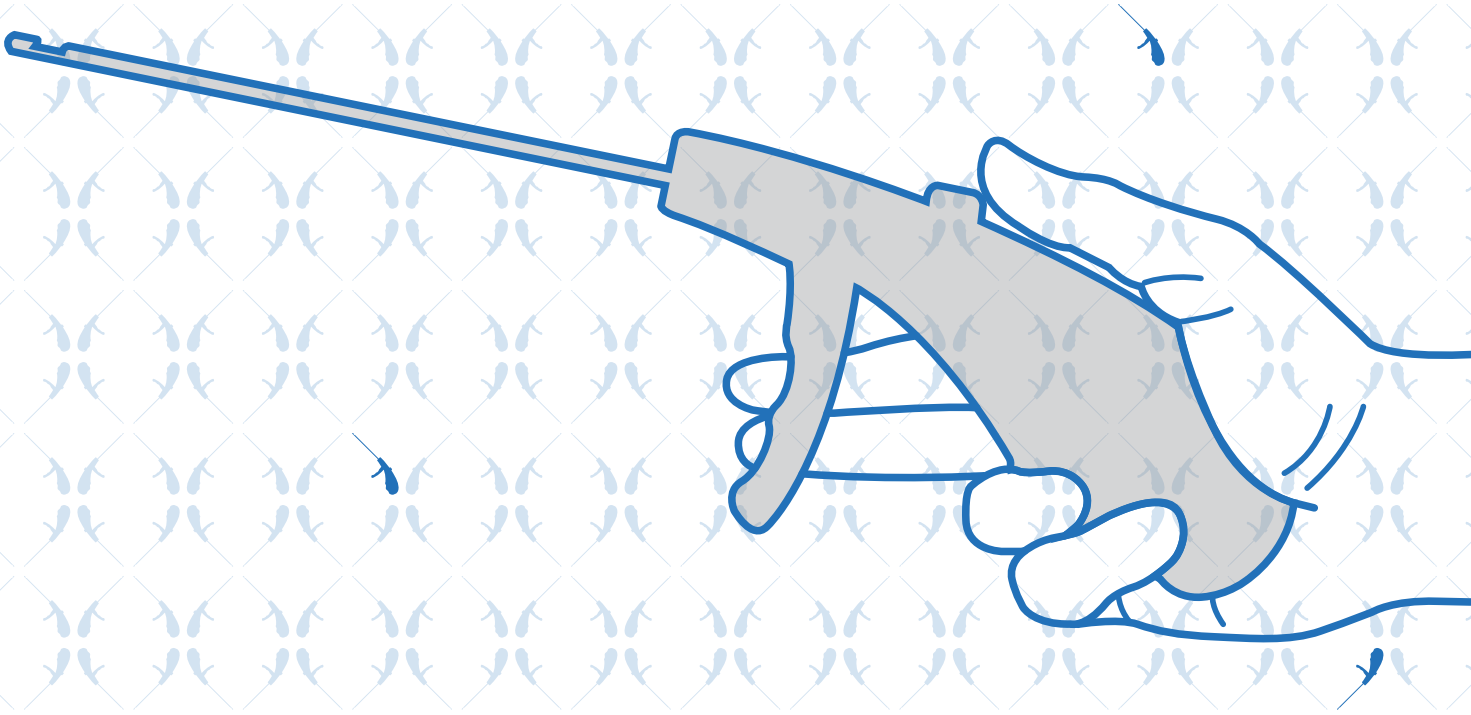
A. M. Sendrowicz

# The NeuroPunch

A single-handed rotatable neurosurgical punch capable of storing multiple bone pieces



TU Delft

DEAM

# The NeuroPunch

A single-handed rotatable neurosurgical punch capable of storing multiple bone pieces

By

A. M. Sendrowicz

in partial fulfilment of the requirements for the degree of

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TU Delft

# Preface

This thesis describes the final project and last step in the fulfillment of the Master Biomedical Engineering at the Delft University of Technology, which took part from May to December 2018. This paper presents the process and results of a study focusing on the design and development of a neurosurgical bone punch; a process in which I closely collaborated with DEAM Corporation and with a group of surgeons from the University Medical Center Groningen (UMCG). The aim was to improve one of the instruments used during skull base surgery. I had fun digging into the subject and I enjoyed the variety and challenges during this project.

I am satisfied with the result and the realization of this thesis, which marks the end of a fantastic study period during which I have met countless great people and gained a lot of knowledge in many different fields.

For their help, I would like to thank the following people in particular:
Paul Breedveld, supervisor during this study, for his constructive feedback and insights, and for his time, even when walking into his office unannounced.
Jules Scheltes and Wimold Peters from DEAM, for giving me the opportunity to realize this project, and for their guidance and creative input during this process.
Rob Vergeer, Astrid Korsten-Meijer, Jos Kuijlen, Tom van der Laan and Robert Feijen, surgeons from the UMCG, for inviting me to attend multiple skull base surgeries, but also for their inspiring, sophisticated and thoughtful input throughout the discussions and observations during the other sessions in this project. It was a true experience.
David Jager and Wim Velt, for sharing their experience and extensive knowledge on the manufacturing of several parts of the prototype.
Lastly I would like to thank my family and friends for their motivation and genuine interest in this project, Jasper for the tremendous amount of well-timed and amusing coffee breaks, and Adinda, for her everlasting optimism and support.

Alexander Sendrowicz

Delft, December 2018

# Content

# **The NeuroPunch** - A single-handed rotatable neurosurgical punch capable of storing multiple bone pieces

*Abstract* - **During endonasal pituitary surgery - an approach of skull base surgery - long slender instruments are inserted through the nose of the patient, in order to remove a pituitary lesion. One of the instruments which is repeatedly used is the surgical punch, which is able to remove pieces of bone in order to create access to the lesion. The drawback of the currently used surgical punches is twofold: first of all, they do not allow for rotation of the tip relative to the handle orientation in order to align the tip properly to the bone to be cut. Furthermore, the successive introduction and extraction of the instrument from the operational area after each cut, increases the risk of introducing bacteria and slows down the procedure.**

**A novel surgical punch was designed and developed called NeuroPunch. Throughout the course of this study, a human-centered design approach combined with a systematic engineering process was followed leading to several conceptual solutions for different functional parts of the NeuroPunch. By combining these conceptual solutions, a design was set for a first functional prototype including an ergonomic handle, a mechanism for the storage of punched bone pieces, and a mechanism for rotating the tip relative to the handle orientation.**

**A first evaluation of the functional 1:1 scale prototype with end users shows positive results indicating that the NeuroPunch might be a proper replacement for the currently used punches in endonasal pituitary surgery. Several iterative steps are required to produce a fully functional prototype of the NeuroPunch which can be evaluated in a preclinical setting (e.g. cadaver study). The NeuroPunch shows much potential to be used for other surgeries as well, and it is demonstrated that the NeuroPunch will enable a safer and more comfortable endonasal pituitary surgery while potentially reducing operating time.**

***Keywords: Surgical punch, Skull Base Surgery, Bone, Design***

## 1. Introduction

### 1.1 Background

The skull base forms the lowest part of the skull and isolates the brain from the facial area. In the skull base many neurovascular structures (i.e. nerves and vessels) are located, which makes the skull base a very complex anatomical area [1]. Due to this complex anatomical area, skull base surgery (SBS) has regularly been considered as challenging, and is often referred to as the surgical 'no man's land' [2].

The conventional approach to treat lesions in the skull base is the 'open approach'. In this approach, large incisions are made in order to get access to the location of the lesion (Fig. 1). Throughout the last decades, an explicit transformation towards the minimally invasive approach can be recognized [3]. In this approach, the surgeon is able to reach the skull base with long and rigid instruments, through a small incision or through a natural orifice (e.g. nose and mouth). The minimally invasive approach shows clear advantages over the open approach, such as a faster recovery time because either small or no incisions are made, fewer side effects (e.g. internal bleedings and infections), and less manipulation of the brain during surgery [4].

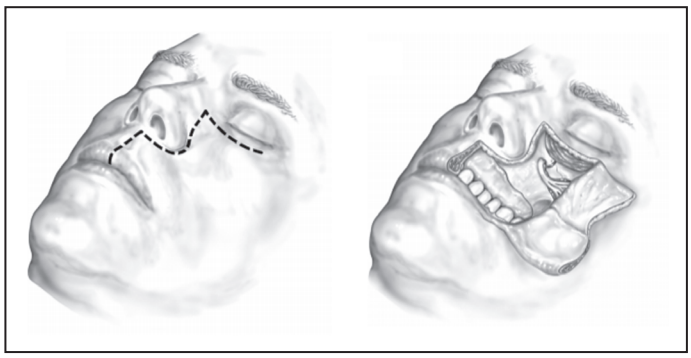

Fig. 1: The Weber-Ferguson incision: one of the open approaches to treat lesions in the skull base [6].

One of the minimally invasive approaches in which no incisions are made and the instruments are inserted through a natural orifice is the endoscopic endonasal approach. In this approach, the long and rigid instruments are inserted through the nose in order to reach the location of the lesion. This type of skull base surgery provides access to almost the entire region in the skull base in front of the foramen magnum (the hole in the skull base through which the spinal cord runs) (Fig. 2) [5].

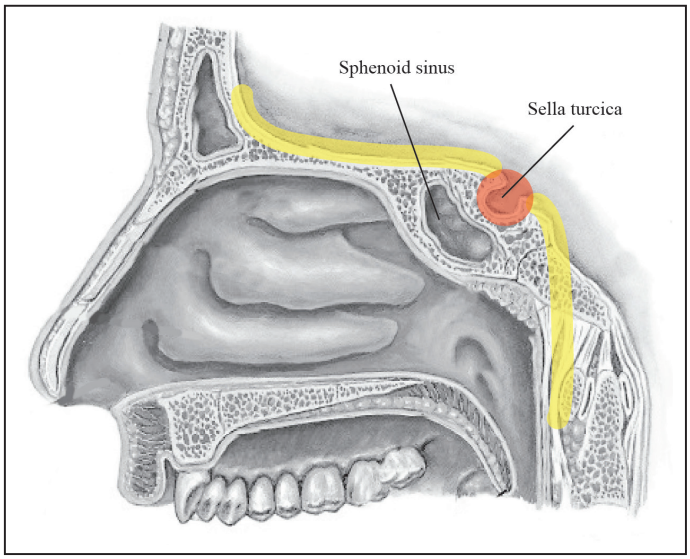


Fig. 2: Schematical representation of the anatomy of the nasal cavity, with the accessible region in the skull base during the endonasal approach highlighted yellow, the sella turcica highlighted red. Adapted from [12].

The concept of reaching the brain through the nose comes from the ancient Egyptians. Excerebration (brain removal) was part of the Egyptian mummification procedure, which was popular around 2686-2128 BC. The removal of the brain through a natural orifice was important in order to preserve the facial features of the deceased [7]. The first endonasal neurosurgical procedure is the transnasal transsphenoidal approach, which was performed for the first time by Hermann Schloffer in 1907. In this procedure, Hermann Schloffer removed a pituitary tumor from a living patient for the first time in history [8]. The first large serie of transnasal transsphenoidal surgeries was performed by Harvey Cushing, during the 1920s. Due to the inadequate diagnostic instruments during this period, the transnasal transsphenoidal approach did not become the standard procedure, but the surgery of pituitary tumors shifted towards the transcranial (through the skull) approach [9]. Due to the development of better diagnostic techniques as computed tomography (CT) and magnetic resonance imaging (MRI) the endoscopic endonasal approach reclaimed its popularity during the 1990's. These techniques allowed for adequate visualization of the anatomical structures in the skull base in order to treat pituitary tumors, positioned in the sella turcica (Fig. 2) [10]. Subsequently, the more frequent use of the endoscope led to the development of the extended endonasal approach, which was for the first time described in 1987. This approach was developed in order to reach suprasellar regions (i.e. behind the sellar region, deeper into the skull base) [11]. These procedures are nowadays considered as 'the golden standard' for the removal of pituitary lesions. By inserting the endoscope and the other neurosurgical instruments through a natural orifice, the least traumatic path to the sellar region can be taken and visible scars can be avoided.

### 1.2 The endonasal procedure

***Overview***

The endoscopic endonasal pituitary surgery is generally performed by a neurosurgeon in close collaboration with an Ear-Nose-Throat (ENT) surgeon. In order to reach the sellar region, detailed anatomical knowledge of the nasal cavity is required. The endoscopic instruments can be inserted through either one nostril (uninostril approach) or through both nostrils (binostril approach), by either one surgeon (two-handed technique) or by two surgeons (four-handed technique). In general, the four-handed technique is preferred [13]. With this technique, one surgeon can hold the endoscope which passes through one of the nostrils, while the other surgeon is able to use the other surgical instruments through the second nostril (Fig. 3).

The first stage of endonasal surgery is the nasal stage, in which the surgical corridor is prepared. This is done by removing a small portion of the nasal septum (the bone wall separating the two nostrils) in order to allow the passage of the surgical instruments. In the sphenoid stage, the sphenoid ostium (an opening that connects the sphenoid sinus with the nasal cavity) is identified and enlarged, which provides access to the sphenoid sinus (Fig. 4). Next, an opening into the frontal wall of the sphenoid sinus is created, also known as a sphenoidotomy. A sphenoidectomy provides access to the sellar floor, which must be opened in order to remove the pituitary lesion. This third stage is called the sellar stage, in which the lesion is exposed by opening the sellar floor and the dura. During these phases, different surgical instruments are interchangeably used, such as a punch, a suction tube and other tissue-manipulating instruments, which will be discussed in more detail below. When the tumor is exposed, it can be removed with a curette and suction tube. After tumor removal, the fourth and last stage is the reconstruction stage. In this stage the tumor cavity is filled with fat graft (e.g. from the leg), and the sellar floor is reconstructed with a small piece of cartilaginous graft and biologic glue [17].

***Instrumentation***

During endoscopic endonasal pituitary surgery, multiple rigid instruments are inserted into the nasal cavity towards the pituitary tumor (Fig. 5). These instruments are controlled from outside the body. The endoscope is a long slender instrument which provides the field of

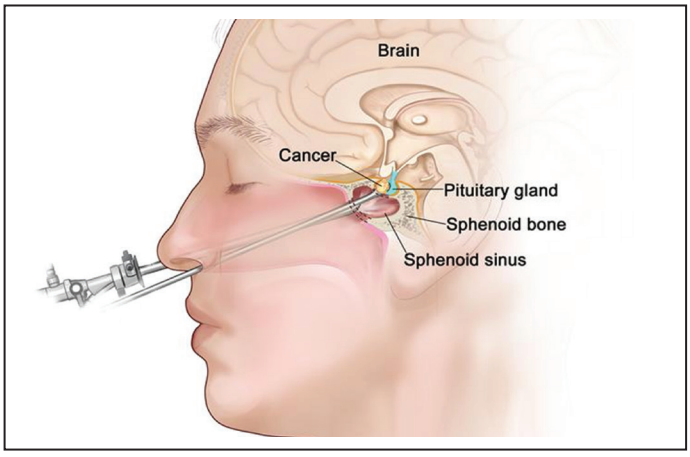


Fig. 3: The endoscopic endonasal approach [14].

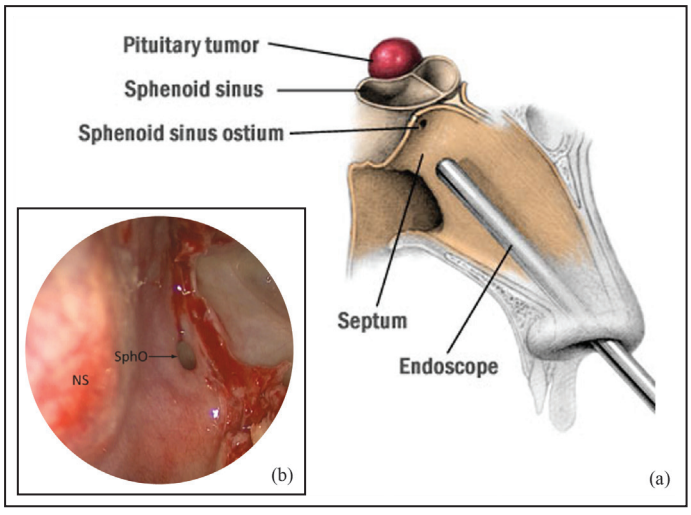


Fig. 4: (A) An endoscope is inserted towards the pituitary lesion (tumor) [15]. (B) The endoscopic view of the sphenoid ostium (SphO) and nasal septum (NS) [16].

vision in the nasal cavity. This is visualized on one of the screens in the OR. In order to interact with tissue with the other instruments, the endoscope will always be inserted to provide a field of vision. The instruments which are typically used to interact with tissue are scissors and knifes to cut soft tissue, curettes to scrape soft tissue, dissectors to manipulate tissue, drills to drill bone, punches to cut bone and bipolar forceps to coagulate tissue. Furthermore, a suction tube allows for suction of blood, tissue pieces and other fluids.

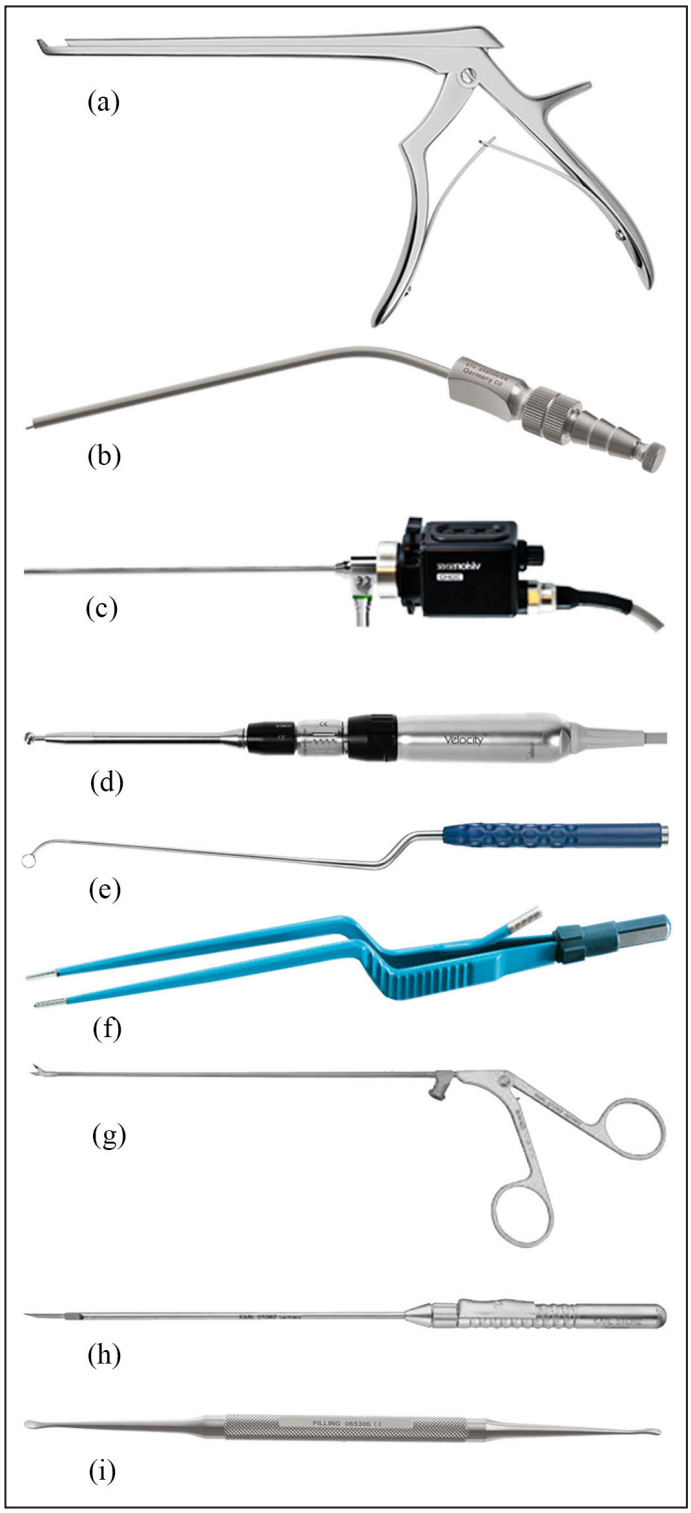


Fig. 5: Selection of instruments used in endoscopic endonasal surgery. (a) Punch [18]. (b) Suction tube [19]. (c) Endoscope [20]. (d) Drill [21]. (e) Curette [21]. (f) Bipolar forceps [22]. (g) Scissors [23]. (h) Knife [23]. (i) Dissector [23].

***Limitations***

Endonasal surgery requires very close collaboration between an ENT surgeon and neurosurgeon. In the two-nostrils-four-handed technique, one holds the endoscope and the other directly interacts with the tissue inside the nasal cavity, with one or two instruments. In general, most bone drilling tasks are performed by the ENT surgeon, while the neurosurgeon mostly focuses on the dissection of deeper situated tissue [25]. Due to the use of multiple instruments at the same time, it is important that insertion of these instruments through the nasal cavity is planned adequately. Especially when bleedings or other unforeseen circumstances occur, and quick task performance is required, this can be challenging. Furthermore, the use of multiple instruments at the same time, through the same corridor, can cause 'sword fighting' (i.e. instruments getting in each other's way). This limits the maneuverability of the instruments and can be uncomfortable for the surgeons. The lack of maneuverability is also due to the fact that the instruments which are currently used are mostly rigid and straight, having zero degrees of freedom (DOF). The absence of flexibility and/or steerability in the instruments requires them to pivot around the entrance point in the nostril. Because of the large distance between the pivotal point of the straight and rigid instruments and the operative site, the range of motion is limited [26].

***Clinical input and focus***

In the beginning of the project, two endonasal pituitary surgeries were attended. During these first two OR sessions (May 2018) the usage of the neurosurgical instruments was analyzed (Fig. 6). It was observed that multiple limitations occurred during surgery, such as inadequate reachability of several surgical instruments and the inappropriate use thereof. However, within the scope of this study, only

Fig. 6: Surgical team performing an endonasal surgery in the operating room (OR). The neurosurgeon and ENT surgeon work closely together, performing the 'binostril four-handed technique'.

a selection of these problems can be dealt with. Due to the fact that the limitations of the surgical punch (which will be discussed in the next section), are a repeatedly described phenomenon in the literature [25,26] combined with the confirmation of this problem by the group of neurosurgeons and ENT surgeons, it was decided to focus on this problem.

### 1.3 The surgical punch

In the endonasal endoscopic surgery, the primary function of a punch (Fig. 5a) is to remove pieces of bone, in order to create access to the lesion which is located behind the sella turcica (Fig. 2). The use of this instrument mainly appears during the sphenoid stage and the sellar stage of the endonasal pituitary surgery. During these stages the punch is used to widen the sphenoid ostium, to cut the nasal septum, to partly remove the anterior sphenoid sinus wall and to open the sellar floor in order to reach the pituitary lesion. Fig. 7 illustrates the use of a surgical punch when opening the sellar floor. Depending on the thickness of the sellar floor, sometimes a drill is used prior to the use of the punch in order to reduce the thickness of the bone, thereby enhancing the controllability of the punching step and reducing the amount of force required to cut. The punch can be used to cut the bone circumferentially from the opening. Hereby, the initial opening is further increased (to expose the dura mater) thereby providing access to the tumor.

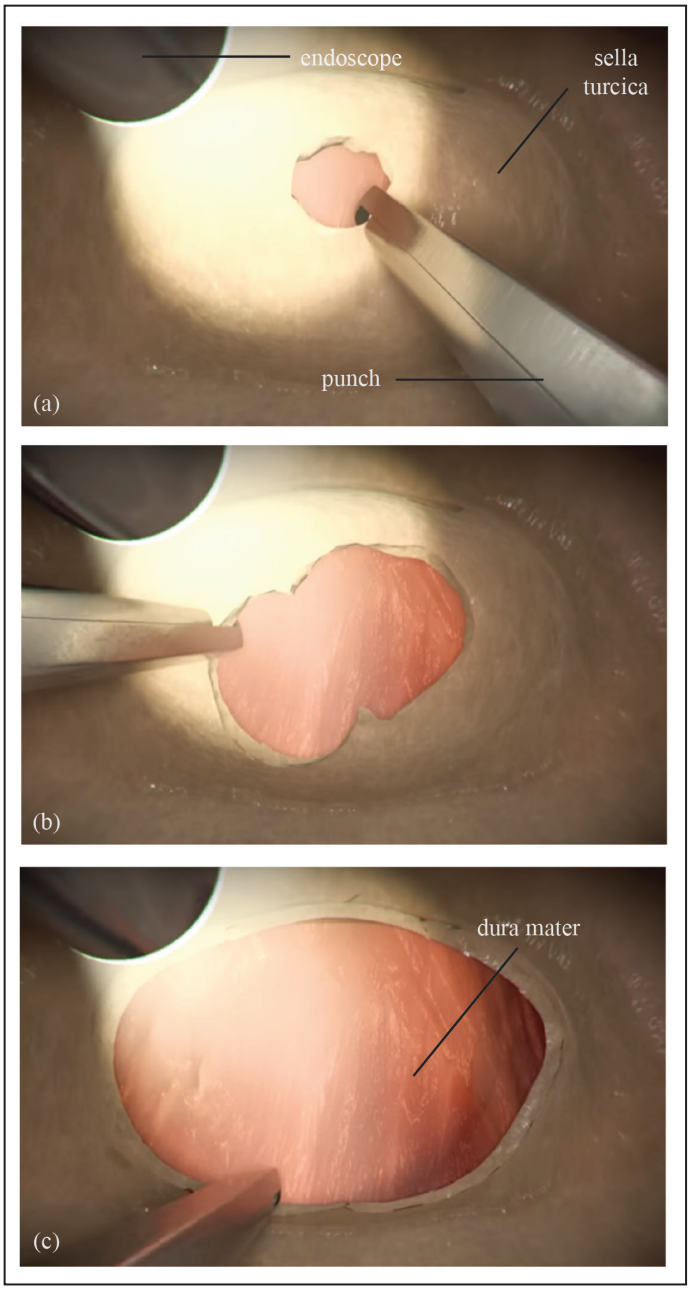


Fig. 7: Stepwise procedure of opening the sellar floor with a punch. Adapted from: [27].

Fig. 8 depicts the surgical punch (Kerrison) which is currently widely used in endonasal pituitary surgery in the 'open' and 'closed' configuration. By squeezing the handle, the two reciprocating beams close the tip, thereby cutting a piece of bone. In order to remove a piece of bone, the punch is inserted through the nose together with the endoscope, and if necessary, the suction tube for blood removal. After aligning the tip properly to the bone, a cut is made. Consequently, the punch is extracted in order to remove the punched piece of bone from the tip of the instrument. Hereafter the punch is inserted again, to remove a second piece of bone. These steps are repeated until the proper amount of bone is removed to get access to the pituitary lesion.

### 1.4 Problem definition

The problem with the currently used punches is twofold:

- In order to align the tip of the instrument properly to the bone to be punched, the complete instrument has to be rotated around its longitudinal axis. This leads to awkward hand positioning of the surgeon. Furthermore, the rotational movement of the punch could result in undesired collisions with the endoscope, thereby frequently obstructing the

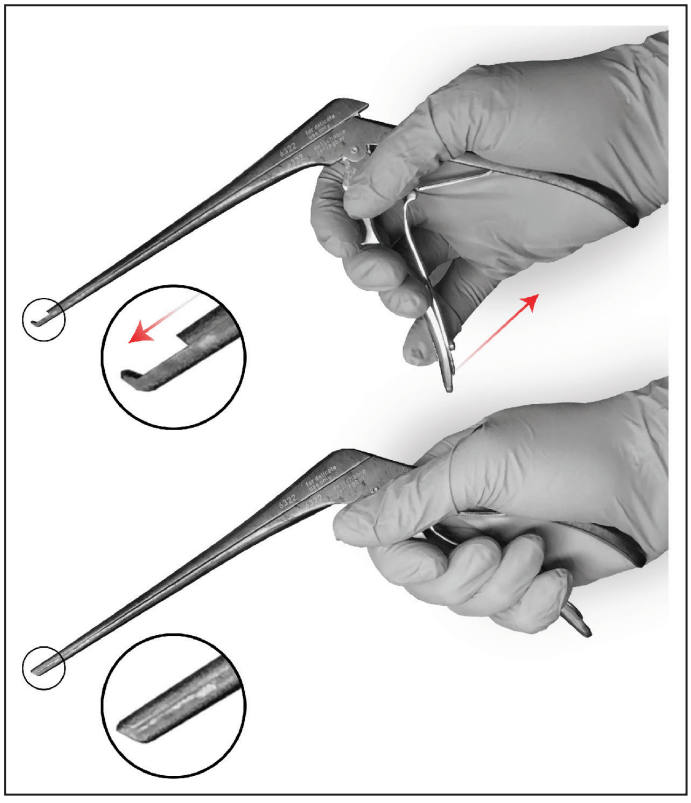

Fig. 8: Open and closed configuration of the surgical punch, including close-up of the tip.

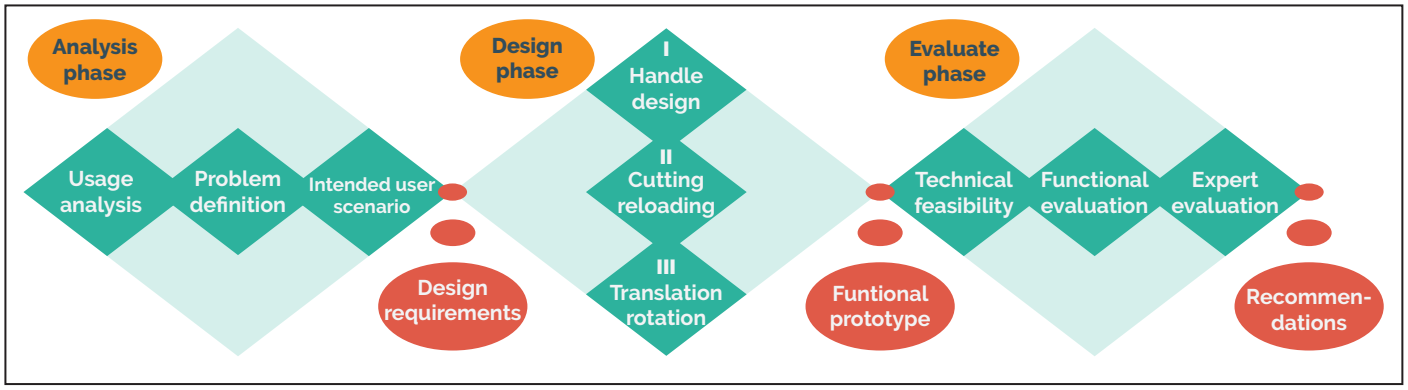


Fig. 9: Schematic representation of the design process

endoscope from providing its field of vision.

• After each cutting step, the punch is extracted from the nose, in order to remove the punched bone pieces from the tip of the instrument thereby clearing the cutting area. These undesired interruptions cause the procedure to slow down, and increase the risk of introducing bacteria [28].

### 1.5 Goal of the study

An analysis on the currently existing neurosurgical punches was performed. Based on this analysis and a discussion with a group of clinical experts, it was found that no neurosurgical punch exist providing the ability to rotate the tip of the instrument with a single hand. Furthermore, bone punches providing the ability to clear the tip of the instrument neither have been found. The goal of this study is to develop and evaluate a surgical punch, primarily dedicated to the tasks to be performed during endonasal pituitary surgery: cutting bone and proper allowance for single handed controllability of the alignment of the tip to the bone. Furthermore, providing an alternative for the undesired and frequent extraction of the instrument from the nose, by allowing the surgical punch to cut multiple subsequent pieces of bone in the operational area. The newly designed instrument will be conceptualized to a functional prototype and validated in order to verify its usability and its enhancement to the current procedure.

### 1.6 The design process

A broad variety of literature can be found on product design methodologies and engineering processes. Although these researchers and designers all provide different insights in the design process, the main phases of the design process mostly rely on similar principles [29]. Most design processes are divided into three or four main phases: an analysis phase, a (conceptual) design phase, an embodiment/detail design phase, and an evaluation phase [30]-[32] (whereas the second and third phase could be combined to a single design phase [33]).

During this process, a human-centered design (HCD) approach was followed. In this approach, the users (neurosurgeons and ENT surgeons) play a crucial role and are interactively involved in different steps of the design process (e.g. user analysis, product evaluation). By involving the user in the different steps of the design process, the final product is very likely to be suitable for the user scenario in which the product will be used [34]. Fig. 9 shows a schematic representation of the design process for this study. As depicted, the design process consists of similar phases as described before. In the analysis phase, the user will be thoroughly observed and involved in defining the problem, leading to a first set of design requirements. In the conceptual design phase, several of these design requirements are further specified to sets of sub-requirements (i.e. unambiguous deviations of the design requirement) specifically adapted to three parts of the design: the handle design, the cutting and reloading method and the translation-rotation mechanism. Based on these (sub-) requirements, solutions are created, clustered, and transformed into concrete (tangible) models to verify each sub-solution. During these steps, many alternations are made between highly abstract thinking and very concrete solutions. Towards the end of this phase, the conceptual design solutions are combined towards a functional prototype. In the last step of this design process the functional prototype is evaluated, leading to recommendations for the next steps in the development of the product.

### 1.7 Structure of this thesis

This thesis report will describe the design process of a novel instrument called NeuroPunch. The structure of this report will be described in a similar course as the design process of this project (Fig. 9). In Section 2, the intended user scenario of the NeuroPunch will be described, followed by a list of design requirements. Sections 3 to 5 will describe the different conceptual design phases leading to a final design of the NeuroPunch. In Section 6 the manufacturing and assembly of the first functional prototype of the NeuroPunch will be discussed. The manufactured and assembled NeuroPunch will be evaluated, which will be described in Section 7. In Section 8, the design process and its outcomes will be discussed, followed by a conclusion in Section 9.

## 2. Design requirements

### 2.1 Introduction

This section focusses on the intended user scenario,

the design requirements and the associating product specifications of the product which will be designed. First of all, the intended user scenario should be described in order to clarify the purpose of the design and its user. Subsequently, design requirements are formulated which are based on the user observations and the intended user scenario of the product which will be designed, from the perspective of the user of the product. Lastly, these design requirements are 'converted' to product specifications, which are concrete (technical) descriptions of the design requirements, and which represent the product design from the perspective of the designer. The product specifications thereby provide 'guidance' for verification of the design requirements.

### 2.2 Intended user scenario

The intended user scenario describes the field of application and the use of the novel instrument. The intended user scenario is written early in the development process, before the product is being created. It is written by the design-team and is based on the observations of end users, and will be used as input for formulating the design requirements.

The product will be used for performing endoscopic endonasal pituitary surgery, which is surgery through a natural body opening (the nose) in order to treat diseases and extract tissue samples for diagnostic purposes in the brain. The main function of the product is to cut bone in areas in and around the brain, such as the nasal cavity and the pituitary region. The primary users of the product will be the neurosurgeon and an ENT surgeon. A neurosurgeon is a physician who is specialized in the diagnosis and treatment of diseases and disorders of the central and peripheral nervous system [35]. An ENT surgeon is a physician who is specialized in the diagnosis and treatment of patients with diseases and disorders of the ear, nose, throat (ENT), and related structures of the head and the neck [36]. In general, during endonasal pituitary surgery, the neurosurgeons and ENT surgeons work very closely together. The product is intended to be used by the described users, in a patient, which can include all age ranges, and be both male and female. The product will be used in combination with an endoscope, a suction tube, and with other endoscopic instruments used in this type of surgery (Fig. 5).

The steps of the intended user scenario of the product have been divided into three types of steps: pre-operative steps, intra-operative steps and post-operative steps. Pre-operative steps are steps to be taken before the product is inserted into the patient. Post-operative steps are steps which are taken after using the product in the patient. Within the scope of this research, the focus is on the intra-operative steps, which are the steps to be taken between insertion and withdrawal of the product from the patient. The intended user scenario of the intra-operative steps are listed as follows:

- The surgeon inserts the distal end of the instrument into the nose of the patient, and slides it forward until the nasal cavity is reached.
- The surgeon manipulates the instrument (tilting/ sliding), thereby checking its orientation under endoscopic vision.
- The surgeon manipulates the handle of the instrument, thereby locating the instrument at the desired position.
- The surgeon orients the tip of the instrument by manipulating (a control element of) the handle, until the desired orientation of the tip is reached.
- When the instrument is placed in the correct position, the handle will be manipulated, thereby opening and closing the tip, and cutting bone.
- After making a cut, the surgeon manipulates the handle in order to change the orientation and location of the instrument to make a subsequent cut.
- When in place, a subsequent piece of bone can be cut.
- When sufficient cuts have been made, the instrument is extracted from the nose.
- These steps can be repeated for different operational areas in which bone should be removed.

### 2.3 Design requirements

The design requirements describe the needs for what users require from the instrument. They are not intended to be technically written, thereby allowing readers with only a general knowledge of the product to understand the design requirements. The requirements within the scope of this project are based on assessments that have been generated over the period of May 2018 to December 2018. They are based on the user observations and the intended user scenario. Additionally, the user requirements are confirmed by the users. The design requirements are classified as functional requirements (F), dimensional requirements (D), medical safety requirements (S) and ergonomic requirements (E). Although the medical safety requirement can take many safety aspects into account, within the scope of this review this requirement only incorporates the safety aspects of the tissue interactions within the direct environment of the instrument. The design requirements are listed in Table 1. This list provides global descriptions of the requirements the product has to fulfill. Several of these requirements are further subdivided into associating sub-requirements. These sub-requirements are unambiguous deviations of a design requirement. Although a sub-requirement might be interpreted as 'less important' than a design requirement, it should be mentioned that sub-requirements and design requirements have an equal level of importance. The sub-requirements to these design requirements are specified in the chapter in which each design requirement has the most influence on the design of the product. In appendix B, the design requirements and the sub-requirements are completely described and defined, including the acceptance criteria, the method to demonstrate the conformity of each requirement, and the product specifications of these requirements.

Table 1: Design requirements for the punch. Design requirements are subdivided into functional requirements (F), dimensional requirements (D), ergonomic requirements (E), and medical safety requirements (S). Associating sub-requirements are in between the brackets.

| | |
|---|---|
| F | 1. The instrument must be able to cut through a bone layer. |
| F | 2. The instrument tip is able to be rotated, independent from the handle orientation, in order to align the tip to the bone to be cut. |
| F | 3. The instrument must be able to punch multiple bone pieces without the need for clearing the cutting area of the instrument (reloading). |
| D | 4. The shaft height and width are sufficiently small to enable simultaneous use of the instrument, scope and suction tube in the operational area. |
| D | 5. The shaft length is sufficient for the use of the instrument in the operational area. |
| D | 6. The tip dimensions should allow for maximized reachability in the operational area (D6.1 - D6.3). |
| E | 7. The instrument should be used single handed. |
| E | 8. The instrument should be usable in the left or in the right hand. |
| E | 9. The handle should fulfill the general ergonomic guidelines (E9.1 – E9.8). |
| E | 10. The instrument handle allows for proper interaction with the other instruments during use. |
| S | 11. The risk of damaging healthy, surrounding tissue should be minimized (E11.1 – E11.4). |

# 3. Conceptual design part I: handle design

## 3.1 Introduction

The first conceptual design part of this project reflects the process of the design of an ergonomic handle for the NeuroPunch. The goal of this conceptual design part was to determine the preference of different handle designs for a rotatable punch based on subjective usability features. A challenge is to determine how the user can operate the additional functionalities as described in Section 2.3 (Functional requirements) with a single handed instrument. Three handle designs were designed and modelled to full-scale mock-up models, based on the user requirements. Subsequently, these mock-up handle models were evaluated by a group of technology students, and by a group of neurosurgeons and ENT surgeons. Based on the results of these evaluations, a concept was chosen to be further elaborated in the final design.

## 3.2 Design requirements: handle

In Section 2.3, four ergonomic design requirements regarding the handle of the instrument were listed (Table 1). Based on guidelines on ergonomics found in the literature [37], an analysis on existing surgical instruments and the user observations during discussions throughout the course of this study, a group of specific sub-design requirements for design requirement 9 has been formulated (Table 2). This list describes the sub-requirements any handle design should comply with regarding the intended user scenario of the NeuroPunch. Several of the design requirements and sub-requirements describe the functional and dimensional needs of the handle, which can be thereby objectively implemented in the design (in Table 2 indicated with an 'O'). However, other sub-requirements describe usability aspects of the handle, which require user evaluation in order to examine their fulfillment (in Table 2 indicated with an 'S'). The complete overview and further specifications of these (sub-) requirements can be found in Appendix B. Besides the abovementioned ergonomic (sub-) design requirements, the outcomes of the discussions with the users indicated that the intuitiveness and the attitude of the handle also were important aspects to consider for the handle design.

## 3.3 Handle type analysis

First, an analysis on the existing handle types for medical instruments was performed in order to get an indication on the different types of handles used in surgery. In laparoscopy, generally three different handle types are distinguished: ring handles, shank handles and pistol handles [38]. Each of these groups can be subdivided again in two configurations: handles which are configured as in-line (axial) handles, and handles which have their general

Table 2: Sub-requirements of ergonomic requirement 9. The 'O' and 'S' indicate whether the sub-requirement is objective or subjective, respectively.

| | |
|---|---|
| E9.1 | **O** - Actuation of the punching-function must be performed with the finger flexors. |
| E9.2 | **O** - Contact area pressure must be prevented. |
| E9.3 | **O** - Actuation of the rotation-function must be performed with the thumb or index finger. |
| E9.4 | **O** - The force needed to punch bone should be acceptable.\| |
| E9.5 | **S** - The control components (rotation knobs and levers) should be easily accessible. |
| E9.6 | **S** - The dimensions of the functional elements are acceptable. |
| E9.7 | **S** - Cramped positions as well as excessive shoulder movements should be avoided when using the instrument. |
| E9.8 | **S** - The instrument grip must be stable (firmly fixed). |

configuration, in which the shaft is angled to the instrument handle (Fig. 10).

In each of these groups, the handles can differ much in functionality and usability, but the 'overall' grip for each of these groups is quite similar.

### 3.4 Idea generation

Based on this analysis, ideas for different handle designs were generated, which were evaluated on their fulfillment to the objective design requirements. As a result, three handle designs remained for further elaboration towards a final design.

Handle design 1 was inspired by the 'biopsy handle', or the 'biopsy grip' (Fig. 11a), which can be often seen at instruments used for taking biopsies of e.g. the bone marrow. The handle design consists of an axially configured grip which can be held in the palm of the hand and is provided with functional elements to rotate the shaft and to punch bone (Fig. 11b), respectively.

Handle concept 2 was inspired by the shank handle (Fig. 12a), which is also the handle type of the surgical punch currently often used for endonasal pituitary surgery. In this concept, the lever pivots around a rotation axis relative to the handle. Fig. 12b depicts a sketch of the handle design 2.

Handle concept 3 was based on the pistol handle (Fig. 13a), regarding to the categorization of surgical handle types described by Matern and Waller [38]. As depicted in Fig. 13b, the lever pivots around a rotation axis relative to the handle. The instrument can be held between the little finger, the ring finger and the palm of the hand.

After sketching and evaluating the first ideas, the three handle designs were further elaborated. High density polyurethane (PU) foam was used to create physical mock-up models, in order to evaluate the main dimensions, shapes and potential placement of the control components (Fig. 14). Subsequently, a first user test was performed (with three technology students) to receive input for the further elaboration of the handle concepts, as depicted in Fig. 15, including a mock-up model of the endoscope.

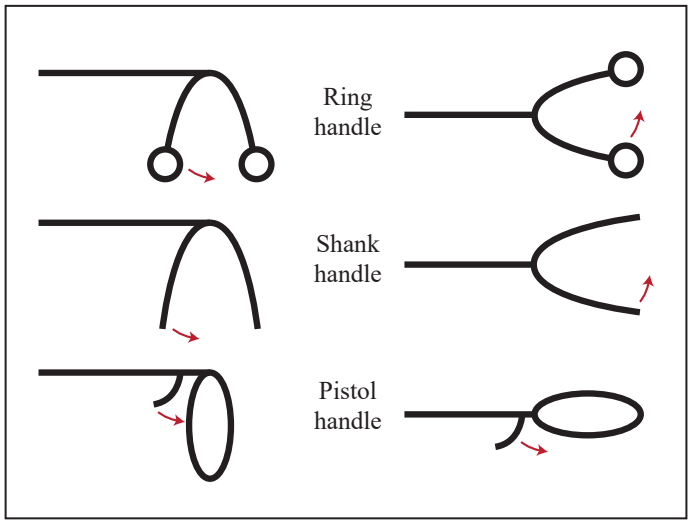


Fig. 10: Handle types in their configurations. Adapted from [23]

### 3.5 Handle mock-up model manufacturing

Based on the input on the first conceptual mock-up models, the conceptual designs of the handles were optimized and modeled in SolidWorks (Solidworks, premium edition, 2018). The non-functioning control elements (levers and handles) of the conceptual handle mock-ups were designed as separate parts, in order to make them movable when 3D printed. The levers should represent the function of punching whereas the rotation-knob should represent the rotational alignment of the tip to the bone to be punched.

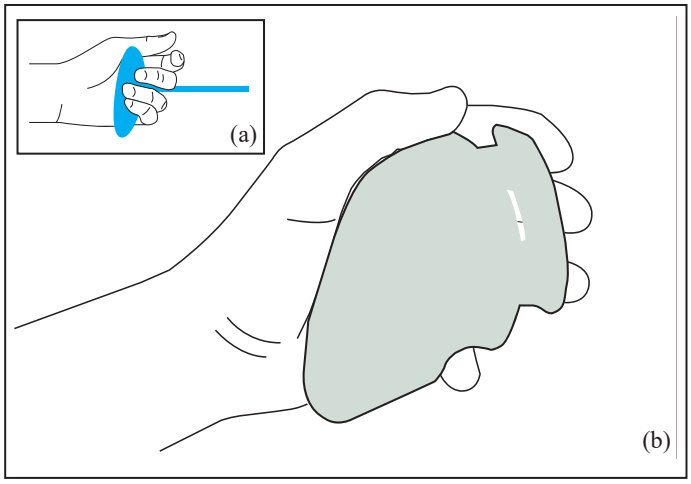


Fig. 11: (a) Biopsy handle. (b) Sketch of handle design 1.

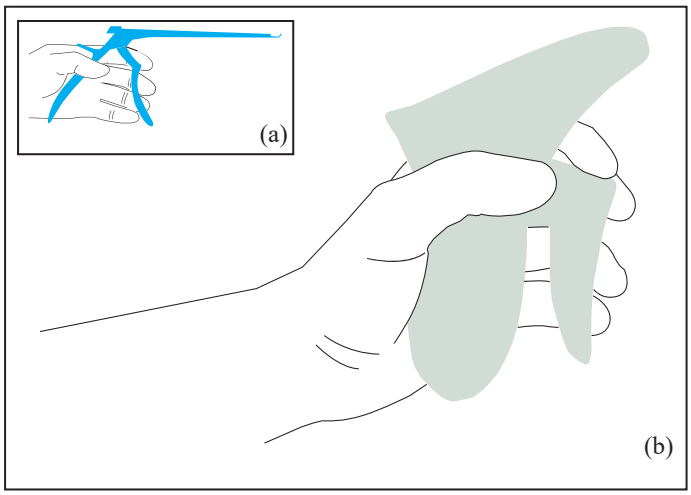


Fig. 12: (a) Schematic representation of currently used handle (Kerisson). (b) Sketch of handle design 2.

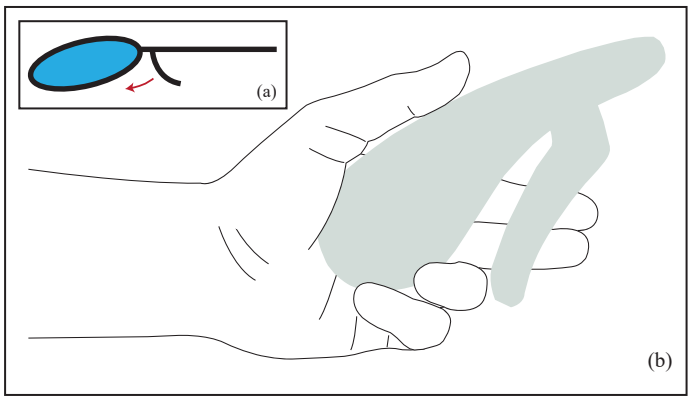


Fig. 13: (a) Schematic representation of the pistol handle [38]. (b) Sketch of handle design 3.

Subsequently, the models were fabricated using selective laser sintering (SLS), from (white) polyamide (PA), and afterwards the models were 'media tumbled' (also known as 'vibro polished') to provide a smooth finish. Fig. 16 depicts the 3D printed parts.

Finally, the 3D printed handles, rotation-knobs and levers were assembled to three complete handle mock-ups, including a shaft (4mm steel tube) (Fig. 17). Although the rotation wheels, levers and shafts are non-functioning elements, the completely assembled handle mock-up models could provide an excellent indication of a fully functioning instrument. The mock-up model of handle design 2 was presented in two configurations: one in which the rotation knob was manipulated by the thumb, and one configuration in which the rotation knob was manipulated with the index finger. Both configurations were implemented in the same model.

### 3.6 Handle evaluation I: quantitative test

***Goal of the evaluation***

The three handle models were evaluated based on the subjective design requirements (Section 3.2). A group of eight research participants took part (students from the Delft University of Technology, age ranging from 20 to 24, 4 male – 4 female). The goal of the test was to quantitatively measure the preference of the three handle designs regarding the different usability aspects. Based on the quantitative data which was obtained during the test, conclusions reflecting the usability of the handle designs could be drawn.

Fig. 14: Three handle models in high density PU foam.

***Experimental set-up***

A silicone phantom model of the nose was used in order to recreate the operating site. Furthermore, a scale model endoscope with mock-up handle was used to test the interaction between the endoscope and the handle types. Fig. 18 shows the experimental set-up. The participants were asked to grab the handle mock-up model, and to manipulate the control components. Subsequently they were asked to insert the shaft in the phantom model, and to manipulate the control components again. These steps were repeated for each of the handle mock-up models. For the purpose of eliminating order bias, different orders of the handles during the test were followed. During the performance of these tasks (e.g. holding, manipulation of control components), the participants were asked to 'think aloud', thereby explaining the difficulties, struggles, but also the pleasant aspects in the use of each concept. After performing these tasks, the subjects were asked to complete a questionnaire. The questionnaire consisted of 12 statements for each of the handle designs, which could be judged on a Likert-scale (1 = totally disagree, 7 = totally agree). The statements examined the subjective design requirements, the intuitiveness, the appearance and the interaction of the handle with the endoscope. The questionnaire can be found in appendix C. Lastly, after completing the questionnaire, the participants were asked to give their overall preference of the concepts.

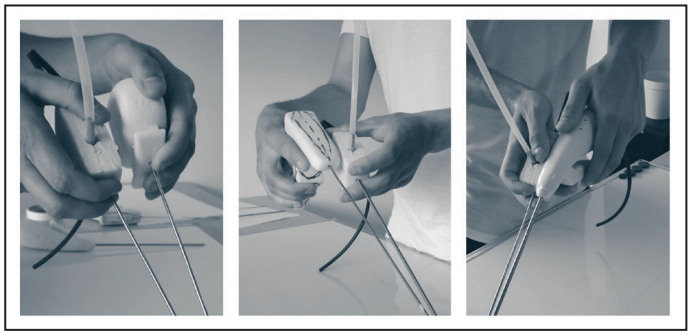

Fig. 15: Three handle models tested. The second hand holds the mock-up endoscope.

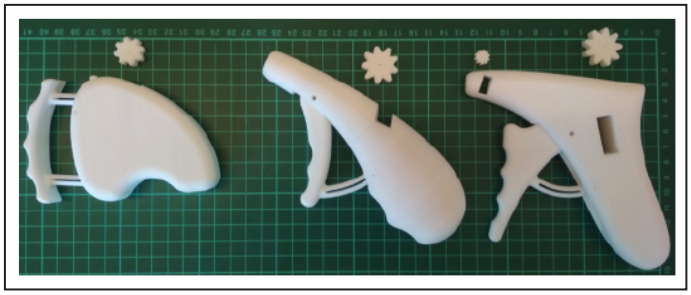

Fig. 16: 3D printed parts of each of the handle models.

***Results***

The graph depicted in Fig. 19 presents the results of the test. It was found that for 10 out of 12 statements handle design 3 was scored the highest, out of which 6 statements having an advantageous difference of more than 0.5 on the Likert-scale compared to the other handle types. Furthermore, all participants indicated that their overall preference for the handle type was handle design 3. The complete set of results can be found in appendix D.

### 3.7 Handle evaluation II: Qualitative test

Besides the quantitative test, a qualitative test was performed in which two experienced neurosurgeons (one male, one female, both right handed) were involved. The test took place in a skill-lab at the University Medical Center Groningen and the same mock-up models were evaluated. The skill-lab resembles a complete surgical setting involving the use of surgical supplies and imaging equipment, in which human cadavers are prepared. This qualitative test allowed for observing experts and their usage of the handle mock-up models, but also for asking questions to get insight in the difficulties that the participants experienced. The participants were asked to hold, to manipulate and to insert the handle mock-up models into the nose of the prepared bodies. When inserted, the participants were asked to manipulate the control elements of each of the handle designs (Fig. 20). During these tasks, questions were asked about the different usability aspects, based on the subjective design requirements.

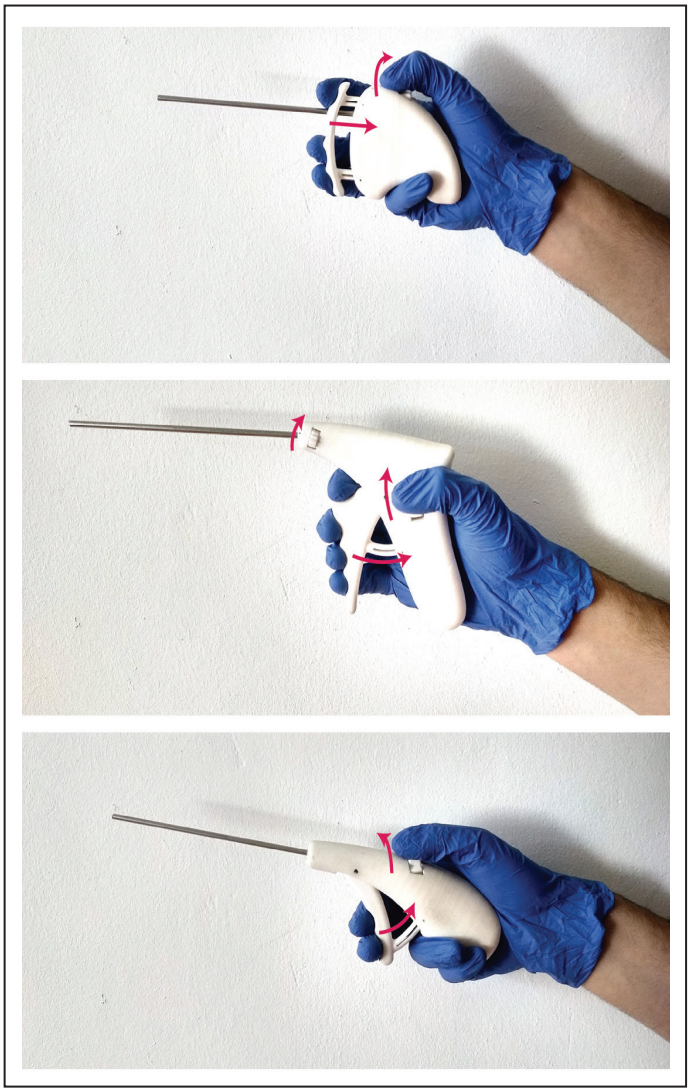

Fig. 17: Three assembled handle mock-up models. Note that handle design 2 has two rotation-knob options.

### 3.8 Findings and results

Both experts indicated that the overall preference goes to handle design 3. The surgeons indicated that this is mostly due to the stability when manipulating the control elements and when holding the instrument. It was indicated that the stability was mostly due to the ease of gripping by only the ring finger, little finger and palm of the hand, thereby having the thumb and index finger 'free' at any time during the procedure, to manipulate the control components. Furthermore, the female surgeon indicated that the control elements of handle design 1 and handle design 2 could be positioned approx. 1cm closer to the palm of the hand, since she could not reach every control element easily enough. However, the rotation knob of handle concept 3 could be positioned approx. 1cm distally to its current position. Both surgeons indicated that all concepts can be manipulated with a single hand, and that all instruments are sufficiently robust. Thumb rotation-wheel handling is preferred by both surgeons, over manipulating the rotation wheel with the index finger.

### 3.9 Conclusion

Three handle designs were designed and manufactured to full-scale mock-up models, based on the user requirements. Subsequently, these handle mock-up models were evaluated by a group of technology students, and by a group clinical experts. In both the quantitative and the qualitative test, handle design 3 was preferred by the users. Based on the results of these evaluations, conceptual handle design 3 was chosen to be further elaborated in the final design of the NeuroPunch.

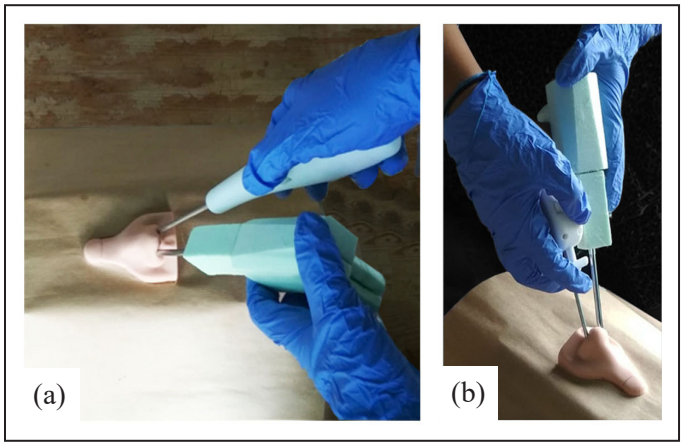


Fig. 18: Experimental set-up of the quantitative user test.

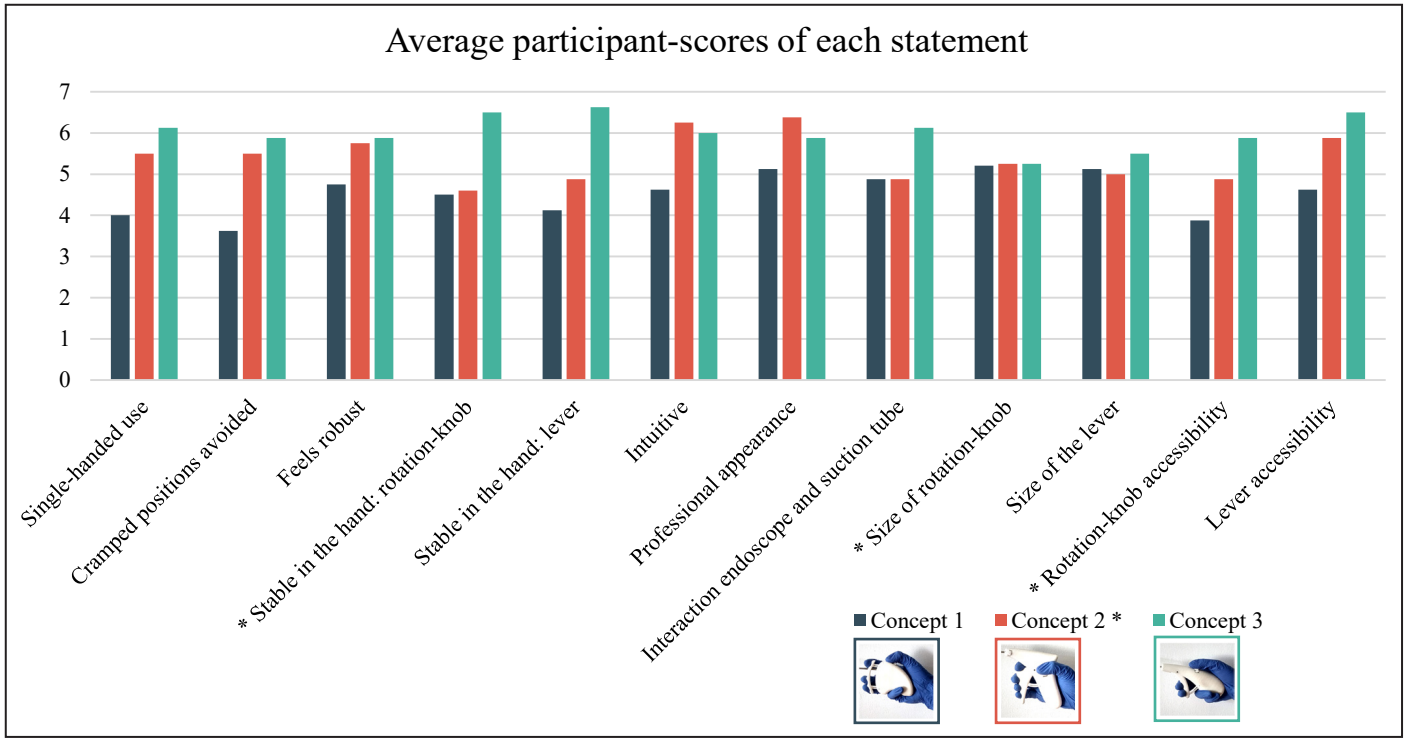


Fig. 19: Results of the questionnaire regarding the subjective design requirements for the design of the handle.
* The figure only provides the highest average for concept 2 (which was in all cases the thumb finger rotation knob).

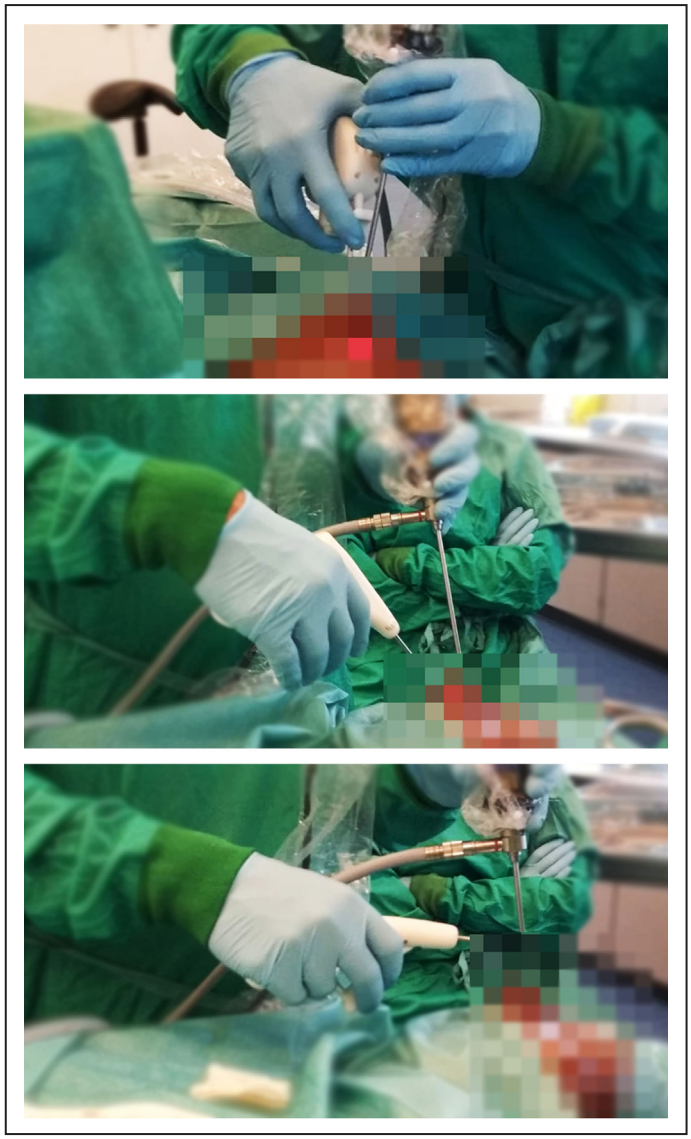

Fig. 20: Testing the handle types in a skill-lab.

# 4. Conceptual design part II: punching and reloading

## 4.1 Introduction

The second conceptual design part of this project reflects the process of the design of a punching mechanism, which involves the distal section of the instrument, including the shaft. The goal of this conceptual design part was to design a mechanism which fulfills the functional requirements (F1 – F3), the dimensional requirements (D4 – D6) and the medical safety requirement (S11), as described in Section 2.3. Although the medical safety requirement can take many safety aspects into account, within the scope of this review this requirement only incorporates the tissue interactions within the direct environment of the instrument. First, several of the design requirements were further specified. Based on the list of (sub-) design requirements, several brainstorm activities were performed, resulting in potential solutions which were structured and critically analyzed. Subsequently, the most proper solutions were selected and implemented in the final design.

## 4.2 Design requirements: punching and reloading

In Section 2.3, the design requirements were discussed based on an analysis on existing instruments used in endonasal pituitary surgery [23,24] and based on the input from the users during discussions throughout the course of this study. Two of these design requirements (D6 and S11) were further specified to unambiguous deviations of these requirements (sub-requirements) for the design of the punching and reloading method for the NeuroPunch. These sub-requirements are listed in Table 3. The corresponding product specifications, acceptance criteria and method to

demonstrate the conformity of the (sub-) requirements are described in Appendix B. Throughout this section, the requirements and sub-requirements will be used as criteria to evaluate the conceptual solutions for the punching and reloading method.

### 4.3 Punching method

The first part for the design of the punching element was the punching method. The primary function of the instrument is the ability to cut pieces of bone in the nasal cavity and sellar region of the patient. Several brainstorm sessions were performed and ideas of possible methods to cut pieces of bone were generated. Separating two pieces material can be done in many different ways. However, since the procedure is performed in highly delicate and vulnerable areas, it was assumed that a purely mechanical, non-motorized, and non-energy working principle would be the safest, when comparing this to e.g. high pressure water cutting, the use of high speed rotational elements (sawing), or high temperature laser cutting. Furthermore, due to the preferred lever actuation described in the previous section, the conceptual solutions were focused on translational-actuated mechanisms. Within the scope of this procedure, a translational-actuated mechanical working principle was therefore the starting point of the brainstorm session.

The conceptual solutions for (mechanical) punching of bone pieces are depicted and categorized in Fig. 21, in which the green components indicate the moving elements of the system. The conceptual solutions can be distinguished by means of different aspects: the force transmission throughout the instrument (direct/indirect), the stationarity/movability of the distal end of the instrument when punching, and the presence of protruding elements, instead of the tip being an extension of the shaft. As depicted in Fig. 21, punching methods A-E, I and J, do theoretically provide a direct force transmission from the handle to the tip. So, the force which is generated in the handle, is directly exerted on the bone. In contrast, methods F-H and K require a force transmission in the shaft of the instrument, therefore the force generated in the handle is indirectly exerted on the bone. When reviewing the conceptual solutions regarding the presence of protruding elements, it was found that solutions I-K do consist of protruding elements, whereas solutions A-H are an extension of the shaft of the instrument.

Table 3: Sub-requirements of dimensional requirement 6 and medical safety requirement 11.

| | |
|---|---|
| **D6.1** | The tip opening should allow for the introduction of bone. |
| **D6.2** | The tip height and width are sufficiently small to enable simultaneous use of the instrument, scope and suction tube in the operational area. |
| **D6.3** | The tip dimensions allow for cutting an acceptable sized piece of bone without undesired interactions with the suction tube or endoscope. |
| **S11.1** | The instrument provides good grip on bone when it is cut. |
| **S11.2** | The punching step should produce a 'burr-free' cut without damaging the surroundings of the cut. |
| **S11.3** | The distal end of the tip should be stationary (not moving) when the cut is made. |
| **S11.4** | The distal end of the tip should be small as possible and atraumatic. |

In order to select one of the conceptual solutions as punching method, the ideas were reviewed and critically judged based on three criteria, which were derived from the set of design requirements:

- The distal end of the tip should be able to be held at a stationary position when the cut is made.
- Protruding elements possibly leading to undesired interactions with other instruments or limited maneuverability in the operational area should be minimized.
- The force transmission should be direct.

The first criteria is based on discussions with the clinical experts, in which they indicated that the stability and positioning of the tip of the instrument is of high importance, i.e. the ability to anchor the distal end of the instrument behind the bone piece to be cut, while the distal end is stationary. Since the distal part does not move when cutting, the cut can be thereby controlled more easily and safely. Ideas C-E, J and H do not fulfill this criteria. The second criteria was derived from the geometrical design requirements of the instrument. Since stiff protruding elements require a larger opening through the nose and might interfere with the other instruments used in the operational area, the presence of these elements is undesired. Ideas I-K do not fulfill this criteria. Lastly, the force transmission from the handle of the instrument to the tip of the instrument should be direct. Since the instrument must be able to cut bone, relatively high forces are required in the tip of the instrument. Ideas F-H and K require the force in the handle to be transmitted through the shaft in an indirect way (e.g. with the use of a lever), and therefore require undesirably complex or small elements. Based on these requirements, ideas A and B are judged to be the most suitable as mechanical punching method and are therefore further elaborated.

### 4.4 Punching shaft configurations

Based on the general mechanical punching method, more detailed conceptual solutions for the tip configuration were developed. The configuration of the tip is essential because of the importance to be able to align the tip of the instrument properly to the bone which has to be cut. Either the instrument should be able to rotate the tip of the instrument, or the instrument should be designed in such a way that it always aligns properly to the bone. Fig. 22 depicts three conceptual tip configurations which are

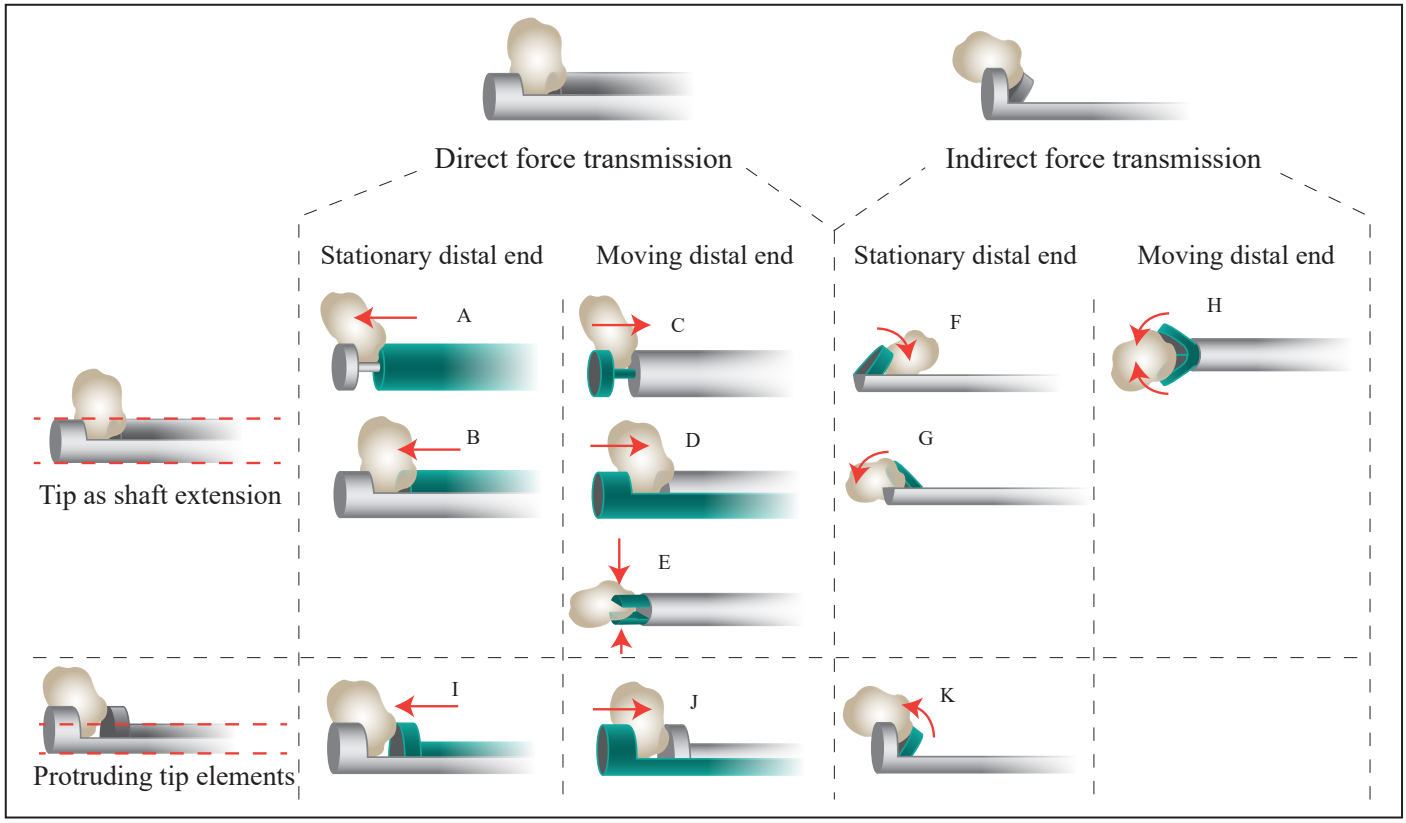


Fig. 21: Categorization scheme of the conceptual solutions for mechanical punching methods. The green parts are the moving elements of each system.

derived from the conceptual solutions A and B from Fig. 21. These configurations all consist of one reciprocating shaft relative to a stationary shaft, resulting in a punching movement in which the bone is clamped and cut between the shafts. The first configuration (Fig. 22a) consists of two rotational-symmetric shafts, in which the inner shaft reciprocates relative to the outer shaft. This configuration results in an instrument which does not require to be rotated in order to align the tip properly to the bone. This type of cutting method is seen more often in several medical punching devices [39]. The second configuration (Fig. 22b) consists of a reciprocating shaft, which is configured to be positioned onto a stationary shaft, in which the stationary shaft consists of a base at the distal end of the shaft, onto which the reciprocating shaft can be pressed, in order to cut bone. This principle is similar to the working principle of many bone punches used nowadays in surgery (Fig. 8). The third configuration (Fig. 22c) shows two shafts of which the inner shaft reciprocates into an outer shaft, thereby surrounding the inner shaft. A recess in the outer shaft allows for space to insert pieces of bone, which can be cut. Here the inner shaft can be reciprocated relative to the outer shaft.

The three punching shaft configurations were judged on two criteria: their cutting efficiency and the bone storing capacity. The cutting efficiency can be described as the ratio between the cross section of the outer shaft and the area of the punched bone piece. The first configuration consists of two rotational-symmetric shafts and does not require rotational elements. However, due to the shaft which runs through the center of the instrument, the cut which can be made by each reciprocating movement, is small, relative to the cross sectional area of the outer shaft, as depicted on the left side of Fig. 22a. Therefore its cutting efficiency is low. The other two configurations which consist of two reciprocating shafts, have a higher cutting efficiency, due to the absence of a centralized shaft. However, by providing two centralized hollow shafts (Fig. 22c), instead of a configuration in which the shafts are placed onto each other, a higher cutting efficiency can be achieved. Furthermore, this configuration has a bigger bone-storing capacity, which will be discussed in the next section. Therefore, the third configuration will be further elaborated.

### 4.5 Tip reloading mechanism

***Categorization***

Besides the ability to align the tip of the instrument properly to the bone, another functional requirement of the device is to be able to make multiple cuts without the need for extracting the instrument from the operational area, since these undesired interruptions slow the procedure down and increase the risk of introducing bacteria, as described in the design requirements [28]. Therefore, a method for clearing, or in other words, 'reloading' the cutting area and thereby providing the ability to make multiple consecutive cuts, is desired. By means of several brainstorm activities, ideas of possible mechanisms to store or eject pieces of bone, were generated. These ideas are structured and presented in Fig. 23. The ideas were subdivided based on the reloading mechanism; either the bone pieces are ejected or the bone pieces are stored internally (i.e. in the instrument). Furthermore, the storage-ideas were subdivided into bone

pieces which were stored proximally to the tip or stored distally to the tip. Lastly, a distinction was made between active and passive mechanisms. Each subdivision and its associating ideas will be further described below.

***Sideways ejection***

In the sideways ejection subdivision, one mechanism is able to passively eject the bone pieces sideways to the tip of the instrument. The inner shaft of the instrument is provided with a lumen, through which a piece of bone can transfer. By each punching step, a new piece of bone is inserted in this lumen, simultaneously pushing the previous bone piece outwards the instrument. Since no additional ejection-step is required, this mechanism is a passive mechanism. The other mechanisms in this subdivision are active reloading mechanisms, requiring an additional action in order to eject the bone pieces when they are cut. In the air pressure mechanism, a lumen is running through the outer shaft. When activated, pressurized air flows through this lumen, thereby forcing the bone pieces outwards sideways from the instrument tip. Similarly, this lumen can be used to provide a pathway for pressurized water in order to eject the punched bone piece. Another mechanism consists of a spring which can be compressed, and when required, the pressure can be released resulting in a spring force which ejects the bone piece. Lastly, a mechanism is visualized which uses an ejection pin located at the outer shaft able to eject the punched bone piece.

***Distal storing***

Different to the ejection mechanisms, in the storing subdivision mechanisms are described which allow the bone pieces to be stored internally. In the distal storing subdivision, the bone pieces are stored at the distal section of the instrument, by means of an elongated, hollow extension of the outer shaft. Different mechanisms were found, allowing for transferring these punched bone pieces into the 'storing section'. In the categorization scheme, these storing sections are highlighted by a dashed line. Similarly to the sideways ejection category, passive and active mechanisms are described. One of the passive mechanisms only requires the inner shaft to reciprocate relative to the outer shaft. By doing so, the bone piece is directly transferred to the storing section, resulting in the storage of the bone pieces distally to the instruments' cutting section. In addition to this passive storing mechanism, thin needles can be attached, thereby pushing each bone piece over this needle, in order to sustain the bone pieces in the storing section. Further mechanisms in this subdivision provide similar mechanisms as described before: water pressure, spring force, an ejection pin and air pressure can be used to transfer the punched bone piece into the storing section.

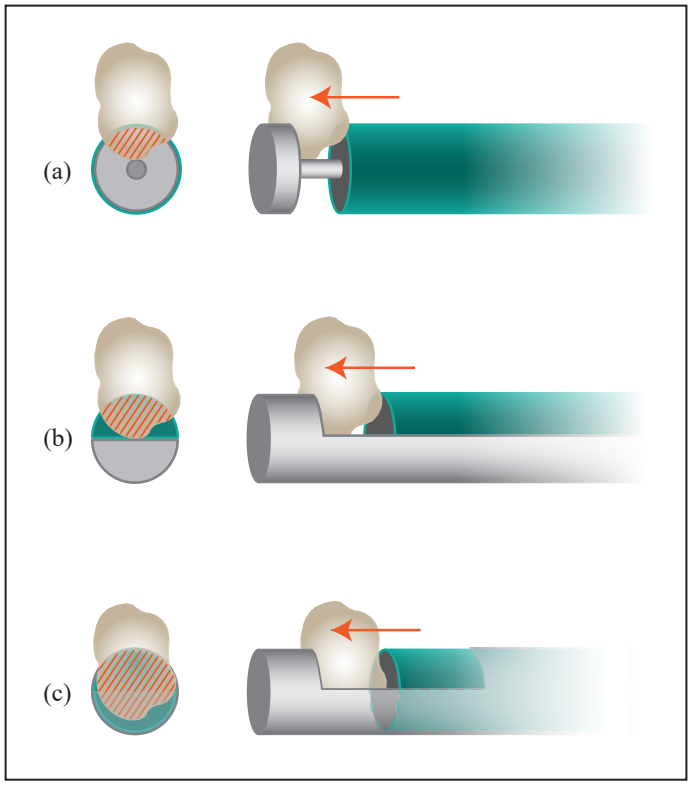


Fig. 22: (Left) The cutting efficiency for each of the configurations. (Right) Three conceptual solutions for the shaft configuration.

***Proximal storing***

The last category describes mechanisms which allow the bone pieces to be stored proximally to the tip of the instrument, particularly inside the inner shaft of the instrument. The passive mechanisms do not require an additional action subsequently to the punching step, in which the inner shaft reciprocates in a distal direction relative to the outer shaft. In order to store these bone pieces in the inner shaft of the instrument, the inner shaft can be shaped in a conical geometry, thereby preventing the bone pieces from getting stuck inside the inner shaft, and from falling out the inner shaft. Another passive mechanism provides an inner shaft in which profiles are extruded, providing more space for the bone pieces to be stored. Another passive mechanism provides an inner shaft including subsequent 'teeth cavities', allowing for each bone piece to be stored in each teeth cavity. Another passive mechanism provides an inner shaft which has a variable inner diameter, which is smaller closest to the cutting section. This results in bone pieces to be primarily positioned in the inner shaft section with the smaller diameter, and next to be shifted to the inner shaft section with a bigger diameter. Thereby, the bone pieces are first secured in the inner shaft, and next they can freely move in the inner shaft, reducing the resistance for the next cut. Another mechanism provides an inner needle. By each cut, the bone piece is perforated by the needle, and is thereby secured. It should be noticed that in order to passively store the punched bone pieces, the inner shaft should translate relative to the outer shaft. If the shafts are reversibly configured, a second action is required in order to push the punched bone pieces inwards. Active mechanisms which allow bone pieces to be stored in the inner shaft, are air suction, water pressure, the use of an injection pin or a spring, as described previously. Furthermore, the inner shaft can be provided with a cable mechanism allowing

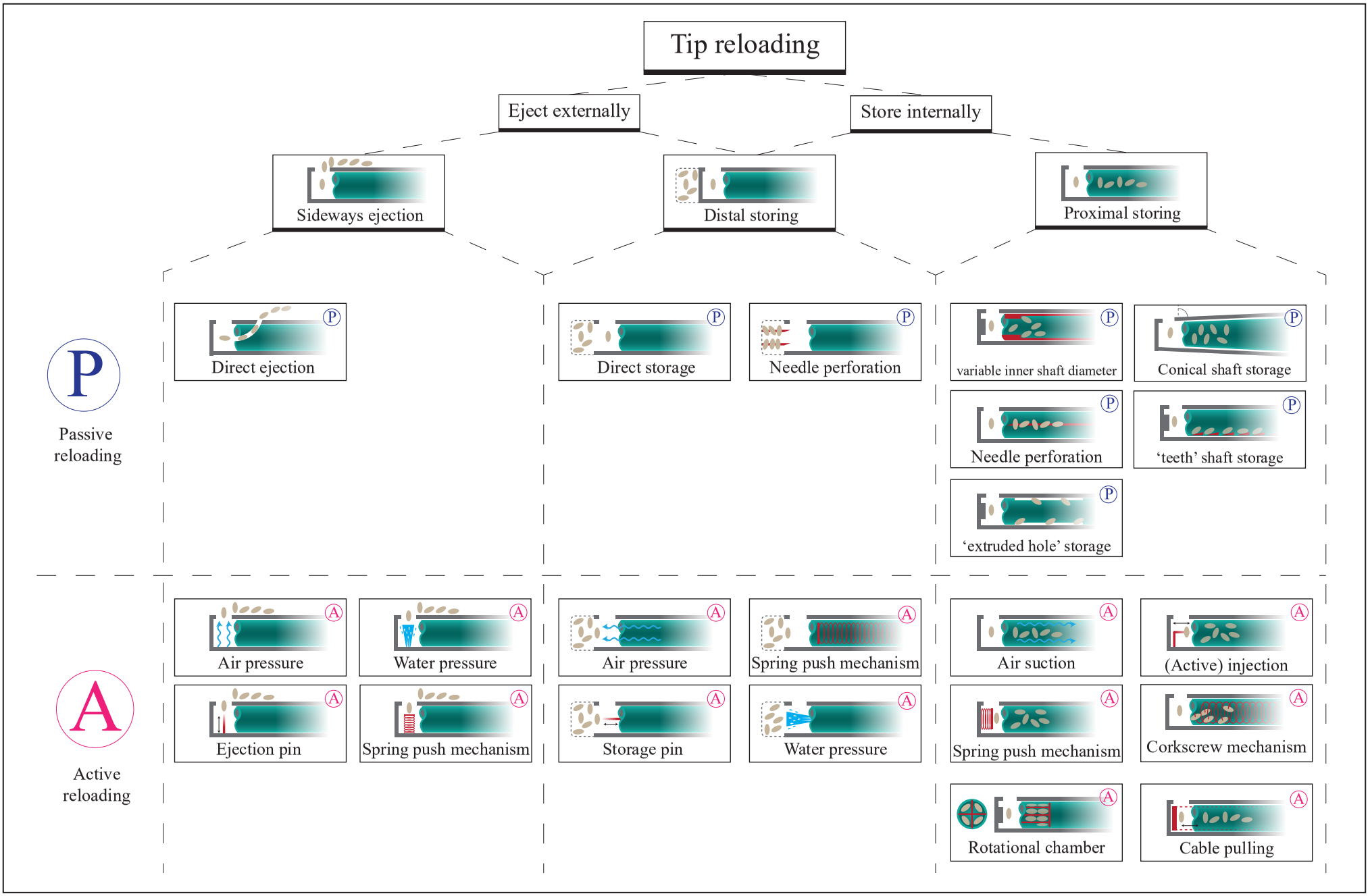


Fig. 23: Categorization of tip reloading ideas. The solutions are subdivided into ejection-ideas and storing-ideas, whereas the storing-ideas were subdivided into distal storing and proximal storing. Furthermore, a distinction was made between passive and active mechanisms.

for the bone pieces to be 'pulled in'. Another mechanism is described as a 'corkscrew' mechanism, in which a helical screw can be rotated, in order to perforate and store the bone pieces. Lastly, a rotational chamber mechanism is described. In this mechanism, the inner shaft consists of a rotational part, which consists of different 'storage chambers'. By rotating the part after each cut, the bone pieces are stored in different storage chambers.

### 4.6 Idea decision making

For the selection of one of the reloading solutions, three criteria were used to judge each idea. These criteria were based on the design requirements, which are previously described. First of all, the distal section of the instrument relative to the punching-section should be minimized, in order to reach the complete operational area. Second, the undesired interactions with the other instruments (e.g. the endoscope or suction tube) should be minimized. Lastly, reloading of the tip should be as easy as possible, and the required amount of actions thereof should be minimized. Each idea was judged on the criteria described above. The complete argumentation for each individual idea can be found in Appendix E, below the argumentation is shortly explained. Regarding the first criteria, the minimization of the distal section of the tip of the instrument, the ideas which are categorized in the group of distal storing can be excluded. Since these mechanisms require space at the distal section of the instrument, the accessibility in the nasal cavity is reduced. Ideas categorized in the sideways ejection category, do not directly increase the risk of damaging distally located tissue. However, by ejecting the bone pieces sideways, the bone pieces might stack up in the operational area, thereby impeding the field of vision. Besides, these mechanisms require the use of a suction tube to remove the bone pieces, leading to an increased operation time and possibly to undesired interaction between the instruments. Concerning the last criteria, ideas which require an extra action in order to reload the tip of the instrument, thereby requiring an active reloading step, were judged to be less favorable than passive reloading methods. In the active reloading methods, the surgeon must activate, for example, an air suction mechanism, a cable pulling action or water pressure. These active methods require complex mechanisms and besides, they require extra time in order to complete these actions. Therefore, passive reloading steps are preferred over active reloading steps.

Based on this review, it was concluded that the ideas in which a passive, proximal bone storing method was described, were the most favorable bone reloading methods. In this group, two mechanisms are described in which the resistance increases after each cut, thereby reducing the ease of cutting. These mechanisms are the 'needle perforation' mechanism and the 'teeth shaft storage' mechanism. Consequently, the following three mechanisms were further elaborated: 'conical shaft storage', 'variable inner shaft diameter storage', and 'extruded hole storage' (Fig. 24). The conical shaft storage method is provided with a conically shaped distal end of the inner shaft (Fig. 24a), allowing for the storing of bone. The conical shape reduces the chance of obstructions in the inner shaft and the shape prevents the bone pieces to escape through the entrance site of the shaft. The variable inner shaft diameter system (Fig. 24b) consists of two inner shaft sections, in which the distal piece consists of a smaller inner diameter. In this way, the bone pieces are stored in the inner shaft firstly at the distal section, but afterwards at the proximal inner shaft section, thereby able to transfer smoothly inside this shaft. The extruded hole storage system consists of a single inner shaft, through which long slender holes are extruded. When the bone pieces are pushed inwards, they become able to translate inside the inner shaft, having a lower resistance due to the reduced contact area with the inner shaft at the sites of the extruded holes. All three methods provide the similar functionality of being able to store the bone pieces and cutting the bone pieces. However, in terms of the manufacturability and structural integrity of each of the solutions, several differences can be seen. First of all, the inner shaft of the second solution might either consist of two different parts (Fig. 24b), thereby requiring

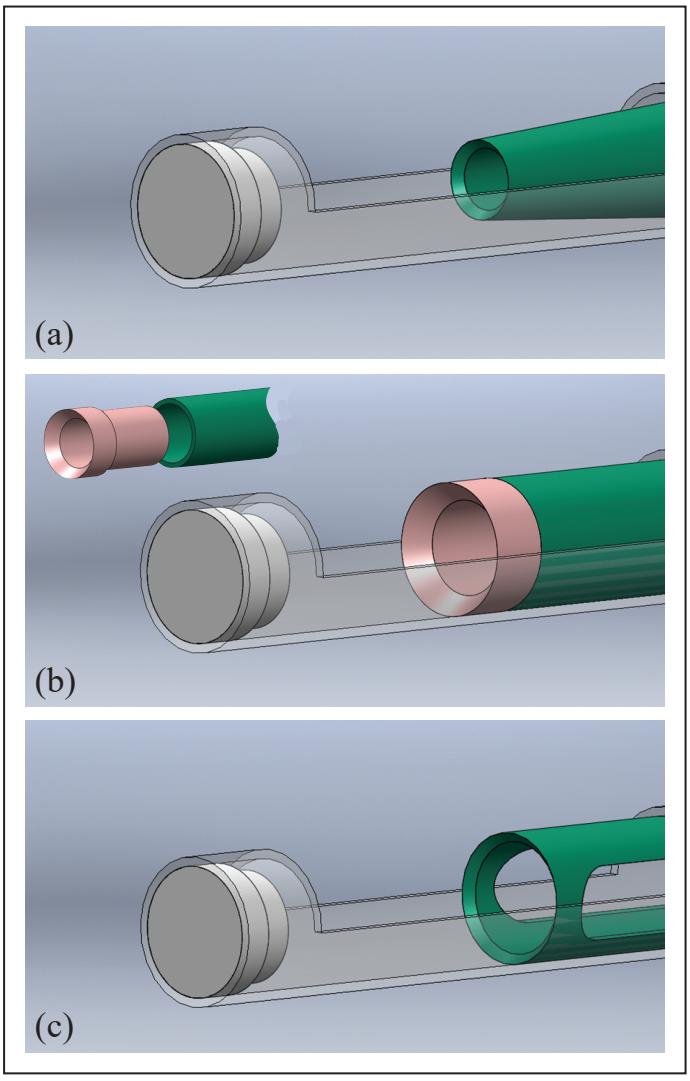


Fig. 24: The three most promising conceptual solutions. (a) Conical shaft storage (b) Variable inner shaft diameter storage (c) Extruded hole storage

an extra assembly step, or could be produced from a single part, requiring a complex manufacturing method: the production of the distal part of the inner shaft (pink) needs to be machined, which is a costly process compared to the use of stock products. In contrast, the extruded hole solution requires a single piece of tubing, from which holes should be extruded. Regarding to the conical shape method, the construction consists of either a single, or two parts. When producing the construction from two parts, an assembly step is required. When using a single part, extensive machining-work is required in order to produce the required shape. Furthermore, when producing the inner shaft from two different parts, the assembly step requires either welding or a form-closure, thereby requiring more space, which all are disadvantageous options in order to keep the inner shaft wall thickness as small as possible. Based on these manufacturing techniques and structural integrity of each of the methods, the hole extrusion method is preferred and further elaborated.

### 4.7 The shear effect

One of the requirements for the punching element of the instrument, is that the instrument should cut the bone pieces, instead of breaking, thereby creating a 'burr-free cut'. This is of particular importance due to the presence of extremely delicate and vulnerable structures in the operational area. When a bone piece is pulled, broken or ripped off, there is a chance of damaging a vessel, nerve, or other sensitive structures, increasing the risk of medical trauma.

In order to effect a cut, shear forces on the material to be cut are required. These shear forces are unaligned forces which push on the bone in opposite directions. These forces are generated by the inner shaft and the outer shaft of the instrument, as shown in Fig. 25.

As indicated in Fig. 26, the cutting edge of the inner and outer shafts both are flat. This produces a cut without a shearing angle, in which the complete piece of bone is cut simultaneously during the punch. By shearing with a flat cutting edge, the resulted cut could be inconsistent, inaccurate, and torn edges may occur.

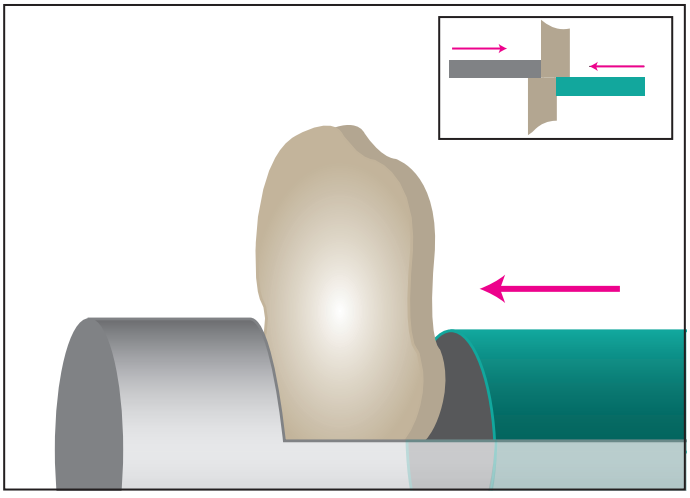

Fig. 25: Shear forces generated by the inner and outer shaft of the instrument.

Furthermore, since the complete surface of the inner shaft is used to cut simultaneously, the required force in order to cut the piece of bone is high, because the shearing area is equal to the complete piece of punched bone. On the other hand, when providing either the outer or inner shafts of the instrument with an angled shear surface, a gradual exertion of the shear forces will result, as shown in Fig. 27. Subsequently, the cut will be scissor-like, and therefore burr-free and accurate. Furthermore, the forces required to cut the bone piece are reduced, because the shearing area is smaller compared to when using a flat shearing surface.

The angle and direction of the shearing surface depend much on the functionality and use of the instrument. Regarding to the design requirements, it was indicated that the distal end of the instrument should be able to be anchored behind a piece of bone, thereby allowing for easy control of the shaft movements when cutting. Therefore, it was decided that the direction should be pointing in a proximal direction, at an angle of approximately 45°. During analyses of endonasal pituitary surgeries, it was noticed that different types of punches were interchangeably used, depending on the area in which is operated. Therefore one particularly preferred angle

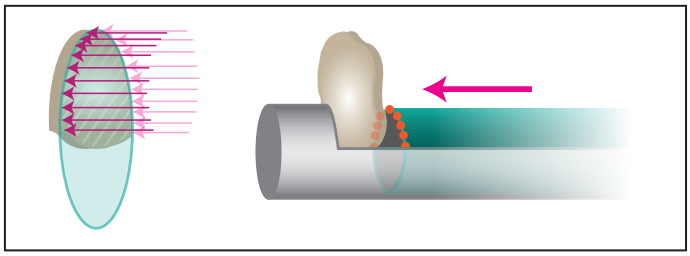

Fig. 26: The left image shows the simultaneously exerted forces (arrows) when shearing with a flat surface. The right image shows the complete shearing area when shearing with a flat surface (orange dots).

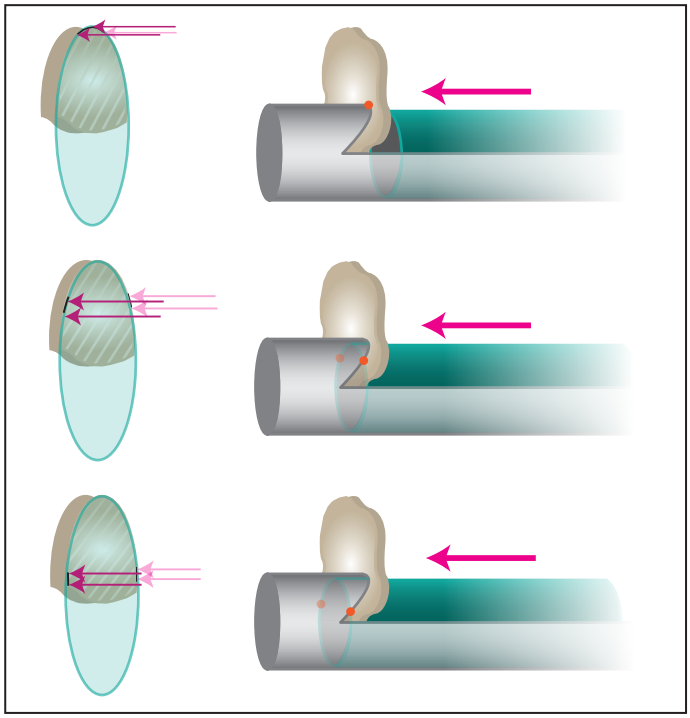

Fig. 27: Gradual force exertion on bone pieces when using an angled shearing surface. Orange dots indicate the force exertion sites at three steps of the punching sequence.

direction was not distinguished, and future research should provide more insight in the exact preferable tip angles.

### 4.8 The edge type and angle

In general, two types of cutting edges are being distinguished: convex edges and beveled edges (Fig. 28). Convex edges are very sharp edges that taper to a sharp point. Beveled edges are in general less sharp, and have a constant edge. Due to the sharp edges of the convex edges, they generally provide a smoother and lighter cut. However, this edge type has a tendency to dull faster, and they are more difficult to produce. On the other hand, beveled edges, require a higher force to cut, but they are more durable and easier to produce [40].

In order to decide whether to use a beveled edge or a convex edge in the tip of the instrument, a literature analysis on existing punches has been performed. The outcomes of the analysis indicate that no medical punches have been found with convex edges. Presumably, the main reasons for the preference of beveled edges is due to the ease of manufacturing of this edge type, and due to the durability of this type edge, especially when cutting a hard material, such as cortical bone. As shown in Fig. 28, the bevel angle α is constant. In order to determine the preferred bevel angle, the analysis on existing punches having a beveled edge is extended, in order to find the range of bevel angles used in medical punches. Furthermore, the bevel angles of other instruments have been analyzed, such as scissors and knifes, in order to get an impression of the important parameters for the preferred bevel angle. Table 4 shows the bevel angle (α) for different punching devices punching either cartilage or bone. As can be seen, the bevel angle used for cartilage-punches is lower than for bone-punches. This can be explained by the fact that cartilage is softer tissue, and therefore this can more easily be cut. Harder materials require a bigger bevel angle in order to reduce the chance of dulling. When analyzing other types of instruments, such as scissors of knifes, a similar difference in bevel angle can be seen: the harder the material to be cut, the bigger the bevel angle to prevent the instrument from getting dull. For scissors, bevel angles ranging from 20° to 45° have been found [45, 46]. For knifes, even smaller bevel angles have been found, ranging between 10° and 30° [47].

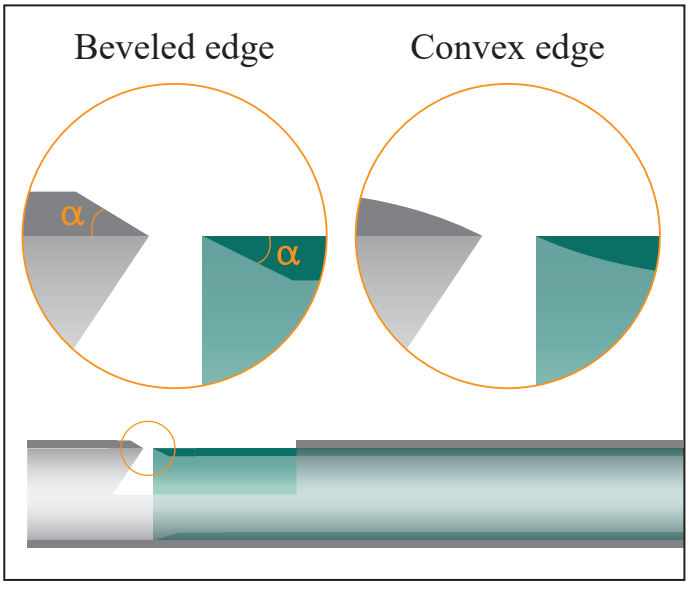


Fig. 28: Beveled edge with constant angle (α), and convex edge.

Based on these analyses, the bevel angle for the punch has been set to 37° for both the inner and the outer shaft of the instrument. A complete analysis and experiment in order to find the optimal bevel angle has not been performed due to time constraints of this project. However, it is recommended to perform such an experiment in a next stage of the design process.

### 4.9 Scaled proof-of-concept model

A proof-of-concept model was assembled in order to demonstrate the cutting and reloading principle. The goal was to demonstrate that the model was able to punch and store the pieces in the inner shaft. The concept consisted of an inner shaft (outer diameter (OD) 4mm, inner diameter (ID) 3.5mm), an outer shaft (OD 5mm, ID 4mm), and of several small pieces of tubing which were clamped in the outer shaft at its distal end, thereby allowing the inner shaft to be shifted only partly through the outer shaft (Fig. 29). The distal end of the inner shaft was grinded to a sharply edged shaft. The outer shaft was roughly shaped to its required dimensions (using a Dremel) thereby resembling the intended angled cutting edge. The extrusions in the inner shaft were not made due to inadequate manufacturing tools. It was shown that the model is able to cut and store pieces of polyurethane foam.

### 4.10 Force analysis

As explained previously, the force by which the bone piece is punched, is a shearing force. These are the unaligned forces which push on the bone in opposite directions. These forces are generated by the combined action of the inner and outer shaft of the instrument. In order to determine the amount of shearing force required to cut a piece of bone, the shear properties of the material, and the dimensions of the material are needed. The required shear force (F) can be calculated as follows:

Table 4: Bevel angles of different punching devices for cartilage and bone.

| Instrument | Tissue type | Bevel angle α |
|---|---|---|
| **Biopsy punch [41]** | Cartilage | 20° |
| **Biopsy punch [42]** | Cartilage | 20° |
| **Bone punch [39]** | Bone | 36° |
| **Bone punch [43]** | Bone | 37° |
| **Bone punch [44]** | Bone | 30° |

$$\tau = \frac{F}{A} \qquad (1.1)$$

In which:

- $\tau$ = the shear stress of cortical bone
- F = the required force
- A = the surface of the cross sectional area of the bone to be cut parallel to the applied force direction.

The punch will be used particularly in the nasal cavity and in the sellar area of the skull base. In these regions the tissue is mostly (thin) cortical bone [48]. A study performed by Lazaridis et al. [49], in which 24 adult Caucasian cadavers were undertaken to assess the anatomical measurements within the nasal cavity and the sphenoid sinus, indicates that the thickness of these bone regions can vary much, depending on the patient. For example, the thickness of the anterior sellar wall ranges between 0.4-1.5mm, and the thickness of the sellar floor ranges between 0.5-2.2mm. During discussions with the clinical experts (Section 1.3), it was indicated that the thickest bone structures in the nasal cavity and sphenoid sinus are first grinded to a thinner bone structure, in order to reduce the amount of required punching force and enhance the controllability of the punch, towards approximately 1mm. A study performed by Turner et al. [50], in which the shear properties of human cortical bone have been determined, indicates that the shear strength of human cortical bone equals 51.6 MPa. Although this study is performed on cortical bone of the femur, instead of on cortical bone in the nasal cavity, this value gives a good (the best available) indication of the order of magnitude of the shear stress of human cortical bone in general. Since no studies have been found determining the shear properties of cortical bone in the human nasal cavity or skull base, this value will be used in order to determine the required force to punch bone pieces in the nasal cavity region.

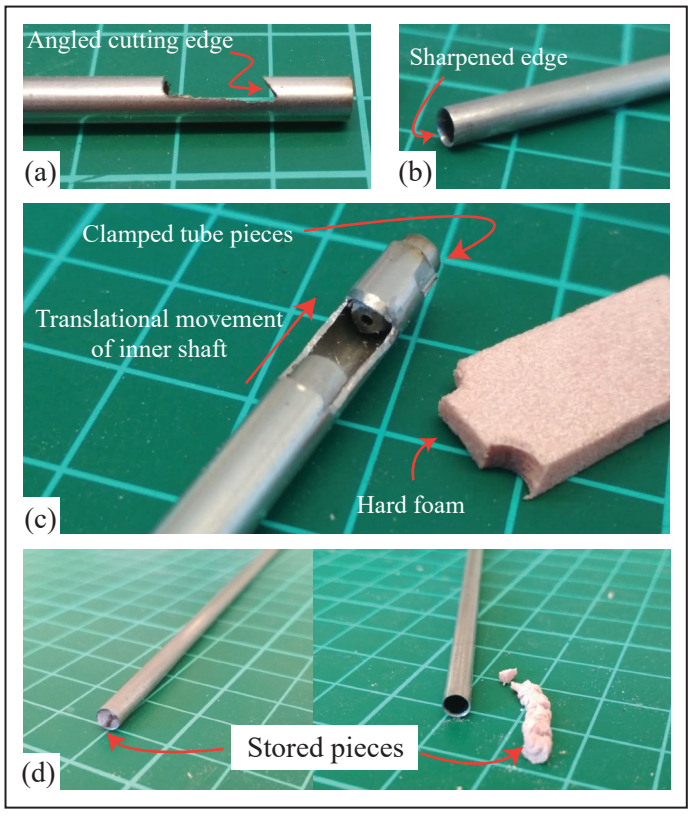


Fig. 29: Conceptual solution of cutting mechanism. (a) Inner shaft. (b) Outer shaft. (c) Shaft assembly. (d) Stored pieces.

As described in the requirements, the outer diameter of the instrument should be 4mm at maximum. Assuming an inner diameter of this shaft to be 3.4mm (thereby the wall thickness of the shaft is 0.3mm), the punched bone piece will have an outer diameter of 3.4mm. As mentioned before, the shafts are preferred to have an angled shearing area, in order to reduce the shearing surface. As depicted in Fig. 30, the cutting line, which is the contact area between the outer shaft and the bone piece at the moment of punching, of the configuration when there is no shearing angle, is equal to the inner radius of the outer shaft (1.7mm) multiplied by $\pi$ (the circumference of a semicircle), which is 5.34mm. Assuming that a bone piece with a thickness (t) of 1mm is punched, the shearing surface (A) will be equal to the multiplication of 5.34mm and 1mm, resulting in a shearing area of 5.34mm². The required force in order to punch this piece of bone then becomes 5.34 mm² multiplied by the shear stress of human cortical bone (51.6 MPa). This results in a required punching force of 275.5 Newton.

When comparing this punching force with the force required when cutting with an outer shaft provided with a shearing angle, the cutting line is drastically decreased, as depicted in Fig. 31. When punching with a shearing angle, the required force will be dependent of the cutting depth in the bone, resulting in a gradual exertion of the shear force on the bone. In order to exactly determine the highest shear

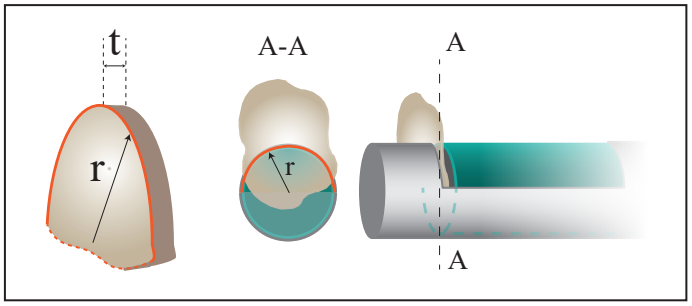


Fig. 30: (Left) the punched bone piece and cutting line. (Right) configuration of the shafts when there is no shearing angle with cutting line (orange).

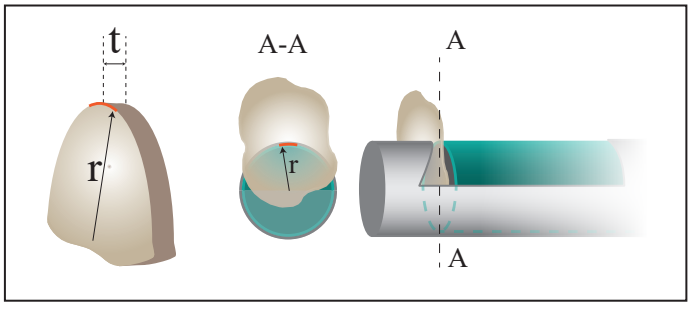


Fig. 31: (Left) the punched bone piece and cutting line. (Right) Configuration of the shafts with shearing angle and cutting line (orange).

force during this gradual force exertion on the bone, the outer shaft has been modelled in SolidWorks (Solidworks, premium edition, 2018). Subsequently, the exact (inner) contact area of the outer shaft could be measured, for each of the cutting steps, starting from the point where the bone touches the cutting point of the shaft, until the point where the bone is completely cut. The graph in Fig. 32 depicts this gradual force exertion on a bone piece with a thickness of 1mm, including four indications of the progress of cutting. The shear force, which is shown on the y-axis, is calculated by the multiplication of the surface of the cross-sectional area of the bone to be cut parallel to the applied force and the shear stress of bone (51.6 MPa). Based on this graph, it is concluded that the force required to cut a 1mm piece of bone is equal to 92N. The complete table of all measurements can be found in Appendix F. It should be noticed that these calculations are a (rough) estimation, instead of experimentally determined (exact) values. For the abovementioned calculations, among others, a completely static environment is assumed, in which the speed of cutting, the rupture of bone pieces as a result of the initial crack and the biological properties (e.g. the alignment of the collagen structures) resulting in a different shear properties of cortical bone, are neglected.

### 4.11 Materialization

Although the geometrical features of the final design of the punching and reloading part are completed, the materialization and manufacturing methods of the design are not yet described. As indicated, the distal section of the outer shaft should withstand a force of 92N and should have an outer diameter of maximally 4mm. Based on these two parameters, a Final Element Analysis (FEA) was performed. Based on this analysis it was concluded that, in order to cut pieces of bone in the operational area, the required outer shaft thickness should be at least 0.35mm, and the yield strength of the material should be at least approximately 1.000 MPa. One of the materials which is widely used in other surgical cutting instruments is stainless steel grade 420. This material has a higher yield strength and could therefore possibly be used as shaft material. The results of the FEA and its accompanying design considerations are further described in the discussion section.

## 5. Conceptual design part III: Rotation-translation mechanism

### 5.1 General mechanical design

The third conceptual design part of this project reflects the process of the design of a mechanism able to rotate the tip of the instrument and to allow for a translating movement of the inner shaft relative to the outer shaft, thereby transferring the gripping force in the lever to a translational movement of the inner shaft relative to the outer shaft. The design process of this part of the study mainly focusses on the implementation of the previous two design parts as described in Section 3 and Section 4. Therefore it should be noted that a less systematic approach was followed in order to design this rotation-translation mechanism. The main components and close ups of the working principle are visualized in Fig. 33.

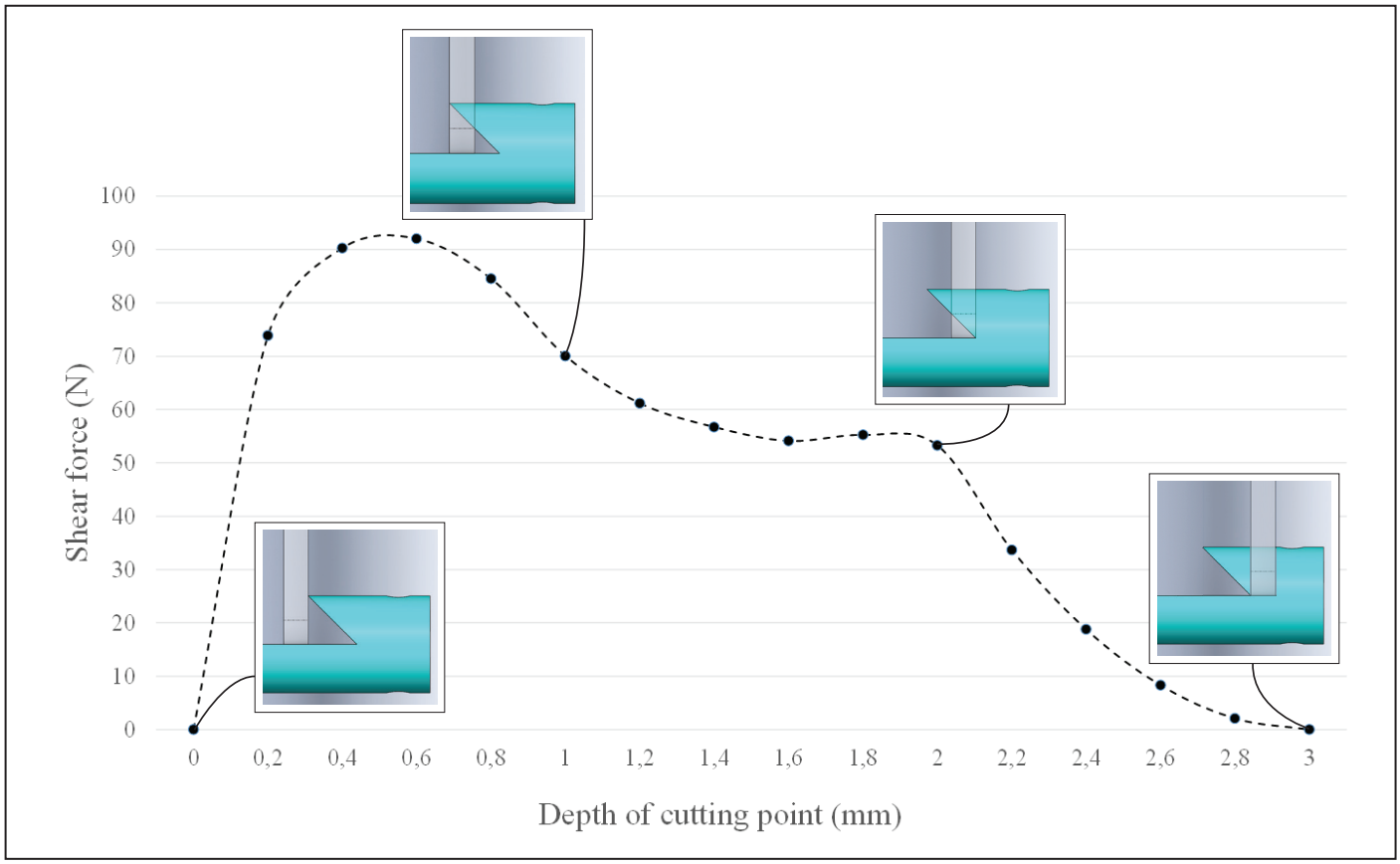


Fig. 32: Graph showing the gradual shear force exertion of the cutting edge on the bone structure, relative to the depth of the cutting point.

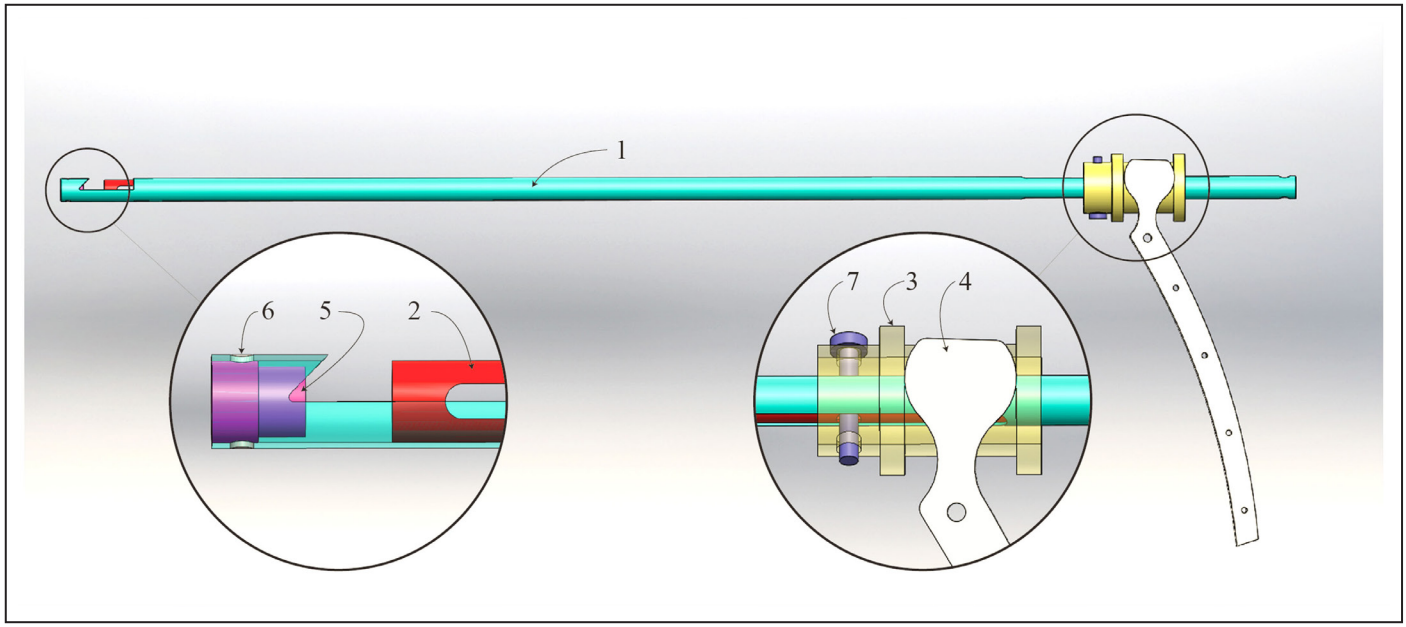


Fig. 33: Side view of internal rotation-translation mechanism, consisting of: outer tube (1), an inner tube (2), a transmission ring (3), a translation-rotation pin (4), distal cap (5), dowel pin (6), and a transmission-ring screw (7).

As depicted in Fig. 34a, the translation-rotation pin (light gray component) pivots around axis A, thereby shifting the transmission-ring (yellow) over the outer shaft. Since the transmission-ring is connected to the inner shaft by a screw, the inner shaft will translate relative to the outer shaft (Fig. 34b), when the translation-rotation pin is pivoted. Fig. 34c depicts a part of the mechanism in a three-dimensional view. As can be seen, two translation-rotation pins are used, both placed at one side of the transmission ring. The hole which runs through the transmission ring allows for insertion of a screw, thereby connecting to the inner shaft. The extruded groove from the outer shaft allows for the translational movement of the transmission ring and the inner shaft relative to the outer shaft.

In Fig. 35 the rotation-translation mechanism is depicted including the rotation-knob (green). The rotation-knob can be connected to the outer shaft by placing a screw through the holes of both components. As a result, rotation of the rotation-knob will cause the outer shaft to rotate simultaneously. The rotation-knob is provided with two extruded grooves, which allow for the passage of the transmission-ring screw, when the inner shaft is translated relative to the rotation-knob and the outer shaft. Due to the presence of the transmission-ring screw, the inner shaft will rotate as well, when the rotation-knob is rotated.

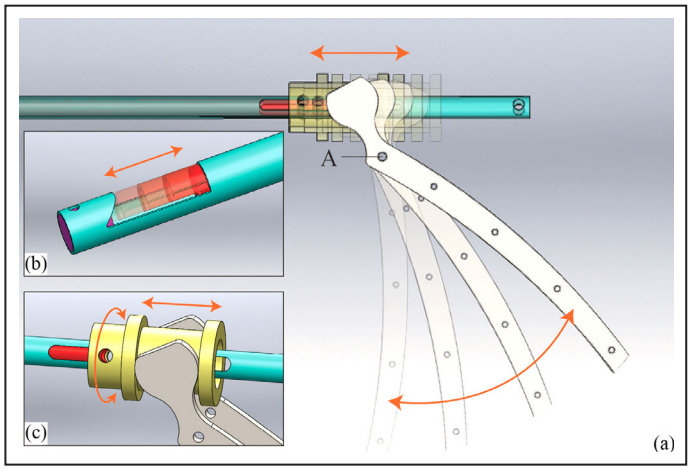


Fig. 34: (a) Mechanism which allows for rotation of the outer shaft and translation of the inner shaft resulting in the translational motion of the inner shaft relative to the outer shaft. (b) Translating inner shaft relative to the outer shaft. (c) Close-up of rotation-translation mechanism.

### 5.2 Lever length

As described previously, the required force to cut a circular piece of cortical bone with a thickness of 1mm, and a diameter of 3.4mm is approximately 92N. Based on the design requirements, the allowable gripping force may not exceed 1/3$^{rd}$ of the maximum gripping force generated by the users' index finger and middle finger [51]. According to Astin [52], the maximum index finger strength for female users when pulling an object with the finger pad, is approx. 50N. Assuming that the maximum pulling strength of the index finger and the middle finger together will generate the double (100N), the lever force may not exceed 33N (1/3$^{rd}$ of the maximum force). As illustrated in Fig. 36, the force $F_{FINGER}$ may not exceed 33N, and the force $F_{BONE}$ should be at least 92N. Therefore, the ratio of lengths L1 and L2 should be approximately 1:3 (or longer L2). This estimation does not take into account the presence of a

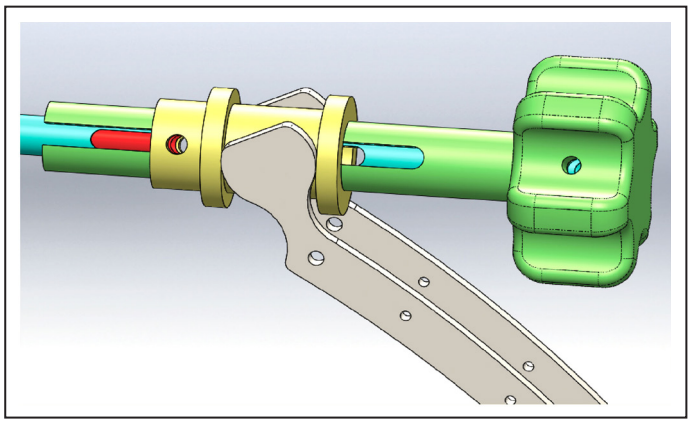

Fig. 35: Rotation-translation mechanism including rotation knob (green).

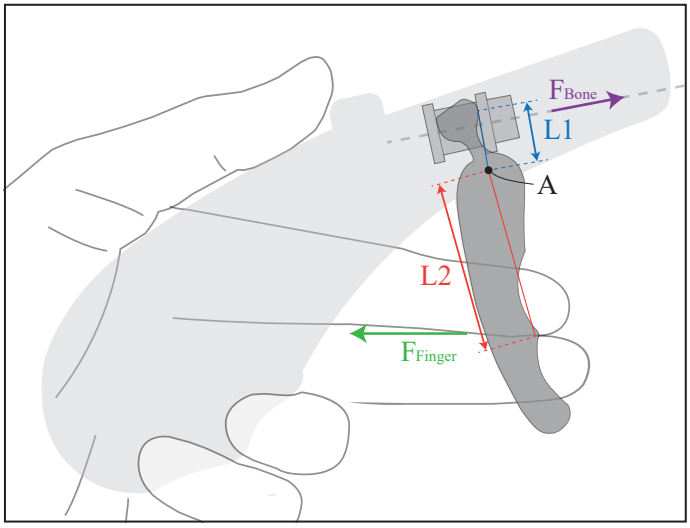

Fig. 36: Schematic view of the instrument with its lever, which pivots around axis A, with its corresponding lengths and forces.

spring, which will be placed between the rotation-knob and the handle of the instrument, in order to keep the instrument in an 'open position' when the lever is not pressed (Section 6). Furthermore, a complete frictionless movement of the components is assumed. Therefore, the required force in order to cut bone would be slightly higher than calculated above, which is allowable within the estimation.

# 6. Final design and prototyping

## 6.1 Final design

Implementation of the handle design, the storing mechanism and the rotation-translation mechanism, of which the design processes are described in the previous sections, resulted in the final design of the instrument. Fig. 37 shows an exploded view of the final design of the instrument, including a close up of the distal end of the instrument. The spring (3) which is visible on the exploded view is arranged between the handle part (9) and the transmission ring (4), ensures that the shaft configuration will be in the 'open position', when no forces are exerted on the lever (7). The translation-rotation pins (6) can be positioned into the lever. The lever and translation-rotation pins will be connected to the handle part (9) by the rotation axis (8), which causes the leverage of the translation rotation pins. The distal cap (12) will be connected to the outer shaft (1) with a dowel pin (13). The inner shaft (2) will be connected to the transmission ring (4) with a screw. The outer shaft (1) will be connected to the rotation-knob (5) by a similar type of screw. When the shafts and lever are properly placed, the assembly can be finished by connecting the handle cap (10) onto the handle part (9) with four screws.

## 6.2 Prototype

***Prototype purposes***

The purpose for developing a functional prototype were (1) to evaluate the manufacturability and feasibility of a correctly dimensioned prototype, (2) to test the functioning of the translational-rotational mechanism, the cutting ability and the bone storing capability, (3) and to evaluate the prototype on a human phantom model, by discussing and analyzing the usability aspects of the prototype with clinical experts.

***Part dimensioning and positioning***

In order to construct the functional prototype, the final conceptual design has been completely (CAD) modelled in SolidWorks (Solidworks, premium edition, 2018) in the proper dimensions. The parts were constructed such that they would be able to be manufactured with the proper manufacturing method. When the CAD model was finalized, the suitable materials were gathered in order to manufacture the parts, which will be discussed below.

The outer shaft has an outer diameter of 4.0mm. Although it was indicated that the required shaft material should have a yield strength of approximately 1.000 MPa (e.g. stainless steel 420), this material was not available. Therefore, the outer shaft and inner shaft are constructed from a standardized capillary stainless steel (304) tube. The outer shaft has an inner diameter of 3.5mm and the inner shaft has an outer diameter of 3.5mm and an inner diameter of 3.0mm, thereby able to slide smoothly into the outer shaft. The spring is a standardized 'music wire' steel spring (Tevema BV, Almere, the Netherlands) and has an outer diameter of 8.8mm and an inner diameter of 7.2mm. The unloaded length is 21.50mm, thereby fitting perfectly into the handle part. Due to its thickness of 0.8mm, the spring provides sufficient resistance to properly squeeze the lever in order to close the tip of the instrument. The transmission ring has an inner diameter of 7.1mm, thereby fitting over the rotation-knob, which has an outer diameter of 7.0mm at its distal section. The inner diameter of the rotation-knob at its distal section is 4.1mm, which allows the outer shaft to be inserted. The position of the rotation-knob relative to the handle part has been altered compared to the position of the rotation-knob in the previous conceptual design (Section 3.5), based on the results of the handle evaluation (Section 3.6). The other dimensions of the handle part have been remained the same as the handle part in the previous conceptual design (Section 3.1). The handle cap and handle part are provided with holes with a diameter of 1.9mm, to allow for the fixation of both parts with standardized M2 screws. The distal cap has a variable outer diameter. At its distal end, the diameter is 3.5mm, and at its proximal end the diameter is 3.0mm. As a result, the distal end of the part fits perfectly into the outer tube, whereas the proximal part fits perfectly into the inner tube. The distal cap is provided with a 1mm hole through its distal part, and can be connected to the outer tube by a standardized dowel pin with a diameter of 1mm. The lever is provided with two extrusions over the complete length of the lever, in order to allow for the placement of the translation-rotation pins into the lever. The translation-rotation pins have a thickness of 1.5mm, are shaped such that they exactly fit onto the transmission ring. The

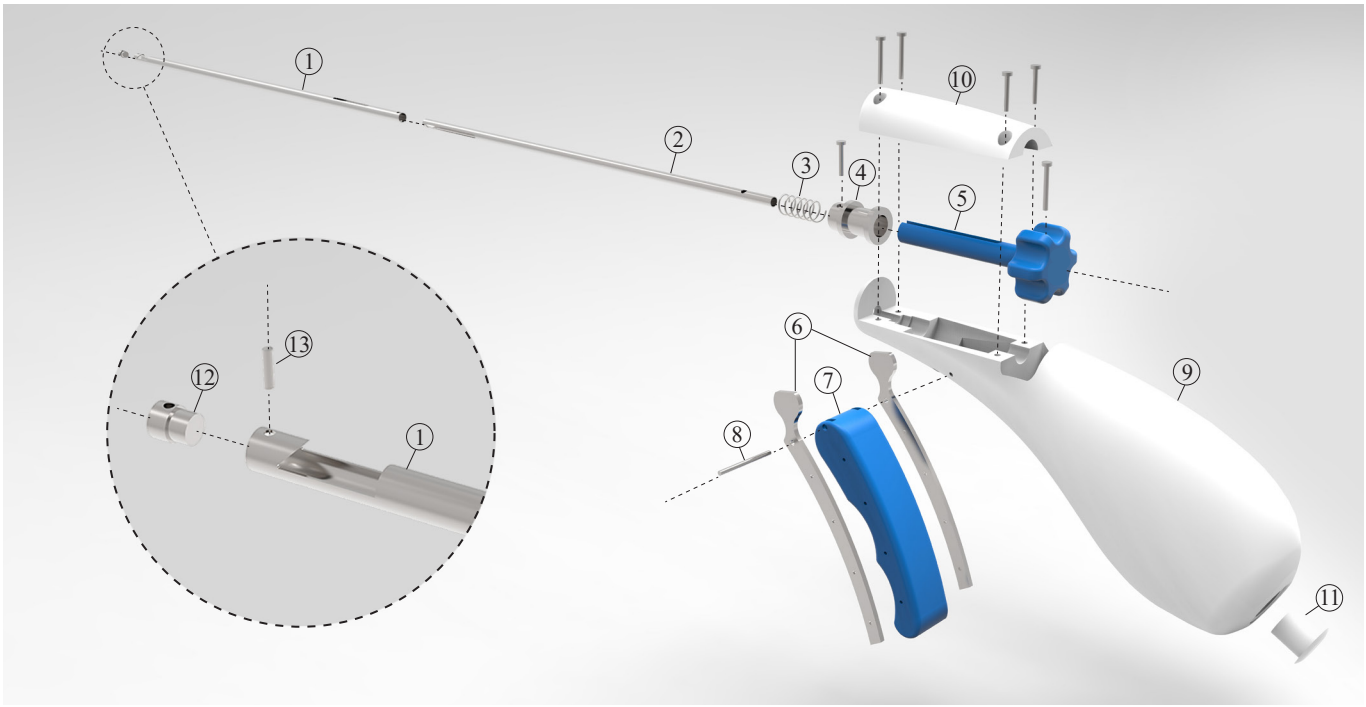


Fig. 37: Exploded view of final design including all components: (1) outer shaft, (2) inner shaft, (3) spring, (4) transmission ring, (5) rotation-knob, (6) rotation-translation pin, (7) lever, (8) rotation axis, (9) handle part, (10) handle cap, (11) proximal cap, (12) distal cap, (13) dowel pin.

translation-rotation pins and the lever are provided with a 1.5mm hole to allow for the insertion of a rotation axis, which is a standardized stainless steel tube. Since the intended manufacturing method of the handle part is 3D printing, the handle part is provided with an extruded hole at the proximal section, in order to reduce printing costs. The hole can be closed with the proximal cap. In appendix G the technical drawings of the parts can be found.

***Manufacturing and assembly***

Except the standardized spring, all parts required some type of manufacturing in order to create the desired part.

All manufactured parts are depicted in Fig. 38. The standardized M2 screws and the dowel pin were shortened to the correct length. The rotation axis was made from a standardized 1.5mm steel tube. The rotation-translation pins were laser cut from 1.5mm stainless steel sheet. Afterwards they were polished in order to remove burrs. The distal cap and the transmission ring were machined, by means of turning. Afterwards, both parts were drilled with a pillar drill in order to create the proper holes. Furthermore, in one of the created holes of the transmission ring, a thread was created using a threading tool in order to allow for the fixation of the transmission ring (M2) screw. The distal cap was manufactured from stainless steel, whereas the transmission ring was manufactured from bronze, due to its excellent frictional properties, which are desired since the translation-rotation pins are sliding into the transmission ring. The inner and outer shaft were manufactured by means of wire-cut electrical discharge machining (EDM) at DEMO, TU Delft. The handle part, handle cap, proximal cap, rotation-knob, and lever were 3D printed (selective laser sintering) from PA12 (Oceanz, Ede, the Netherlands), and vibro polished afterwards, resulting in smoothly finished parts. All parts have been manufactured twice, in order to create two identical prototypes. Fig. 38 shows all manufactured parts for one of the prototypes.

To assemble the functional prototype, a (partly) specific order of assembly was followed (Fig. 39). First the distal cap was placed into the outer shaft, and connected using the dowel pin (Fig. 39a). Secondly, the rotation-translation pins were placed into the 3D printed lever (Fig. 39b). Consequently, the rotation axis was placed through the handle part, the lever, and the translation-rotation pins, thereby connecting these parts. Eventually the rotation knob, the transmission ring and the spring were placed into the handle part such that the transmission ring and the rotation-translation pins were aligned properly (Fig. 39c). Hereafter the shafts were placed into the handle part by screwing the transmission ring screw (M2 screw) through the transmission ring and the inner shaft, and by screwing another M2 screw through the rotation knob and the outer shaft (Fig. 39d). Lastly, the handle cap was screwed onto the handle part, resulting in a finalized prototype (Fig. 39e).

The assembly time of the complete prototype is approximately 5 minutes. This includes all steps as described previously. Since most of these steps are only required to be performed once, the assembly and disassembly step of the shafts to the handle provide more information on the ease of assembling of the prototype in use. In order to remove the punched bone pieces from the inner shaft, both shafts have to be disassembled from the handle. This can be done by removing the handle cap, and by removal of the transmission ring screw and the rotation-

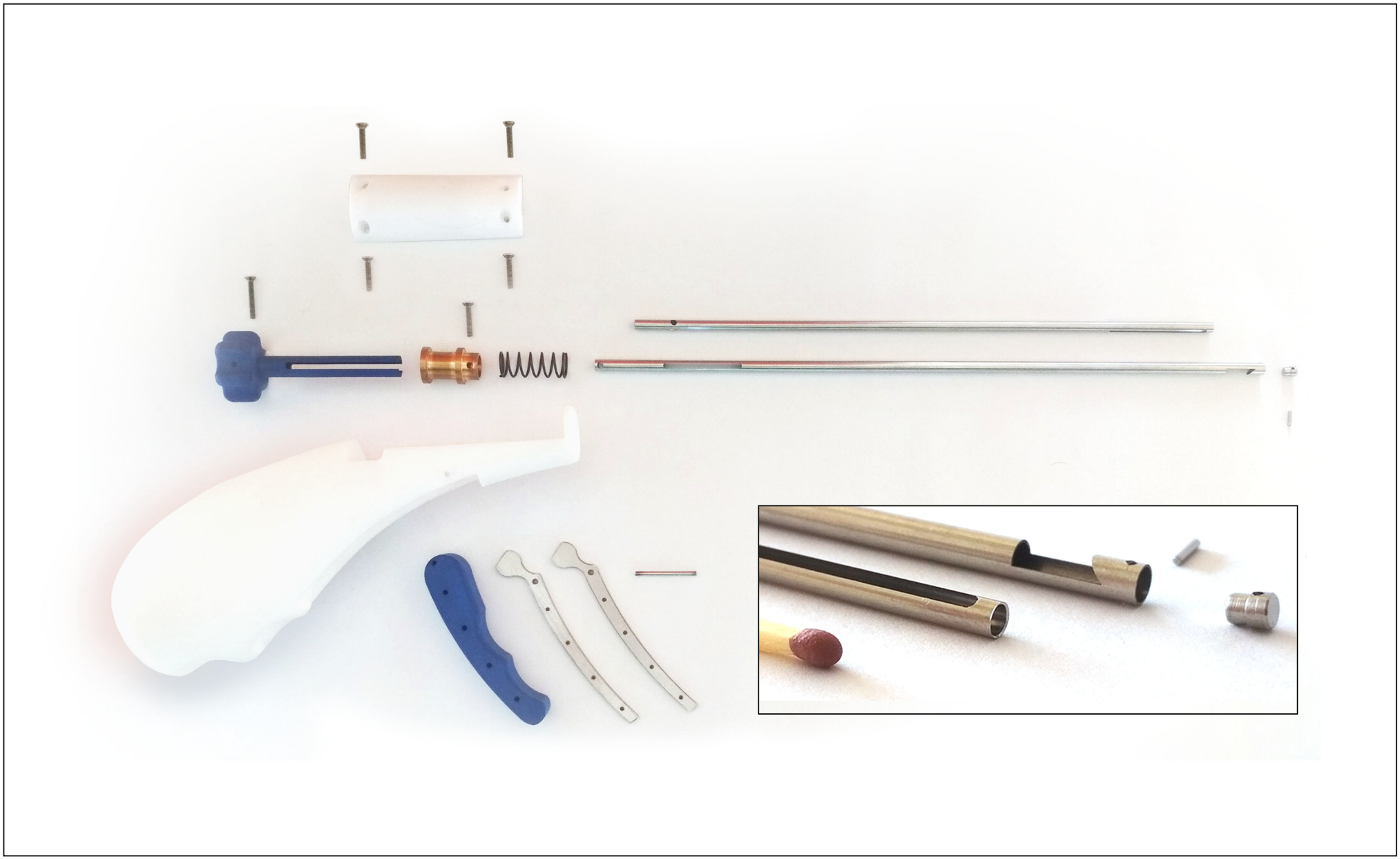

Fig. 38: All manufactured components, including close up of distal components. Match for scale.

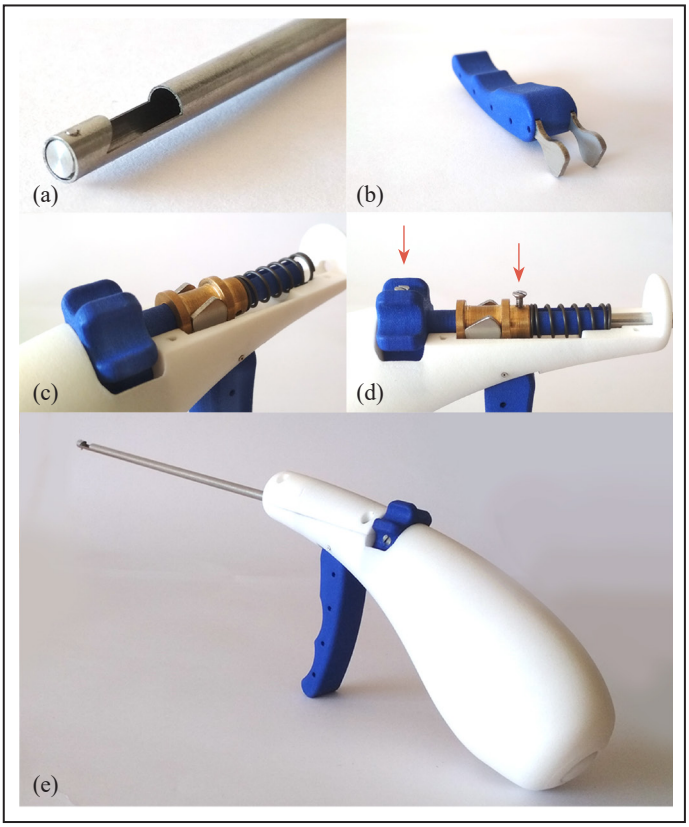


Fig. 39: Assembly steps of the prototype. (a) The distal section. (b) The lever and translation-rotation pins. (c) The translation-rotation mechanism placed in the handle. (d) The shafts connected to the translation-rotation mechanism by screws. (e) The completely assembled prototype.

knob screw. This takes approximately 60 seconds. In order to assemble the shafts to the handle again, the shafts have to be inserted into the handle, aligned to the holes of the transmission-ring and the rotation-knob, and fixed with both screws. Subsequently, the handle cap should be placed into the handle. The assembly of the shafts to the handle takes approximately 80 seconds. The difference in (dis)assembly-time can be explained by the time needed to align the holes in both shafts to the holes in the handle, prior to the screw fixations. Removal or placement of the handle cap takes approximately 30 seconds of this (dis) assembly-time. Since the handle cap does not contribute to the structural integrity of the handle, it could be helpful to replace this four-screw fixation by a snap-fit, in order to increase the ease of assembling.

# 7. Prototype testing

## 7.1 Evaluation steps

After manufacturing and assembling the prototype, the evaluation of the prototype was performed, which is described in this section. This evaluation can be subdivided in three evaluation steps. First, the technical feasibility of the rotational functionality and the translational functionality are evaluated. The goal of the second evaluation step is to determine whether the prototype is capable of actually cutting and storing pieces of material. The last evaluation step includes the evaluation of the usability aspects with a group of clinical experts. Below, these steps will be further described.

## 7.2 Test 1: Technical feasibility

The first step to evaluate the prototype was performed in order to demonstrate the technical feasibility of the prototype and to see whether the initially conceived mechanical working principles would perform as predicted. The first basic function the mechanical working principle should perform is the translational movement of the inner shaft relative to the outer shaft as a result of the force being exerted on the lever, resulting in the closure of the tip opening. The second basic function the mechanical working principle should perform is the rotational movement of the outer shaft and inner shaft as a result of the rotational force being exerted on the rotation knob of the instrument, allowing for aligning the tip properly to the material to be punched. Fig. 40 depicts the result of the (inward directed) force exerted on the lever in three steps: the lever completely open, the lever pushed inwards halfway, and the lever completely pushed inwards. As can be seen in the close-ups, the inner shaft moves distally as a result of the exerted force on the lever, thereby closing tip. Fig. 41 depicts the result of the rotational force exerted on the rotation knob by the thumb, thereby rotating the inner and outer shaft relative to the handle. The figure depicts three steps of the rotational motion, thereby depicting the maximal rotational movement of the shafts which can be made at a time. Accordingly, in each rotation step made by the thumb, the inner and outer shaft can rotate 180 degrees. Both pictures only depict a three step motion of the translational and rotational movement respectively, although the translational and rotational movements actually go continuously and smoothly.

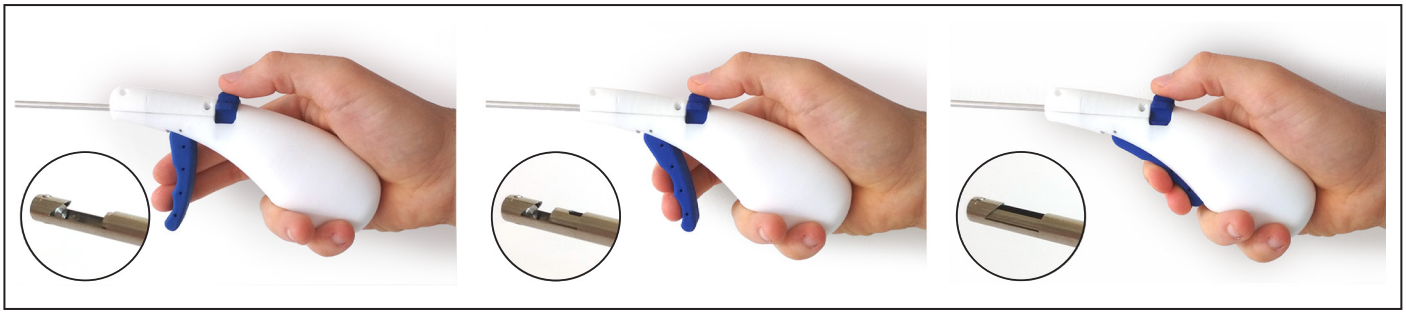

Fig. 40: Translational motion of the inner shaft relative to the outer shaft as a result of the exerted force on the lever in an inward direction.

Fig. 41: Rotational movement of the outer and inner shafts relative to the handle as a result of the exerted rotational force on the rotation knob.

### 7.3 Test 2: Cutting and storing ability

***Introduction***

The second evaluation step was performed to assess the cutting and storing capability of the prototype. In Section 4.10 it was demonstrated that a force of approximately 92N is required to cut a 1mm thick piece of cortical bone with the prototype. A finite element analysis (FEA) was performed (Solidworks, premium edition, 2018) in order to measure whether the prototype, with the currently used materials, was able to withstand these force. The result was that the forces needed to cut these bone pieces would lead to an undesired plastic deformation of the outer shaft. The results of this FEA are further elaborated in the discussion section.

***Material and methods***

The goal was to determine the characteristics of the cutting and storing mechanism. As previously explained, the prototype will not be able to cut complete pieces of bone due to several dimensional constraints and the material of the shafts. However, in order to evaluate the potential of cutting and storing complete pieces of bone, different samples were tested in order to get a proper indication of its cutting and storing characteristics, which will be described next.

***Material I: Modified pieces of chicken femur***

Several pieces of chicken (femur) bone were prepared (cooked at 100°C for 60 minutes and cut through the half for bone marrow removal), leaving clean pieces of cortical chicken bone with an approximate thickness of 1mm (Fig. 42). These pieces were modified and partly pre-cut such that the area of cutting of a proper piece of bone was minimized. In this way, the required force to cut the piece of bone was drastically decreased, thereby allowing to evaluate the storing capability of actual pieces of cortical bone.

***Material II: Pink Obomodulan© board pieces***

The second sample material which was used are pieces of pink Obomodulan© board, which is high density polyurethane (PU) foam, having a density of approx. 300kg/m³ [53]. Although the mechanical properties of this material are remarkably lower than the mechanical properties of cortical bone, this material is being extensively applied as a sample material for mimicking cancellous bone [54]. Due to its rigidity and low mechanical properties, this material could be easily shaped to the proper sample pieces (thickness approximately 1mm), and the prototype would not plastically deform when complete pieces of this sample material would be punched. Fig. 43 depicts these sample pieces.

***Methods***

After preparing the sample pieces, the cutting and storing characteristics of the NeuroPunch were examined. In order to examine these characteristics, first the characteristics of the cutting and storing functionality were defined. The following five steps were defined as the main functional characteristics of the punching and storing capability:

- **1 - Clamping**: The shafts of the prototype clamp the sample pieces without undesired movements of the sample pieces (e.g. in a controlled manner).
- **2 - Cutting**: The prototype cuts completely through the sample pieces in one complete lever movement.
- **3 - Pushing inside**: The punched sample pieces are pushed into the inner shaft.
- **4 - Remaining**: The punched sample pieces remain in

Fig. 42: Chicken femur cortical bone sample pieces.

Fig. 43: Pink Obomodulan© board sample pieces.

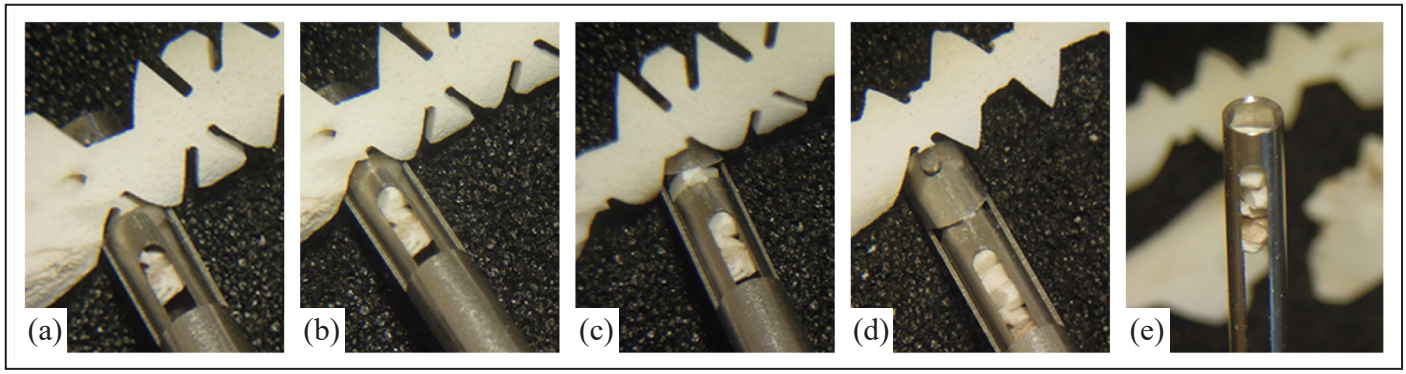

Fig. 44: Cutting and storing steps using cortical chicken femur as sample material (microscopic view).

the inner shaft when the inner shaft is retracted or kept completely vertical.

- **5 - Repeating**: The abovementioned steps can be repeated 5 times.

Both sample materials were used to test the NeuroPunch on the abovementioned functional characteristics. Fig. 44 and Fig. 45 depict the cutting steps of bone and Obomodulan©, respectively, of which the results will be described next.

***Results***

The prototype of the NeuroPunch was able to complete the five tasks as described as the functional characteristics of the punching and storing capability, for both the cortical (femur) bone, as for the high density PU. In Table 5, these results are summarized.

***Discussion***

As described previously, the prototype of the NeuroPunch is not able to punch complete pieces of bone due to several dimensional constraints (stress concentrations and shaft thickness) and the material of the prototyped shafts (stainless steel 304). Therefore it was decided to 'pre-cut' the cortical (femur) bone pieces, prior to the cutting action of the prototype on the material. As a result, all pieces could be easily cut by the NeuroPunch, thereby allowing the NeuroPunch to be tested on the remaining functional characteristics of the punching and storing capability. As summarized in Table 5, all other functionalities were completed for both materials. Although these results do not yet demonstrate the complete functionality of the NeuroPunch, these test results definitely demonstrate the potential of cutting and storing complete pieces of bone from the operational area during endonasal pituitary surgery. Despite these satisfactory results, attention should be paid to the importance of several iterative design aspects in order to test all the functional characteristics of the NeuroPunch in a real surgical environment, which will be discussed in the discussion section of this report.

***Postliminary analysis***

After performing the experiment, a postliminary analysis was performed in order to thoroughly inspect the details of the tip of the NeuroPunch. First of all it was tested how long the NeuroPunch was able to continue with cutting the sample pieces (only for Obomodulan©). It was observed that as long as the extruded section of the inner part (storage section) was not completely full, the pieces of material could be easily pushed into the inner shaft. However, immediately after the sample pieces filled the extruded part of the inner shaft over its complete length, a drastic increase of friction was felt thereby obstructing the next pieces from being pushed inside.

Table 5: results of the cutting and storing ability test

| Task | Cortical bone | Obomodulan |
|---|---|---|
| **1. Clamp** | Yes | Yes |
| **2. Cut** | N/A | Yes |
| **3. Push inside** | Yes | Yes |
| **4. Remain** | Yes | Yes |
| **5. Repeat** | Yes | Yes |

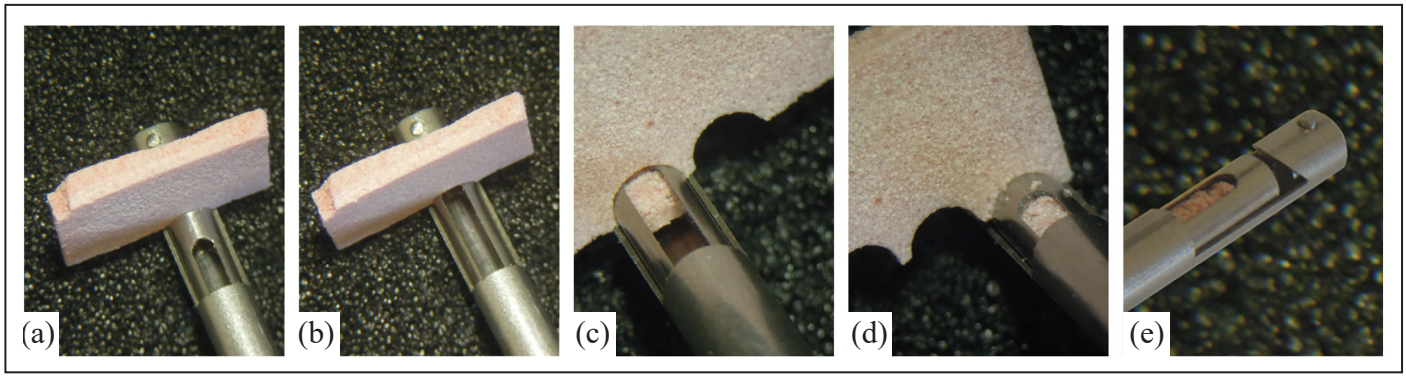

Fig. 45: Cutting and storing steps using Obomodulan© board as sample material (microscopic view).

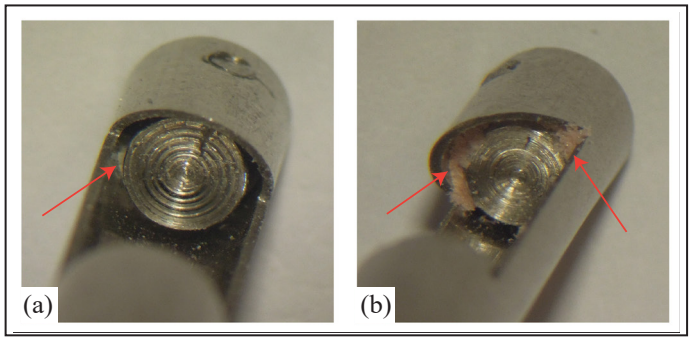

Fig. 46: Postliminary (microscopic) view of the distal end of the NeuroPunch after cutting bone (a) and Obomodulan© (b). The arrows indicate remaining sample material.

Furthermore, the distal end was inspected under microscopic vision. It was observed that the area between the outer shaft and the distal cap, at the distal end of the instrument, was (partly) filled with small particles of sample material, especially for the Obomodulan© samples. This is depicted in Fig. 46 for both materials. Although this could be explained by the tendency of the material to 'crumble' fast, it is highly recommended to test this 'crumbling behavior' on real cortical bone in a real surgical environment (e.g. cadaver test in skill-lab) in order to examine whether this could cause any difficulties during surgery.

### 7.4 Test 3: Expert evaluation on a human phantom model

***Goal of the test***

The third test was performed to evaluate the prototype on the basis of the problem definition as defined in Section 1.4. As defined there, the problem is twofold: the currently available bone punches do not allow for easy alignment of the tip to the bone and require the instrument to be extracted from the operational area after each cut. The goal of this test was to determine whether the newly designed prototype would potentially be a proper alternative for the currently available punches, thereby solving the problems as described above.

***Material and methods***

In order to recreate the anatomy in which the surgery would be performed, a test facility was created which would allow for testing of the prototype (Fig. 47). This test facility consisted of several main components, including a mock-up endoscope (Fig. 47a), a screen displaying the endoscopic view and a phantom nose model including a cylindrical hole underneath to which three sample pieces were attached circumferentially, angled at 120 degrees relatively (Fig. 47b). The test took place at the University Medical Center Groningen in which four clinical experts were involved (two neurosurgeons and two ENT surgeons, all male, all right handed). The participants were asked to fulfill the following tasks:

1. Insert the NeuroPunch into the nose and navigate the tip downwards.
2. Navigate and align the tip of the instrument properly to the first sample piece, prior to making a cut.
3. Cut a piece of material.
4. If necessary, remove the sample piece from the tip of the instrument, and cut a second piece of material.
5. Navigate and align the tip of the instrument properly to the second sample site, prior to making a cut.
6. Cut a piece of material from the second sample.
7. If necessary, remove the sample piece from the tip of the instrument, and cut a new piece of material.
8. Navigate and align the tip of the instrument properly to the third sample piece, prior to making a cut.
9. Cut a piece of material from the third sample.
10. Extract the instrument from the nose.

This set of tasks was aimed to be performed for two instruments: the Kerrison punch, currently often used during endonasal pituitary surgery, and the NeuroPunch (Fig. 48). Afterwards the participants were asked to rate both instruments to the following statements, on a Likert-Scale (1 – totally disagree, 7 – totally agree):

- **Positioning**: I can easily position and align the tip of the instrument to the (bony) structures before cutting.
- **Interactions**: I do not experience any undesired hand positions and/or undesired interactions with the endoscope during punching.
- **In & out**: I can punch (bone) structures without often introducing and extracting the instrument from the nose.
- **Phantom**: The phantom model is a good representation of the reality.

Based on the opinion of the surgeons on each of the statements, questions were asked to get a deeper understanding of the reason behind their level of agreement to the statements. Furthermore, open questions were asked regarding improvements to the NeuroPunch, the potential reusability or disposability of the NeuroPunch, and the next steps towards preclinical testing of the NeuroPunch.

***Findings and results***

All clinical experts indicated that they could more easily align the tip of the NeuroPunch than when using the Kerrison punch. Furthermore they all preferred the NeuroPunch over the Kerrison punch regarding the minimization of undesired interactions with the endoscope. Also, they all indicated that the NeuroPunch was preferred over the Kerrison punch regarding the amount of introductions and extractions of the instrument from the nose. Lastly, all surgeons indicated that the setting with the human phantom model was a good representation of a real surgical setting. Table 6 shows the average scores of the test for both instruments on each of the four statements. In Appendix A, all results can be found.

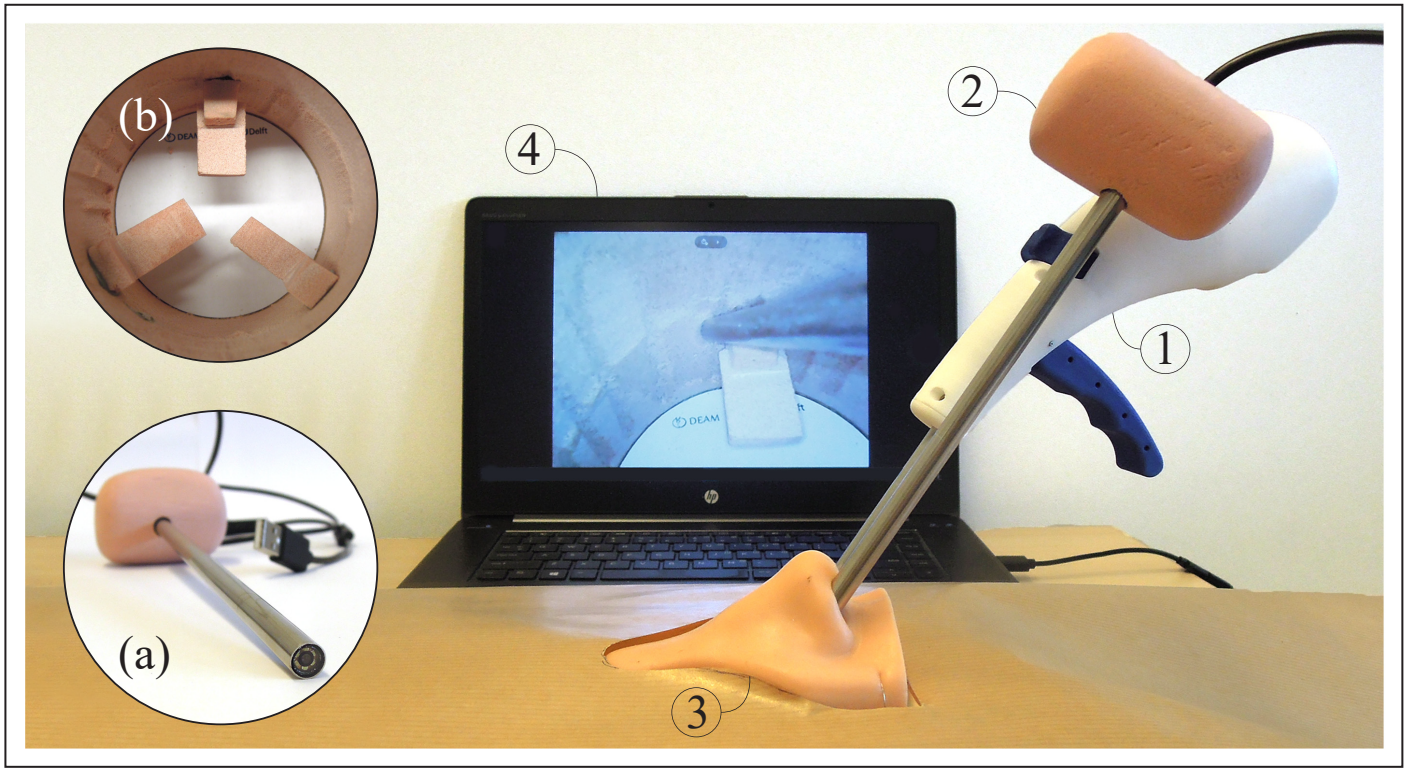


Fig. 47: test set-up with the phantom model and the NeuroPunch (1). Close-up (a) depicts the mock-up endoscope (2) visible on a laptop screen (4) and close-up (b) depicts the view of the interior of the model, located below the phantom nose (3).

Besides the statements which were judged by the surgeons, open questions were asked to receive more qualitative input on several aspects of the design of the NeuroPunch. Below, the most important results of this discussion are listed.

- All surgeons highly recommended to test the NeuroPunch, when manufactured to be able to cut cortical bone pieces, in a real surgical environment (e.g. skill-lab).


Fig. 48: Three participants testing the NeuroPunch. Close-up (a) depicts the hand positioning when using the NeuroPunch, in which the interaction between the endoscope and NeuroPunch is clearly visible.

- The sharp edge of the outer shaft could provide a risk of damaging healthy surrounding tissue. This should be altered towards a more atraumatic distal section.
- The distal section of the outer shaft should be as small as possible, and if possible, further minimized in order to allow the distal end to be used as an atraumatic 'manipulator' as well, thereby able to manipulate soft tissue.
- The width of the proximal section of the handle could be reduced in order to minimize 'sword fighting'. Fig. 48a depicts the area of handling the NeuroPunch when holding the handle. In case even more instruments will be introduced, this area was preferred to be further reduced, by a reduction of the width of the handle.
- Some clinical experts stated that the mock-up endoscope, which has an outer diameter of 7mm, led to a worse representation of the real surgical environment instead of when using a real endoscope.

The results of the test with the group of clinical experts indicate that the NeuroPunch shows much potential and

Table 6: average results of the clinical experts' opinion on each of the statements based on a Likert-schale (1 = totally disagree, 7 = completely agree). * Gives the same value for both instruments because the statement is unrelated to instrument characteristics

| | **Kerrison** | **NeuroPunch** |
|---|---|---|
| **Positioning** | 4.5 | 6.75 |
| **Interactions** | 5.5 | 6 |
| **In & out** | 3.5 | 6.5 |
| **Phantom*** | 5 | 5 |

might be a proper replacement for the currently used punches in endonasal pituitary surgery. However, the clinical experts underscored the importance of testing the NeuroPunch in a real surgical setting (e.g. a cadaver test in a skill-lab). Furthermore, several iterative steps (e.g. the shaft material and tip shape) should be taken in order to measure its actual potential, which will be discussed in the discussion section of this report.

# 8. Discussion

### 8.1 The NeuroPunch

Throughout the course of this study, it was researched whether the design and development of the NeuroPunch into a functional prototype was technically feasible, and whether the NeuroPunch could potentially be a proper replacement for the currently used bone punches in endonasal pituitary surgery. The problem described in the introduction section of this report is twofold: the currently available bone punches do not allow for easy alignment of the tip to the bone and require the instrument to be extracted from the operational area after each cut. Based on the intended user scenario and the meetings with clinical experts, the design requirements were described. Subsequently, conceptual solutions were found for different parts of the NeuroPunch, leading to the development of a functional prototype. In this discussion section, the conformity of the NeuroPunch to the design requirements will be discussed. Based on the conformity to the design requirements, several iterative design aspects will be discussed. Lastly, a speculative (future) viewpoint on the further steps towards a commercially available NeuroPunch will be provided.

### 8.2 Conformity to design requirements

The table provided in Appendix B shows a complete list of the design (sub-) requirements which are generated based on discussions with clinical experts throughout the course of this study and on the intended user scenario of the NeuroPunch. Furthermore, the acceptance criteria for each of the requirements are described, which are then rewritten towards concrete product specifications. The second-last column indicates whether the conformity of the current prototype of the NeuroPunch can be demonstrated to each of these design requirements (green), or not (yet) (red). As can be seen, two requirements are red:

- The instrument must be able to cut through a cortical bone layer the anatomical area.
- The distal end of the tip should be small as possible and atraumatic.

The first requirement to which the current prototype of the NeuroPunch does not (yet) demonstrate conformity emerged during the manufacturing phase of the prototype. The directly available stainless steel (304) tubes were used in order to reduce manufacturing time and costs. However, this material is a relatively weak stainless steel (regarding its yield strength) compared to other stainless steels which are often applied in surgical instruments.

The second requirement to which the current prototype of the NeuroPunch does not yet demonstrate conformity was noticed and discussed during the evaluation session of the functional prototype of the NeuroPunch with the group of clinical experts. As described in Section 7.3 it was indicated that the direction of the shearing angle might potentially result in an increased risk of damaging healthy surrounding (soft) tissue when extracting the instrument from the operational area. Furthermore, it was indicated that the length of the distal section of the NeuroPunch preferably would be decreased, in order to increase the reach of the tip, especially when punching the sellar floor (Fig. 8).

In the next sessions, several iterative design aspects regarding the abovementioned design requirements will be discussed. Considering the remaining design requirements, it can be concluded that based on the results of the different validation sessions, the currently produced prototype of the NeuroPunch fulfills them, thereby showing it to be of high potential for the future of surgical punching during endonasal pituitary surgeries.

### 8.3 Iterative design aspects and validation

***Cutting bone***

Based on this study, the further development of the NeuroPunch for the use during endonasal pituitary surgeries is a feasible next step. However, in order to evaluate its potential in clinical practice, several iterative design aspects should be reconsidered, which will be discussed below.

As previously described, the structural integrity of the shafts of the current prototype are insufficient in order to cut the required bone layer, e.g. to be able to withstand sufficient load. In Section 4.10 it was calculated that the required force to punch a piece of bone would be 92N. Fig. 49a shows the results of a Final Element Analysis (FEA) with the currently used outer shaft (stainless steel 304). As depicted, stress concentrations can be noticed in the sharp corners of the shaft, and the Von Mises stress exceeds the yield stress of the material. Thereby it can be concluded that a plastic deformation would occur. Fig. 49b shows the results when using a material with enhanced mechanical properties, stainless steel 420, which is often used in other surgical applications. Besides the different material, several design alternations have been made in order to increase the structural integrity: sharp corners are rounded in order to reduce stress concentrations and the thickness is increased by 0,1mm. As can be seen, plastic deformation will not occur when cutting cortical bone pieces of 1mm, thereby exerting a force of approximately 92N on the distal end of the outer shaft, even when the force is increased by a (safety) percentage of 40%.

***Atraumatic and reduced distal cap***

As previously described, the second iterative aspect to reconsider is the distal end of the NeuroPunch. It was indicated that the distal end of the NeuroPunch was preferred to be smaller in order to increase the reach of the punch. Furthermore it was indicated that the direction of the shearing angle could potentially result in an increased risk of damaging healthy tissue when retracting the instrument from the nose, due to the sharp edge as depicted in Fig. 49a. Based on the feedback sessions with the clinical experts, it was found that the capability of manipulating soft tissue with the tip of the instrument could be a valuable addition (Section 7.4). Based on this feedback, solutions were found in order to propose several iterative design aspects which could be a potential solution. Fig. 50 shows a first illustration of a possible solution for the 'atraumatic' distal section of the NeuroPunch. Furthermore, the solution is dimensioned such that when using the proposed material (stainless steel 420), the forces exerted on the distal end of the instrument would not result in undesired plastic deformations. It should be noted that this possible solution is a first draft in which manufacturability is not yet taken into account.

***Amount of bone pieces***

Considering the extruded section of the inner shaft, which allows for the 'frictionless' storing of pieces of bone, the length of the cutout section of the inner shaft of the current prototype is 30mm, thereby assuming that approximately 30 pieces of bone will be cut throughout the surgery. During the testing sessions of the prototype, it was noticed that when the cutout section was full, much more force was required in order to push each punched piece into the inner shaft. Since the clinical experts indicated that the amount of punched pieces can very much between different patients (approximately 20 to 50 cuts per operation), further research is required to find the optimal length of the cutout section of the inner shaft.

***Evaluation in a real surgical environment***

In the upcoming months, the NeuroPunch will be further developed in collaboration with the group of clinical expert of the UMCG and with DEAM. Based on the next iteration, a new prototype will be manufactured in which these iterative design aspects will be fully integrated, thereby allowing the NeuroPunch to cut bone and to evaluate the remaining design requirements. As described in Section 7.3, all clinical experts specifically indicated the importance of testing the NeuroPunch in a real surgical environment (e.g. skill-lab), similar to the setting as described in Section 3.7. Therefore, it was decided that in the beginning of 2019, the new prototype will be evaluated by clinical experts in a skill-lab. During this test, the newly prototyped NeuroPunch will be evaluated based on the set of design requirements, focusing on the ability to cut and store bone, and on the atraumatic distal end of the NeuroPunch. Furthermore, the NeuroPunch will be added to the product portfolio of DEAM. Based on the results of the test in the skill-lab, steps towards the commercialization of the NeuroPunch will be reconsidered.

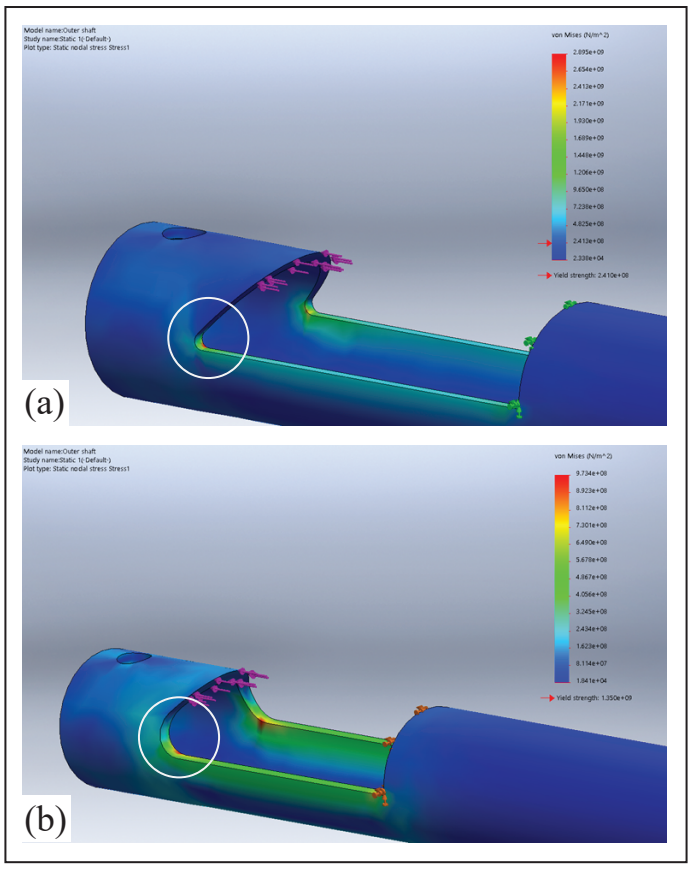


Fig. 49: FEA analysis on the current prototype (a) and the prototype of the NeuroPunch based on a next iteration (b)

## 8.4 Future design considerations

***Reusable vs disposable***

Besides the iterative parts mentioned above, one of the first future design considerations is whether the product will be reusable or disposable, which has not been taken into account during this project. However, this is an important aspect to reconsider in the early phases of the design process, since the consideration whether to reprocess the NeuroPunch fairly influences several design aspects. The choice whether to design the NeuroPunch to be a reusable or disposable device mainly depends on the cost-effectiveness of the device. Different studies suggest that reusable medical devices provide economic and environmental advantages over disposable devices [55]-

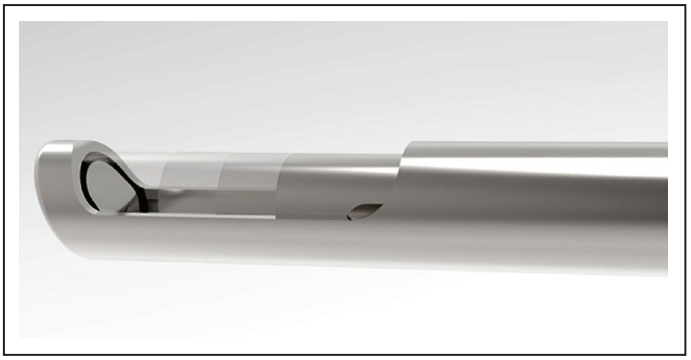

Fig. 50: Possible solution for an atraumatic distal end of the NeuroPunch.

[57]. However, additional aspects such as quality of the device, safety, sterility, ease of use and ease of assembly are important aspects to reconsider during this process. According to the design guidelines provided by the FDA regarding the design for reusables, shaft-within-lumen configurations, fine channels and articulating surfaces present particular difficulties to be cleaned [58,59]. During several tests with the NeuroPunch, it was noticed that the removal of the punched pieces from the inner shaft was challenging and potentially could damage the inner shaft when forcefully pushing the pieces outwards. Furthermore, considering the proposed next iteration as depicted in Fig. 50, the outer shaft consists of either one part including a fine channel for the introduction of the inner shaft, or consists of a distal cap, dowel pin and shaft (similarly configured as the current prototype), which result in several assembly challenges. In accordance with these design configurations, it is suggested to make the shaft configuration of the NeuroPunch disposable. Regarding the proximal section of the NeuroPunch, which does not necessarily have to be in direct contact with the patient if the shafts are properly designed, it is suggested to make this section reusable. The connection between the handle cap and the handle part, which are fixed by four screws in the current prototype, can be replaced by a snap-fit thereby increasing the ease of assembling. Furthermore, the connection between the shafts and the handle, currently made by two screws, might also be replaced by a snap-fit mechanism allowing for a screw free assembly of the device, by simply clicking the shafts onto the handle part of the NeuroPunch. Lastly, the current handle design of the prototype is primarily dedicated to a production method such as 3D printing. Although this method is still very suitable for the next iterations of the prototype, future (large batch-size) manufacturing methods should be considered as well, in which its specific design guidelines should be taken into account (e.g. wall thicknesses, draft angles and sharp corners when injection molding). Although many more design aspects of the NeuroPunch have to be reconsidered in order to properly implement the proposed approach, the abovementioned suggestions show potential to increase the quality, usability and safety in the future development of the NeuroPunch.

***Other applications for the NeuroPunch***

Although the NeuroPunch is explicitly designed and dedicated to be used during endonasal pituitary surgery, other applications for the NeuroPunch could additionally be described. First of all, due to the relatively simple mechanisms used in the design of the NeuroPunch, downscaling of the shafts to a 3mm or 2mm version would be technically feasible, thereby providing the ability to produce different models of the NeuroPunch which can be used throughout endonasal pituitary surgery. Furthermore, the potential to downscale the shafts of the instrument also allows for the NeuroPunch to be used in operations in which even better reachability is required, such as for pediatric or some veterinary surgery. Besides the usability of the NeuroPunch in the pituitary area, surgeries at other body sites in which bony or cartilaginous tissue has to be removed could potentially be a proper application for the use of the NeuroPunch as well, such as spinal surgery, cranial surgery or several orthopedic surgeries.

## 9. Conclusion

This study describes the design and development of a novel surgical punch to be used during endonasal pituitary surgery called NeuroPunch. The goal of the study was to design and develop a surgical punch of which the tip is able to be rotated independent from the handle orientation, thereby allowing to align the tip properly to the bone to be punched. Furthermore, the NeuroPunch is intended to be able to make multiple subsequent punching steps without the need for the extraction of the instrument from the operational area. Throughout the course of this study, a systematic approach was followed leading to several conceptual solutions for different functional parts of the NeuroPunch. By combining these conceptual solutions, a final design was proposed including an ergonomic handle, a mechanism for the storage of punched bone pieces, and a mechanism for rotating the tip relative to the handle orientation. Next, the NeuroPunch was manufactured towards a functional 1:1 scale prototype. The evaluation shows positive results indicating that the NeuroPunch might be a proper replacement for the currently used punches in endonasal pituitary surgery. Several iterative steps are required to produce a fully functional prototype of the NeuroPunch. However, the NeuroPunch shows much potential to be used for other surgeries as well, and it is demonstrated that the NeuroPunch will enable a safer and more comfortable endonasal pituitary surgery while potentially reducing operating time.

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## Appendix A – User input sessions

This appendix describes and summarizes the wordings and discussions of meetings with the target group for the development of the NeuroPunch, which were performed throughout the course of this study.

**User input session 1 – May 2018**
***Location: UMCG, OR neurosurgery***
An endoscopic endonasal pituitary surgery was visited to obtain a proper idea on the use of the neurosurgical instruments in endonasal surgery (Fig. 6, Section 1). Questions on the use were asked during and after the procedure.

Remarks:

- The user uses many different neurological instruments during endonasal pituitary surgery.
- When using them, the endoscope is always inserted.
- The suction tube is often used in order to remove fluids, but the suction tube is also used to manipulate tissue.
- The punch is used in order to cut bone. When rotating the instrument around its longitudinal axis, the handle often collides with the handle of the suction tube and the endoscope (Figure below).
- The neurosurgeon indicates that this is undesired.

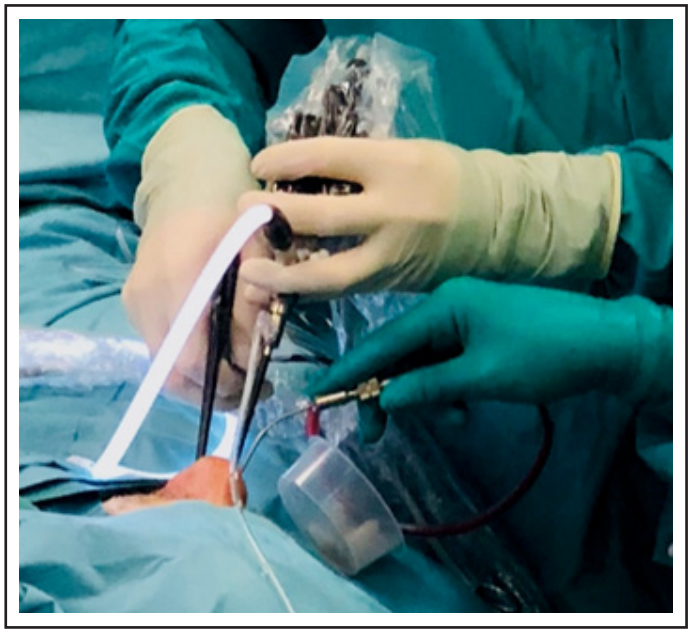
**User input session 2 and 3 – June 2018**
***Location: UMCG meeting room neurosurgery***
Two discussion sessions were conducted. The first session was with Dr. T. van der Laan (ENT) and the second session with a group of neurosurgeons and ENT-surgeons. The goal was to discuss the user requirements for the novel neurosurgical device. Questions on the current use were asked in order to get a deeper insight into the problems encountered during the current usage of punches. Furthermore, user requirements were discussed.

During the session, three main subjects were discussed:

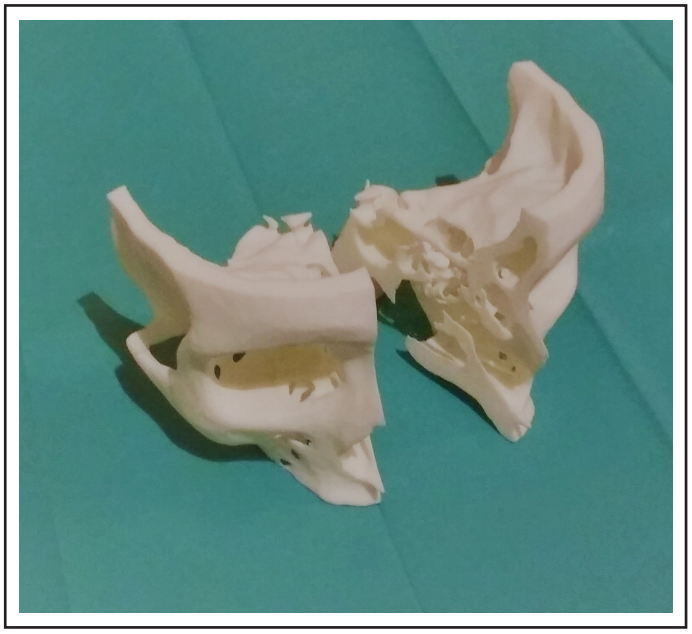
1. The general anatomy of the nasal cavity focusing on the sites which are mostly removed by a punch.
2. General important aspects during punching
3. Disadvantages in current use

A 3D printed model of the nasal cavity was shown (Figure below) and questions regarding the anatomy were asked. The outcomes are described below.

- The 3D model is a good representation of the human nasal cavity. However, the thin structures in the nasal cavity aren't visible in this model.
- The punch is used in the nasal cavity during endonasal pituitary surgery. Among others, the frontal wall of the sinus sphenoidalis (sphenoid sinus) is punched very often, and here 'quite thick' pieces of bone are being punched. One of the parts which are not directly removed by a punch is the rostrum, since it is too thick. Therefore, the rostrum is first being drilled.
- The natural osteum is being removed with a punch as well. After removing the natural osteum, you reach the upper wall of the sella. This is punched towards the sellar floor.
- In the frontal regions of the nasal cavity, the walls are mostly pushed away, instead of punching, since this is mostly softer tissue (cartilage).
- The thickness of the punchable bone pieces are approx. 1mm. This goes for: sellar floor, etmoid pieces, sinus sphenoidalus frontal wall.
- The punch is mostly used because of its safety: by 'sliding' or 'hooking' the distal part of the instrument under the 'to be punched structure', you are in complete control of the punch which is taken. Furthermore, the tissue behind this punch is totally safe for any damage. This is in contrast with dissectors or graspers, which do not allow for this way of controlling the instrument.



Use of a punch during endonasal pituitary surgery.



3D printed model of human skull and nasal cavity.

- A punch is meant to cut and not to pull. Surgeons have been trained to take two bites, in order to be sure that the complete cut is made. If not, you have a possibility of pulling off a bigger piece of bone, which can include delicate structures. Sometimes the surgeons indeed pull instead of cut, because it takes a very long time to take every small bite twice. This only happens when the punch is not in delicate areas.
- When opening the sellar floor, a drill is used to drill the sellar floor until it has the thickness of an egg shell, prior to the punching step. This is done because the surgeon must be able to see the tip of the punch when it is located under the sellar floor. It is too dangerous to punch without being sure that the punch is on the correct place.
- In case the punched bone structures are released into the nasal cavity while punching, this would not lead to problems: the nasal cavity it completely cleaned after the surgery. Bone pieces aren't reused.
- Currently the 2mm Kerrison punch is mostly used. The extremely thick structures can't be removed by this punch, so have to be primarily drilled.
- An importance difference can be seen in the usage of a punch by a neurosurgeon, or by an ENT surgeon: the neurosurgeon most often has two hands to use the punch, so there is sufficient space for a suction tube, whereas the ENT-surgeon only uses one hand, since the ENT-surgeon has to hold the endoscope.
- Advantage of a bigger tip is that bigger punch pieces can be taken. This saves time.
- The amount of punches per operation can vary a lot. This goes from 20 punches to 50, depending on many factors: anatomy, type of surgery (extended or not), etcetera. Dr. R. Vergeer estimated the amount of punches on 30.

*Disadvantages in current use:*

- When a piece of bone is punched, it has to be removed in order to 'clear' the tip of the punch. After making a punch, a second punch cannot be made before it is cleaned. Sometimes the punch is cleaned while being in the nasal cavity, with the use of the suction tube.
- When the punch has to be rotated, the scope is blocking the punch. In general, the 'performing' instrument is always aligned under the scope. However, when the punch has to be rotated, the scope sometimes has to be rotated or re-located as well. This can lead to the fact that the vision of the scope is blocked by blood or mucous membrane. The result is that the surgeon is not able to see and only can feel where he is punching.
- When the punch is inserted through the left corridor, it punches at the right section of the nasal cavity. When the punch is inserted through the right corridor, in order to punch at the left section of the nasal cavity, the camera can block access. The camera is not small, and consists of a big handle which is hard to hold.
- When punching structures nearby 'bloody tumors', often a bleeding occurs, leading to a reduced visibility by the endoscope. When this bleeding occurs, the punch has to be removed, and the suction tube has to remove the blood. This takes time and can be annoying for the surgeon. Later on in the procedure, when there is sufficient space, the four-handed technique allows for the insertion of the suction tube. When multiple instruments are inserted when there isn't sufficient space, sword fighting occurs.

This session allowed us to discuss the procedure and use of the punch during endonasal pituitary surgery. It gave insight in many aspects of the surgery, and leaded to several concrete design requirements, which are listed below:

- The punch must be able to be controlled with a single hand.
- The punch must be able to be rotated around its longitudinal axis independent from the handle orientation.
- The punch must be able to cut through a bone layer of 1mm.
- The punch must be able to ake multiple cuts when inserted.
- The punch must be very sharp, in order to cut the bony tissue. This is also directly related to the forces needed to punch the tissue: the sharper, the less force is needed to cut.

It must be noted that the rotational function of the punch is of primary importance, regarding to Dr. J. Kuijlen. However, multiple functional improvements in the device would be useful as well, as long as possible.

**User input session 4 – July 2018**

***Location: UMCG skills-lab***

A discussion and test-session was conducted with two experienced ENT surgeons. Three prototyped handle designs were tested in a body (cadaver) and evaluated and discussed by the surgeons.

During the session, three prototyped handle designs were evaluated (Fig. 20, Section 3). The handle designs were 3D printed from the same material, and all consisted of a shaft with a diameter of 4mm. The handles were non-functioning instruments, but all control elements could be manipulated: rotation-knob could rotate and levers could be squeezed.

The surgeons were asked to hold, manipulate the control elements and insert the handles into the body. Furthermore, they were asked to squeeze the levers, and to rotate the rotation knob. They were allowed to think-aloud, to ask questions and to share their opinion on each of the individual handles, on specific elements of each of the handles, and on the interaction with the scope.

Based on the discussions and observations during the session, the following conclusion can be made:

- Both experts indicated that the overall preference has the semi-axial pistol handle. Both surgeons indicated that this is mostly due to the stability when manipulating the control elements and when holding the instrument. In this type of handling, the stability mostly comes from the fact that the thumb and index finger are 'free' when holding the instrument. This means that the thumb and index finger, at any time, have the ability to manipulate a control element, without losing stability.
- Both surgeons indicated that all concepts can be manipulated with a single hand, and that all instruments are sufficiently robust. Thumb rotation-wheel handling is preferred by both surgeons, over manipulating the rotation wheel with the index finger (fore finger). Lastly, both surgeons indicated that an angled shaft would be a 'nice to have', since this allows them for easier positioning of the instrument in the nasal cavity.

**User input session 5 – October 2018**
***Location: UMCG, meeting room neurosurgery***
A user test was conducted with four experienced clinical experts (two neurosurgeons, two ENT surgeons). The first functional prototype of the NeuroPunch was tested in a phantom model and evaluated and discussed by the surgeons (Fig. 47 and 48, Section 7).

The surgeons were asked to fulfill the following tasks:

1. Insert the NeuroPunch into the nose and navigate the tip downwards.
2. Navigate and align the tip of the instrument properly to the first sample piece, prior to making a cut.
3. Cut a piece of material.
4. If necessary, clean the tip of the instrument, and cut a second piece of material.
5. Navigate and align the tip of the instrument properly to the second sample site, prior to making a cut.
6. Cut a piece of material from the second sample.
7. If necessary, clean the tip of the instrument, and cut a new piece of material.
8. Navigate and align the tip of the instrument properly to the third sample piece, prior to making a cut.
9. Cut a piece of material from the third sample.
10. Extract the instrument from the nose.

The tasks were performed for both the Kerrison (K) as for the NeuroPunch (N). Afterwards, the participants were asked to complete a questionnaire regarding the functionalities of both devices and the quality of the phantom model. The table on the right shows the (average) results of the questionnaire to the following statements (1=completely disagree – 7=completely agree):

1. **Positioning**: I can easily position and align the tip of the instrument to the (bony) structures before cutting.
2. **Interactions**: I do not experience any undesired hand positions and/or undesired interactions with the endoscope during punching.
3. **In & out**: I can punch (bone) structures without often introducing and extracting the instrument from the nose.
4. **Phantom**: The phantom model is a good representation of the reality.

Besides the statements which were judged by the surgeons, open questions were asked to receive more qualitative input on several aspects of the design of the NeuroPunch. Below, the most important results of this discussion are listed.

- All surgeons highly recommended to test the NeuroPunch, when manufactured to be able to cut cortical bone pieces, to test the instrument in a real clinical setting (e.g. skillslab)
- The sharp edge of the outer shaft could provide a risk of damaging healthy surrounding tissue. Perhaps this could be redesigned towards a more atraumatic distal section.
- The distal section of the outer shaft should be as small as possible, and if possible, further minimized in order to allow the distal end to be used as an atraumatic 'manipulator' as well, thereby able to manipulate soft tissue.
- The width of the proximal section of the handle could be reduced in order to minimize 'sword fighting'. Fig. 48a depicts the area of handling the NeuroPunch when holding the handle. In case even more instruments will be introduced, this area was preferred to be further reduced, by a reduction of the width of the handle.
- Some surgeons stated that the mock-up endoscope, which has an outer diameter of 7mm, led to a worse representation of the clinical setting instead of when using a real endoscope.

Results of the user test on both the Kerrison (K) and the NeuroPunch (N). *Gives the same value for both instruments because the statement is unrelated to instruments characteristics

| | P1 | P2 | P3 | P4 | Avg. |
|---|---|---|---|---|---|
| **Positioning** | | | | | |
| Kerrison | 4 | 2 | 6 | 6 | **4.5** |
| NeuroPunch | 7 | 7 | 7 | 6 | **6.8** |
| **Interactions** | | | | | |
| Kerrison | 6 | 7 | 5 | 4 | **5.5** |
| NeuroPunch | 6 | 7 | 6 | 5 | **6** |
| **In & out** | | | | | |
| Kerrison | 4 | 3 | 3 | 4 | **3.5** |
| NeuroPunch | 7 | 7 | 6 | 6 | **6.5** |
| **Phantom*** | 3 | 7 | 4 | 6 | **5** |

# Appendix B: Design requirement scheme

| # | Design requirement | # | Sub-requirement | Acceptance criteria | Product specification | Method to demonstrate conformity | Current Conformity | Pot. future Conformity | Origin |
|---|---|---|---|---|---|---|---|---|---|
| F1 | The instrument must be able to cut through a bone layer of the anatomical area | | | The instrument cuts through cortical bone of 1mm. | Cutting force in tip ≥ 92N | Visual inspection of functioning prototype<br>*OR*<br>Calculation | | • Optimize dimensions<br>• reduce stress concentrations<br>• Stronger material | [48-50] |
| F2 | The instrument tip is able to be rotated independent from the handle orientation, in order to align the tip properly to the bone to be cut | | | The instrument tip can make a complete rotation of 360° relative to the handle orientation | Tip able to make a sweep of 360° without rotating the handle. | Visual inspection of functioning prototype | | | User Input session 2 and 3 |
| F3 | The instrument must be able to punch multiple bone pieces without the need for clearing the cutting area of the instrument | | | Instrument cuts an acceptable amount of bone pieces without the need for cleaning the tip or nasal cavity/corridor | ≤ 10 consecutive bone pieces | Visual inspection of functioning prototype | | | User Input session 2 and 3 |
| D4 | The shaft height and width are sufficiently small to enable simultaneous use of the instrument, scope and suction tube in the operational area. | | | Reaches the pituitary gland without undesired interactions with the scope and suction tube | Height ≤ 4 mm<br>Width ≤ 4 mm | Determine anatomical dimensional constraints<br>*OR*<br>Compare to currently used instruments<br>*OR*<br>Validation in user test | | | [23], [24] |
| D5 | The shaft length is sufficient for the use of the instrument in the operational area. | | | Reaches the pituitary gland without undesired interactions with the scope and suction tube | 170mm ≤ length ≤ 280mm | Determine anatomical dimensional constraints<br>*OR*<br>Compare to currently used instruments<br>*OR*<br>Validation in user test | | | [24] |
| D6 | The tip dimensions should allow for maximized reachability in the nasal cavity | D6.1 | The tip opening should allow for the introduction of bone. | The tip opening is bigger than the bone to be cut and easily allows for the introduction of bone | Tip opening ≥ 8 mm | Determine anatomical dimensional constraints<br>*OR*<br>Compare to currently used instruments<br>*OR*<br>Validation in user test | | | [24] |
| | | D6.2 | The tip height and width are sufficiently small to enable simultaneous use of the instrument, scope and suction tube in the operational area | Reaches the pituitary gland without undesired interactions with the scope and suction tube during surgery | Height ≤ 4 mm<br>Width ≤ 4 mm | Determine anatomical dimensional constraints<br>*OR*<br>Compare to currently used instruments<br>*OR*<br>Validation in user test | | | [23] |
| | | D6.3 | The tip dimensions allow for cutting an acceptable sized piece of bone without undesired interactions with the suction tube or endoscope | The tip cutting area is sufficiently big to cut an acceptable sized piece of bone | Height ≥ 4 mm<br>Width ≥ 4 mm | Compare to currently used instruments<br>*OR*<br>Validation in user questionaire | | | [46] |
| E7 | The instrument should be single-handed | | | The majority of users agrees that the instrument can be easily used with a single hand. | N/A | Validation in user questionnaire | | | User Input session 2 and 3 |
| E8 | The instrument should be usable in the left or the right hand | | | The instrument must be symmetric | Symmetric handle design | Visual inspection of functioning prototype | | | User Input session 2 and 3 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| E9 | The handle should fulfill the general ergonomic guidelines | E9.1 | Manipulation of 'grip force' must be produced by finger flexors. | The lever must be moving 'inwards' in order to make a punch | N/A | Visual inspection of functioning prototype | | | [37] |
| | | E9.2 | Contact area pressure must be prevented. | The handle consists of rounded edges and big contact edges should be avoided | Contact areas ≥ 10mm | Visual inspection of functioning prototype<br>OR<br>Validation in user questionnaire | | | [37] |
| | | E9.3 | Actuation of the rotation-function must be performed with the thumb or index finger. | Instrument must be provided with knob to allow for rotation of the tip. | N/A | Visual inspection of functioning prototype | | | [37] |
| | | E9.4 | The force needed on the handle to punch bone should be acceptable | The force on the handle needed to punch should be lower than one-third of the maximum gripping force of the user | Lever force ≤ 33N | Measure the cutting force on functioning prototype<br>*OR*<br>Calculate the required force of functioning prototype | | | [51] |
| | | E9.5 | The control components (rotation knobs and levers) should be easily accessible | The majority of users agrees that functional elements are easily accessible | N/A | Validation in user questionnaire | | | [37] |
| | | E9.6 | The dimensions of the control components (rotation knobs and levers) are acceptable | The majority of users agrees that the dimensions of the functional elements are acceptable | N/A | Validation in user questionnaire | | | [37] |
| | | E9.7 | Cramped positions as well as excessive shoulder movements should be avoided when using the instrument. | The majority of users agrees that the cramped positions and excessive shoulder movements are avoided when using the instrument | N/A | Validation in user questionnaire | | | User Input session 2 and 3 |
| | | E9.8 | The instrument must be hold stable (=firmly fixed) when using the instrument | The majority of users agrees that the instrument provides a stable grip when using it | N/A | Validation in user questionnaire | | | User Input session 2 and 3 |
| E10 | The instrument handle allows for proper interaction with the other instruments during use. | | | The majority of users agrees that the instrument interacts properly with the other instruments during use. | N/A | Validation in user questionnaire | | | User Input session 2 and 3 |
| S11 | The risk of damaging healthy surrounding tissue should be minimized | S11.1 | The instrument provides good grip on bone when it is cut | The bone pieces should be 'anchored' or 'fixated' by the instrument prior to the cutting step | N/A | Visual inspection of functioning prototype<br>*OR*<br>Validation in user questionnaire | | | User Input session 2 and 3 |
| | | S11.2 | The punching step should produce a 'burr-free' cut without damaging the surroundings of the cut. | The separation of the bone piece from its surroundings should be done by shearing | 60° ≤ Shearing angle ≥ 30°<br>35° ≤ Cutting edge ≥ 40° | Visual inspection of functioning prototype<br>*OR*<br>Validation in user questionnaire | | | [38,40-43] |
| | | S11..3 | The distal end of the tip should be stationary (not moving) when a cut is made. | A punch can be made while the distal end of the instrument is not moving, thereby making it easy to control the punching step. | N/A | Visual inspection of functioning prototype<br>*OR*<br>Validation in user questionnaire | | | User Input session 2 and 3 |
| | | S11..4 | The distal end of the tip should be small as possible and atraumatic | The distal section may not result in the damaging of surrounding tissue when using or introducing/ extracting the instrument | N/A | Visual inspection of functioning prototype<br>*OR*<br>Validation in user questionnaire | | • Distal end reduction (Less sharp & angle oppositely directed) | User Input session 2 and 3 |

This table shows the list of design requirements. Several design requirements are further specified into sub-requirements. Each (sub-) requirement is further specified by its acceptance criterion (which describes when the product fulfills the (sub-) requirement), the product specification (which is the 'technical definition' of the requirement), and the method to demonstrate the conformity to the each (sub-) requirement. The 8th and 9th column indicate whether the current prototype fulfills (or not) each requirement (and if not, how the conformity could be proven)

## Appendix C: Questionnaire handle design

This appendix shows the questionnaire which was completed by the participants during the handle design evaluation. Note that concept 2 has two different configurations (implemented in the same model), to which questions 2, 4 and 8 apply.

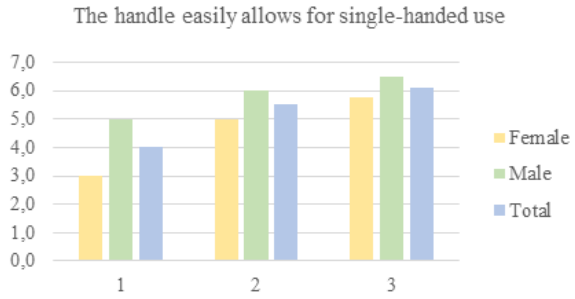
| | Concept 1  | Concept 2  | Concept 3  |
|---|---|---|---|
| The handle easily allows for single-handed use. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The rotation-knob is easily accessible. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | (F) 1 – 2 – 3 – 4 – 5 – 6 – 7<br>(T) 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The lever is easily accessible. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The size of the rotation knob is acceptable. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | (F) 1 – 2 – 3 – 4 – 5 – 6 – 7<br>(T) 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The size of the lever is acceptable. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| Cramped positions as well as excessive shoulder movements are avoided. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The instrument is robust. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The instrument is stable in the hand when rotating the shaft. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | (F) 1 – 2 – 3 – 4 – 5 – 6 – 7<br>(T) 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The instrument is stable in the hand when the handle is grabbed. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The instrument handle is intuitive in its use. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The instrument has a professional and medical-device like appearance. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |
| The interaction between the device and the suction tube is good. | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 | 1 – 2 – 3 – 4 – 5 – 6 – 7 |

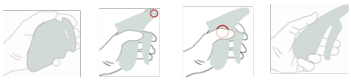
## The overall preference has concept:

# Appendix D: Handle design evaluation results

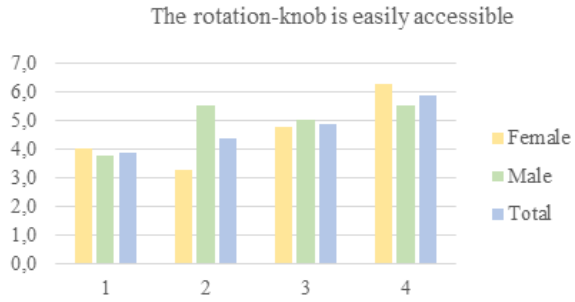
The tables and graphs below show the results of the quantitative user test as described in Section 3.6. Each table shows the result for an individual question in the questionnaire (Appendix C). Handle type 2 was modelled in two rotation-knob configurations. Therefore, the results of statement 2, 4 and 8 consist of an additional column/graph.

| The handle easily allows for single-handed use | | | |
|---|---|---|---|
| Participant 1: Female - age 20 | 1 | 5 | 6 |
| Participant 2: F - 21 | 3 | 3 | 6 |
| Participant 3: F - 21 | 3 | 7 | 6 |
| Participant 4: F - 24 | 5 | 5 | 5 |
| Participant 5: Male - age 20 | 5 | 6 | 6 |
| Participant 6: M - 21 | 6 | 6 | 7 |
| Participant 7: M - 24 | 4 | 5 | 6 |
| Participant 8: M - 24 | 5 | 7 | 7 |
| Average Female participants | 3,0 | 5,0 | 5,8 |
| Average Male participants | 5,0 | 6,0 | 6,5 |
| Average total | 4,0 | 5,5 | 6,1 |

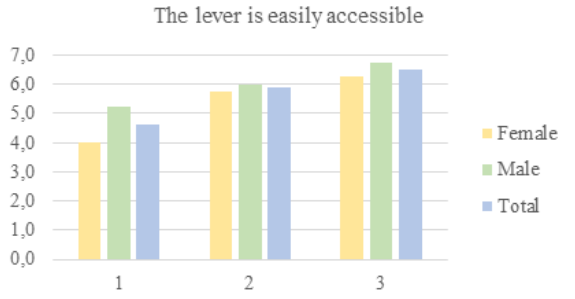


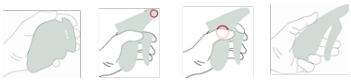



| The rotation-knob is easily accessible* * Concept 2 has two rotation-configurations (Forefinger (F) rotation or Thumb (T) rotation) | | | | |
|---|---|---|---|---|
| Participant 1: F - 20 | 3 | 5 | 4 | 7 |
| Participant 2: F - 21 | 6 | 3 | 3 | 6 |
| Participant 3: F - 21 | 3 | 4 | 6 | 6 |
| Participant 4: F - 24 | 4 | 1 | 6 | 6 |
| Participant 5: M - 20 | 3 | 5 | 5 | 7 |
| Participant 6: M - 21 | 3 | 5 | 6 | 3 |
| Participant 7: M - 24 | 4 | 6 | 5 | 5 |
| Participant 8: M - 24 | 5 | 6 | 4 | 7 |
| Average Female participants | 4,0 | 3,3 | 4,8 | 6,3 |
| Average Male participants | 3,8 | 5,5 | 5,0 | 5,5 |
| Average Total | 3,9 | 4,4 | 4,9 | 5,9 |

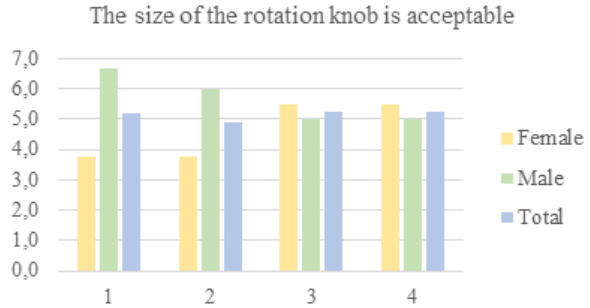



| The lever is easily accessible | | | |
|---|---|---|---|
| Participant 1: F - 20 | 5 | 6 | 6 |
| Participant 2: F - 21 | 4 | 6 | 6 |
| Participant 3: F - 21 | 3 | 7 | 7 |
| Participant 4: F - 24 | 4 | 4 | 6 |
| Participant 5: M - 20 | 6 | 6 | 7 |
| Participant 6: M - 21 | 6 | 6 | 6 |
| Participant 7: M - 24 | 4 | 6 | 7 |
| Participant 8: M - 24 | 5 | 6 | 7 |
| Average Female participants | 4,0 | 5,8 | 6,3 |
| Average Male participants | 5,3 | 6,0 | 6,8 |
| Average Total | 4,6 | 5,9 | 6,5 |

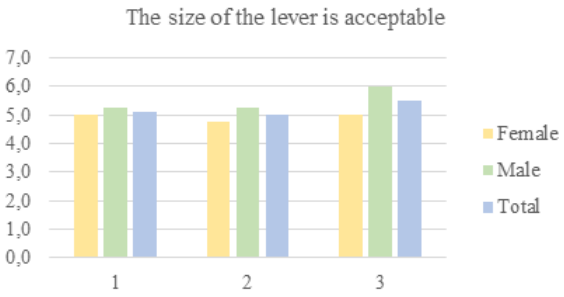


| The size of the rotation knob is acceptable* * Concept 2 has two rotation- configurations (Forefinger (F) rotation or Thumb (T) rotation) | | (F) | (T) | |
|---|---|---|---|---|
| Participant 1: F - 20 | 4 | 4 | 5 | 6 |
| Participant 2: F - 21 | 4 | 3 | 5 | 5 |
| Participant 3: F - 21 | 4 | 6 | 6 | 6 |
| Participant 4: F - 24 | 4 | 2 | 6 | 6 |
| Participant 5: M - 20 | 3 | 6 | 5 | 5 |
| Participant 6: M - 21 | 6 | 6 | 6 | 4 |
| Participant 7: M - 24 | 7 | 7 | 6 | 6 |
| Participant 8: M - 24 | 7 | 5 | 3 | 5 |
| Average Female participants | 3,8 | 3,8 | 5,5 | 5,5 |
| Average Male participants | 6,7 | 6,0 | 5,0 | 5,0 |
| Average Total | 5,2 | 4,9 | 5,3 | 5,3 |

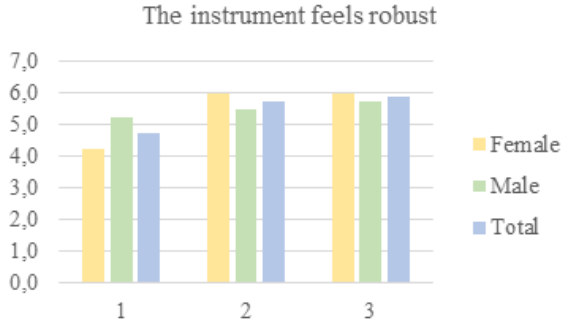


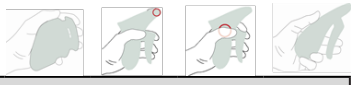
| The size of the lever is acceptable | | | |
|---|---|---|---|
| Participant 1: F - 20 | 6 | 2 | 4 |
| Participant 2: F - 21 | 3 | 6 | 4 |
| Participant 3: F - 21 | 5 | 6 | 7 |
| Participant 4: F - 24 | 6 | 5 | 5 |
| Participant 5: M - 20 | 5 | 4 | 6 |
| Participant 6: M - 21 | 6 | 6 | 6 |
| Participant 7: M - 24 | 5 | 6 | 7 |
| Participant 8: M - 24 | 5 | 5 | 5 |
| Average Female participants | 5,0 | 4,8 | 5,0 |
| Average Male participants | 5,3 | 5,3 | 6,0 |
| Average Total | 5,1 | 5,0 | 5,5 |



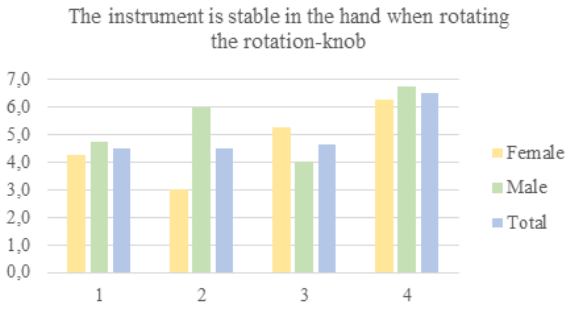

| Cramped positions as well as excessive shoulder movements are avoided | | | |
|---|---|---|---|
| Participant 1: F - 20 | 1 | 4 | 5 |
| Participant 2: F - 21 | 2 | 6 | 6 |
| Participant 3: F - 21 | 6 | 7 | 7 |
| Participant 4: F - 24 | 4 | 4 | 5 |
| Participant 5: M - 20 | 2 | 6 | 5 |
| Participant 6: M - 21 | 6 | 6 | 5 |
| Participant 7: M - 24 | 4 | 6 | 7 |
| Participant 8: M - 24 | 4 | 5 | 7 |
| Average Female participants | 3,3 | 5,3 | 5,8 |
| Average Male participants | 4,0 | 5,8 | 6,0 |
| Average Total | 3,6 | 5,5 | 5,9 |


| The instrument feels robust (the ability to withstand high forces and other events) | | | |
|---|---|---|---|
| Participant 1: F - 20 | 3 | 6 | 6 |
| Participant 2: F - 21 | 3 | 6 | 5 |
| Participant 3: F - 21 | 6 | 7 | 7 |
| Participant 4: F - 24 | 5 | 5 | 6 |
| Participant 5: M - 20 | 4 | 5 | 5 |
| Participant 6: M - 21 | 6 | 6 | 6 |
| Participant 7: M - 24 | 5 | 6 | 6 |
| Participant 8: M - 24 | 6 | 5 | 6 |
| Average Female participants | 4,3 | 6,0 | 6,0 |
| Average Male participants | 5,3 | 5,5 | 5,8 |
| Average Total | 4,8 | 5,8 | 5,9 |

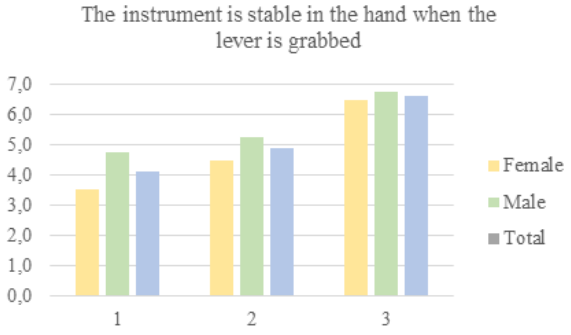


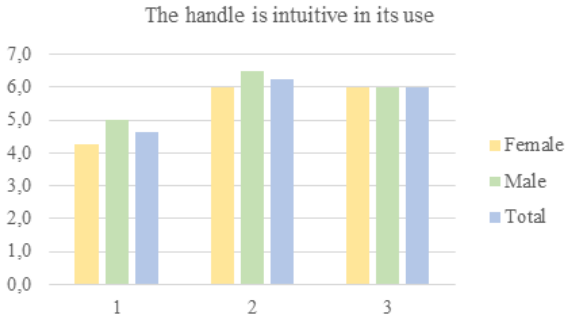
| The instrument is stable in the hand when rotating the rotation-knob* * Concept 2 has two rotation-configurations (Forefinger (F) rotation or Thumb (T) rotation) | | (F) | (T) | |
|---|---|---|---|---|
| Participant 1: F - 20 | 5 | 3 | 3 | 6 |
| Participant 2: F - 21 | 3 | 2 | 5 | 6 |
| Participant 3: F - 21 | 4 | 6 | 7 | 7 |
| Participant 4: F - 24 | 5 | 1 | 6 | 6 |
| Participant 5: M - 20 | 4 | 6 | 2 | 6 |
| Participant 6: M - 21 | 6 | 6 | 6 | 7 |
| Participant 7: M - 24 | 6 | 7 | 5 | 7 |
| Participant 8: M - 24 | 3 | 5 | 3 | 7 |
| Average Female participants | 4,3 | 3 | 5,3 | 6,3 |
| Average Male participants | 4,8 | 6 | 4,0 | 6,8 |
| Average Total | 4,5 | 4,5 | 4,6 | 6,5 |



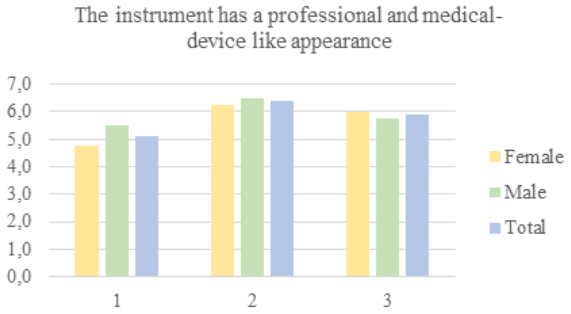
| The instrument is stable in the hand when the lever is grabbed | | | |
|---|---|---|---|
| Participant 1: F - 20 | 3 | 2 | 6 |
| Participant 2: F - 21 | 3 | 6 | 7 |
| Participant 3: F - 21 | 3 | 6 | 7 |
| Participant 4: F - 24 | 5 | 4 | 6 |
| Participant 5: M - 20 | 5 | 4 | 7 |
| Participant 6: M - 21 | 6 | 6 | 6 |
| Participant 7: M - 24 | 4 | 6 | 7 |
| Participant 8: M - 24 | 4 | 5 | 7 |
| Average Female participants | 3,5 | 4,5 | 6,5 |
| Average Male participants | 4,8 | 5,3 | 6,8 |
| Average Total | 4,1 | 4,9 | 6,6 |



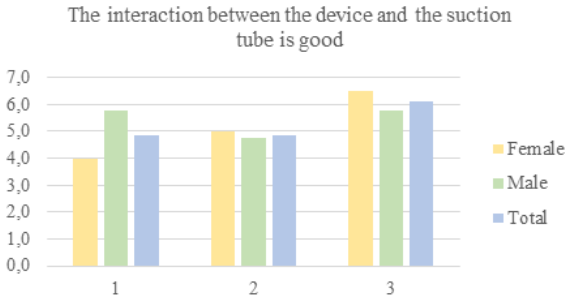

| The instrument handle is intuitive in its use | | | |
|---|---|---|---|
| Participant 1: F - 20 | 3 | 5 | 6 |
| Participant 2: F - 21 | 3 | 7 | 5 |
| Participant 3: F - 21 | 5 | 6 | 7 |
| Participant 4: F - 24 | 6 | 6 | 6 |
| Participant 5: M - 20 | 5 | 6 | 7 |
| Participant 6: M - 21 | 6 | 7 | 4 |
| Participant 7: M - 24 | 4 | 7 | 7 |
| Participant 8: M - 24 | 5 | 6 | 6 |
| Average Female participants | 4,3 | 6,0 | 6,0 |
| Average Male participants | 5,0 | 6,5 | 6,0 |
| Average Total | 4,6 | 6,3 | 6,0 |




| The instrument has a professional and medical-device like appearance | | | |
|---|---|---|---|
| Participant 1: F - 20 | 5 | 6 | 6 |
| Participant 2: F - 21 | 4 | 6 | 5 |
| Participant 3: F - 21 | 5 | 7 | 7 |
| Participant 4: F - 24 | 5 | 6 | 6 |
| Participant 5: M - 20 | 6 | 7 | 5 |
| Participant 6: M - 21 | 6 | 7 | 6 |
| Participant 7: M - 24 | 5 | 6 | 6 |
| Participant 8: M - 24 | 5 | 6 | 6 |
| Average Female participants | 4,8 | 6,3 | 6,0 |
| Average Male participants | 5,5 | 6,5 | 5,8 |
| Average Total | 5,1 | 6,4 | 5,9 |

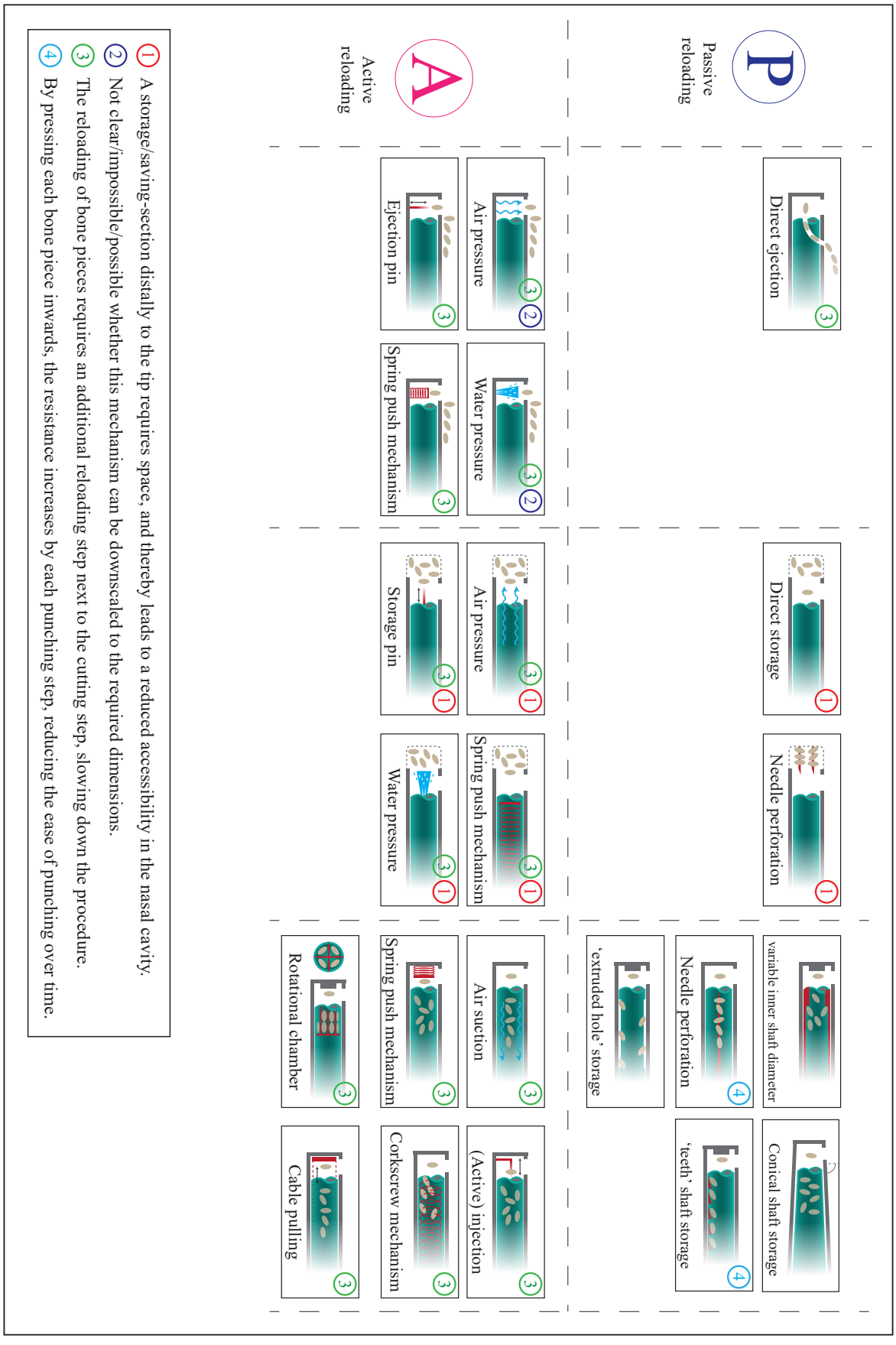



| The interaction between the device and the suction tube is good | | | |
|---|---|---|---|
| Participant 1: F - 20 | 5 | 6 | 6 |
| Participant 2: F - 21 | 3 | 5 | 7 |
| Participant 3: F - 21 | 4 | 6 | 7 |
| Participant 4: F - 24 | 4 | 3 | 6 |
| Participant 5: M - 20 | 6 | 6 | 6 |
| Participant 6: M - 21 | 6 | 5 | 6 |
| Participant 7: M - 24 | 5 | 4 | 4 |
| Participant 8: M - 24 | 6 | 4 | 7 |
| Average Female participants | 4,0 | 5,0 | 6,5 |
| Average Male participants | 5,8 | 4,8 | 5,8 |
| Average Total | 4,9 | 4,9 | 6,1 |



# Appendix E: Design decision making - cutting & reloading

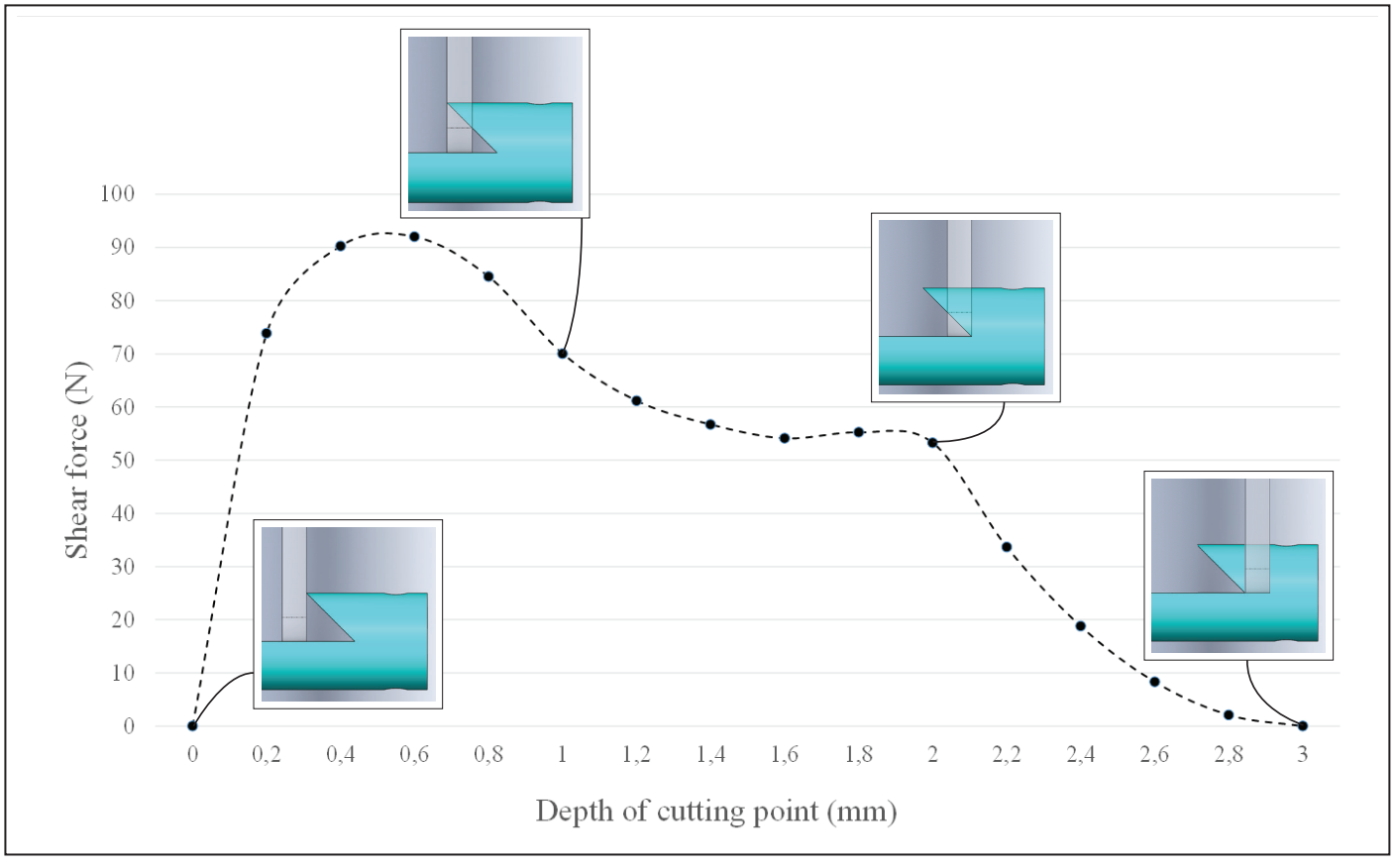
Each method is judged on each of the five criteria, as mentioned previously. In the argumentation scheme, four argumentations are provided, explaining why each individual tip reloading method fulfills, or not, each criterion. In the scheme, the arguments are numbered and when relevant, placed in the upper right corner of each tip reloading method image. As a result, the methods conical shaft storage, variable inner shaft diameter storage, and extruded hole storage remained, thereby fulfilling all criteria.



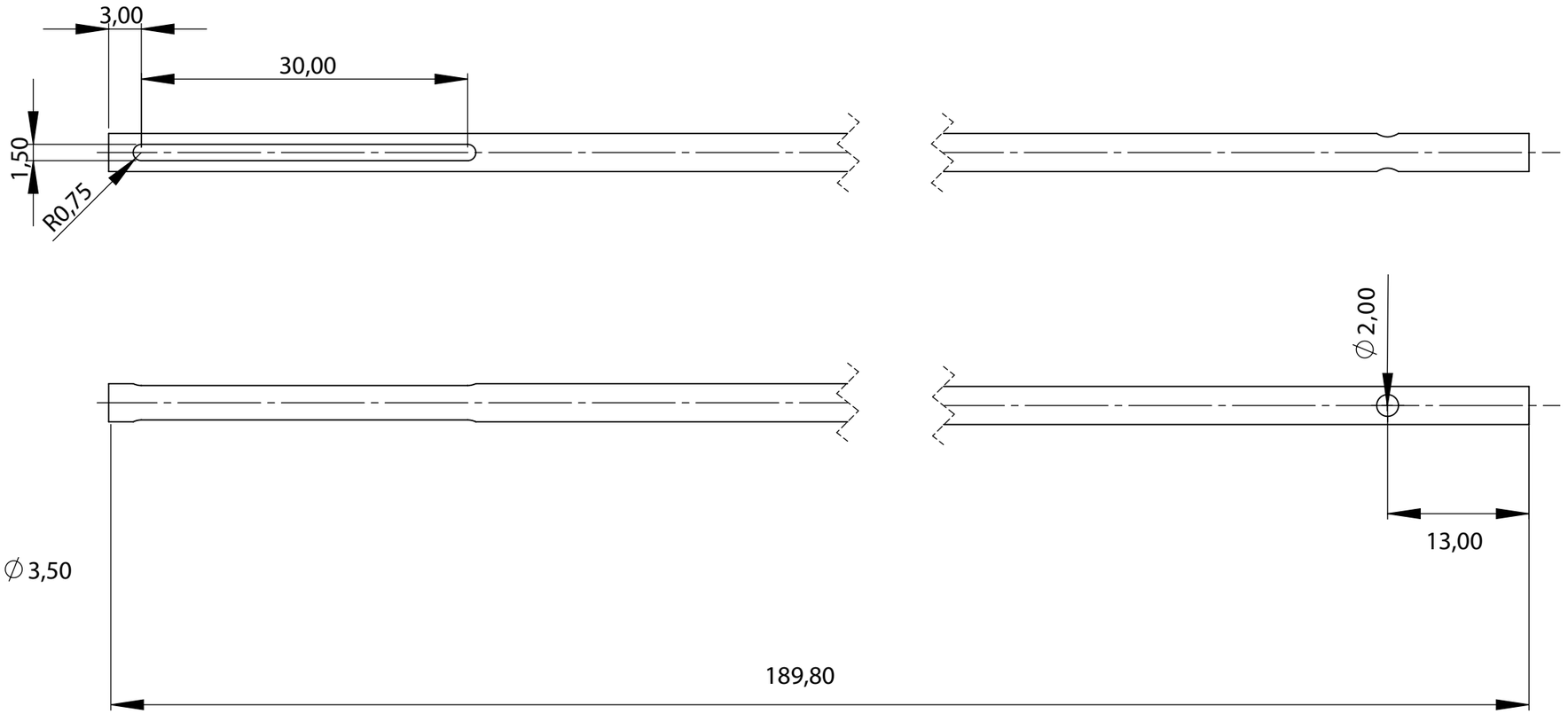
## Appendix F: Calculation cutting areas

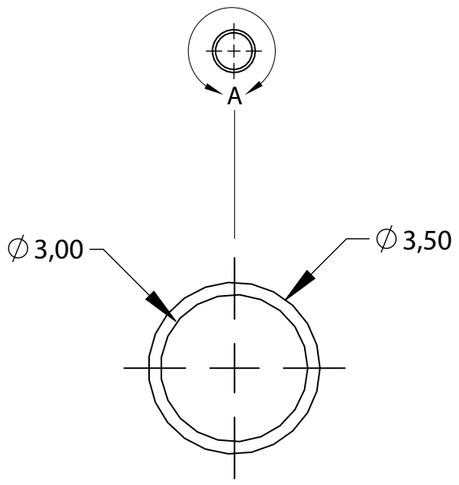
The table below indicates the different variables during each cutting step, from 0 to 3mm. When 0, the distal end only touches the bone to be cut. When 3mm, the bone piece is completely cut. The punched bone area and the bone area to be cut together form the total bone area. The shear force is the result of the multiplication of the *bone area to be punched* and the *shear stress of bone*.

| Depth of cutting point (mm) | (Variable) bone area (mm²) | Punched bone area (mm²) | Bone area to be punched (mm²) | Shear stress of bone (MPa) | Shear force (N) |
|---|---|---|---|---|---|
| **0** | 0 | 0 | 0 | 51,6 | 0 |
| **0,2** | 1,653 | 0,221 | 1,432 | 51,6 | 73,889 |
| **0,4** | 2,379 | 0,630 | 1,749 | 51,6 | 90,253 |
| **0,6** | 2,947 | 1,164 | 1,783 | 51,6 | 92,022 |
| **0,8** | 3,442 | 1,804 | 1,638 | 51,6 | 84,516 |
| **1** | 3,896 | 2,539 | 1,357 | 51,6 | 70,031 |
| **1,2** | 4,326 | 3,140 | 1,185 | 51,6 | 61,162 |
| **1,4** | 4,738 | 3,638 | 1,099 | 51,6 | 56,711 |
| **1,6** | 5,141 | 4,092 | 1,049 | 51,6 | 54,113 |
| **1,8** | 4,940 | 3,869 | 1,070 | 51,6 | 55,235 |
| **2** | 5,341 | 4,308 | 1,032 | 51,6 | 53,271 |
| **2,2** | 4,273 | 3,620 | 0,653 | 51,6 | 33,678 |
| **2,4** | 3,204 | 2,841 | 0,364 | 51,6 | 18,776 |
| **2,6** | 2,136 | 1,976 | 0,161 | 51,6 | 8,295 |
| **2,8** | 1,068 | 1,028 | 0,040 | 51,6 | 2,066 |
| **3** | 0 | 0 | 0 | 51,6 | 0 |



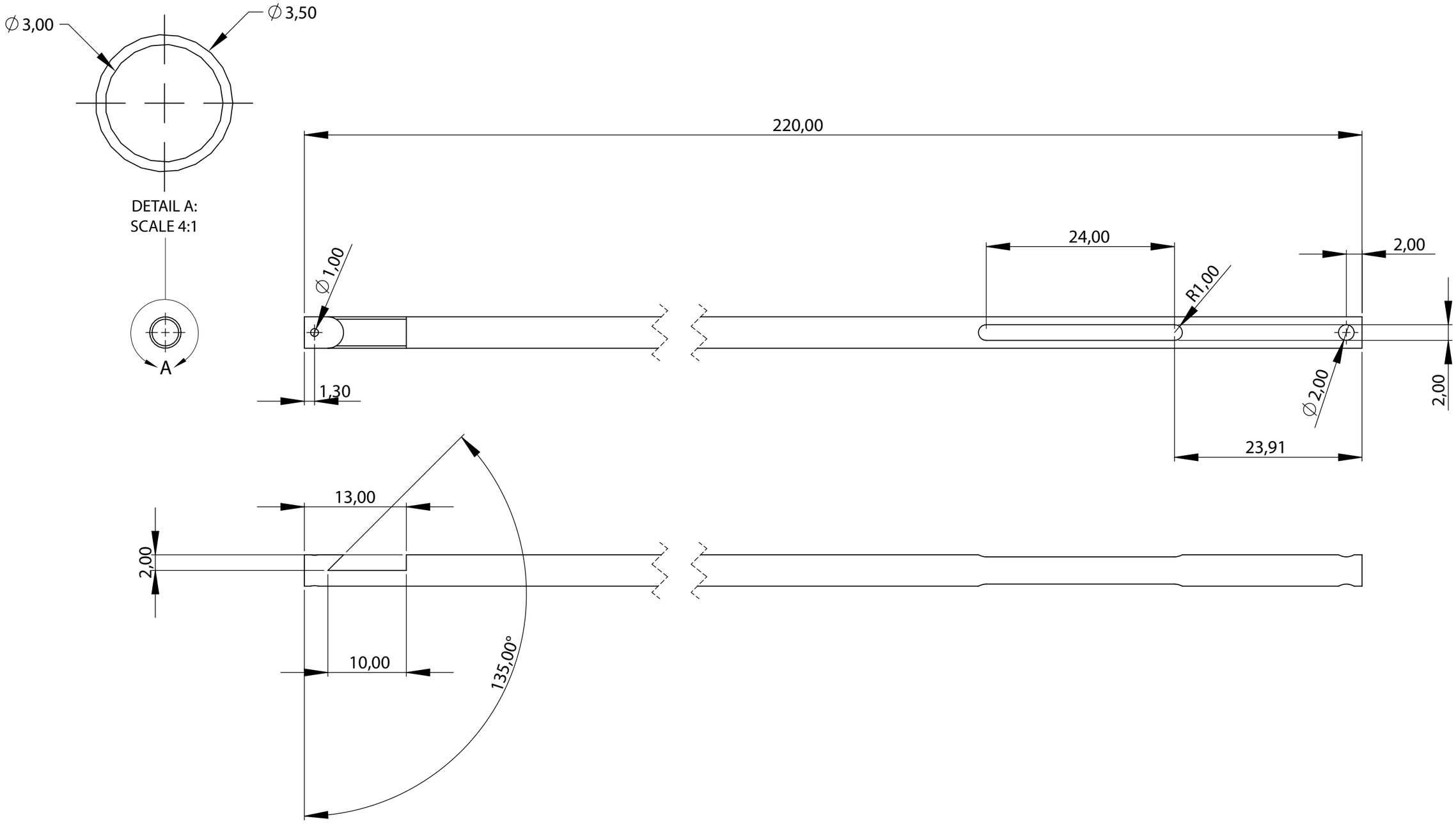

Graph showing the gradual shear force exertion of the cutting edge on the bone structure, relative to the depth of the cutting point.



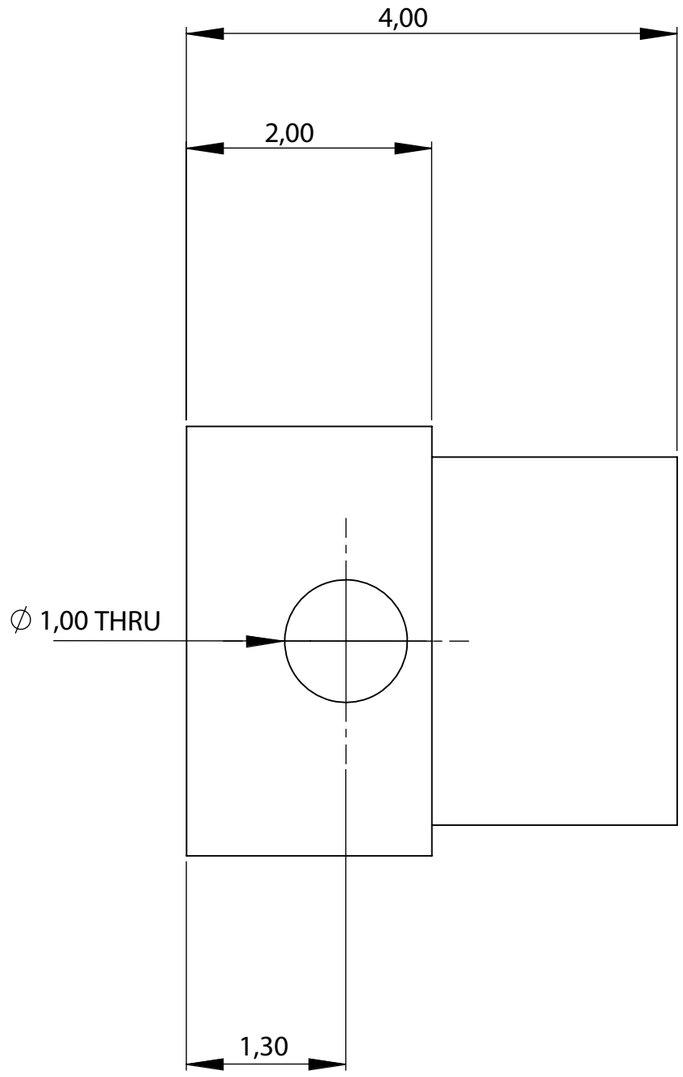



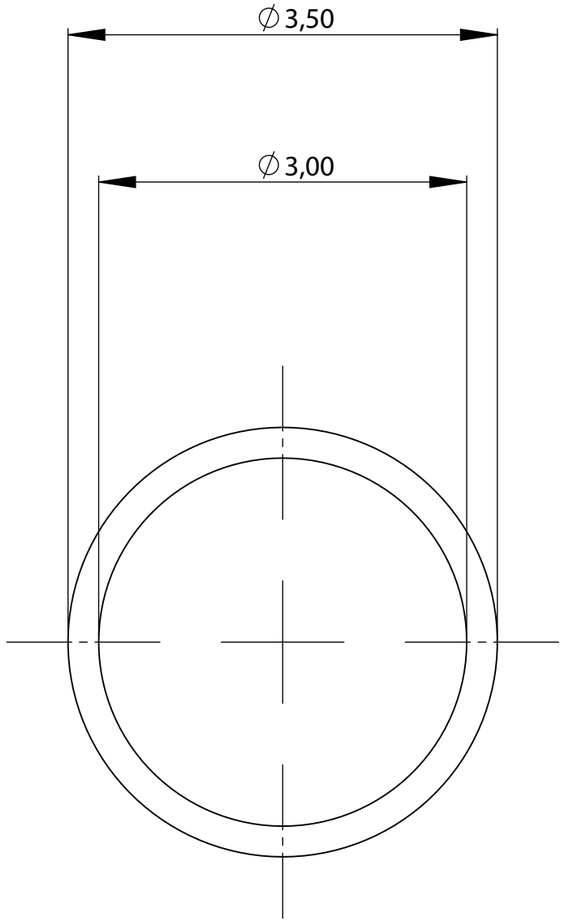

DETAIL A:
SCALE 4:1

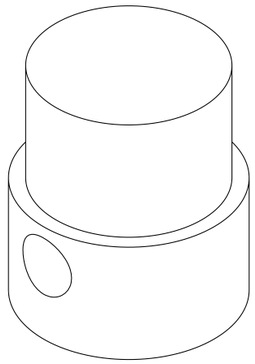
| | | | | |
|---|---|---|---|---|
| Name: **Inner Shaft** | | | Format: **A3** | Units: mm |
| DEAM | Scale: 2:1 | Date: 12/09/2018 | Material: AISI304 | Drawing number: 1/9 |
| | Remarks: | | | Signed: A. Sendrowicz |



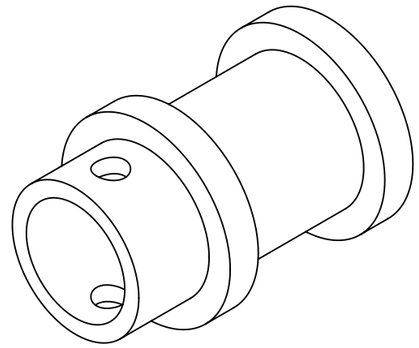

| | | | | | |
|---|---|---|---|---|---|
| Name: **Outer Shaft** | | | | Format: **A3** | Units: mm |
| DEAM | Scale: 2:1 | Date: 12/09/2018 | Material: AISI304 | | Drawing number: 2/9 |
| | Remarks: | | | | Signed: A. Sendrowicz |

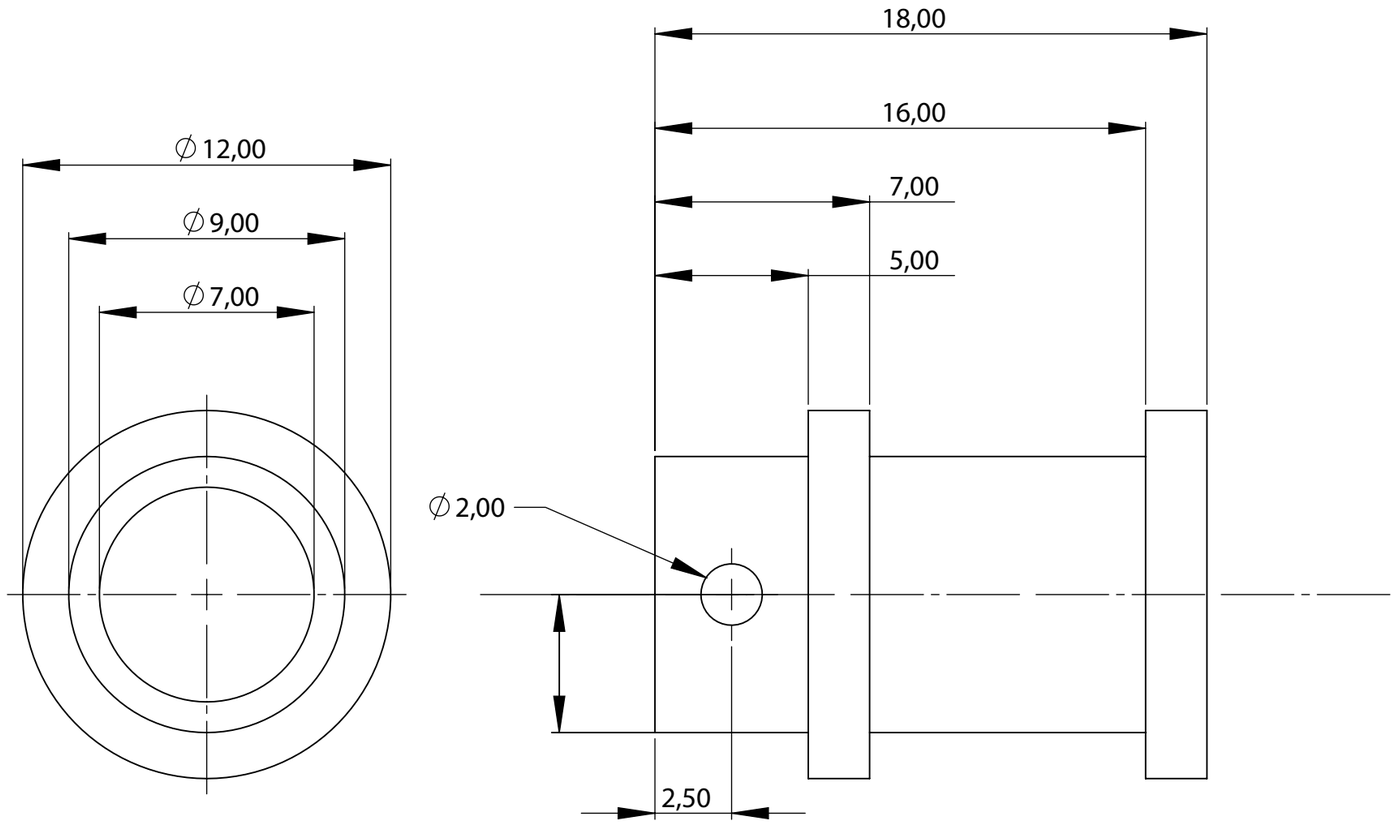


| | | | | | |
|---|---|---|---|---|---|
| Name: Distal cap | | | | Format: A3 | Units: mm |
| DEAM | Scale: 20:1 | Date: 12/09/2018 | Material: AISI304 | | Drawing number: 3/9 |
| | Remarks | | | | Signed: A. Sendrowicz |






Name

# Cross ring

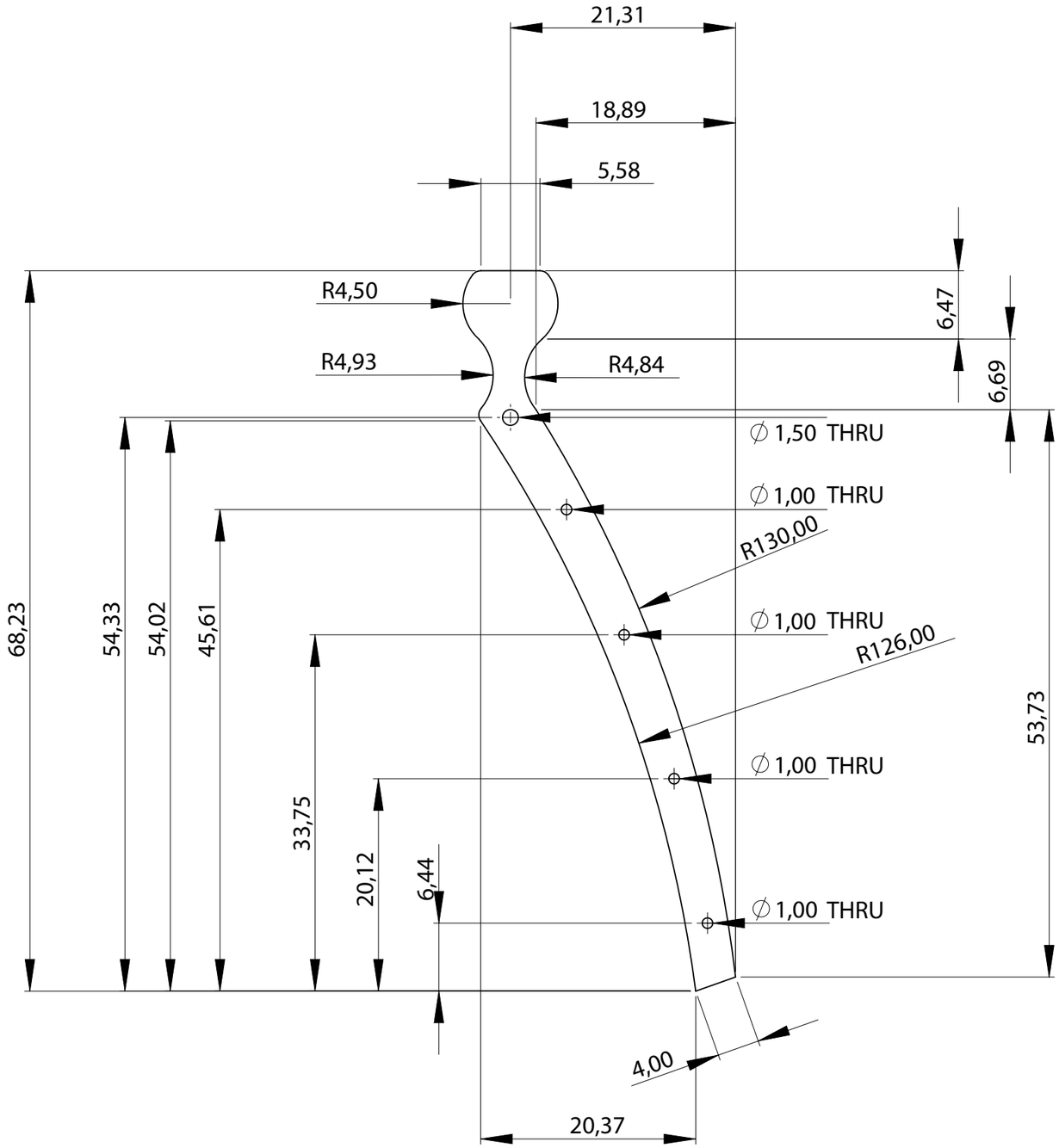
| Format | Units |
|---|---|
| A3 | mm |

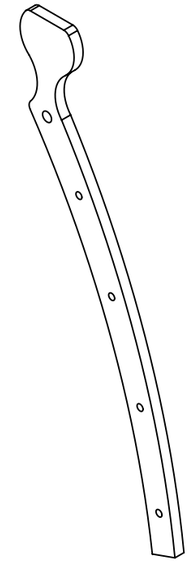
| Scale | Date | Material | Drawing number |
|---|---|---|---|
| 5:1 | 12/09/2018 | Bronze | 4/9 |

DEAM

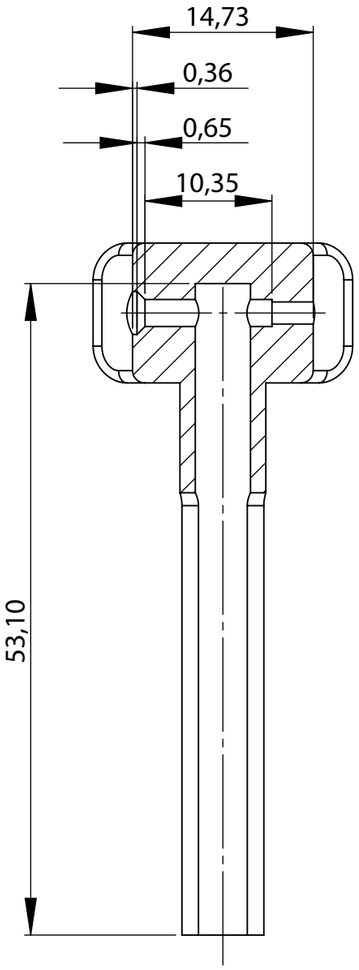
Remarks

Signed: A. Sendrowicz

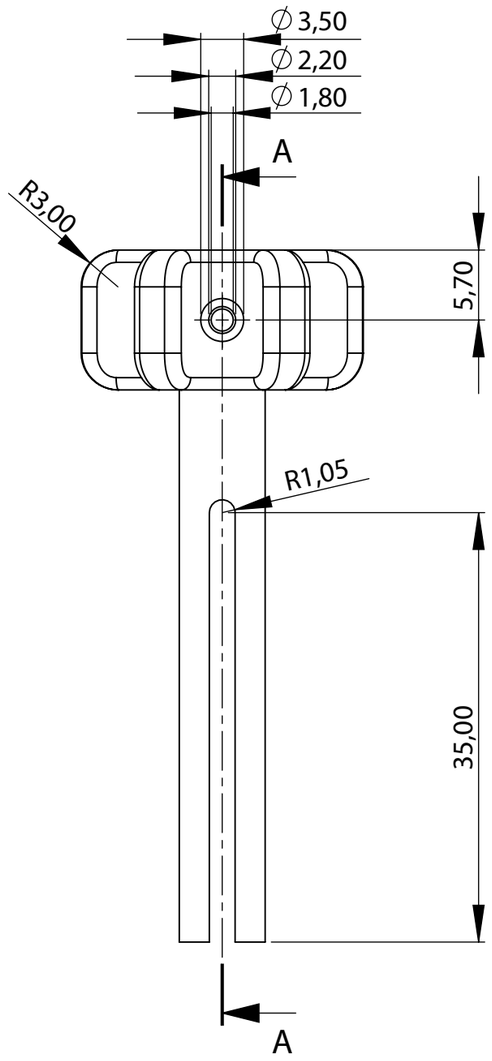


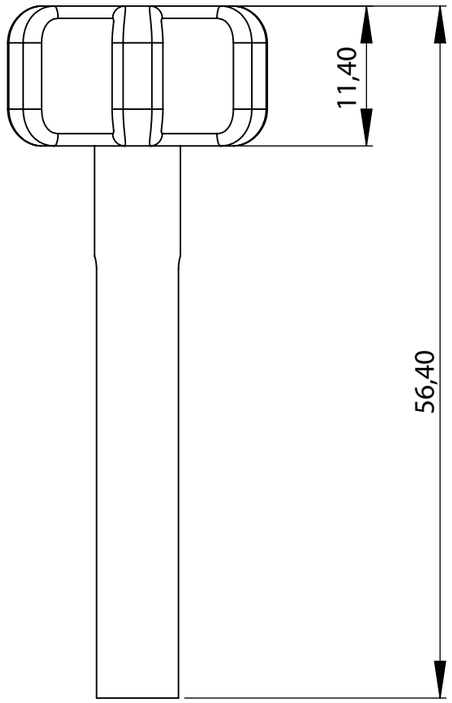



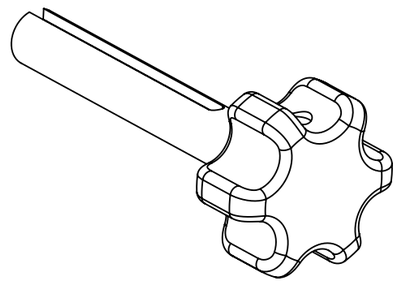
| | | | | |
|---|---|---|---|---|
| Name: **Translation-rotation pin** | | | Format: **A3** | Units: mm |
| DEAM | Scale: 2:1 | Date: 12/09/2018 | Material: AISI304 (plate) | Drawing number: 5/9 |
| | Remarks: Thickness: 1,5<br>Unspecified fillets: R1 | | | Signed: A. Sendrowicz |

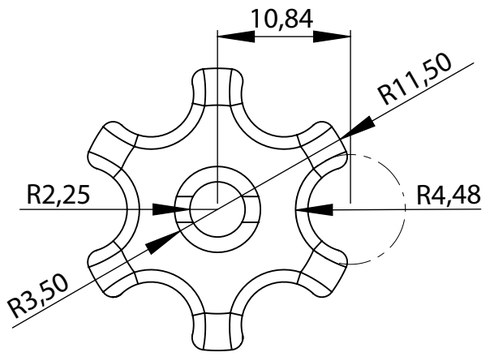



SECTION A-A

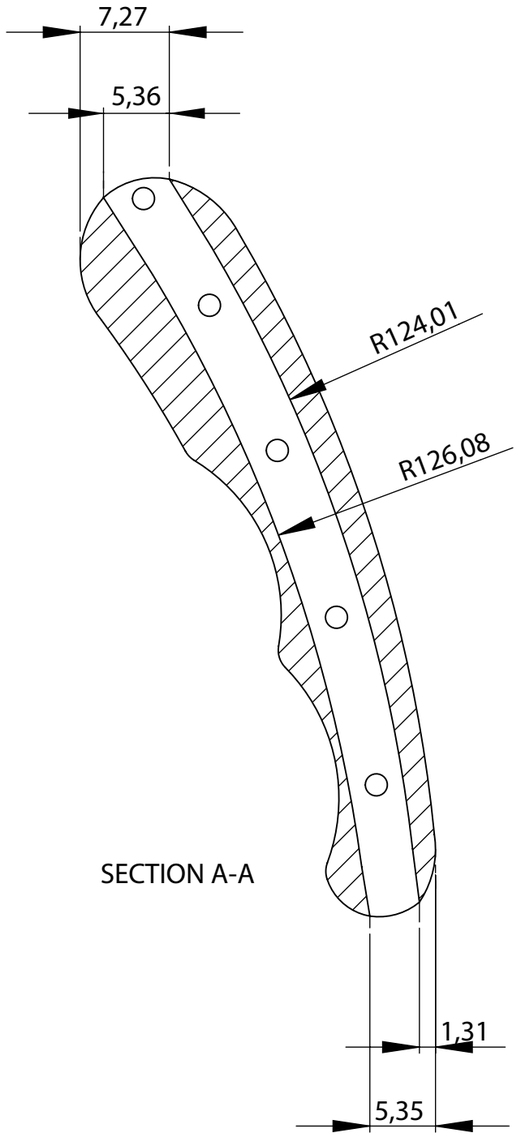


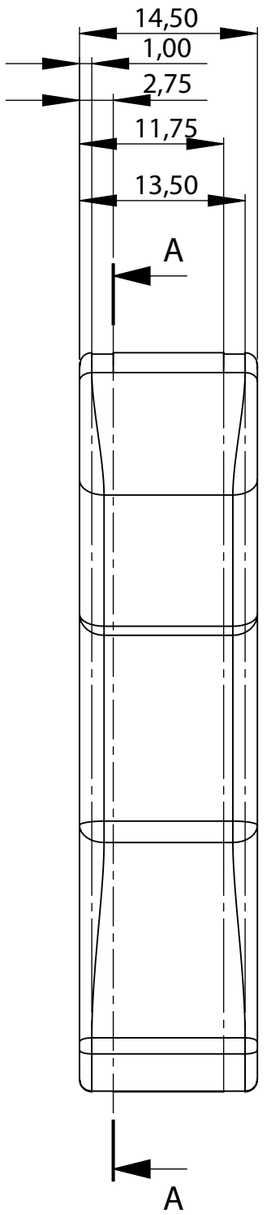



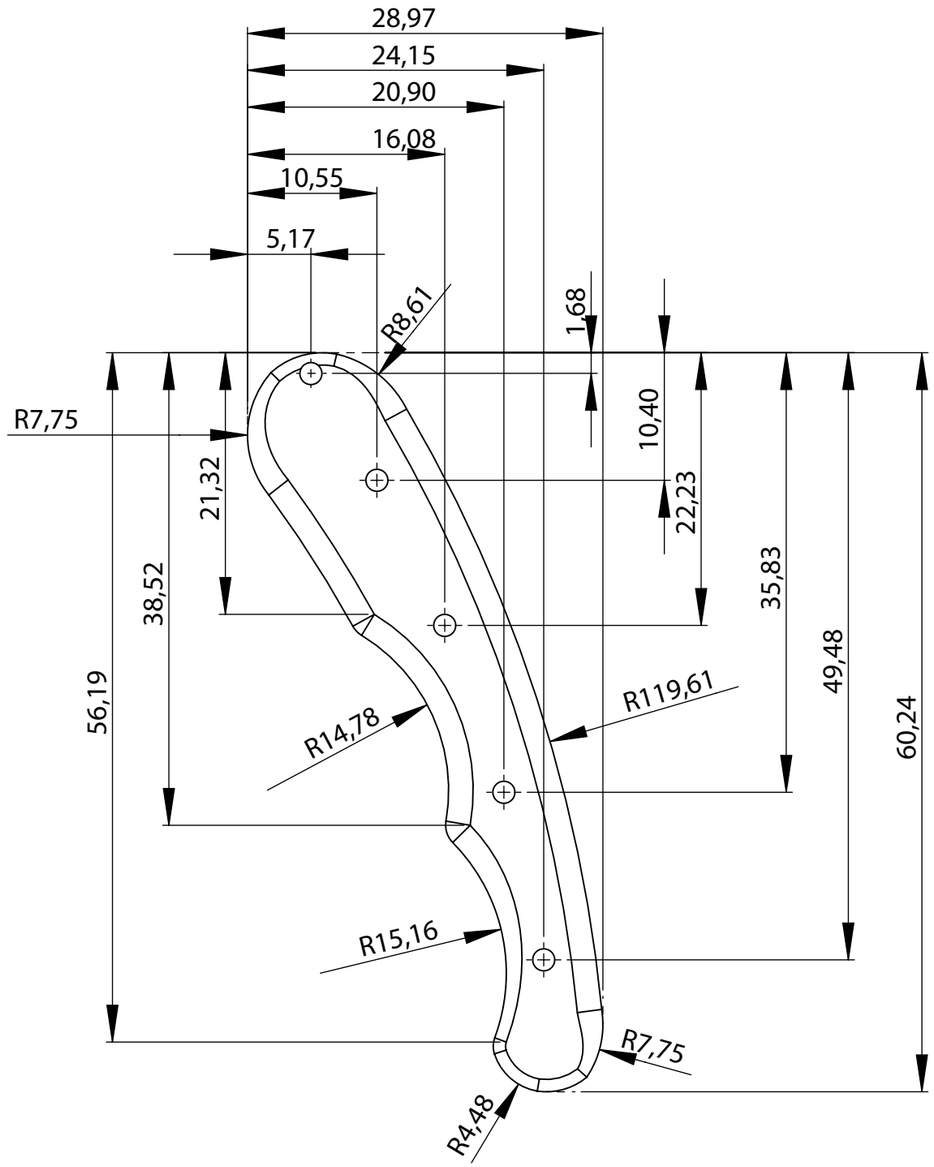


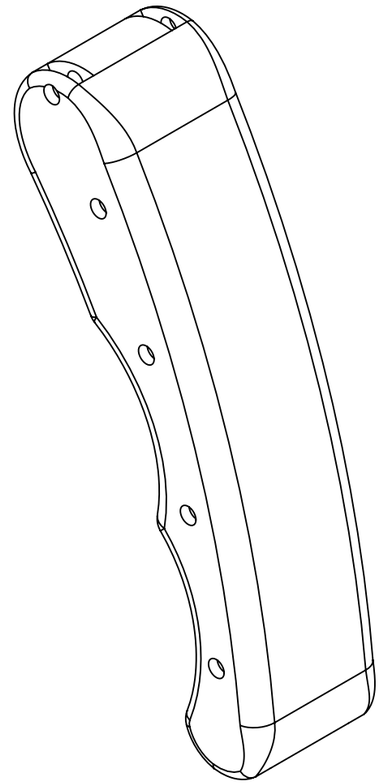

| | | | | |
|---|---|---|---|---|
| Name: **Rotation knob** | | | Format: **A3** | Units: mm |
| DEAM | Scale: 2:1 | Date: 12/09/2018 | Material: PA12 (nylon) | Drawing number: 6/9 |
| | Remarks: Unspecified fillets: R1 | | | Signed: A. Sendrowicz |




SECTION A-A

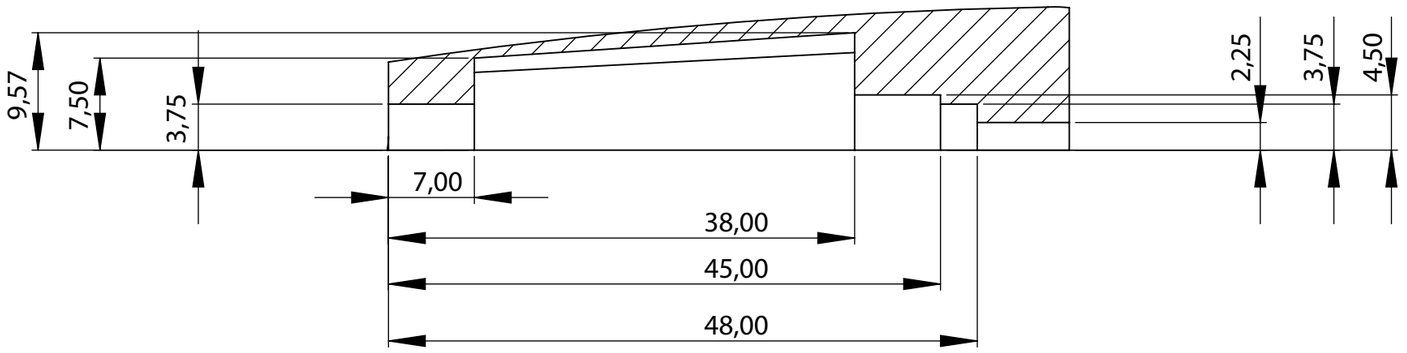


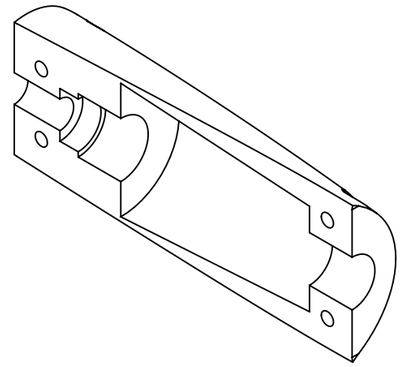



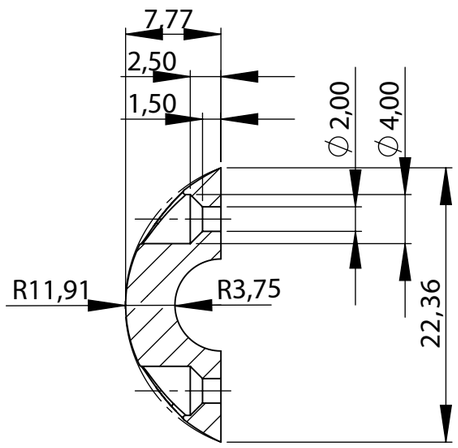



| | | | | | |
|---|---|---|---|---|---|
| Name: Lever | | | | Format: A3 | Units: mm |
| DEAM | Scale: 2:1 | Date: 12/09/2018 | Material: PA12 (nylon) | | Drawing number: 7/9 |
| | Remarks: Unspecified fillets: variable fillet R1 - R2<br>Unspecified holes: R0,9 - THRU ALL | | | | Signed: A. Sendrowicz |

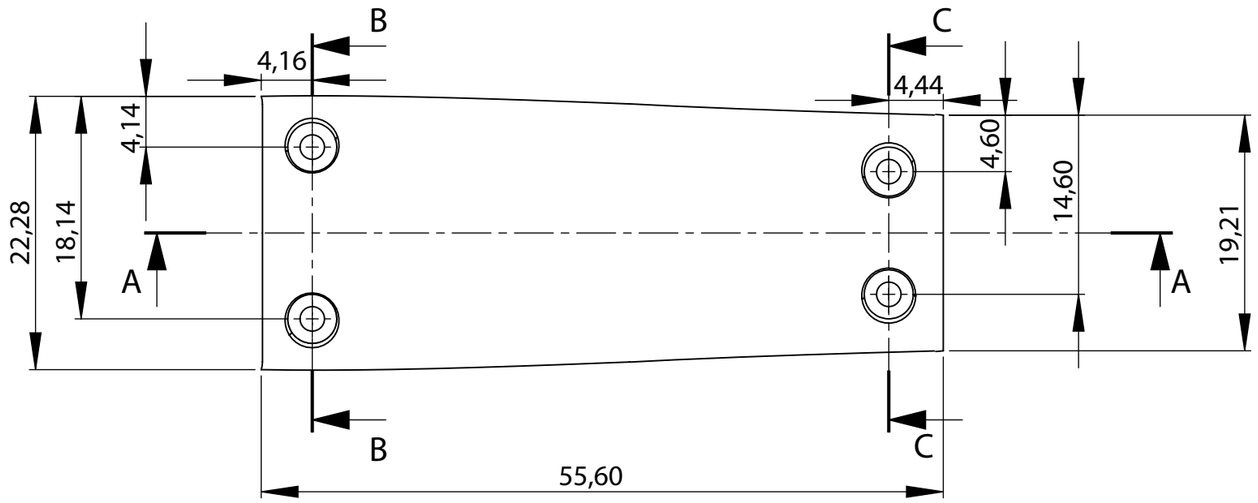
SECTION A-A

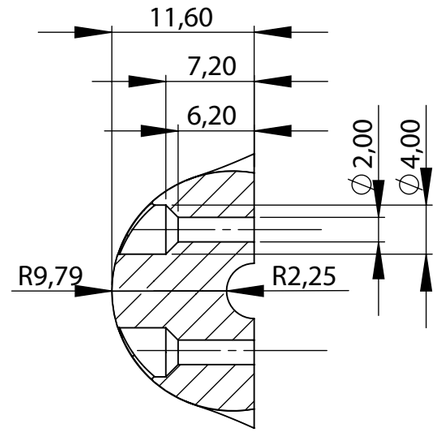


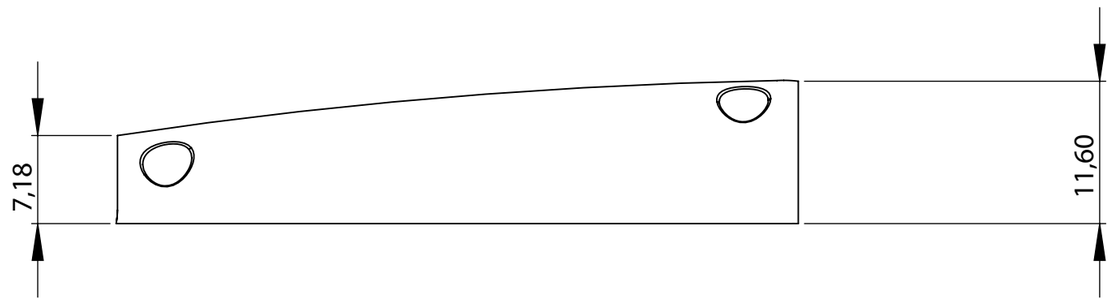



SECTION B-B

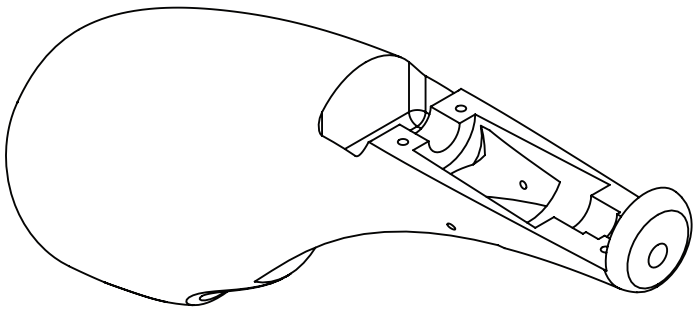


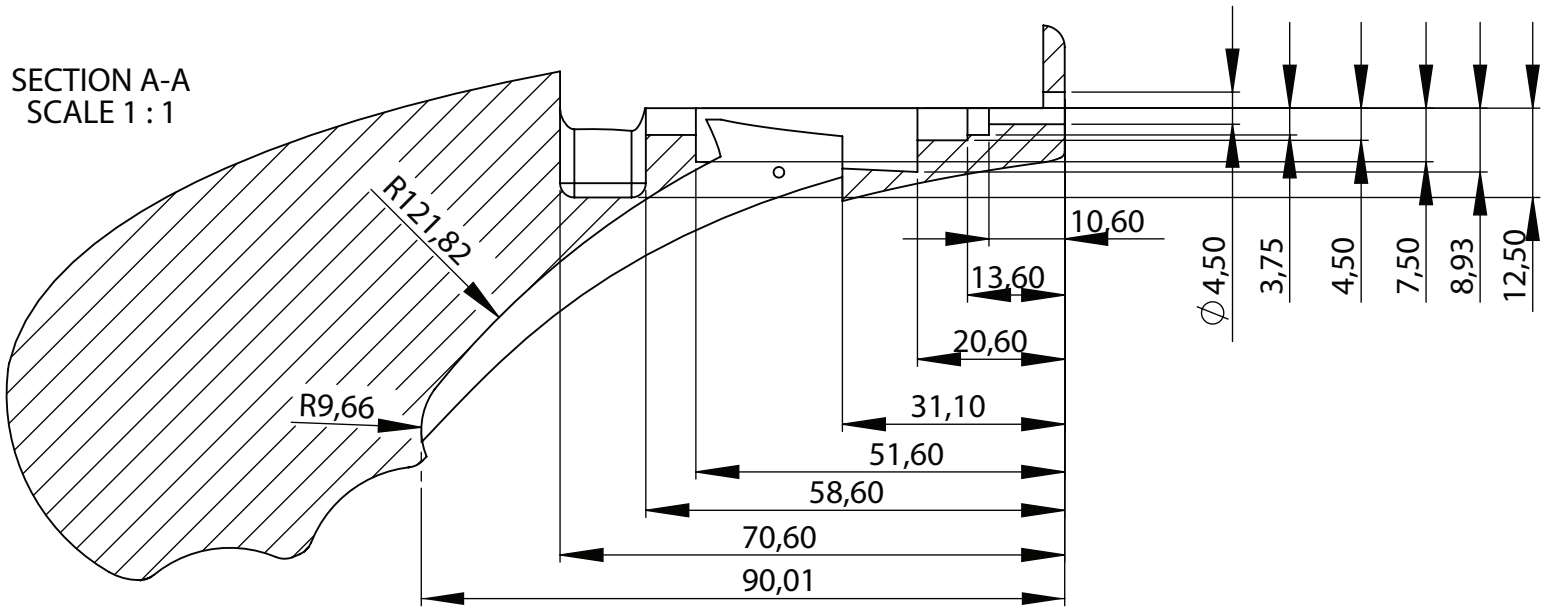

SECTION C-C

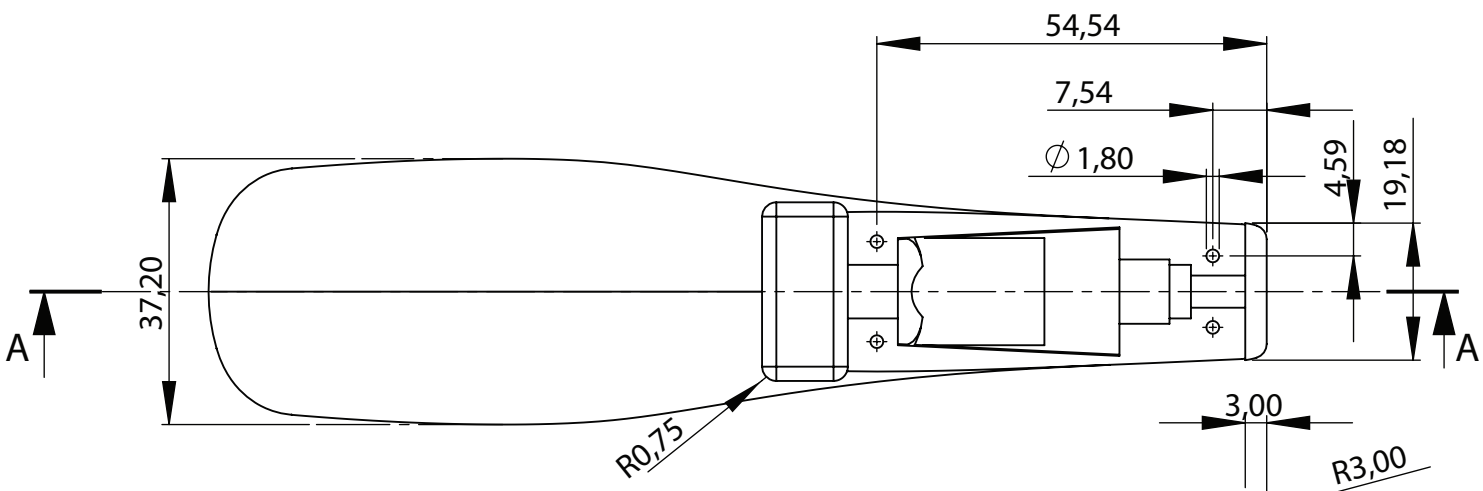


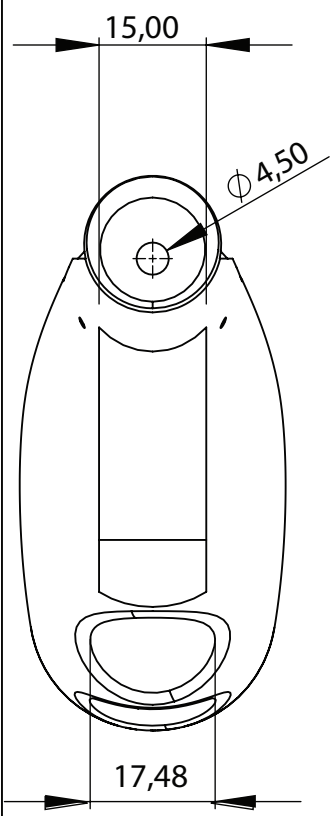

| | | | | |
|---|---|---|---|---|
| Name: **Handle cap** | | | Format: **A3** | Units: mm |
| DEAM | Scale: 2:1 | Date: 12/09/2018 | Material: PA12 (nylon) | Drawing number: 8/9 |
| | Remarks: Unspecified fillets: R0.2 | | | Signed: A. Sendrowicz |

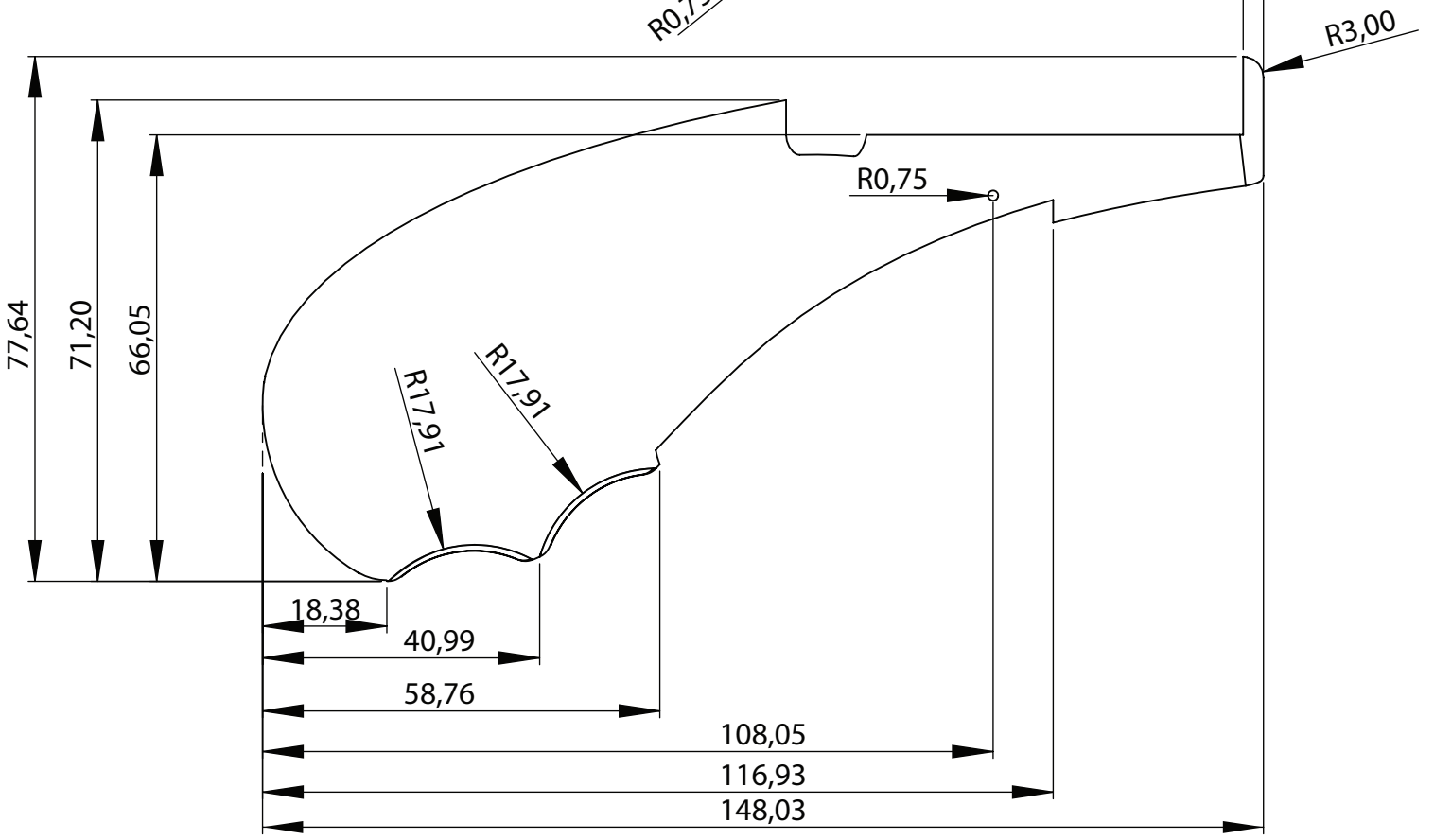


SECTION A-A
SCALE 1 : 1




| | | | | | |
|---|---|---|---|---|---|
| Name: **Handle** | | | | Format: **A3** | Units: mm |
| DEAM | Scale: 1:1 | Date: 12/09/2018 | Material: PA12 (nylon) | | Drawing number: 9/9 |
| | Remarks: Unspecified fillets: R3 | | | | Signed: A. Sendrowicz |

2018
Master's Thesis
The NeuroPunch

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