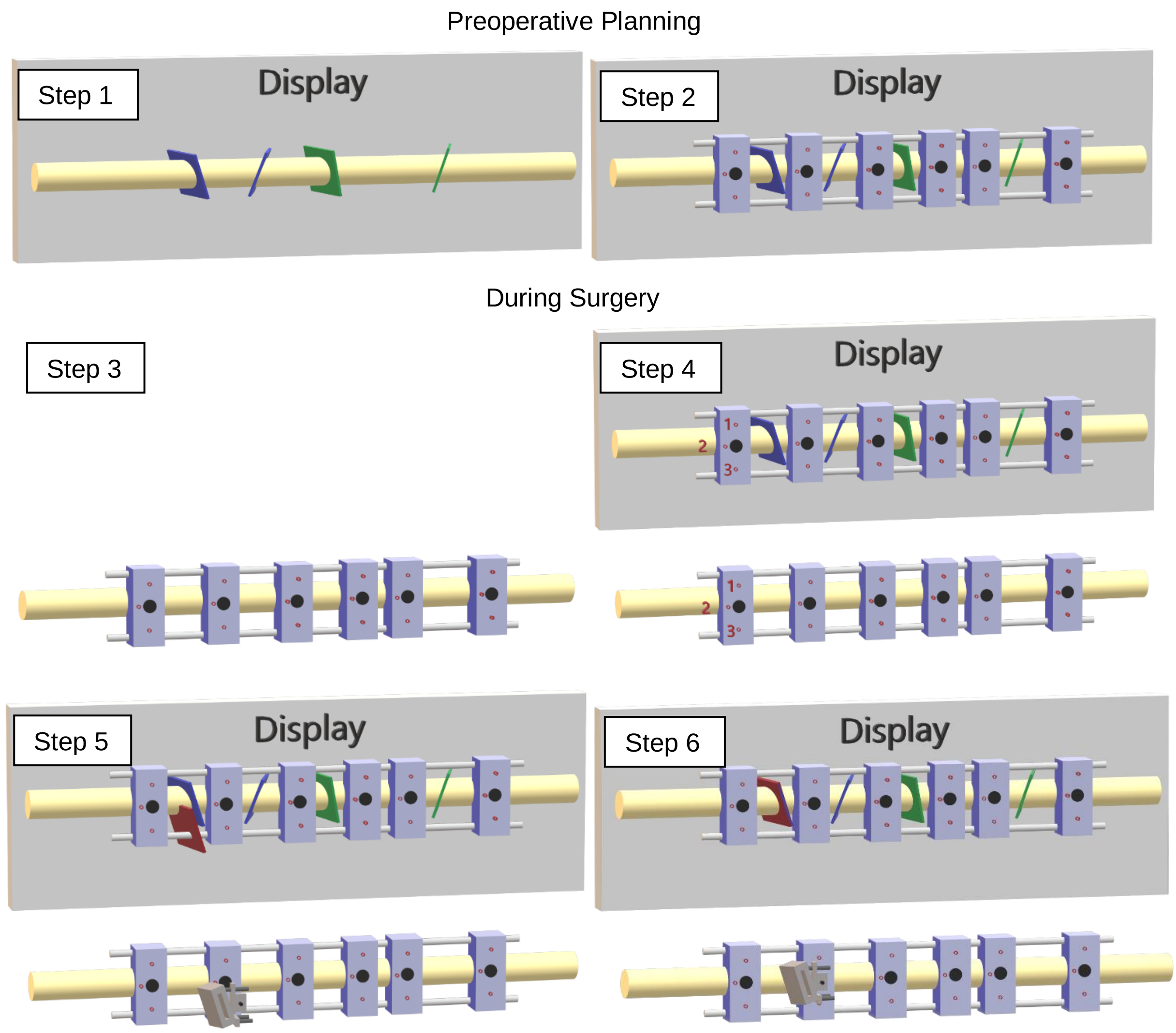


Figure 46: Navigation concept. Step1) The preoperative plan with in blue the cutting planes for a hypothetical segment 1 and in green the cutting planes for a hypothetical segment 2. Step 2) Virtual register guide positioned onto the fibula in the preoperative planning. Step 3) Register guide is positioned onto the fibula in the operation room. Step 4) The virtual register guide is registered to the actual register guide using the red fiducials. Step 5) the cutting guide is registered to the register guide. The cutting guide's guidance slot is now tracked and visualized in the preoperative plan (red plane). Step 6) The cutting guide is positioned onto the fibula such that the guidance slot (red plane) is matched to the first cutting plane. The first cut can now be made.

3. Projection by laser or beamer

Translation of the planning can also be achieved by projection of the cutting planes onto the fibula bone. The main advantages are:

- ability to project right onto the bone

The main disadvantages/problems are:

- despite the use of projection lines, it is still preferred to have a cutting guide to support and guide the saw along this projection line. This may proof to be cumbersome. In addition, matching the cutting plane of the guide to the projection line may result in some inaccuracy.
- Power source is needed to energize the projection lines.

Concept:
A cutting guide that uses laser projection to set the correct yaw and roll rotations. It consists of a lower frame and an attachable upper frame (figure 47). The lower frame consists of at least three fixation blocks. Two on the outside and one in between the laser projection to support the to be cut segment. All three lower fixation blocks are moveable along a rails, such that all length combinations can be realized. The upper frame consists of two moveable blocks that contain each a planar projection laser. These lasers can rotate over the x-axis (roll) and y-axis (yaw). Step 1 is to fixate the outer lower fixation blocks and correctly set the laser projections (figure 47, step 1). Once the correct orientation is obtained, the blocks containing the lasers can be moved such that the correct segment length is obtained on the bone. This can be measured on the lower frame. Once the lasers are set in the correct position the middle lower fixation block can be fixated as well. Step 2 is to match the separate cutting guides with the laser projections and fixate them onto the bone, as can be seen in figure 47, step 2. In step 3 the upper frame containing the lasers can be removed to obtain working space to saw the segments (figure 47, step 3).

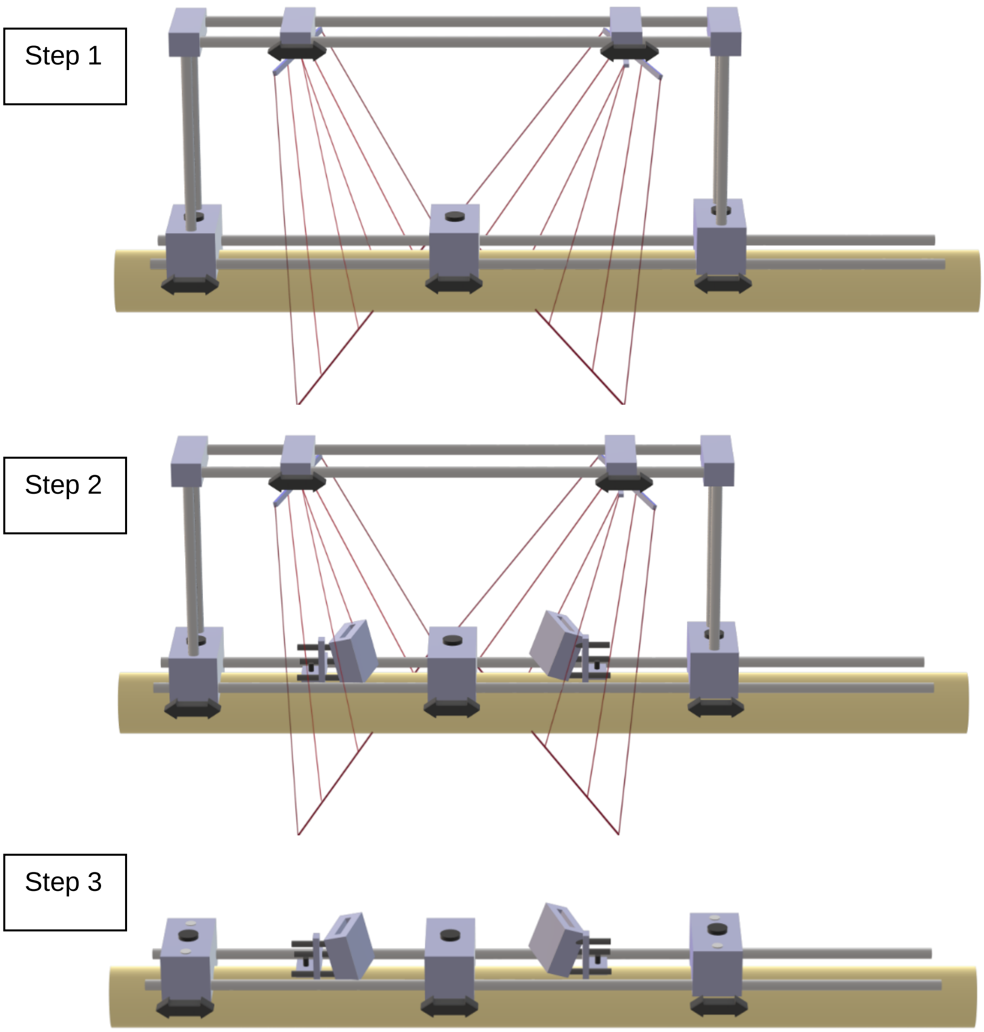


Figure 47: Projection concept. Step 1)The lower frame is fixated to the bone. The upper frame is fixated onto the lower frame. The lasers are set to the correct cutting planes. Step 2) the cutting guides are positioned correctly onto the bone through guidance of the lasers. Step 3) the upper frame is removed. The first cut can now be made.

4. Standard guides with fixed angles

Guides that have fixed angle setups. For example, if an osteotomy with a roll of 5° and a yaw of 15° is to be made, a guide that supports these angles is taken. The guide can then be fixated onto the bone and be sawn through by a standard saw.

Main advantages:

- Easy to use
- Fast to use

Main disadvantages:

- Many different guides will be needed to enable cutting many different angle combinations.

5. Robotics

The use of a robot to cut the fibula bone according to plan has the following advantages:

- High accuracy possible if registration is accurate.
- Fast and easy use. Robot cuts the bone in seconds.

Main disadvantages/problems:

- Expensive
- Long time before actual clinical application
- Use in delicate areas with vessels and nerves may be a safety concern
- Surgeon hands over full control to robot

Although robotic surgery may be the future of operating, no concepts are elaborated further. This because one of the requirements is to create a fibula cutting guide that can be used in the near future. Implementing a robot will take years. In addition, the robot is highly expensive if to be used for just this procedure (couple of patients a year). The robot should therefore be ready to use in other procedures as well. To develop something like this, will not be possible in one or two years.

6. Self-guiding saw

Self-guiding saws distinguish themselves from other concepts by being the guide themselves. Self-guiding saws may come in two forms:

1. Self-guiding by navigation. The saw may be navigated by EM or optical tracking and similar to concept 2 (figure 46 step 5 and 6) can ‘find’ the plane to cut and saw it accordingly.
2. Self-guiding by instrumental accessories that enable it to make certain angles. For example a mechanism that holds the saw orthogonal to the bone. Yaw and roll angles can then be accomplished by a bendable and rotatable saw tip.

Main advantages:

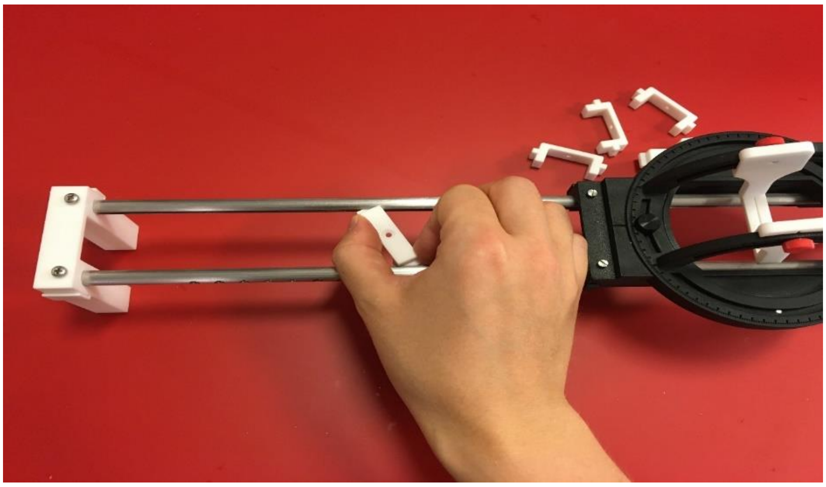
- No extra guides are needed. The saw guides itself.
- Easy to use

Main disadvantages:

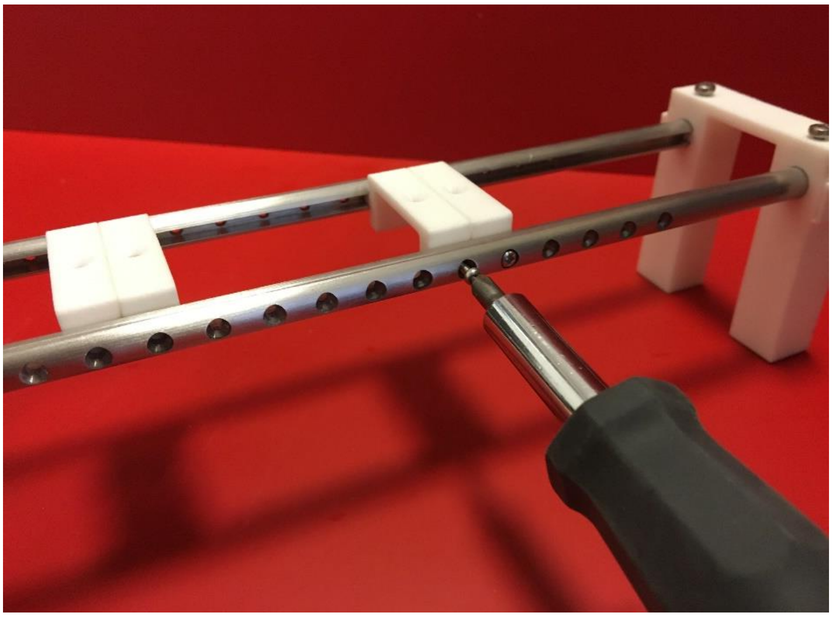
- With the first concept there is no real fixation for the saw to the bone. The saw is guided, but the surgeon still saws in the free air, which may be the cause for inaccurate cuts after all.
- With the second concept there is a fixation to the bone, but realizing an orthogonal positioning will be hard due to the irregular surface of a fibula. Inaccurately cut angles may be the consequence.

Appendix B: Fibula guide usage guide

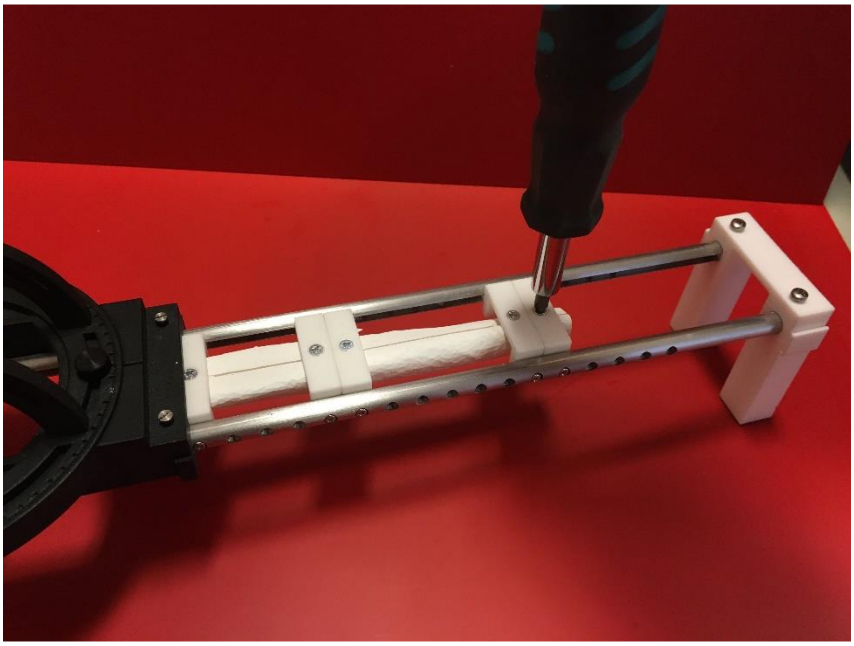
Step 1: Click fixation blocks between the rods and position them correctly

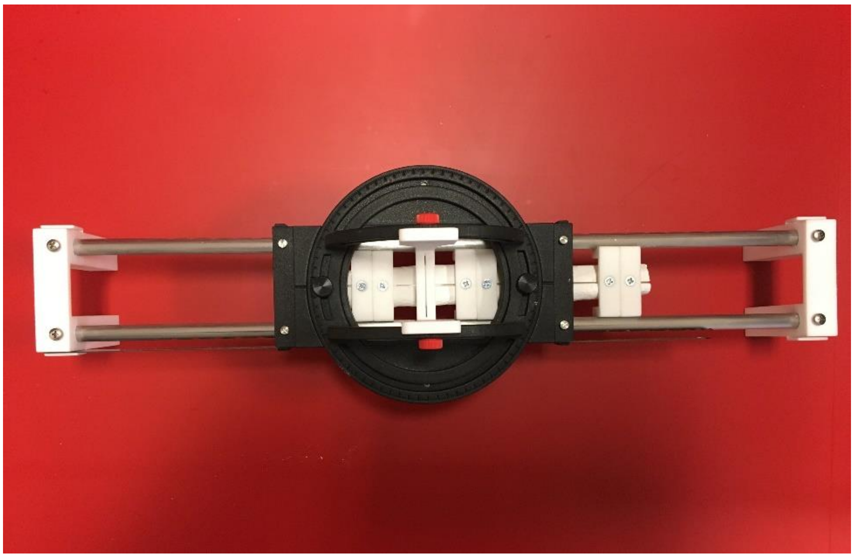


Step 2: fixate the fixation blocks to the rods by use of screws

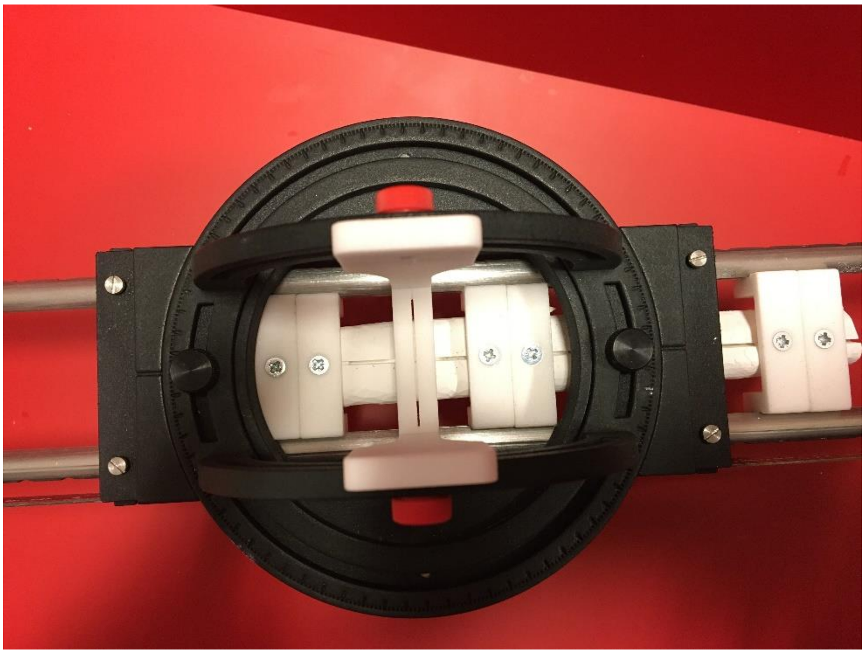


Step 3: Fixate the fibula to the fixation blocks (and hence the guide)

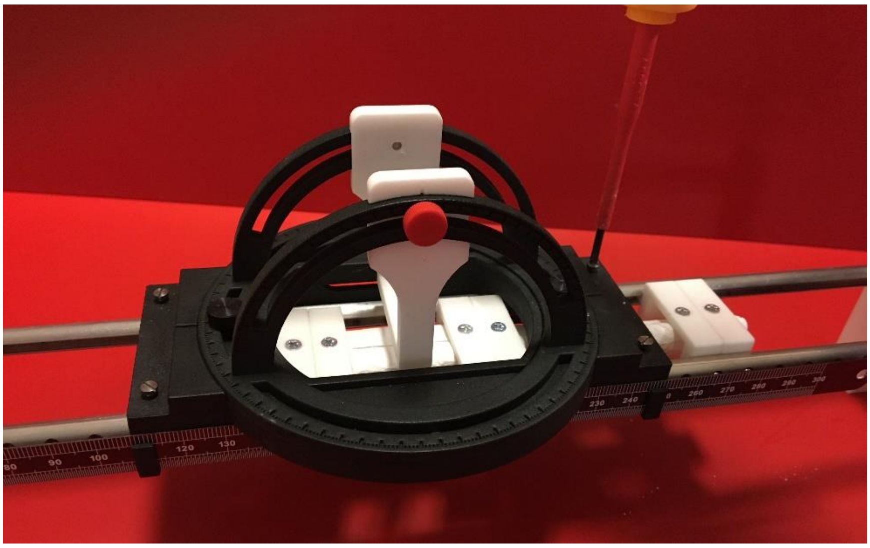




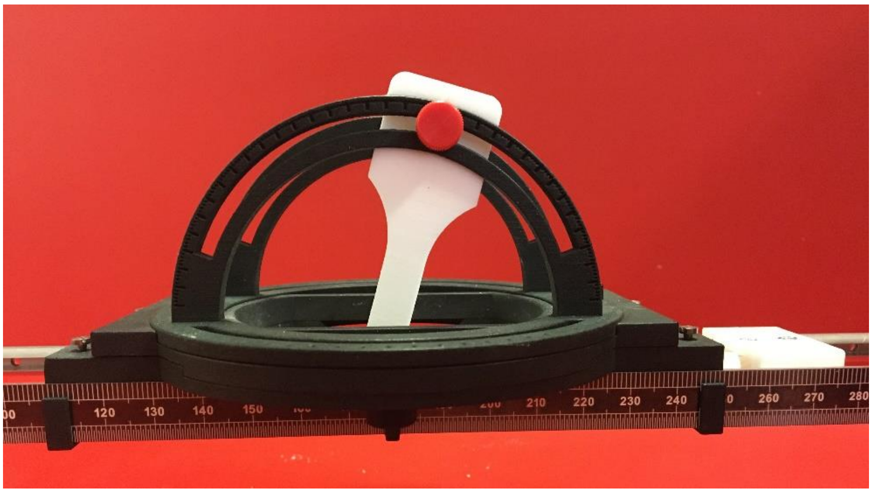
Step 4: Slide the guide to the correct location on the fibula using the ruler.



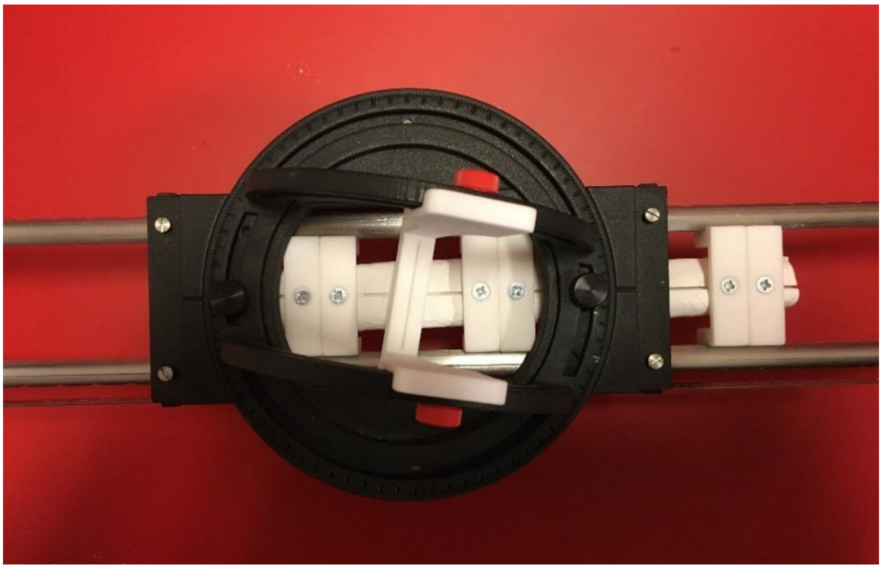
Step 5: Fixate the base block in this preferred position to the rods by turning on screws on the base block ends



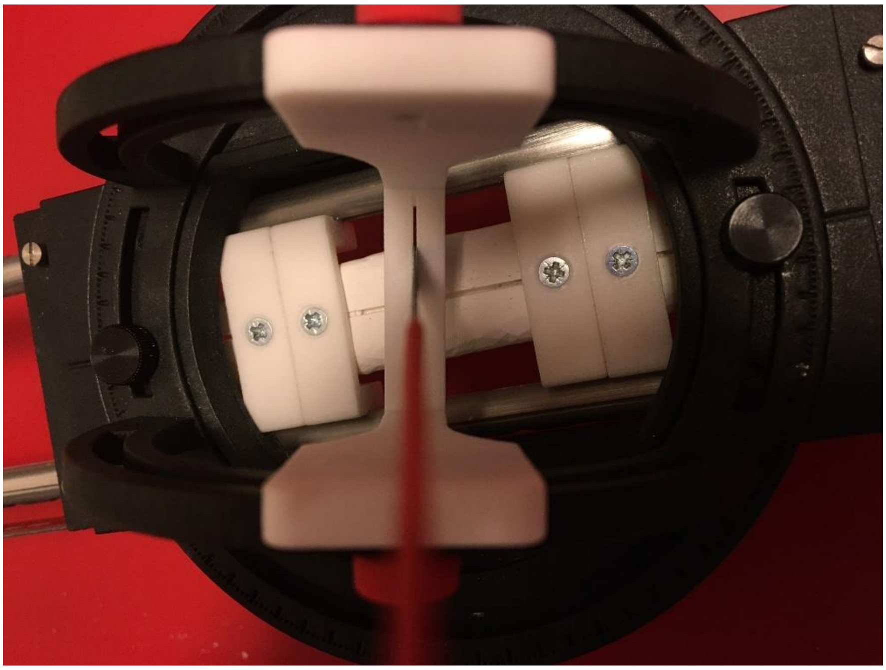
Step 6: Rotate the guide to the preferred yaw angle and fixate by turning the red knobs on the arches



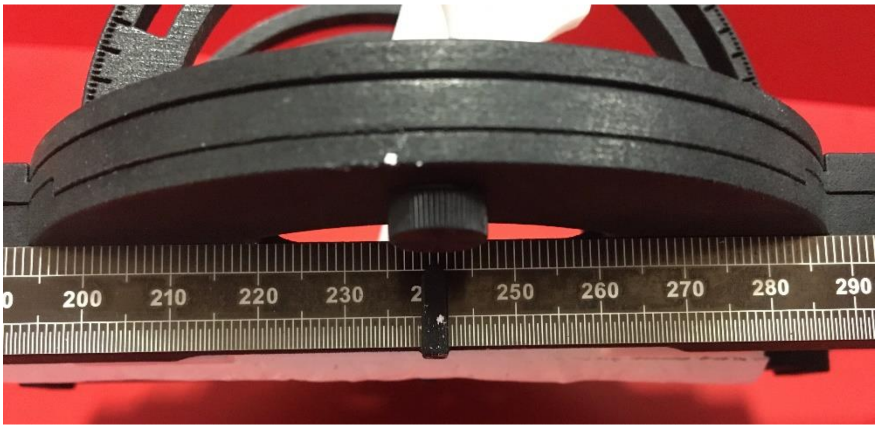
Step 7: Rotate the guide to the preferred roll angle and fixate by turning the black knobs on the ring



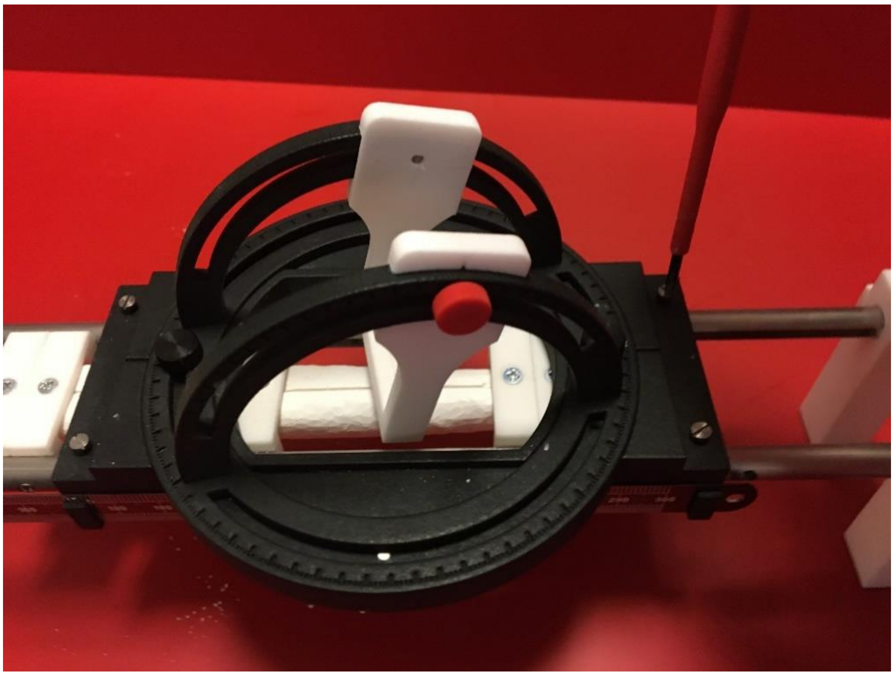
Step 8: Saw the first plane



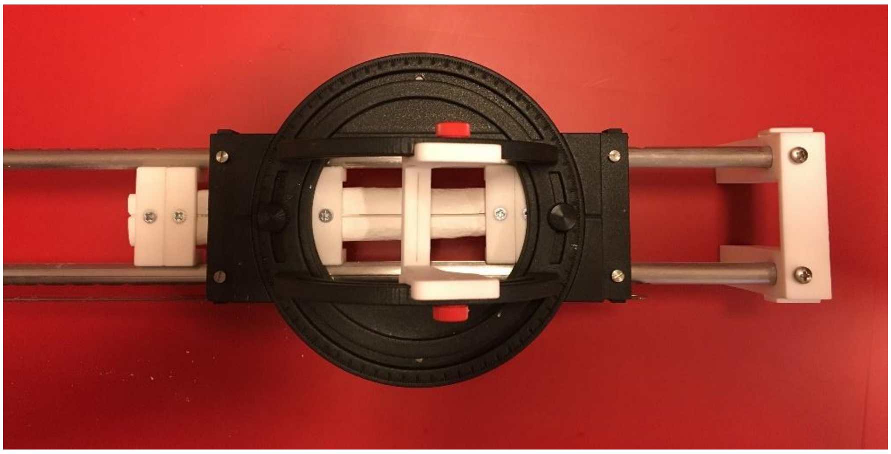
Step 9: Release the screws that fixate the base block and move it to the location of the second plane.



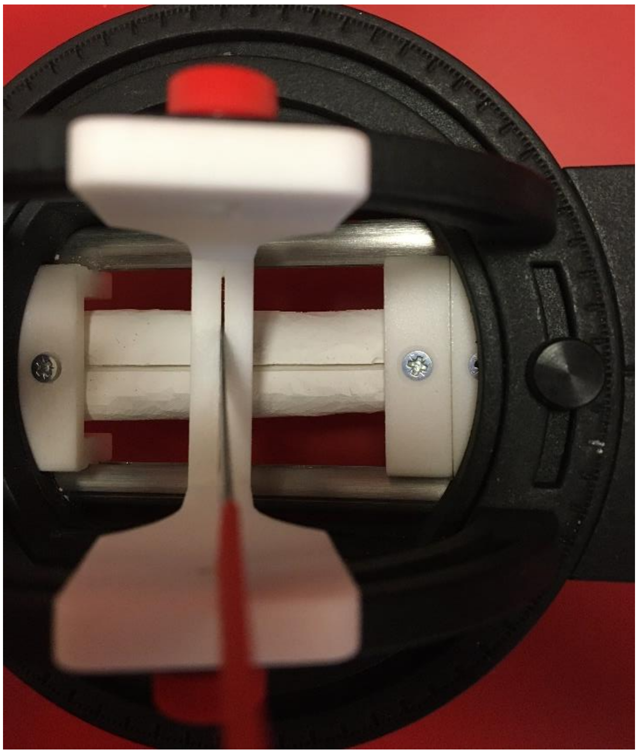
Step 10: Fixate the base block in this new position to the rods again by turning the screws

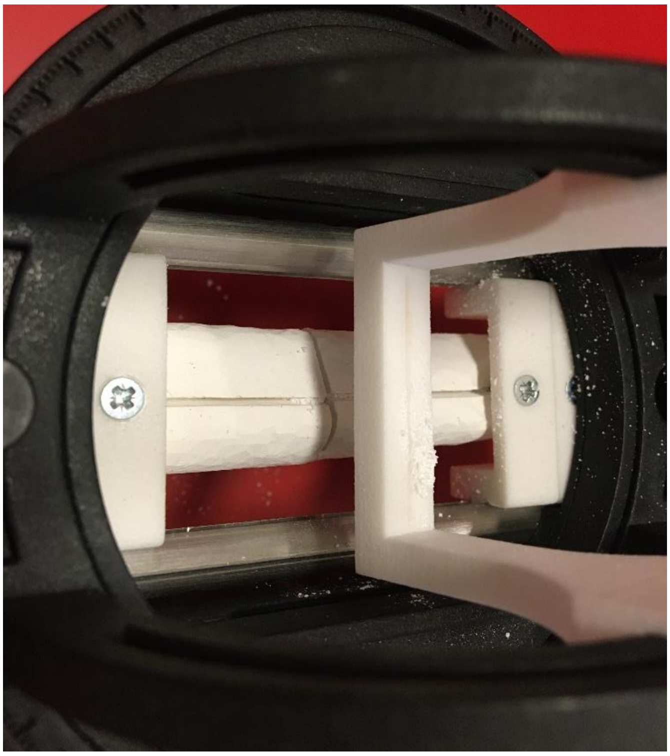


Step 11: Set the roll and yaw angle to the preferred angles again. Fixate by turning the black and red knobs respectively.

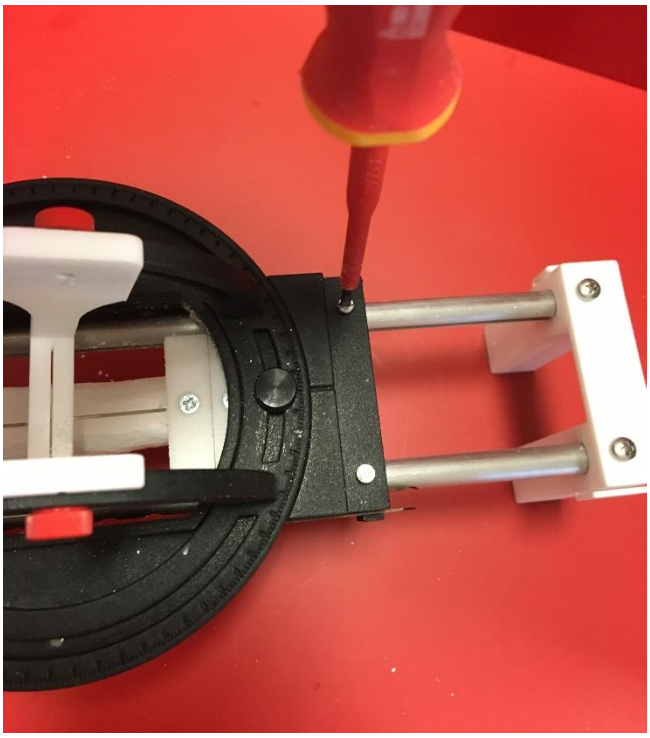


Step 12: Saw the second plane

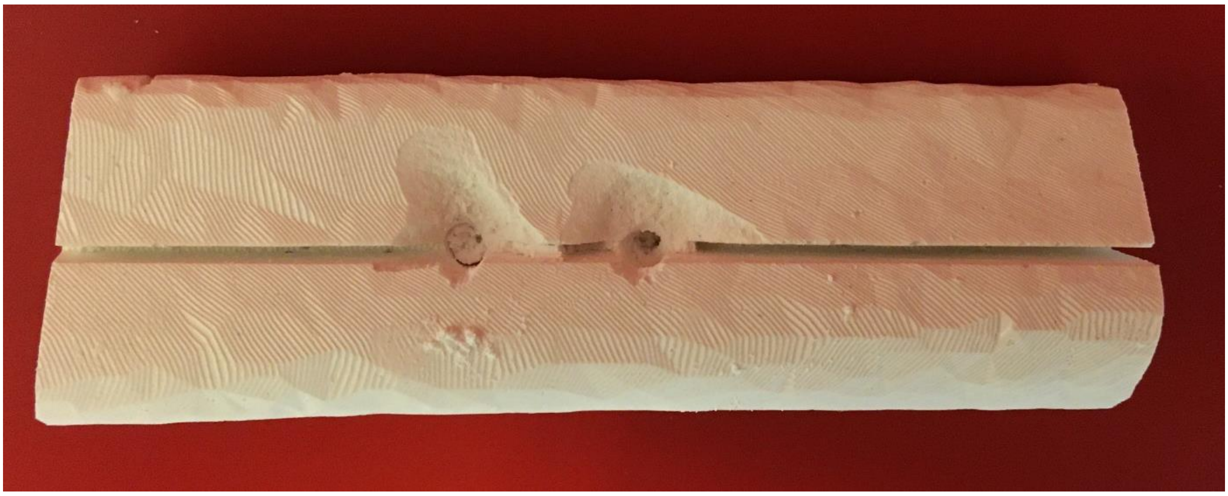


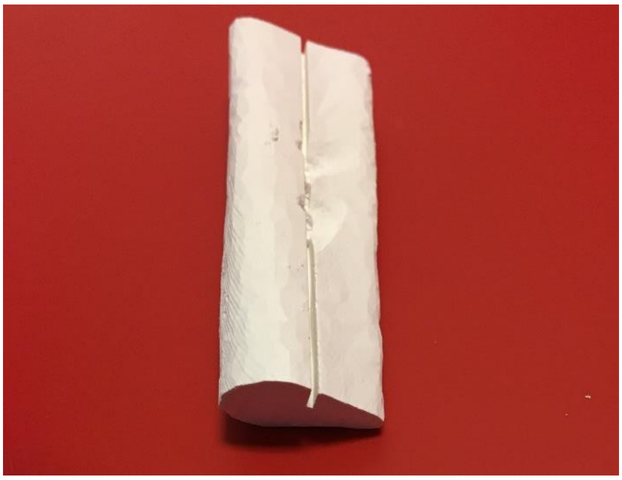


Step 13: Release the screws that fixate the base block to the rods and unscrew the screws fixating the bone to the fixation blocks



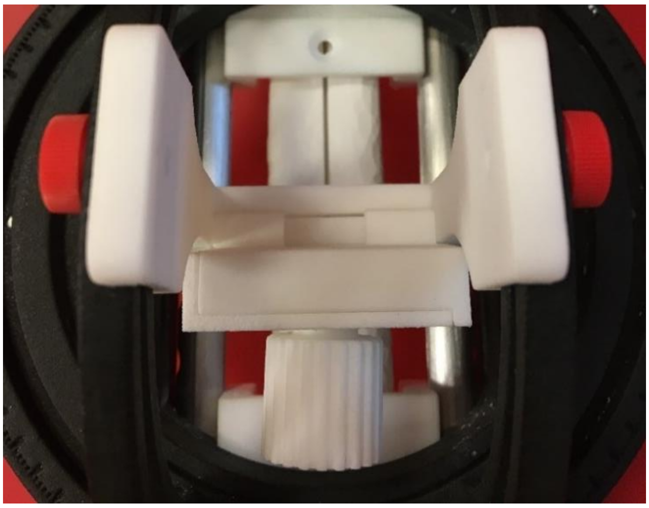
Step 14: Get the fibula segment



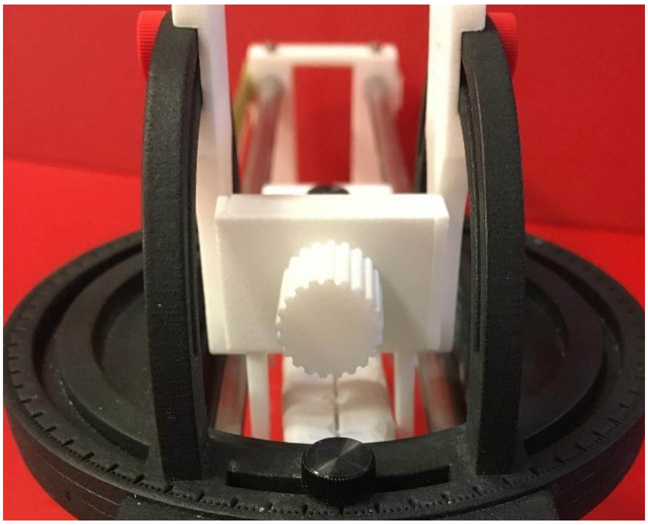


If the fibula is curved, and the guide is not centered over the fibula execute the following steps before cutting:

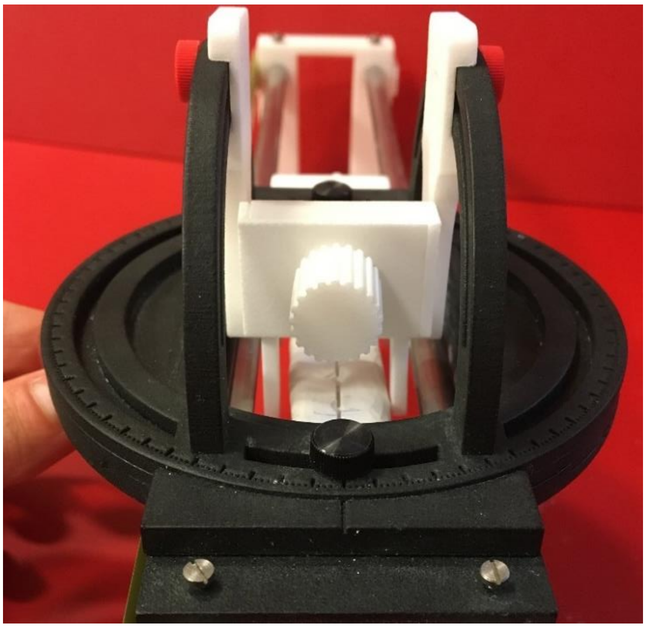
Step 1: Position the ‘Middefiner’ on the guide by placing it between the supporting arms of the guide as shown in the figure on the right.



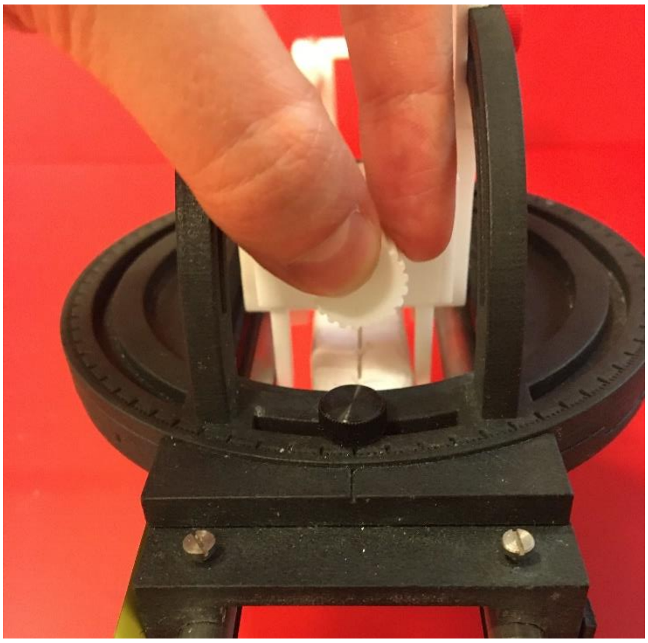
Step 2: Turn the knob on the ‘Middefiner’ to move the bars to ‘grab’ the bone. If both bars touch the bone, the guide is over the center of the bone. In this situation, this is not the case. Let’s reposition the guide.

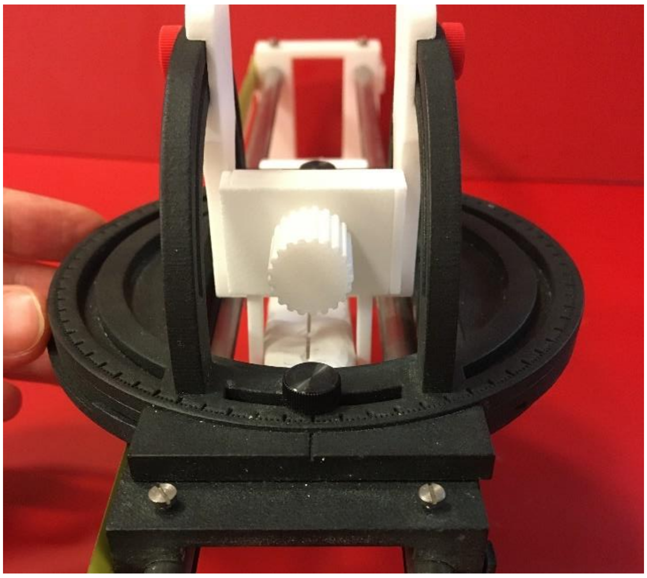


Step 3: Loosen the guidance element by loosening knobs at the bottom.

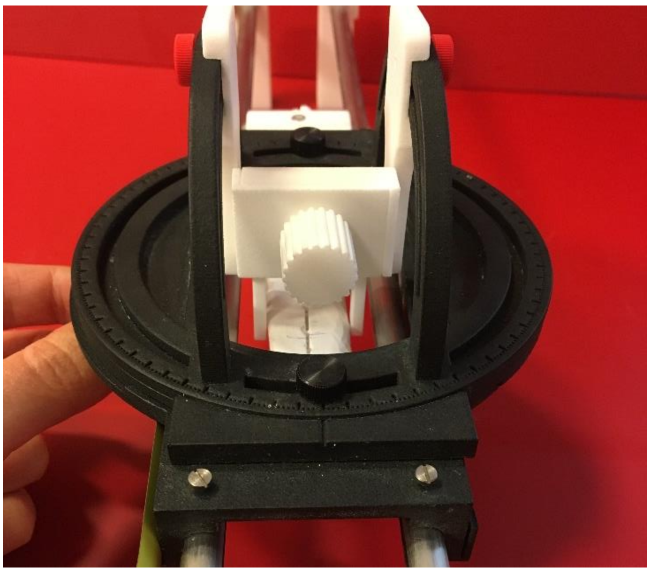


Step 4: Turn the knob on the 'Middefiner' to synchronously move the rods towards each other. To accomplish this movement the guide needs to slide horizontally to the right. Slide the guide until both legs touch one side of the fibula. The guide is now positioned over the middle of the fibula.

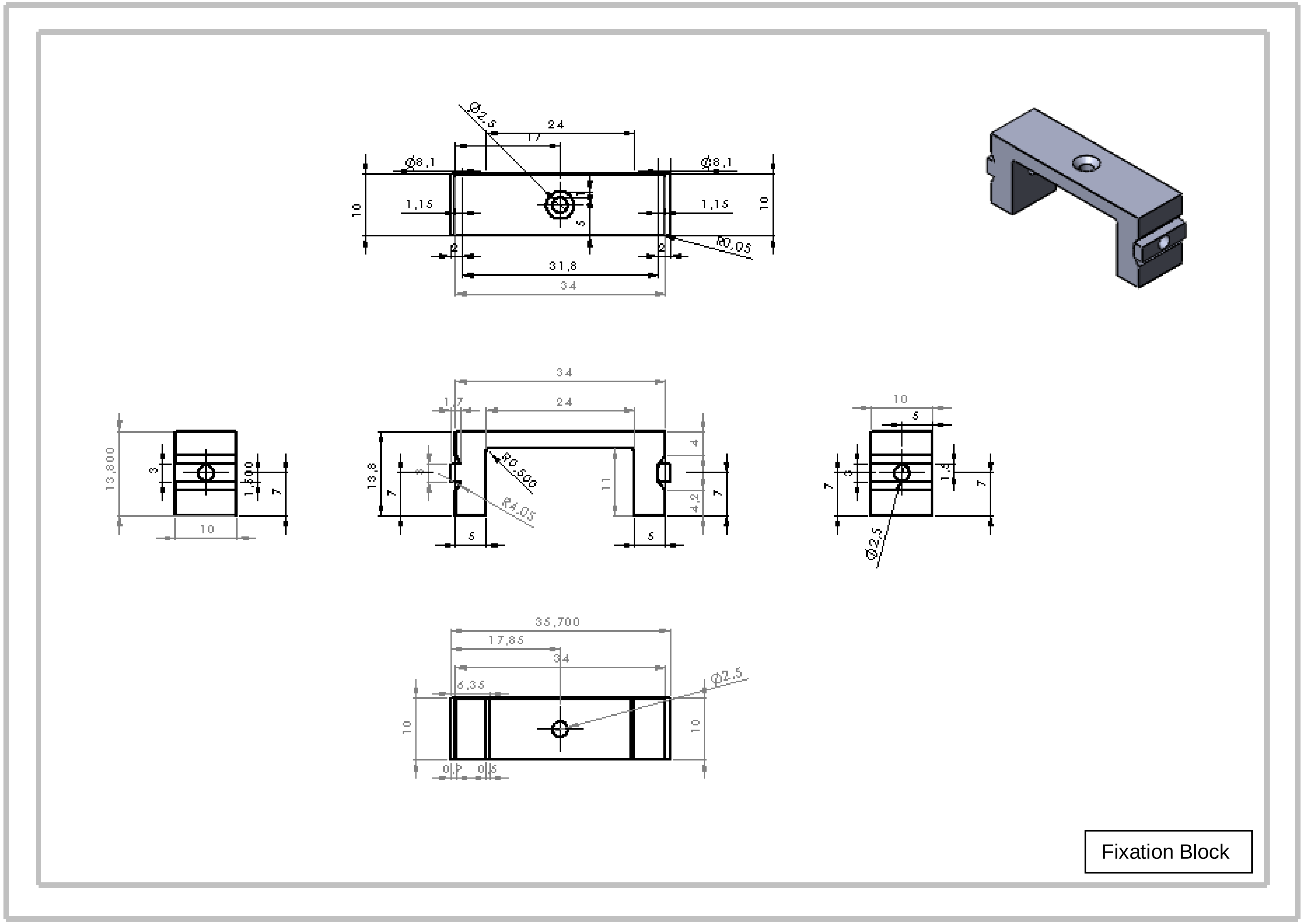


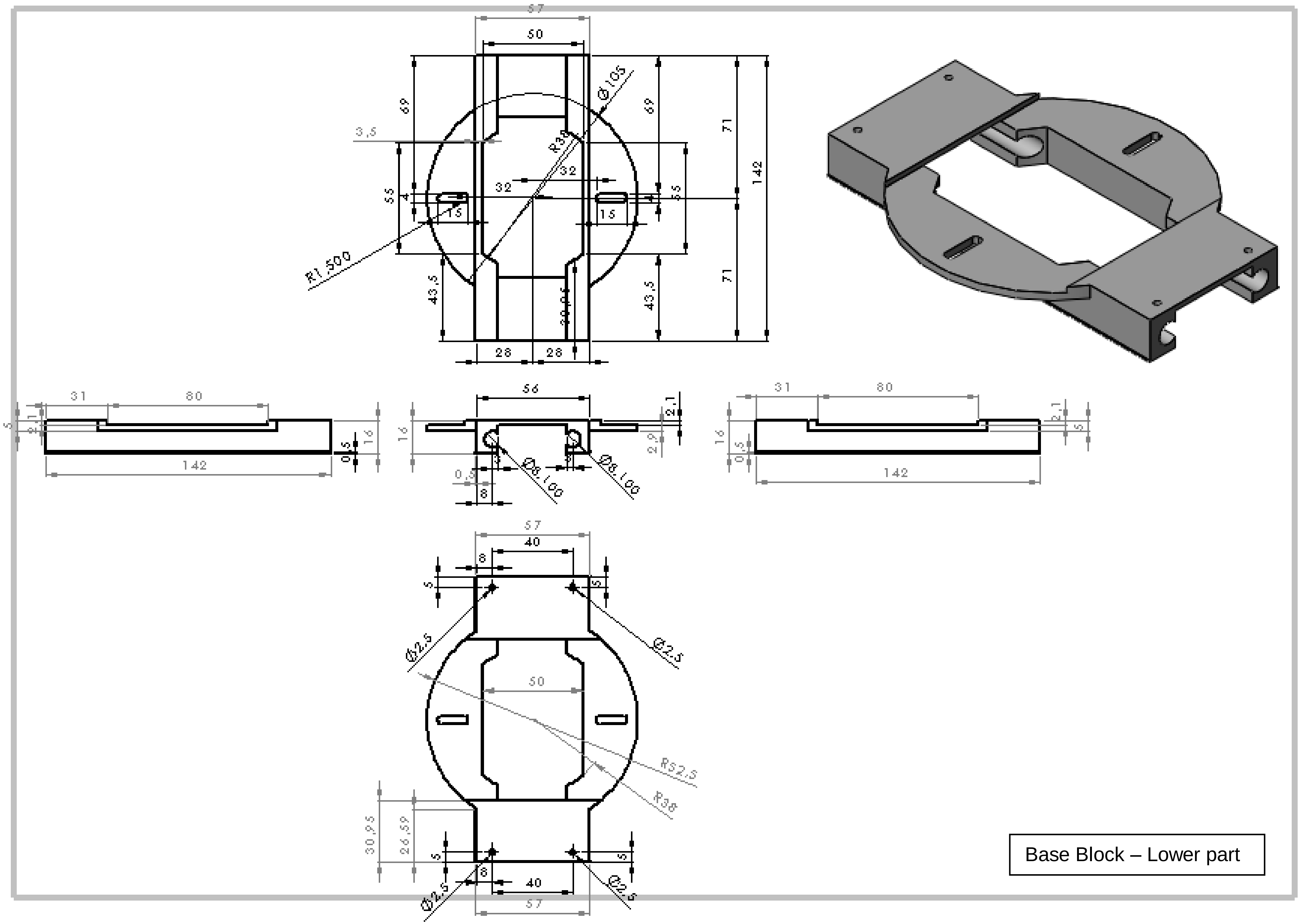


Step 5: Fasten the guide in this new position by tightening the knobs on the bottom. Remove the 'Middefiner' from the guide.

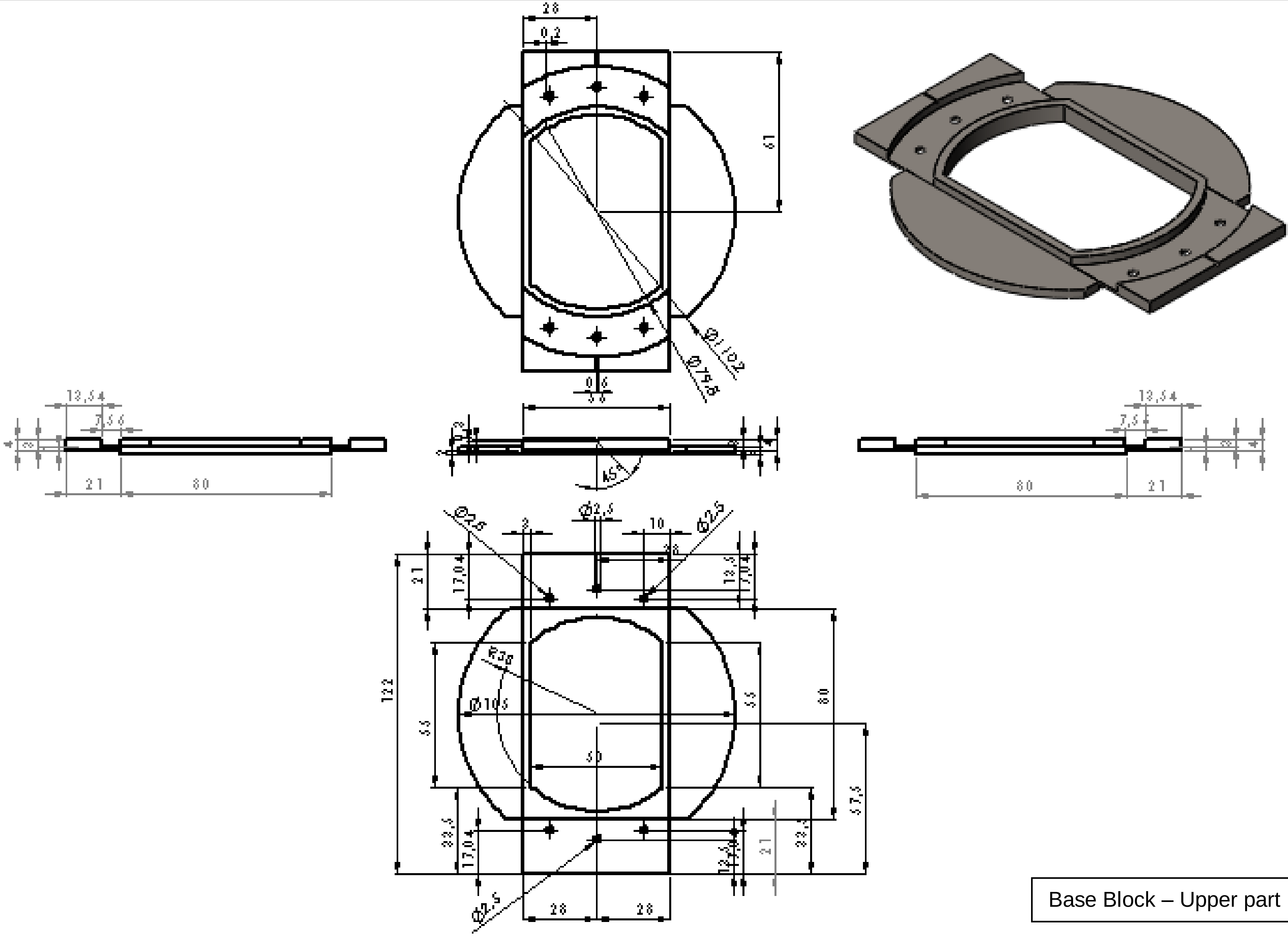


Appendix C: Blueprints final product

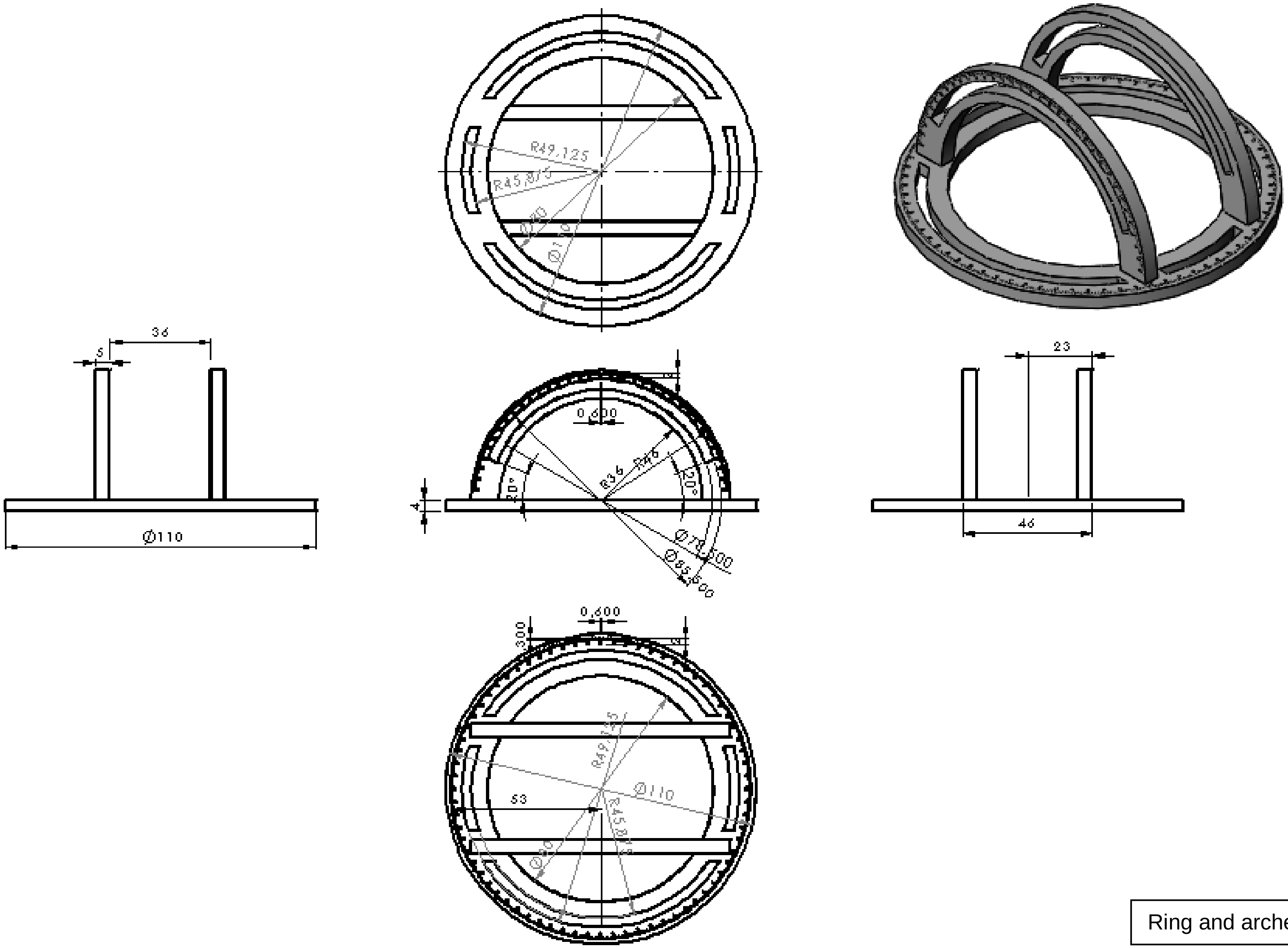




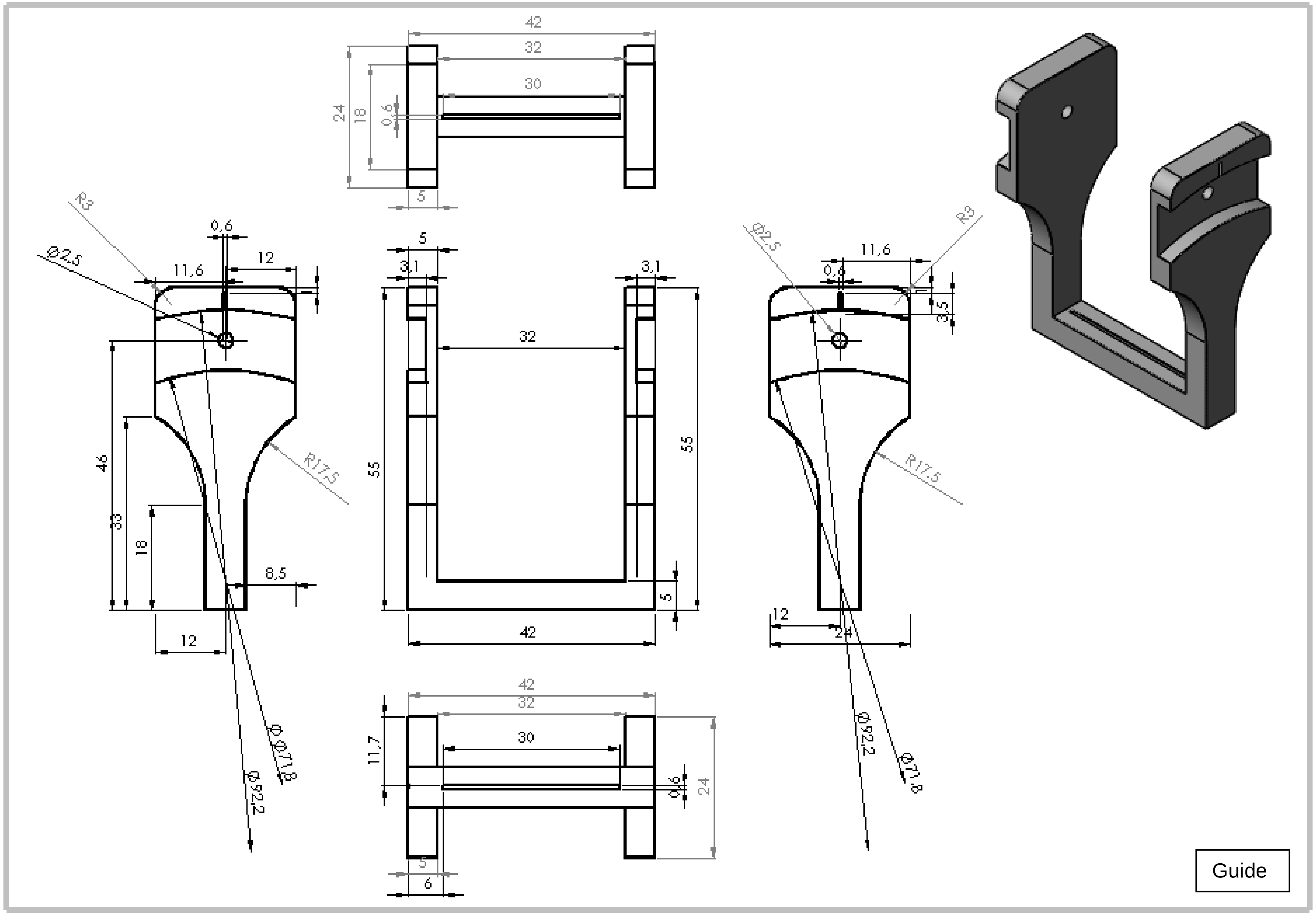
Base Block – Lower part

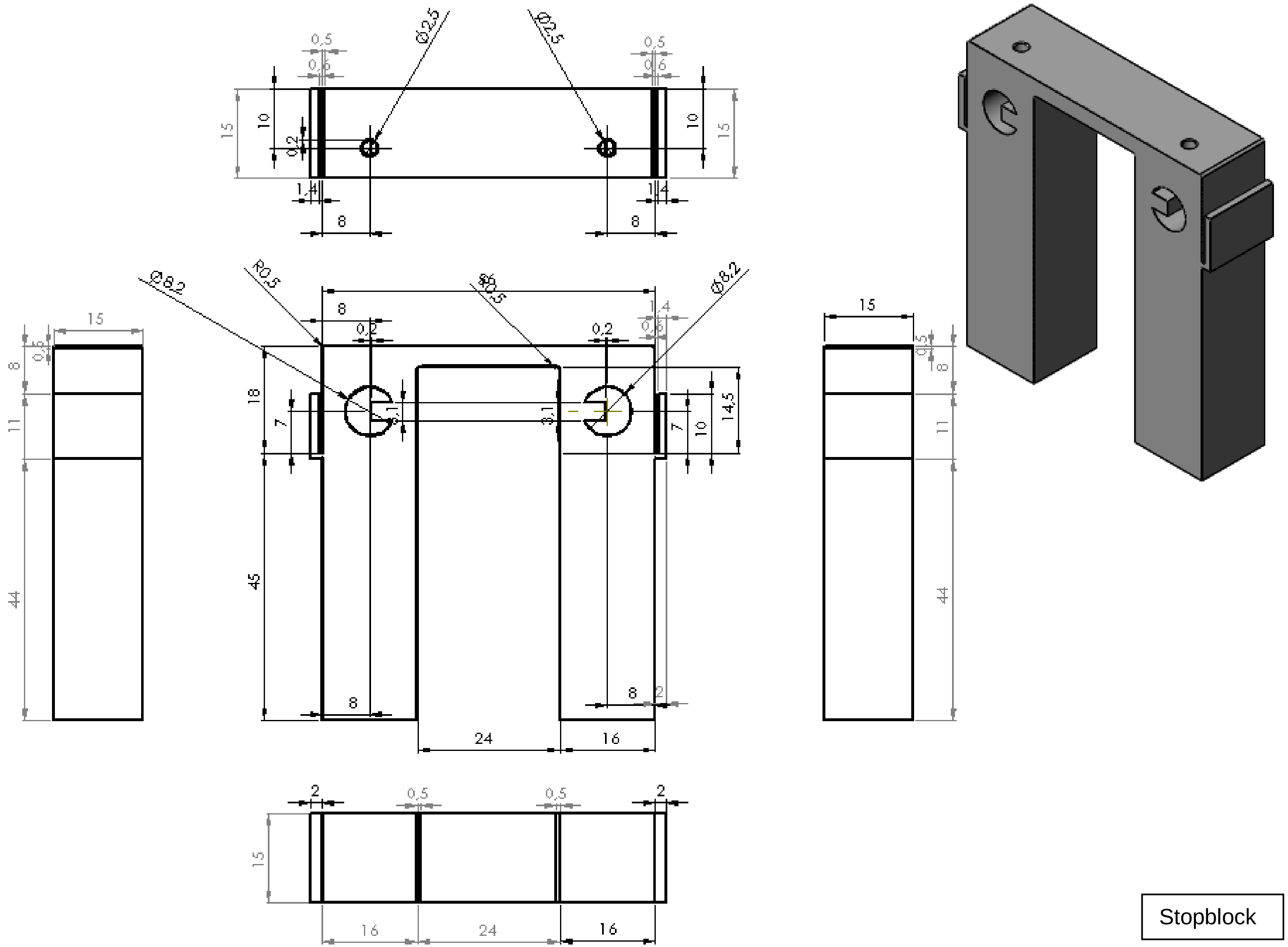


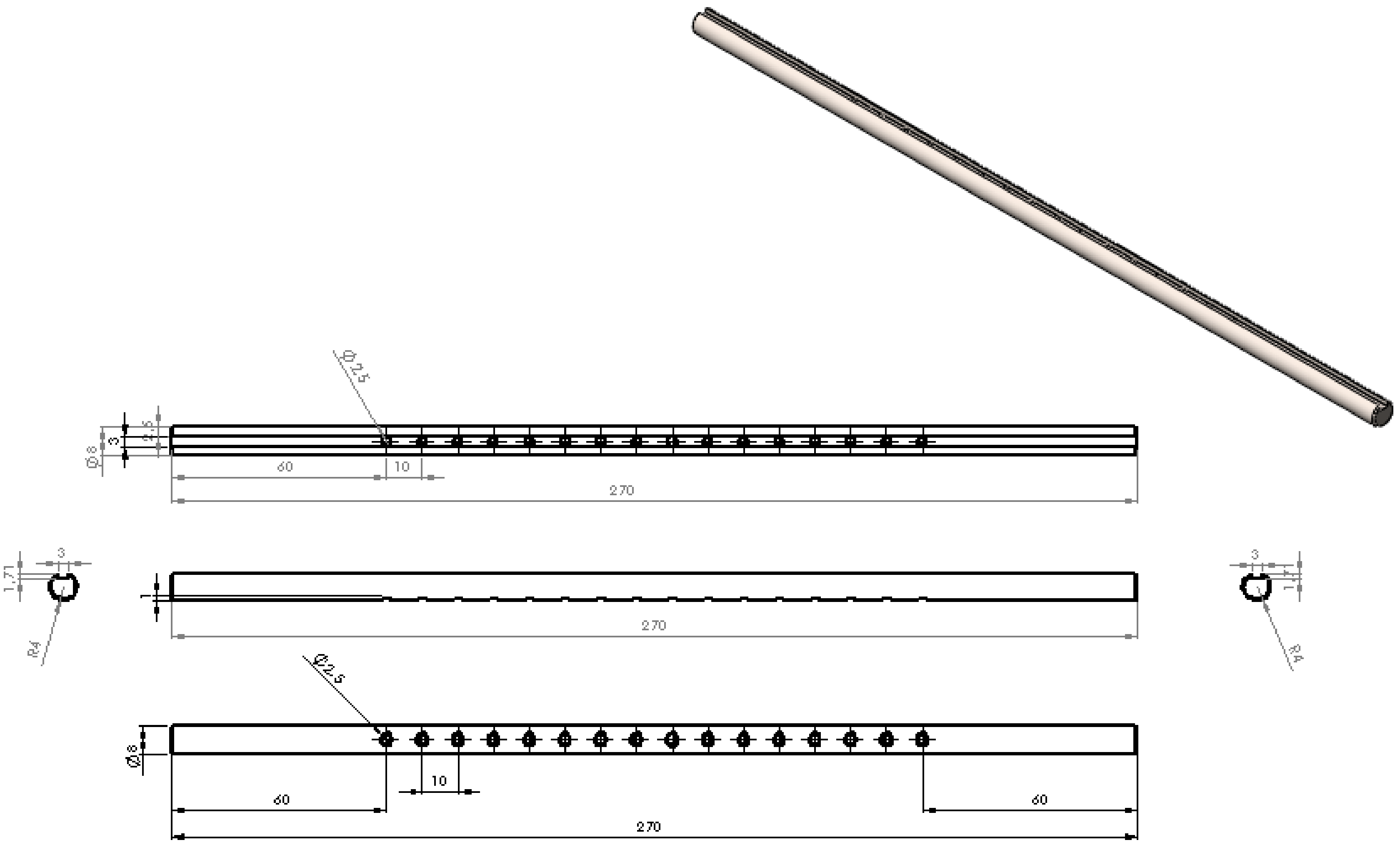
Base Block – Upper part



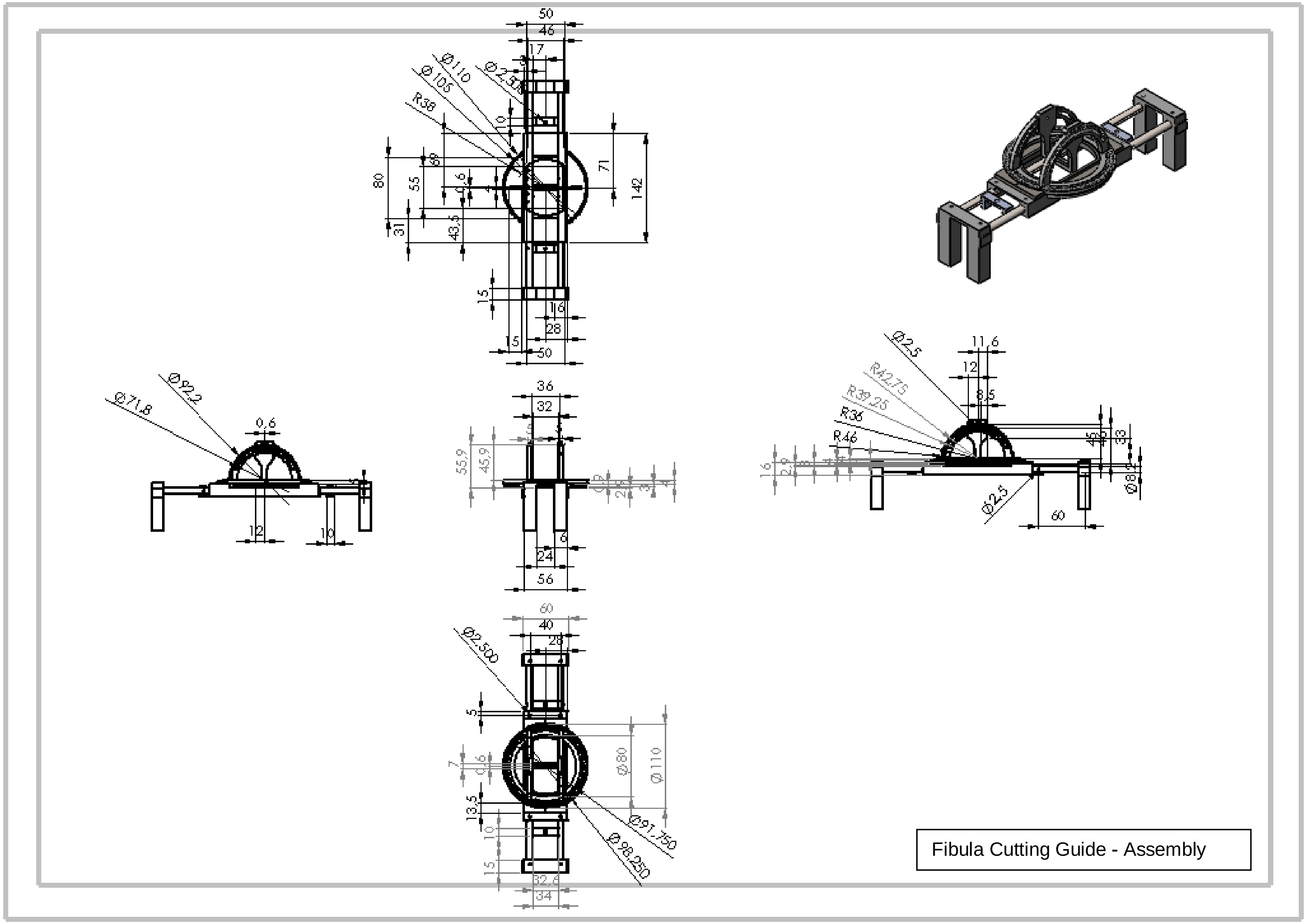
Ring and arches


42
32
30
24
18
0,6
5
R3
Ø2,5
11,6
12
3,1
3,5
46
33
8,5
55
R17,5
Ø71,8
Ø92,2
11,7
6
Guide


Stopblock



Rod


Fibula Cutting Guide - Assembly
50
46
17
Ø110
Ø105
Ø2,5
R38
10
80
55
39
0,6
71
142
31
43,5
15
16
28
50
Ø92,2
Ø71,8
0,6
12
10
36
32
55,9
45,9
6
24
56
Ø2,5
11,6
12
8,5
R42,75
R39,25
R36
R46
45
33
60
Ø8,2
60
40
28
Ø2,500
5
7
0,6
13,5
10
15
Ø80
Ø110
Ø91,750
Ø98,250
32,6
34

Appendix D: Full phantom study results

P# = type of phantom and number. Cyl I = Group Cyl. identical, Cyl V = Group Cyl. variable, Fib N = Group Fib identical new guide, Fib C = Group Fib identical current guides.

Roll/Yaw (plan) ° = the cut angle defined by analysis (the angle defined by plan) in degrees

Corr. Error neg/pos ° = the error between the sawn angle and planned angle corrected for rotational errors (positive or negative angles)

Corr. Error reading ° = the error between the sawn angle and planned angle corrected for reading errors (+/- 5 degrees)

Abs. error ° = absolute errors of the latter. These are the errors used for accuracy determination

Table 18: Osteotomy angles for each individual phantom including the calculated errors.

	Plane 1								Plane 2							
P#	Roll (plan)°	Corr. Error neg/ pos °	Corr. Error reading °	Abs. error °	Yaw (plan) °	Corr. Error neg/ pos °	Corr. Error reading ° °	Abs. error °	Roll (plan)°	Corr. Error neg/ pos °	Corr. Error reading °	Abs. error °	Yaw (plan) °	Corr. Error neg/ pos °	Corr. Error reading °	Abs. error °
Cyl I.1	-10.7 (10)	0.7	0.7	**0.7**	2.1 (0)	2.1	2.1	**2.1**	-0.8 (0)	-0.8	-0.8	**0.8**	-11.2 (10)	1.2	1.2	**1.2**
Cyl I.2	-11.6 (10)	1.6	1.6	**1.6**	1.2 (0)	1.2	1.2	**1.2**	0.9 (0)	0.9	0.9	**0.9**	-8.8 (10)	-1.2	-1.2	**1.2**
Cyl I.3	-9.9 (10)	-0.1	-0.1	**0.1**	4.2 (0)	4.2	-0.8	**0.8**	1.1 (0)	1.1	1.1	**1.1**	-10 (10)	0	0	**0**
Cyl I.4	-11.3 (10)	1.3	1.3	**1.3**	1.8 (0)	1.8	1.8	**1.8**	-0.9 (0)	-0.9	-0.9	**0.9**	-10.1 (10)	0.1	0.1	**0.1**
Cyl I.5	-11.2 (10)	1.2	1.2	**1.2**	2.1 (0)	2.1	2.1	**2.1**	0.6 (0)	0.6	0.6	**0.6**	-10.8 (10)	0.8	0.8	**0.8**
Cyl V.1	1.0 (0)	1	1	**1**	5.4 (0)	5.4	0.4	**0.4**	-7.2 (5)	2.2	2.2	**2.2**	0.3 (0)	0.3	0.3	**0.3**
Cyl V.2	6.8 (5)	1.8	1.8	**1.8**	-5.3 (5)	0.3	0.3	**0.3**	-1.7 (0)	-1.7	-1.7	**1.7**	-7.4 (5)	2.4	2.4	**2.4**
Cyl V.3	-10.2 (10)	0.2	0.2	**0.2**	-8.9 (10)	-1.1	-1.1	**1.1**	29.9 (30)	-0.1	-0.1	**0.1**	1.8 (0)	1.8	1.8	**1.8**
Cyl V.4	-0.6 (0)	-0.6	-0.6	**0.6**	-29.5 (30)	-0.5	-0.5	**0.5**	25.8 (30)	-4.2	0.8	**0.8**	-32.3 (30)	2.3	2.3	**2.3**
Cyl V.5	-5.7 (5)	0.7	0.7	**0.7**	-19 (20)	-1	-1	**1**	13.6 (15)	-1.4	1.4	**1.4**	-21.9 (20)	1.9	1.9	**1.9**

Fib N.1	11.1 (10)	1.1	1.1	**1.1**	-4.7 (0)	-4.7	-0.3	**0.3**	1.5 (0)	1.5	1.5	**1.5**	-15.3 (10)	5.3	0.3	**0.3**
Fib N.2	11.2 (10)	1.2	1.2	**1.2**	-1.5 (0)	-1.5	-1.5	**1.5**	0.4 (0)	0.4	0.4	**0.4**	-10.2 (10)	0.2	0.2	**0.2**
Fib N.3	12 (10)	2	2	**2**	-1.2 (0)	-1.2	-1.2	**1.2**	0.6 (0)	0.6	0.6	**0.6**	-10 (10)	0	0	**0**
Fib N.4	11.3 (10)	1.3	1.3	**1.3**	0.9 (0)	0.9	0.9	**0.9**	1.3 (0)	1.3	1.3	**1.3**	-10.1 (10)	0.1	0.1	**0.1**
Fib N.5	11.4 (10)	1.4	1.4	**1.4**	0.4 (0)	0.4	0.4	**0.4**	0.3 (0)	0.3	0.3	**0.3**	-10.2 (10)	0.2	0.2	**0.2**
Fib N.6	12.1 (10)	2.1	2.1	**2.1**	-0.3 (0)	0.3	0.3	**0.3**	0.3 (0)	0.3	0.3	**0.3**	-9.3 (10)	-0.7	-0.7	**0.7**
Fib C.1	9.3 (10)	-	-	**0.7**	0.2 (0)	-	-	**0.2**	2.1 (0)	-	-	**2.1**	8.3 (10)	-	-	**1.7**
Fib C.2	10.4 (10)	-	-	**0.4**	-1.3 (0)	-	-	**1.3**	-3.3 (0)	-	-	**3.3**	12.1 (10)	-	-	**2.1**
Fib C.3	10 (10)	-	-	**0**	-5.2 (0)	-	-	**5.2**	0.0 (0)	-	-	**0.0**	12 (10)	-	-	**2**
Fib C.4	10.1 (10)	-	-	**0.1**	-5.2 (0)	-	-	**5.2**	1.0 (0)	-	-	**1.0**	10.3 (10)	-	-	**0.3**
Fib C.5	10.6 (10)	-	-	**0.6**	-2.6 (0)	-	-	**2.6**	1.3 (0)	-	-	**1.3**	11.8 (10)	-	-	**1.8**

Table 19: Segment lengths for each individual phantom, including the expected segment lengths and absolute errors.

	Planned segment length (mm)	Expected segment length (mm) *	Obtained segment length (mm)	Absolute length Error (mm)
Cylinder I.1	50	48.2	46.9	**1.3**
Cylinder I.2	50	48.2	47.7	**0.5**
Cylinder I.3	50	48.2	46.7	**1.5**
Cylinder I.4	50	48.2	47.5	**0.7**
Cylinder I.5	50	48.2	47.1	**1.1**
Cylinder V.1	50	49.1	49.7	**0.6**
Cylinder V.2	50	50.0	48.8	**1.2**
Cylinder V.3	50	51.8	51.5	**0.3**
Cylinder V.4	55	55.0	52.8	**2.2**
Cylinder V.5	50	50.0	48.5	**1.5**
Fibula N.1	50	48.2	46.0	**2.2**
Fibula N.2	50	48.2	46.5	**1.7**
Fibula N.3	50	48.2	45.1	**3.1**
Fibula N.4	50	48.2	47.1	**1.1**
Fibula N.5	50	48.2	46.9	**1.3**
Fibula N.6	50	48.2	47.4	**0.8**
Fibula C.1	50		50.4	**0.4**
Fibula C.2	50		50.3	**0.3**
Fibula C.3	50		50.8	**0.8**
Fibula C.4	50		50.4	**0.4**
Fibula C.5	50		50.4	**0.4**

* Calculations for expected segment length cylinders I.1-I.5 and fibulas:
The yaw is 0° for plane 1 and 10° for plane 2. The direction of the yaw on plane 2 causes a decrease in segment length of:

$\tan(10°) * 9.9\ mm = 1.8\ mm$

This leaves the expected segment length to be:

$50 - 1.8 = 48.2\ mm$

<u>For cylinders V.1-V.5:</u>
cylinder V.1: $\tan(5°) * 9.9\ mm = 0.9\ mm \rightarrow 50 - 0.9 = 49.1\ mm$

cylinder V.2: $\tan(5°) * 9.9\ mm = 0.9\ mm$ → $50 + 0.9 - 0.9 = 50.0\ mm$

cylinder V.3: $\tan(10°) * 9.9\ mm = 1.8\ mm$ → $50 + 1.8 = 51.8\ mm$

cylinder V.4: $\tan(30°) * 9.9\ mm = 5.7\ mm$ → $55 + 5.7 - 5.7 = 55.0\ mm$

cylinder V.5: $\tan(20°) * 9.9\ mm = 3.6\ mm$ → $50 + 3.6 - 3.6 = 50.0\ m$