Design of a Novel Mechanism for Use in a Cancellous Bone Biopsy Instrument

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Abstract

Background: Minimally invasive cancellous bone biopsy is a common medical procedure in which a needle is used to extract a piece of cancellous bone for examination. Unfortunately, this procedure is not always successful, as sometimes the biopsy can slip partially or completely, necessitating a new biopsy. The occurrence of these errors is not well documented, but the main causes are believed to be an inadequate grip on the biopsy by the current golden standard or improper use of the additional instrument of the golden standard. This study aimed to design a novel mechanism for use in a biopsy needle, with the goal of combating the causes of the errors by providing an integrated design that guarantees the extraction of a biopsy.

Methods: The design process was explored by plotting the potential variations onto a design tree. This resulted in four distinct concepts. Criteria were established to evaluate the concepts. The Cam-follower concept was chosen as the final design. This mechanism was then constructed into a functioning prototype. This prototype was tested in a visual experiment and in a material experiment using gelatin and artificial bone tissue phantoms.

Results: The cam-follower mechanism was able to close off 89% of the end of the needle prototype. It was successful in extracting complete biopsies from the gelatin tissue phantom. The analysis of the softest bone was challenging due to the lengthwise compression of the biopsies. The needle prototype had difficulty penetrating the medium hard artificial bone and broke beyond use during these tests. The needle prototype was not put through its paces on the most difficult artificial bone type prepared for the experiment because of the harm it had sustained.

Discussion and conclusion: The Cam-follower mechanism is an integrated instrument that is intended to improve the efficacy of minimally invasive bone biopsy instruments. The current needle prototype was able to extract biopsies of higher quality and size from the gelatin tissue phantom compared to the golden standard. However, it failed to extract a viable biopsy from the artificial bone tissue phantoms, meaning that the design did not meet its goal. It is possible that the tissue phantoms used in this study did not accurately replicate real bone tissue, which could have impacted the results. Additionally, the main focus of the design was on the mechanism when the bone was already penetrated, so any issues that arose during penetration were not addressed before the material test. It is recommended to further refine the design with these results in mind. Small changes, such as incorporating elements from the golden standard like the tapered end and the sharpened cutting edge of the outer needle, could have a positive effect and enable the cam-follower to guarantee extraction of a biopsy, which would open the door to a clinical application.

CONTENTS

I. Introduction

A. The bone biopsy procedure

Bone biopsy is a medical procedure used to obtain bone tissue samples for diagnostic, therapeutic, or research purposes. The procedure involves the removal of a small piece or fragment of bone for examination, which helps in the diagnosis of various bone disorders and helps guide appropriate treatment decisions.

Bone is a complex and dynamic connective tissue composed mainly of three types: cortical bone, cancellous bone, and bone marrow. Cortical bone, also known as compact bone, forms the outer layer of bones and provides strength and support. It is dense and consists of tightly packed layers of mineralised bone tissue. Cancellous bone, also called trabecular or spongy bone, is found inside cortical bone and has a porous structure with a lattice-like network of interconnected trabeculae. Among these trabeculae, the cancellous bone contains bone marrow, a soft and spongy tissue responsible for the production of blood cells and the storage of fat. However, most prominently in the shafts of long bones such as the femur in the thigh, the bone marrow can be found directly below the cortical bone layer without the presence of cancellous bone.

Four different types of bone biopsies are recognised.

1) Non-invasive biopsy: Using an imaging device like CT or X-ray to inspect the target tissue. This type of biopsy does not cause tissue damage, but is limited because it can only acquire information about the tissue structure and not about the cell composition. The non-invasive method does not remove any tissue from the patient, so it might not be considered a biopsy method in the conventional sense.
2) Minimally invasive biopsy: Using a small needle-shaped instrument to specifically target the target tissue through a small incision in the skin. This procedure yields very small biopsies, but it can provide information about both the structure and composition of the cancellous bone.
3) Bone marrow aspiration: Using a syringe, liquid bone marrow is sucked out of the bone. Often, this procedure is performed before or after a minimally invasive or open biopsy, as it requires a similar hole through the cortical bone.
4) Open biopsy: A large incision is made in the skin and with scalpels a larger piece of bone is removed. This procedure is quite invasive for the patient but yields a large biopsy in comparison to other techniques.

As the title indicates, the focus of this study will be on the minimally invasive cancellous bone biopsy. This operation is quite common, and surgeons often prescribe the procedure when there is an indication of problems such as osteoporosis or disease within the bone marrow. It is estimated that in the UK alone more than 220,000 such procedures are performed each year [1].

Trepanning, which is a procedure that can be seen as a precursor to modern minimally invasive bone biopsy, has been practised for thousands of years. However, the first known instance of using a surgical trephine to obtain a cancellous bone sample for diagnostic reasons dates to 1903 [2]. Since then, steady progress has been made in improving the procedure, until the most recent major improvement proposed by Khosrow Jamshidi in 1971, whose name is carried by the current golden standard, the Jamshidi needle. Various small changes have been made, but the overall design is still in use to this day.

A typical Jamshidi needle is shown in Figure 1a. It consists of an outer needle and a trocar, which fit into each other to form a rigid instrument. The most important addition by Jamshidi is the tapered distal end of the outer needle. The tapering increases the chance that the biopsy stays inside the needle during extraction. In Figure 1b it is shown how the instrument is operated.

Step 1, the assembled instrument is inserted through the outer cortical bone.

Step 2, when the needle has passed the layer of cortical bone, the trocar is removed.

Step 3, the outer needle is advanced into the cancellous bone, until a large enough piece of tissue has entered the needle. This piece of tissue will be the biopsy.

Step 4, the outer needle is removed from the bone, with the biopsy inside.

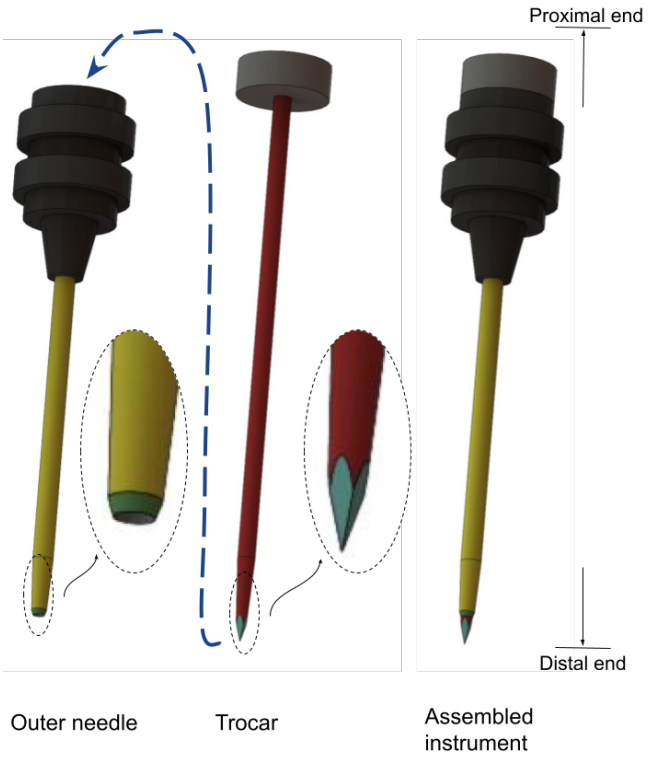
The fourth step raises the problems that are addressed in this study.

B. Challenges in the bone biopsy procedure

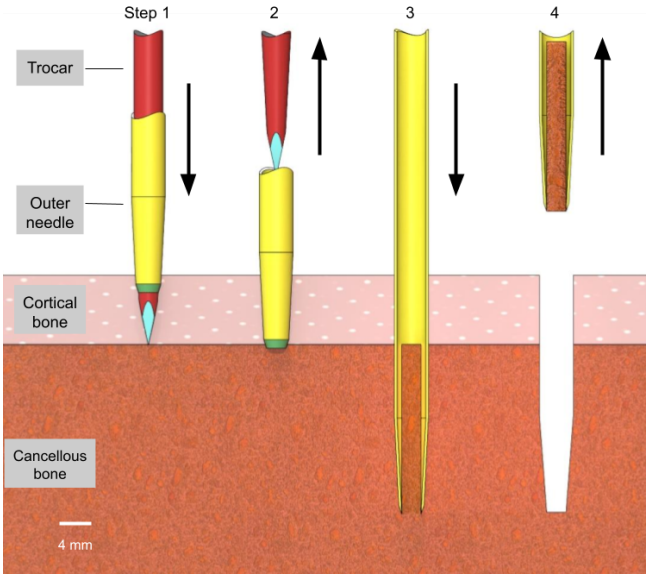
Minimally invasive cancellous bone biopsy is an old and commonly performed operation. Deciding that a biopsy is necessary is often not a grave decision, as it is quick and leaves a small, albeit deep wound. There is a chance of serious complications from the procedure, but the chance is very slim. Of the 19 259 procedures reported to Bain, only 16 procedures indicated adverse effects [1]. Interestingly, only severe complications were reported. After consulting with doctors and medical technicians, it seems there is a not uncommon chance of non-severe errors. The main non-severe error is that the biopsy accidentally slips out of the needle during extraction. This error can occur in two ways, either the whole biopsy slips out, or the biopsy breaks in half, and only part of it slips out. When this happens, the surgeon will decide whether an additional biopsy is necessary and therefore a new incision should be made at a different location.

For the patient, such an error is, of course, very unpleasant. Although the wound is not very large, it is deep and it can take some time for the wound to heal fully. As stated before, the chance of severe complications is quite small, only 0,08%, but having to perform the biopsy procedure twice instead of one time doubles the chance of severe complications for the patient.

Sadly, very little is documented about these incomplete biopsy extractions, so only personally documented instances are available to indicate the severity of this problem. The consulted practitioners estimate that at least 90% of the time the procedure is executed successfully and no subsequent



(a)



(b)

Figure 1: Figures illustrating the Jamshidi needle used for the minimally invasive cancellous bone biopsy procedure. a) The complete needle is shown in disassembled and assembled state. In yellow, the outer needle is indicated, with its cutting edge coloured green for visibility. In red, the trocar with a light blue coloured cutting point. b) The steps necessary for the cancellous bone biopsy procedure. The same colours are used for the same components as in Figure a), but for visibility, large parts outside of the bone have been omitted.

biopsy is necessary. However, the technicians consulted indicate that the delivered biopsy being smaller than expected occurs ”quite often”. A thorough analysis and report on the occurrence of such relatively minor errors is beyond the scope of this study.

Current solutions that are intended to assist in biopsy extraction are often not easy to use and require additional instruments to be inserted during the procedure. It is estimated that the current golden standard achieves a success rate of 90% to 95%. The assessment is that the main reason for the lower than 100% success rate is because of limited closure at the distal end of the needle. A short analysis of the current golden standard is included in Appendix A. The strategy employed by the golden standard to address this problem consists of an additional instrument to be added halfway through the procedure. Field study has indicated that insertion of additional instruments during the procedure is not easy to do, and surgeons often disregard the additional steps in favour of a quicker and easier procedure. This additional instrument is rarely used and, therefore, is not a suitable strategy.

The problem this study aims to combat is therefore the fact that, too often, a cancellous bone biopsy slips from the needle during extraction or is incomplete after extraction. The solution provided by the current golden standard provides inadequate ease of use for the practitioner and, therefore, inadequate ability to grasp the biopsy.

C. Goal of the study

Minimally invasive cancellous bone biopsy instruments are relatively common in hospitals, but for the last 50 years they have not changed very much in a way that addresses the problem of incomplete biopsy extractions. This brings us to the main goal of this study:

Design an ***integrated instrument****, which aids* ***extraction of a cancellous bone biopsy*** *using a* ***minimally invasive*** *technique.*

The instrument having an **integrated design**, means that any separate parts of the instrument should be integrated into a single functioning system during operation. No parts should be added or removed for the main function of the design. **Extraction of a cancellous bone biopsy** is the core function of the instrument. How well the device functions will be verified by how well this core function is executed. The method the device should employ is the **minimally invasive** technique.

D. Report structure

After the introductory section detailing the context and problem, Section II discusses the design process and the final design and prototype generated by this study. Section IV describes the design validation process by testing the prototype. Section VI will present a discussion on the findings of the design and validation results, describe the limitations of the study and future recommendations, and Section VII will conclude the paper.

II. Design

A. Design criteria

The first step of the design process is defining the requirements to which the final design is supposed to conform. These requirements should be measurable, clear, and defined so that the designs can be tested with the requirements in mind. Ten requirements are defined, divided among three main categories: Functional requirements, Dimensional requirements, and Clinical requirements.

1) Functional requirements: The functional requirements are formed from the basic necessary functions of the device. These are the basic criteria on which a bone biopsy instrument can be tested to determine whether it performs its function.

- **Insertion:** The device must be insertable into a bone.
- **Cut:** The device should cut off a piece of bone away from the surrounding tissue. This piece will form the biopsy.
- **Grasp:** The device must employ at least one strategy to enhance its grip on the biopsy.
- **Extract:** The device should guarantee the extraction of the biopsy by closing the distal end.

2) Dimensional requirements: The dimensional criteria stem from the requirement that a novel device have dimensions at least comparable to the current golden standard. The biopsy should also be of a size comparable to current biopsies.

- **Biopsy size:** The size of the biopsy should be at least as large as a biopsy obtained by the golden standard. In the case of a cylindrical biopsy, this should be a diameter of 2 mm and a length of 20 mm.
- **Hole size:** The hole made by the device should be as small as possible, and not larger than the hole made by the current golden standard. The hole should be smaller than a circle with a diameter of 4.1 mm.
- **Wall thickness:** For a cylindrical needle, the above two requirements combine to a wish to keep the wall thickness of the needle to a minimum. The maximum wall thickness is 1 mm. This is the design space available in the radial direction.

3) Clinical requirements: The device will be intended for use in a medical setting. Therefore, it will be used by a surgeon and will come into contact with the internals of a patient. The medical requirements aim to cover the intricacies of such a context.

- **Ease of use:** The device must be easy to use by a surgeon. The intended use must be clear from the design and comprise fewer intricate operations than the golden standard.
- **Biocompatibility:** The device must be made from biocompatible materials, which means materials with no adverse side effects for the patient. Among such materials are several types of stainless steel, alloys such as nitinol, and polymers such as polyethylene [3].
- **Damageless:** The device should do as little damage as possible to the bone and surrounding tissues, aside from the hole made to extract the biopsy. This means that all damage done to the bone must be contained within the volume of the hole.

B. Design directions

To properly map the applicable mechanisms for minimally invasive cancellous bone biopsy, a thorough research was conducted into the various strategies such a mechanism could employ. These possible strategies are visualised in Figure 2. A clear first division is between *passive* and *active* mechanisms.

The passive side encompasses the mechanisms that do not require movement between parts of the device. The interaction between the device and the bone is enough for the device to work. Several different basic strategies were investigated, which should work passively. However, all of these strategies fail to deliver a promising concept, mainly because they do not guarantee a successful biopsy extraction. Some of these strategies are shown in Figure 3c. These three strategies are based on the interaction between the device and the biopsy tissue being stronger than the connection between the biopsy tissue and the surrounding tissue. This means that the aim is to sever the biopsy tissue from the surrounding tissue without actually cutting between them.

The active part of the tree houses the traditional mechanisms with parts moving relative to each other and will be the main focus of this study. Both sides of the tree have been divided into categories based on the amount of walls present in the device. For example, a single needle is *single-walled*, while two hollow needles slid one into the other comprise a single *double-walled* needle. *More than double-walled* encompasses mechanisms with three or more walls or needles slid into each other. On the active side of the tree, each category is further divided into whether the action requires *rotation* or purely *translation*. These movements are defined in the axial direction, as indicated by the motions shown in Figure 2.

All these different mechanisms had to be filtered to arrive at a few promising designs which comply with the design criteria. Of the *active* side of the tree, the mechanisms in the *more than double-walled* division were all discarded because of difficulties due to small scale or because the wall thickness clearly exceeded the requirements. For each of the remaining four categories, a single mechanism was selected, which was novel and promising enough to be worked out into a full design. These will be discussed here.

C. Concept solutions

1) Concept Pull-flexures: The first concept is found in the single-walled section of the design tree, with a translating active part. In other words, the mechanism of this concept is embedded in a single cylindrical needle, while activating the mechanism requires a motion in the same direction as the axle of this needle. This particular mechanism was given the name pull-flexures and is shown in Figure 4a. The figure shows that this mechanism is cut from a single piece of tube. It works by pulling on the long,

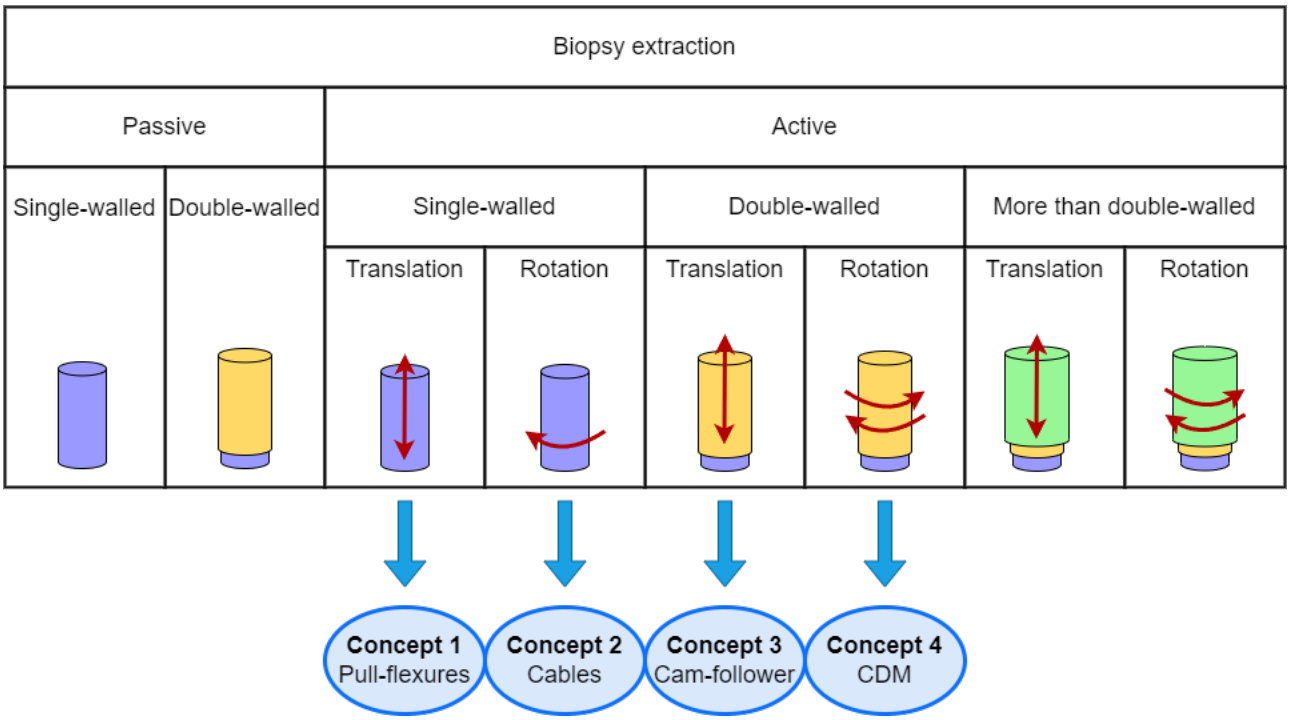


Figure 2: Design tree resulting from the design process. The top-level function "Biopsy extraction" is split between Passive and Active mechanisms. These types of mechanism are divided between Single-walled, Double-walled and More than double-walled mechanisms. The Active part of the tree has been further split into active systems which employ a Translation or Rotation for their function. The four concepts are indicated below their branch of origin.

thin part in the middle, while holding on to the thicker parts on the side. A simplified version of how the mechanism is supposed to work is shown in the bottom right of Figure 4a, the thin lines ares supposed to work as wires, connected to long flexures on the sides. When the thin wires are pulled, the points are pulled toward each other, and the flexures in the thick parts will bend and allow the points to move inward. This movement closes the end of the needle and enhances the grip of the concept on the biopsy inside. Holding the end closed, the instrument can be removed from the patient.

Pulling the ends closer together by pulling on the thin wires means that there exists an outward facing force somewhere in the thick parts. These are pushed outward, away from each other, which means that they are pushed into the surrounding bone of the patient. This is definitely undesirable; therefore, an outer needle should be placed over the mechanism to withstand this outward facing force. However, this outer needle is only meant for structural support and not as part of the mechanism.

2) Concept Cables: The second concept is active and single-walled, just like the first concept, but its mechanism is activated by rotation. The design is shown in Figure 4b. It is clear from the figure why this concept is called Cables: a single tube is cut with a series of holes, leaving a row of thin cable-like structures in the wall of the needle. When the end is held in place and the rest of the needle is rotated, these cables will cross each other across the centre of the needle. This will have a cutting effect and simultaneously close the end of the needle. How this mechanism works is visualised in a simulation shown in the bottom right of Figure 4b. This concept also needs an outer needle, even though its not used in the mechanism per se. Holding the end of the needle in place is not possible with just the single needle; therefore, an outer needle is needed to hold the end in place.

3) Concept Cam-follower: The first true double-walled concept depends on a translation to actuate its mechanism. This concept is called the cam-follower concept and is shown in Figure 4c. The concept consists of an inner needle, which has the actual function of cutting the end of the biopsy and closing the end, and a rigid outer needle, which guides the movement of the inner needle through a cam. When the outer needle is held steady and the inner needle is advanced, the cam will push the guides that stick out of the inner needle closer together. The guides being forced together moves the tips of the inner needle toward the middle, closing the end of the needle. If the inner needle is advanced into the tissue, this cam will ensure that a clean cut is made into the tissue when closing the tip.

4) Concept Cylindrical developable mechanism: The final concept consists of a mechanism based on the cylindrical developable mechanisms developed by Seymour *et al.* [4], Nelson *et al.* [5] and Greenwood *et al.* [6]. Cylindrical developable mechanisms are mechanisms located 'flat' on a cylindrical surface, but which are able to translate or rotate out of that surface. This seemed a very promising candidate for this application; therefore, this concept was developed.

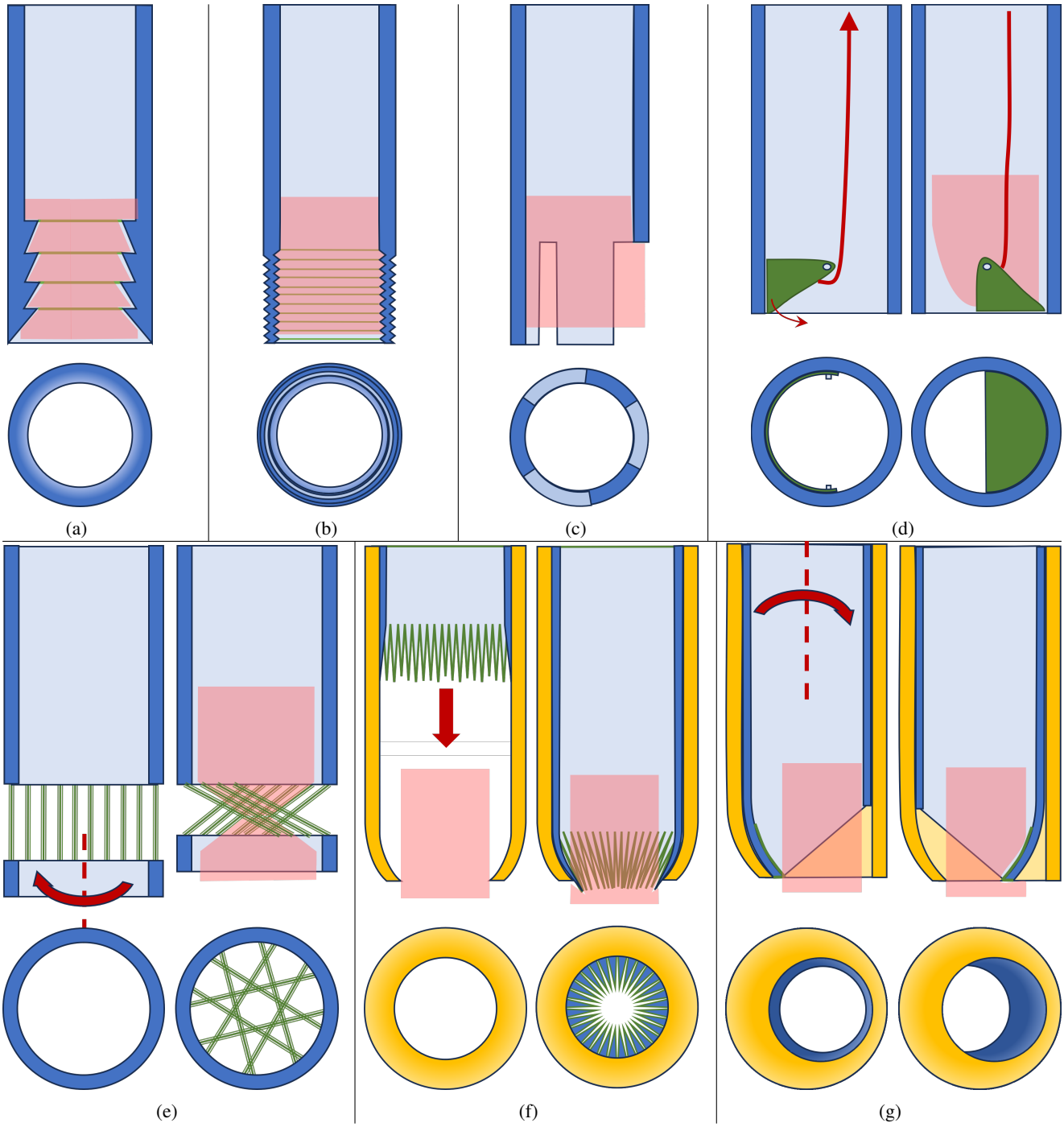


Figure 3: Figure illustrating a possible mechanism for each design direction, except for the *more than double-walled* category. Each figure consists of a sectioned side view of the mechanism, with a frontal view of the needle below. For the active systems, a first and second step are shown next to each other, to visualize the movement. For each figure: In blue, the hollow needle or inner needle is indicated; in green, the cutting edges and cutting parts are highlighted; in red, the movements and actuating parts are indicated; in yellow, the outer needle is indicated; in pink, most figures have a sample biopsy inserted to illustrate how the concept interacts with the biopsy. a), b), c) Three potential variations of passive mechanisms. d) A potential mechanism based on the Active - Single-walled - Translation branch of the design tree. Pulling the red line rotates the green triangular shaped knife around the pivot point in the direction of the arrow, in front of the open end; cutting and closing at the same time. e) A potential mechanism based on the Active - Single-walled - Rotation branch of the design tree. Rotating the end of the needle causes the wires to twist and rotate in front of each other, effectively cutting through the middle of the needle. f) A potential mechanism based on the Active - Double-walled - Translation branch of the design tree. Pushing the inner needle forward, the pointed ends are pushed inward, in front of the open end. g) A potential mechanism based on the Active - Double-walled - Rotation branch of the design tree. Rotating the inner needle inside the outer needle partially closes the open end.

The concept, shown in Figure 4d, is based on the internal scissors mechanism described by Seymour *et al.* [4].

This design works by rotating the inner needle and holding the outer needle steady. When doing so, the hinges on the red and green parts in Figure 4d pull the parts towards the middle of the needle. This movement has both a cutting function and closes off the end of the needle.

On the small scale of these needles, such hinges are very unpractical to make and may not handle the required forces well. Therefore, a design has been made how these parts can be designed as compliant joints and cut from two separate tubes. These figures are shown in Appendix **??**.

D. Concept selection

To help choose between the generated concepts, a Harris Profile was created. This profile, shown in Figure 5, evaluates the four concepts using five criteria, which are based on the design criteria mentioned in the beginning of this section. The criteria are arranged in order of importance; the first is the most important and the last is the least important.

The first of these criteria is *Closure*. This criterion is the main indication of how well the design performs its extraction function. The concepts have been assessed based on how much of the open area at the end of the needle can be covered by the mechanism if the biopsy is inside. Thus, the concepts gained a score based on the following indicators:

++ 100% coverage possible
+ maximum of 75% coverage
- maximum of 50% coverage
- - maximum of 25% coverage

The Pull-flexures concept has a high coverage limit, but around the forward bending flexures will always exist some non-covered area. The Cables concept will always have a hole in the middle, since the cable flexures are cut from steel and are not as flexible as needed at this scale. This is clear from the simulation in Figure 4b. With a very long flexure length and very thin cables, greater coverage might be possible, but this will compromise the length of the biopsy inside. The Cam-follower concept has the highest score, since it is the only concept with the potential for a 100% closure of the end. The Cylindrical developable mechanism concept is clearly lacking in this category, since the amount of coverage will all come from the thin needle walls. From the demonstration of the mechanism in Figure 4d, it is clear how little of the frontal area can be covered by this mechanism.

A similar criterion is the *Cut-off*. This criterion is also very important in how well the device is able to extract the biopsy, as the biopsy needs to be severed from the surrounding bone. This connected bone needs to be cut off at least partially to properly extract the biopsy. Since the concepts are all circular, each can be rotated to move a cutting edge around. The only important indicator therefore is how far to the centre the mechanism can cut. For indication, a helpful figure was made, Figure 6. In this figure, is shown how far to the centre a mechanism has to cut to gain the corresponding score:

++ Cutting fully to the center
+ 25% away from the center
- 50% away from the center
- - 75% away from the center

Two concepts are able to extend all the way to the center: the Pull-flexures concept and the Cam-follower concept. The Cables concept scores the worst, because the entanglement of the steel cable flexures will ensure that they get stuck on each other well before reaching the centre of the opening. This assertion was validated by the results of a simulation of this situation, as shown in Figure 4b. As is clear from Figure 4d, the Cylindrical developable mechanism concept will not be able to fully reach the centre, but it will come quite close.

The third criterion, *Wall thickness*, seems easy to define. The best scores go to the concept with the thinnest walls, and the concepts with thicker walls get worse scores. However, in the concept phase no specific geometry has been defined and the wall thickness is not set yet. Therefore, the rating has been based on the types of structures proposed by the mechanism. A completely single-walled design without the need for an outer needle will get the ++ score. If a mechanism needs an outer needle with a very limited function, a + score will still be applied, since it may imply that the outer needle can be very thin-walled. Mechanisms with axial structures over the full length will lose a lot of their structural integrity and therefore need much more support from an outer needle. This outer needle may even need a special shape to support the inner needle. Finally, any mechanism with radial structures in its design will earn the lowest score, as radial structures directly rely on the wall thickness to increase their functionality.

++ Completely single-walled design
+ Tangential structures or outer needle with limited function
- Axial structures over the full length
- - Radial structures

The Pull-flexures concept has a low score, because even though it is a single-walled mechanism, the long flexures across the whole length significantly lower its structural integrity. As mentioned above, this will imply the need for a robust outer needle or other strategies for support that will increase the wall thickness. The Cables concept has a one + score. It does need an outer needle, but it can be quite thin because it does not need to transfer much force. The Cam-follower has a radial structure; these are the guides sticking out of the inner needle into the cam of the outer needle. These guides need at least a certain length to function, which must be reflected in the thickness of the outer needle, and therefore it will receive a – score. The Cylindrical developable mechanism has parts of its mechanism dependent on the wall thickness. If the device has a high wall thickness, the mechanism will work better and be able to cover more of the open end.

The *Ease of use* criterion is based on the fact that the device needs to be operated by a surgeon in a medical

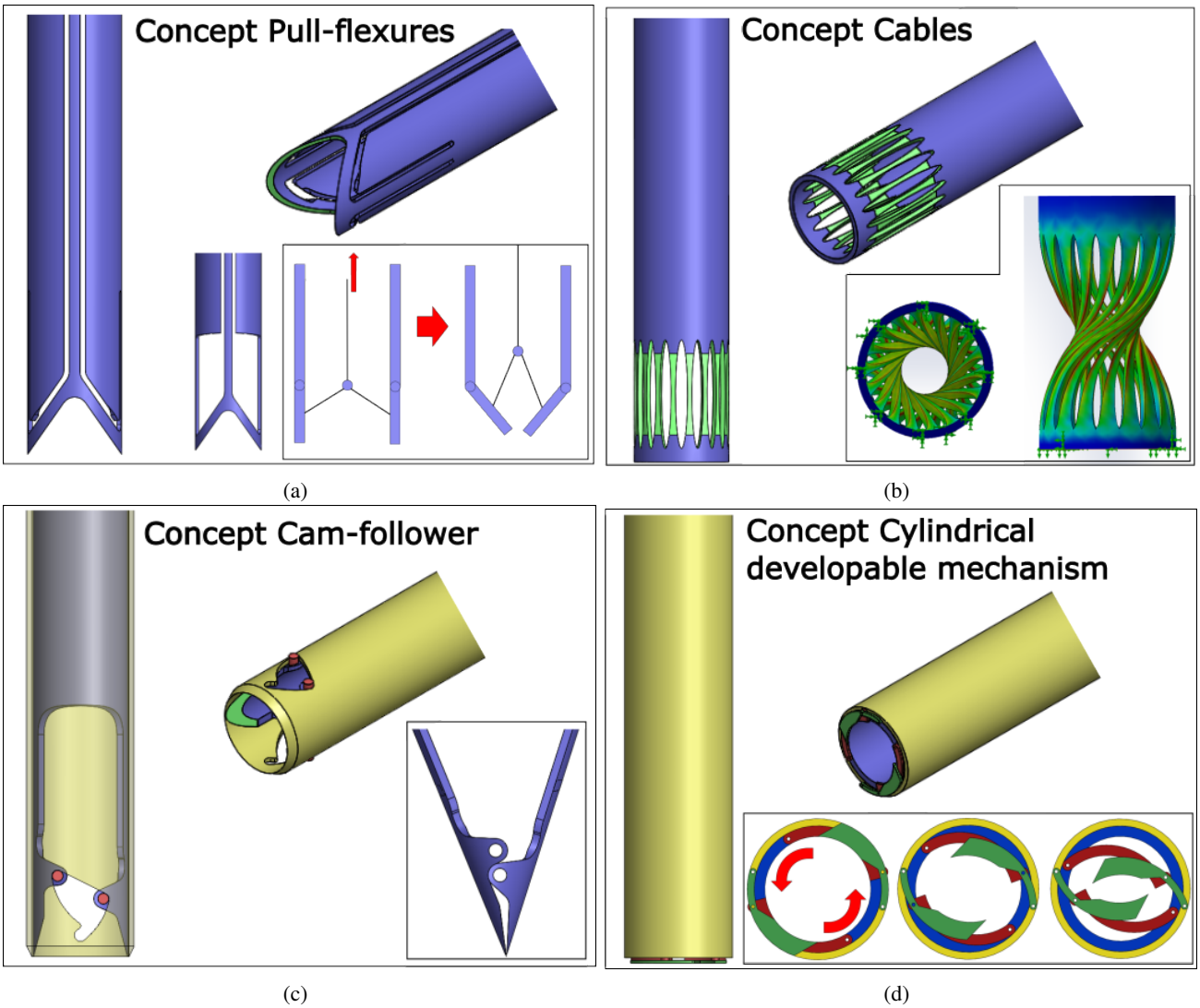


Figure 4: The four generated concepts, only the distal end of each needle is shown. Each figure uses similar colours: In blue, the hollow needle or inner needle is shown; in yellow, the outer needle is shown; in green, cutting edges are indicated; in red, movements and mechanism parts are indicated. For each concept, a side view is shown on the left, an isometric view is on the top, and further explaining figures are shown on the bottom right. a) Concept based on the Pull-flexures mechanism. Next to the side view, a similar side view is shown. It presents a clearer view of the flexures. The figures on the bottom right indicate how the mechanism is supposed to function; the thin flexures work like the wires in these figures and pulling the centre pulls the sides inwards. b) The concept based on the Cables mechanism. The figures on the bottom right show the results of a simulation. It clearly shows how far the open area can be shrank until the cables become tangled. c) The concept based on the Cam-follower mechanism. The figure on the bottom right shows how the tips of the inner needle are supposed to fit into each other when the followers (in red) are pushed inward and past each other. d) Concept based on the Cylindrical developable mechanism. The figures in the bottom right show three subsequent positions when the inner needle is rotated inside the outer needle. The further the inner needle rotates, the further the green members move in front of the open end of the needle.

setting. Any superfluous actions are therefore undesirable, and use of an instrument should be as clear as possible.

++ A single, well defined action
+ A single action, with little direct feedback
- Two successive actions
- - More than two succesive actions

Each concept scores at least well for this criterion. The Pull-flexures concept and Cables concept use a single action but are not quite clear when the end of the action is reached. They need an additional gauge to show how far must be pulled or rotated. The Cam-follower concept and Cylindrical developable mechanism concept score better because there is an endpoint of the mechanism and there should be a clear difference in force when reaching that end point.

The last of the criteria is *Manufacturability*. Since most medical instruments of this type are single-use, the cost of such an instrument is definitely a concern. However, a cost analysis is beyond the scope of this study. Manufacturability will therefore also mean how difficult it is to build a prototype of the concept.

	Pull-flexures				Cables				Cam-follower				Cylindrical developable mechanism			
	--	-	+	++	--	-	+	++	--	-	+	++	--	-	+	++
Closure			X				X				X	X		X		
Cut-off			X	X		X					X	X			X	
Wall thickness		X					X		X	X			X	X		
Ease of use			X				X				X	X			X	X
Manufacturibility			X	X		X				X			X	X		

Figure 5: This Harris Profile was used to judge the four concepts on the most important criteria. the minuses indicate a low score, the pluses indicate a high score.

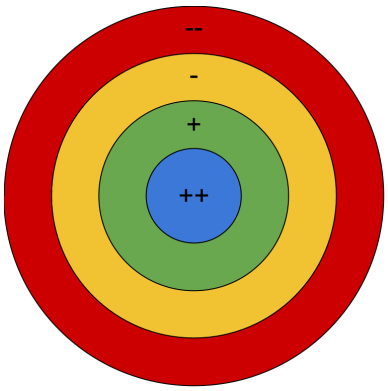


Figure 6: This figure indicates the score a concept gets for the cut-off criterion. A concept is awarded the indicated score when it can reliably cut to within the corresponding ring.

++ 2D machining
+ 3D machining
- 2D machining and attachment of parts
- - 3D machining and attachment of parts

The Pull-flexures concept is relatively easy to fabricate. It requires two concentric tubes, with several 2D operations on the smaller tube to make the inner needle. The Cables and Cam-follower concepts are slightly more difficult since both need the attachment of two parts to each other, probably done by welding. The Cylindrical developable mechanism concept is definitely the most difficult. Apart from cutting the moving parts from the tubes, there need to be hinges of some type, which will probably require 3D machining to be done.

From the Harris Profile, it is clear that the Cylindrical developable mechanism concept scores worst. Therefore, this concept is scrapped immediately. The Cables concept follows, but does show some mediocre potential. However, the cables machined for this concept were deemed to be prone to failure. The concept is therefore scrapped. The choice is left between the Pull-flexures concept and the Cam-follower concept. Both score well enough to argue for a final design, but the Pull-flexures design was also scrapped. The reason for this was that the most important criterion, closure, is performed significantly better by the Cam-follower concept. The Cam-follower concept is further developed into a final design.

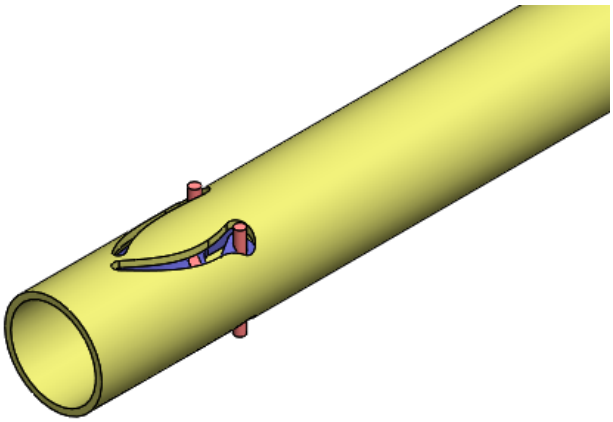
E. Final design

1) 3D model: The 3D model made in Solidworks for the Cam-follower concept from the concept phase is a rough outline of how the eventual design should look. It lacks the specifics needed for a final design. To transform the concept into the final design, the mechanism was streamlined and dimensions were adjusted to fit off-the-shelf materials. The assembled Solidworks model is shown in Figure 7a. Since the handle is out of the scope of this study, only the end of the design is shown in the figures.

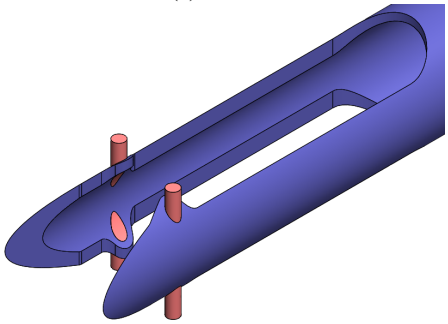
The inner needle, shown in blue, is arguably the most important part of this design; this is the part that cuts the biopsy and closes off the end of the needle to keep the biopsy inside. That is why the ends are shaped like a knife, to cut through the cancellous bone as smoothly as possible. This is needed because the flat sides of the inner needle may not be as strong since the circular structure of the needle is removed. The ends of the inner needle are designed such that they fit neatly together when pushed together. This fit ensures complete closure of the end of the needle.

The outer needle, shown in yellow, is needed to guide the inner needle to a closed position. The largest difference from the concept design is the change of an open cam to two separate slots. These slots are designed so that the inner needle is closed gradually and completely. These long slots are designed to limit crushing of the biopsy as much as possible by making sure that the inner needle makes a smooth cutting motion while closing. Furthermore, there are two larger holes at the beginning of the slots. The function of these holes is twofold. The main function is to make sure there are no residual forces acting on the guides when the inner needle is in its retracted state, since that is the state in which the instrument is in when it is inserted into the bone. At that point, the guides are located exactly at the centre of the holes, should not touch the outer needle at all, and should receive as little force as possible. The second function of the holes is to allow additional room for welding the guides in place on the inner needle.

The guides, shown in red, are the connecting element between the inner and outer needles. They are welded to the inner needle and move along the slots in the outer needle. The slots push the guides toward each other when the inner needle is moved forward. When the guides are pushed all the way to the front of the slots, the design is such that the



(a)



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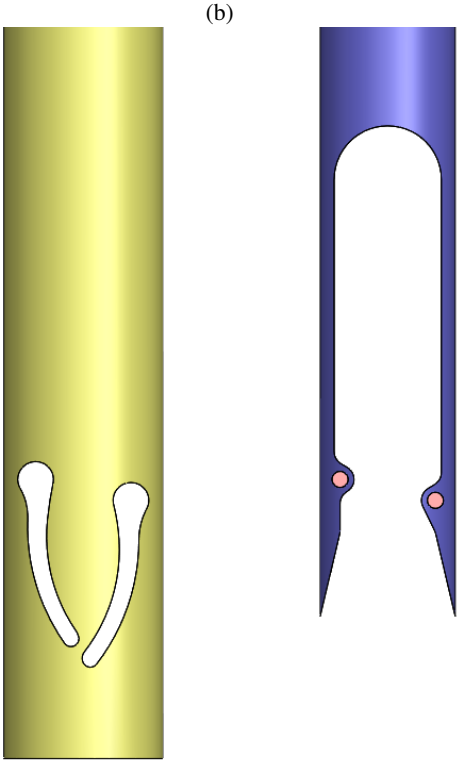


(c)

Figure 7: These 3D models showing the final design were made in the Solidworks 3D CAD design software. In yellow, the outer needle is shown, the inner needle is shown in blue, and the guides are shown in red. a) Isometric view of the assembled instrument. Inside the outer needle, the inner needle is positioned, which can be seen by the red guides that stick through the slots. b) Isometric view of the inner needle. The red guides are welded to the blue inner needle. c) Side view of the outer needle on the left and the inner needle on the right. It offers a clear view of the size and shape of the slots.

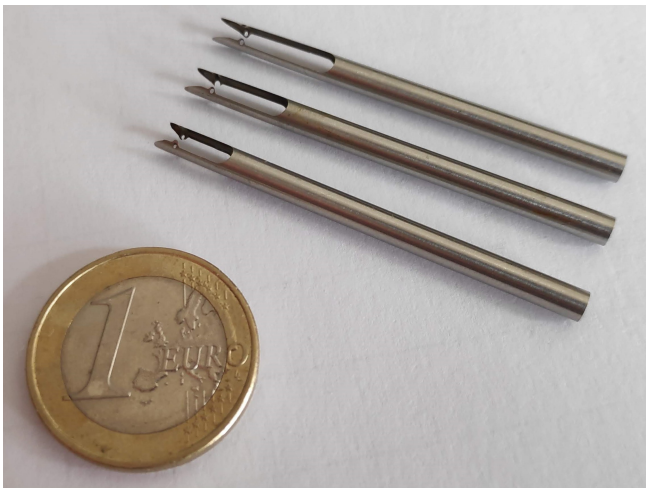


Figure 8: The three intermediate prototypes. To indicate the scale, the prototypes have been pictured next to a euro coin.

halves of the inner needle should fit neatly into each other and close off the end of the needle.

The design is made such that both the inner and outer needles should be cut from a single direction, both with a single two-dimensional machining action. This drastically simplifies the fabrication process. However, the red guides need to be attached to the blue inner needle. These guides are to be made from two solid rods that stick through holes at the end of the inner needle, as shown in Figure 7b. When stuck through, the rods can be welded to the inner needle. Hereafter, the pieces sticking through the inside can be cut away. The welding of the guides to the inner needle will probably complicate the fabrication quite a lot but are a necessary step for the function of the mechanism.

For a material, the inner and outer needles will be made of stainless steel, AISI 304, which is a material that is often used for such instruments. This material is often used for its high strength and toughness, even when machined into thin tubes or strips. When the material is machined into a thin strip, however, its high flexibility is excellent for bending mechanisms such as those used in this design. The nickel-titanium allow known as nitinol was considered as an even more suitable material for this application, because it is extremely flexible compared to stainless steel, but it was discarded as an option because of its limited availability. Stainless steel type 304 is also often used due to its good biocompatible application [3]. Finally, its relatively low cost and high availability as well as its high recycling potential make it a good candidate for single-use instruments, such as the bone biopsy needle, which is considered as the golden standard in this study.

2) Intermediate prototype: The 3D model was manufactured into three intermediate prototypes. These three prototypes have a varying length of flexure, as shown in Figure 8. The tip of each prototype was dimensioned such, that each prototype would close its tips flush to each other. Effectively, the tips of the prototype with the shortest flexure length also has slightly shorter tips, and vice versa.

III. Technical evaluation

A. Spring flexure characterisation experiment

The tips of the inner needle are supposed to move toward each other, therefore, the long slender flexures should be designed so that a bending motion is achieved. The design of the bending motion of these flexures is a compromise between two competing effects. First, the dimensional requirement of the biopsy requires the biopsy to be as large as possible. Therefore, the end of the biopsy should be cut off as perpendicularly as possible. Second, even though most medical instruments of this size and complexity are single-use, this study requires that a single prototype be used multiple times without the number of tests interfering with the quality of these tests. This means that the flexure bend should be elastic without plastic deformation. Therefore, the first requirement is that the flexures be as short as possible so that the cut-off is as steep as possible and no tissue is cut too thin, while the second requirement requires that the flexures be long enough so that no plastic deformation occurs.

The shape of the flexures, being only a small part of the outside of a cylinder, compounded with the scale of the design of less than a millimetre thick, made a thorough and comprehensive calculation of the plastic or elastic effects of the flexures outside of the scope of this study. However, a simplified calculation was made which approximated the outcome by assuming the flexures to have a rectangular cross section.This calculation gave reason to believe that the limit of elastic motion of the actual flexures would lie somewhere between the flexures having a length of 5 mm and 10 mm.

A short test was conducted to investigate the preferred flexure length. To simplify the test, the choice was made to test flexures of 5 mm, 7.5 mm, and 10 mm in length. These three lengths are reflected in the three intermediate prototypes.

The goal of this test is to determine the best applicable length for inner needle flexures. In this case, the best length is the shortest length at which plastic deformation of the flexures is negligible. Furthermore, how well the tips of the prototypes fit together is also considered.

B. Variables of the technical evaluation

The variables in this test are categorized between one independent variable, three dependent variables and four control variables.

Independent variables:

- Flexure length; Three different prototype needles with flexure lengths of 5 mm, 7.5 mm and 10 mm respectively.

Dependent variables:

- Maximum deflection force; Measured using a load cell, in N. This is the maximum force measured during a single full deflection of the flexure. For this test, a decrease in maximum force is assumed to indicate non-negligible plastic deformation.
- Residual bending; The curve left in the test needles after the removal of external forces is evaluated by visual inspection. Before the first test, each needle shows a straight flexure. After the tenth test, the flexures may show visual signs of residual bending, which indicates plastic deformation.
- Closure; How well the distal tips of the needles close is evaluated by visual inspection. This has no effect on whether the flexure undergoes plastic deformation, but it is important to assess its efficacy.

Control variables:

- Tube diameter; 3.4 mm, each prototype is cut from the same tube.
- Wall thickness; 0.25 mm
- Flexure cross section; 0.42 mm^2, the cross sectional shape of each flexure is identical.
- Deflection distance; 1.5 mm is the same distance from the outside of the needle towards the inside to simulate a closed tip.

C. Evaluation setup

The three tested needles are the prototypes discussed in Figure 8. In Figures 9a, 9b and 9c is shown how these test needles are meant to close. Each of these needles was placed in a state as shown in Figure 9d, clamped in a test setup with a load cell ready to push down and a piece of millimetre paper behind to indicate the scale and review whether the flexure is pushed far enough.

D. Evaluation protocol

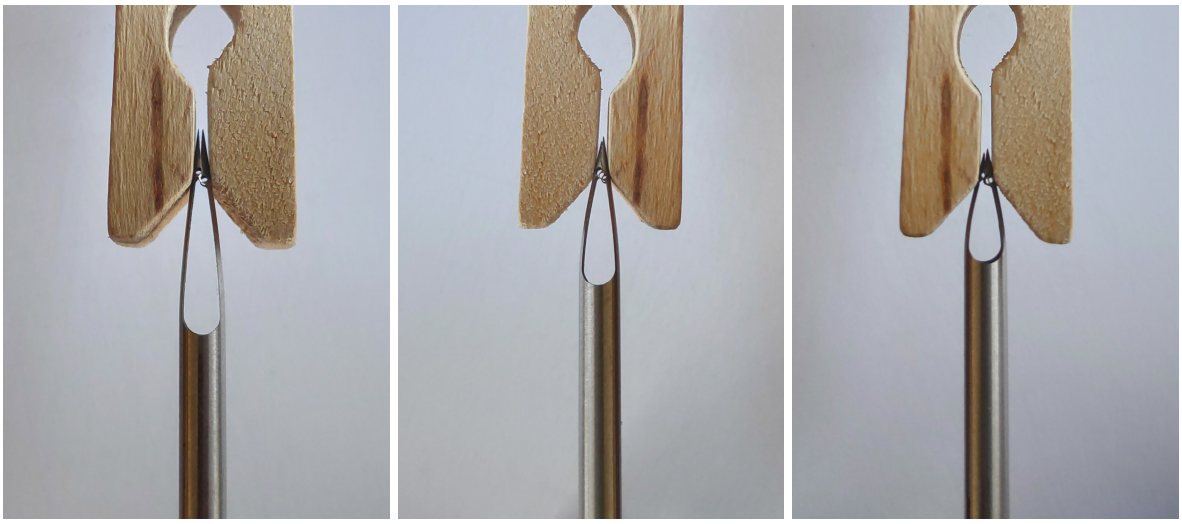
Each test was started with the position shown in Figure 9d. Then the test was performed by lowering the load cell unto the end of the needle until the end was in the desired position, as shown in Figure 9e, then the load cell was raised back up until the flexure of the needle was fully relaxed. Each time, the load cell was raised slightly above the needle, to ensure an end of the contact between the load cell and the needle.

Each needle was tested ten times. The results were recorded digitally by connecting the load cell to a computer.

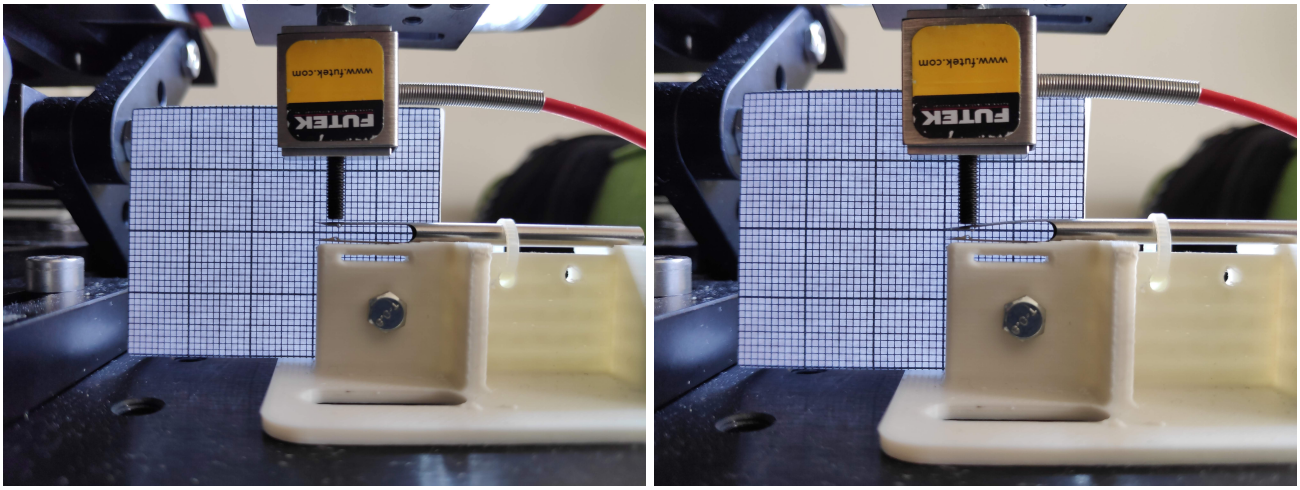
Each needle was also visually inspected, as a reference to the digital results. After the tenth load cell test, each needle was inspected for residual bending in the flexures, which could indicate plastic deformation. Additionally, each needle was pushed fully closed by hand to inspect how well the design closes the end of the needle. These final visual inspections of the closure are shown in Figures 9a, 9b, and 9c.

E. Test results

The results of the tests are summarised in Figure 9f. It shows the maximum force measured by the load cell on the vertical axis for each of the ten tests for each needle. It is clear that the tests with the shorter flexures required more force than the tests with the longer flexures. The first test with the 5 mm flexure reported a maximum force of 5.7 N, the first test with the 7.5 mm flexure a maximum force of



(a) (b) (c)



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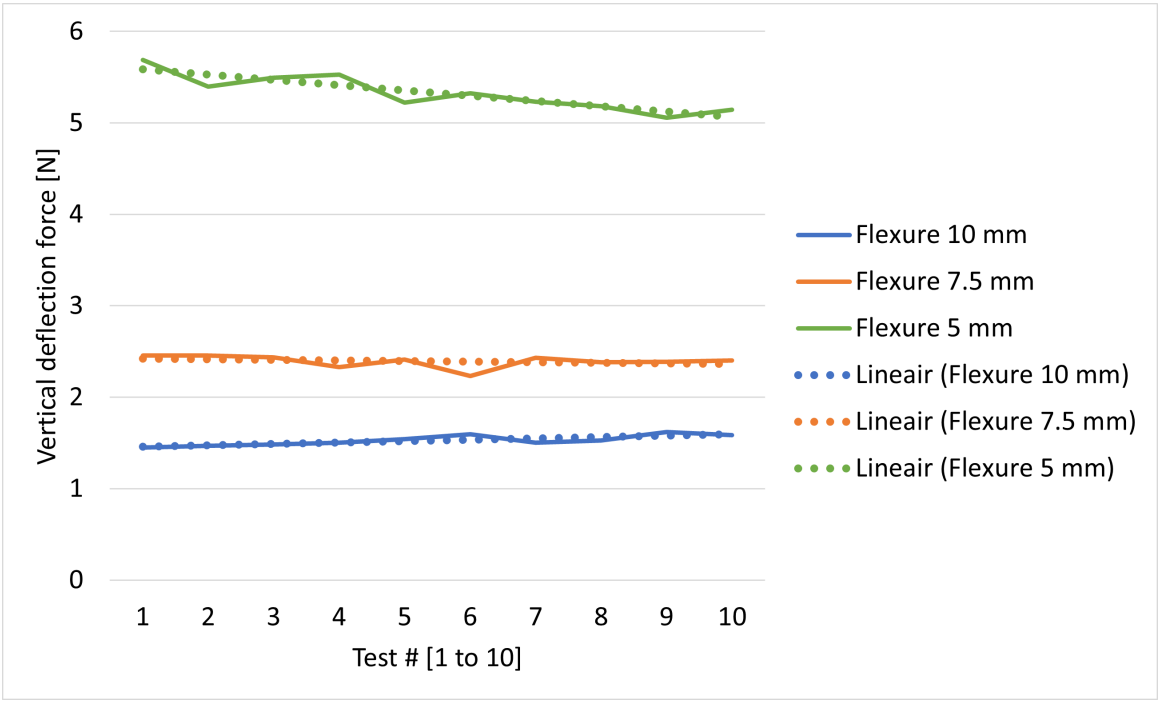
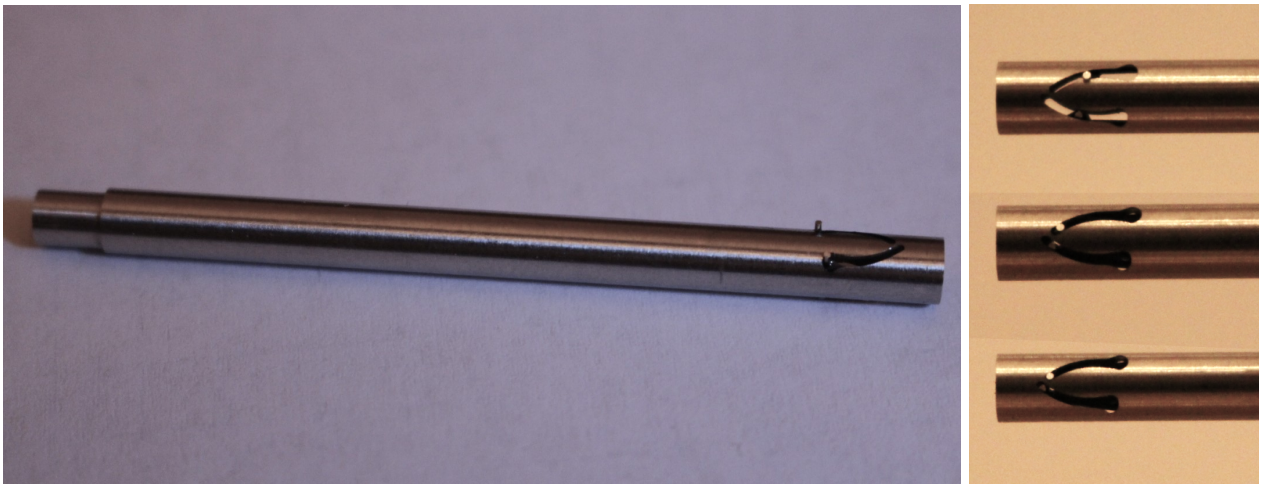


(f)

Figure 9: Final design flexure test. (a - c) The three test needles in their closed position. A peg is used for this photo. (d and e) The test setup of the flexure test at the initial and final positions, respectively. (f) The results of the flexure test. For each flexure length, the maximum tested force in each test is indicated by the continuous line, with a dotted linear fit plotted on the results.



(a) (b)

Figure 10: These figures show the manufactured prototype. (a) The prototype in its natural state. This figure shows how the inner needle extends from the back of the outer needle while in its open position. (b) The cam-follower mechanism in three positions, distinguishable by the location of the guides. At the top, the mechanism is in its open state. In the middle, the mechanism is partially closed. At the bottom, the mechanism is fully closed.

2.5 N, and the first test with the 10 mm flexure a maximum force of 1.5 N. This is expected and was already clear from the preliminary simple calculations. A shorter flexure with constant deflection implies a larger deflection per millimetre of flexure, which would require a larger force to overcome.

More interesting than the location of the measurements is the slope of the measurements along the tests. The slopes of the measurements of flexures of 10 and 7.5 mm remain relatively horizontal, indicating a constant amount of force needed to deflect the flexures. This constant force is an indication for the flexures to express elastic behaviour, with minimal plastic deformation. However, the slope of the 5 mm flexure clearly shows a downward trend. This downward trend means that, in later tests, less force was needed to deflect the flexure than the force needed for earlier tests. This reduction in the necessary force indicates an influence of plastic deformation.

The plastic deformation measured with the load cell also corresponds to the visual inspection. It was difficult to capture in a photograph, but the 5 mm flexure appeared to be slightly bent inward, more so than the 7.5 mm and 10 mm flexures.

Finally, as the pictures in Figures 9a, 9b, and 9c show, the points of the needles with a flexure of 5 mm and 10 mm do not touch when the ends are moved towards each other. On the contrary, the needle points with a flexure of 7.5 mm do touch when the ends are moved toward each other. The reason behind this difference is probably due to the flexures not deforming exactly as expected when they were designed, as the design presumed the flexures to deflect in a neat circular shape when a force is put on the ends.

F. Final prototype

In conclusion, the tests indicate that a flexure cut from a tube with an outer diameter of 3.4 mm and wall thickness of 0.25 mm will deform plastically when deflected to the centre if the flexure has a length of 5 mm or less, while a flexure of 7.5 mm or more will not show plastic deformation or will show it to a negligible amount.

An additional point of interest was the fact that two of the three needles do not neatly close when the ends are pushed together. Only the needle with a flexure of 7.5 mm closes neatly and fits best together. The exact reason behind this is unclear, since each the tips of each needle were designed with the same guiding principles, and not especially fit to the flexure of 7.5 mm Since it is clearly the most promising candidate, the final design will make use of a flexure length of 7.5 mm.

This design was made into a working prototype, shown in Figure 10. The needle prototype closely follows the intended design shown by the 3D models. First, two stainless steel tubes of the necessary dimensions were acquired for the inner and outer needles. Then, both tubes were cut to their corresponding function using the *electronic discharge machining* (EDM) method. This method was well applicable because of the high conductivity of the materials. In the inner tube, two holes were made to hold the guides, as shown in Figure 7b and in the figures of the technical evaluation test. These holes were made by EDM hole drilling. Then, the cutting graspers were cut from a single direction. The inner tube is equal to the inner tube with flexures of 7,5 mm shown in the middle in Figure 8 and in Figure 9b. The outer tube slots were started with a hole by EDM hole drilling, whereafter the full slot was cut open by regular EDM.

After the inner and outer needles were prepared, the inner needle was inserted into the outer needle, and when the holes were aligned with the slots, the guides were put in. The guides then consisted of straight rods sticking all the way through both needles. At this time, the guides were

attached to the inner needle by *laser beam welding* (LBW). Finally, the parts of the guides that remained inside the inner needle were filed out and the needle prototype was finished as shown in Figure 10. The design drawings are enclosed in Appendix B.

IV. Visual validation

A. Visual test goal

Validation of the needle prototype has been divided into two subsequent tests. These tests together will assert whether the needle prototype conforms to the design criteria defined in Subsection II-A.

First, a visual test will be performed by engaging the mechanism without any tissue. This test will convey a general sense of the mechanism's functionality and efficacy.

Second, a material test will be performed. This experiment consists of using the needle prototype on tissue phantoms made from gelatine and artificial bone. The material test will be discussed in Section V

The goal of the visual test is to validate the performance of the needle prototype regarding the cutting and grasping function. For these functions, it is essential that the inner needle can cut to the centre of the needle and fully close off the open end. In this test, these functions will be validated in air, without a tissue phantom, to inspect if the needle prototype functions as expected and completely closes the inner needle.

B. Variables of the visual validation

The variables present in this test are divided between a single independent variable and two dependent variables. These are defined as follows:

Independent variables:

- Cam-follower position; The mechanism will be validated in two positions: 1) fully open and 2) fully closed.

Dependent variables:

- Covered area; The covered area is the size of the area at the end of the needle closed off by the mechanism. It is shown in Figure 11c as a red area. The covered area is defined in pixels squared or in millimetres squared.
- Closure; The closure is a percentage defined by the ratio between the covered area and the total area inside the outer needle.
- Cut distance; The cut distance is the distance the grasper tips cut toward the centre of the needle. Specifically, it is the distance from the inside of the outer needle to the open concentric circle that fits between the grasper tips. The cut distance is indicated in Figure 11c by the green arrow, measured in pixels or millimetres, with the open concentric circle indicated by the green circle. When the cam-follower mechanism is in its closed position, this is when the cut distance is expected to be largest.
- Cut-off; The cut-off is a percentage defined by the ratio between the cut distance and the radius of the outer needle.

C. Visual validation setup

The needle prototype is placed inside a mount to ensure a steady hold. This setup is shown in Figure 11. Figure 11a shows the separated parts of the test setup. The mount, on the right, is made of several different components laser cut from clear PMMA plastic sheet and glued together. An M4 bolt is fixed to the mount to provide steady, reliable linear motion to the needle prototype. Next to the mount is shown the needle prototype, glued in a 3D printed ABS holder to ensure a steady grip. The holder is glued to the outer needle only, so that the inner needle may move inside the outer needle, its movement only limited by the cam-follower.

In Figure 11b is shown how the two parts of the test setup are assembled. The prototype-holder-assembly is slid into the mount from the side until it is located right in front of the bolt. In this configuration, the needle prototype is ready to be tested.

D. Visual validation protocol

The test starts in the configuration as shown in Figure 11b, with the mechanism in its open position. At this moment, a photograph is taken of the open end of the needle prototype. This photograph shows whether the inner needle is fully open at the start of the test.

Hereafter, the bolt is slowly tightened by hand until the mechanism is in its closed position. At this position, a photograph is taken again of the end of the needle prototype, which should now be closed. This photograph provides the open area of the closed needle, as well as the cut distance.

E. Experimental results

During the execution of the experiment, the results were documented by photographs of the end of the needle. These photographs were digitally analysed by painting the area covered by the tips of the grasper and calculating the pixels covered by the coloured areas. Such an analysis is shown in Figure 11c.

The open position of the visual test shows the baseline open area of the initial position, as well as the zero cut distance. One of these photographs with the indicated variables is shown in Figure 11d. In light blue, the inner edge of the outer needle is highlighted, and the area within this circle is the maximum open area. This maximum open area is independent of the cam-follower mechanism position. In red, the area covered by the inner needle is shown. This covered area depends on the movement of the inner needle. In the open position, it indicates the minimum covered area. The maximum open area minus the minimum covered area is defined as the baseline open area. The baseline open area is 71% of the maximum open area. In green, the largest concentric circle not covered by the inner needle is illustrated. This circle will be called the open concentric circle. The cut distance is indicated by a green arrow. In the open position, this is the zero cut distance. This zero cut distance is equal to 22% of the radius of the outer needle.

In Figure 11e a photograph is shown of the end of the needle in its closed position. The same variables are

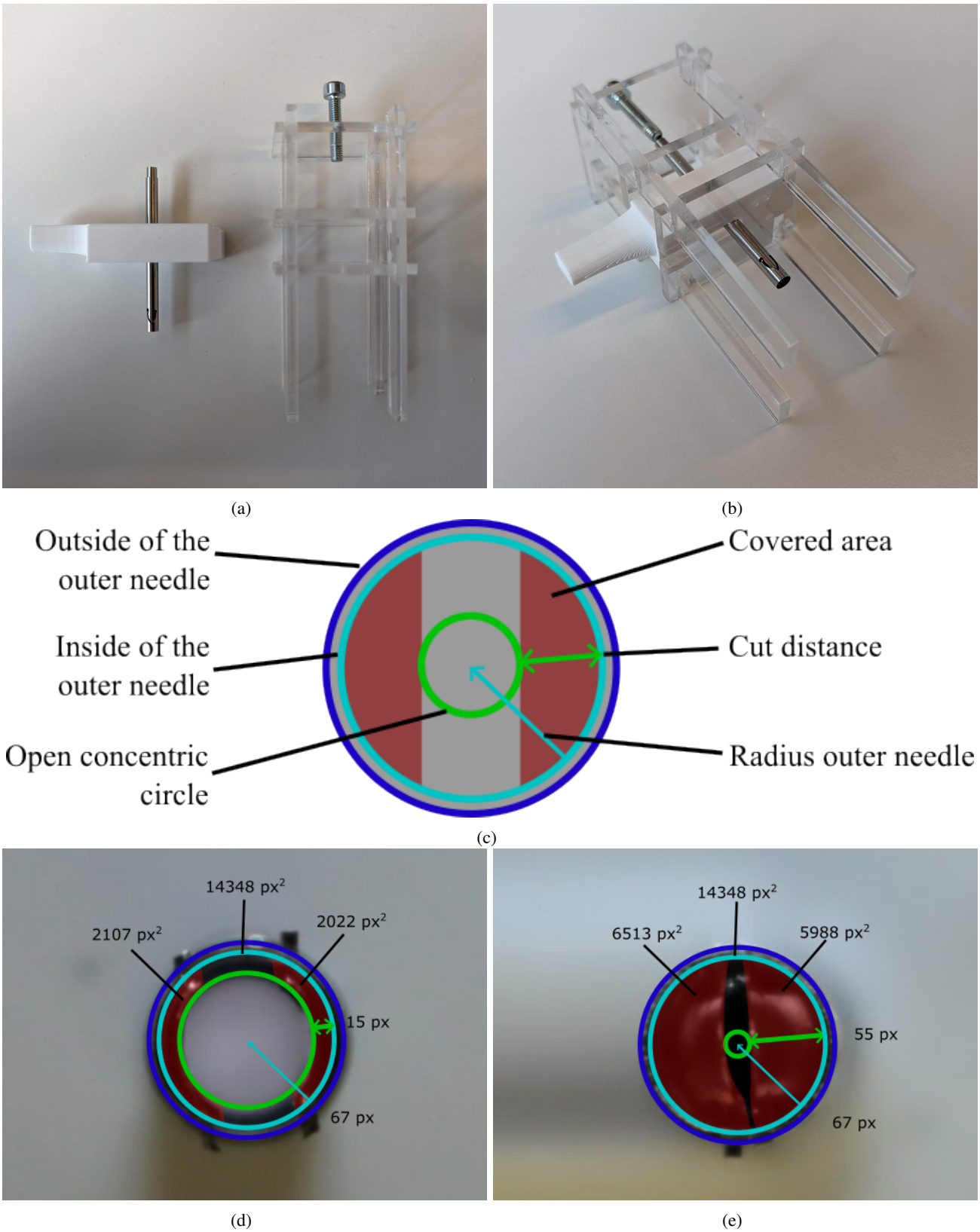


Figure 11: Figures (a and b) show the test setup used in the visual test and material test. (a) Top view of the needle prototype glued into the prototype holder on the left and the mount on the right. (b) The assembled test setup. The holder with the needle prototype is slid in from the side, positioning the needle exactly in the middle, in front of the positioning bolt. (c) The terms used in the visual test, with lines pointing to their corresponding annotations. Next, we have two photographs of the distal end of the needle prototype in its (d) open and (e) closed positions. The annotations from (c) are overlaid and fit onto the photographs, with the values of the key results indicated, measured in pixels or pixels squared. Specifically, the covered areas of the left and right side, the area inside of the outer needle, the cut distance, and the radius of the outer needle are indicated.

illustrated with the same colours, with the sizes of the maximum open area and the covered areas indicated in the figure. The closure has grown to 89% of the maximum open area. The cut-off distance of the closed position has grown to 82% of the radius of the outer needle.

V. Material validation

A. Material test goal

The objective of the material test is to determine whether the needle prototype conforms to a second set of design criteria as defined before: the functional requirements *Insertion* and *Extract*, the dimensional requirements *Biopsy size* and *Hole size*, and the clinical requirements *Ease of use* and *Damageless*.

This goal is divided into two subgoals, one for each type of tissue phantom.

1) The goal of the experiment with the gelatin tissue phantom is to determine the size of the biopsy extracted by the needle prototype and to determine the size and quality of the hole left in the tissue. This type of tissue phantom is necessary because the transparency of gelatin allows for easy inspection of the needle motion.
2) The goal of the experiment with the artificial bone tissue phantom is to simulate a more authentic tissue strength. It indicates whether the needle prototype will withstand the toughness of the artificial bone and if no exceptional force is needed to close the mechanism.

To provide a meaningful comparison, these same tests are also executed with the golden standard.

B. Variables of the material validation

The variables present in this test are divided between a single independent variable, six dependent variables, and a control variable. These are defined as follows:

Independent variables:

- Material: gelatine, artificial bone of grade 5, 10 and 15 by Sawbones. As mentioned in the ASTM F1839 standard for rigid polyurethane foam, the number of each grade is defined by its density in lbm/ft^3 [7]. These densities are defined in SI units by:
  - Density grade 5 pcf: 80.1 kg/m^3
  - Density grade 10 pcf: 160.2 kg/m^3
  - Density grade 15 pcf: 240.3 kg/m^3

  Furthermore, the compressive strength for these grades is defined in the standard:
  - Median compressive strength grade 5 pcf: 0.6148 MPa
  - Median compressive strength grade 10 pcf: 2.283 MPa
  - Median compressive strength grade 15 pcf: 4.935 MPa

  The standard mentions that while the foam is not intended to reproduce the exact mechanical properties of real bones, it is intended to provide a consistent and uniform material for use in testing the interaction between a devices and bone material.

Dependent variables:

- Biopsy size. The biopsy extracted by the needle prototype is measured and its length and diameter are documented. When the biopsy has a nonconsistent diameter, the average diameter over the whole biopsy is measured. To avoid errors in measuring length, the biopsy is laid out straight on paper and measured in length.
- Biopsy quality. The quality of the extracted biopsy is inspected. If the biopsy sides are smooth and its shape is cylindrical, this indicates a high quality. Ragged edges with many different signs of damage or uneven or non-circular circumference indicate a low biopsy quality.
- Hole size. The hole left in the tissue phantom by the needle prototype is measured for its diameter.
- Hole quality. The quality of the hole left in the tissue phantom by the needle prototype is inspected. A smooth and even hole suggests a high quality, ragged edges with many different indications of damage, or an uneven or noncircular circumference indicates a low hole quality.

Control variables:

- Hole depth. By design of the test setup, each hole will be exactly the same depth if the experiment is conducted properly. However, to verify this, the depth of each hole will also be measured.

C. Material validation setup

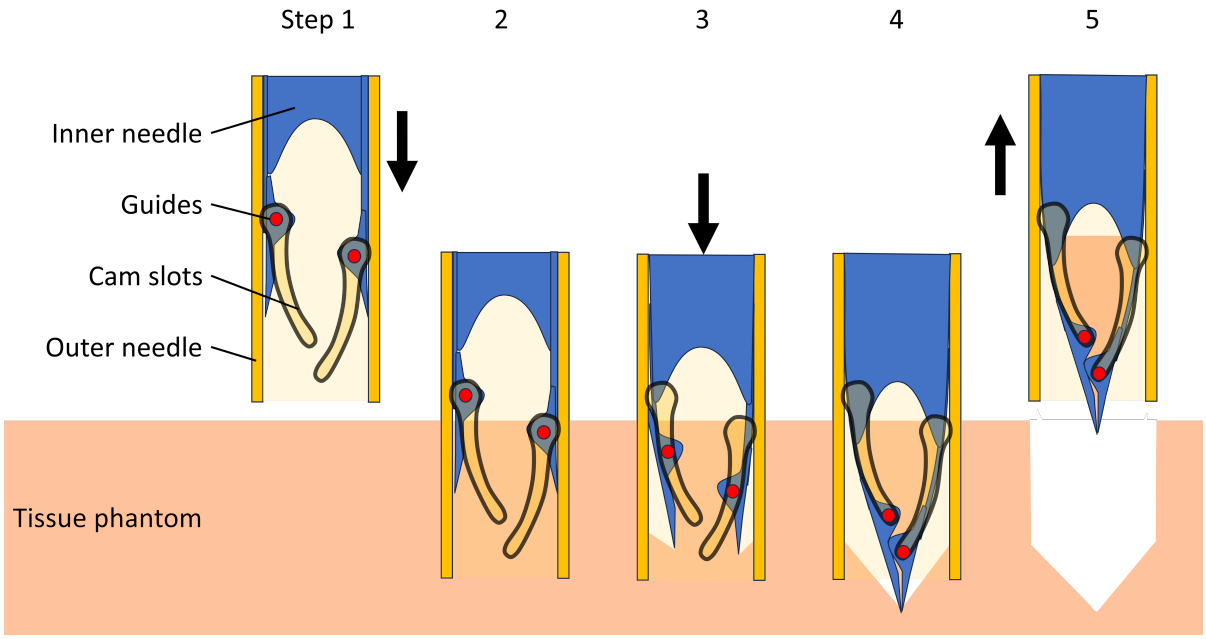
The test is setup very similar to the setup of the visual test. The same mount is used as in Figures 11a and 11b. The mount is designed so that there is space to present the tissue phantom in front of the needle prototype in a linear movement. The four types of tissue phantoms are prepared to fit to the mount.

1) Gelatin. This gelatin is made with 88 w%, as recommended to mimic biological tissue [8]. The liquid gelatin is then poured into a mould to quickly divide the different gelatin blocks and set in a refrigerator for 24 hours before the test.
2) Grade 5 artificial bone.
3) Grade 10 artificial bone.
4) Grade 15 artificial bone.

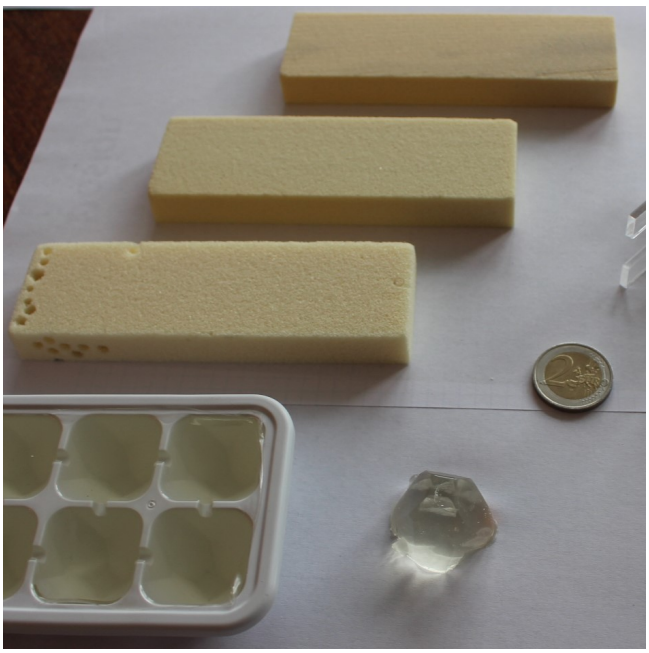
These tissue phantoms are shown in Figure 12b. Finally, the probe from the set of the golden standard will be used in this test to remove the biopsy from the needle prototype. This probe is shown in Figure 14b of Appendix A.

D. Material validation protocol

For each tissue phantom, the experiment was repeated five times. Each experiment was carried out with the same sequence of actions. First, the needle prototype and the tissue phantom were placed in the setup. The tissue phantom was then pushed onto the needle prototype needle until a depth of 20 mm was reached, as shown in Figures 13



(a)



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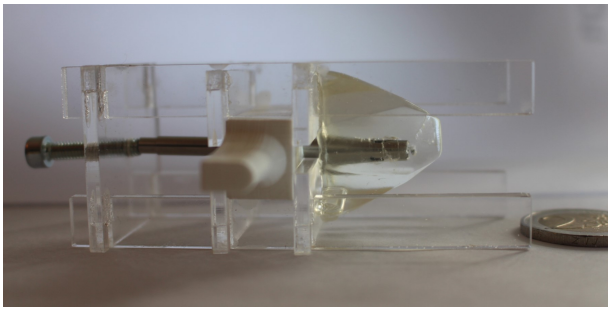

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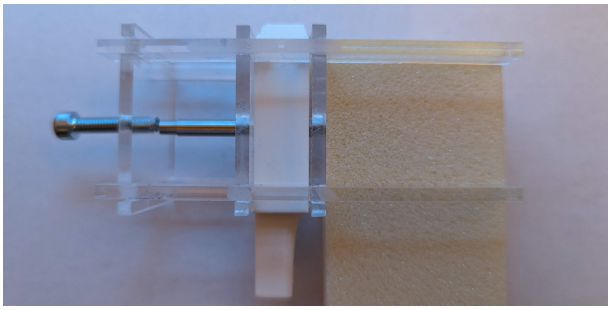

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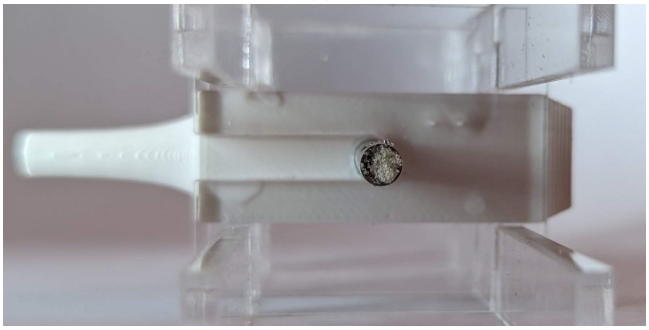


(f)

Figure 12: Material test figures. Some photographs include a coin to indicate the scale. (a) Illustrated is the protocol, which is followed during the material test. Step 1 and 2: push the needle prototype into the tissue phantom up to the desired depth. Step 3 and 4: tightening the bolt outside of the figure pushes the inner needle forward inside the outer needle. Step 5: remove the needle prototype to extract the biopsy. In (f), the tissue phantoms are ordered with the gelatin on the bottom, and the grade 5 pcf, 10 pcf and 15 pcf artificial bone in order from bottom to top. Photographs (c and d) show how (c) the gelatin and (d) the artificial bone tissue phantoms are pressed onto the needle prototype in the test setup. Photographs (e and f) illustrate the state of the experiment right after the biopsy is extracted from (e) the gelatin and (f) the artificial bone tissue phantoms.

and 12d. The bolt was fastened until the back of the inner needle was fully inside the outer needle, indicating that the cam-follower mechanism is in its closed position, and subsequently the tissue phantom was removed from the setup. After this, the bolt was retracted until it no longer made contact with the inner or outer needle. The holder with the needle prototype was removed from the setup and the cam-follower mechanism was retracted to allow removal of the biopsy. The probe from the golden standard was used to gently eject the biopsy from the needle prototype, ready for analysis, as shown in Figures 12e and 12f.

E. Experimental results

The results of the material test are shown in Table I, with Figure 13a for the extracted biopsies and 13b for the holes left in the material. For the gelatin test, the results show five successful biopsies, with a large variation in length and quality. It is clear that the first biopsy shows a lower quality than the next four biopsies. The first came out of the needle in two separate parts, as visible in the figure, and their length indicated by the two numbers in the results table. The second up to the fifth biopsy were extracted in a single piece and each with higher quality. The holes left in the gelatin show a similar story. The first test left a hole, which was more difficult to analyse than the subsequent tests. The first hole had a high quality on the outside, but deeper in the hole the boundary between the hole and the surrounding gelatin became more vague; therefore the depth of the hole could not be measured accurately.

Below the gelatin test results, the results from the test in the 5 pcf tissue phantom are shown. Very obvious are the large differences in biopsy length, as well as the steep drop in biopsy quality. The biopsies are much shorter than the depth of their respective holes. The diameters of the biopsies as well as those of their corresponding holes are quite constant across the experiments. The needle prototype was sometimes quite difficult to drive through the artificial bone. This culminated in one of the guides breaking off from the inner needle during the final test of this category.

Even though one of the guides had broken off, the needle prototype still managed to close its end almost as much as it did when it still had all four of its guides. Therefore, the attempt to obtain at least some biopsies from the 10 pcf tissue phantom was deemed useful. Penetrating this grade of artificial bone was much more difficult. The first test reached a depth of 12.5 mm before the attempt was ended. The second test reached a depth of only 7.1 mm and the experiment was stopped. The data from these attempts is shown in the third section of Table I.

To compare the results of the needle prototype, each tissue phantom was also tested with the golden standard, with the same test protocol. The results of these tests are shown in Table II. The golden standard extracted very low-quality biopsies from the gelatin tissue phantom, while it extracted very high-quality biopsies from each type of artificial bone tissue phantom. Since the needle prototype did not extract a biopsy from the grade 15 pcf artificial bone, the results from that tissue phantom by the golden standard have been omitted.

VI. Discussion

A. Main findings

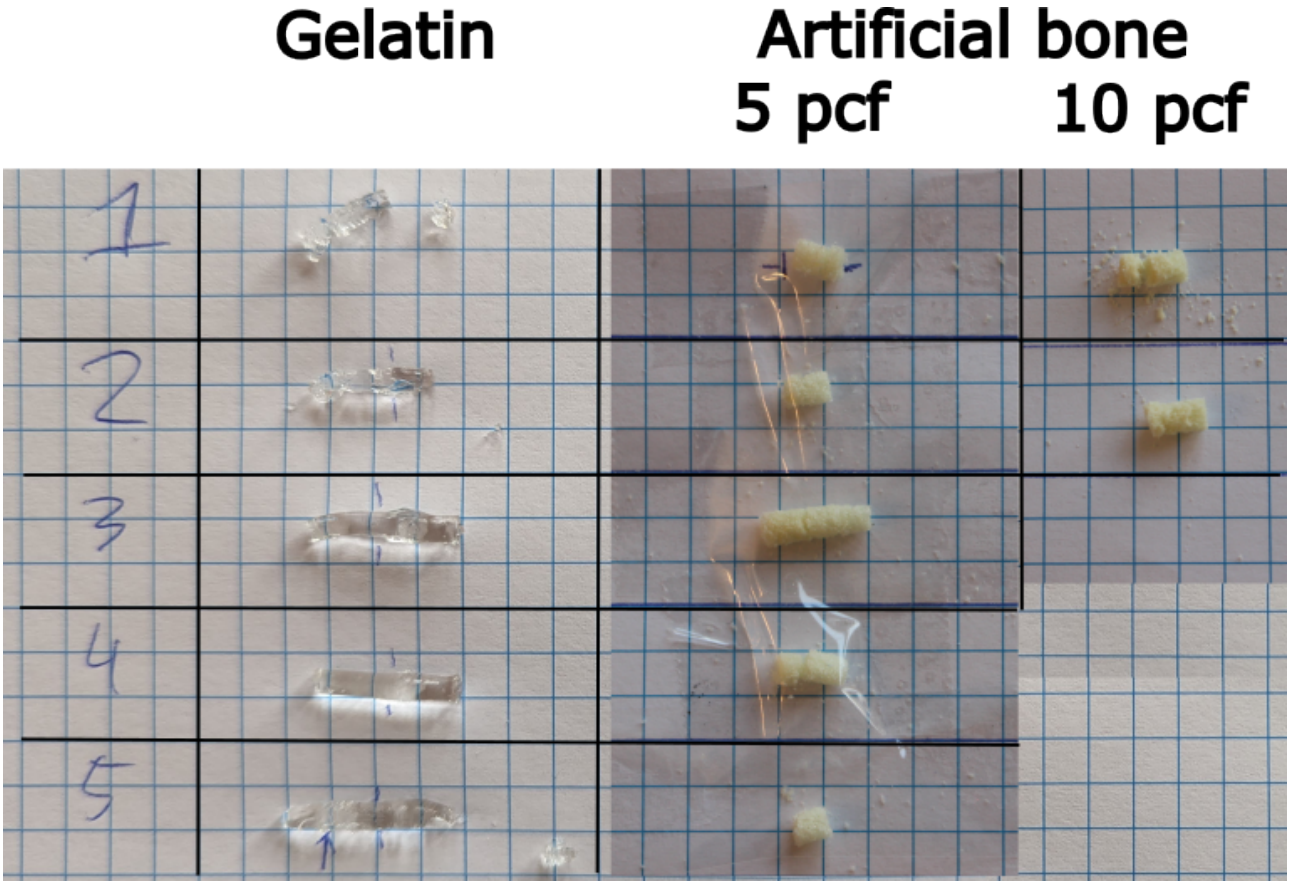
In this study, a novel mechanism for use in a minimally invasive cancellous bone biopsy device was described, designed and tested. This mechanism was to conform to a set of design requirements, subdivided into functional requirements, dimensional requirements, and clinical requirements. On the basis of these requirements, a thorough design study was conducted, which generated a design tree. From this design tree, four concepts were generated which had the potential of being developed into full designs. The final design generated a mechanism based on a concept design called the cam-follower. Before a full prototype was created, three different inner needles were produced with varying lengths of flexures. These three test needles were tested in a flexure test to investigate the ideal flexure length. The flexure length of 7.5 mm was concluded as the shortest of the three flexures that showed no signs of plastic deformation and was therefore considered suitable for this application.

The final design of the biopsy needle was expected to fully conform to the design requirements, therefore, it was synthesised into a prototype that was to be tested thoroughly. During the fabrication of the needle prototype, some difficulties were encountered. Stresses were found to be present in the capillary tubes. When the holes were cut, these residual stresses caused the ends of the tube to deform. This was resisted by fixing the tube in a jig and inserting a plug to support the sides of the tube during cutting. However, there still exists some residual bending due to this effect. The interior of the guides was meant to be cut using the same EDM method as the rest of the prototype, but due to difficult orientations and residual bending, the guides had to be filed through from the inside.

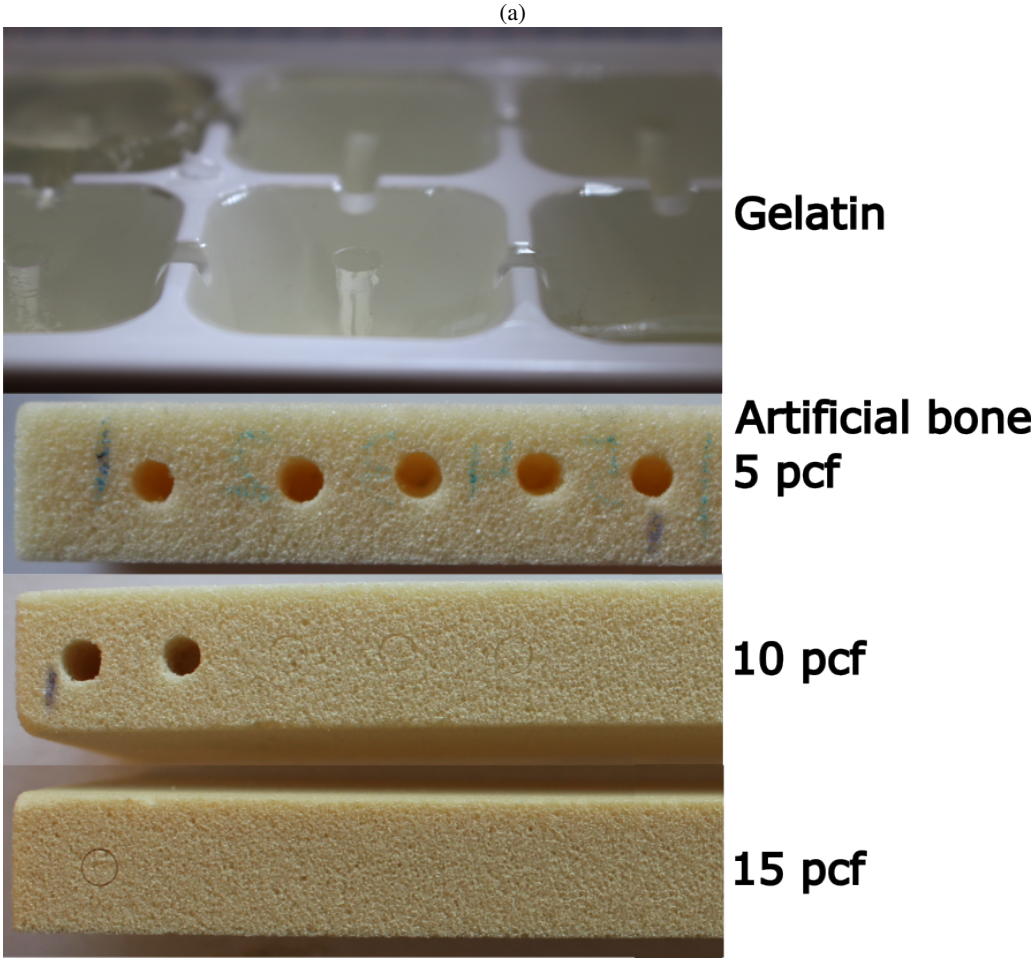
Two separate experiments were conducted to be able to adequately assess the design on each design requirement. First, the needle prototype was subjected to a visual test to inspect whether the mechanism behaves as expected. Second, the needle prototype was submitted to a material test to inspect whether the needle prototype was able to extract biopsies which conform to the stated requirements.

B. Verifying the design criteria

The Insertion criterion is verified by performing the material test. In the test, the device was successfully inserted into three types of tissue phantom. The gelatin tissue phantom was not a problem for the needle, as was expected with such a soft material. The grade 5 pcf artificial bone was more difficult to penetrate using the needle prototype, but was definitely possible. However, grade 10 pcf artificial bone could only be penetrated for a little more than 10 mm and certainly not up to 20 mm. Grade 15 pcf artificial bone was almost impossible to penetrate with the needle prototype. The main problem encountered during penetration was the



(a)



(b)

Figure 13: Material test result figures. Photo (a) is a composite of the results from the gelatin and artificial bone tissue phantom tests. Photograph (b) shows the tissue phantoms after extraction of the biopsies. From these results, Table I has been produced.

Gelatin	Biopsy			Hole		
Test #	**Length [mm]**	**Diameter [mm]**	**Quality**	**Depth [mm]**	**Diameter [mm]**	**Quality**
1	11 + 3	2,8	- -	15	3,3	+/-
2	14	2,9	+/-	17,7	4,2	+ + +
3	17	2,8	+	16,6	4	+ + +
4	16,5	2,9	+ + +	16,3	4,1	+ + +
5	19	3	+	16,8	4,2	+ +
5 pcf	**Biopsy**			**Hole**		
Test #	**Length [mm]**	**Diameter [mm]**	**Quality**	**Depth [mm]**	**Diameter [mm]**	**Quality**
1	6.1	3.6	- -	18.5	3.9	+ +
2	5.2	3.9	- -	17.5	4.1	+ +
3	12	3.8	-	19	4	+ + +
4	7.8	3.8	- - -	15.5	3.9	+/-
5	4.3	3.7	- - -	14.5	3.8	+ +
10 pcf	**Biopsy**			**Hole**		
Test #	**Length [mm]**	**Diameter [mm]**	**Quality**	**Depth [mm]**	**Diameter [mm]**	**Quality**
1	7.3	3.9	- -	12.5	4.1	+ +
2	6.5	4	- -	7.1	3.8	+ + +

TABLE I: Results of the material test, belonging to Figures 13a and 13b.

Gelatin	Biopsy			Hole		
Test #	**Length [mm]**	**Diameter [mm]**	**Quality**	**Depth [mm]**	**Diameter [mm]**	**Quality**
1	-	2.1	- - -	18.8	2.6	+ +
2	11 + 2	2.4	+/-	21.1	3	+ + +
3	20.8	1.8	+	19	3	+ +
5 pcf	**Biopsy**			**Hole**		
Test #	**Length [mm]**	**Diameter [mm]**	**Quality**	**Depth [mm]**	**Diameter [mm]**	**Quality**
1	19	2.7	+ + +	20.5	3.5	+ +
2	18.5	2.7	+ + +	23	3.5	+ +
3	19	2.7	+ + +	21.5	3.5	+ +
10 pcf	**Biopsy**			**Hole**		
Test #	**Length [mm]**	**Diameter [mm]**	**Quality**	**Depth [mm]**	**Diameter [mm]**	**Quality**
1	20	2.9	+ + +	21.5	3.5	+ + +
2	20.5	2.7	+ + +	21.5	3.4	+ + +
3	20.5	2.7	+ + +	21.3	3.5	+ + +

TABLE II: Results of the material tests conducted with the golden standard biopsy needle

compacting effect on the artificial bone. On the grade 5 pcf artificial bone, the biopsy was often compressed to a third of its length prior to extraction. This means that the needle prototype had too large a force transfer to the biopsy and surrounding tissue during insertion, more than was needed to cut through the artificial bone. The needle prototype should not have enough grip on the biopsy during insertion to be able to transfer such a force. In comparison, each type of artificial bone tissue phantom was easier to penetrate using the golden standard biopsy needle. Three main differences are clear between the needle prototype and the golden standard, when comparing Figure 10 to Figure 14 from Appendix A:

1) The golden standard is easier to penetrate bone with because of the large handle which provides a good grip.
2) The last 16 mm of the golden standard are shaped into a tapered end.
3) The penetrating edge of the golden standard is formed into a sharp point with a waving edge.

The first difference increases the amount of manual force possible to put on the golden standard. The second difference lowers the force delivered to the biopsy within the needle. This is clear from the fact that the biopsies from the needle prototype are compacted during insertion of the needle, while the biopsies from the golden standard keep their original length. The third difference lowers the force delivered by the outside of the needle, since the sharp edge allows the golden standard to have a better cutting interaction with the tissue.

The cut criterion is checked in the visual test. Figure 11e clearly shows how the mechanism cuts most of the way through to the centre. However, a cut distance of 82% is not equal to the desired complete cut to the centre. This criterion was again checked in the material test. The cam follower mechanism worked correctly in the gelatin and had the desired effect. However, in the artificial bone, the mechanism did not work as well. It was possible to close the mechanism within the bone, but the grasper seemed to be compressing the biopsy from the sides just as much as cutting it. In the gelatin, this was not a problem because it is a very flexible material, but once the gas pockets in the artificial bone are compressed, the tissue becomes very strong. As shown in the short biopsies extracted, the artificial bone already gets compressed solid before the inner needle is pushed closed. Therefore, the biopsies by the needle prototype from the artificial bone tissue phantoms are probably not cut off, but instead are teared off from the end.

The grasp criterion is combined with the extract criterion, which are also checked with the visual test. The strategy applied to enhance the grip of the device on the biopsy is also the one that guarantees the extraction of the biopsy. For

this reason, the closure was defined in the visual test. The results show a closure of 89%, which is quite high but not as complete a close as was desired. The area that remains open is located between the ends of the inner needle, which should have touched each other when in the closed position. The main reason for this seems to be excessive slack between the guides and slots of the cam-follower mechanism. As shown in the top picture of Figure 10b, the guides start to follow the cam slots when they have already passed the halfway point of the mechanism. This should be a lot sooner in the cam. A subsequent design iteration should investigate how much slack is needed between the cam and the follower guides and keep this slack as low as possible. Furthermore, an indication of why the inner needle does not fully close could be because of the flexure not behaving the way it was designed. The simulation of the flexure bending was not carried out fully during the design process, and only an estimation of the bending motion was made, which seemed to be correct from the results of the flexure test in the design section. However, the prototypes of the flexure test were not bent by the guides, but rather by pushing on the sides of the tips, which could have influenced their function.

The biopsy size criterion is satisfied by inspecting the results of the material test. All biopsies extracted by the needle prototype from the tissue phantoms easily conform to the minimum diameter of 2 mm. To the length, there is no real minimum or maximum defined since there are no counteracting mechanisms further in the needle, so the length should be restricted by the depth of the cancellous bone. However, the length of the biopsy is often not correlated with the length of the hole, which raises the question why. Two of the gelatin biopsies are shorter than their holes are deep, two are longer than their holes are deep, and only one is about the same size. This is probably because gelatin is a flexible material, which bounces back slightly when a hole is left. Also probable is an inaccuracy in measuring the depth of the holes. The holes are measured by inserting the appropriate part of a caliper until it visually touches the end of the hole. Although the gelatin was transparent, it did deflect light slightly and therefore might have introduced inaccuracies in this type of measurement. Furthermore, the quality of the biopsies extracted from the gelatin was quite high, indicating that when the design can obtain a complete biopsy, it will be a viable one.

The hole size criterion is also satisfied by the results of the material test. The holes left by the needle prototype are generally smaller than 4.1 mm in diameter. Two holes in the gelatin are larger, at 4.2 mm. This could be the true hole size, but it could also be due to measurement inaccuracies, since the scale is very small and gelatin is so flexible that any measurements have to be done visually without tactile feedback. The holes in the artificial bone tissue phantom all conform to the hole size criterion and are therefore acceptable.

The wall thickness and biocompatibility criteria are satisfied by the prototype itself. The wall thickness is measured to be 0.5 mm, exactly as it was designed to be. The entire prototype is made up of stainless steel 304 and 302, which are deemed biocompatible for surgical instruments [3].

The ease of use criterion is satisfied by performing the experiments. The prototype was very easy to set up and requires no complex movements. The integrated design ensures that no instruments need to be assembled during operation.

The damageless criterion is satisfied by examining the holes left by the device during the material test, in particular the gelatin tests. The overall quality of the holes left by the needle prototype is very good for each type of tissue phantom. Any additional damage done because of the guides sticking out is negligible.

Of the ten design criteria, six were passed nicely. The cut, grasp, and extract criteria were inconclusive. The design will probably pass them with a little adjustment. The needle prototype did not pass only the insertion criterion, which had the far-reaching effect of being unable to obtain a viable biopsy from the artificial bone tissue phantom. Due to these compressed tissue phantoms, the mechanism was unable to adequately display its function. If a viable artificial bone biopsy was present in the prototype, the mechanism would probably have cut through cleanly and be able to extract a neat biopsy. This is shown in the gelatin tissue phantom, where the needle prototype did indeed extract some very promising biopsies. Four out of the five gelatin biopsies were of higher quality and size than the biopsies extracted by the golden standard. These two different tissue phantoms together show how the device might be able to extract a viable biopsy from bone tissue but that there are still a few problems which need to be ironed out iteratively.

The artificial bone being physiologically different from real bone, may have had a negative influence on the results of this study. The artificial bone tissue phantoms did not have bone marrow inside their open space. This absence of bone marrow, as well as the composition and structure of the tissue, may have influenced how much force was exerted on the biopsy during insertion.

C. Future work

1) Design adjustments: The next step in the design of this cam-follower mechanism is to design a needle that will not suffer from the same compressing effects on the biopsy as the needle prototype suffered from, with a cutting edge and possibly a tapered end, counteracting the compression of the biopsy by inserting the device into the tissue. It should be studied how much the waving shape of the golden standard edge actively supplements the cutting function. The design of the grasper ends and the flexure must be reviewed to make sure that the end of the needle can be completely closed and cut all the way to the centre of the needle by lowering the slack between the cam and the follower. Furthermore, the movement of the grasper ends imposed by the cam-follower should be reevaluated to make sure that they properly cut into the tissue and perform as little compression of the tissue as possible. This forced compression could have put an excessive force on

the guides that they were not intended to carry, which is the main reason that two of the guides broke off during the experiments. The guides also stick out from the outer needle when the cam-follower mechanism is in its open position. This sticking out has a minute negative impact on the quality of the hole left in the tissue. While the guides stick out from the outer needle, the surrounding tissue also enacts a force directly on the guides, which is also not an intended effect and could negatively impact their lifespan.

2) Towards clinical use: One step further, would be to prepare the cam-follower mechanism for use in a clinical setting. To achieve this, a full device should be designed and synthesised that includes a longer needle and a proper handle. This handle should contain a proper mechanism for concentrically moving the inner needle forward within the outer needle. This mechanism should ideally be actuated using only one hand, while the surgeon could use their other hand to stabilise the needle in the patient. In addition, a strategy should be employed to breach the cortical bone. The current design was expected to only encounter cancellous bone, but ideally a complete assembled device should be able to breach through cortical bone without needing a separate instrument to facilitate a hole. After these adjustments, a clinical trial process could be investigated.

3) Research opportunities: A key basis of this study is the understanding that the biopsy slipping out of the current golden standard of minimally invasive cancellous bone biopsy instruments is a real problem. However, no peer-reviewed article was found to report the extent of this problem. Due to this, the basis of this study lies in the verbal report of several clinicians and technicians of a single hospital. To properly identify the prevalence of failed biopsies during an extraction, it is recommended to perform a thorough survey at multiple different hospitals over multiple years. This survey should connect various chances of serious or minor errors or complications to the type of biopsy needle set used and the prevalence of the correct usage of all the instruments included in such a needle set.

When a complete instrument is designed using the proposed mechanism, a thorough study should be conducted to determine whether the proposed greater ease of use is actually beneficial to the procedure. Furthermore, a thorough survey must be conducted among practitioners to determine whether the device is preferable compared to other devices currently available. Additionally, a commercial analysis should be performed on the device. This commercial analysis should aim to answer whether the device would be more expensive to produce than currently available devices and whether hospitals would be willing to use a more expensive instrument, even if the instrument would grant a lower likelihood of complications for their patients.

VII. Conclusion

In this study, a novel mechanism was presented for use in a cancellous bone biopsy instrument based on a cam-follower design. This mechanism was derived from a detailed design study into different design directions that were condensed into four main concepts that were submitted to a selection procedure. The cam-follower design was developed into a full-fledged final design. This cam-follower works by a double-walled design, based on translating an inner needle inside an outer needle. The distal end of this inner needle is cut from the side to create two ends of a grasper. The ends of this inner needle can be pushed together by following a cam in the outer needle, with the cam designed so that the grasper ends of the inner needle are pushed together. Part of this design stage was to experimentally determine the optimal flexure length of the grasper ends, to ensure that the needle prototype would be reusable and would not suffer plastic deformation. The resulting design was then made into a working prototype. This needle prototype was then validated for each design criterion through a visual test and a material test. The visual tests showed that the cam-follower mechanism works and is capable of closing off 89% of the end of the needle. The material tests showed that the needle prototype was able to extract high-quality biopsies from a gelatin tissue phantom. The needle prototype was unable to extract viable biopsies from an artificial bone tissue phantom. The main problem encountered during the artificial bone test was the compression of the biopsy within the needle prototype during insertion, which compacted the biopsy to such a high strength that the grasper was unable to cut properly. Additional design iterations are required to adequately test the cam-follower mechanism on artificial or real bone. This novel design is a first step toward revitalising innovation in a clinical application that has seen little change over the past 50 years.

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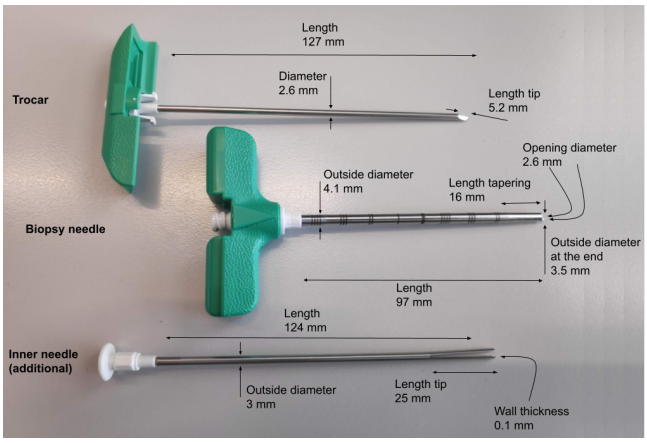
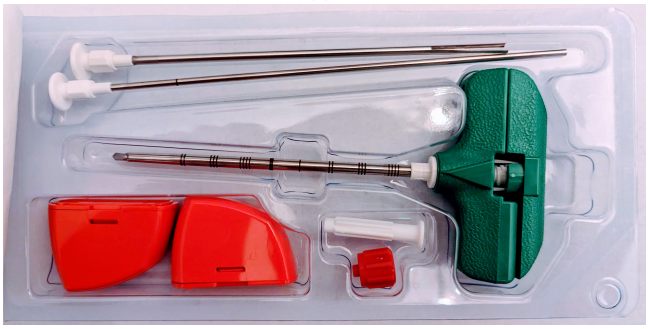


(a)



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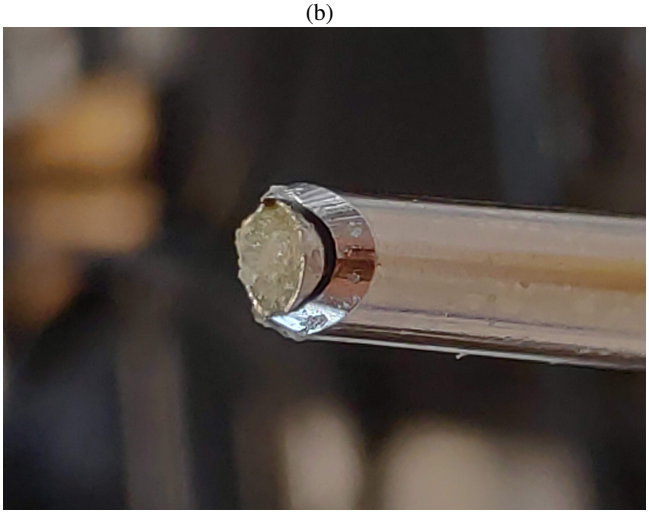


(c)

(d)

Figure 14:

APPENDIX

A. *Golden standard*

As the current golden standard is taken the device which is used at the polikliniek of the Reinier de Graaf Gasthuis Hospital. The device is an Argon T-Lok Bone Marrow Biopsy Needle, shown disassembled in Figure 14a. The figure also shows the key dimensions of the needle, which are used to determine the size of the hole made by this device. The outer diameter of 4.1 mm is used to determine the maximum size of the proposed design in the design criteria.

In Figure 14b is shown how the needle is presented for use. All components are sealed together in single-use packaging. The needle and trocar are presented in an assembled state. This is desirable because it is now ready to penetrate the cortical bone. However, the assembled instrument is fitted with a protective plastic tube, which will need to be removed before use. The inner needle and a probe are also fitted with a protective tube.

In Figure 14c it is shown how the instrument is supposed to look with the inner needle inserted to grip a biopsy. In the next photo, Figure 14d, shows how the inner needle is supposed to extract the biopsy from the outer needle. The biopsy is clearly visible on the inside of the grippers of the inner needle. For these photos, a sample tissue was used, no real or artificial bone.

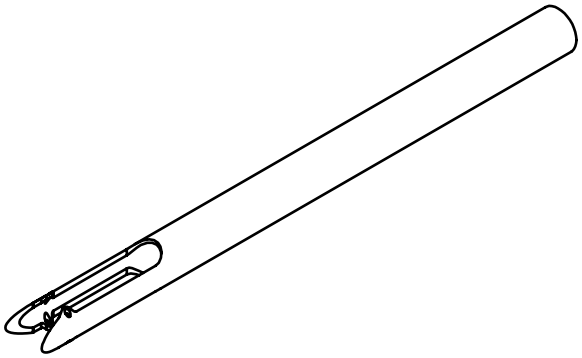
At this point, the probe from the set can be used to gently push the biopsy out of the inner needle. This is not the only function of the probe. It may also be used to measure the length of the biopsy inside the needle, when the needle is still inside the patient.

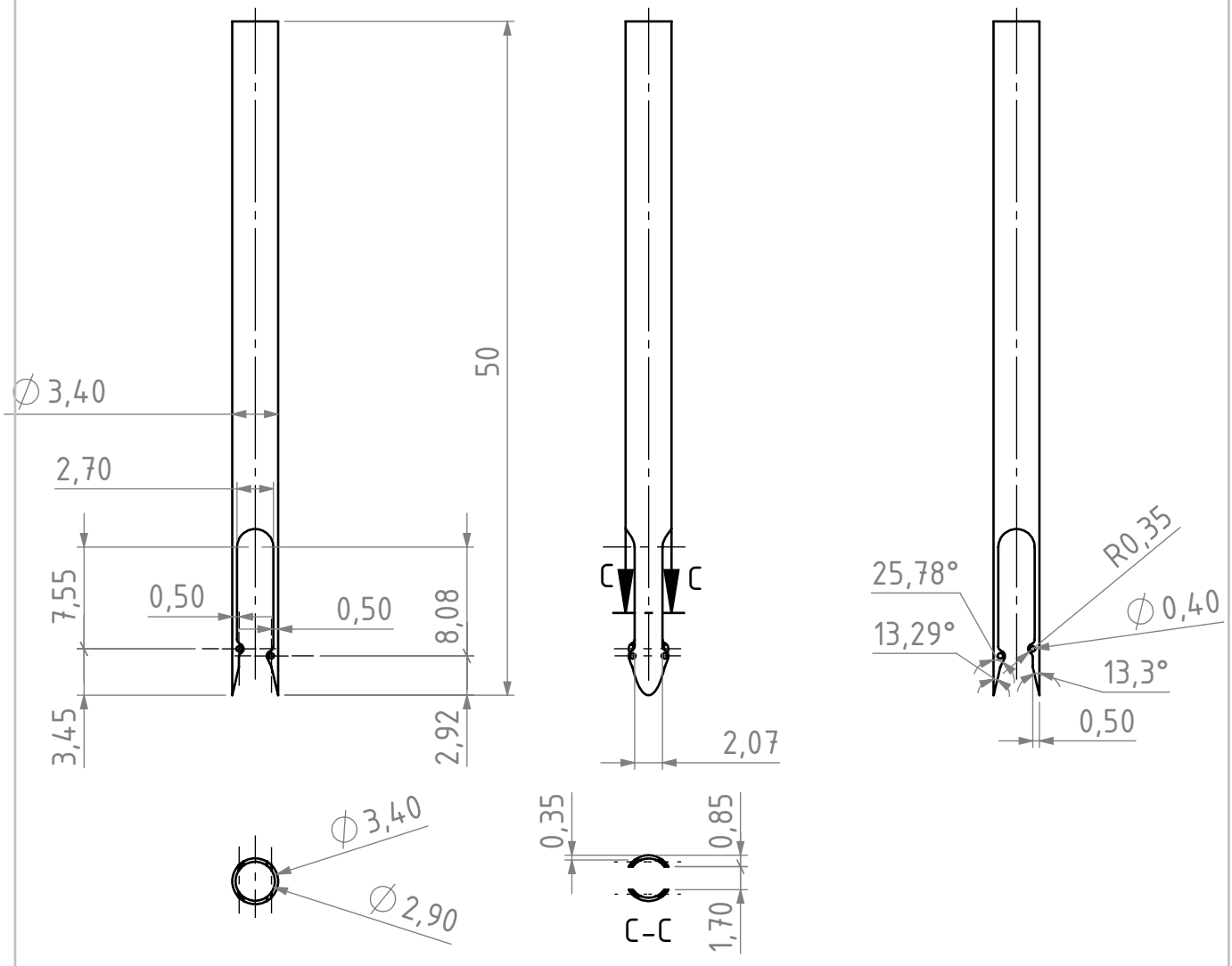
For the sake of comparison, this golden standard design would belong to the Active, Double-walled, Translation branch of the tree shown in Figure 2. This is the same branch as to which the final design belongs, so they have some design characteristics in common with each other. As indicated by their category, both comprise an inner and an outer needle, with a mechanism actuated by a translation between those needles. For both designs, when they are fully inserted into the cancellous bone, the outer needle stays in position, and the inner needle is advanced to grasp the biopsy located inside. Both outer needles force their inner needle to close in this way.

There are some key differences, however. First, the Cam-follower design is already assembled before the procedure, while the inner needle of the golden standard needs to be inserted halfway through the procedure. Furthermore, the outer needle of the golden standard closes the inner needle by tapering the diameter, pushing the ends of the inner needle together. The outer needle of the final design features a cam, which the ends of the inner needle follow and are consequently pushed closed. The major difference between these two designs is, therefore, that the end of the final design is closed off almost completely with a cutting motion, while the end of the golden standard is only partially closed off with a compressing motion.

B. Design drawings

On the following pages, the design drawings of the final design are included. These drawings were made from the 3D models designed in Solidworks, as presented in the final design Section II-E.





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material AISI 304				mass 0.83gr	
author Jos Boetzkes 4285247				assembly Cam-follower	TU Delft Delft University of Technology
name InnerNeedle				format A4	drawing no. 1/4
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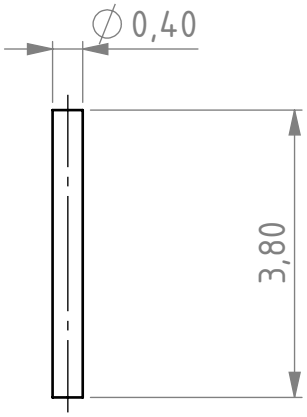

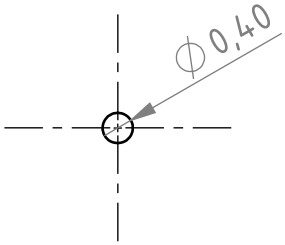

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material AISI 304				mass 0.004gr	
author Jos Boetzkes - 4285247				assembly Cam-follower	TU Delft Delft University of Technology
name OutercamGuide				format A4	drawing no. 2/4

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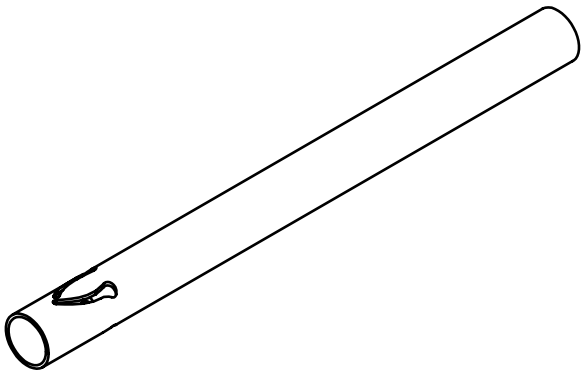
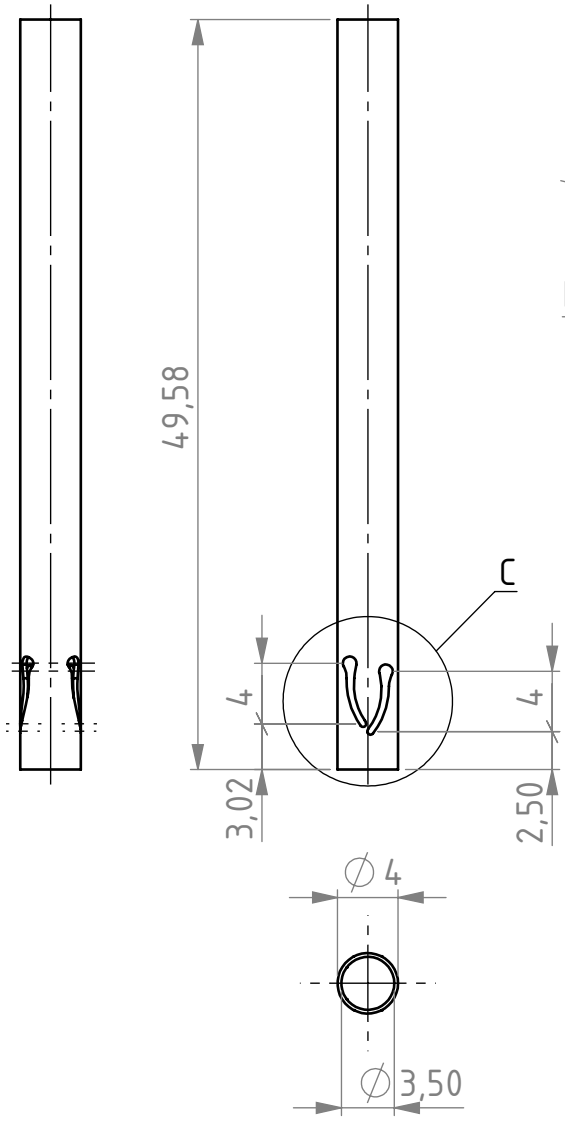
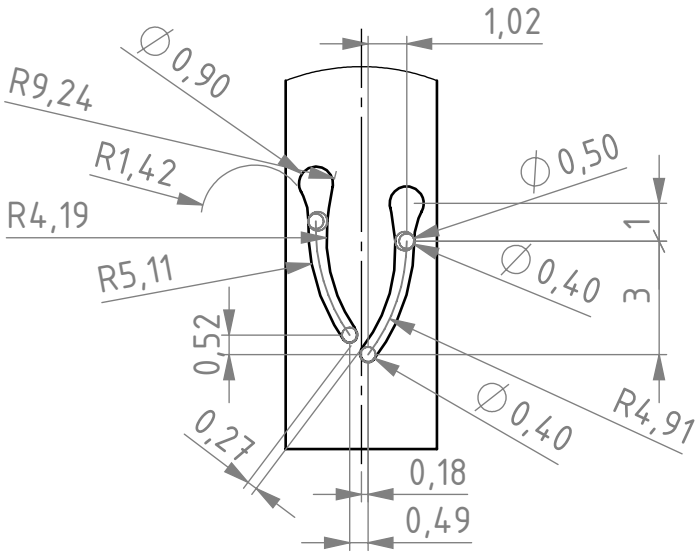
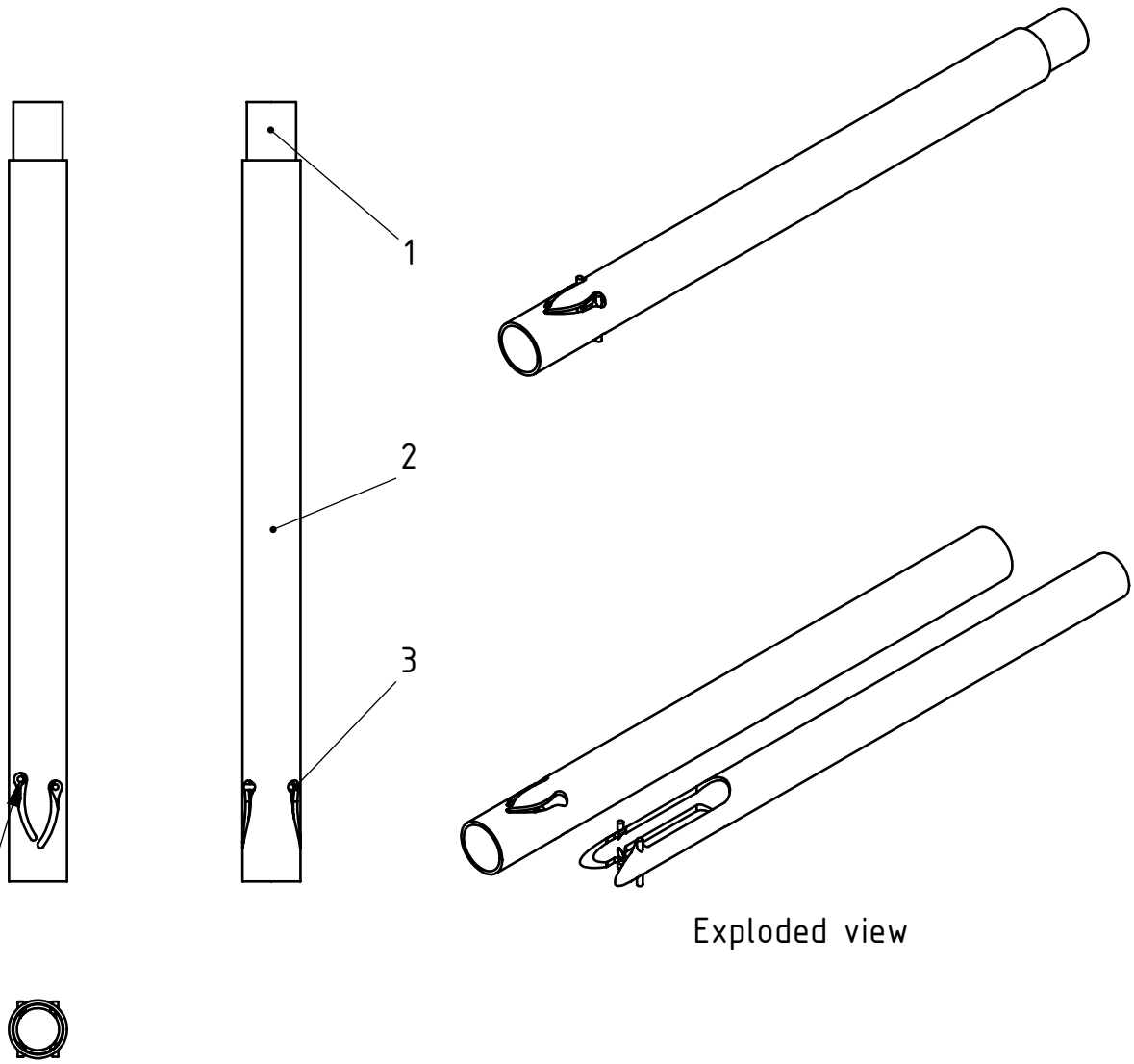






C (5 : 1)

	units mm	scale 2:1	quantity 1	date 29/10/2023	remark Made from capillary tube
material AISI 304				mass 1.14gr	
author Jos Boetzkes - 4285247				assembly Cam-follower	TU Delft Delft University of Technology
name OuterNeedle C:\Users\Jos\Documents\Afstuderen\3D Modellen\Final\				format A4	drawing no. 3/4



Exploded view

Insert the tabs through the holes in the inner needle, while inside the outer needle. Hereafter weld the tabs to the inner needle and cut out the parts of the tabs sticking through the centre.

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	InnerNeedle	The inner needle of the final design	1
2	OuterNeedle	Outer needle of the final design	1
3	OutercamGuide	Guide, to be fastened to the inner needle	2

	units mm	scale 2:1	quantity 1	date 29/10/2023	remark Welding and cutting is necessary
material		AISI 304 (parts)		mass 1.98gr	
author	Jos Boetzkes - 4285247				

TU Delft Delft University of Technology

name	Cam-follower	format	drawing no.
C:\Users\Jos\Documents\Afstuderen\3D Modellen\Final\		A4	4/4

C. Bone Biopsy Instruments: A Patent Review

Attached to this document is the literature review which preceded this study. It is named ”Appendix C. Bone Biopsy Instruments Patent Review.pdf”.