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Development of a device to assist force generation for high-load orthopaedic actions

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Abstract

Orthopaedic surgery includes frequent removal of bony tissue with large instruments that require a significant force to operate. An increasing number of surgeons, especially female and older surgeons, cannot operate high-load orthopedic instruments properly because they lack the necessary force or hand span. The goal of this study is to develop a device that assists surgeons with force generation for high-load orthopaedic actions. It should enable surgeons of any age, gender and gripping strength to operate bone excision instruments with their dominant hand only by amplifying the users gripping force. **Methods:** The device was designed for the "worst case scenario": a 60 year old female surgeon cutting hard cortical bone with a large rongeur. The device amplification (2.2x) was determined by calculating the discrepancy between the available gripping force for this person (207N) and the maximum bone cutting force (474N), determined by cutting 90 slices of tibia with a large Luer-Stille rongeur. Several qualitative requirements were taken into account, such as maintaining haptic feedback and sterilizibility. The prototype features an amplification mechanism based on ratchets that enables two operating modes: it can either be used like a traditional rongeur or with extra amplification where needed. The device was evaluated by experimentally comparing the amplification of the prototype with the intended amplification. **Results:** The prototype provided more than the necessary amplification: gripping force is amplified at least 2.8 times in amplification mode. **Conclusions:** The proposed design shows potential to be a valuable addition to orthopedic instruments because it enables surgeons with less gripping force to cut through hard tissue with one hand. The presented prototype delivers the necessary amplification of gripping force but shows some limitations, for which solutions were presented. When these limitations are solved, clinical testing can be initiated.

Keywords: orthopedic, rongeur, gripping force, mechanical amplification, ratchet mechanism, bone exision

1. Introduction

In 2009, over 200000 orthopedic operations were performed in the Netherlands. The most common types of operations are total hip and knee arthoplasty [4]. Bone excision (removal by cutting) is often involved in these operations. Common tissues that are removed are (in order of hardness): (sclerotic) bone, osteophytes (bony projections that form along joints), cartilage or disc tissue. Surgeons have several reasons to remove these tissues. Osteophytes, which form with bone transformation due to aging or wear, can limit joint movement and cause pain. Sclerotic bone must be removed because it can negatively effect the stability of implants such as artificial knees and hips (Fig. 2).

For the excision of bony tissue, instruments like the rongeur, the bone cutting forceps and punches are used to nibble and cut bone. These instruments are preferred to be operated with one hand so that the other hand can perform other tasks, such as holding a suction device or accurately positioning the instrument tip (Fig. 6).

However, it is not without reason that orthopedic surgeons are said to resemble gorillas [1], because significant force is required for bone excision with the mentioned instruments. As a result, surgeons with small(er) hands and low gripping force sometimes lack sufficient gripping force to operate the bone excision instruments

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with one hand (Fig. 1). These surgeons experience problems with the high-load instruments, which cause physical injury and irritation for the surgeon and might compromise the quality of the operation. Giraud et al. report that bone cutting has always been a problem for surgeons, because bone is a hard living material [2]. Berguer and Hreljac report that hand size is a significant determinant of difficulty using laparoscopic surgical instruments [3].

An inital survey (see J.14) among 31 orthopedic surgeons proved the existence of the problem: 60% experiences the unability to close the instrument with one hand and 40% experiences an unstable grip due to a slipping instrument. The consequences of these problems are serious: 60% admit the problems result in a longer operating time, and 30% admit a negatively influenced accuracy of the operation. Furthermore, the surgeons themselves suffer from the cumbersome high-load instruments: among the complaints of the surveyed group were reports of arthritis, cramped hands and callus [5].

Current solutions to this problem are instruments that are equipped with a simple double mechanical lever construction (Fig. 4). This solution is not proficient because it does not provide satisfactory assistance, and due to its construction, has wide handles that are hard to grip.

The goal of this study is to develop a device that enables all surgeons to excise all tissues under all circumstances with one hand only. To achieve this, the device should assist in force generation during high-load orthopedic actions and must allow a comfortable grip for all hand sizes.

[5]due to the relatively low number of participants (31), these results just indicate trends for the surveyed group

Figure 1: Surgeon having trouble operating bone excision instrument with one hand

First, the technical and qualitative design requirements are explained. Subsequently, design choices are presented, followed with the dimensional design of the final concept. A prototype was created and tested, of which the results are presented and discussed. This paper ends with conclusions and discussions.

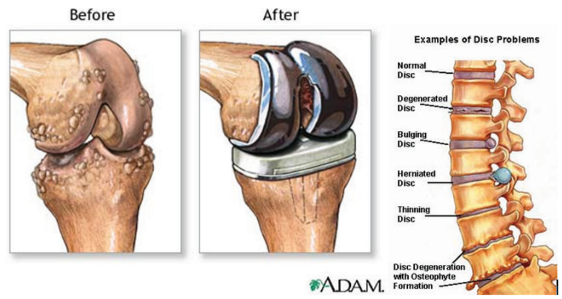


Figure 2: Examples of bony tissue that is excised with high-load orthopedic instruments. Sclerotic bone, shown on the left, must be removed because it can negatively affect the stability of implants such as artificial knees and hips. On the right, the formation of osteophytes is seen, which must be removed to alleviate nerve pressure.

2. Methods

In this section, the design requirements are presented, which were divided into technical and qualitative requirements. The technical requirements describe the mechanical function of the device that must be satisfied to enable *any surgeon* to use *high-load orthopedic instruments* on *all tissues* with his/her dominant hand only. Following from this goal, it can be seen that the technical requirements depend on several factors, such as the user, the instrument and the tissue that is excised. To satisfy the goal, a “worst case scenario” is used, which poses the most demanding technical requirements: the weakest surgeon needs to be able to cut the hardest tissue with the largest instrument.

The qualitative requiremens represent user demands and other essential demands required to enable use of the device in the specific operating room environment.

2.1. Technical requirements

The main reason for the problems with high-load orthopedic instruments is the discrepancy between the user’s maximum gripping force, F_{user}, and the necessary bone cutting force, F_{bone}, during a certain interval Δx_{device} (Fig. 3). To be able to advance the instrument beak through the bone, a certain bone cutting force is needed (F_{bone}, Fig. 3) which is simplified to F_{total}. F_{total} should exceed the highest of bone cutting forces during the entire interval and is to be directed parallel to F_{user} for simplicity of the design and to include a margin for error. The user can exert a maximum gripping force (F_{user}, Fig. 3) on the handles of the instrument, depending on the handle span x_r. At some point (d_1) during the closing action, F_{user} is insufficient to advance the instrument any further into the bone. At the moment the necessary force drops below the users maximum gripping force F_{user}, the device's assistance is obsolete and it can thus disengage (point d_2). Thus, the device needs to provide assistance during the interval Δx_{device}.

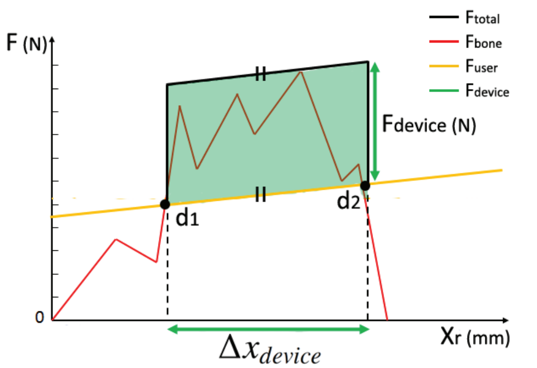


Figure 3: The force necessary to advance the rongeur beak through the bone, F_{bone} (simplified to F_{total}), exceeds the users maximum gripping force, F_{user}, during the interval Δx_{device}. During this interval, assistance from the device is needed, either by amplifying the user gripping force or adding force. x_r is the instrument handle span, further illustrated in Fig. 4

There are two options for the intended device to create F_{total}: adding force to the system (option 1) or amplifying the user gripping force (option 2).

Option 1: device adds force

The device adds force to the instrument during the interval Δx_{device}. In this case, F_{device} is found by subtracting the user gripping force from the F_{total}.

$$F_{total} = F_{user} + F_{device} \tag{2.1}$$

$$F_{device} = F_{total} - F_{user} \tag{2.2}$$

Option 2: device amplifies gripping force

The device mechanically amplifies the user gripping force with a factor k during the interval Δx_{device}. Factor k is found by dividing F_{total} by the user gripping force.

$$F_{total} = F_{user} \cdot k_{device} \tag{2.3}$$

$$k_{device} = F_{total}/F_{user} \tag{2.4}$$

To be able to calculate k_{device} and F_{device}, the actual values of F_{total} and F_{user} were determined.

2.1.1. *Determining gripping force*

Any person's gripping force depends on several variables, such as age, gender, grip type and hand span [4][5][6][7]. Since women posess approximately 50 to 67% of male gripping force [4], the identified problems are most frequently present amongst female surgeons. It is also known that gripping force decreases with age. Therefore, a 60 year old female was chosen within the "worst case scenario". This person will be reference to as the "case person". The maximum gripping force for the case person was determined 293 N [4]. This value is measured in an ideal position, that is with tested indiviuals seated with their shoulders adducted, their elbows flexed 90 degrees, and their forearms in neutral [4]. However, the surgeon is standing behind an operating table and was observed to have a non-ideal position. To take this into account, the maximum gripping force was multiplied with the influences of the variables shown in Table 1. This way, the realistic maximum gripping force for the case person as a function of x_r was obtained (Table 1 and Fig. 5).

2.1.2. *Determining F_{total} and Δx_{device}*

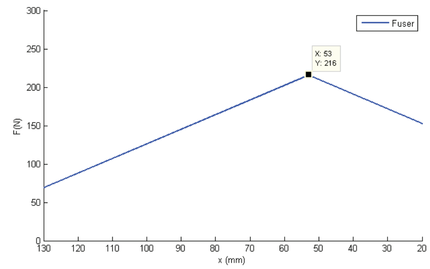
Numerous literature on bone cutting forces exist [8][9][10]. While these papers provide information about the relationship between bone cutting forces in different directions, chisels and speeds, the setups do not resemble a situation comparable to the cutting of bone with high-load orthopedic instruments. Furthermore, specimens tested have significantly different properties than human cortical bone[8]. Therefore, the necessary data was obtained with an experiment.

The goal of this experiment was to retrieve the maximum bone cutting force when cutting hard human bone with a high-load orthopedic instrument.

Experiment instrument Many types of orthopedic instruments exist, such as rongeurs, bone forceps and punches. Furthermore, many variations of every type are possible. To indicate: 25 different rongeurs, of which 3 per type circulate through the Erasmuc MC hospital. Because the instruments show similarity in construction and working principle, one representative instrument can be used to develop a solution that is applicable for the other instruments as well. Noting the

Table 1: Determining maximum user gripping force

Variable	Value[1]	(influence on) F_{user} [2]
Grip type	power grip[3]	-
Sex and age	female, 60 yr	$F_{user,max}$ = 293 N
Sitting/standing	no influence	-
Which hand	dominant hand	-
Shoulder posture	20° abduction[4]	
Elbow flexion	30-120°	$F_{user,max} \cdot 73.8\%$
Wrist deviation	10°	
Wrist flex./ext.	10°	
Hand span	20 -100 mm [5]	$F_{user,max} \cdot 0.738 - 1.9(x_r - 53)$
$\boldsymbol{F_{user}}$ **=**	$\mathbf{216 - 1.9(x_r - 53)}$ (shown on the right)	



[1] The values were based on observations in the operating room and dicussions with surgeons.
[2] Taken from [4][5][6][7]
[3] See Fig. 6
[4] See appendix for explanation of these values
[5] Case person's maximum grip span A.32

time individual large, high-load instruments were used, showed the rongeur was used most frequently during orthopedic operations. Furthermore, the highest percentage (60%) of the survey participants indicated to have problems with the rongeur. Therefore a Luer-Stille "original" is used (Fig. 4), which was the largest rongeur in terms of handle span and beak size as used in the Erasmus MC.

Experiment tissue Bone hardness is not only dependent on the individual bones, but also affected by age, gender, type of bone, the mobility of the person and degenerative diseases such as osteoporosis [11]. To comply with the "worst case scenario it is important to establish the maximum amount of force needed, therefore hard human cortical bone was used. During surgery, the surgeon cannot choose the alignment of the osteophytes, because the patient is stationary. Therefore, the direction of highest cutting resistance, SI/transverse [12], was used (Fig E.40).

Experiment protocol and results Ninety 15-mm slices of human cadaveric tibia were cut with an experimental setup that imitated the cutting of an osteophyte (Fig. 4). A pull bench provided which forces the handles to close simultaneously through a pulley system (4).the force-displacement profiles of cutting the pieces with the rongeur. The full experiment protocol can be found in Appendix E.

Figure 5 is a plot of some of the bone cutting forces, including the run that exceeds F_{user} for the longest Δx_{device} and the run with the highest peak force.

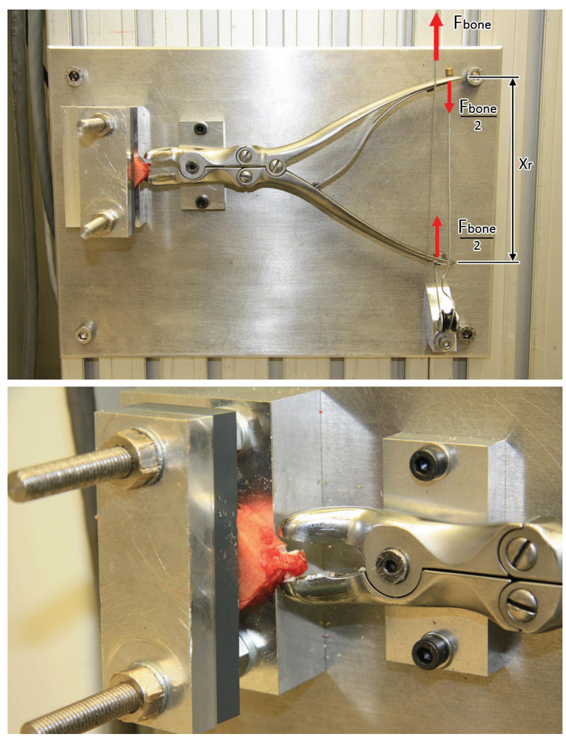


Figure 4: Setup imitating cutting of an osteophyte. A pull-bench pulls the rongeur handles closed and measured the necessary bone cutting force as a function of handle span, plotted in Fig. 5

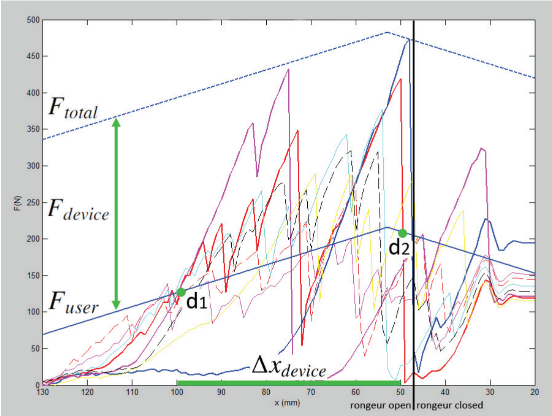


Figure 5: Plot of some of the bone cutting runs (measured at the end of the rongeur handles). Simplified bone cutting force F_{total} and user gripping force F_{user} are shown, as well as Δx_{device}.

The largest bone cutting force was found at x_r=48, where $F_{total}(48)$ = 474N and $F_{user}(48)$ = 207N, as measured at the end of the rongeur handles (Fig. 4). With this information, the technical requirements were calculated:

$$k_{device} = \frac{F_{total}}{F_{user}} = 2.2 \quad (2.5)$$

$$F_{device} = \frac{F_{total}}{F_{user}} = 267\text{N} \quad (2.6)$$

The assistance must be present during an interval Δx_{device} 50 mm (Fig. 5).

2.2. *Qualitative requirements*

The qualitative requirements were used to guide the design process and for the concept selection.

They were gathered by watching operations (Table B.8 and C.38), conducting a survey[6] (see B.33 and B.36), reviewing literature and discussing with medical company and lead users (J.15). The well-known implications of using devices in the OR (operating room) environment were also included. This partly sterile environment is bounded by strict regulations and specific demands on many aspects such as instrument handling, human interaction and safety measures.

The qualitative requirements were summarized in Table 2, which also shows the guideline for scoring the concepts to the qualitative requirements, used in the multicriteria analysis (Table 3).

Fit for all hand sizes Surgeons complain about the sheer size of the high-load orthopedic instruments [3]. 60% of the survey participants thought their problems were also caused by their hands being too small to properly grip the instruments (Table B.33). Therefore, the device should be adaptable to different hand sizes, and people with smaller hands should be able to get a firm grip on the instrument. The maximum grip span was estimated to be 100 mm (Fig. A.32) with the power grip (Fig. 6, observing operations showed that this grip was most used).

Haptic feedback Operating accuracy depends highly on the haptic feedback[7] that surgeons receive through the instruments. Basically, a two step technique is used with the conventional instruments. First a small gripping force is to feel and inspect if the right rissue is being cut. Secondly, upon verification, a high force is applied for actual separation of the tissue. If the haptic feedback during the first step is too different from what can be expected in practice, it could increase the risk of cutting undesired tissue. During some types of surgery, this might be branches of the spinal chord, which touching or scraping might severely affect body functions. Therefore, the proposed device must maintain haptic feedback during the first step of bone cutting. Preferably, a physical connection is established between the user hands and the instrument to increase accuracy within this cutting step.

Instrument stability To maintain current accuracy the new device should have minimal clearance within its own design and within the connection with conventional instrument (parts).

Single handed operation The device could ideally be operated with one hand only. Surgeons prefer to use their non dominant hand for other purposes, such as holding a suction device or grasper.

Safety of operation The device must be intrinsically safe, which means that the device should not release energy without user input, and should contain no switches that can be accidentally operated. It should also not release uncontroleld forces when a part breaks as a result of wear. Therefore, a voluntary opening

[6]among 26 Orthopedic surgeons and 5 neurosurgeons, for results see Fig. B.33

[7]feedback of forces and displacement

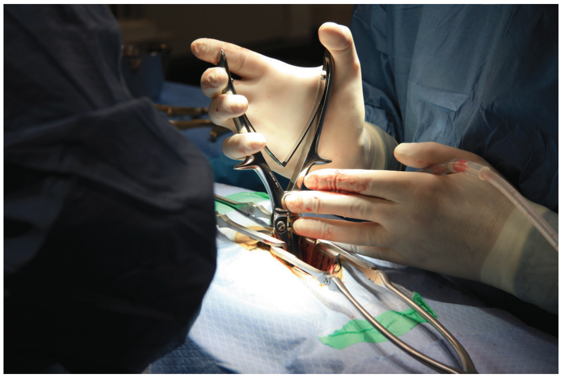


Figure 6: This figure demonstrates the grip that was most used by the observed surgeons. With this grip, called the power grip, the instrument is held in the palm of the hand with the force from the thumb opposed by the combined forces from the other fingers, and muscular force application is dominant [13]. Also visible is the need to be able to operate the instrument single-handedly. In this case the other hand is used to accurately direct the instrument and hold a suction device.

device is desired.

Excision speed In general, it is desired that operations should be performed in the shortest time with the best accuracy and maximum patient safety. with as little as compromise among each. Therefore, bony tissue should be removed as fast as possible, and the new device should by no means increase the average operation time.

Simple construction A simple construction without complex or vulnerable parts made is preferred, since observations show that the instruments are treated rough and costs must be kept to a minimum. The current reductions in reimbursement and limited resources, hospital administrators and operating room managers have to be careful about adopting new technologies into the operating room. Hospitals must balance the improved care or operating speed a new technology can provide on the one hand with its additional costs on the other hand [14].

Minimum overhead Overhead is the amount of time and work used for preparing and using the proposed device. This includes attaching peripherals, setting up power lines, detaching device, etc. Basically every additional action to the routine situation is considered overhead and should be avoided.

Sterilization There are many factors that have to be considered to determine whether and how a device can be sterilized[8] with existing methods (such as autoclaving) [15]. The head of the central sterilization department of the Erasmus MC explained that if the device has crevices and hinges like the existing rongeurs, it should be no problem to steam-sterilize as normal. Tight areas such as tubes, and electronics, should be avoided.

[8] the absolute elimination or destruction of all forms of microbial life

Table 2: Qualitative design requirements and scoring guidelines for the multi-criteria analysis

Requirement	Score 1 when:	Score 5 when:
Usable with all hand sizes[1]	Small hands can't grip instrument	Firm grip with small hands possible
Haptic feedback[2]	None left	Same as current
Instrument stability	Indirect, distal grip on rongeur with possible play	Direct, firm grip on rongeur
Single handed operation[3]	Significant work needed from other hand	No other hand needed
Safety of operation[4]	Possible sudden or unstable movement	Device stationary without user input
Fast excision speed[5]	Multiple repetitive actions to close	No repetitive actions to close
Simple construction	Many (critical) parts, difficult to remove play	Few parts, solid construction
Minimum overhead	Multiple time consuming actions to detach/attach	Nothing to detach/attach
Sterilization	Must be disassembled in many parts	Same complexity as current rongeurs

[1] This means handle span during high-load action cannot exceed 100 mm, see Fig. A.32
[2] During first step of cutting process where tissue determining is essential
[3] Non-dominand hand hand not used to add force
[4] Safe construction for both patient and surgeon means no tissue damage can occur when the instrument is released
[5] Excision speed is ideally as fast as cutting soft tissue with a normal rongeur

3. Conceptual design

This section presents the conceptual design choices, followed by the most promising concept is selected. Finally, the working method of the final concept is elaborated.

3.1. Design choices

Before considering the design choices (Fig. 7), the author zoomed out on the process of bone excision by mechanical machining as the current routine practice (Appendix K). Other ways of achieving the intended goal, which was the removal of small sized pieces of bony tissue, were considered. From this higher level analysis, it was determined that mechanical machining by a hand powered and controlled device was most likely to be succesful in solving the problems while complying with the qualitative requirements.

The following design choices were then made based on the qualitative requirements. The design choices led to four concepts for a hand-powered device which can be attached to existing beak sections of orthopedic instruments (Fig. 9)

Changing current instrument or attaching a device The intended amplifiation or force addition can be established with either a redesign of the current rongeur or with a separate device that can be attached to current instrumentation. The latter option has the advantage that the existing instruments can be used and only a few additional new devices will have to be purchased. However, observations showed that surgeons can use up to 6 different bone excision instruments during surgery and change between instruments up to 40 times per operation. Furthermore, it became clear that surgeons would like the scrub nurse to hand over instruments in under 2 seconds. As a consequence, attaching and detaching a separate new device would significantly slow down the operation. Besides that, due to the different handle shapes and sizes of the rongeurs, attaching a separate device to form one integrated cutting instrument for all existing types would pose a big challenge. An integrated design for the rongeur is less likely to enounter stability issues and could potentially decrease operating time. To avoid high purchasing costs, inventory could be gradually replaced.[9]

[9]rongeurs and bone forceps are replaced every 15 years, punches every 2 years

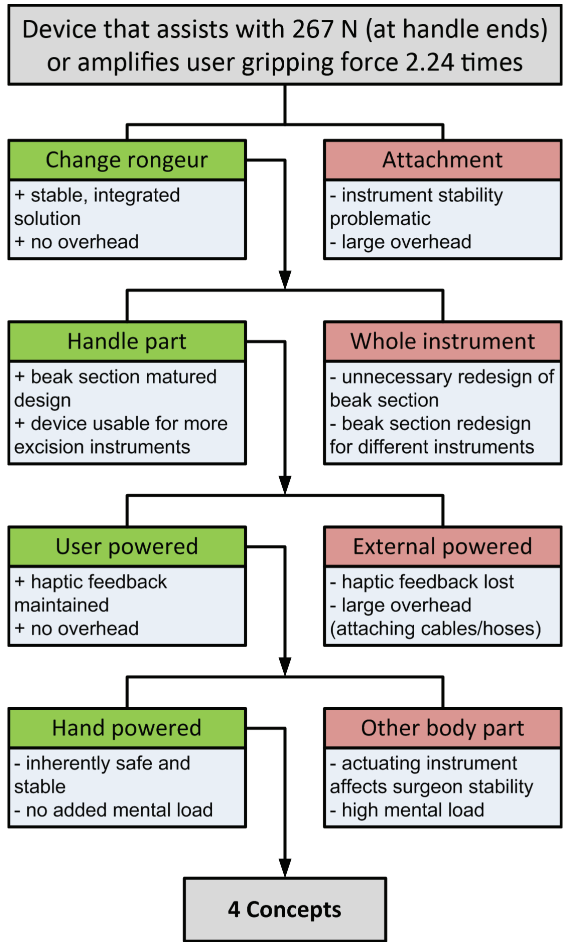


Figure 7: Design choices that led to the creation of four concepts.

Change the handle parts or the whole instrument Taking a closer look at the bone excision instruments circulating with the Dudok tracking system at the Central Sterilization Department of the Erasmus MC, showed that many of the large high-load instruments are of similar construction: a handle and a beak section, connected by screws that serve as hinges(Fig. 8). Therefore, it was possible to create a device that can be attached to existing beak sections. This way, only the handle parts of existing instruments needs to be replaced, reducing costs and making it more likely to make the device a success.

User powered or externally powered The power sources for the device can be divided into user power or external power. External power, such as springs

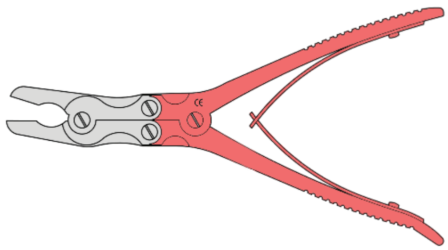


Figure 8: Handle section of rongeur shown in red. Because many problematic instruments are based on the same construction, the handle parts can be exchanged.

and pneumatics could assist with force generation and decrease the surgeon's effort. Weight should not have to be a problem, because springs and pneumatics posess a high power-to-weight ratio [16]. However, haptic feedback, which is essential during the first step of the cutting process, is lost[10]. Furthermore, overhead is substantially increased because the power source has to be connected and/or recharged. User power is always available. Moreover, haptic feedback is maintained, making a user powered device more safe.

Hand powered or powered by other body part User power can come from the hand or from another body part. In the world of prosthetics, the work needed to open the prosthesis is usally generated by moving another limb, such as the shoulder [16]. This demands previous installation of a harness and a means to transmit the force, introducing overhead. Furthermore, actuating the instrument effects the surgeon's stability and introduces a higher mental load on the surgeon. Therefore, the hand is the power source of choice.

Thus, concepts were designed that can replace the existing handles,attach to the existing beak sections and mechanically amplify user gripping force.

3.2. Concepts

Following the line of reasoning from the design choices, mechanical amplification of the user gripping force was most likely to provide the best solution. Two methods of mechanical amplification were considered: a lever system or gear system. Four concepts were made (Fig. 9).

Subsequently, these concepts were evaluated.

[10] To illustrate: a survey conducted by the author showed 16 out of 25 people were afraid they would lose feeling when using the KAIRison pneumatic punch [17]

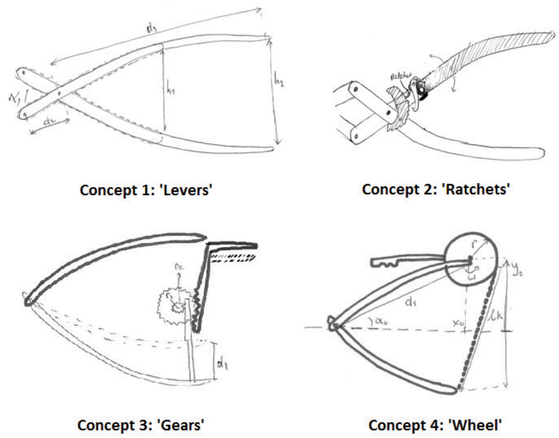


Figure 9: The four concepts. Concept 1: elongated handles. Concept 2: extra amplification enabled by retracting handle and a ratchet-pawl system. Concept 3: two gears on the same shaft amplify gripping force. Concept 4: a wheel and chain amplify user gripping force. For further explanation of the concepts and a technical analysis, see Appendix I

3.3. Concept selection

The following steps were used to select the final concept out of the four concepts.

1. **Evaluate technical feasibility**

   Initial calculations were made to see whether individual components would not become too large to handle, could withstand mechanical stresses involved and would not conflict with other parts. This analysis proved 3 out of 4 concepts technically viable (Fig. 9: Concept 2-4). Concept 1 ('levers') was not feasible, because elongating the handles increased handle span, thus making the device even more difficult to grip with small hands.

2. **Evaluate qualitative requirements**

   A multicriteria analysis was used to asses the qualitative requirements for the concepts that were technically viable (Concept 2, 3 and 4). Only signifant results (larger than 0.5 point difference) were taken into account. Concept 2 ('ratchets') scored significantly better than the other two and was therefore chosen as the final concept.

Opinions of a medical company and lead users were highly important during this latter process.

Table 3: Multicriteria analysis of concepts

	Factor	Weight	Factor x Weight	Concept 2 'ratchets'	Concept 3 'gears'	Concept 4 'wheel'
Requirements						
Haptic feedback	2	5	10	5	3	3
Instrument stability	2	5	10	5	3	3
Single handed operation	2	5	10	4	4	4
Safety of operation	2	5	10	5	5	5
Minimum overhead	1	5	5	4	4	4
Excision speed	1	4	4	4	3	3
Simple construction	1	3	3	5	2	3
Sterilization	1	2	2	4	5	4
				4.6	**3.6**	**3.7**

Concept 2 'ratchets' scored significantly higher than concept 3 and 4.

3.4. Final concept: ratchet

From the basic mechanical relation of torque equals force times distance, it follows that amplifying the user gripping force increases the distance the device handles have to travel to close the instrument beak. Therefore, a system was needed that maintains the same handle travel but can still close the beak with the available travel the users hand can make. Inspiration for such a system came from a ratchet pruner, available in any hardware store. A simple ratchet system is used in these pruners to enable closing of the beak with multiple hand contractions. The author was also looking for a way to design the device such that it can be used in "normal mode" as well in "amplification mode". That way, the surgeon does not have to contract his/her hand multiple times to close the instrument or change to a normal rongeur when cutting soft tissue. The idea for such a ratchet system came from a patent of a two-phase pressure-applying device [18] (Fig. 10).

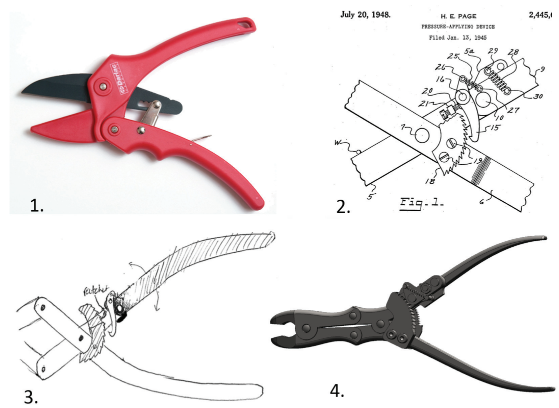


Figure 10: Inspiration for the final concept came from a ratchet pruner (1), and with the help of a patent [18], evolved (3) into the current design (4).

These systems were developed into the device as is shown in Fig. 10. The device is a redesign of the handle part of the rongeur and can be attached to the beak sections of different types of excision instruments. This way existing instrumentation can be changed without purchasing entirely new instrument, and medical companys can maintain part of the production process.

Working principe Following figure 24, the invented device has two operating modes: traditional mode or amplifier mode . In *traditional mode* (where the amplification is not used), the surgeon can use the device on softer tissues and during the first phase of the cut. This way, the haptic feedback is exactly the same as with the current rongeur, and the surgeon will not have to adapt to changing feedback. When hard tissue needs to be cut, the surgeon closes the device until (s)he cannot advance further. The *amplification mode* is then enabled by loosening the hand grip and making the pre-loaded spring rotate the hinging handle outwards. The pawl then advances down on the ratchet. The surgeon opens his/her hand and the upper part of the handle until his maximum grip span is reached, and then presses back both handles. This causes an extra amplification of 2.2x (experimentally determined) is then generated, making sure (s)he can advance through bony tissue. This process of reopening the upper handle and closing both handles is repeated until the beak of the device is closed. The device can then be opened again. For a step-by-step explanation of the working principle, see Figure 24.

In this section, some design considerations of several parts are discussed.

Handle block for traditional mode The handle block is responsible for one of the unique features of the device. It enables the surgeon to use the device in traditional mode, as if it were a normal rongeur. Fig. 11 illustrates how. Because of this block, the handle can only be retracted outwards, but makes contact with the rest of the handle when these parts are in line.

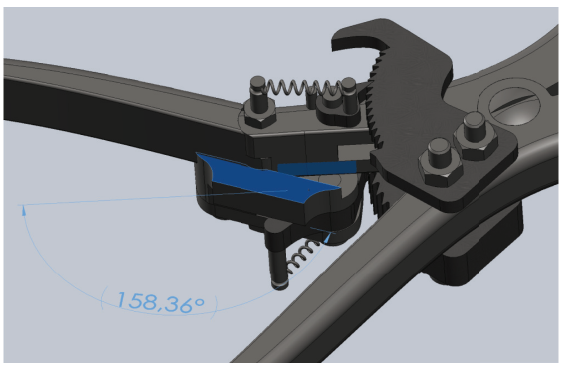


Figure 11: The handle blocker, shown in blue, prevents the active handle to make an angle over 180 degrees with the rest of the handle because it is blocked by the rest of the handle (light blue patch). This way, the device can still be used in normal mode without using the amplification.

Front high-load pawl and ratchet

The amplification of the device in amplification mode relies on the high-load pawl and ratchet on the front. Some aspects to this design are the pawl size, the amount of teeth on the ratchet, and the geometry of both parts. First of all, the pawl must be as small as possible within safety factor limits, so the amount of teeth on the ratchet can be maximized. However, the minimization of pawl size is limited by the forces on the pawl and ratchet, which are in the order of 1000N. The highest amount of teeth possible with the smallest possible pawl size was 13, dimensions can be found in appendix [].

To make sure the pawl doesn't push itself out of the ratchet, a tooth geometry guideline must be followed. A line perpendicular to the face of the ratchet-wheel tooth must pass between the center of the ratchet wheel and the center of the pawl pivot point[19] (Fig. 12). The ratchet and pawls were designed according to these guidelines.

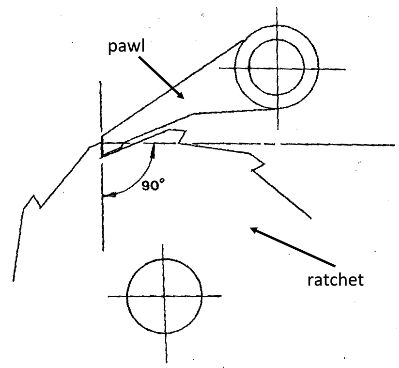


Figure 12: Ratchet design rule of thumb: A line perpendicular to the face of the ratchet-wheel tooth must pass between the center of the ratchet wheen and the center of the pawl pivot point to prevent the pawl pushing itself out. [19]

Back low-load pawl and ratchet

When the device handle (active handle, Fig. 16) is retracted to prepare for another squeeze, the beak section must not re-open but stay in its current position. However, when the beak is fully closed, its must be able to open again. Therefore a bistable pawl&ratchet construction has been added on the back of the device (Fig.13). When the device is in its open position, the pawl is pulled against the ratchet. When the device is almost fully closed, the design of the ratchet rotates the bi-stable pawl to its other position. The beak can then be opened. When the beak is almost fully open, the ratchet engages with the special shape of the ratchet and is rotated back past its bistable point and flips to the position where it is pulled against the ratchet.

The idea of the design of the bi-stable system and especially the part flipping the pawl in its end states, came from the armrest in passenger cars. Such an armrest, of which a picture from a patent [20] is shown in Fig. 14, can be set in several positions and can be moved all the way down again when it reaches the upper position.

Because this construction is only meant to keep the beak open, its only has to counteract the forces of the spring pushing the device open. Therefore, the ratchet teeth and pawl can be smaller than those of the high-load ratchet and pawl so more locking positions are possible.

Bi-stable parts Two bi-stable pawls have been incorporated in the design, one for locking the beak and one for the amplification function. The defining

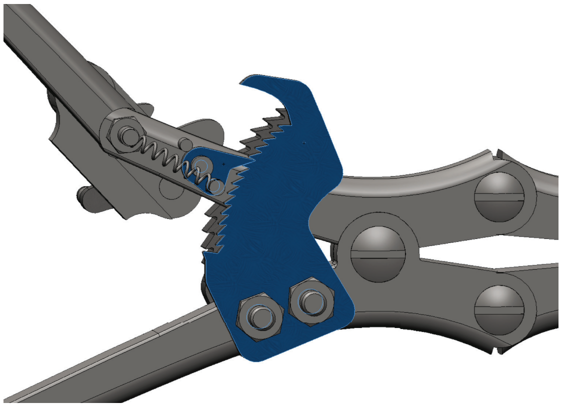


Figure 13: Back of the device showing ratchet and pawl that keep the beak section from opening when the device handle is retracted for another squeeze.

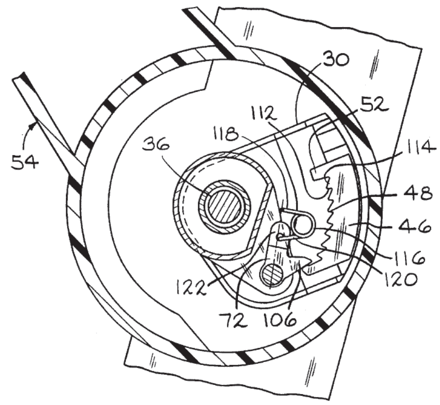


Figure 14: The idea of the design of the bi-stable system and especially the part flipping the pawl in its end states, came from the armrest in passenger cars. This figure shows the patent from Bart [20] for such an armrest which was used as inspiration.

characteristic of bistability is simply that two stable states (minima) are separated by a peak (maximum). Bistability as applied in the design of mechanical systems is more commonly said to be "over centre". Work is done on the system to move it just past the peak, at which point the mechanism goes "over centre" to its secondary stable position. The result is a toggle-type action. For the front, high load pawl, this is desirable when the device's amplifying fuction is not necessary: the pawl does then not have to be pulled back when the device is fully closed and can be flipped to its non-active state. For the back, low-load pawl, this is necessary to enable opening the device again once its fully closed. (see instructions in section 24)

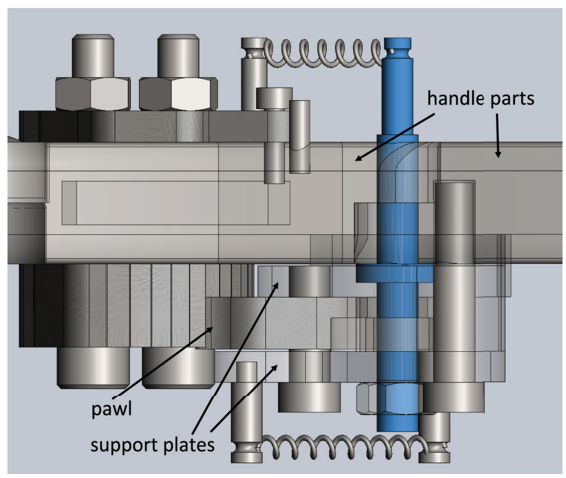


Figure 15: The connection shaft, shown in blue, has several extrusions to prevent handles from generating too much friction with one another, but still enable the support plates to be bolted firmly onto the handle.

Connection shaft The connection shaft (Fig. 15) needs to connect the handle parts and the support plates. The shaft has a special design to make sure that the pressure between handle parts and the pressure between the support plates and the active handle part can be regulated with different nuts. The support plates are pressed against the extrusion on the shaft so do not affect the pressure between the handle parts. The latter should not be too much or too much friction will occur for proper operation. That is why the nut holding the parts together is driven onto another shaft extrusion and not agains the handle itself.

4. Dimensional design

4.1. Dimensioning

The goal of this section is to present the calculations for important device dimensions (dn_1 and dn_2, Fig. 16 and Table 4) such that the amplification of the device is exactly as intended. From these values, dn_3 and dn_4 follow. Then, the resulting amount of squeezes necessary to close the device were calculated.

Device amplification ratio

To determine dn_1 and dn_2 it is first important to know what the amplification ratio is of the normal rongeur. This enable calculation of the forces that are delivered to the beak (F_h, Fig. 16).

It is known that the user force F_t, acting on the original rongeur at the end of the handles (Fig. 16, must be amplified 2.2 times at that point (see equation 2.5). Because we are interested in the forces delivered to the beak (F_h), we first calculate the amplification ratio of the rongeur.

$$F_h = \frac{F_{user}}{2} \cdot k_{rongeur} \tag{4.1}$$

$$k_{rongeur} = s_2/s_1 = \frac{d_1 \cos(\alpha_1)}{d_2 \cos(\alpha_2)} \tag{4.2}$$

Since angles α_1 and α_2 change during closing of the instrument, the rongeur amplification ratio changes between the open and closed state of the handles and beak. Therefore, $k_{rongeur,open}$ and $k_{rongeur,closed}$ were calculated (Fig. 17)

$$k_{rongeur,open} = s_1/s_2 = \frac{d_1 \cos(\alpha_{1,open})}{d_2 \cos(\alpha_{2,open})} = 5.2 \tag{4.3}$$

$$k_{rongeur,closed} = s_1/s_2 = \frac{d_1 \cos(\alpha_{1,closed})}{d_2 \cos(\alpha_{2,closed})} = 7.3 \tag{4.4}$$

The device must amplify $k_{rongeur,open}$ and $k_{rongeur,closed}$ 2.2 times, which gives:

$$k_{device,open} = 2.2 * k_{rongeur,open} = 11.6 \tag{4.5}$$

$$k_{device,closed} = 2.2 * k_{rongeur,closed} = 16.4 \tag{4.6}$$

With these values, it can be calculated whether the new ratchet handles can deliver the desired amplification ratios in the open and closed position (Fig. 17 and equation 4.5). The following assumptions were made (Fig. 16:

- the lower part of the device is fixed
- the pawl is locked into the ratchet, so it is fixed in y direction.
- the pawl axis is considered fixed as well

Thus, the upper handle hinges around the fixed point shown in Fig. 16. Analogous to the current congeur, the amplification ratios for the open and closed positions of the new design are calculated:

$$F_h = F_p \cdot \frac{sn_3}{s_2} = \frac{F_{user}}{2} \cdot \frac{sn_1 + sn_2}{sn_2} \frac{sn_3}{s_2} \tag{4.7}$$

The amplification ratio of the new device consists of two parts:

$$k_{device} = \frac{sn_1 + sn_2}{sn_2} \frac{sn_3}{s_2} \tag{4.8}$$

$$k_{device} = \frac{dn_1 \cos(\beta_1) + dn_2 \cos(\beta_1)}{dn_2 \cos(\beta_1)} \frac{dn_3 \cos(\alpha_1)}{d_2 \cos(\alpha_2)} \tag{4.9}$$

$$k_{device} = \frac{dn_1 + dn_2}{dn_2} \frac{dn_3 \cos(\alpha_1)}{d_2 \cos(\alpha_2)} \tag{4.10}$$

It follows from 4.8 that the device also has a variable amplification ratio because of changing angles, just like the original rongeur. The changing angles have no influence on the first part of the amplification ratio because the term $\cos(\beta_1)$ can be eliminated (see Equation 4.8). However, the second part does influence the amplification ratio depending on the position of the device handles.

Just like was done for the original rongeur, the equations for the amplification ratio in the open and closed position can be calculated using 4.8:

$$\begin{aligned} k_{device,open} &= \frac{dn_1 + dn_2}{dn_2} \frac{dn_3 \cos(\alpha_{1,open})}{d_2 \cos(\alpha_{2,open})} \\ &= \frac{dn_1 + dn_2}{dn_2} \cdot 1.9 \end{aligned} \tag{4.11}$$

$$\begin{aligned} k_{device,closed} &= \frac{dn_1 + dn_2}{dn_2} \frac{dn_3 \cos(\alpha_{1,closed})}{d_2 \cos(\alpha_{2,closed})} \\ &= \frac{dn_1 + dn_2}{dn_2} \cdot 2.6 \end{aligned} \tag{4.12}$$

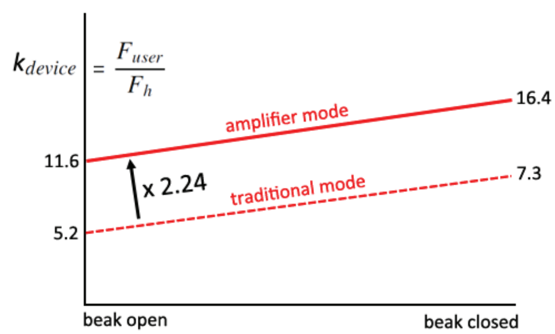


Figure 17: Amplification ratio of the device in traditional and amplifier mode, simplified to lineair relation. In traditional mode, the device has the same amplification as the unchanged rongeur. In amplifier mode, this amplification is increased 2.2 times, as determined necessary (section 2.1.2. For meaning of symbols, see Fig. 16)

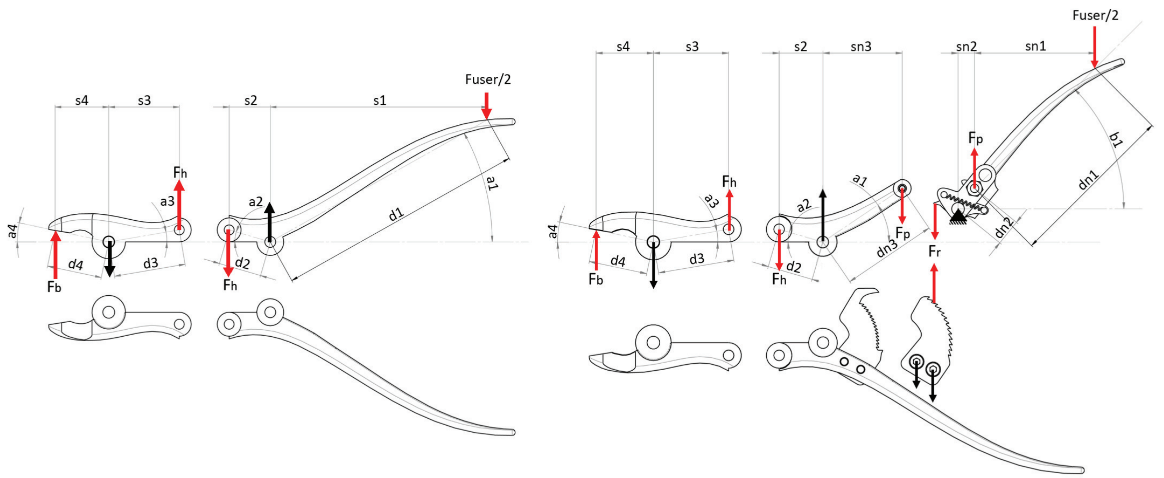


Figure 16: Static analysis of current rongeur (left) and device (right). The bottom half of the instruments is assumed fixed for calculation purposes. All forces in y-direction were considered and the values shown in Table 4. The triangle indicates a point that is assumed fixed because the pawl locks into the ratchet. The amplification ratios are defined as as input force F_t divided by F_h.

Using the device amplification ratio's at open and closed position of the current rongeur (Eq.4.5) and Equations 4.11/4.12 gives:

$$\frac{dn_1 + dn_2}{dn_2} = \frac{11.6}{1.9} \qquad \frac{dn_1 + dn_2}{dn_2} = \frac{16.4}{2.6} \tag{4.13}$$

$$\frac{dn_1 + dn_2}{dn_2} = 6.1 \qquad \frac{dn_1 + dn_2}{dn_2} = 6.3 \tag{4.14}$$

This implies that the deviation from the exact needed amplification ratio between open and closed position, Δk_{device} is:

$$\Delta k_{device} = \frac{6.3 - 6.1}{6.3} = 3\% \tag{4.15}$$

These formulas prove that if a combination of dn_1 and dn_2 is chosen such that $\frac{dn_1+dn_2}{dn_2} = 6.2$, an amplification is achieved that deviates a maximum of 1.5% from the exact desired device amplification. Now dn_1 and dn_2 can be determined.

Table 4: Dimensions and angles rongeur and device*

$\alpha_{1,open}$	$= 29.9°$	$\alpha_{2,open}$	$= 16.2°$
$\alpha_{1,closed}$	$= 8.4°$	$\alpha_{2,closed}$	$= 37.7°$
d_1	$= 125$	d_2	$= 21.5$
d_3	$= 35.9$	d_4	$= 27.6$
dn_1	$= 80$	dn_2	$= 15.4$
dn_3	$= 125 - dn_1 = 45$		

* See Fig. 16

Determining dn_1 and dn_2

There are several possibilities for dn_1 and dn_2. They were determined with these boundary conditions:

- dn_1 has a minimum value of 80 mm (average female hand width [11])
- Minimize amount of necessary squeezes to close instrument: maximize dn_2, minimize dn_1.
- Minimize forces on ratchet: maximize dn_2, minimize dn_1.

All combinations of dn_1 and dn_2 that lie on the green patch in Fig. 18 give the device the necessary amplification ratio (Fig. 17. Using the boundary conditions, the values were determined as follows:

$$dn_1 = 80 \qquad dn_3 = 45 \tag{4.16}$$

$$dn_2 = 15.4 \qquad dn_4 = 21.5 \tag{4.17}$$

Amount of squeezes

It is now calculated how many times the device has to be squeezed in the "worst case situation", in which amplification is needed during Δx_{device}=50 mm. To calculate this, the necessary displacement of point 2 (dp_2, Fig. 19) should be determined for fully closing the beak.

[11] http://dined.io.tudelft.nl/

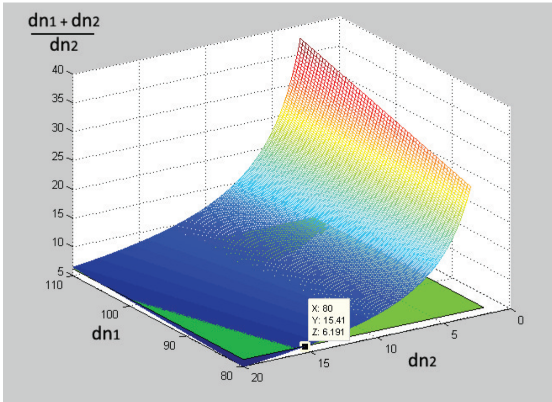


Figure 18: All combinations of dn_1 and dn_2 on the green patch create a wanted new amplification factor (11.6-16.4x). The highlighed point was selected based on the boundary conditions: $dn_1 = 80$ $dn_2 = 15.4$

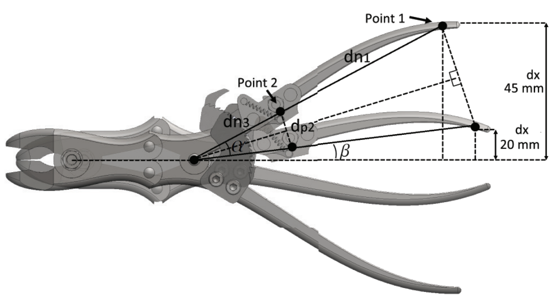


Figure 19: Dimensions and angles used for calculating necessary displacement of point 2 (d_{p2})

By calculating angle β (Fig. 19);

$$\beta = \arcsin \frac{20}{dn_1 + dn_3} \tag{4.18}$$

α can be calculated:

$$\alpha + \beta = \arcsin\left(\frac{45}{dn_1 + dn_3}\right)$$

$$\alpha = \arcsin \frac{45}{dn_1 + dn_3} - \arcsin \frac{20}{dn_1 + dn_3} = 11.9° \tag{4.19}$$

Figure 19 shows that:

$$\sin\left(\frac{\alpha}{2}\right) = \frac{1}{2}\frac{d_{p2}}{dn_3} \tag{4.20}$$

With this, the total necessary displacement of point 2, d_{p2} is calculated.

$$d_{p2} = 2dn_3 \sin\left(\frac{\alpha}{2}\right) = 9.3\text{mm} \tag{4.21}$$

This means that, if the device needs to assist the user during 50 mm of handle displacement, point 2 needs to displace 9.3 mm. If we now determine how much point 1 (Fig. 20) displaces on average for every squeeze, we can calculate how much point 2 displaces per average squeeze as well.

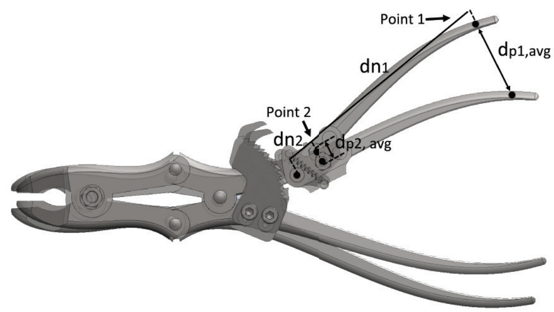


Figure 20: Dimensions and angles used for calculation of the average displacement of point 2 ($d_{p2,avg}$) for the average closing distance ($d_{p1,avg}$)

The term 'average squeeze' is defined, because if amplification is just needed, the handles have a span of 90 mm (2·45mm), leaving only 10 mm (2·5mm) of space to retract the active handle (Fig. 20), because the maximum hand span is 100 mm (see A.32). However, during the last squeeze, the device handles are much closer to each other leaving more space for retracting the active handles, thus making a larger displacement of point 1 (d_{p1}) possible. The average displacement of point 1, $d_{p1,avg}$, is calculated as follows:

	dx	max. hand span	d_{p1}
first squeeze	45	50	5
last squeeze	20	50	30
$d_{p1,avg} = (30 + 5)/2 = 17.5$ mm			

With $d_{p1,avg}$, $d_{p2,avg}$ can be calculated: this is the average vertical displacement of point 2 for every squeeze.

$$d_{p2,avg} = \frac{dn_2}{dn_1 + dn_2} \cdot d_{p1,avg} = 2.8 \tag{4.22}$$

This then enables to calculate the number of squeezes necessary to completely close the device

$$n = \frac{d_{p2}}{d_{p2,avg}} = \frac{9.3}{2.8} = 3.3 \tag{4.23}$$

So, in the "worst case scenario", 3.3 squeezes are necessary to close the attached beak. In situations other than this scenario, less than 3 squeezes will be enough to excise the bone piece.

4.2. Dimensioning of critical parts

All parts that encounter high forces (shaft, pawl, plate and ratchet, see Fig. 23) were tested with the finite element analysis package Solidworks Simulation Xpress v10, Dassault Systemes, USA. The results obtained from this package were verified by simplified calculations. To determine a proper choice of part dimensions, a uniform distributed load (Table 5 is applied in its working direction which are seen in Fig. 23.

The gripping force of the user is divided between the two handles, so (see section 2.1.2):

$$F_t = \frac{F_{user,max}}{2} = \frac{216}{2} = 108\text{N} \tag{4.24}$$

So the vertical reaction force in the shaft (Fig. 23) is equal to:

$$F_s = F_t \frac{sn_1}{sn_2} = F_t \frac{dn_1}{dn_2} = 560\text{N} \tag{4.25}$$

It is estimated that the total shaft force vector makes 60° with F_s. This means that:

$$F_{shaft} = \frac{F_s}{\cos(60)} = 1120\text{N} \tag{4.26}$$

The pawl and ratchet force are all assumed the same value as F_{shaft}. Because there are two plates taking the load of the shaft, the plate force is half of F_{shaft}, see Table 5.

Dimensions of these parts were then optimized to create a safety factor of at least 1. This means that the maximum von Mises stress that occurs in the parts stays below the yielding stress of the material. The von Mises stress is used to predict yielding of materials under any loading condition from results of simple uniaxial tensile tests. The von Mises yield criterion is applicable for the analysis of plastic deformation for ductile materials such as metals.

For the ratchets and pawls, toolmaking steel was used (1.2312, Young's modulus $2.1 \cdot 10^11$ N/m^2, yield strength $6 \cdot 10^8$ N/m^2). For the other parts, stainless steel was used (1.4401, Young's modulus $1.9 \cdot 10^11$ N/m^2, yield strength $5.2 \cdot 10^8$ N/m^2).

Results of the stress analysis are shown in Fig. 21 and in Table 5 and were checked with the following calculation for the pawl shaft. First the shear stress in the shaft is calculated

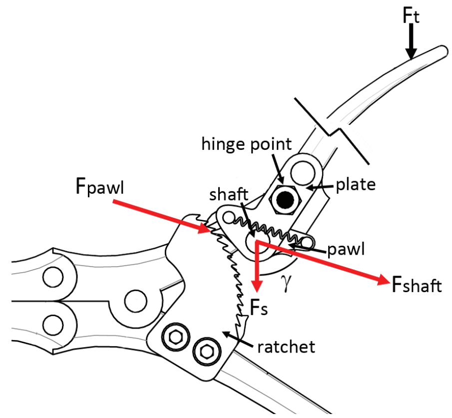


Figure 23: Load directions on critical parts

Table 5: Critical parts loads and simulation results

Part	Load (N)	SF	Max. displacement
F_{pawl}	1120	1.34	7.8 e-3 mm
F_{shaft}	1120	2.68	1.7 e-3 mm
F_{plate}	1120	2.3	2.6 e-2 mm
$F_{ratchet}$	560	1.81	1.6 e-2 mm

Maximum user gripping force, 216 N, is used as input, see section 2.1.2. For load directions and part locations, see Fig. 23. SF=Safety factor.

$$\tau = \frac{F}{A} = \frac{1120}{\pi r^2} = 89.1 \cdot 10^6 \tag{4.27}$$

The van Mises-Hencky theory states that a ductile material starts to yield at a location when the von Mises stress becomes equal to the stress limit. In case of pure shear stress, failure occurs if the shear stress exceeds τ_{max} (k_y=yield strength):

$$\tau_{max} = \frac{k_y}{\sqrt{3}} = \frac{520 \cdot 10^6}{\sqrt{3}} = 300 \cdot 10^6 \tag{4.28}$$

The safety factor SF for the pawl shaft is then calculated as follows:

$$\text{SF} = \frac{\tau_{max}}{\tau} = \frac{300}{89.1} = 3.37 \tag{4.29}$$

The calculated safety factor (3.37) is almost equal to the safety factor Solidworks calculates (3.35), so the results for the other parts are assumed correct as well.

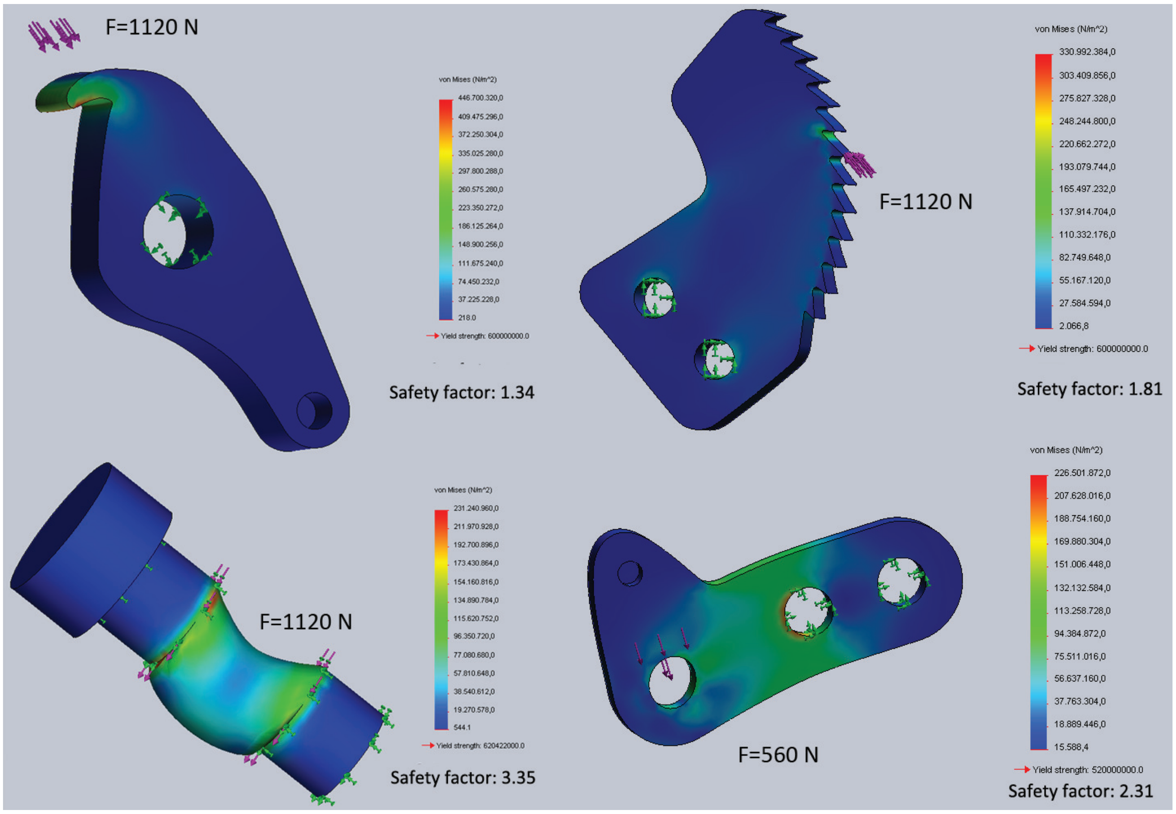


Figure 21: Solidworks Xpress stress results of critical parts, loaded with the calculated forces from Table 5 and in the directions shown in Figure 23.

Figure 22: The prototype. The front contains the mechanical amplifier with the high-load pawl and ratchet. The back of the device contains the locking pawl and ratchet, which keep the beak section in its position when the handle is retracted.

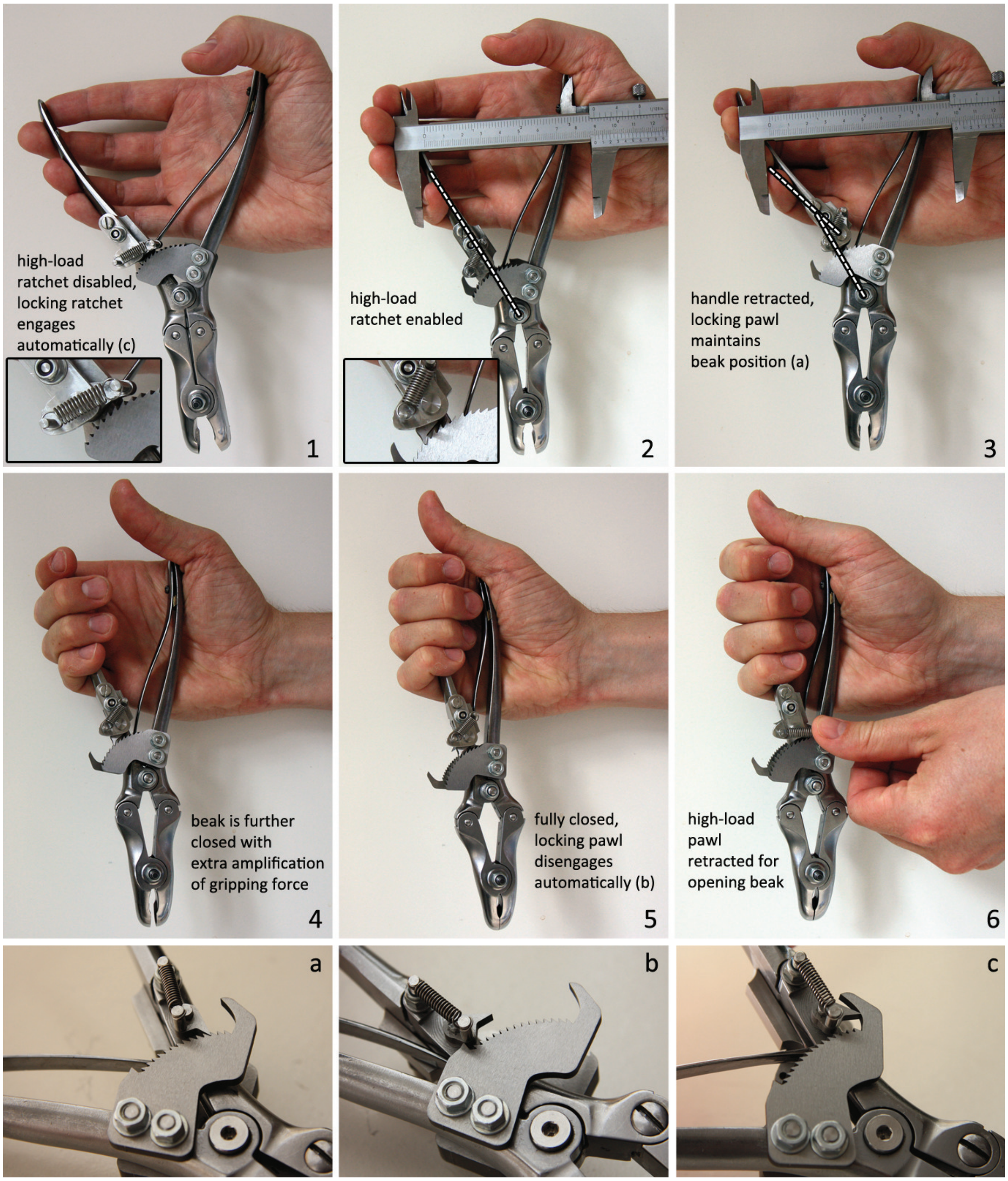


Figure 24: Operating the device. The high-load pawl is engaged by pulling it past its bistable point (1). The handles are closed upto the point that assistance is needed (2). Following the worst case scenario, this is 50 mm (x_{device}) before closing, so at 90 mm of handle span separation. The low-load ratchet on the back locks the beak section (a) making it possible to retract the instrument handle (3). Gripping force is now amplified at least 2.2 times, making advancing through the bony tissue possible (4). This process of handle retracting(3) and further closing(4) is repeated until the beak is fully closed (5). The beak section must then be able to open again, thus the locking ratchet on the back is pushed into its non-contact bistable position (b). The device can then be opened when the high-load pawl is retracted (6). Before the device is fully automatically re-opened, the locking ratchet is flipped back to its locking position (c).

4.3. Prototype

A prototype was created by adapting the rongeur used for the bone cutting experiment to prove the working principle of the ratchet system as an adjustable mechanical amplifier (Fig. 22). Pawls and ratchets were fabricated using electrical discharge machining.

5. Evaluation

Two aspects of the device were evaluated: a) the number of squeezes to close the beak in the "worst case situation" and b) the amplification ratio of user input force in amplification mode compared to the amplification in traditional mode (Fig.16 and Fig. 17).

Amplification ratio of device The device was designed to amplify F_{user} 2.2 times more in amplification mode than in traditional mode (see Eq. 4.5 and Fig. 17). This is indicated by the performance factor:

$$\text{Performance factor } PF = \frac{k_{device,ampl.mode}}{k_{device,trad.mode}} \quad (5.1)$$

It should deliver this extra amplification ratio during an interval (Δx_{device}) of 50 mm (Fig. 5), which is chosen to start at 50 mm before the instrument handles are in closed position, so at x_r=90 mm. The device operates satisfactory if the following conditions are satisfied:

$$130 \leq x_r \leq 90: \qquad PF \geq 1 \quad (5.2)$$

$$90 \leq x_r \leq 40: \qquad PF \geq 2.2 \quad (5.3)$$

To find the amplification factors of the device in traditional and amplification mode, the device is fixed in a setup as used to perform the bone cutting experiment. It is fixed to the setup by its hinge around which it can rotate freely (Fig 25). Two pulley-cable systems transmit the input force (resembling user gripping force F_{user}) and the output force (resembling F_h). The input force is delivered by a measured mass of 2,12 kg, corresponding with 20.8 N. The output force is measured with the same pullbench as was used for the bone cutting experiment (Fig. 4). Due to the outward flexion of the hinging device lever in amplification mode (lower lever in Fig. 25), x_r cannot be measured at the device handle ends. Therefore, x_r is translated to x_h, which is the distance between the hinges connecting the device to the beak section (Fig 25). For corresponding values of x_r and x_h, see Table 6.

F_h was measured three times for 10 different lever positions (x_r=130,120,110,100 mm) in traditional mode, and for 6 different positions in amplifier mode (x_r=90,80,70,60,50,40 mm). The results are shown in Table 6 and plotted in Figure 17.

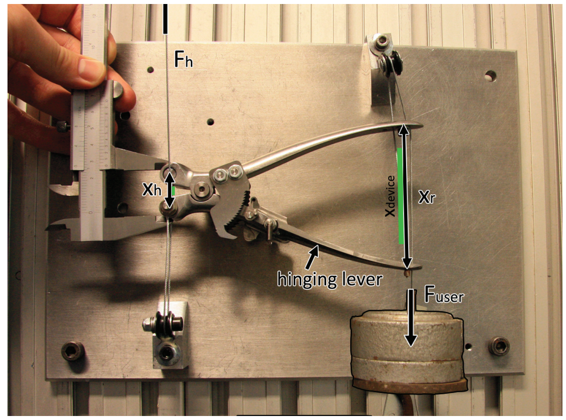


Figure 25: Experiment setup to evaluate the amplification function of the device in traditional and amplifier mode.

Number of squeezes To determine the amount of squeezes, the "worst case scenario" was imitated. This implies that the maximum distance between the handles (see Fig. 24) is 100 mm (see A.32) and the device is in amplification mode for Δx_{device}=50 mm (Fig. 5). The number of squeezes is determined as follows (see Fig. 24). First, the device is closed in traditional mode until reaching x_r=90 mm. Then, the handle is retracted. Pressing back on the handle closes the device further. This is repeated until the beak is fully closed and the amount of squeezes are recorded.

6. Results

A lineair regression is applied to the plotted results to determine the slope through these points.

First of all, the performance factor (Eq. 5.1) varied from 2.8 to 3.3 (Table 6 and Fig. 26). This means that in amplifier mode, the device amplifies the user input force with at least 2.8 times more than during traditional mode.

Secondly, the measured k_{trad} was 27-51% lower than the theoretical k_{trad}. Furthermore, in contrary to the theoretically expected increase in k_{trad} with decreasing x_r, k_{trad} decreased with decreasing x_r.

Similar results were found for the measured k_{ampl}, which was 18-35% lower than the theoretical k_{trad}. Furthermore, k_{ampl} decreased with decreasing x_r, gainst the calculated tendency.

Table 6: Evaluation results

x_r (mm)	x_h (mm)	traditional mode[1] F_h (N)	traditional mode[1] k_{device}	amplifier mode[1] F_h (N)	amplifier mode[1] k_{device}	PF [2]
130	19.1	81.7 +/- 4	3.9 +/- 0.2	82.2 +/- 2	4.0 +/- 0.1	1.0 +/- 0.05
120	21.3	78.6 +/- 2	3.8 +/- 0.1	79.6 +/- 3	3.8 +/- 0.1	1.0 +/- 0.04
110	22.6	74.6 +/- 5	3.6 +/- 0.2	80.3 +/- 1	3.9 +/- 0.1	1.1 +/- 0.07
100	24.4	77.6 +/- 3	3.7 +/- 0.1	77.4 +/- 4	3.7 +/- 0.2	1.0 +/- 0.06
90	26.0	76.7 +/- 3	3.7 +/- 0.2	231 +/- 6 †	11.1 +/- 0.3 †	3.0 +/- 0.2 †
80	27.5	77.6 +/- 3	3.7 +/- 0.2	233 +/- 6 †	11.2 +/- 0.3 †	3.0 +/- 0.1 †
70	29.0	74.7 +/- 4	3.6 +/- 0.2	234 +/- 6 †	11.2 +/- 0.3 †	3.1 +/- 0.2 †
60	30.4	73.0 +/- 3	3.5 +/- 0.1	231 +/- 9 †	11.1 +/- 0.4 †	3.2 +/- 0.1 †
50	31.9	75.0 +/- 1	3.6 +/- 0.1	227 +/- 9 †	10.9 +/- 0.4 †	3.0 +/- 0.1 †
40	33.2	79.8 +/- 3	3.8 +/- 0.1	227 +/- 5 †	10.9 +/- 0.3 †	2.8 +/- 0.1 †

The input force F_{user} = 20.8 N
† Amplification mode enabled
[1] Values are averages of three runs
[2] see Eq 5.2

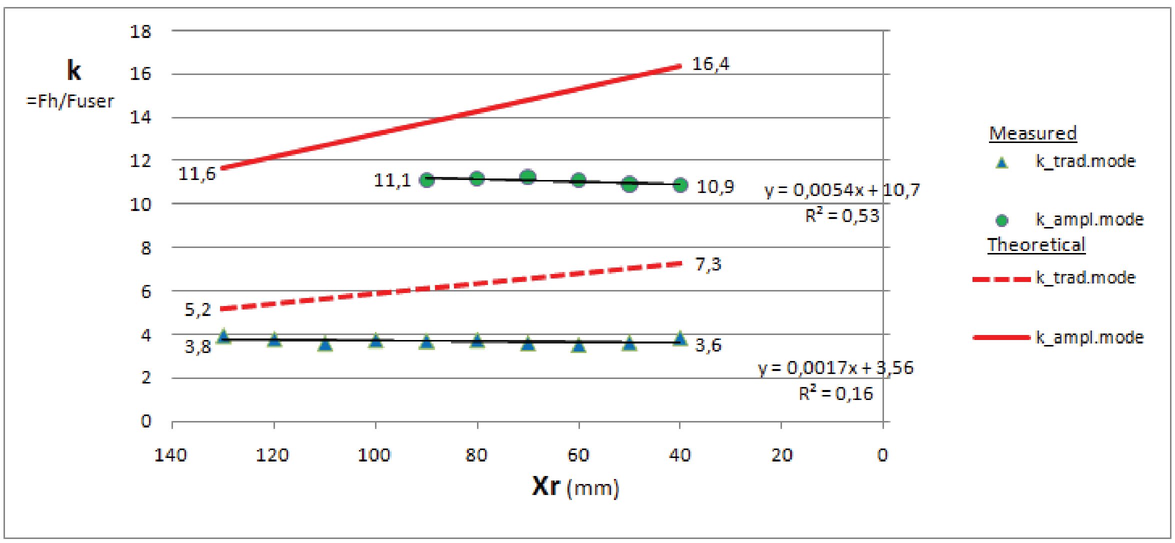


Figure 26: Theoretical and measured amplification factor k in traditional and amplification mode

Closing the device in the worst case scenario can be done in three squeezes, excluding the initial squeeze of the first part where the device is in traditional mode.

7. Discussion

In this paper, a solution is presented to the problems surgeons with smaller hands and less gripping force encounter when using high-load orthopedic instruments. A device was developed and evaluated that enables surgeons of any age, gender and gripping strength to operate bone excision instruments with their dominant hand only during high-load orthopedic actions. The device does so by amplifying the users gripping force with a ratchet-like mechanism. Furthermore, it complies to large extent with other, qualitative requirements, such as providing haptic feedback, instrument stability and single handed operation.

7.1. Technical evaluation

Although more testing is recommended for a solid technical evaluation of the device, the initial results shows that the prototype outperforms the technical specification that was required. Instead of amplifying the user gripping force with an extra 2.2 times, as determined necessary in bone cutting experiments, it amplifies with at least 2.8 times. This results implies that:

1. The weakest surgeon (female, 60yrs old) is now able to cut hardest tissues by using her maximum gripping force.
2. All other surgeons to cut the hardest tissues without using their maximum gripping force.

7.1.1. Friction influences

Before gathering the evaluation data, friction in the setup was reduced as much as possible. Because the cables from and to the pulleys initially made contact with the instrument handles, the location of the pulleys was altered so this did not occur. However, the measured amplification ratio of the device in traditional mode was still up to 51%less than the theoretical calculated amplification. This could be explained by the fact that somewhere in the setup or device, friction is present. Several potential locations can be identified:

- The hinges, which are basically screws creating sliding contacts.
- The point where the device is attached to the setup.
- The cables and pulleys, although expected minimal due to good lubrication.
- The cables exerting forces on the device from different angles, loading the device in non-planar directions.

The mentioned sources of friction were noticable during the evaluation experiment, because the device could be moved into several positions with the same input load.

The effects of friction do not alter the results of this study and the performance of the device. After all, the goal of the device is to amplify user gripping force with an extra 2.2 times in comparision to the amplification it delivers in traditional mode. Even with potential extra friction due to higher loads on the internal hinges in amplification mode, the device amplifies user gripping force with an extra 2.8 times. The amplificiation factor 2.2 was determined by a bone cutting experiment, where the force on the handles, necessary to close the instrument, was recorded including the friction present in the experiment setup. The rongeur used for that experiment can be considered the same as the device in traditional mode. Because the setup did not change either, friction in the same order of magnitude or lower is expected in the evaluation experiment. This is another indication that the results are valid.

Potential increases in amplification efficiency can be made by replacing sliding contacts of the hinges with rolling contacts such as bearings. Testing of traditional high-load instruments is needed to determine the real potential benefits if internal friction is decreased. However, the potential increase in transmission efficiency (minimum 27%, assuming all friction occurred in the device itself) is not enough to be able to cut the hardest bone with this particular rongeur. Even if friction in existing high-load orthopedic instruments would be strongly reduced, the need for a device like the one proposed here remains.

To provide a well-weighed judgement of the practical usability of the device, more tests are necessary. First of all, the experiment should be repeated with more measurements to increase the power of the statistical data. Secondly, the maximum loads predicted with the simulation should be confirmed. Finally, the usability should be determined by performing (clinical) user tests.

7.2. Qualitative rating of prototype

The succes of the device does not only depend on the technical functioning, but should also fulfill the qualitative requirements (Table 2).

Haptic feedback during the crucial first step of the cutting process is kept equal to the original rongeur. The user is free to choose the moment of engaging amplification mode. The instrument stability appears the same as the unadapted rongeur and can be further increased in future designs. Single handed operation is not fully possible. The non-dominant hand is needed for retracting the high-load pawl from the ratchet after using the amplifier. Although not ideal, no significant force is needed from the non-dominant hand. In comparison to the current situation, where the case person often needs to assist with large force from the non dominant hand, this is a significant improvement.

Although the handle span of the device is the same as the original rongeur, it can still be used by surgeons with smaller hands, because it can be gripped on a smaller part of the handles, closed partly, and then closed further with the hands more proximal to the handle ends. The device would ideally be adaptable to different hand sizes. This can be achieved with a simple screw stop that sets the outer position of the handles. Surgeons with smaller hands then need more ratcheting actions than surgeons with large hands, but both can grip the instrument properly. Furthermore, the proposed ratchet mechanism can be implemented in high-load instruments with smaller handle spans.

Safety of operation is overall good, since the device is stationary when no input is delivered to the handles. The prototype does possess some sharp edges and pointy extrusions, which should be removed. The pawls and ratchets should be integrated and shielded off, preventing tissue to get stuck in between.

Excision speed could not yet be determined with the prototype because it is not yet fully functional. However, it is expected that exsision speed is faster because repositioning the device, wiggling to rip of parts of tissue, helping with the other hand will not occur when using the device.

The device is of a relatively simple construction, but the alignment of the pawls and ratchet is crucial. The prototype contains 16 parts including connection shafts, nuts and bolts and little shafts on which the springs are mounted. The author expects that if an integrated, optimized design is created, the amount of parts can be halved by combining functions, such as the ratchets, and changing the springs to compliant mechanisms integrated into other parts.

Overhead is not increased as no prior attaching of power lines or special tools has to be performed. The device does not contain smaller crevices than current high-load orthopedic instruments. Therefore, it is expected that the entire device can be sterilized with traditional methods without taking it apart, and can be included in the OR nets.

7.3. Future design

To make the device a commercial succes, the following recommendations are made.

First of all, the number of parts should be reduced. This can be done by combining functions in one part, such as the two ratchets. The extension springs can be replaced with torsion springs eradicating the spring shafts which further sleekens the design. Sharp edges and pointy extrusions should be removed preventing the device to cause injury to patient and medical staff. The pawls and ratchets should be integrated and shielded off, preventing tissue to get stuck in between. A functional limitation of the prototype should be solved before the device can be clinically tested. When the amplification function has been used, the locking ratchet on the back becomes disengaged, so the leaf spring wants to push the handles apart. However, the high-load pawl is then still locked in the ratchet. This creates an unnatural movement which cannot be controlled with one hand. A possible solution could be making the high-load pawl disengage automatically after the instrument is fully closed. Alast, the resolution of the locking ratchet could be improved, to find more positions in which the beak section can lock. This way, firm contact with the excised tissue is maitained when the amplifier is engaged. This could be achieved with a freewheel bearing.

7.4. Methods

In this paper, a method has been used that to find the real problems independent of a solution and forming them into specific requirements. Dividing them into technical and qualitative requirements provides a good balance between a product that can be proven to mechanically function, and still produce a commercially viable design. A combination was made between experimentally gathering essential information, such as bone cutting forces, and reviewing literature. The most essential information for determining the design requirements came from thorough and systematic discussions with surgeons and observations in the operating room.

The used method has been proven to work, because a working prototype for a challenging problem was found that does not require major changes to be successful. Part of the succes of this method was that it is based on the “market pull” instead of “technology push” principle. An existing problem that was recognized by surgeons provided the basis for this research instead of pushing technological innovation towards the marketplace. The author expects that the new generation of medical expert, brought up in a technologically driven environment, poses a critical view towards the surgical instrumentation they are introduced to. Their critical opinion will create chances for many multidisclipinary engineering projects in the field of surgical instruments, where collaboration between engineers and medical experts can improve surgeon and patient wellbeing.

Figure 27: Different types of high-load orthopedic excision instruments to which the device could be adapted

Table 7: Patents of special transmission mechanisms*

Patent category	Description
B26B17/02	Hand cutting tools with jaws operated indirectly by the handles, eg through cams or toggle leavers
B25B7/12	Pliers involving special transmission means between handles and jaws
A61B17/28B	Surgical forceps with two or more pivotal connections
A61B17/16C	Surgical instruments for bone cutting such as chisels and rongeurs
A61B17/3201	Surgical cutting scissors
B26B13/26	With intermediate links between the grips and blades

* Sourced from www.espacenet.com

7.5. *Other applications*

The proposed device can be connected to the beak section high-load instruments, such as bone forceps, rongeurs and punches (Fig. 27). Several applications for this mechanism can be identified outside the clinical environment as well. A unique feature of this device is that the user can automatically switch between traditional mode (average force amplification and hand travel) and amplifier mode (large force amplification and hand travel). A search through relevant patent categories (Table 7) showed that this feature is unique and could be applied to forceps for industrial use.

8. Conclusion

The proposed design has potential to be a valuable addition to current orthopedic instruments, because it enables surgeons to cut through hard tissues with one hand. Furthermore, the device prevents physical injury and can decreases operating time. The presented prototype delivers the necessary amplification of gripping force but shows some limitations, for which solutions were presented. If these limitations, such as the need for manual ratchet retraction are solved, clinical testing can be performed.

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9. Appendices

Appendix A. Determining gripping force

The following influences were investigated:

- grip type
- which hand
- age and gender
- sitting/standing
- shoulder, elbow wrist posture
- hand span

not investigated: mental state, concentration, air temperature, hangovers, time of the day

Appendix A.1. Grip type

To achieve the the maximum gripping force during surgery the power grip is used (Fig. **??**. With the power grip, the instrument is held in the palm of the hand with the force from the thumb opposed by the combined forces from the other fingers, and muscular force application is dominant []. Also visible is the need to be able to operate the instrument single-handedly. In this case the other hand is used to accurately direct the instrument.

Appendix A.2. Which hand

Surgeons always use the instruments with their dominant hand and there is no reason to not do so. Therefore differences between hands are not relevant, as gripping force data is all measured on dominant hands. [12]

Appendix A.3. Age and gender

It is known that sex, age, body mass, and height, influence grip strength, as do occupation and leisure activities [Age-related and sex-related differences]. Many studies have shown that males have greater hand grip strength than females. Therefore, a test case person will be selected, who is a woman of 60 years old. [] The subject's grip strength can be found in Fig. A.28.

It can be seen that the case person has a gripping force of 293.3 N. This value will not be available in all situations, because the other influences decrease this value. $F_{user,max} = 293.3N$ will be used as a starting point for these calculations.

Appendix A.4. Sitting/standing

Using identical upper extremity positions, grip strength is equivalent when tested in the supine and sitting positions. Thus, when determining grip strength, grips measured while the subject is supine can be compared with norms collected while the subject is sitting, provided the upper extremity position is invariant. [5]

[12] the used data is all based on dominant hand measurements

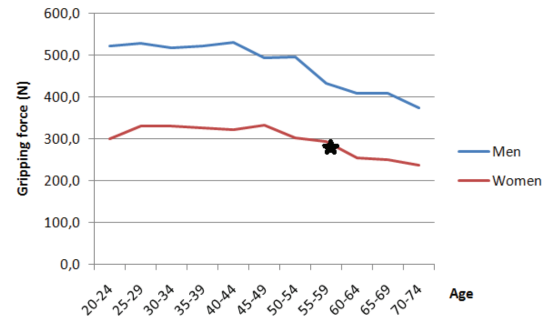


Figure A.28: Grip strength of men and women decreases with age. The grip strength of the case person (female, 60yrs old) is 293,3 N. Adapted from [4]

Appendix A.5. Shoulder, elbow & wrist posture

Contrary to the belief that maximum grip strength is exerted in the 'neutral posture' of the body (shoulder at 0 degrees, elbow at 90 degrees, and wrist at neutral), the results of this study show that it occurs at elbow flexed at 135 degrees with shoulder and wrist in the neutral postures.[6]

During observations, deviations from neutral posture showed to be very likely. Observations have provided the author with input about realistic shoulder, elbow and wrist posture combinations.

Shoulder posture: Operation table is usually adjusted to the most comfortable working height for the leading surgeon. The (entry to) the operation site cannot always be approached with the person in optimal posture: the elbow flexed at 135 degrees with shoulder and wrist in the neutral postures. Therefore, an estimated realistic 20 degrees of shoulder abduction is included.

Elbow posture: The upper arm is usually in an extended position relative to the torso because the surgeon has to lean over the patient and table to reach the operation site. The elbow range is an estimated 30 to 120

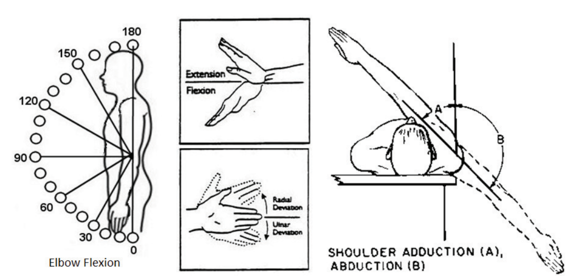


Figure A.29: Shoulder, elbow wrist posture terminology. Illustration adapted from [6] degrees of flexion. 90 Degrees flexion results in less gripping force then 135 degrees flexion, so values for 90 degrees flexion are used.

Wrist position combinations: Surgeons have to get into the operating site at different wrist position angles. However the surgeon has enough moving space alongside the table in lateral direction to control his wrist position. Extending your wrist feels uncomfortable, flexion is also not preferred. Therefore a range of 10 degrees flexion and 10 degrees extension is assumed. 10 degrees of both ulnar and radial deviation is assumed.

So the following values are used to find the influence on the gripping force:

- 20% shoulder abduction
- 90° elbow flexion
- +/- 10° of ulnar/radial deviation
- +/- 10° of flexion/extension

Figure A.30 shows the **percent decrement in grip strength** as postures deviate from the neutral posture. Highlighted area marks the value which exceeds 100%. This value is found at a 135 degree elbow posture and the wrist in the neutral posture. Decrements of up to 42% can be seen as elbow and wrist posture deviate to the extreme flexion and ulnar deviation postures. Interpolating the underlined values gives the influence on maximum gripping force in the proposed posture situation.

The maximum gripping force is now 73,8% of the maximum gripping force in the 'strongest' position .

Appendix A.6. Hand span

The maximum gripping force also varies with hand span (the distance between the instruments handle/hand interface) because of the following reasons:

1. The finger/hand grip span affects the precontractile length in the finger flexor muscles of the forearm. Accordingly, the number of cross-bridges that can be formed differs, which affects the muscle force correspondingly (Huxely 1973).
2. The force-loss at wide hand grip spans may also be due to a change in handle arms; as the hand grip span increases, the handle moves from the proximal to the distal part of the fingers. Thus, the handle, arm of the extension moment, which opposes the finger flexion, increases correspondingly. As a consequence, the force output of a wide hand grip span is lower than that of a narrow hand grip span.
3. For wide hand grip spans, ail fingers cannot grip properly around the handle of the tool, implying a corresponding loss of force. [Hand strength: the influence of grip span and grip type]

Grip strength for different posture combinations as percentage of grip strength at neutral posture

Shoulder posture (degrees)	Elbow posture (degrees)	Wrist posture (degrees)	0 U	1/3 U	2/3 U
0	90	0 F	100	77.75	74.31
		1/3 F	82.01	73.79	71.92
		2/3 F	73.29	69.50	62.00
	135	0 F	**102.92**	87.51	80.48
		1/3 F	83.23	76.37	76.37
		2/3 F	80.14	71.00	71.08
	180	0 F	98.00	80.32	71.41
		1/3 F	79.11	76.55	67.30
		2/3 F	72.44	71.00	58.23
20	90	0 F	93.68	77.58	76.90
		1/3 F	81.50	68.14	65.40
		2/3 F	73.65	64.21	62.00
	135	0 F	98.12	86.30	78.42
		1/3 F	84.60	74.70	71.07
		2/3 F	76.55	72.60	71.60
	180	0 F	91.20	82.53	68.84
		1/3 F	78.42	72.00	64.21
		2/3 F	70.00	59.08	59.08

Note: U = Ulnar deviation; F = Flexion.

	Source values 1/3 U/F	Desired value	User source value
Flexion	+/- 25°	+/- 10°	(0F and 1/3 F)/2
Ulnar/radial deviation	+/- 8°	+/- 10°	1/3 U
Result: F = Fmax * 73,8%			

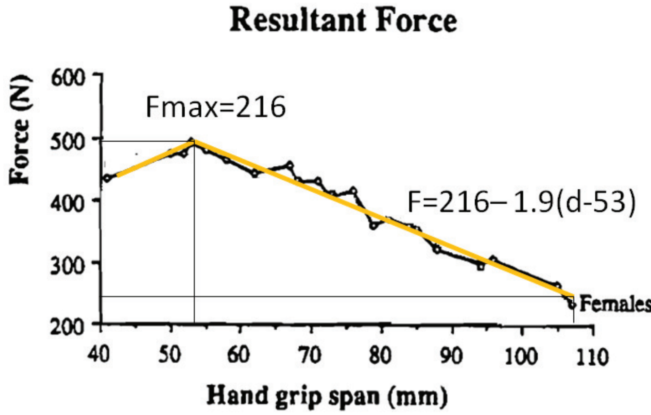
Figure A.30: Percentage decrement (of Fmax) in grip strength with postures deviating from neutral posture. From []

Figure A.31 shows the influence of hand span of females on the gripping force.

A formula for the slope was derived by deriving a relation between gripping force and hand grip span from values in the paper. This resulted in the formula for the final value of $F_{user} = 293 - 1,78(x - 53)$ with x being the hand span or instrument handle distance (see 3).

The case person's maximal hand span is also of interest for designing the device and was estimated 100 mm with the grip the surgeons prefer to use (Fig. A.32)

THe max handspan for the grip used (see Figure ...) coulnd not be found in lieterature and was therefore estimated by taking the hand length and subtracting the

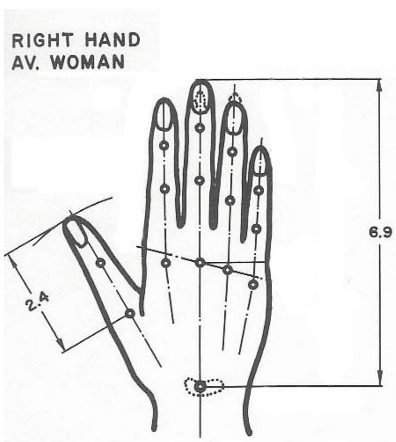


	Source data	Own data
F (53)	500	216
F (110)	250	216*(250/500)=108
F= Fmax - ((216-108)/(110-53)) * (d-53) **F = 216 - 1.9(d-53)**		

Figure A.31: Influence of hand span on gripping force for women. Existing data was used to derive the relationship between hand grip span and gripping force. Adapted from []

thumb length. This gave:

$$\begin{aligned} Handspan_{max} &= l_{hand} - l_{thumb} \\ &= 100.2mm \text{ (for 5th percentile)} \end{aligned} \tag{A.1}$$



HAND DATA	WOMEN		
	2.5 % tile	50. % tile	97.5 % tile
hand length	6.2	6.9	7.5
hand breadth	2.6	2.9	3.1
3d. finger lg.	3.6	4.0	4.4
dorsum lg.	2.6	2.9	3.1
thumb length	2.2	2.4	2.6

Figure A.32: Maximum hand span in inches. Adapted from [21]]

All influences and final value of the case persons gripping force are found in Table **??**.

Appendix B. Survey

26 Orthopedic surgeons, of which 11 AIOS[13], and 5 neurosurgeons of which 2 AIOS were interviewed with the same survey which can be found in appendix []. They all received the same introductory talk. Some of the questions included:

- How often do you use this instrument?
- How often do you encounter problems using this instrument?
- Which problems arise?
- How often do you encouter these consequences?

The answer possibilities were: (almost) never, now and then, often, frequently, (almost) always. These particular answer options were suggested by a medical statistics expert from Erasmus MC, and chosen above a simple ordinal scale to prevent the false objectivity. The surgeons gave quick answers and had not kept records of for example the amount of times per unit that they use the rongeur.

The test group was also asked about more design-specific opinions. They were for example presented with a list of design requirements which they rated on importancy.

Due to the small group of test persons, the results were not significant and thus indicate trends for the test-group and cannot be extrapolated to al larger group of surgeons.

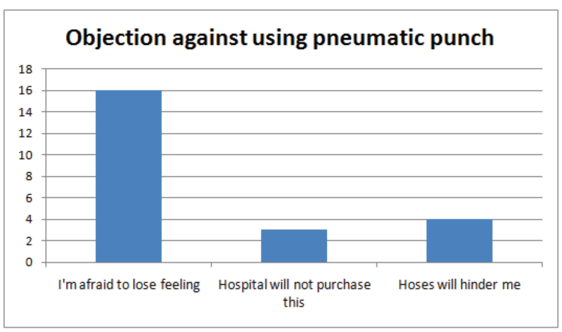


Figure B.34: Objections against using pneumatic punch

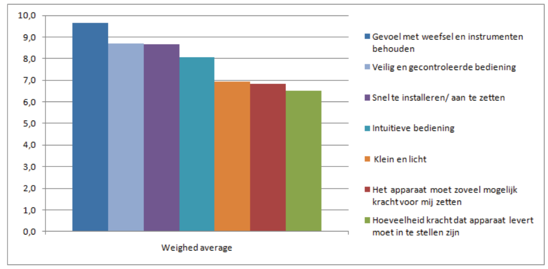


Figure B.35: Average importancy surgeons gave certain requirements (definite list of requirements as in scoring was not yet known at this point

Appendix C. Observing operations

9 Operations among 5 different surgeons in three Dutch hospitals were observed (see Table B.8). These include 3 total knee placements , 1 spondilodesis, 3 laminectomies, 1 total hip placement and a decompression spinal stenosis. Fig. C.38 and C.39 shows the form used for systematical noting of the following:

- Total time using large, high-load instruments
- Total operating time to provides an indication about how often high-load instrumens are used during different types of operations.
- Special observations concerning instrument handling which might help forming a clear picture of problems later
- Grip type and hand position to obtain an indication on how surgeons grip different instruments

These observations showed grip type 2 was used most, both in combination with the rongeur, bone forceps and punch. The fact that this grip is favorite is mostly due to the position of the surgeon, overlooking the patient. His arms are in such a position that grip type 1 would mean that he would have to bend his wrist a lot.

Furthermore, on tools without wings, grip b was used most. On tools with wings, the hand is held against the wings or with one finger on the distal side of the wings, to prevent slipping easily. Surgeons prefer to hold the handle in the proximal position,which means between the first and second phalanx of the fingers. The other handle is placed on the heel of the hand.

[13] AIOS: Arts in Opleiding tot Specialist with an average of two years of experience in assisting surgeons with the operation.

Appendix D. Bone excision experiment

To calculate the minimal amount of force that has to be added by the device, the force required to cut and knibble bone must be determined. The following variables influencing the bone excision force were considered:

- Bone cutting direction
- Amount of bone in beak
- Bone hardness
  - Age
  - Bone location
  - Gender
  - Mobility of person
  - Diseases of person, such as osteoporosis
- Instrument
  - Beak sharpness
  - Friction
  - Lever lengths & construction
- Test setup

Bone cutting direction The setup has been constructed in such a way that a combination of SI and transverse direction is obtained when knibbling the bone. This approach is comparable to normal surgical knibbling.

Amount of bone in beak The more bone in the beak, the larger the forces to cut the bone, due to a higher cutting area and increased closing pressure to to a larger amount of bone compression that has to take place. To make the experiment as realistic as possible, the amount of bone that will be knibbled has been determined in discussion with surgeons and own observations. What is important here is that an amount is knibbled off that a surgeon would want to remove in real life. These can be osteophytes that have to be removed to prevent excessive prosthesis wear. Not so much the individual dimensions of the bone pieces are important, more the volume of the pieces knibbled off. Because every piece that the surgeon removes is different in size and shape, it is impossible and unrealistic to measure the exact dimensions of the pieces beforehand. Therefore, the tibia slice is places such that an expected normal amount is knibbled off.

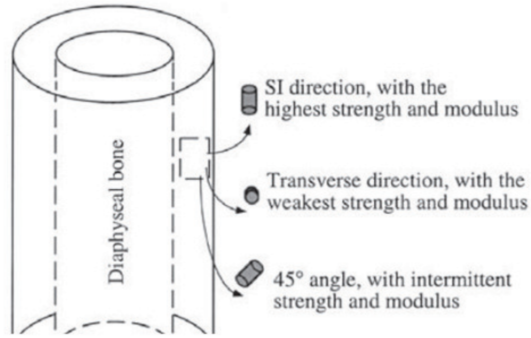


Figure D.40: Bone cutting direction. The bone cutting direction is one of the factors influencing the bone cutting force.[12]

Figure D.41: Experiment setup

Table B.8: Observed operations

Surgeon	Hospital	Operation
Prof. P. Verhaar	Erasmus MC (Rotterdam)	Spondilodesis, TKP
Dr. H. Sonneveld	Meander MC (Amersfoort)	THP
Dr. A. van der Zwan	Meander MC (Amersfoort)	3x Laminectomy
Dr. H. Verburg	Reinier de Graaf (Delft)	2x TKP
Dr. A. Stadhouder	VU MC (Amsterdam)	Decompression spinal stenosis

During these operations, the OK Form (C.38) was used to consequently gather useful information

Table D.9: Estimation of current percentage of high-load instrument use where one hand is not satisfactory for the case person

Tibia	Runs exceeding F_{user}	Runs not exceeding F_{user}	Total runs
10	1,2,3,4,9,10	6,7,8	9
11	1,3,4,5,7,10	9,8	8
12	2,3,8,9,10	1,6,7	8
13	1,2,3,5,6,7,8,9		8
17	1,2,4,5,6,8,9,10	3	9
18	1,2,4,5,6,8,9	3,7,10	10
19	1,3,5,7,8,9,10	2,4,6	10
21	3,5,7,9,10	6,8	7
	52 (75%)	17 (25%)	69 (100%)

Amount of bone cutting runs that exceeded or stayed below the maximum user gripping force during the entire run. 75% of the cases where realistic size pieces of bone with tibia hardness is excised, the test person does not have enough gripping force to excise the bone and has to help with her other hand or replace the instrument to take smaller bites.

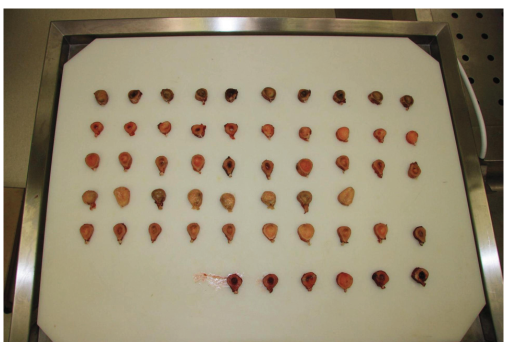


Figure D.42: Cut bone samples.

Bone hardness It is known that the hardness of the bone is not only dependent on the individual bones, but affected by age, gender, type of bone, the mobility of the person and degenerative diseases such as osteoporosis. For the purpose of the thesis it is important to establish the maximum amount of force needed, so the strongest bone will set the bar. Therefore 9 tibia's from different individuals have been used to study the variation in bone hardness.

Instrument There are many different types of rongeurs, an estimated 21 different ones in the Erasmus only. Not only does their construction influence the amplification ratio, their beak size, beak sharpness, maintenance and friction also influence the necessary force. The used instrument is properly sharpened, does not show any unusual roughness except for the first start of the movement, where the wheel that lets the spring push off on the handles starts rolling. These variations occur in real life as well, so as long as a representative instrument is used, realistic values are obtained.

Test setup Care has been taken to ensure that friction between instrument and setup and cable and setup is reduced to a minimum. However, friction forces might still occur. Therefore closing of the rongeur is measured beforehand, without bone. The angles of the cables that pull the rongeur closed will also be taken into account.?

Appendix D.1. Experiment protocol

The rongeur was placed in a custom built aluminum setup, being able to rotate and open/close freely. To simulate a real hand closing action, the gripping force created by a pull bench was divided over the two handles by a cable pulley system. The pull bench speed has been set to 50 mm/s, which comes close to a realistic operating speed as seen during observing operations. The pull distance was set to 50 mm, which makes sure the rongeur is closed and under tension in its end position (in under 1 second).

Before every new tibia, a 'freerun' was done without bone in the setup, to record friction forces and to determine the point the rongeur was closed.

Nine fresh-frozen, human tibia were sliced into 10 pieces of 15 mm thickness. These were all labeled (bonenumber.piecenumber) and could be traced down to the corps they came from for future reference. All 9x10 pieces were placed in the setup and fixed in all directions with a pressure plate with integrated pins, holding the sample in place. This was necessary because of the significant reaction force during the cutting motion.

All Force-time data was recorded with PTBench software written by AMC engineers and stored for further reference. The pullbench was calibrated with 45 kilo's of weigth which provided with an accuracy of 0.45 N.

The full experiment protocol can be found in Appendix ...

Cutting bone with a rongeur-like instrument presents a jagged force-displacement curve F_{bone}. This is because pressure is built up in a piece of the brittle bone, which fractures at some point, lowering the force necessary to advance the beak into the bone, until another piece is about to be cut off.

Table D.10: Technical requirements results

variable	value
F_{user}	$216 - 1,9(x - 53)$
F_{total}	$483 - 1,9(x - 53)$
$\boldsymbol{\Delta x_{device}}$	**50 mm**
$\boldsymbol{F_{device}}$	**267 N**
$\boldsymbol{k_{device}}$	**2.2**

s

Appendix D.2. Experiment results

KS-test shows that the results are not normally distributed. [1] Massey, F. J. "The Kolmogorov-Smirnov Test for Goodness of Fit." Journal of the American Statistical Association. Vol. 46, No. 253, 1951, pp. 68-78.

Therefore, the ususal [] method of determining the maximum by taking average +3s is not valid. Therefore, the maximum has been looked up in the data.

The maximum value is found in sample 19.1

Fmaxmax = 473.59 +/- 0.45 N

The average of the maximum of all samples = 290.1394 +/- 0.45 N

Appendix E. Marketing

Appendix E.1. Target group

Discussion with surgeons and taking a look in to the 'Dudok' instrument tracking system (as used by the central sterilization deparment) of the Erasmus university hospital showed that the problem instruments were used in the departments Orthopedics, Neurology and Traumatology.

Among the target group are:

- People with small hands and less gripping force
- Women
- Older people
- People experiencing fatigue, soreness, aching or blisters with instruments
- People working sub optimally because of problems with instruments
- All people who want to have less fatigue at the point they want to concentrate on the critical parts of the surgery.

The device is designed for the weakest person. This means that:

1. The weakest surgeon is now able to cut hardest tissues with any rongeur by using her maximum gripping force.
2. All other surgeons to do the same with using only a percentage of their maximum gripping force (see Fig. F.43.

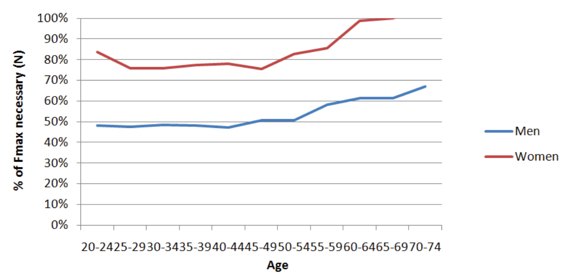


Figure E.43: Device enables weakest person to cut all tissues. This means that all users with more gripping force can now cut the hardest tissues without using their maximum gripping force

To now find the amount of operations per year in which the excision of bone is involved, Prismant can be consulted in two ways:

1. By specialization: Adding up the total hospitalization amounts of Traumatology, Neurology and Orthopedics can be added. These numbers include p
2. By operation: adding up the amount of operations which involve bone excision. 171090 operations where bone is excised.

There are thus between 200-260k operations in Holland only, per year, that include the excision of bone and, very likely, usage of the problem instruments. This means around 500 operations take place every day, around 500 orthopedic surgeons ((http://www.orthopedie.nl/content/misc/orthopedie.asp).

Table E.11: Bone excision operations by group NL hospitals / 2009 (Prismant)

Operation	Amount
Overige operaties bot	36220
Overige operaties gewrichten	124938
Overige operaties bot- en spierstelsel	4556
Overige operaties ruggenmerg(kanaal)	5376
Operaties fracturen en luxaties	38323
total	**209413**

Table E.12: Intakes NL hospitals /2009 (Prismant)

Operation	Amount
Orthopedic surgery	260510
Neurosurgery	34405
Trauma	1304
total	**261814**

http://www.zorgkaartnederland.nl/chirurg/chirurgie 579 chirurgen met als specialisme chirurgie

Appendix F. Future steps

Product rollout steps:

1. Create working prototype
2. Initial testing by surgeons, who must be convinced of added value to their and patient's wellbeing. Interested lead users available from connections made during thesis.
3. Clinical tests with optimized prototype.
4. Hospital must be convinced of economic and/or patient added value by a teamed effort of inventor, company and lead users.
5. Company produces instruments.

Appendix G. Background information

Appendix G.1. Surgical operations and bone excision

Surgical operations usually involve opening the affected area, creating working space, removing tissue, fixing deformities and problems and closing up the wound. Common tissues that are removed can be (in order of hardness): (sclerotic) bone1, osteophytes (bony projections that form along joints), cartilage or disc tissue. There are several reasons a surgeon chooses to remove these types of tissues. Osteophytes, which form with bone transformation due to aging or wear, can limit joint movement and cause pain. Sclerotic bone must be removed because it can negatively affect the stability of implants such as artificial knees and hips.Bulging disc tissue must be removed to alleviate pain caused by neural impingement.

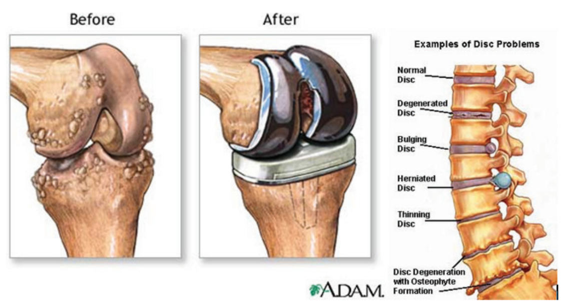


Figure G.44: Two situations where bony tissue needs to be excised. Left: sclerotic bone. Right: osteophyte formation on spine discs. [spineuniverse.com,

The surgeon ideally would like optimal accuracy and speed. For sake of surgeon, patient and bigger systems (hospital, care provider), and for shortest hospitalization time, returns, reoperations and optimal patient comfort, operations should be performed in the shortest time with the best accuracy, with no compromise among each. For accuracy and speed, both haptic feedback and a managable operating force is needed.

Several discussions have made clear that accuracy in this operation depends highly on the haptic feedback that surgeons receive through the instruments. WHen he places the beak of the forceps in the tissue, a small gripping force is applied so the surgeon can feel if he is cutting the right tissue. If the force feedback is too different from what he expects from practice, it may mean that other tissue exists in the place he wants to cut. This is very important to maintain, because especially during neurosurgery, this other tissue might be a nerve. Such as the (branches of) the spinal chord. Even touching or scraping this never might severely affect body functions.

Appendix G.2. Excision instruments

Several articulating surgical instruments have been developed for the removal of bony tissues. The most frequently used ones are:

- Rongeur (NL: knabbeltang)

- Bone cutting forceps (NL: snijdende beentang)
- Punch (kerrison rongeur) (NL: punch)

The most known manufacturer of high grade quality orthopedic equipment is the Swedish Stille and Aesculap (division of BBraun) http://www.chirurgische-instrumente.info/en/search.html?kw=punch . Their orthopedic instrument variants have been used for this section. Variations exist in size, amount of hinges, wings or not, handle size, handle grip etc.

Figure G.45: Different types of high-load orthopedic excision instruments

Appendix G.3. instrument handling

Several observations of in total 9 surgeries (see ta ble) showed grip type 2 was used most, both in combination with the rongeur, bone forceps and punch. The fact that this grip is favorite is mostly due to the position of the surgeon, overlooking the patient. His arms are in such a position that grip type 1 would mean that he would have to bend his wrist a lot.

Furthermore, on tools without wings, grip b was used most. On tools with wings, the hand is held against the wings or with one finger on the distal side of the wings, to prevent slipping easily. Surgeons prefer to hold the handle in the proximal position,which means between the first and second phalaux of the fingers. The other handle is placed on the heel of the hand.

Appendix G.4. Problems with excision instruments

Survey conducted among see table

Also literature reports this Hand strength: the influence of grip span and grip type [Charlotte Fransson] The relationship between hand size and difficulty using surgical instruments: A survey of 726 laparoscopic surgeons [R. Berguer]

Table G.13: Survey participants

Discpline	Amount
Orthopedic surgeon	26
Neurosurgeon	5
Total	31 (30f, 1m)
Ages	30-54 yr

Appendix H. Technical concept analysis

Appendix H.1. Preconditions

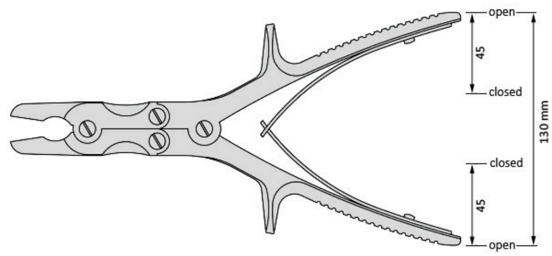


Figure H.46: Rongeur handle span in opened and closed state

Some important inputs to start the calculations with.

- Rongeur travel (open-close) = 90 mm
- Maximum bone cutting instrument travel where extra force is needed (Δx_{device}) = 50 mm (both handles 25 mm)
- Maximum hand span case person = 100 mm [21] (see formula A.1)
- Minimum hand span case person = 20 mm (estimated)
- Two options for device:
  - Amplification of input force (k_{device})= 2.2
  - Addition of input force(F_{device})= 267 N

Appendix H.2. Concept 1: "levers"

Working principle The rongeur handles are elongated. They must still be able to be gripped with small hands, so preferably h2¡h1. d2 and a1 are fixed, otherwise the beak section of the rongeur will not close.

Explanation Constant d2 and a1 mean only d1 can be varied. With an amplification of 2.2x, d1 must be 2.2x as long as it is currently. But, for every mm of elongation, h2 increases more. Therefore this concept

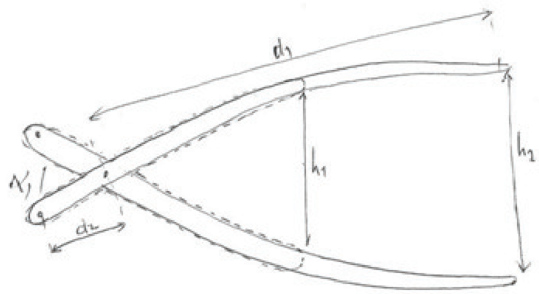


Figure H.47: Concept 1: “levers”

is impossible.

Variables

Var	Explanation	Value
h_1	Original rongeur max handle span	130 mm
h_2	Elongated rongeur handle span	100 mm
d_1	Lever long part length	-
d_2	Lever short part length	-
α	Lever angle	-
n	Amount of hand closing actions necessary	-

Conclusion
Impossible concept: two demands conflidt. The handle span must be decreased while handle length must be increased.

Appendix H.3. Concept 2 “ratchets”

See section 4
subsectionConcept 3: “gears”
Working principle A large and a small gear connect to each other and rotate around the same shaft. Outer device handles turn the large gear which, by turning the small gear, translates the gear racks that are connected to the rongeur handles. So by every handle translation the instrument is closed further. A ratchet system keeps the instrument in position.

Explanation We calculate the travel d2 necessary to close the instrument, which needs travel d1 to close.

Variables

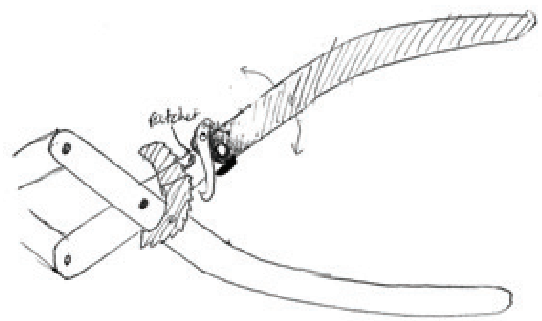


Figure H.48: Concept 2 “ratchets”

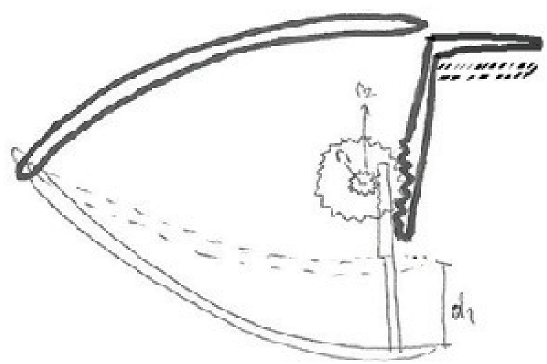


Figure H.49: Concept 3: “gears”

Var	Explanation	Value
k_1	Small gear radius	-
k_2	Large gear radius	-
d_1	Rongeur handle travel	45 mm
d_2	Device handle travel	-
a	Amplification factor	2,24
n	Amount of strokes	-
h	Hand stroke	100-20=80mm

Formulas

$$\frac{d_2}{d_1} = \frac{k_2}{k_1} = a = 2.2 \tag{H.1}$$

$$d_2 = d_1 a \tag{H.2}$$

$$= 45 \cdot 2.2 = 101mm \tag{H.3}$$

$$n = 2d_2/h \tag{H.4}$$

$$= 202/80 = 2.5 \tag{H.5}$$

Assumptions

- There is a position in which the device handles can move freely but still enable the surgeon to keep control and feedback over the rongeur during all times
- The gears have to be attached to a fixed point that is attached to the rongeur
- Gear racks and gears do not obstruct the instrument or users hands

Results 2.5 hand contractions have to be made to close the instrument.

Conclusion This concept delivers enough amplification and enables closing of the instrument in 2.5 hand contractions. Using a different gear system (such as planetary) changes r1 and r2, but since the amplification factor must stay the same, this has no influence on the amount of handcontractions.

Appendix H.4. Concept 4: "wheel"

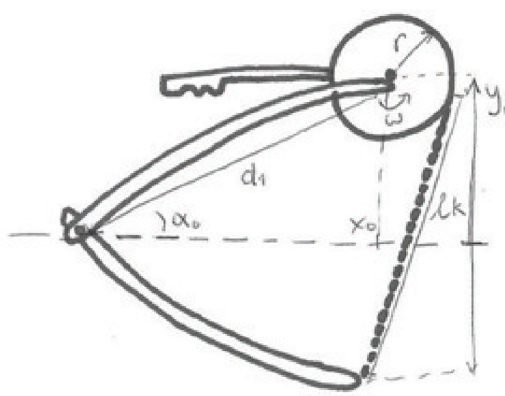


Figure H.50: Concept 4: "wheel"

Working principle A disk, such as a chain wheel, is connected to the upper lever of the rongeur. It incorporates a cable/chain that is connected to the lower rongeur lever. A device lever with length d is connected to the disk. The hand grips around the lower rongeur lever and the device lever. By closing the hand, the device lever is rotated and will rotate the disk to which it is connected, thus pulling the lower lever closer.

Explanation Choose an ω, r can then be calculated. With r and the amplification factor a, d can be calculated. Then with the maximum hand span travel h, the rtation of the disk for every hand closing action can be calculated. The amount of closing actions is then found by dividing ω by .

Variables

Var	Explanation	Value
ω	How many degrees the wheel rotates to close the rongeur	Input: 360,180,90
k_t	Rongeur travel	90 mm
r	disk radius	$f(\omega)$
d	Lever length	$f(r)$
h	Maximum hand span	-
α	the rotation of the disk for every hand closing action	$f(h, d)$
a	Amplification factor	2,24
n	Amount of hand closing actions necessary	100-20=80mm

Assumptions

- Instrument does not interfere with disk and cable geometry
- A position of the lever can be found such that the hand can grip the instrument properly and keeps pressure on the instrument at all times, from the first to the last stroke.

Formulas

$$r = \frac{rt}{2\pi} \cdot \frac{\omega}{360} \tag{H.6}$$

$$d = 2.2r \tag{H.7}$$

$$\alpha = \arcsin(\frac{0.5h}{d}) \tag{H.8}$$

$$n = \omega/\alpha \tag{H.9}$$

Results

ω	r	d	α	n
360	14.3	64.2	51.2	7.0
180	28.6	128	22.9	7.9
90	57.3	257	11.2	8.0

Conclusion The amount of strokes must 7 or more, which is too much. The concept is therefore rejected.

Appendix I. Problem analysis

To completely understand the problems encountered when using the high-load orthopedic instruments, important questions were answered, of which the most critical are shows in Table J.14. Several resources were used to provide the necessary information. These included finding literature, discussions with orthopedic and neurological surgeons [app], observing surgeries [app] and conducting a survey [app]. This information was used to compile the qualitative requirements, was used during the designing process and enabled focussing the research to a type of instrument and user (see .

Appendix J. Initial design choices

Contact or contactless excision Several methods exist for machining bone, and can be categorized in contactless methods, such as laser or water jet ablation, and contact methods, such as cutting[22] [23] . Contactless methods show advantages, such as the ability to make considereable smaller incisions compared to mechanical tools but need a robotic control system and can cause serious risk to surrounding tissue[24][2]. Contact excision have the advantage of sustaining haptic feedback and can be simple and cheap to design. The downside is that bigger instruments can cut less accurately, but this can be solved by taking a smaller instrument where more accuracy is needed.

Stationary or moving blade Multiple methods for contact machining are found in every hardware store, and can be divided into tools with stationary and moving blades. Instruments with moving blades, such as circle or reciprocating saws, can machine objects faster than instruments with stationary blades, such as loppers and pruners. However, serious harm can be brought to the patient when this type of instrument would slip.[14]. Furthermore, instruments with stationary blades provide the user with haptic feedback and are inherently safer.

Direct or indirect control Two types of control are considered: direct or indirect control. Direct control incorporates a mechanical connection between the user and the instruments, where indirect control is built with sensors and actuators. Direct control is chosen because the device must provide feedback to the surgeon while being both simple and cheap to build. A master-slave system like the DaVinci robot, is extremely complicated and therefore not compliant with the study goals.

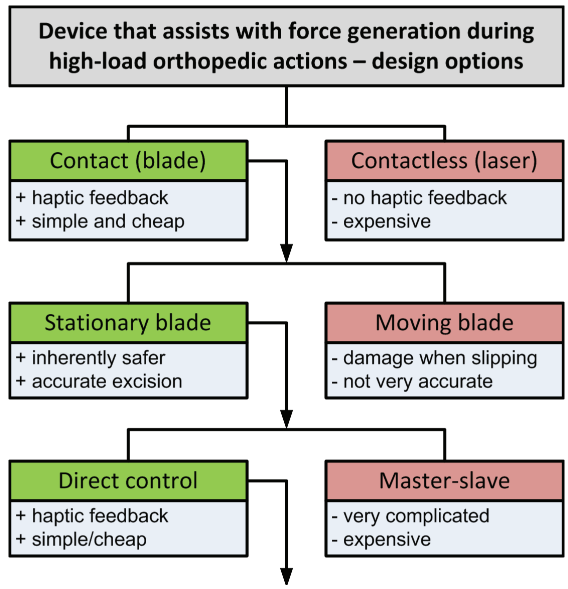


Figure J.51: Inital design choices

Appendix K. Drawings

[14] A reciprocating saw is used during total knee placements, but it is guided by pins and slots jammed into the patients tibia and femur. The pieces removed by hand are harder to reach, installing a guiding system for every piece is too time consuming and uncertain if at all possible

Table I.14: Problem analysis summary

Information collectedy by **conducting a survey** (26 Orthopedic surgeons and 5 neurosurgeons, see appendix []) and **observing operations** (9 orthopecic and neurological operations among 5 different surgeons in 3 Dutch hospitals) as well as **discussions** with over 10 surgeons.

Question	Result
What are the problem instruments?	(Large) Rongeurs, bone forceps and punches
Which instrument type is the most problematic? [1]	(Large) Rongeurs
How are these instruments used? [2]	Power grip, hand location b, proximal finger location
What are the problems exactly?	• Unable to close instrument with one hand (60%) [3] • Unstable grip, instrument slips (40%) • Muscle soreness (40%) and callus (20%)
What is the cause of the problems?	• Lack of gripping force (80%) • Too small hands (60%)
What is the consequence of the problems?	• Avoiding heavy operations (10%) • Longer operating time (60%) • Negatively influenced accuracy (30%) • Arthritis
Other important observations	• Haptic feedback very important [4] • Surgeons use non dominant hand for other purposes [5] • Frequent instrument changing

[1] See Figure **??** for grip type, hand and finger location which were systematically tallied during observing operations
[2] The 'most problematic instrument' is taken als the uitgangsinstrument for this paper, because of its highest contribution to the problems. This was determined by observing which instrument had the highest combination of frequency and intensity of use. This became evidend by struggling surgeon, slow excision progress or obvious high load exertion.
[3] Percentages have been rounded offbecause of the non significant results of the survey predict trends among test group,
[4] Haptic feedback=feeding back force & displacement information (feeling what you are doing). This is very important during the first part of the excision (the initial cut) because the location of the instruments beak has to be in the right location before making the excision to prevent damaging or cutting nervous tissue.
[5] Such as holding a suction device or grasper

Figure B.33: Survey results

DOLS enquete

Naam:
Email:
Functie:
Leeftijd:
Ervaring excl opleiding (jaar):
Handschoenmaat:

	Knabbeltang	Beentang	Punch
Hoe vaak gebruikt u dit instrument?			
(bijna) nooit			
af en toe			
regelmatig			
(bijna) altijd			
geschat aantal keer per operatie			
Hoe vaak ervaart u problemen met het gebruik van dit instrument?			
(bijna) nooit			
af en toe			
regelmatig			
(bijna) altijd			
Welke problemen treden er op?			
blaren of eelt (teken in plaatje)			
kramp of vermoeide handen/armen			
mijn hand glijdt weg			
ik heb niet genoeg knijpkracht			
ik heb te kleine handen			
Anders, namenlijk:			

Ervaart u een van de onderstaande gevolgen wel eens? Hoe vaak?	(bijna) nooit	af en toe	regelmatig	(bijna) altijd
minder nauwkeurig opereren				
langzamer opereren				
ik vermijd zware langdurige operaties waarbij veel bot wordt verwijderd				
anders, nl:...				

Figure B.36: DOLS survey page 1

1. Het afgebeelde apparaat is een pneumatisch bekrachtigde punch. Verschillende punchformaten kunnen in het handvat geklikt worden.

    1. Bent u op de hoogte van het bestaan van onderstaand instrument?
    2. Ziet/weet u bezwaren tegen het gebruik van het instrument? (graag aankruisen)
        a. Ben toch bang gevoel te verliezen
        b. Ziekenhuis wil dit niet aanschaffen
        c. Slangen zullen mij in de weg zitten
        d. Anders, nl:
        ……
        ……
        ………………

2. Naar welke van de onderstaande twee opties gaat uw voorkeur uit? (omcirkel optie)
    a. Eén apparaat dat uw knijpkracht versterkt, onafhankelijk van welk instrument u in uw hand heeft. Het apparaat moet welk elke keer aan het gebruikte instrument worden gekoppeld.
    b. Drie bekrachtigde instrumenten (zoals in vraag 4): een bekrachtigde punch, een bekrachtigde knabbeltang en een bekrachtigde beentang.

3. Stel dat een apparaat wordt ontworpen dat u op het instrument dat uw eerder aangegeven praktische problemen oplost. Hoe belangrijk zijn de volgende producteisen naar uw idee?

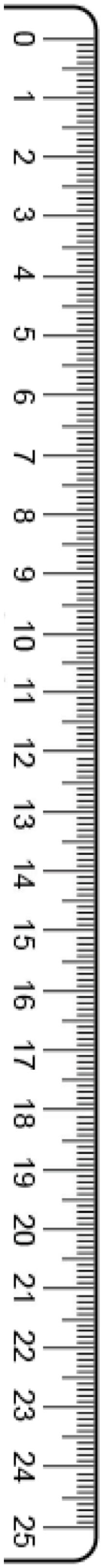
    1. Gevoel met weefsel en instrumenten behouden
    0 1 2 3 4 5 6 7 8 9 10
    Onbelangrijk zeer belangrijk
    2. Het apparaat moet zoveel mogelijk kracht voor mij zetten
    0 1 2 3 4 5 6 7 8 9 10
    Onbelangrijk zeer belangrijk
    3. Hoeveelheid kracht dat apparaat levert moet in te stellen zijn
    0 1 2 3 4 5 6 7 8 9 10
    Onbelangrijk zeer belangrijk
    4. Snel te installeren/ aan te zetten
    0 1 2 3 4 5 6 7 8 9 10
    Onbelangrijk zeer belangrijk
    5. Intuitieve bediening
    0 1 2 3 4 5 6 7 8 9 10
    Onbelangrijk zeer belangrijk
    6. Klein en licht
    0 1 2 3 4 5 6 7 8 9 10
    Onbelangrijk zeer belangrijk
    7. Veilig en gecontroleerde bediening
    0 1 2 3 4 5 6 7 8 9 10
    Onbelangrijk zeer belangrijk

    Anders, nl:……

Heeft u uw vingers al op de liniaal afgemeten?

Bedankt voor uw medewerken!

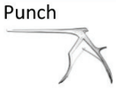
Figure B.37: DOLS survey page 2



OK Form

Date:	24-9-2010
Contact person:	Heleen Sonneveld
Surgical operation:	A van der Zwan – Laminectomie (rugchirugie)
Operation description:	Verwijderen kraakbeen en discusweefsel bij rugwervel
Operation time:	30 min
Surgeon hand dexterity:	R
Surgeon glove size:	7,5
Surgeon hand span:	20,5 cm
Surgeon's problems:	Eelt op twee plekken op de hand van de punch

Instrument observations

Type	Occurrence	Finger Pos.	soorten	Movement	Interesting observations
Bone rongeur 	3 minutes total use		3 types groot naar klein		
Cutting forceps 			1 enorme		
Punch 	12 minutes total use, wordt vaak dicht bij scharnier vastgehouden		4x		Kost meeste kracht, gebruikt I n kritische omgeving
Paktangetjes	50% van de tijd gebruikt				
Spreader					

Other observations

- Naar schattig 80% van de tijd gebruik punches en rongeurs
- Kleine punches breken snel
- Er zijn 8 vrouwen van de 50 neurochirurgen

Figure C.38: OK form page 1

Occurrence legenda		
Hand	**Grip type**	**Hand location**
R: Right hand	 1)	 a)
L: Left hand	 2)	 b)
	 3)	 c)

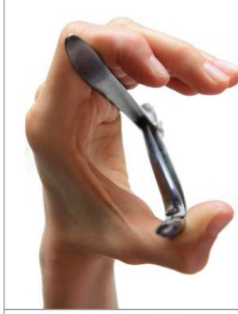
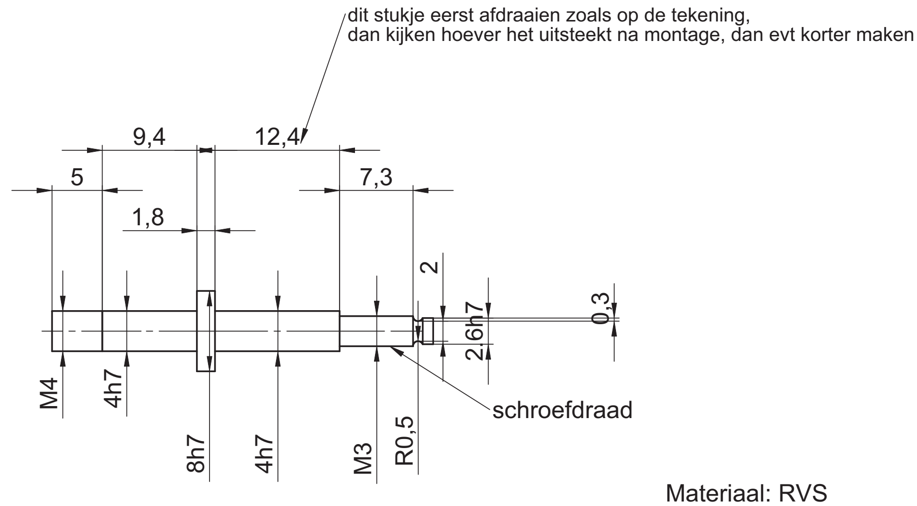
Fingers legenda	
	
proximal(P)	distal (D)

Figure C.39: OK form page 1

Table I.15: Contacts made during thesis

Naam	**Functie**	**Locatie**	**Omschrijving relatie**
Margot van der Grinten Een van de initiatoren	Chirurg orthopedie	Erasmus MC	mvdgrinten@hotmail.com
Hanneke van West	AIOS orthopedie	Erasmus MC	Initator project, erg behulpzaam bij onderzoek, examencommissie
Caroline ...	Operatieassistente	Erasmus MC	instrumenten geregeld
Imme Zengerink	AIOS orthopedie	Erasmus MC	meegeholpen met onderzoek, operaties geregeld
Jos ...	AIOS orthopedie	Erasmus MC	Operatie meegekeken
Prof. Verhaar	Prof. Orthopedie	Erasmus MC	Operatie meegekeken
Peter Pilot	Senior onderzoeker	Reinier de Graaf	Operatie geregeld in RDGG
Hennie Verburg	Chirurg orthopedie	Reinier de Graaf	Meegekeken bij TKP, geinteresseerd in uitkomst onderzoek
Heleen Sonneveld	Chirurg orthopedie	Meander MC	Meegekeken in Meander en via haar bij Neuro meegekeken
A. Van der Zwan	Neurochirurg	Meander MC	Meegekeken met 3 operaties, mooie foto's gemaakt
A. Stadhouder	Chirurg orthopedie	VUmc	Meegekeken bij 2 operaties, goede informatie gekregen, in contact gebracht met dr Peerdeman
Dr. Saskia Peerdeman	Neurochirurg	VUmc	Zeer duidelijke info over problemen met instrumenten, enquete doorgestuurd aan neurchirurgen
Arno vd Linden	Hoofd CSA	Erasmus MC	geholpen met tidok tracking system en behulpzaam bij bepaling aantal instrumenten
Ton de Wit	Sales manager LINK	LINK schiedam	Contactpersoon bij LINK, project gesponsord, 2x aan gepresenteerd.



Materiaal: RVS
Aantal: 1

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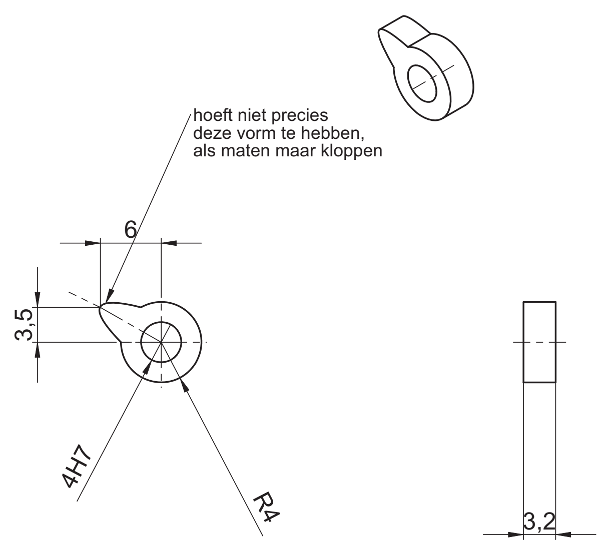

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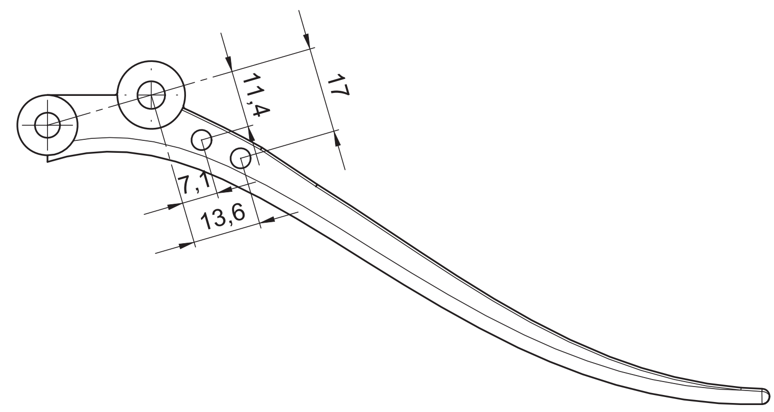

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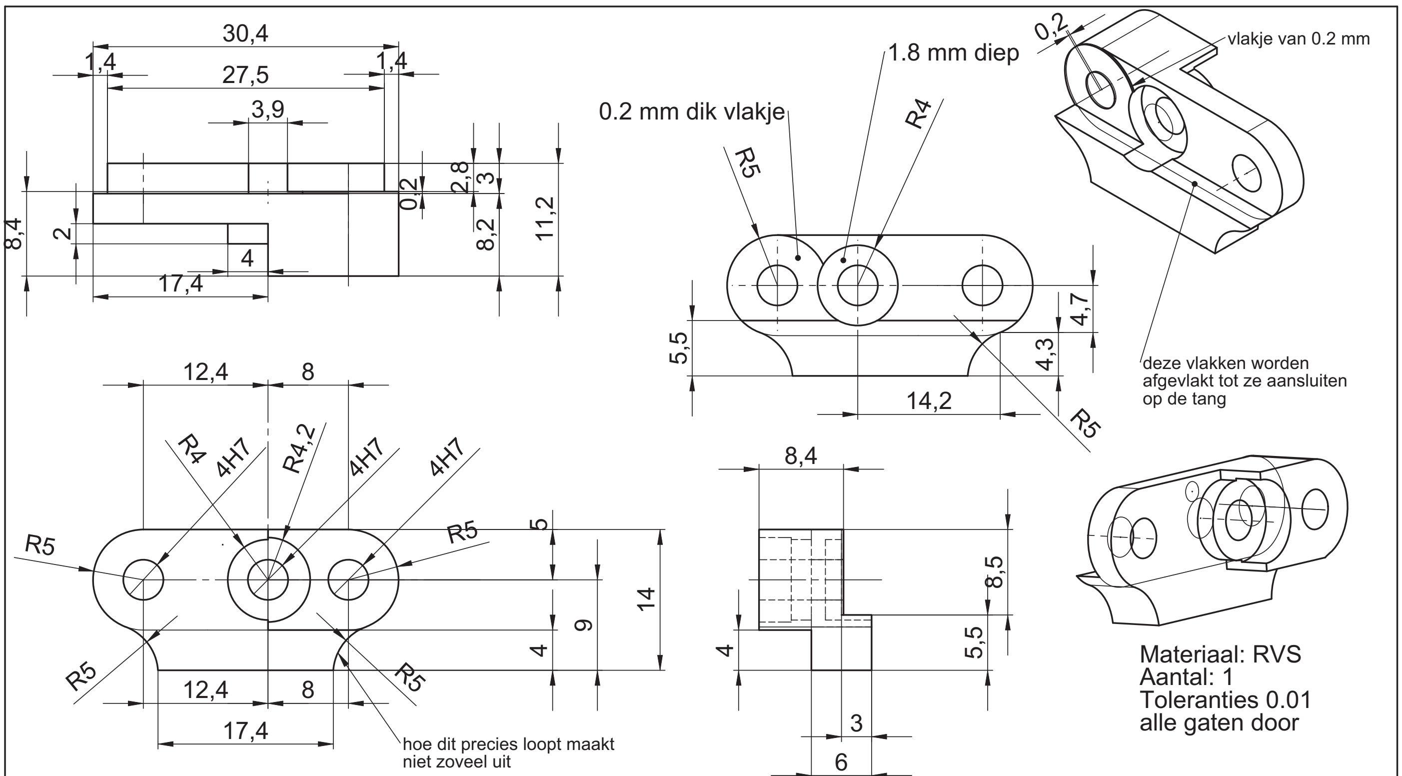

Materiaal: RVS
Aantal: 1
Toleranties 0.01
alle gaten door

TU Delft Industrial Design Engineering	benaming Part62		datum 13-4-2011		maateenheid <<maateenheid>>
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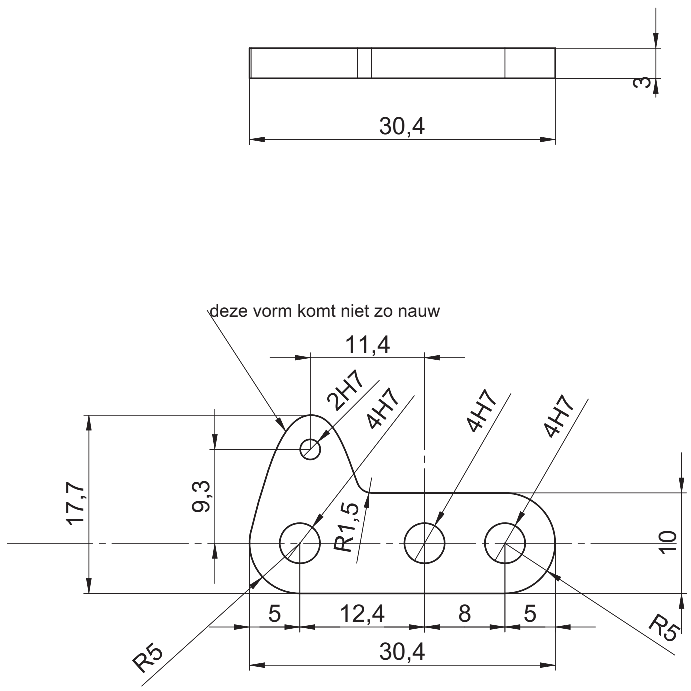

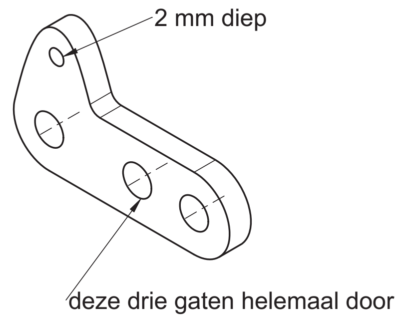

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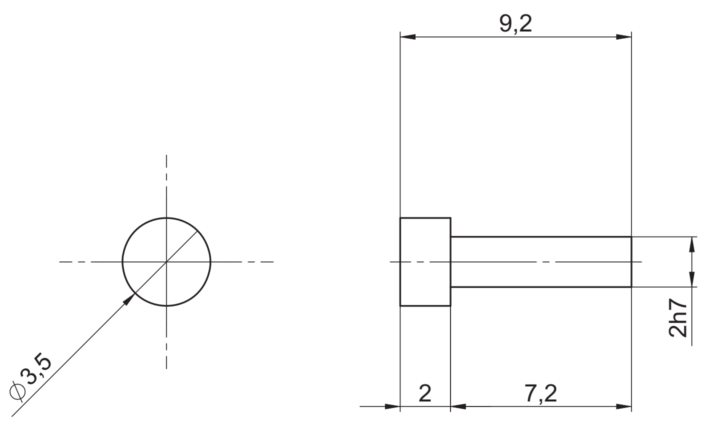
Aantal: 1



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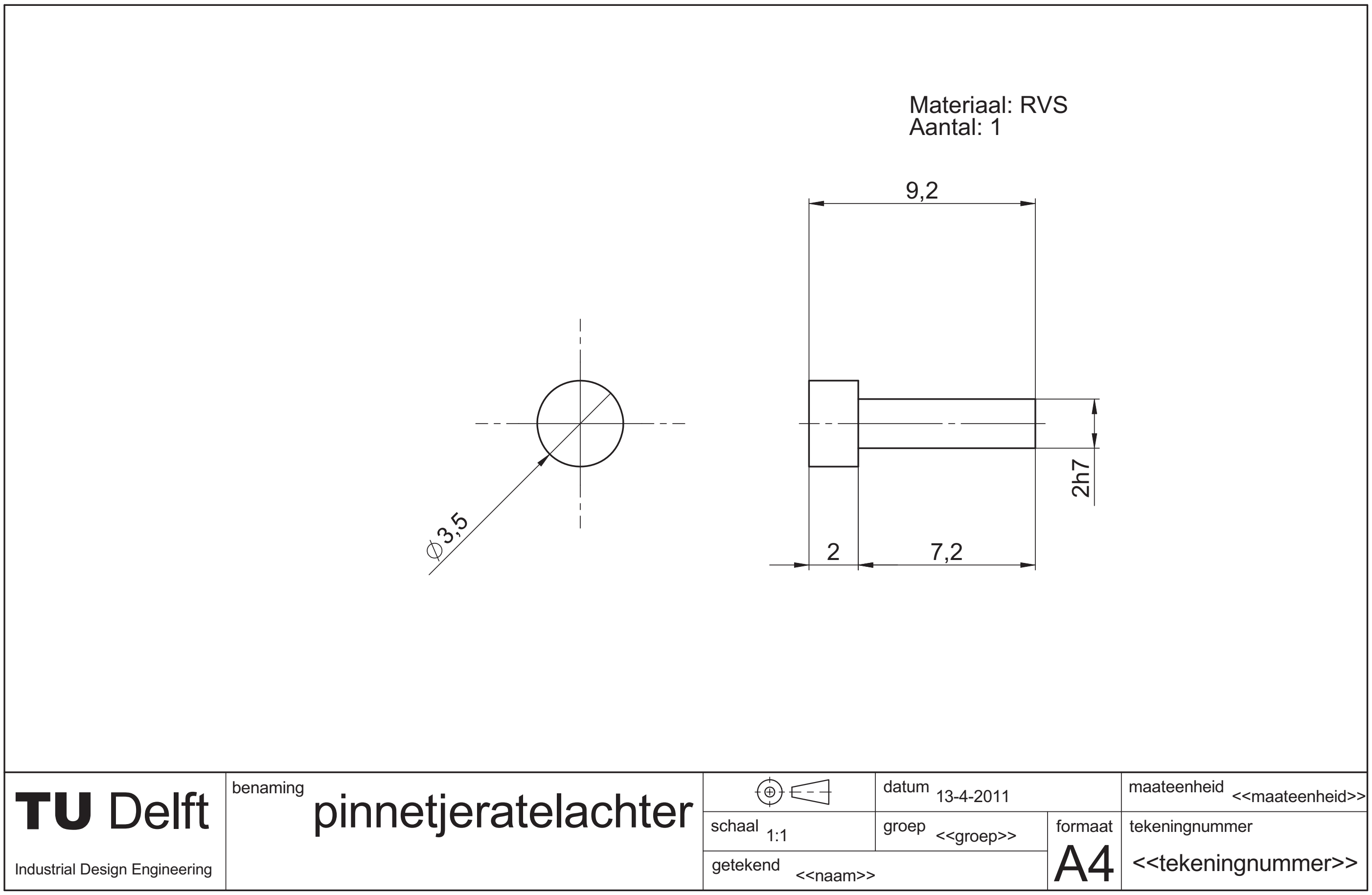

Materiaal: RVS
Aantal: 1
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Industrial Design Engineering
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maateenheid
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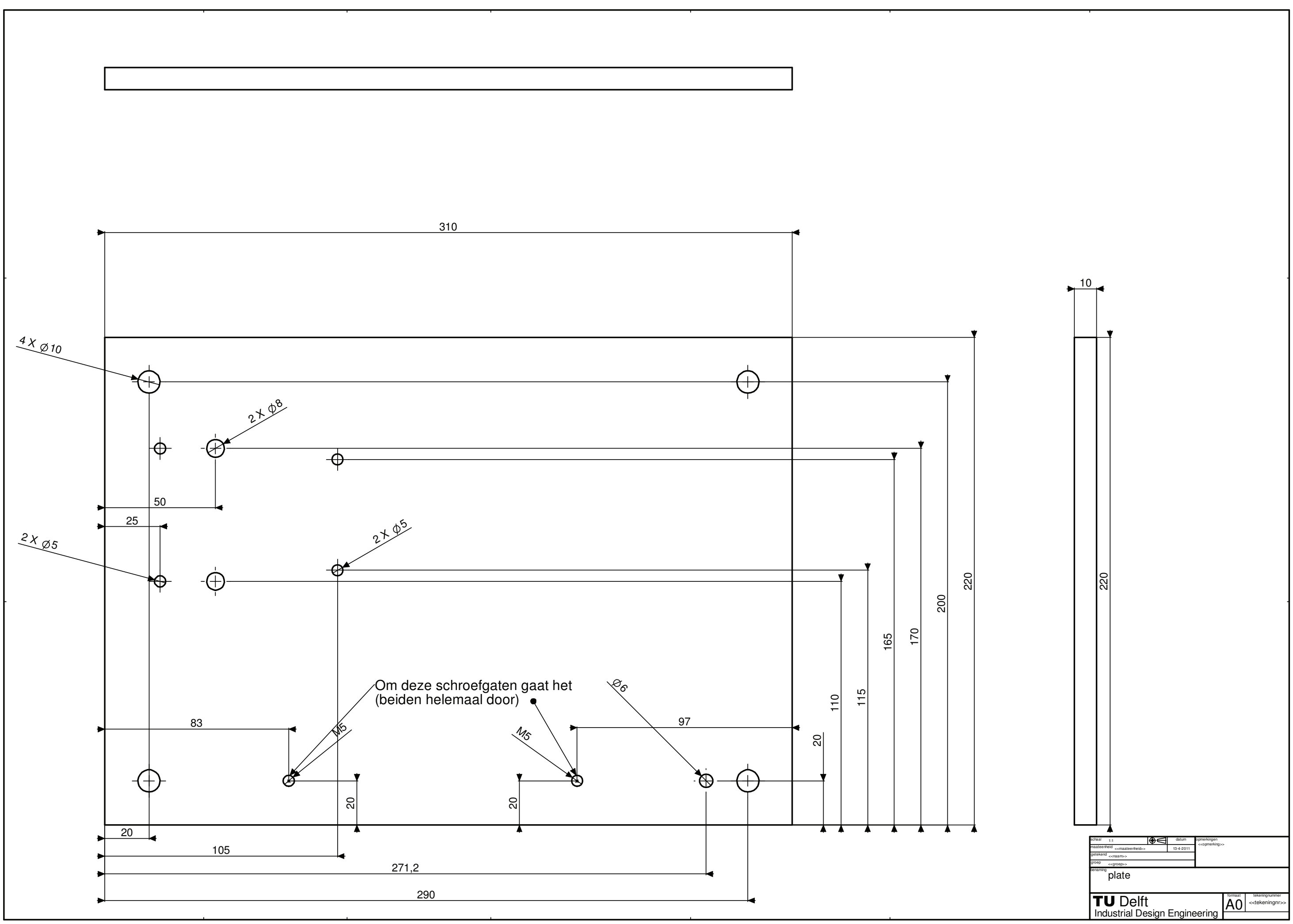

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4 X Ø10
2 X Ø8
2 X Ø5
2 X Ø5
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25
Om deze schroefgaten gaat het
(beiden helemaal door)
M5
M5
Ø6
83
97
20
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220
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271,2
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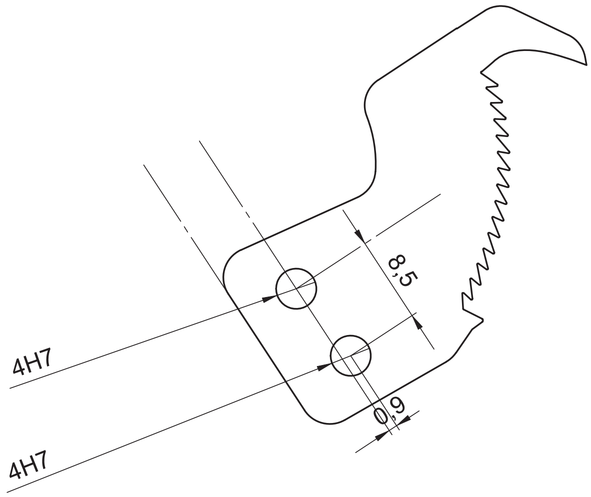
plate
TU Delft
Industrial Design Engineering
A0

Gevonkt bij DEMO



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materiaal: 1.2312

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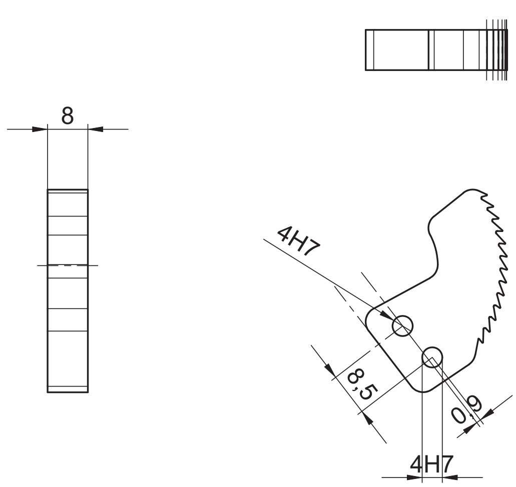

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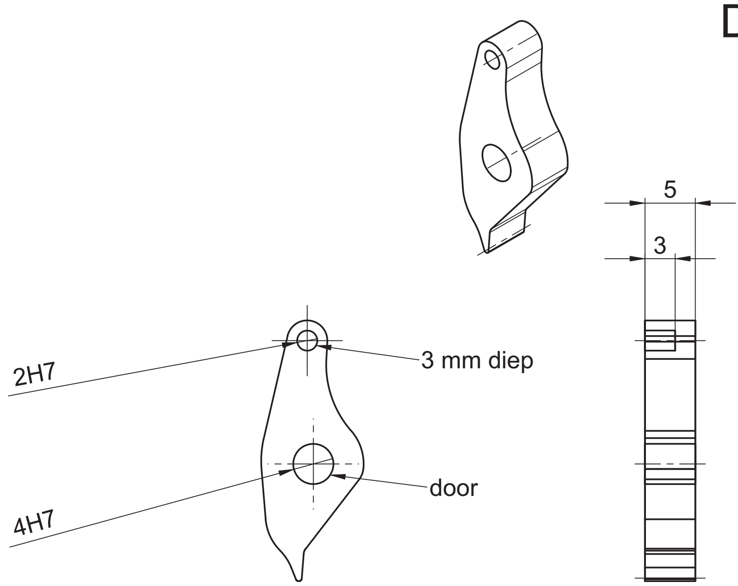

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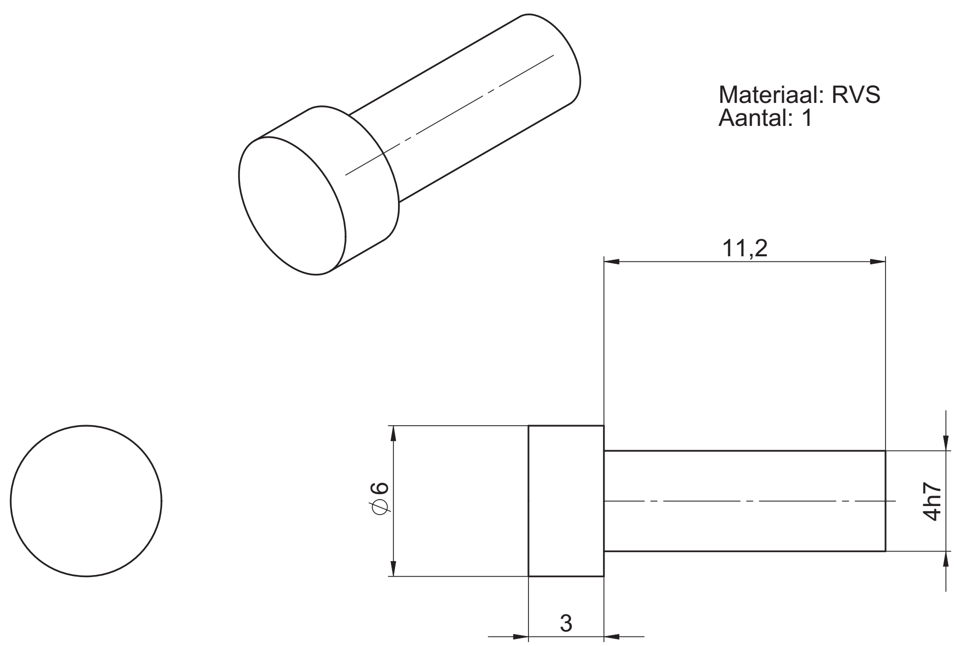

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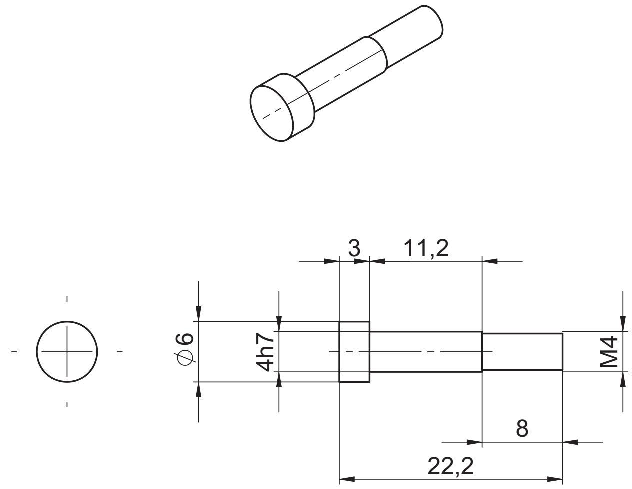

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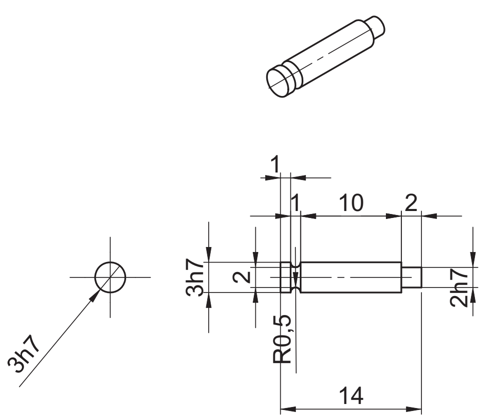

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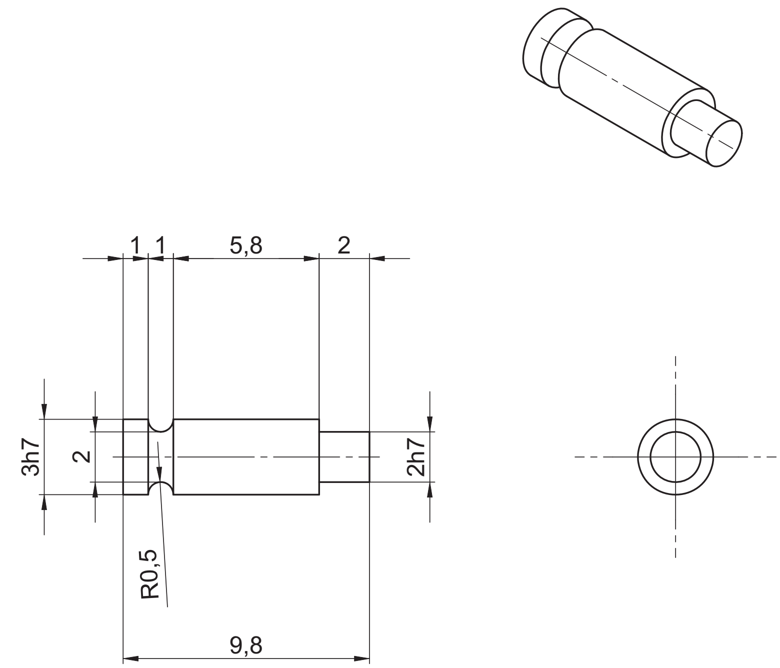

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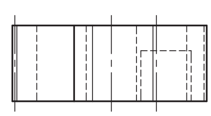

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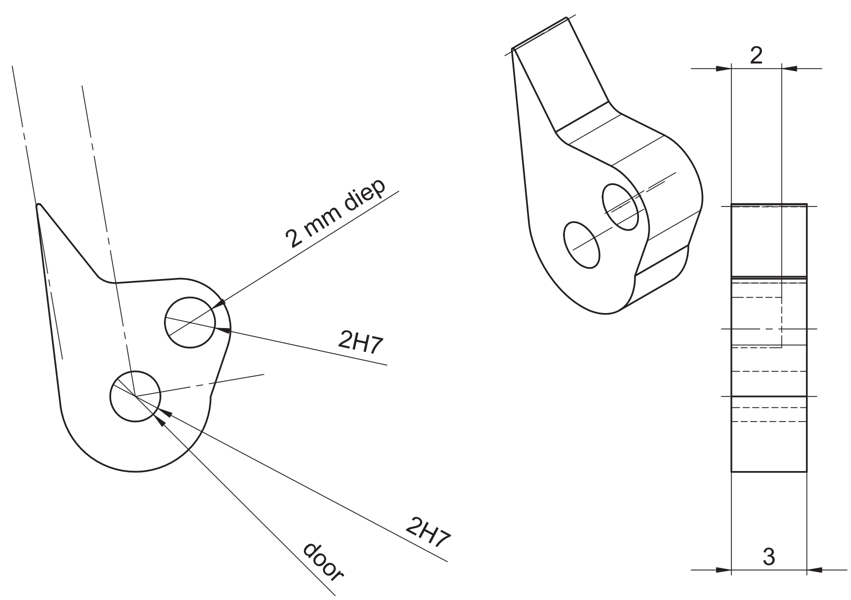

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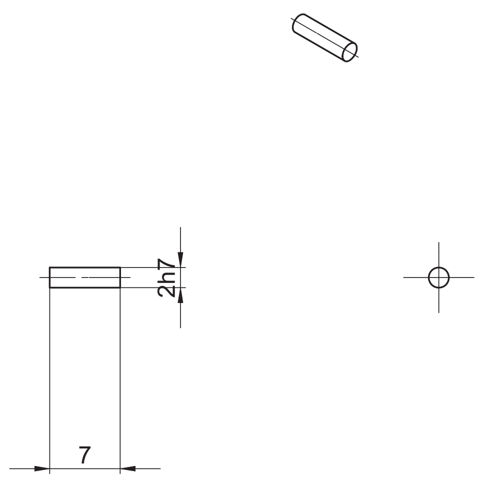

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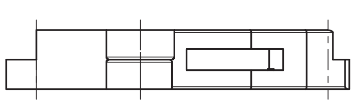

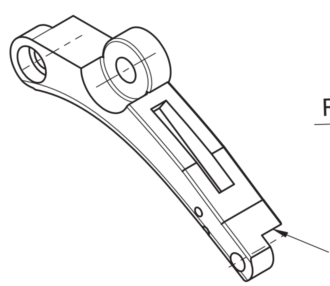

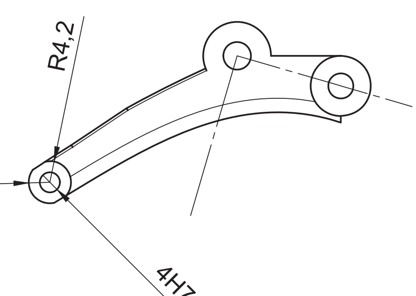

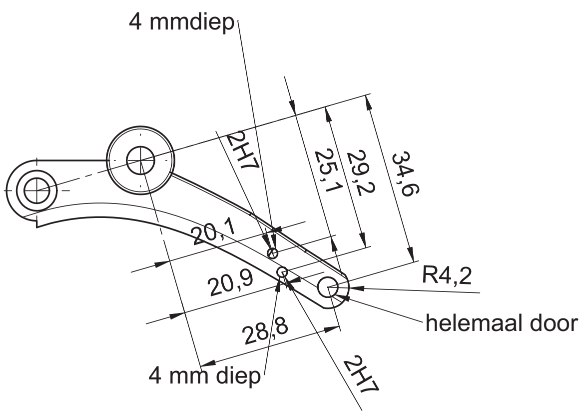

Materiaal: tang
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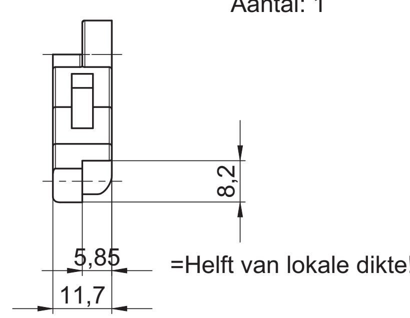

TU Delft Industrial Design Engineering	benaming upperhandlegoodprt1		datum 13-4-2011	maateenheid <<maateenheid>>
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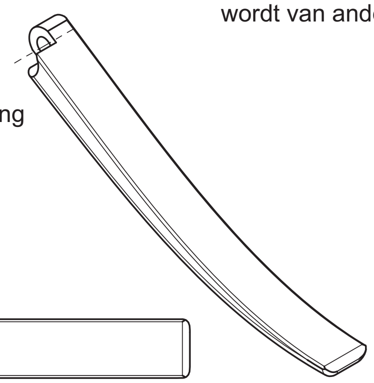
Dit deel wordt uit de andere tang gehaald.
Het enige dat hierbij belangrijk is is dat
- hij vrij kan roteren door het gat
- de oppervlakken aansluiten bij de andere tang
- de lijjn door beide gaten in lijn ligt met de andere tang

wordt van andere tang gemaakt!



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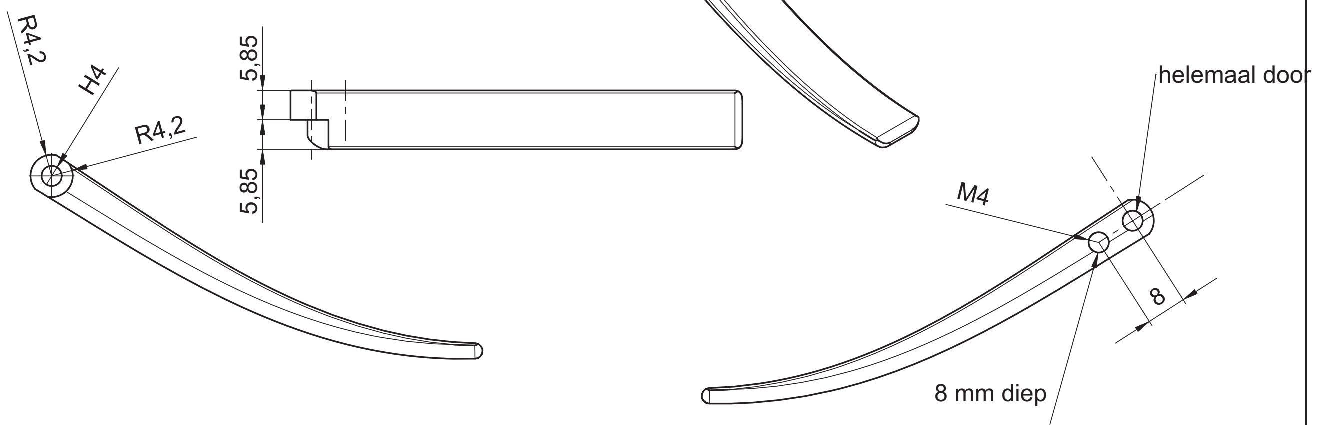

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