DEVELOPMENT OF A NOVEL NEEDLE GUIDE TOOL FOR PERCUTANEOUS INTERVENTIONS WITH AN OMNIDIRECTIONAL STEERABLE NEEDLE DURING REAL-TIME US-GUIDANCE

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ABSTRACT

Radiofrequency ablation (RFA) is a localized thermal intervention technique with the purpose to destroy small tumours (< 3 cm) by heating the tumour tissue [1]. For image-guided interventions like RFA, Ultrasound guidance is the best choice to use: compared to CT-guidance, US guidance is more attractive because of the shorter procedure time, lack of radiation, more cost-effective technique, less needle passes and the portability [3,9,10].

Due to various challenges with targeting and visualisation during RFA, the clinical need of steerable needles is present for radiologists [14]. Helwig, B.P. developed a new omnidirectional steerable needle for this purpose. However, this needle is not yet ready for implementation in the operation room (OR) because no clinical testing is performed in vivo. Also, no interaction factors between the steerable needle and helping tools are examined yet. Therefore, the aim of this thesis is to develop a novel needle guide tool for percutaneous interventions with an omnidirectional steerable needle during real-time US-guidance.

In order to examine the visibility of the steerable needle, an experimental study has been conducted. This study is a reproduction of the methodical quantification of needle visibility and echogenicity in ultrasound images [22]. The steerable needle has a promising visibility in Polyvinyl alcohol and is expected to be well visible during ultrasound guided interventions. The needle guide development process towards a novel end-product consists of a complete view of the problem, clear programme of requirements, selection of the best concept and the iteration process of the design, eventually evolving to a novel solution. Several systematic methods are used to support the process.

The developed needle guide tool is called UShift and provides both the benefits of needle guided puncturing and free-hand puncturing. Which are for free-hand puncturing: freedom of movement of both the probe and needle during puncturing and for needle guided puncturing: a shorter procedure time, reduced needle manipulation and improved needle visualisation. The working principle of the UShift is as follows: when it is desirable to detach the needle from the guide, the probe can carefully be manipulated to let the needle follow the path towards the direction the end, the exit, of the path. When the needle is detached, the probe can be relocated free-handed at the desired place. When the needle should be placed back from free-hand puncturing to guided puncturing, the path can be followed backwards to reach the fixation point of interest. Moreover, at any time another angle orientation can be chosen.

A user test is performed to verify how the needle guide is performing compared to the currently used needle guide while hypothetical using the Omnidirectional steerable needle. The difference between the two puncture techniques is 0,9 seconds, the UShift is 23% faster. This is a promising result, because it is to be expected that the learning curve of the experts will yet increase while using the UShift more frequently. The UShift has several advantages in comparison with the Verza: there is no relocation of the hands needed while shifting the needle through the guide. In addition, while using the UShift it is possible to easily switch back from free-hand puncturing to needle guided puncturing.

In conclusion, this project resulted in a novel needle guide tool that can be used in combination with the omnidirectional steerable needle during percutaneous interventions. The UShift has great benefits compared to currently used needle guides and is therefore stated as innovative.

More gain is to be expected through future research concerning production methods, material options, the cost-effectiveness and other application fields of the UShift.

CONTENTS

11 APPENDIX

LIST OF ABBREVIATIONS

CNR	Contrast-to-noise ratio
CT	Computed Tomography
EC	Experimental conditions
HCC	Hepatocellular Carcinoma
IP	In-plane
OOP	Out-of-plane
OR	Operation room
PVA	Polyvinyl alcohol
RFA	Radiofrequency Ablation
US	Ultrasound
USP	Unique selling point

1 INTRODUCTION

1.1 RADIOFREQUENCY ABLATION (RFA)

Image-guided percutaneous ablations are currently recommended as first diagnosis and treatment choice for liver cancer considering small tumours (<3 cm) [1]. Radiofrequency ablation (RFA) is a localized thermal intervention technique purposed to destroy tumour cells by heating the tumour tissue up to 50 °C and higher. Resulting from this, the intracellular proteins are denatured and cell membranes are teared down through dissolution and melting of lipid bilayers [2].

Percutaneous RFA has been proved to be effective to cure small Hepatocellular Carcinoma (HCC) [3]. When transplantation or surgical resection is not possible for patients, RFA is currently recommended as the best alternative [1].

Different studies have shown that RFA is safe, with minimal morbidity and mortality [4-7]. RFA appears to be equivalent to resection and compared to resection RFA has shorter hospital stays, lower complication rates and lower costs [8].

1.2 IMAGING TECHNIQUES DURING RFA

For image-guided percutaneous interventions like radiofrequency ablation, abscess drainage or tissue biopsy often Ultrasound (US) guidance or Computed Tomography (CT) guidance is used. The preference for primary guidance modality of radiologists depends mostly on the experience and training of the radiologist. For example, radiologists from the United States prefer CT guidance and interventionalists from Europe, however, tend to use US guidance more. This preference has continued to influence the training and practice for many radiologists [9].
Besides a preference, technical efficiency of the techniques is important. An effective cure is defined as no local tumour recurrences, a complete ablation rate and overall survival rate [3].

Studies have shown that no significant difference between US- and CT-guidance is found in complication rate and there is no statistically significant difference in complete ablation rate and recurrence rate [3, 9]. Therefore, based on technical efficiency no difference can be made between US- and CT guidance. Due to real-time feedback when using US, a smaller number of needle passes is measured for tissue biopsies compared with CT guidance [9]. Proven is that compared to CT guidance, US has a shorter procedure time during a tissue biopsy intervention [3,9,10]. Aspects contributing the procedure time are equal for both CT and US guidance. CT guidance has a high puncture accuracy and a high image resolution [11]. US guidance during percutaneous interventions is more cost-effective than CT techniques [9,10,12]. Moreover, US guidance has absence of ionizing radiation and is portable [12].

In conclusion, for most cases of small HCC, US guidance is the best choice to use. Because of the shorter procedure time, lack of radiation, more cost-effective technique, less needle passes and the portability US guidance is very attractive.

1.2.1 PUNCTURE TECHNIQUES

Direct US guidance can be divided in two puncture techniques; using needle guidance devices (fig. 1) and free-hand puncturing (fig. 2) [13,19,23,25]. The needle guidance devices are commonly attached to the transducer and provide a predetermined direction for the needle to keep the needle in plane due to, for example, a tube.

Alternatively, the free-hand puncturing technique consists of only the needle and US probe. No predetermined direction and angle are set. Several studies investigated the advantages and disadvantages of both the techniques.

The main advantage of free-hand puncturing is that the probe can move freely, therefore

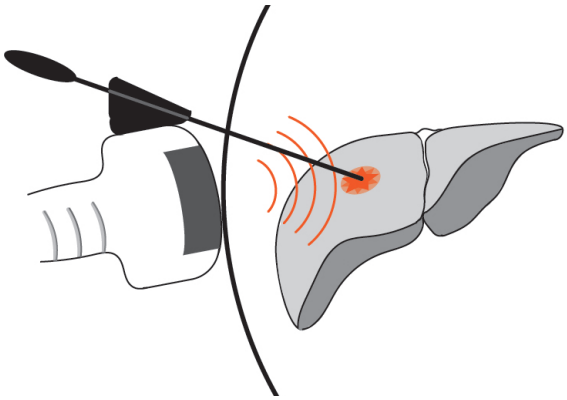


Figure 1: RFA with US-guidance in combination with a needle guide device.

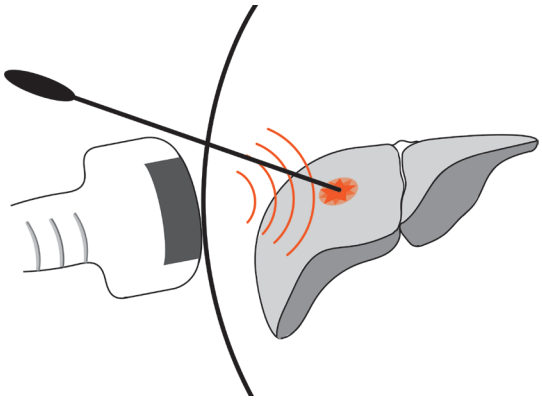


Figure 2: RFA with US-guidance, free-hand puncturing.

adjustments can be made on the positioning of both the probe and needle path [13,23,25].

Phal et al. investigated the influence of experience of the interventionalists on the time difference between the techniques. Shown is that especially unexperienced operators experience benefits from using a needle guide while placing the needle under US-guidance [23,25]. Unexperienced operators (< 10 clinical biopsies) have greater time savings than experienced ones, but even experienced operators gain time profits [25]. Using the needle guide leads to reduced needle manipulation and thus less procedure time is needed to reach the target with the needle [23,25].

Geffen, v. et al. investigated the difference in procedure time and visibility of both the techniques. The needle guidance technique shortened the procedure time with a significantly improved needle visualisation [25]. Because of the fixation of the needle guide device the benefit of using a needle guide is greater for deeper structures. Consequently, a longer needle is needed, the increased flexibility can cause deviation of trajectory [19]. No significant difference in quality is shown between the free-hand technique and use of the needle guide device (e.g. accuracy in interventional procedure) [25].

In conclusion, the benefit of free-hand puncturing is the freedom of movement of both the probe and needle during puncturing. Needle guided puncturing has the benefits of a shorter procedure time, reduced needle manipulation and improved needle visualisation. The choice of technique is often based on experience and habits.

1.3 VISUALISATION OF A NEEDLE

Several studies investigated the visibility of different needles while using US image-guidance [13,17-21]. A surface in US imaging is described as visible when the surface produces different echoes than its surroundings, which means that the foreground and background areas differ from each other. The contrast-to-noise ratio (CNR) quantifies this difference in signal strengths and therefore describes the visibility in US. On the other hand, you have the echogenicity which describes the surface property, independent of the background properties. A signal ratio can be used to relate the foreground properties to the reflection standard [22].

Various aspects contribute to good visualisation of the needle during RFA, which can be divided in; technical aspects, anatomical aspects, positioning techniques and material properties.

1.3.1 TECHNICAL ASPECTS

Properties of the US transducer and needle are determinative for the quality of the real-time feedback. Therefore, technical aspects of the US system of influence are: display set-up, depth control and gain control. Depth control represents the depth of the needle in the structures, this should be set until the structure of interest is close to the centre of the image. The gain control alters the brightness of the image [19].

Needles with a small diameter (gauge) are harder to visualise [13, 14, 19]. The visualisation of the needle will be interfered when it deviates from the US beam, this can be caused by needle bending [14].

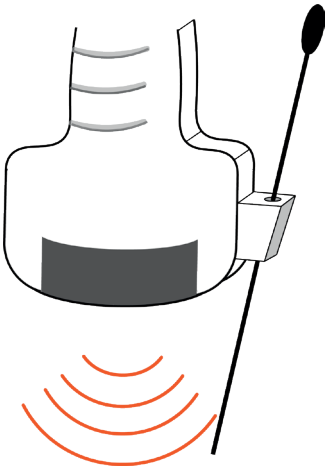


Figure 3: IP puncture technique, longitudinal configuration.

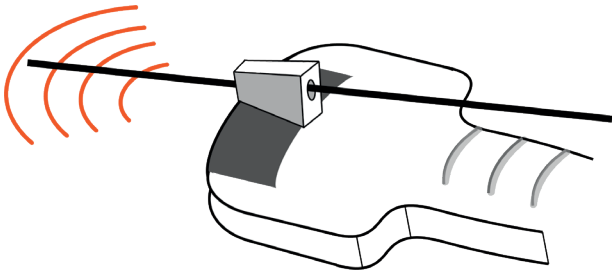


Figure 4: OOP puncture technique, transverse configuration.

1.3.2 ANATOMICAL ASPECTS

Anatomical aspects of the patient can be very determining for a good visibility. Difficulties can be deeply located targets or targets that are surrounded by tissue interfaces that have sufficient different acoustic impedances which will cause an acoustic shadow [19]. Furthermore, the (irregular) breathing from the patient can cause movement of the target, which can cause complicated reachability of the target [14].

1.3.3 POSITIONING TECHNIQUES

Probe orientation and the angle between the probe and needle play an important role in visualisation of the needle. Two viewing point techniques are used with US guided puncturing; the in-plane (IP) technique (fig. 3), where the entire needle shaft and tip are visualised and the out-of-plane (OOP) technique (fig. 4), where the needle will only be visible in cross-section which means a spot can be seen on the real-time screen [23].

Needles that are placed parallel (IP) to the US beam are better visual than needles placed perpendicular (OOP) to the beam, therefore the longitudinal configuration allows a more improved visualisation of the needle than the transverse approach [19]. Additionally, needles in general become less visible when the angle between the US beam and the needle tip decreases. Alternatively, the visibility improves when an angle of 90 °C is approached [19].

1.3.4 MATERIAL PROPERTIES

Properties such as surface properties, needle material and coating can be influencing the needle visibility in US imaging. The so called 'scattering' effect of the needle tip can be used to visualise the shaft of the needle better, this can be done to roughen or to create an irregular surface of the shaft of the needle [18,19]. In order to obtain a high contrast-to-noise signal (CNR), texture similar to the compliant joint structure is recommended instead of a smooth surface needle [17]. Moreover, polymeric coating increases echogenicity due to the micro air bubbles [24].

1.4 NEEDLE GUIDE SYSTEMS

Literature shows multiple ways to assist during percutaneous interventions. Manual and robotic systems concerning needle placements can be considered as two different developments [15]. This thesis will be focused on manual percutaneous interventions. Systems such as computer assisted systems and dual-armed robotic system can be considered as robotic assistance systems and will therefore be disregarded. Needle guide devices, non-electronic devices that are clinical proved to work, are for our interest.

1.4.1 NON-ELECTRONIC DEVICES MENTIONED IN LITERATURE

The basic working principle of such a needle guidance device in a percutaneous intervention is as follows: 1) The target area is scanned to get the target in sight. 2) The needle guidance attachment is attached to the transducer of the US. 3) The scanner is positioned so that the needle pathway crosses the target on the oscilloscope. 4) The depth of the lesion is determined and targeted due to real-time scanning. 5) The needle is inserted through the needle guide and subsequently inserted into the body. 6) The procedure is performed and the target is treated [26].

Needle guidance devices can be fixed to the transducer or are detachable. The fixed version lies within the sterile sheath together with the US transducer. The detachable devices are attached onto the sterile sheath and are either disposable or can be sterilized for reuse [19].

In table 1 different needle guide devices are mentioned which are found in literature. For more extensive information about the needle guides, including their working principle and advantages and disadvantages, see appendix A.

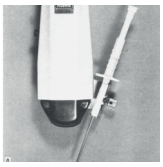
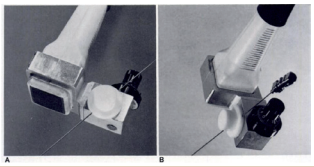
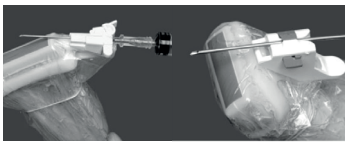
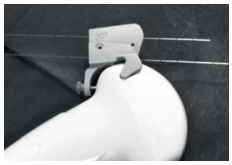
Device	Reusable/ Disposable	Needle diameter(s)	Available angle(s)	Procedure/ intervention	Advantages
Real-time guidance for percutaneous puncture (Saitoh et al., 1972) 	Reusable	Several sizes	20 degrees	Biopsy	Needle can be detached from the attachment
Steerable real-time needle guidance system (Buonocore et al., 1981) 	Reusable	22 to 14 gauge	All angles	Biopsy	Flexibility of variation in the angle orientation
Sterile disposable needle guides (Chapman et al., 2003) 	Disposable	N/A	N/A, fixed	N/A	Possibility to use device in transverse and longitudinal direction
Lateral-mounted needle guide (Di Costanzo et al., 2013) 	Reusable housing and disposable snap-on needle guide	21 gauge	15 - and 30 degrees	Laser ablation with multiple needles	Ability to prefix the distance between multiple needles

Table 1: An overview of different needle guides found in literature, showing multiple properties.

1.5 PROBLEM DEFINITION

Interventionalists still experience clinical challenges during RFA. Despite the improving technology, accurate puncturing often does not succeed in one attempt [16]. Important to know is what is stated as 'accurate' or as a 'accepted error'. As stated by de Jong et al. the mean maximal accepted error during ablations is 2.7 mm [14].

These challenges of placing a needle can be divided by technical challenges or patient related challenges. Respectively this means unwanted needle bending, poor needle visibility and limited imaging possibilities for technical challenges and movement of target due to breathing, intervening anatomy and movement of target due to insertion for patient related challenges [14].

A major issue for the visualization of the needle while using the IP-technique can be that when the needle even slightly deviates from the path, the visualization of the needle becomes less [19,23]. This can be caused by unwanted bending of the needle, which causes the necessarily of re-puncturing [14].

For the accuracy and efficiency of the RFA intervention visual feedback from the image-guided technique is essential to make the treatment a success [13-15]. Unfortunately, sometimes while using US guidance the ablation needle is not clearly visible in the real-time feedback. Bad visualisation may result in less accurate ablations, which as a result can lead to treatment failure or major complications. Due to various challenges with targeting and visualisation during RFA, the clinical need of steerable needles is present for radiologists [14].

Helwig, B.P. developed an omnidirectional steerable needle which tackles the above mentioned challenges. However, this needle is not yet ready for implementation in the operation room (OR) because no clinical testing is performed in vivo. Also, no interaction factors between the steerable needle and helping tools are examined yet. In order to be able to implement the omnidirectional steerable needle in the OR, several aspects should be taken into account. How visible is the steerable needle during US-guidance? How does the steerable needle work in combination with a needle guide?

It is not clear yet whether the needle is combinable with the current needle guides or how they interact together.

Therefore, the aim of this thesis is to develop a novel needle guide tool for percutaneous interventions with an omnidirectional steerable needle during real-time US-guidance.

2

VISIBILITY OF THE STEERABLE NEEDLE

Before the omnidirectional steerable needle can be implemented in practice, it is important to quantify what the visibility is of this needle during US-guidance. As stated before, the contrast-to-noise ratio (CNR) quantifies the difference in signal strengths and therefore describes the visibility in US [22].

In order to examine the visibility of the steerable needle, an experimental study is conducted. This is a reproduction of the methodical quantification of needle visibility and echogenicity in ultrasound images [22]. For this study a phantom is used, consisting of Polyvinyl alcohol (PVA) to mimic the liver tissue.

2.1 MATERIALS AND METHODS

Because this is a reproduction, the materials and methods section is as much as possible maintained. Only a summary is given of the used materials and methods and several additions are mentioned. For more extensive information the paper of Berg,. N. J. v.d et al. can be used as a reference [22].

2.1.1 SPECIMEN

Two cylindrical PVA specimen with a radius of 19 cm and height of respectively 6 - and 10 cm were prepared for the visibility study. Polyvinyl alcohol (Selvol PVOH 165, Sekisui Chemical Group NJ, US) with a 4 m% PVA to water concentration is used since it mimics the most realistic force reaction of human liver tissue [29].

Warm water is merged with the PVA particles and is heated to 93 °C while it is continuously stirred. This temperature is at least maintained for 30 minutes, next, the mixture is poured in the purposed mould. When the mixture is cooled down to room temperature, the mould is placed in the freezer. Then, the specimens underwent two freeze-thaw cycles of respectively 24 hours and 12 hours. The phantoms should be stored in water at a temperature of circa 7 °C to retain the desired properties.

2.1.2 INSTRUMENTS

The omnidirectional steerable needle is used to perform the experiment. The needle contains a Franseen tip with three symmetrical surfaces. Additionally, alongside the tip holes are added to make a flexible joint. The needle is made from nitinol, a material with super elastic properties. The shaft, e.g. the cannula, is made from nitinol as well [30].

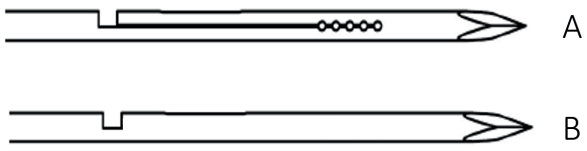


Figure 5: Two positions of the needle, perpendicular to the ultrasound beam.

Two orientations are used for measurements, see fig. 5 for the positions of the needle. These two positions are chosen to ensure high visibility during an intervention, because both positions are possible while inserted in the patient.

These two positions are chosen to ensure high visibility during an intervention, because both positions are possible while inserted in the patient.

2.1.3 EQUIPMENT

Equipment refers to the necessary items for a particular purpose, below the list of used equipment for the set-up of the experiment is given. The numbers refer to the numbers in figure 6.

1. Curved array transducer (C5-2, Philips, NL1)
2. US system (HD7 XE, Philips, NL)
3. Capturing device (USB3HDCAP, StarTech, US)
4. Stepper motor (42BYGHM809, Wantai Motor,CN)
5. Micro stepping driver (Big Easy Driver, Sparkfun, US)
6. Linear micro-stage (PT1/M, Thorlabs, US)
7. Microcontroller board (Arduino Uno R3, Arduino, IT)
8. Custom made platform to support the steering handgrip of the needle
9. Needle template with holes at every 10 mm along the specimen height

2.1.4 SETTINGS EQUIPMENT

The US system was set to: a frequency of 5 MHz, an imaging depth of 15 cm and a focus depth of 9 cm. The gain setting was set as Gn=25 for PVA. The micro stepping driver is set at a constant angular speed of 0.1 rad/s (100 steps/s with 6400 steps in 2rad),

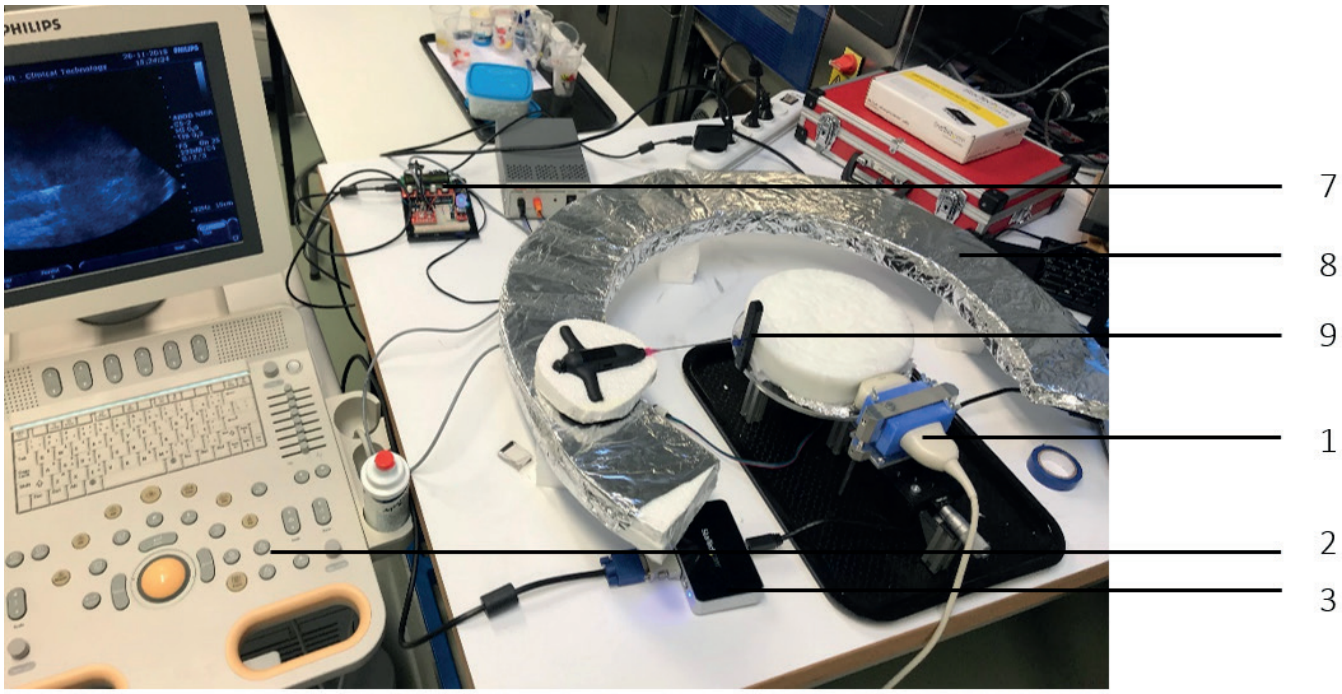


Figure 6: Experimental set-up of the needle visibility experiment

using a microcontroller board (Arduino Uno R3, Arduino, IT). The insertion angle range was limited to [25,...,180]◦ by the needle-transducer contact.

2.1.5 DATA PROCESSING

All the data is captured with the capturing device which connects the US system with the computer. The files were exported as MP4-files. These MP4-files were transferred to Matlab (R2018b, Mathworks, US). For image processing an image processing algorithm is used. This Matlab code is reused of Berg, van de et al., for more extensive information this paper can be used as a reference [22].

2.1.6 EXPERIMENTAL DESIGN

The desired outcome of this experiment is the visibility of the custom-made needle. The rotating platform will cause a variation in angles for the needle. Therefore, one of the independent variables in this experiment will be the orientation of the needle tip. The orientation of the needle will be manipulated in two ways (fig. 5).

In table 2 the condition matrix can be seen, consisting of two different experimental conditions (EC's) that represent a unique combination of levels.

To reduce the experimental error, the orientations will be randomized in order during the experiment. To obtain this randomization a run table using the two EC's is made in advance of the experiment, the run table of the randomized orientation can be found in appendix B.

n=49	Orientation A	Orientation B
	EC11	EC12

Table 2: Condition matrix of the visibility experiment.

2.1.7 EXPERIMENTAL PROTOCOL

To obtain reliable results, the experiment should be retained as much as possible for every repetition. Therefore, an experimental protocol should be followed. Below, the preparation before the experiment is given and next, the steps to follow before and during every repetition of the experiment. The protocol during the experiment is a loop that is repeated for every repetition.

Before the experiment:

- PVA is made following the protocol described by de Jong, T. L., et al.
- The set-up is prepared as can be seen in figure 6.
- A randomized run table is made to know which orientation should be used (appendix B).
- Prepare the specimen and place it in the middle of the rotating platform.
- Set-up the US system (HD7 XE, Philips, NL) with the corresponding settings.
- Start the video capture software.

During the experiment:

- Check which position the needle should be place in according to the run table.
- Place the angle of the platform in the start position.
- Place the needle.
- Adjust the transducer height by means of an all-thread rod, to enabled alignment with the needle.
- Set the correct file name according to the EC.
- Start the recording of the video capture software.
- Start the stepper motor with an angle of 210 degrees.
- Guide the needle through the moving cycle.
- When the stepper motor stops, stop the record.
- Remove the needle.
- Reposition the specimen.

2.2 RESULTS

During the experiment initially 50 repetitions were foreseen. For both positions, test runs were executed which were inadequate. Adjustments had to be made to the experimental set-up and therefore these measurements are left out in the results. In the results 49 repetitions per position are executed according to a randomized run-table (appendix B).

Polar plots of the needle tip - and needle shaft visibility versus insertion angle can be seen in fig. 7 and fig. 8, respectively. The figures consisting the polar plots show the following; on the y-axis the CNR is displayed, which describes the visibility of the needle in PVA. A high CNR value is desired, because it indicates a high visibility and therefore it is to be expected that the needle is well visible during percutaneous interventions. On the x-axis, the insertion angle is displayed, the rotation platform created different angle orientations.

The plot of the needle tip visibility (fig. 7) shows a relatively high SD value as a result of the large variation in data values. The tip visibility for both the positions of the tip resulted in a high visibility for the full angular range.

The distribution of visibility of the shaft (fig. 8) has a less wide angular range than the needle tip (fig. 7). The needle shaft is best visible around an angle of 75 degrees, expected to be caused by specular reflections which were reflected to the US probe. Despite the peak, the shaft is visible at almost every angle.

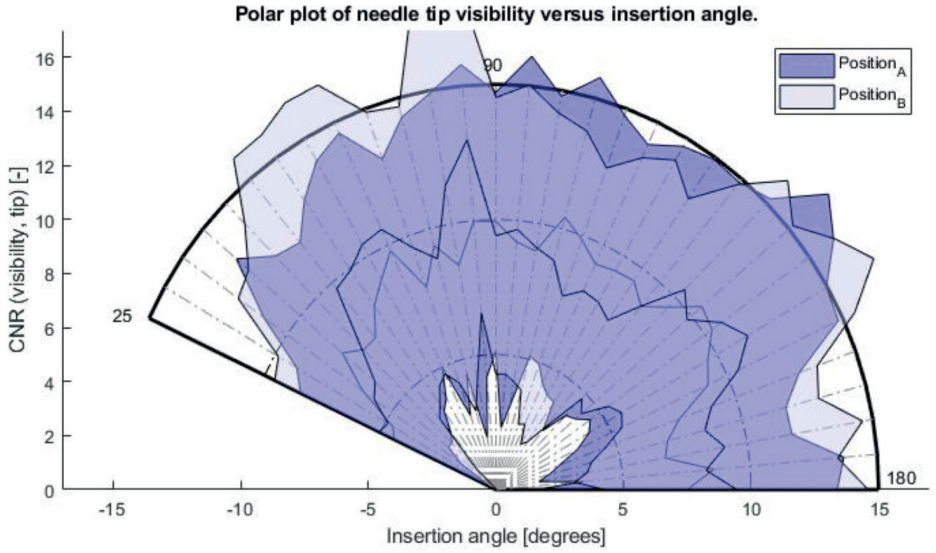


Figure 7: Polar plot of needle tip visibility versus insertion angle. All data included, 49 repetitions per position.

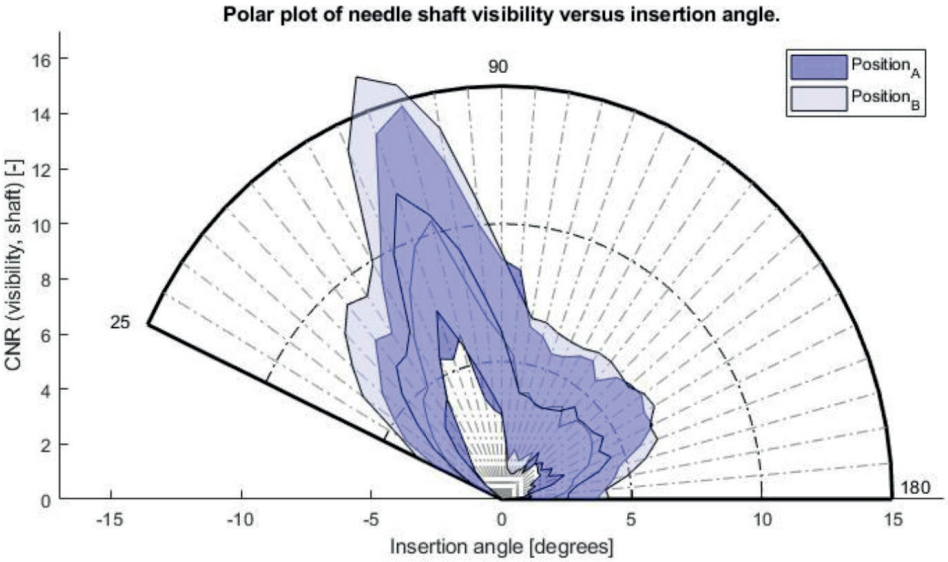


Figure 8: Polar plot of needle shaft visibility versus insertion angle. All data included, 49 repetitions per position.

2.3 DISCUSSION

The results of this study can directly be compared with the previous results of the study of Berg,. N. J. v.d et al. because this study is a reproduction and the same parameters and processing algorithms are used. The visualization results of different needles used in the study of Berg,. N. J. v.d et al. can be seen in figure 9 and figure 10. Four different needles were compared on visibility.

The ideal situation would be that the visibility is high (e.g. high CNR value) at the whole angular range.

Remarkable is that compared to the previous experiments the visibility of the needle tip of the customized needle is even better than the previously measured ones (fig. 9). The CNR value is for a wide angular range higher than the compared needles. A cause could be the small holes that are processed in the needle tip, this creates small spaces in which air could be trapped. Another possibility is that the Franseen tip causes a scattering effect, this is in line with literature that states that the scattering effect and air result in better visibility [18, 19].

The needle shaft of the steerable needle can be considered as a medium result compared to the results in figure 10. The range could be as wide as for example the Trocar needle, however, the customized needle has a more centred peak around 75 degrees. The peak around 80 degrees is commonly for a shaft because the orientation causes a direct reflection to the probe. The result for the omnidirectional steerable needle is therefore comparable to the previously measured needles.

Both the needle tip and needle shaft results are exceeding or comparable to the visibility of the previously measured needles. This is a promising result for the future, in all probability the omnidirectional steerable needle has a high visibility during US-guided percutaneous interventions.

2.3.1 LIMITATIONS OF THE EXPERIMENT

Despite of the promising results, a few limitations of the experiment should be taken into account. Especially for reproduction of the experiment several handlings should be carefully executed. For example, the alignment of the transducer and the needle is adapted every repetition; this should be done very systematic every time before the measurements start. However, the best alignment depends on the visual perception and interpretation of the experimenter and is therefore suggestive.

Next, the needle is inserted manually every time. Because of this, the depth and start angle position is slightly different. These small differences in measurements can cause deviation in the output data.

2.4 CONCLUSION

The experiment consisted of multiple measurement repetitions for the steerable needle and provides the desired data. Some handlings are done manually, which can cause deviations in the data. Because more data is available of a previously performed experiment of several needles, a comparison has been made between the pervious results and the results of the customized needle. To conclude, the omnidirectional steerable needle has a promising visibility and is expected to be well visualized during ultrasound guided interventions. Under the condition that the probe should be correctly aligned with the needle in the right plane.

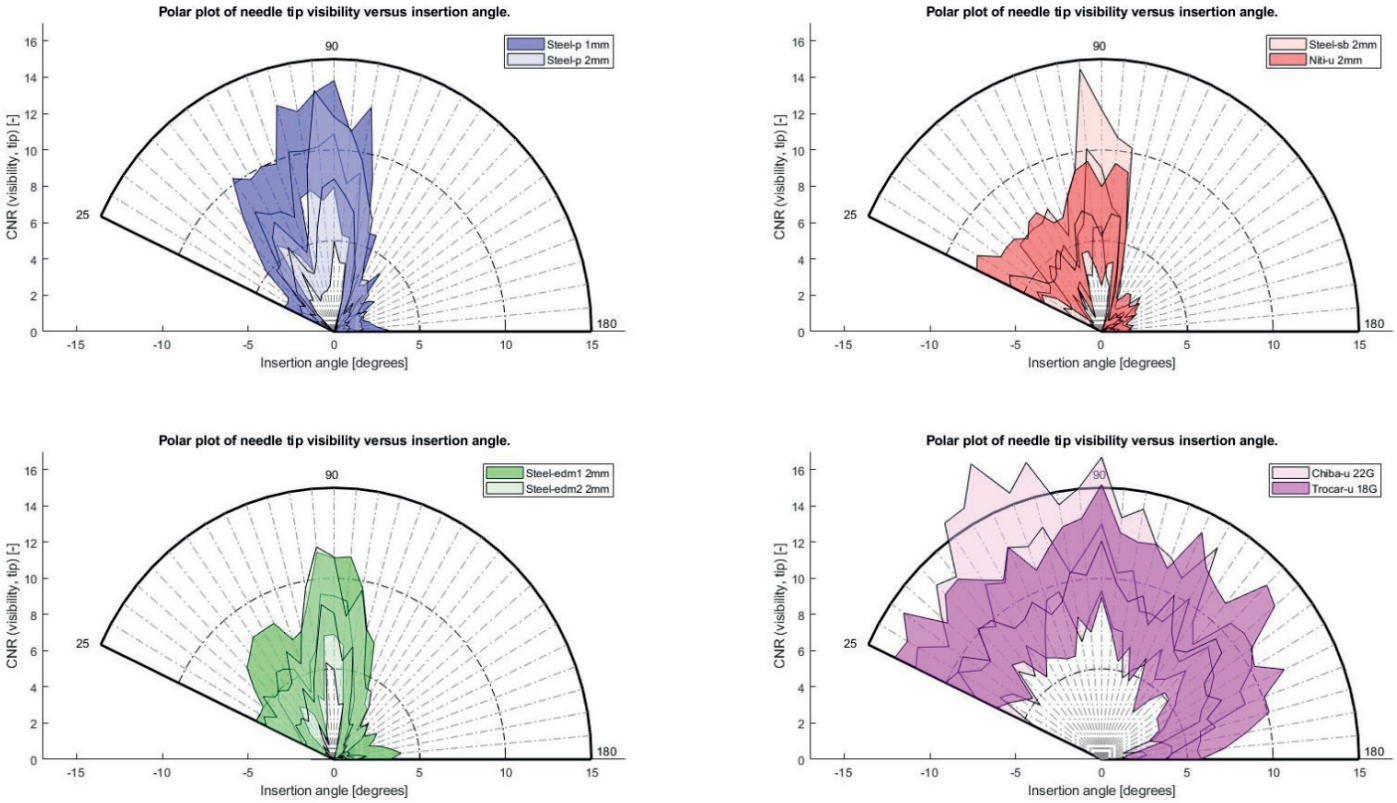


Figure 9: Polar plot of the needle tip visibility versus insertion angle measured for four different needle types [22].

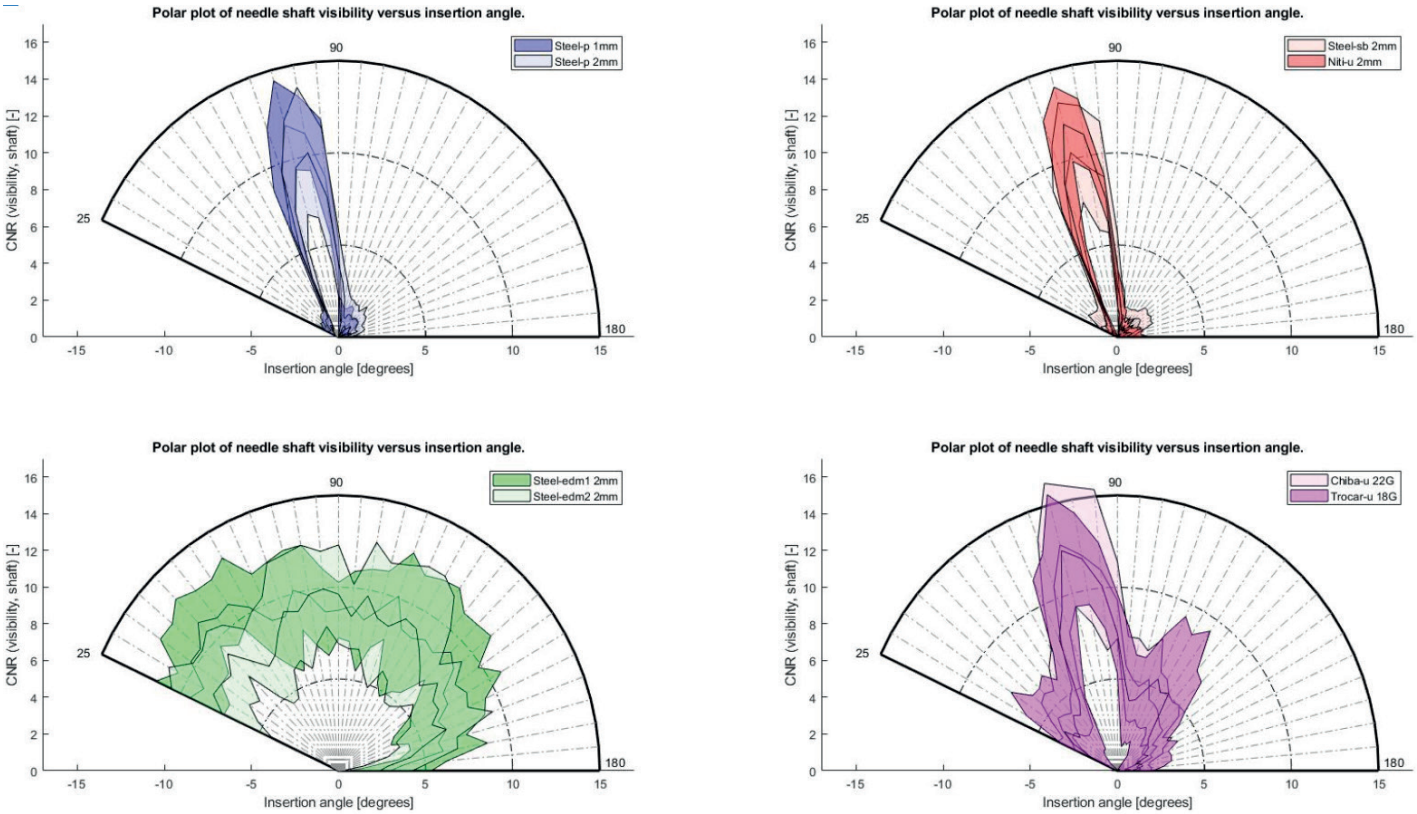


Figure 10: Polar plot of the needle shaft visibility versus insertion angle measured for four different needle types [22].

3
DESIGN PHASE

In this chapter the fundamentals for the design phase of the needle guide are mentioned.

The design process towards a novel end-product consists of a complete view of the problem, clear programme of requirements, selection of the best concept and the iteration process of the design, eventually evolving to a novel solution.

The design process is split up in two chapters; design phase and the Concept selection.

This chapter, the design phase, starts with the problem analysis by looking to the stakeholders and factors that influence the design. Next, the design goal will be defined including a function analysis which results in a complete programme of requirements.

3.1 STAKEHOLDERS AND INFLUENCES

As stated in the introduction, the aim of this thesis is to develop a novel needle guide tool for percutaneous interventions with an omnidirectional steerable needle during real-time US-guidance. To find out the specific design goal, important is to know who is involved with the problem and which other factors are of influence on the design.

3.1.1 THE USER

The user, in this case the radiologist, is of great influence of the performance of the intervention. Every user has its own preferences and habits during the percutaneous intervention. The puncture technique may differ per user; free-hand puncturing or needle guided puncturing or a combination of both is a possibility during usage. Because of the fact that every doctor has a different puncture preference, this should be considered in the final design. Also, the user can be right – or lefthanded, this should not be an issue during the puncturing.

3.1.2 THE PATIENT

The patient is of influence, because every tumour is different positioned and the anatomical aspects will differ for every intervention. Also, the intervention becomes harder when the patient has an irregular breathing rhythm [14]. When a patient has a target that is hard to visualize, more often a needle guide is used in practice.

3.1.3 STEERABLE NEEDLE

Also, the steerable needle will determine the design of the needle guide. How is the steerable needle used in practice and what are the bottlenecks while using it (in combination with a needle guide or not)?

Observation and a user test shows that while puncturing with the steerable needle the freedom of free-hand puncturing is desired, because you can adjust the probe in such a way that the tip of the needle is best visible while steering. Because the tip can 'steer' out of the plane, the plane needs to be adjusted to the right angle. On the other hand, you want the accuracy and time benefits of inserting that you have while using a needle guide.

3.1.4 CURRENTLY USED NEEDLE GUIDES

As stated in the introduction, several needle guides were found in literature. Since they state back to 1972, these are not represented for the currently used needle guides. Before one can develop a new design, a good overview must be there to estimate the state of the art. In table 3 an overview can be seen of the currently used needle guides in practice. For larger figures, see appendix C. All guides are retrieved from commercial manufactures or are used in the Erasmus MC.

The current detachable needle guides claim to easily detach the needle during the procedure to allow the operator to have the freedom of freehand puncturing. However, according to radiologists, in practice the needle either detaches when this is not desired or the detachment provides a lot of effort.

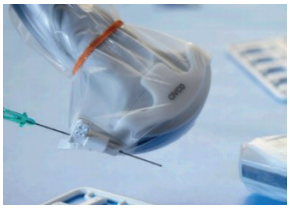
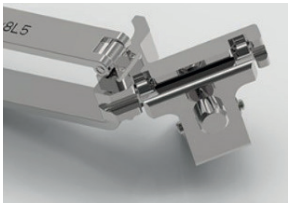
Detachable clip needle guides					
	Name, company	**Advantages**		**Disadvantages**	
	AccuSITE™ Out-of-Plane Ultrasound Needle Guide Replacement Kits, CIVCO [32]	-	High range of possible gauges	-	Multiple handlings when detaching
	Director™ Sterile Needle Guide - 24/ Box, Protek [33]	-	High range of possible gauges	-	Detaches at undesired moments
	Sterile Ultra-Pro II™ Disposable Needle Guides. Mermaid medical [34]	-	High range of possible gauges	- -	Multiple handlings when detaching Multiple components design
Closed clip needle guides					
	Name, company	**Advantages**		**Disadvantages**	
	Multi-Pro 2000™ Ultrasound Needle Guide Brackets, CIVCO [35]	-	Total fixation of the needle during puncturing	-	No possibility to detach the needle during puncturing
	InnoFine JSM-060 Ultrasound Needle Guide For Siemens, National Ultrasound [36]	- -	Reusable Corrosion resistant	-	No possibility to detach the needle

Table 3: Overview of currently used needle guides. Including name, company, advantages and disadvantages.

Other needle guides			
	Name, company	Advantages	Disadvantages
	Ultra-Pro e™ Disposable Variable Angle Needle Guides, Mermaid medical [37]	- Variable angle possibilities	- Only available for small gauge - No fully fixed position of the needle
	Verza™ Ultrasound Needle Guidance System, CIVCO [38]	- Variable angle possibilities - High range of possible gauges	- One way removable - Multiple components design

Table 3: Overview of currently used needle guides. Including name, company, advantages and disadvantages.

3.2 DESIGN GOAL

As stated before, the combination of a needle guide and the steerable needle causes an interesting opportunity for a new needle guide. In table 3 can be seen that most of the advantages of needle guides are related to multiple inserting angles and different gauges possibilities.

However, the currently used needle guides do not cope with the benefits of free-hand puncturing. While puncturing with the steerable needle the freedom of free-hand puncturing is desired, because you can adjust the probe in such a way that the tip of the needle is best visible while steering. On the other hand, you want the accuracy of inserting that you have while using a needle guide.

Therefore, the design goal of the design of a new needle guide for the steerable needle is:

Design a needle guide that provides both the benefits of puncturing with a needle guide and the free-hand technique.

A visual representation of the design goal can be seen in figure 11.

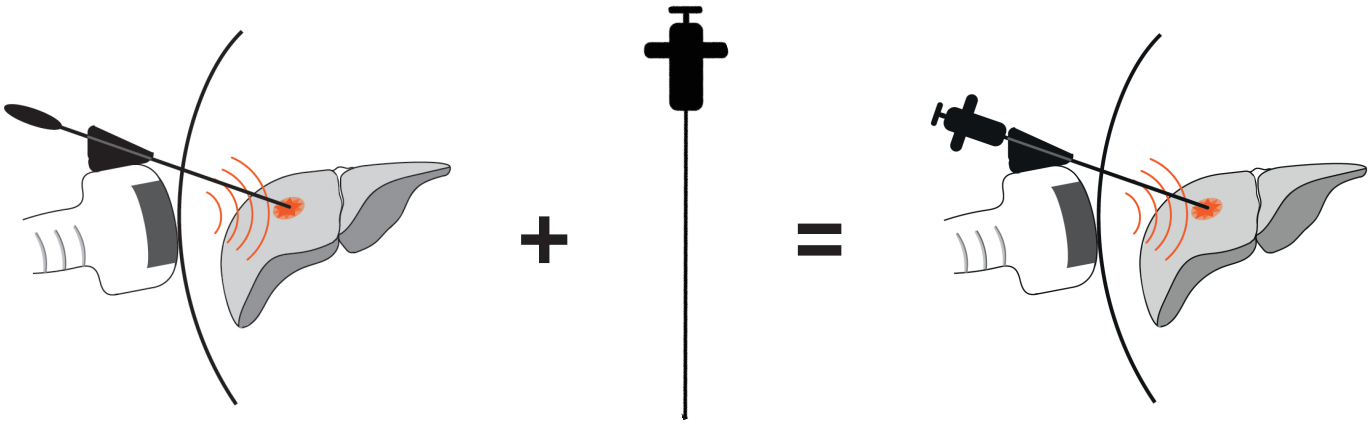


Figure 11: Visual representation of the design goal.

3.3 DESIGN SCOPE

The design scope is a definition of the boundaries of the design challenge. Verza™ Ultrasound Needle Guidance System, CIVCO is used as reference in examples since this is the accessible, currently used needle guide in the Erasmus MC [38]. The guidance system is used as a kit, consisting of a disposable needle guide (fig. 12), a reusable bracket (fig. 13) and a set of different gauge sizes (fig. 14).

3.3.1 FUNCTIONS NEEDLE GUIDE

As stated before, the basic working principle of a needle guidance device in a percutaneous intervention during US-guidance is as follows [27]:

1) The needle guide bracket is attached to the probe.
2) The telescopically-folded sterile cover is pulled over the probe.
3) The target area is scanned to get the target in sight.
4) The needle guidance attachment is attached to the bracket and therefore to the transducer of the US system.
5) The scanner is positioned in such a way that the needle pathway crosses the target on the oscilloscope.
6) The depth of the lesion is determined and targeted due to real-time scanning.
7) The needle is inserted through the needle guide and subsequently inserted into the body.
8) The intervention is performed and the target is treated.

The main function of a needle guide is to serve as a guide for the needle to stay aligned with the beam of the echo probe.

When the target is – almost – reached, the steering mechanism of the needle can be used in order to reach the tumour accurately. In case of steering; the needle and the probe need their freedom of movement to create good visibility of the needle. Therefore, the needle should be able to detach the needle guide to provide the desired freedom of movement.

In conclusion, the main function of the new needle guide design is that the needle guide provides both the benefits of puncturing with a needle guide and the free-hand technique. This main function can be divided in several sub-functions, which will be described below and can be seen in figure 15.

3.3.2 SUBFUNCTIONS NEEDLE GUIDE

- Fixed direction of the needle aligned with the probe beam, while in needle guided position.
- Ability to differ in multiple insertion angles of the needle with respect to the probe beam.
- Switch from a fixed needle guided position to free-hand puncturing.

Figure 12: Verza™ Ultrasound Needle Guidance System, CIVCO [38].

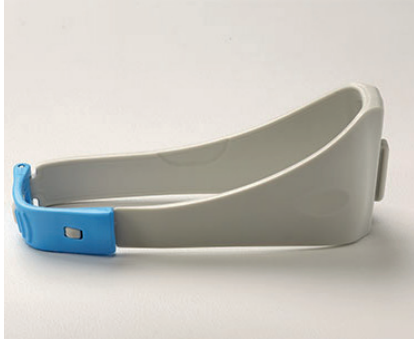


Figure 13: Verza™ Ultrasound Needle bracket, CIVCO [38].

Figure 14: Verza™ Ultrasound Needle expanded gauge range, CIVCO [38].

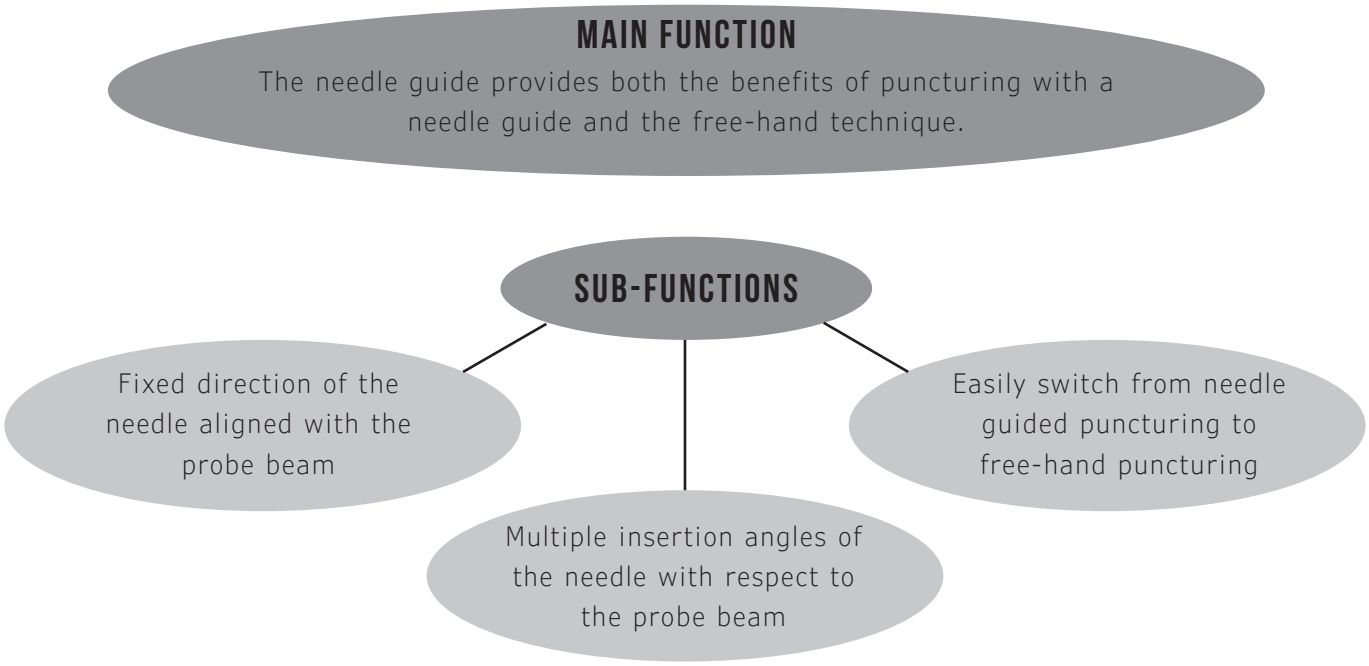


Figure 15: Main design goal with the supplementary sub-goals of the new needle guide.

3.4 REQUIREMENTS

Eekels and N. Roozenburg stated: "The design of a product is considered as 'good' when it meets the programme of requirements". Alternately, the programme of requirements should meet some characteristics to be valid, namely, every requirement should be valid and the whole list of requirements should cover the problem statement [31].

The utility of requirements and wishes is visualized in figure 16. Basically the requirements and wishes ensure convergence in ideas and concepts and lead to the best solution.

All the requirements are obtained through observation, literature research and a first user test of the steerable needle in combination with a needle guide (Verza). A more extensive explanation of the requirements can be found in appendix D.

3.4.1 FUNCTIONAL REQUIREMENTS

Functional requirements describe the requirements which the design should meet, in functional terms.

> *"Among the function of a product we include the possibilities for use, and more generally, the intentions of a product."*
> (Eekels and N. Roozenburg, 1998, pp. 433)

3.4.2 CLINICAL REQUIREMENTS

These requirements are based on the clinical legislation in the Netherlands. Which should meet the requirements that are handled in the OR, according to the Guideline guidelines Sterilization and sterility, NEN [40].

3.4.3 COST REQUIREMENTS

The product should be compatible with the previous needle guides. On terms of costs and manufacturing, the product should meet the current needle guide properties.

3.4.4 PHYSICAL REQUIREMENTS

Physical requirements relate to the properties of the product. Mostly these properties are directly measurable.

3.4.5 REQUIREMENTS

1. Functional requirements
    - 1.1 While inserted in the guide, the needle should not unclick when not intended.
    - 1.2 The needle should not deviate more than 0,5 mm when fixed in the guide.
    - 1.3 The needle should be able to be detached from the guide while the needle is inserted.
    - 1.4 The guide should have an attachment to a bracket.
    - 1.5 The guide should be as time efficient as the currently used Verza guide (not more than 25% slower).
    - 1.6 The guide should ease the switch from guided puncturing to free-hand puncturing.

2. Clinical requirements
    - 2.1 Sterilized production or sterilization possibilities afterwards.
    - 2.2 The use of the guide must be safe for the operators (e.g. no sharp edges or chance of breaking parts).

3. Cost and manufacturing requirements
    - 3.1 The costs of the guide must be able to compete with existing guides.
    - 3.2 The guide should be manufactured in such way that it is cost-benefitable for a disposable product.

4. Physical requirements
    - 4.1 The product cannot be higher than 4 cm and the maximum thickness is 2 cm.
    - 4.2 The product should not weight more than 10 gr.
    - 4.3 The needle guide should be usable for both right- and lefthanded persons.

3.4.6 WISHES

1. As few handlings as possible to detach the needle from the needle guide.
2. As few parts as possible.
3. At least two or more angle orientations possibilities.
4. The loosening of the needle should be as fast as possible.
5. The design should be as compact as possible.
6. Multiple needle diameters should fit the guide.
7. The device is disposable.
8. As less as possible moving parts in the guide.
9. The production should be as cheap as possible.
10. Only one hand needed for manipulation.
11. The insertion angle should correspond with the predetermined angle on the US.

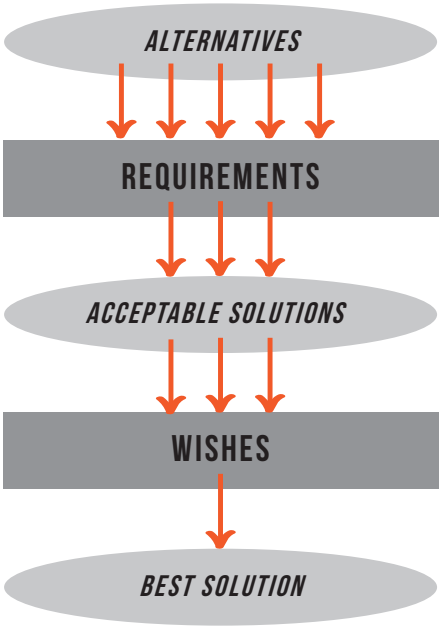


Figure 16: The function of requirements and wishes during selection process of a solution[31].

4
CONCEPT SELECTION

Since the requirements are determined, the acceptable solutions can be evaluated. First the solution generation on the basis of a morphological chart will be evaluated. Next, the most promising solutions are developed to equivalent concepts to compare them. Using the Harris selection tool based on the wishes stated in paragraph 3.4.6 a choice will be made for the most promising solution.

This chapter also comprises the development of the final concept and the design choices made during the iteration process of the new needle guide.

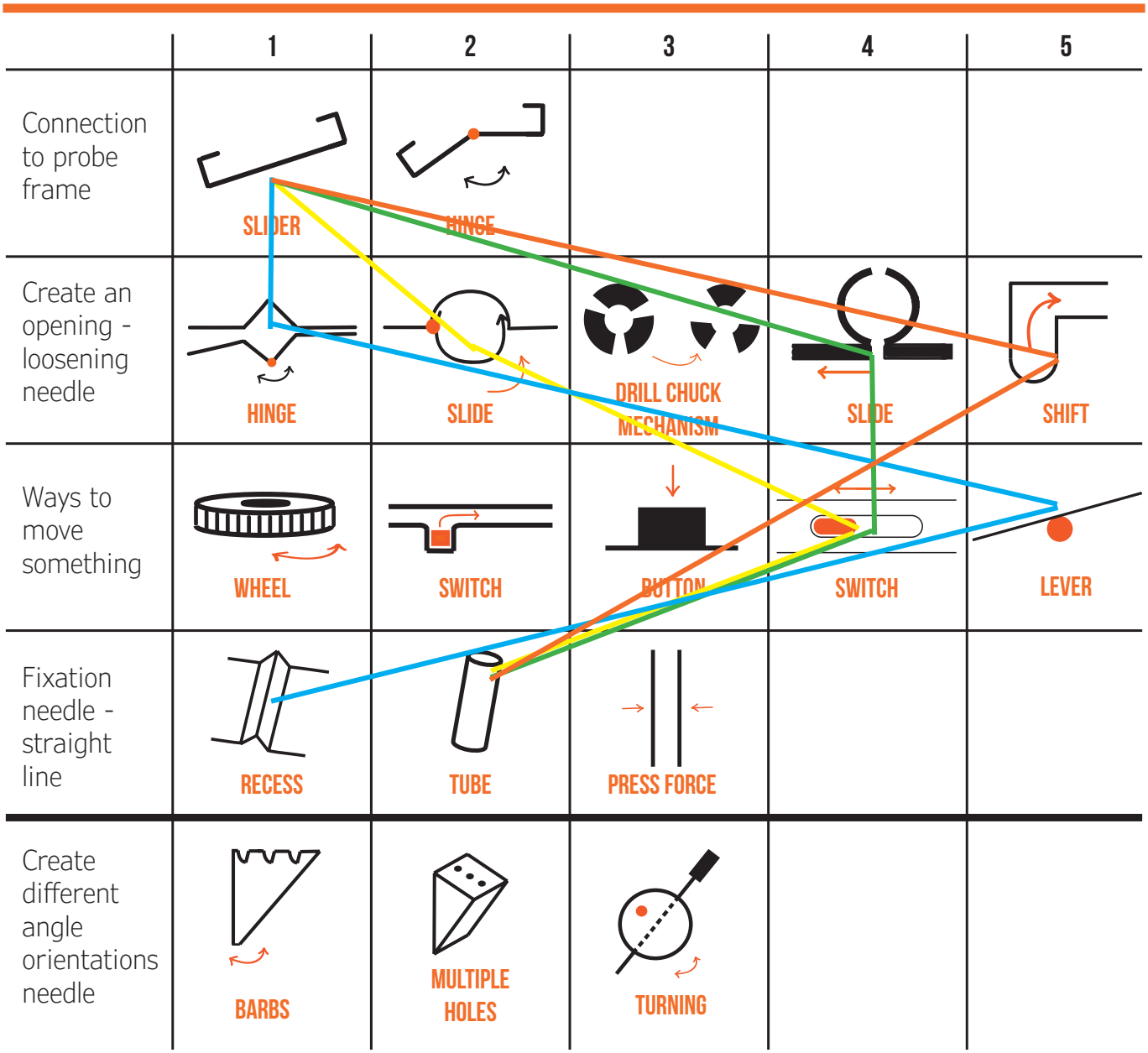


Figure 17: Morphological chart including coloured lines that represent four concepts. Yellow represents concept 1; 'turner', green represents concept 2; 'slider', blue represents concept 3; 'click' and orange represents concept 4; 'maze'.

4.1 MORPHOLOGICAL CHART

The morphological method intends to find all the acceptable solution that are present [31]. The chart consists on the horizontal axis of all the sub-functions and on the vertical axis of solutions of that specific sub-function.

In figure 17 the morphological chart can be seen, including coloured lines, which represent the fundamental solutions for the concepts. The last row, concerning the different angle orientations, is not included in this phase, because it does not contribute to the fundamental working principle of the needle guide. For the morphological chart without the lines, see appendix E.

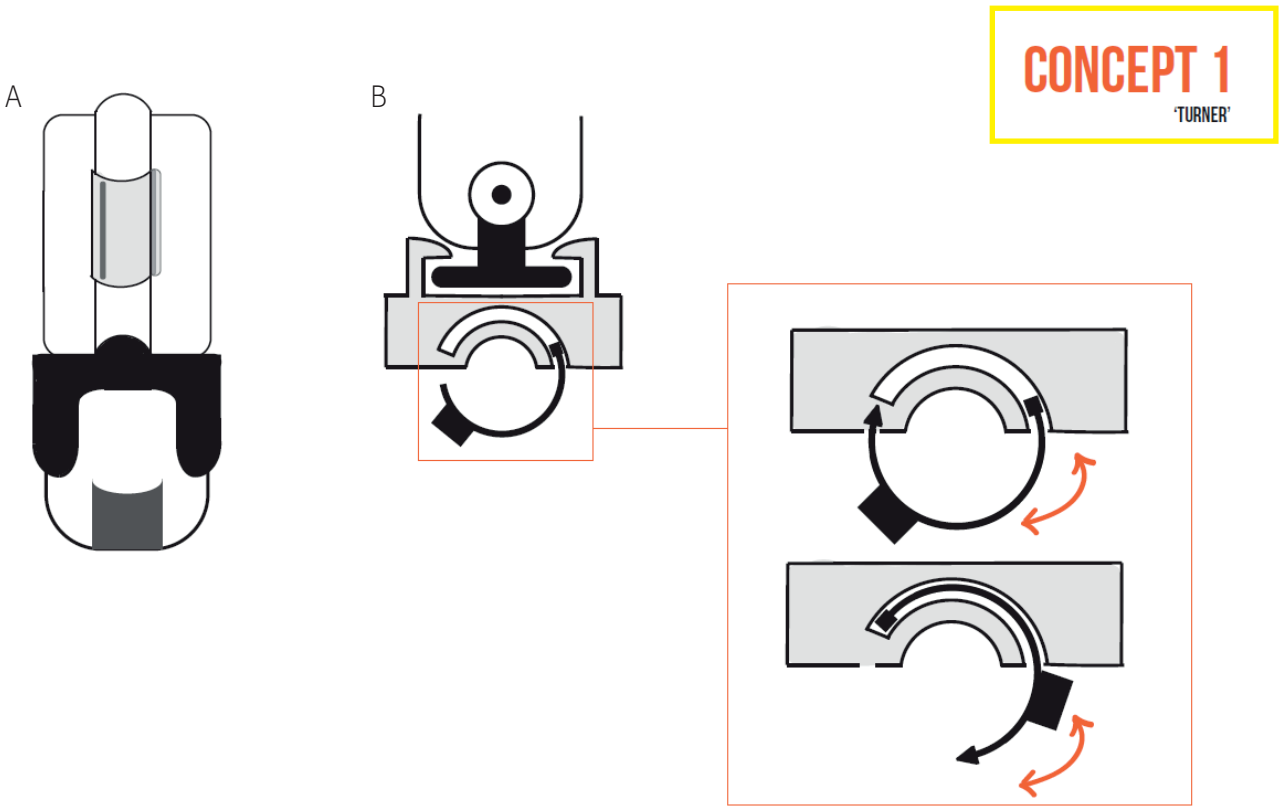
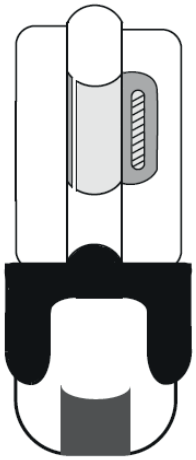


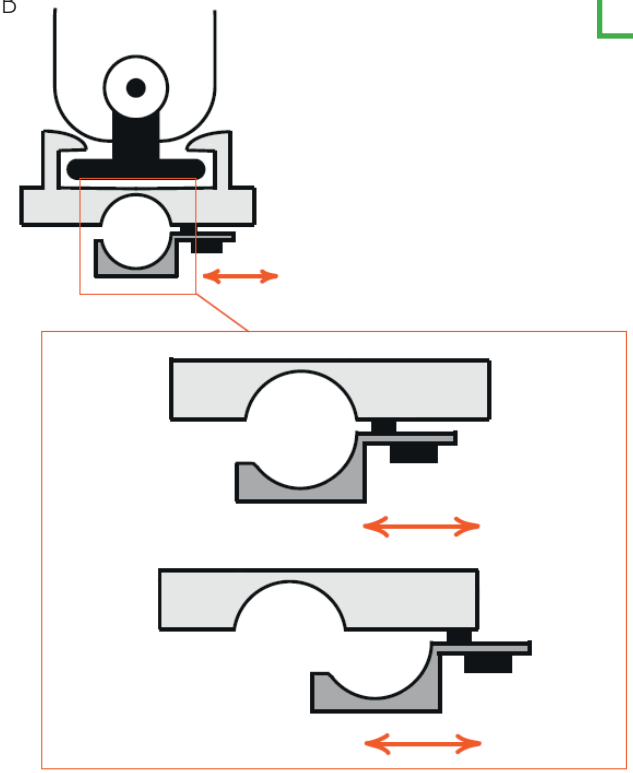
Figure 18: Four concepts, Top left concept 1; 'turner', top right concept 2; 'slider', bottom left concept 3; 'click', bottom right concept 4; 'maze'. A: side view of the probe, B: top view of the probe, C: front view of the probe.

CONCEPT 2
'SLIDER'

A

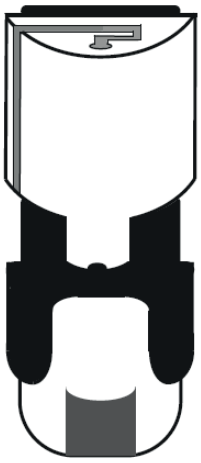


B



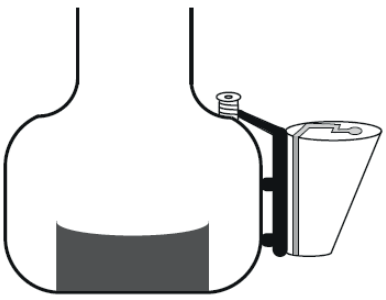
CONCEPT 4
'MAZE'

A



B

C



4.2 SELECTION PROCESS

Four concepts are developed, an overview can be seen in figure 18. The colours in in the top corner correspond with the lines in the morphological chart (fig 17).

Concept 1, called the 'turner', consists of a turning tube mechanism. The tube rolls inwards the needle guide and creates an opening for the needle to detach. Concept 2, called the 'slider', consists of a small slide system which can slide aside to make space for the needle to detach. Concept 3, called the 'click', consists of multiple parts. First, click the guide to the right to create space for the hook, next, the hinge makes sure the guide can be opened as a door to make it possible for the needle to loosen. Concept 4, called the 'maze', provides a path which the needle can follow from the fixation point to the exit of the needle guide.

For more extensive information about the concepts, information about the schematic structure of the concepts and for better images, see appendix F.

To select which solution is the best one, a selection procedure is conducted. A fast and reliable method for this is the Harris profile. This method includes the wishes, ordered at relevance and importance. Only the five most important wishes are selected, to keep a clear view on the relevance.

On the y-axis four scale positions are displayed; -2, -1, 1, 2. They represent a benchmark for the norm of the criteria/ wishes [41]. See appendix G for the defined scale positions for every wish in the Harris profile.

4.3 FINAL CONCEPT CHOICE

Considering the scale positions on the y-axis, the concept that scores the most + and ++, is the best solution for this problem definition. The top wishes contribute more than the bottom wishes, therefore it is not a sum of outcomes.

The Harris profile (fig. 19) shows that concept 4 fits the wishes the best. On almost every aspect concept 4 scores the best of all the concepts.

Besides the Harris profile, concept 4 can be examined per sub-function. All the sub-functions should be and are fulfilled with the new concept.

Subfunctions needle guide

- Fixed direction of the needle aligned with the probe beam, while in needle guided position.
- Ability to differ in multiple insertion angles of the needle with respect to the probe beam.
- Switch from a fixed needle guided position to free-hand puncturing.

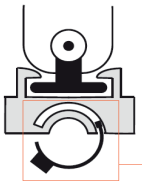
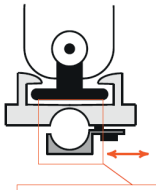
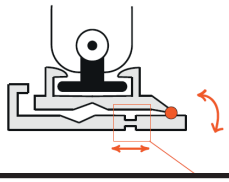
	WISHES \ RATING	- -	-	+	++	- -	-	+	++	- -	-	+	++	- -	-	+	++
1.	Less as possible handlings needed to loosen the needle (e.g. hand movements)		■				■			■	■					■	
2.	As less as possible parts		■				■			■	■					■	■
3.	Possibility of multiple angle orientations			■				■			■					■	■
4.	Speed of loosening needle		■				■			■	■					■	
5.	Flat/small as possible			■				■			■				■		
		CONCEPT 1 				CONCEPT 2 				CONCEPT 3 				CONCEPT 4 			

Figure 19: Harris profile to select the best concept based on the wishes.

4.4 DESIGN CHOICES

During the development of the UShift, several design choices are made. The design went through several iteration processes. After every adjustment, the prototype of the UShift is adjusted and 3D-printed again. All the prototypes are 3D-printed using an Ultimaker 2 Extended + with PLA as used material, a nozzle of 0,4 mm and a layer height of 0,1 mm. For an extensive overview of all the prototypes with all the iteration steps, see appendix H.

The guide development is split up in two parts; the needle guide itself, and the bracket. The bracket is necessary because validation and tests can be performed on the US in our lab. Since the design goal is to develop a new needle guide, the development of the bracket can be found in the appendix (appendix H.2).

The most important steps that are made through the iteration process are given in this section. The design choices are based on the wishes in section 3.4.6 . In figure 21 the first prototype can be seen. The final prototype is shown in figure 22. A final prototype is made for the final user test, however, the final concept is the finally developed UShift. The final concept UShift can be seen in figure 23.

4.4.1 ORIENTATION OF THE FIXATION POINT

The fixation point (red circle in figure 21) is the point in the guide which the needle is inserted through. This point is the start of the path that the needle follows and therefore the insertion angle orientation. The first improvement made to the prototype is the alignment with the probe beam. The fixation point should be in the middle (e.g. the middle of the probe width), the needle

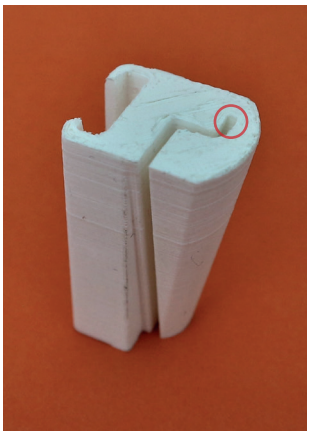


Figure 20: The first prototype of the UShift, 3D-printed model.

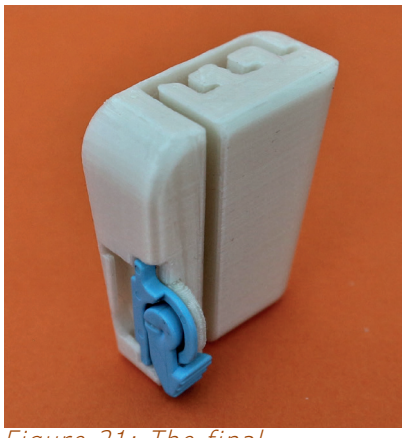


Figure 21: The final prototype, 3D-printed model with a mimicked attachment from the Verza needle guide.

Figure 22: The final concept, 3D-printed model with a slide attachment to the bracket on the probe.

should be precisely aligned with the probe beam, otherwise the needle will deviate from the probe beam which results in bad visualisation.

The second iteration with respect to the fixation point is the actual fixation of the needle. The needle should be located in a small path instead of a point, to make sure that the needle cannot move sidewards back in the general path.

4.4.2 DIFFERENT ANGLE ORIENTATIONS

One of wishes stated: *"At least two or more angle orientations possibilities."*

Considering other wishes like "As few handlings as possible to detach the needle from the needle guide", "As few parts as possible" and "As less as possible moving parts in the guide" the decision has been made to integrate the different angle orientations in one piece. Three deviations of the path are made, which all create a path that represents an angle orientation.

Because the guide is made out of one piece and no movement of parts is needed within the guide itself, all above mentioned wishes are fulfilled.

4.4.3 EXIT POINT OF THE NEEDLE

The exit point (fig. 20C) is located in the middle of the guide to ensure that the needle stays aligned with the probe beam. All the paths have the same endpoint, however, because the angle is different for all the three angle orientations, the needle experienced friction in the third path. Therefore more space is created for the needle and the hole is slightly expanded in the same plane. This resulted in better guidance of the needle and less friction.

4.4.4 ATTACHMENT TO THE BRACKET

One way or another the needle guide should be attached to the probe. As stated earlier, a distinction should be made between the final prototype and the final concept.

Final prototype

For the user test at the Erasmus MC the needle guide should be able to attach to the Philips, EPIQ 7G probe. The attachment mechanism mimicks the Verza needle guide and therefore the needle guide can easily be attached to the probe at the Erasmus MC. However, this decision is only made for practical reasons.

Final concept

For testing purposes several brackets are made, see appendix H.2. For the final concept the choice of attachment is outside the design scope. The design only focusses on the needle guidance system. However, the slide system could be combined with a new bracket. This way it is ensured that the guide exists of only one part and no moving parts.

4.5 WORKING PRINCIPLE USHIFT

From now on, concept 4 will be called UShift. The name is a combination of US, Ultrasound, and shift from shifting the needle though the guide.

In figure 20 the top view of the UShift can be seen, the path structure is based on the working principle of a gearbox in cars. Every hook in the path is equal to an angle orientation. Therefore, the UShift consists of three angle orientations.

Once the UShift is connected to the bracket on the probe and the target is visualized with the probe, the needle is inserted through one of the three fixation points (red circles in figure 20A). Which fixation point is chosen, depends on the desired angle orientation.

The needle is guided by the UShift through the tissue towards the target. When the desire is present to detach the needle from the guide, the probe can carefully be manipulated to let the needle follow the path towards the exit (red square in figure 20A). It is important that the probe is manipulated and not the needle, otherwise the needle can dislocate whilst initially the needle is placed accurately.

When the needle is detached, the probe can be placed free-handed at the desired place. When the needle should be placed back from free-hand puncturing to guided puncturing, the path can be followed backwards to reach the fixation point of interest. Moreover, at any time another angle orientation can be chosen.

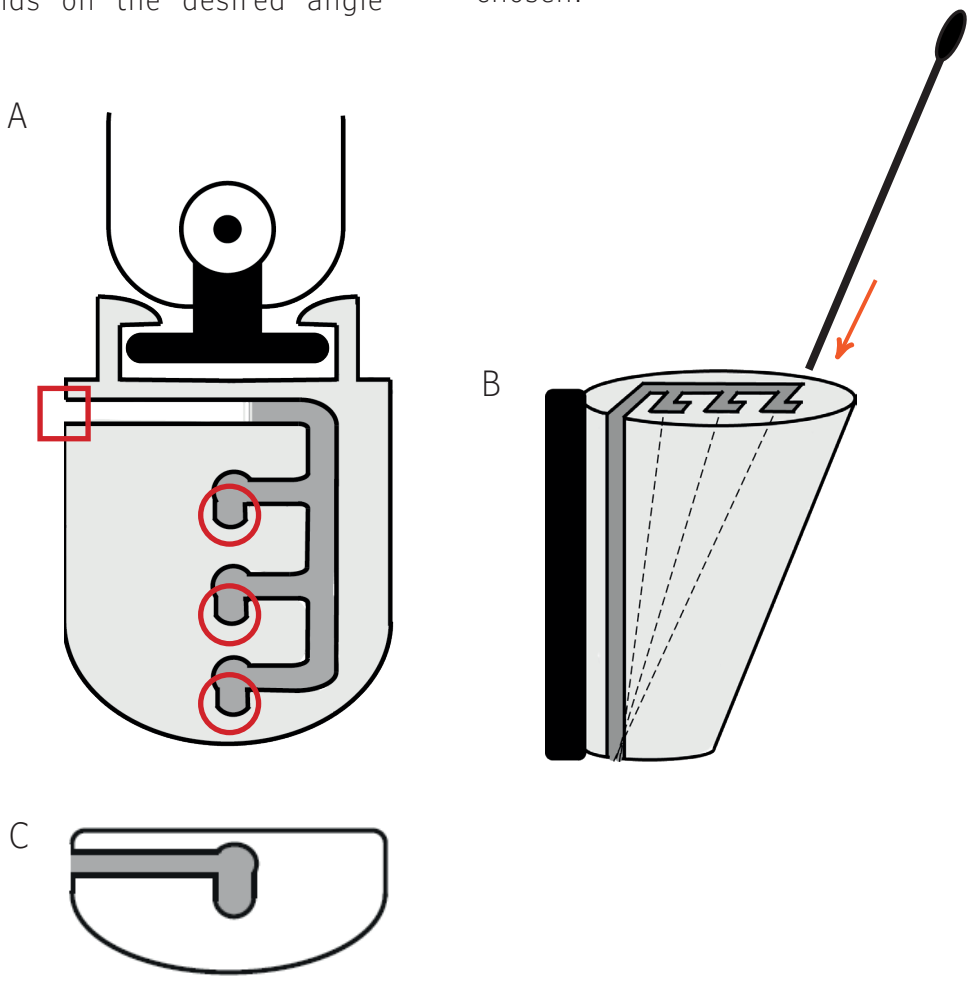


Figure 23: Different views of the UShift. A; top view of the UShift, B; side view of the UShift, C; bottom view of the UShift. The red circles represent the fixation points, the red square represents the exit and the dotted lines are the tube angles within the guide. This figure is not made to scale.

4.6 UNIQUE SELLING POINTS (USP'S)

The UShift is a new needle guide concept. In table 1 (section 1.4) several advantages are given of the needle guides found in literature. In table 4 these advantages are given with additional advantages of currently used needle guides (table 3, section 3.1.4).

The UShift fulfils most of these advantages. The advantages the UShift does not meet, are not applicable for the design scope.

Compared to currently used needle guides, such as Verza needle guide, the UShift has some great advantages. Disadvantages of current used needle guides are translated to advantages of the UShift. These properties that make the UShift unique, are also called Unique Selling Points (UPS).

On the next page the USP's are displayed. These points make the UShift a unique product and distinguishes the UShift from other needle guides.

Advantages other needle guides	UShift	Remarks
Flexibility of variation in the angle orientation	✓	Three angle orientation options are present with the UShift
Ability to prefix the distance between multiple needles	✗	This is not necessary for RFA interventions
Needle can be detached from the attachment	✓	
High range of possible gauges	✓	Different UShift models can be made for corresponding gauge sizes
Total fixation of the needle during puncturing	✓	
Corrosion resistant	✗	N/A
Possibility to use device in transverse and longitudinal direction	✓	Possible with a suitable bracket design

Table 4: Checklist of advantages of existing needle guides, the UShift is checked whether it copes with the property.

UNIQUE SELLING POINTS

NO RELOCATION OF THE HANDS IS NEEDED

- Easy access to switch to another angle orientation of the needle
- No need of letting go of the steerable needle, which prevents the needle from bending

ONE PIECE PRODUCT, NO ASSEMBLAGE NECESSARY

NO MOVING PARTS, LESS CHANCE OF FAILURE

PURPOSED FOR MULTIPLE INTERVENTIONS

POSSIBILITY TO SWITCH FROM FREE-HAND GUIDED - TO GUIDED PUNCTURING

5
VALIDATION

The purpose of this chapter is to validate the UShift. This is done by validating the requirements and through a user test. The validation part of the requirements is a part of the results of the user test, because some of the requirements should be assessed based on results from the user test.

The user test is performed with different medical specialists. The main goal is to verify how the needle guide is performing compared to the currently used needle guide while supposedly using the Omnidirectional steerable needle.

In earlier stages of the development process, several small user tests are conducted to obtain information from experts. These small tests will serve as a starting point of view for the final user test.

The final user test will consist of observation of handlings, capturing of the conversations and handlings and an interview with the participants.

5.1 MATERIALS AND METHODS

5.1.1 SPECIMEN

PVA preparation

To mimic the human body and therefore the human liver, a phantom is needed. As the study of de Jong, et al., (2017) stated, the human liver can be simulated by Polyvinyl alcohol (PVA). As described in the paper, a physically crosslinked PVA (Selvol PVOH 165, Sekisui Chemical Group NJ, USA) phantom was created.

The specimen is initially made by magnetically steering of the hot water with a powder of PVA particles. A soluble concentration of 4 m% PVA to water is retained, which is under the maximum recommended soluble concentration of 7 m% PVA to water [31]. Next, the specimen is poured in the desired shaped container and then subjected to freeze-thaw cycles of respectively 24 hours and 12 hours.

Target generation

In the experiment participants are asked to puncture with the needle towards a target which is processed in the PVA specimen. With a similar phantom to the phantom used in the visibility experiment, tests are preformed to choose the best visible target.

Several targets are processed in the phantom and thereafter visualized with the ultrasound. Afterwards the results are compared and the most visible (e.g. highest contrast ratio with the surroundings) target is used during the experiment. The targets that are used are a piece of cucumber (fig. 24), a piece of painters tape (fig. 25) and a 20 ct. coin (fig. 26). These targets are selected for their different densities and easy access.

As can be seen, the 20 ct coin reflects the most and is the best visible in the US-image. Because searching for the target is not relevant in the experiment, the most visible target (e.g. the coin) is chosen.

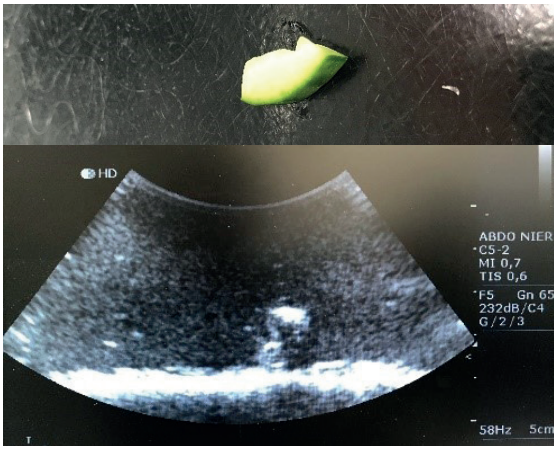


Figure 24: An overview of different targets, visible in the US image. A small piece of cucumber.

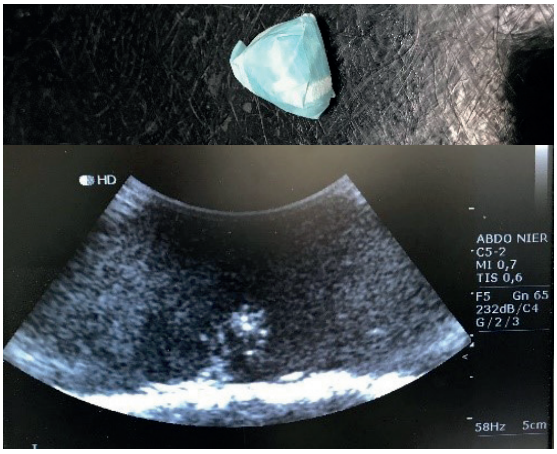


Figure 25: An overview of different targets, visible in the US image. A piece of painters tape.

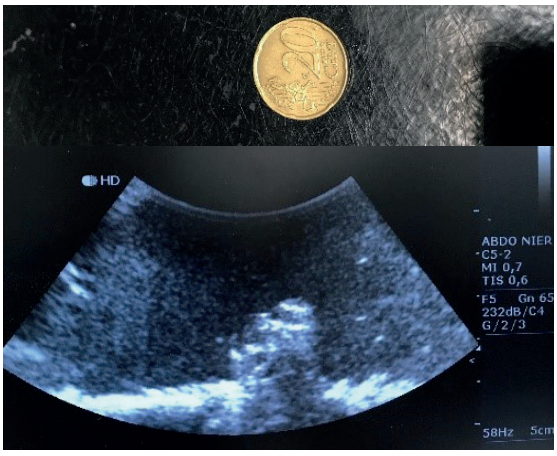


Figure 26: An overview of different targets, visible in the US image. A 20 ct coin.

5.1.2 NSTRUMENTS

Needle

In the experiment a 3-part needle with a diameter of 1 mm is used to mimic the omnidirectional steerable needle. Because the participants should completely focus on the needle guide and not on the needle itself, a plain "dummy" needle is used. Participants should imagine that the needle has abilities to steer.

Verza needle guide

The currently used needle guide in the Erasmus MC for interventions like RFA is the Verza needle guide [38]. This guide is disposable and is available for different needle diameters. The guide can be placed in five different angles and the needle can be detached through a switch.

UShift needle guide

As stated before, the UShift is adjusted to fit the currently used probe frame in the Erasmus MC. The attachment of the frame is mimicked of the Verza needle guide. Therefore the UShift is able to perform on the current probe.

Probe bracket

The bracket is especially made for the echoscope of Philips, developed by CIVCO. This is used as an attachment point for the needle guide. In figure 15 an image can be seen of the probe frame. Both the Verza and UShift fit on the same bracket, this is beneficial because less time is lost during the switch of the guides.

5.1.3 EQUIPMENT

The equipment used during the user test in Erasmus MC is the following:

- US system (EPIQ 7G, Philips, NL)
- Corresponding probe (EPIQ 7G, Philips, NL)
- Camera (EOS M10, Canon)

5.1.3 DELPHI METHOD

For the user test the Delphi research method is used to conduct data from experts. This method states to work as follows:

"The Delphi method is an iterative process to collect and distill the anonymous judgments of experts using a series of data collection and analysis techniques interspersed with feedback."

(J. Skulmoski, G. et al,. 2007)

The Delphi method is a widely used consensus method in healthcare [43,44]. This method involves the opinions of a group of experts with the aim of achieving a consensus.

The research should meet some criteria to be conducted as a Delphi method [42]:

- The participant should be fully anonymous, to limit the social pressure.
- Iteration, participants should be able to refine their views of opinion.
- Controlled feedback, the participant should be informed of others opinion to use that as a reference.
- The results should be converted to statistical aggregation, to be able to have a quantitative analysis and to interpret the results.

The experts who participate in the user test are carefully chosen and meet the following criteria:

"The Delphi participants should meet four "expertise" requirements: i) knowledge and experience with the issues under investigation; ii) capacity and willingness to participate; iii) sufficient time to participate in the Delphi; and, iv) effective communication skills"

(J. Skulmoski, G. et al,. 2007)

In this user test one single Delphi study is conducted. A method that works very well for qualitive research, rather than quantitative research.

Six participants cooperated in the user test and were on beforehand informed about other opinions of previous participants.

Before the final user test, a small variant is conducted with only one expert. The opinion of the expert is asked about the final prototype, during this meeting no phantom and US system were used. The output of this small user test and therefore the feedback of the expert, is used as a reference for the first participant in the final user test.

5.1.4 EXPERIMENTAL DESIGN

As stated before in the introduction of this section, the goal of the experiment is to find out how the UShift needle guide performs compared to the currently used needle guide (Verza). Also the requirements are validated, requirements as 1.5: *The guide should be as time efficient as the currently used Verza guide (not more than 25% slower)* and 1.6: *The guide should ease the switch from guided puncturing to free-hand puncturing* are directly measurable from the results from the user test.

To find this out, the needle guides are compared on several factors. These factors are:

- Ease of use (through an interview)
- Time to reach the goal (captured during experiment)
- Time to switch from guided puncturing to free-hand puncturing (captured during experiment)
- General advantages (through an interview)

To limit the duration of the user test, an interview is conducted instead of a questionnaire. A short introduction to the experiment is given, continued with the user test in which the participants should puncture towards the target with both the needle guides. The first interview consists of general information about the skills and experience of the participants. Afterwards, another short interview is held about the performance and the ease of use of the needle guides and the differences.

The complete introduction for participants can be seen in appendix I.1 and the questions that are discussed in the interview can be seen in appendix I.2.

The participants are asked to perform the same task for both the needle guides. In table 5 the condition matrix can be seen, with two different EC's. Six repetitions are conducted, due to the availability of experts on the radiology department.

To reduce the experimental error, the order in which the needle guides will be used will be randomized during the experiment. Hereby the needle guide that will be used first is randomized for every participant. The run table of the randomized order can be found in appendix I.3.

n=6	UShift Needle	Verza needle guide
	EC11	EC12

Table 5: Condition matrix of the two different needle guides for the user test. Six repititions are conducted.

5.1.5 RESEARCH GROUP

Besides the criteria mentioned in the Delphi method (section 5.1.3), an expert who can participate in the user test should meet the following criteria:

- Participants should have experience with puncturing. Preferable is experience with US-guided puncturing.
- Participants should be familiar with terms like *needle guide, free-hand puncturing, guided puncturing, RFA* and *specimen.*

The criteria will shorten the user test duration because the participants do not need an introduction to puncturing. Furthermore, information about puncturing preferences is desired and to collect that information, participants should have experience.

5.1.6 EXPERIMENTAL SET-UP

The experimental set up can be seen in figure 27 and figure 28. Both the Verza needle guide and UShift can easily be attached to the same bracket. The participants are free to sit or stand during the test and can choose which hand is used for the probe.

The camera is pointed on the phantom and the hands of the participants. No face is recorded to enhance the privacy and anonymously of the participants. Also, permission to film the hands and record the conversation is requested in advance.

5.1.7 EXPERIMENTAL PROTOCOL

Before the user test takes place, some preparations are done.

- The created specimen is placed on a tray to prevent leaking of the PVA model on the table.
- The side in which the target (coin) is located, is placed downwards.
- The probe bracket is attached to the probe and set the echoscope to the default settings for the experiment. The US system should be set to a frequency of 5,1 MHz, an imaging depth of 10 cm, and a focus depth of 5,5 cm.
- Next, set the camera in position to record the experiment.

To obtain reliable results, every participant should receive the same information and the same instructions. Therefore, for each repetition the next steps should be followed;

- Check the randomization list in which order the participants should use the needle guides.
- Tell the introduction text according to the introduction text (appendix I.1).
- Ask for permission to film the hands and record the sound during the experiment.
- Start the film equipment to record the test.
- Perform both tasks. Ask specifically for a sign of the participants when:
  - The **start** of searching the target by puncturing
  - When in **position** near the target
  - The start of 'steering' the needle and therefore **detaching** the needle off the needle guide
  - Starting to **retract** the needle from the PVA phantom
- Ask the participants for their opinions and tell previous findings of other experts preforming the test.
- Check the interview forms for potentially missing information.
- Stop the recording.

Figure 27: The overall set-up of the user test, the US system next to the table with the phantom and the camera.

Figure 28: A closer look on the experimental set-up. The phantom is beneath the camera and both the needle guides are available for testing.

5.2 RESULTS

During the user test personal information with respect to needle puncturing is gathered from the participants. These results are presented in table 6. All the participants meet the requirements of the Delphi method (paragraph 5.1.3) and the additional requirements stated in paragraph 5.1.5 to participate in this experiment.

Four out of six participants have a function of radiologist, who have more than 7 years of experience with puncturing. Furthermore, a minimum of 5 percutaneous interventions a week is performed by these radiologists. The radiologists rate their own puncture skills with a 4 or 5 out of 5. These skills can be characterized as equal to an high puncturing level: the ability of accurate targeting of tumours that are located deeply or are surrounded by delicate tissue. The other two participants are less familiar with percutaneous interventions and therefore have less experience and a lower puncturing level (1-2). These experts have a function where US-guided puncturing is less involved than during radiologist interventions, the frequency is therefore lower for the two experts.

As stated before (section 1.2.1), every operator has its own preference for a puncture technique. Multiple participants indicate to use both puncturing techniques during different interventions, therefore the outcome of this question is the most common used puncture technique of the participant and not the only used puncture technique. The user test shows that 60% of the participants has a preference of free-hand puncturing, conversely 40% choose needle guided puncturing.

Due to bad positioning of the hands of expert 4 with respect to the camera, no time related data could be gathered of this participant. Only observations were included as results, no time related data is included.time related data is included.

	Function	Years of puncture experience	Frequency of echo guided puncturing	Puncture level*	Puncture technique preference
Participant 1	Radiologist	7 years	5 times a week	4 - 5	Needle guided
Participant 2	Radiologist	8 years	5/6 times a week	5	Free-hand
Participant 3	Radiologist	13 years	7 times a week	5	Needle guided
Participant 4	Assistant	N/A	N/A	1	N/A
Participant 5	Abdomen specialist	3 years	1/2 times a week	2	Free-hand
Participant 6	Radiologist	10 years	7 times a week	4 - 5	Free-hand

Table 6: Overview of participant information with respect to needle puncturing.
** Scale definitions puncture level: Beginner 1 – 2 - 3 - 4 - 5 Expert.*

5.2.1 TIME TO REACH THE TARGET

Participants were asked to give a sign at the **start** of searching the target by puncturing and when in **position** near the target. For more accurate measurements, all the time measurements are done afterwards using the recorded images of the test.

The time measurement starts at the moment the needle is inserted into the phantom and stops when the participant gives either verbally a sign or when the needle is released. The table containing data of time measurements can be found in appendix J.1.

In figure 29 the results can be seen of every participant, both the needle guides used by every participant plotted against the time needed to reach the target. Three out of five participants reached the target faster using the Verza.

The biggest time difference between the two needle guides is 6 seconds (participant 1). In figure 30 the average time to reach the target is displayed. The difference is 0,6 seconds, the Verza guide is 6 % faster.

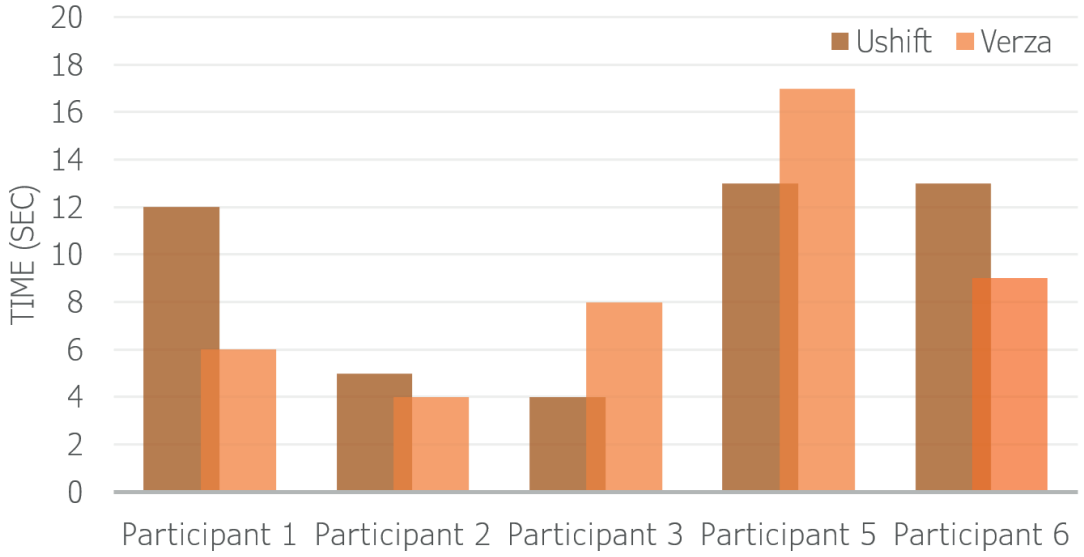


Figure 29: Schematical overview of the time measurements of the time needed to reach the target. Displayed per participant.

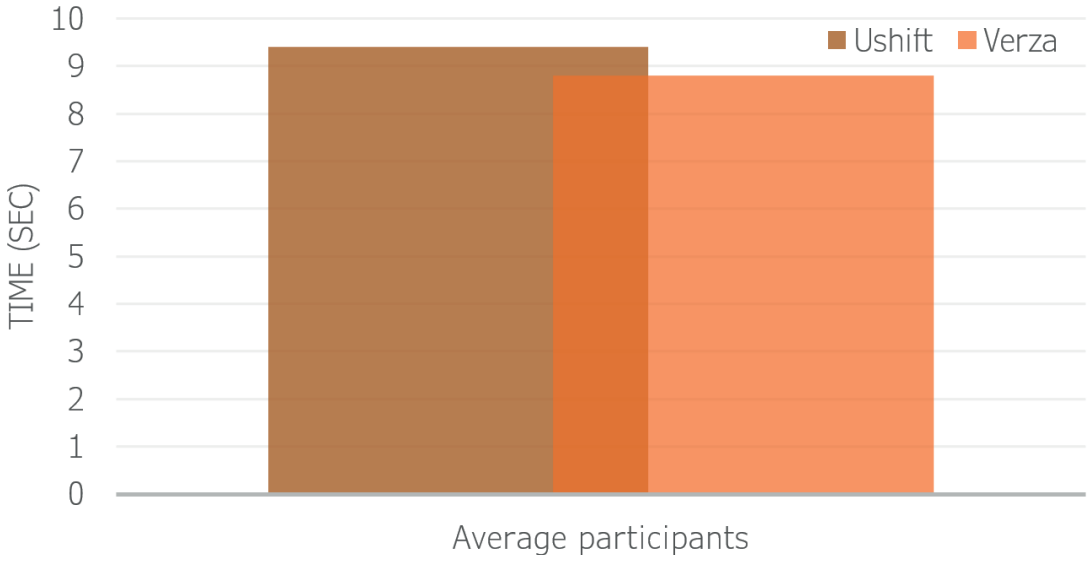


Figure 30: Schematical overview of the average time measurements of the time needed to reach the target.

5.2.2 TIME TO SWITCH FROM GUIDED PUNCTURING TO FREE-HAND PUNCTURING

Participants were asked to give a sign while starting 'steering' the needle and therefore detaching the needle from the needle guide. The time measurement starts for the Verza guide when the participant releases the needle. The time measurement starts for the UShift when the participant starts to move the needle with respect to the needle guide or when the hand indicates to start a movement. For both needle guides, the measurement stops when the needle loses contact with the needle guide. The table containing data of time measurements can be found in appendix J.2.

During the user test the participants had freedom to do multiple attempts apart from the given tasks. This is in association with the Delphi method, the participants have more time to form an opinion. The resulte is that four out of five participants did two attempts to detach the needle from the UShift. A possible existing learning curve for the Verza needle guide should be considered. Therefore, the opportunity to enhance the learning curve for the UShift should be embraced. Therefore, in the results the time measurements used for switching the puncture technique, the second attempt time is used because this is more reliable, since the Verza needle guide is used before by every participant. For the participant who executed no second attempt, the first attempt is used for the average time.

In figure 31 the results can be seen of every participant, , both the needle guides used by every participant plotted against the time they needed to switch from guided puncturing to free-hand puncturing. Three out of five participants needed less time to make the switch using the UShift. Only one participant was faster while using the Verza. One participant needed exactly the same amount of time for both the guides to make the switch. The biggest time difference between the two needle guides is 3,8 seconds (participant 5).

In figure 32 the average time to switch from guided puncturing to free-hand puncturing is displayed. The difference between the two puncture techniques is 0,9 seconds, the UShift is 23% faster.

5.2.3 VALIDATION OF REQUIREMENTS

The requirements, especially the functional and physical requirements, that are evaluated in the user test are discussed in this paragraph. A full overview of all the requirements and wishes validated can be found in appendix K.

Functional requirements

The UShift can be considered as time efficient as the Verza guide. The results show that the Verza gained an average time profit of 0,6 sec during targeting, this is 6% faster than the UShift. Next, the UShift was more time efficient (0,9 sec) during the switch of puncturing technique which is 23% faster than the Verza guide. The experts indicate that the UShift is more user friendly and the switch is made very easily. Additionally, the UShift can also be switched back to guided puncturing.

Physical requirements

The UShift has the following dimensions; a height of 3,7 cm, a width of 3,2 cm and a thickness of 1,6 cm. See appendix K.1 for a visual representation of the dimensions, the dimensions of the Verza are also mentioned. The UShift has a weight of 7,8 gr, the Verza weights 3,7 gr. During the user test the participants had freedom to choose which hand is used. The needle is in both left and right hands used an no comments were given on the usability limitations due to using the UShift right or left handed.

The physical requirements are met and stated as valid.

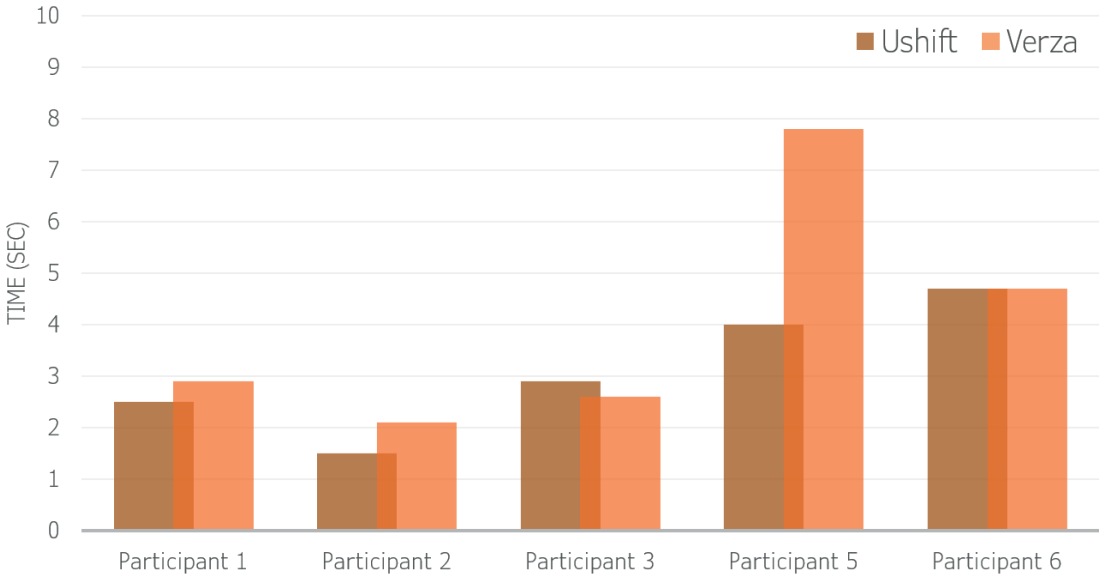


Figure 31: Schematical overview of the time measurements of the time needed switch from guided puncturing to free-hand puncturing. Displayed per participant.

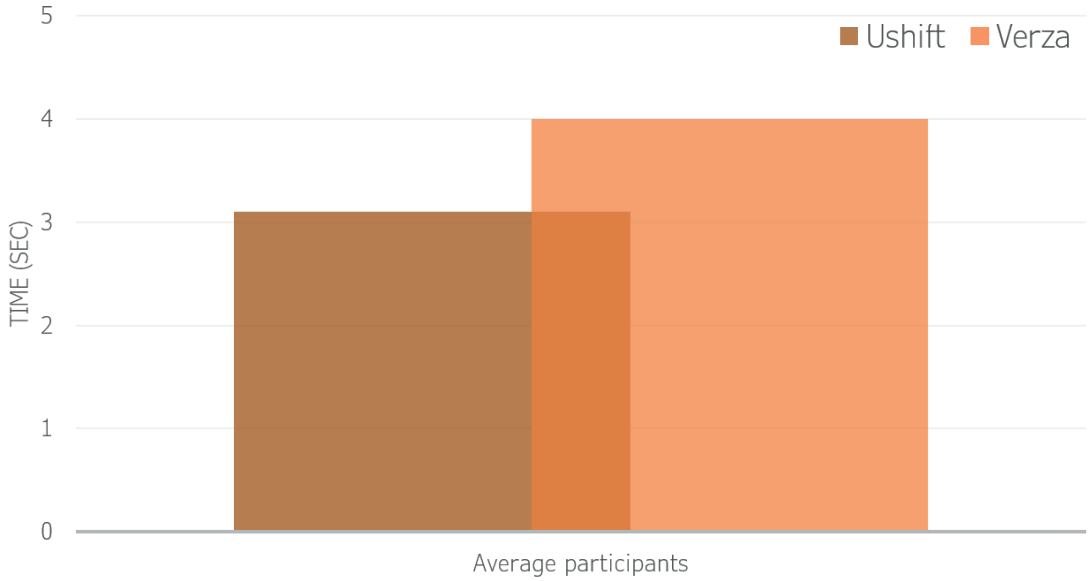


Figure 32: Schematical overview of the average time measurements of the time needed switch from guided puncturing to free-hand puncturing.

5.2.4 EXPERT FEEDBACK

During the final user test the participants were asked to give comments and describe the differences between the needle guides. To summarise the comments: general advantages of the UShift and the Verza are the following;

UShift

- No relocation of the hands is needed, while detaching the needle. The alleged, more heavy, steerable needle can be held instead of letting go. This prevents the needle from bending.
- While using the UShift it is possible to easily switch back from free-hand puncturing to needle guided puncturing.
- No relocation of the hands is needed, while switching the puncturing angle orientation. The needle can easily be shifted into another angle orientation.
- No manual assembly is necessary before the use of the UShift.

Verza

- While free-hand puncturing with the Verza, the needle guide is not in the way of movement of the probe because it is flat.
- The angle orientations of the Verza match the predetermined angles on the US system.

5.3 DISCUSSION

5.3.1 TIME TO REACH THE TARGET

Results show that the average time difference is 0,6 seconds, the Verza guide is 6% faster. The aim to measure this time is to determine the compatibility of the UShift compared to the Verza guide on the basic working principles of a needle guide.

Since the participants used both the needle guides after each other, the time to reach the target was biased because the participants placed the probe back at the spot where the coin was located the second time. This resulted in no need for a second search. Also, it should be considered that the participants already have some experience with the Verza needle guide. The results cannot be considered significant because of the bias and the experience with the Verza guide. However, the only aim of this measurement is to validate the working principle of a needle guide and that can be considered as valid.

Since the time difference is even below the 10%, the UShift can be determined as compatible on the basic working principles of a needle guide compared with the Verza guide.

5.3.2 TIME TO SWITCH FROM GUIDED PUNCTURING TO FREE-HAND PUNCTURING

Results show that the biggest time difference between the two needle guides is 3,8 seconds (participant 5). Participant 5 did not immediately understand the working principle of the UShift and therefore a long first switch time is measured.

An interesting observation is that participant 2 detached the needle of the UShift multiple times (7/8) and was very fast every time, around 1,5 seconds. This shows that some experience ensures smoother shifting of the needle through the UShift, this is in line with the expected learning curve. Another

observation was participant 6 that was 'stuck' in the corner of the UShift during the last 2 seconds. This is a point of improvement and can easily be adjusted in the design.

In conclusion, the difference between the two puncture techniques is 0,9 seconds, the UShift is 23% faster. This is a promising results since the experts still have to gain more experience with the UShift compared with the Verza. It is to be expected that the time to switch becomes less when the UShift is used more often.

5.3.3 GENERAL

Considering the general feedback of the experts in section 5.2.4, are the advantages of the Verza realizable for the UShift. When the UShift will be produced, the software of the US system can either be adjusted to the needle orientations, or the UShift can be slightly adjusted to for example, the angles of the Verza guide. The UShift is not as compact as the Verza, but the right corner could be spared. Not all the experts experienced the UShift as too big, therefore, the UShift can be made smaller but it is not necessary to be as compact as the Verza.

Next, the UShift can be validated on the previously stated wishes (section 3.4.6). The UShift consists out of one piece without moving parts. Three angle orientations are processed and several models are available for different gauge sizes. The guide is considered as easy to use and the time to detach the needle exceeds the time of the Verza. No relocation of the hands is needed while shifting the needle through the guide. A full overview per wish can be found in appendix K.

5.4 CONCLUSION

During the user test the ease of use of the UShift is confirmed. For most of the experts the working principle was instantly clear. Also, the switch between puncturing techniques is fast and takes little effort. The switch is 23% faster than the currently used Verza. This is a promising results since it is to be expected that the learning curve will continue the experts still have to gain more experience with the UShift compared with the Verza.

The aim of the time measurement to reach the target is to validate the basic working principle of a needle guide which can be considered as valid.

The UShift is stated as valid considering the previously stated requirements and wishes and has several advantages compared with the Verza; No relocation of the hands is needed while shifting the needle through the guide and while using the UShift it is possible to easily switch back from free-hand puncturing to needle guided puncturing.

6 DISCUSSION

This chapter comprises the overall discussion of the project and provides recommendations for future research.

To investigate whether the omnidirectional steerable needle is potentially visible during US imaging while preforming a RFA, an experimental visibility study has been conducted. Chapter 2 shows that the needle has promising results for visibility. The tip visibility of the needle has a high visibility for the full angular range. And the visibility of the shaft is comparable with previously tested needles. For more detailed information see section 2.3. Despite the promising results of the visibility study for the omnidirectional needle, a limitation of this experiment is that it is conducted using a PVA phantom (in vitro) and not in vivo. Unfortunately, the visibility study in vivo is not yet conducted and therefore is the steerable needle not yet proved to be well visible in human tissue. However, the used PVA phantom mimics the properties of a human liver and therefore it can be expected that the steerable needle will be visible during in vivo interventions [29].

This project has been conducted with time and resource limitations, such as the unavailability to produce the prototype sterilized and therefore the opportunity to test the prototype in the OR. In the design phase (chapter 3) all the considerations for the prototype have been made with these limitations in mind. Therefore, the requirements and design choices are adjusted to the limited time and resources.

In the validation section (chapter 5) the clinical requirements are validated as if the resources were present to for example sterilize the product. When the product would be developed for actual use, even more strict regulations should be complied concerning the clinical requirements.

Despite the promising results of the user test, some adjustments to the UShift design and future research are required to develop the UShift to an actual medical tool implemented in the OR. The UShift concept can be improved by adjusting some physical aspects. During the user test the wish was expressed to reduce the size of the guide. In figure 33 can be seen which part can be spared (red shaded part). Parallel to the tube of the third angle orientation the guide could be cut off. This allows the probe to have more freedom of movement during free-hand puncturing.

In addition, either the angles of the UShift should cope with the already predetermined angles of the Verza in the Philips US system or the current angle orientations of the UShift should be processed and predetermined in the US system as a reference. The different angles of the Verza and UShift guides can be seen in appendix L.

During the user test one participant had difficulties while detaching the last small part of needle out of the UShift. In figure 34 a visual representation is represented of the adjustment of the exit tube. Expected is that this adjustment will make the detachment of the needle easier, unexpected movements or turning of the probe will not interfere the detachment.

The final addition to the UShift concept is an own bracket design, including an attachment mechanism which is integrated with the UShift body. According to the requirements, the UShift should consist of one part and preferably no moving parts

should be present. This will limit production and assemble costs and provides the benefit of no need to assembly before usage.

The currently used needle guides do not cope with the benefits of free-hand puncturing. While puncturing with the steerable needle the freedom of free-hand puncturing is desired, because the probe is adjustable in such a way that the tip of the needle is best visible while steering. On the other hand, you want the accuracy of inserting that you have while using a needle guide. The currently used probes have an option to detach the needle but the needle either detaches when not intended or the detachment costs a lot of effort.

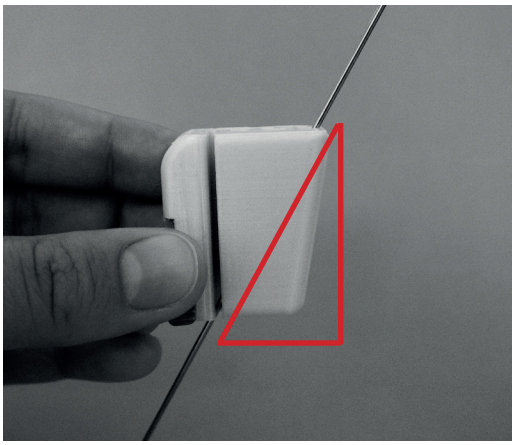


Figure 33: Side view of the UShift, the red triangle is the part that can be spared off, this part has no function.

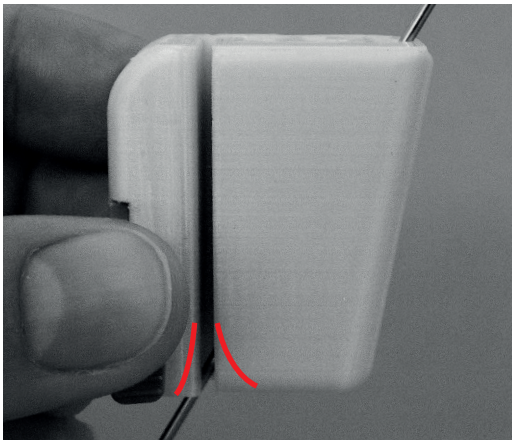


Figure 34: Side view of the UShift, the red lines represent a rounding of the exit path. This should prevent the needle from getting stuck.

In table 3 (section 3.1.4) is visible that most of the advantages of needle guides are related to multiple inserting angles and different gauges possibilities. The UShift is compatible on that part, multiple UShift sizes for different gauges can be made and the UShift provides three angle orientations. Compared to currently used needle guides, such as Verza needle guide, the UShift has some great advantages. The properties that make the UShift unique are the following;

- No relocation of the hands is needed
- Easy access to switch to another angle orientation of the needle
- No need of letting go the steerable needle, which prevents the needle from bending
- The UShift consists out of one piece product, no assemblage necessary
- No moving parts, less chance on failure
- Purposed for multiple interventions
- Possibility to switch from free-hand guided - to guided puncturing

The validation section (chapter 5) is based on a user test performed by experts, observation and validation of requirements. During the user test the prototype has been used. For the validation on requirements, the final concept is used. Six experts participated in the user test, this amount was limited due to the availability of experts on the radiology department of the Erasmus MC. The results would even be more reliable when more experts would participate in the experiment. Due to the Delphi method, and therefore using the input of previous experts valuable information is gathered.

The above listed advantages of the UShift are determined and supported by the participating experts.

The UShift proves to cope with the basic working principle of a needle guide, guiding the needle in a predetermined angle in, in this case, IP orientation. Also, the detachment of the needle during puncturing has been experienced to be more smooth and the UShift provides the option to attach the needle back in when needed. According to the experts the UShift is for more percutaneous interventions applicable than only RFA interventions.

6.1 FUTURE RESEARCH

Several fields of future research would be interesting to look further into. Below the most important fields are pointed out.

It would be interesting to measure the time needed to switch back from free-hand puncturing to guided puncturing of both Verza and UShift. This functionality of the UShift has been discovered during the user test and therefore is not included in the experimental design. It is to be expected that the UShift gains a lot of time profit on this aspect. The Verza is not developed put needle back in. The needle should be positioned exactly in the right plane to align with the small tube.

Several experts indicated that the UShift can be used in other application fields than the RFA interventions. Percutaneous interventions like biopsies and Percutaneous Transhepatic Cholangiography (PTC) are mentioned during the user test. There is a high possibility that the UShift can be used for even more interventions.

When the UShift meets the clinical requirements and regulations, the product can be tested in vivo studies. The visibility of the steerable needle in human tissue and the working principle of the UShift in combination with the steerable needle can be confirmed.

Furthermore, more research should be done concerning the cost effectiveness of the final product. It can be investigated whether a disposable or reusable product is more profitable. Depending on these outcomes a final material choice can be made. The material should cause little to no friction between the needle. PLA served as a sufficient material, however, more research could be done into the possibilities. For example, when the product becomes disposable, a recyclable material can be chosen.

Also, different production methods should be considered. During this project all models are 3D-printed. For prototyping this is a very profitable production technique, since it has low investment costs and it is relatively fast. When the UShift will be produced on the market, 3D-printing is not profitable anymore. It is to be expected that large numbers of the UShift will be produced. For mass-production casting is an interesting production technique. The investment costs for the mould are one-time only.

In conclusion, before the UShift can be implemented in the working field on the OR, more research should be done about the production methods, clinical regulations and selling opportunities. However, the UShift is stated as useful and innovative and therefore it is to be expected that the implementation will not cause any issues.

7
CONCLUSION

The aim of the project was to develop a novel needle guide tool for percutaneous interventions with an omnidirectional steerable needle during real-time US-guidance. The developed needle guide tool is called UShift and provides both the benefits of needle guided puncturing and free-hand puncturing. These benefits are for free-hand puncturing: the freedom of movement of both the probe and needle during puncturing and for needle guided puncturing: a shorter procedure time, reduced needle manipulation and improved needle visualisation.

The sub-functions that the UShift fulfils are providing a fixed direction of the needle, aligned with the probe beam, the ability to differ in multiple insertion angles of the needle with respect to the probe beam and to switch from a fixed needle guided position to free-hand puncturing.

The development process of the UShift consisted of a systematic analysis of currently used needle guides, a complete view of the problem, clear programme of requirements, selection of the best concept and the iteration process of the design, eventually evolving to a novel solution.

The validation of the UShift has resulted in promising results, the UShift can be stated as valid considering the previously mentioned requirements and wishes. The UShift has several advantages compared to the Verza; No relocation of the hands is needed while

shifting the needle through the guide and while using the UShift it is possible to easily switch back from free-hand puncturing to needle guided puncturing.

Therefore, this project resulted in a novel needle guide tool that can be used in combination with the omnidirectional steerable needle during percutaneous interventions. Future research could be conducted concerning production methods, material options, the cost-effectiveness and other application fields of the UShift. The UShift has great benefits compared with currently used needle guides and is therefore stated as innovative.

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APPENDIX

APPENDIX A: FOUR NEEDLE GUIDES FOUND IN LITERATURE

Real-time guidance for percutaneous puncture (Saitoh et al., 1972)

The real-time needle guidance consists of four components; a head, a fixing plate, a connector and a fixing plate. The detachable supplementary metal fittings contain a canal for the needle, different plates with canals can be attached for different sizes needles. The needle guider is able to make an angle of 20 degrees with respect to the transducer. The whole needle guidance device is reusable; all components are made of stainless steel (fig. 36) [26].

Steerable real-time needle guidance system (Buonocore et al., 1981)

For US image guidance biopsy interventions this steerable real-time needle guidance system is developed (fig. 37). The device consists of a movable wheel where the needle can pass through. The wheel can be removed for sterilization. The device has a great flexibility of variation in the angle and the device provides a possibility to handle needles from 22 to 14 gauge. It is clinical proven that the device shortens the procedure and conducts a more accurate result [27].

Sterile disposable needle guides (Chapman et al., 2003)

This disposable CISCO needle guides can be used in both transverse or longitudinal direction. Only one predetermined angle can be used to guide the needle. Not mentioned are the possible needle diameters for this device (fig. 38) [19].

Lateral-mounted needle guide (Di Costanzo et al., 2013)

This needle guide is developed to overcome the steep learning curve that is present for laser ablation [28]. For this particular intervention multiple needles have to be placed. The needle guide provides the possibility to position two needles parallel and uniform with a prefixed distance. The needles are inserted through two separate channels (fig. 39). The angle is either 15 - or 30 degrees [28].

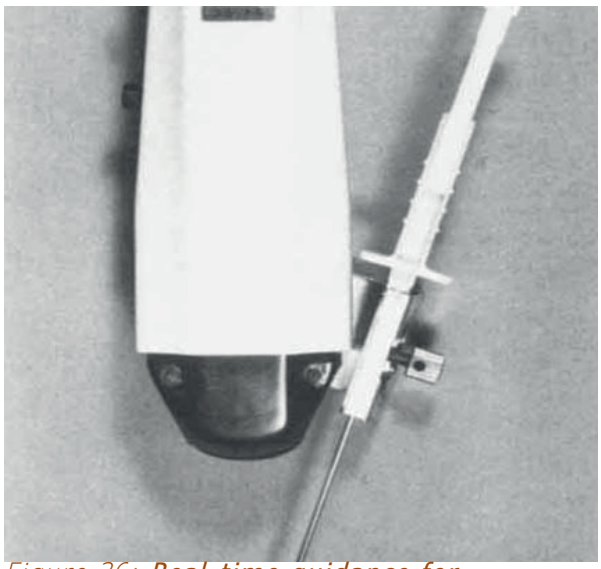


Figure 36: **Real-time guidance for percutaneous puncture (Saitoh et al., 1972).**

Figure 37: **Real-time guidance for percutaneous puncture (Saitoh et al., 1972).**

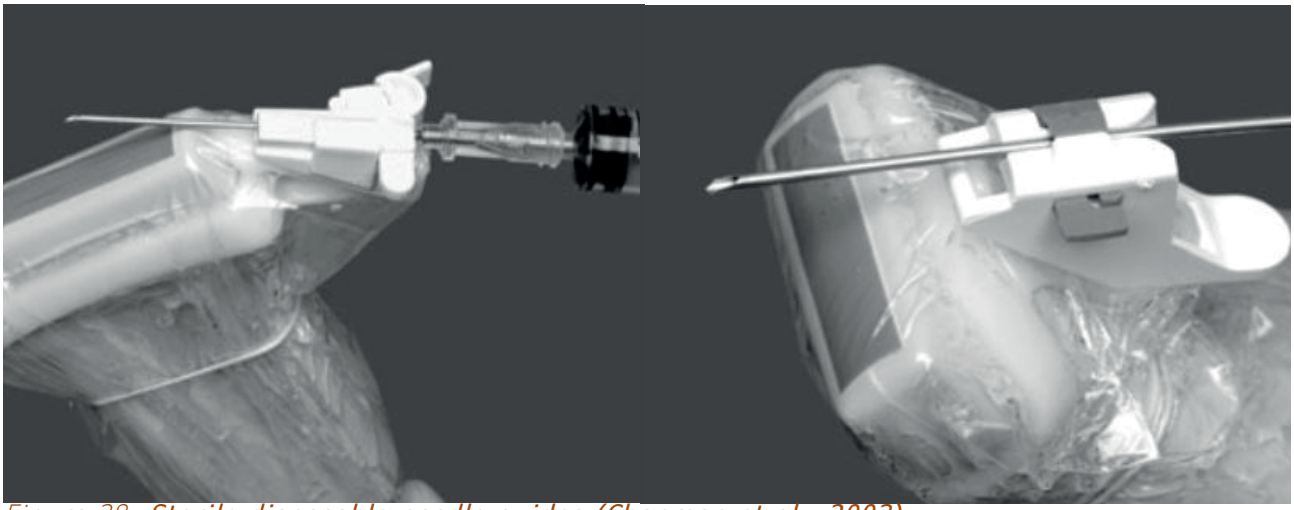


Figure 38: **Sterile disposable needle guides (Chapman et al., 2003).**

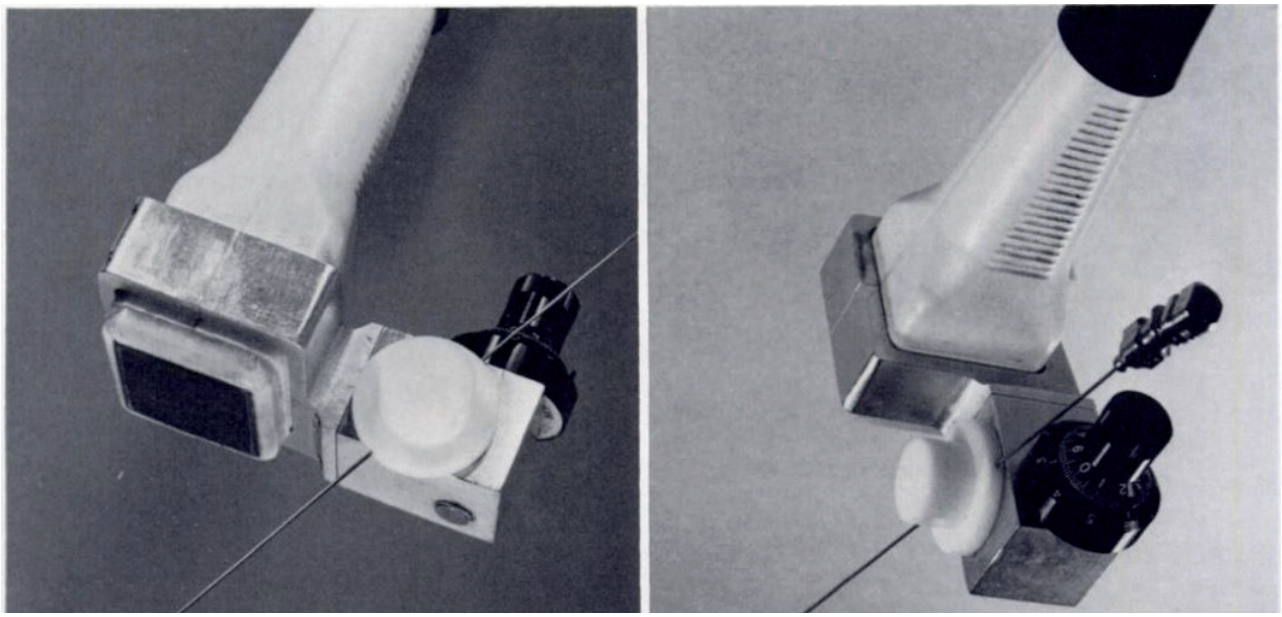


Figure 39: Steerable real-time needle guidance system (Buonocore et al., 1981).

APPENDIX B: RUN TABLE FOR RANDOMIZATION OF THE ORIENTATION OF THE NEEDLE DURING THE NEEDLE VISIBILITY EXPERIMENT

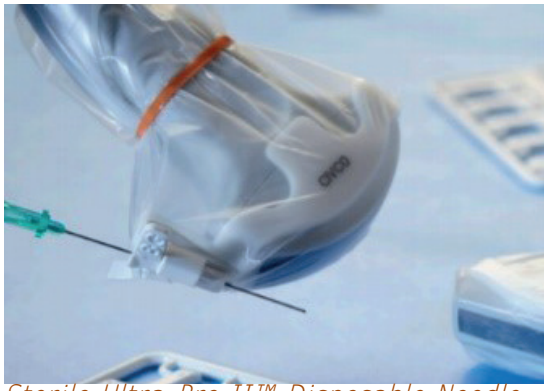
PA= position A 1=Position A
PB= position B 2=Position B

#Experiment	Position		
1	1	NA	
2	2	NA	
3	2	PB2	x
4	1	PA2	x
5	2	PB3	x
6	1	PA3	x
7	2	PB4	x
8	1	PA4	x
9	2	PB5	x
10	1	PA5	x
11	2	PB6	x
12	2	PB7	x
13	2	PB8	x
14	2	PB9	x
15	2	PB10	x
16	1	PA6	x
17	2	PB11	x
18	1	PA7	x
19	1	PA8	x
20	2	PB12	x
21	1	PA9	x
22	1	PA10	x
23	2	PB13	x
24	1	PA11	x
25	2	PB14	x
26	2	PB15	x
27	1	PA12	x
28	2	PB16	x
29	2	PB17	x
30	2	PB18	x
31	2	PB19	x
32	1	PA13	x
33	2	PB20	x
34	2	PB21	x
35	1	PA14	x
36	2	PB22	x
37	1	PA15	x
38	1	PA16	x
39	2	PB23	x
40	1	PA17	x
41	1	PA18	x
42	1	PA19	x
43	1	PA20	x
44	1	PA21	x
45	1	PA22	x
46	2	PB24	x
47	1	PA23	x
48	2	PB25	x
49	1	PA24	x
50	1	PA25	x
51	1	PA26	x
52	2	PB26	x
53	2	PB27	x
54	1	PA27	x
55	2	PB28	x
56	1	PA28	x
57	2	PB29	x
58	1	PA29	x
59	2	PB30	x
60	1	PA30	x
61	2	PB31	x
62	2	PB32	x
63	1	PA31	x
64	2	PB33	x
65	1	PA32	x
66	2	PB34	x
67	2	PB35	x
68	2	PB36	x
69	2	PB37	x
70	1	PA33	x
71	2	PB38	x
72	1	PA34	x
73	2	PB39	x
74	2	PB40	x
75	2	PB41	x
76	2	PB42	x
77	1	PA35	x
78	2	PB43	x
79	2	PB44	x
80	1	PA36	x
81	1	PA37	x
82	1	PA38	x
83	2	PB45	x
84	2	PB46	x
85	1	PA39	x
86	1	PA40	x
87	1	PA41	x
88	1	PA42	x
89	2	PB47	x
90	1	PA43	x
91	1	PA44	x
92	2	PB48	x
93	1	PA45	x
94	1	PA46	x
95	1	PA47	x
96	1	PA48	x
97	2	PB49	x
98	1	PA49	x
99	1	PA50	x
100	2	PB50	x

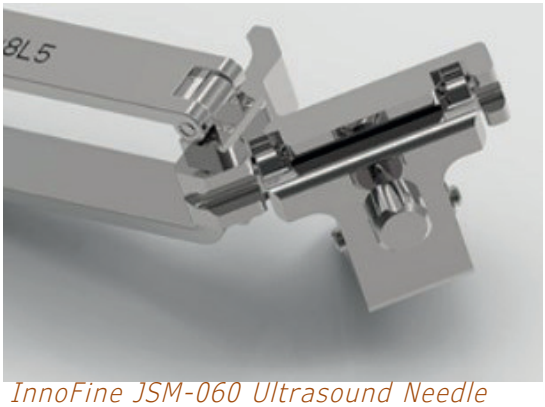
APPENDIX C: CURRENTLY USED NEEDLE GUIDES

AccuSITE™ Out-of-Plane Ultrasound Needle Guide Replacement Kits, CIVCO [32].

Director™ Sterile Needle Guide - 24/Box, Protek [33].



Sterile Ultra-Pro II™ Disposable Needle Guides. Mermaid medical [34].



InnoFine JSM-060 Ultrasound Needle Guide For Siemens, National Ultrasound [36].

Ultra-Pro e™ Disposable Variable Angle Needle Guides, Mermaid medical [37].

Verza™ Ultrasound Needle Guidance System, CIVCO [38].

Multi-Pro 2000™ Ultrasound Needle Guide Brackets, CIVCO [35]

APPENDIX D: EXTENSIVE EXPLANATION OF THE REQUIREMENTS

Requirements

1. Functional requirements:
   - 1.1 While inserted in the guide, the needle should not detach when not intended
     The needle should only detach when this is desired. Undesired detaching is obstructive for the intervention.
   - 1.2 The needle should not deviate in the guide more than 0,5 mm when fixed in the guide
     Deviation in the needle guide can cause dislocation of the needle. The needle can deviation out of the probe beam, visualisation of the needle therefore can decrease.
   - 1.3 The needle should be able to detach from the guide while the needle is inserted in the body
     The purpose of the needle guide is that the detachment finds place at the moment when the needle is almost located at the target in the liver.
   - 1.4 The guide should have an attachment to a bracket
     One way or another, the needle guide should be attached to the probe to ensure alignment of the needle and probe beam.
   - 1.5 The guide should be as time efficient as the currently used Verza guide (not more than 25% slower)
     The guide should be compatible to of exceeding the current solutions.
   - 1.6 The guide should ease the switch from guided puncturing to free-hand puncturing
     This is the main improvement point considered current needle guides.

2. Clinical requirements:
   - 2.1 Sterilized production or sterilization possibilities afterwards
     Otherwise the needle can not be used in the OR.
   - 2.2 The use of the guide must be safe for the operators (e.g. no sharp edges or chance of breaking parts)
     Operators should not be harmed because of the needle guide.

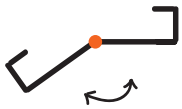
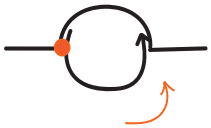
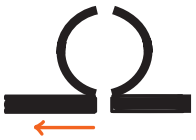
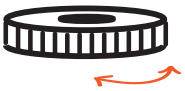
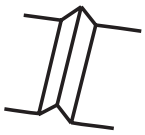
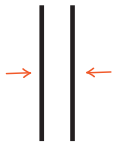
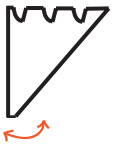
3. Cost and manufacturing requirements:
   - 3.1 The costs of the guide must be able to compete with existing guides
     The guide should be compatible to of exceeding the current solutions.
   - 3.2 The guide should be manufactured such way that is cost-benefitable for a disposable product
     The guide should be compatible to of exceeding the current solutions.

4. Physical requirements:
   - 4.1 The product cannot be higher than 4 cm and the maximum thickness is 2 cm
     The guide should be compatible to of exceeding the current solutions.
   - 4.2 The product should not weight more than 10 gr
     The guide should be compatible to of exceeding the current solutions.
   - 4.3 The needle guide should be usable for both right- and lefthanded persons
     No distinguish should be made between the preference of handling hand.

Wishes

1. As less as possible handlings to detach the needle from the needle guide
   The detachment is preferable as short and fast as possible.
2. As less as possible parts
   The costs and labour decreases when the amount of parts decreases. Furthermore, the radiologists don't want to assemble the product before they going to use it.
3. At least two or more angle orientations possibilities
   For every target another orientation is preferable.
4. The loosening of the needle should be as fast as possible
   The detachment is preferable as short and fast as possible.
5. The design should be as compact as possible
   When free-handed puncturing is preformed, the needle guide should be in the way.
6. Multiple needle diameters should fit the guide
   Multiple diameter needles are used during interventions.
7. The device is disposable
   This fits the current needle guides
8. As less as possible moving parts in the guide
   Moving parts accelerate the wear process of a product
9. The production should be as cheap as possible
   Since the product will be disposable, the production costs should be as low as possible
10. The insertion angle should correspond with the predetermined angle on the US
    The usage of the needle guide is easier when the path of the needle is predicted.

APPENDIX E: MORPHOLOGICAL CHART

	1	2	3	4	5
Connection to probe frame	 SLIDER	 HINGE			
Create an opening - loosening needle	 HINGE	 SLIDE	 DRILL CHUCK MECHANISM	 SLIDE	 SHIFT
Ways to move something	 WHEEL	 SWITCH	 BUTTON	 SWITCH	 LEVER
Fixation needle - straight line	 RECESS	 TUBE	 PRESS FORCE		
Create different angle orientations needle	 BARBS	 MULTIPLE HOLES	 TURNING		

APPENDIX F: CONCEPTS

APPENDIX F.1: EXPLANATION STRUCTURE OF CONCEPT VISUALISATION

Side view:
This represents view on the probe on the side. In figure 40 can be seen that the Protek Director needle guide is viewed on the front and the probe on the side. The black part in the concept visualisation (fig. 42) represents the bracket for the needle guide.

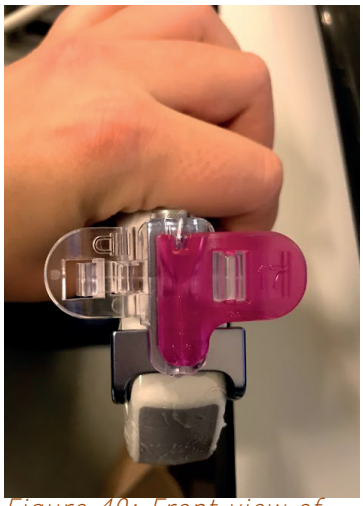


Figure 40: Front view of the Protek Director needle guide.

Top view:
The probe and the needle guide are viewed from the top. The circle in figure 42 represents the screw of the bracket.

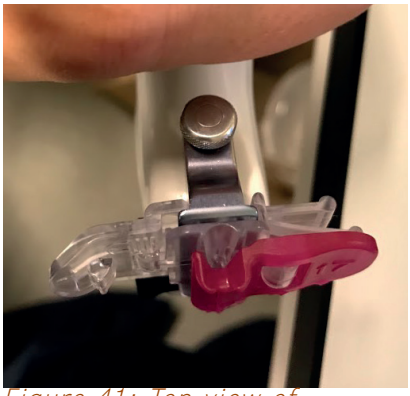


Figure 41: Top view of the Protek Director needle guide.

Orange squares:
The orange squares serve as a clarification of a working principle or a part of the concept.

Concept 4 consists of a front view, at the right.

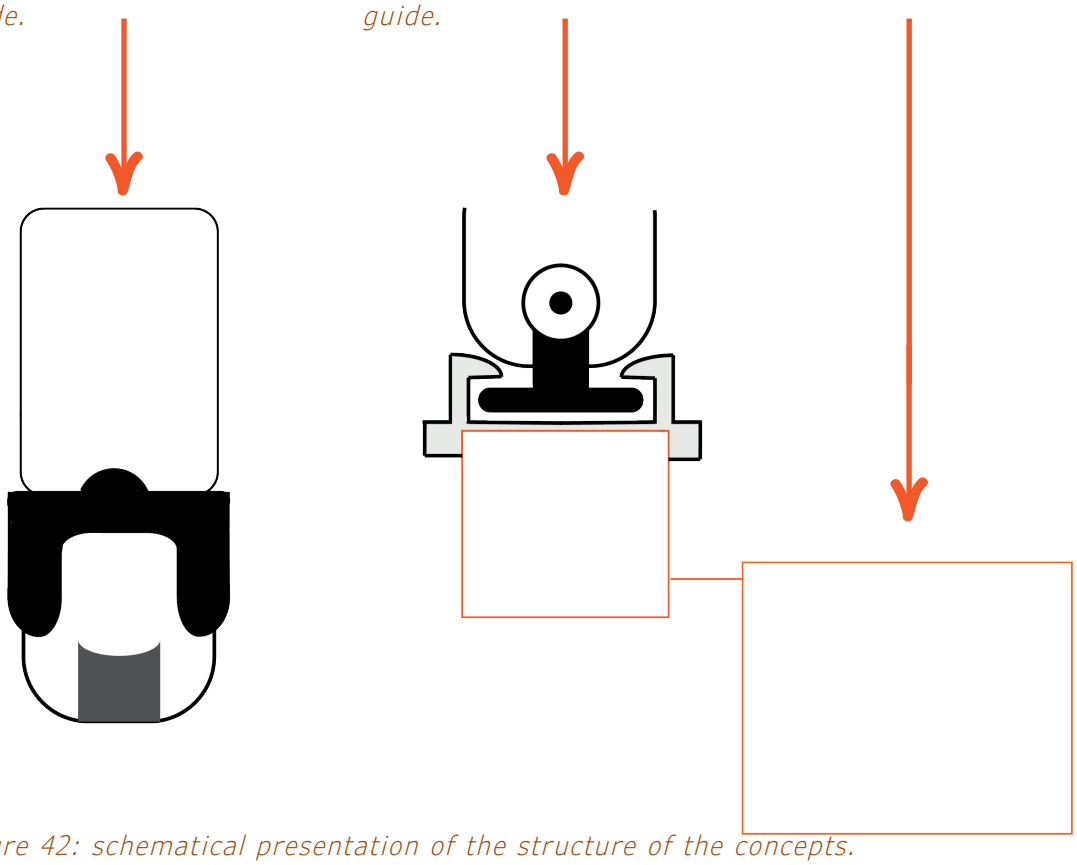
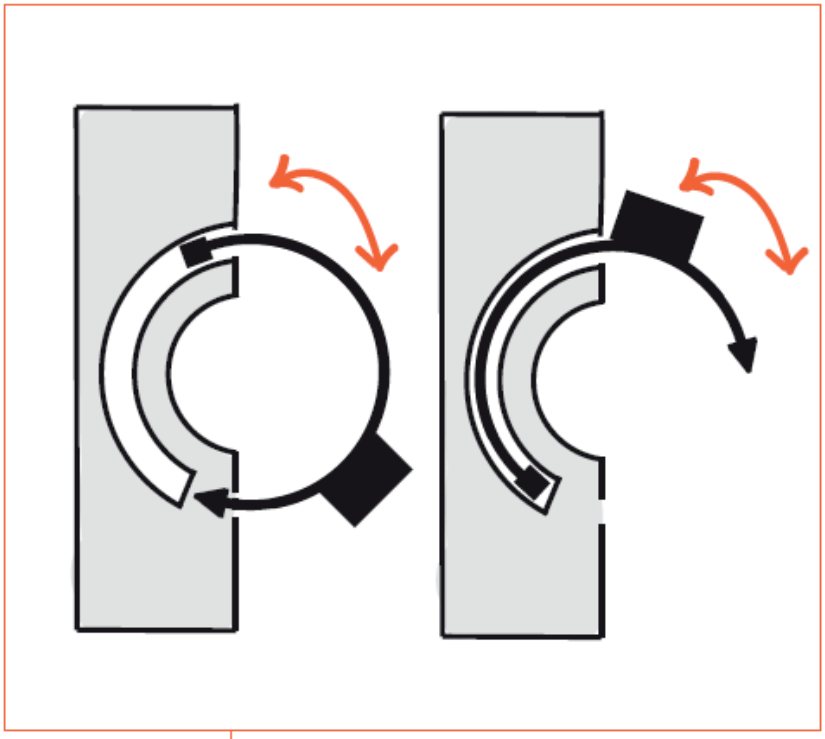
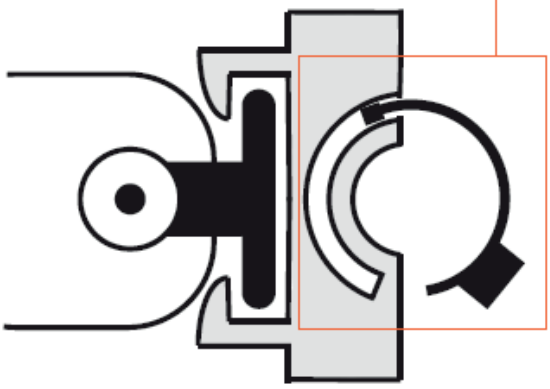


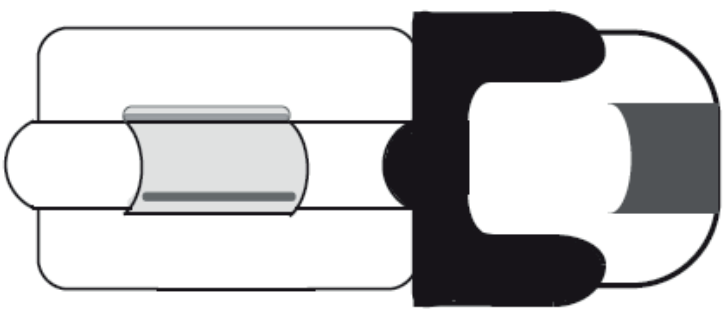
Figure 42: schematical presentation of the structure of the concepts.

APPENDIX F.2: CONCEPT 1 - TURNER

CONCEPT 1
'TURNER'

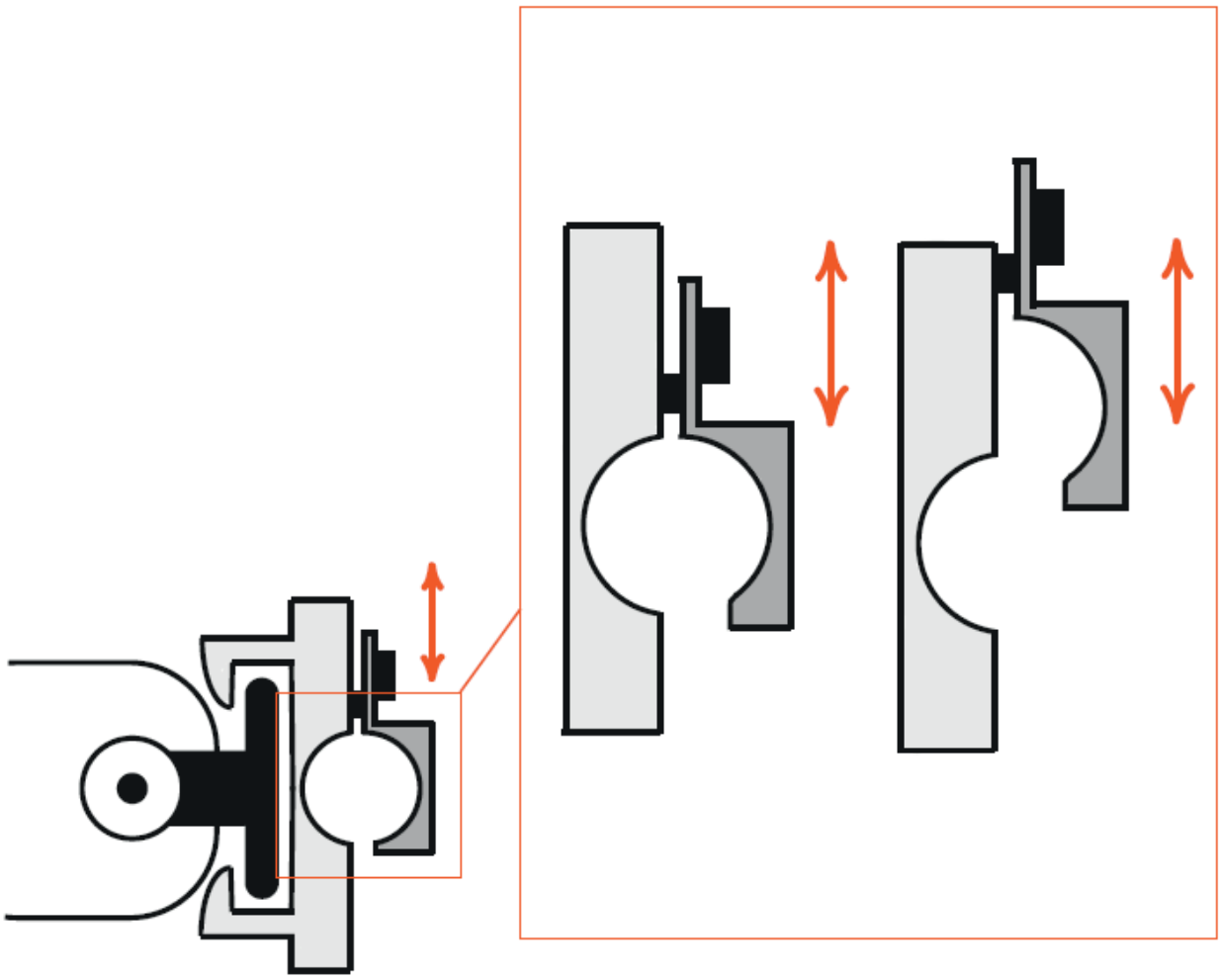


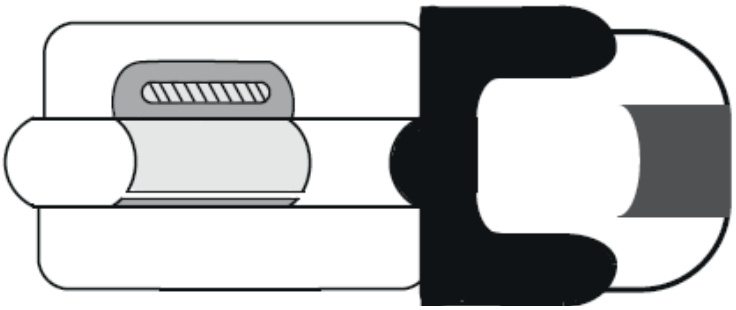




APPENDIX F.3: CONCEPT 2 - SLIDER

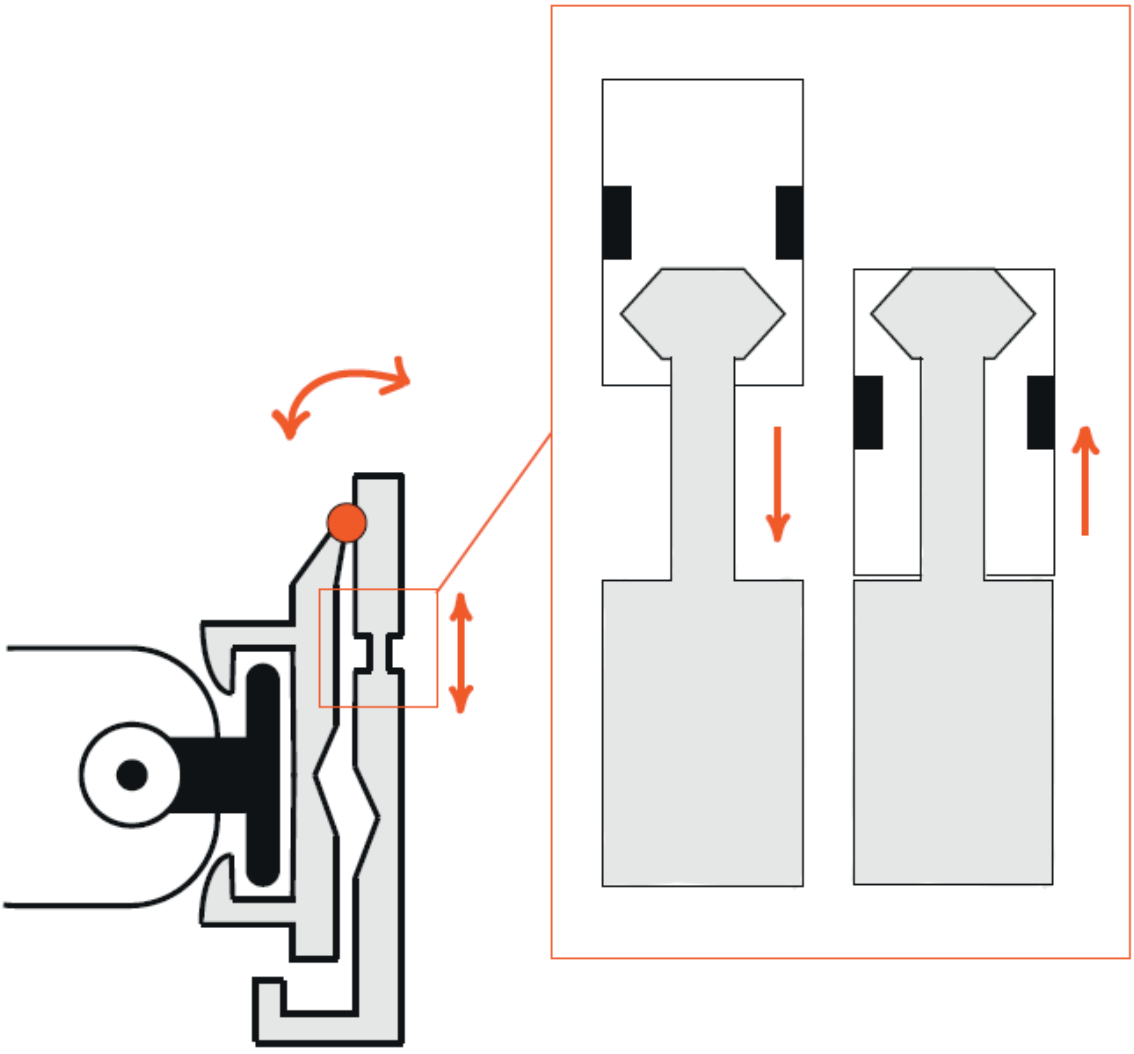
CONCEPT 2 'SLIDER'

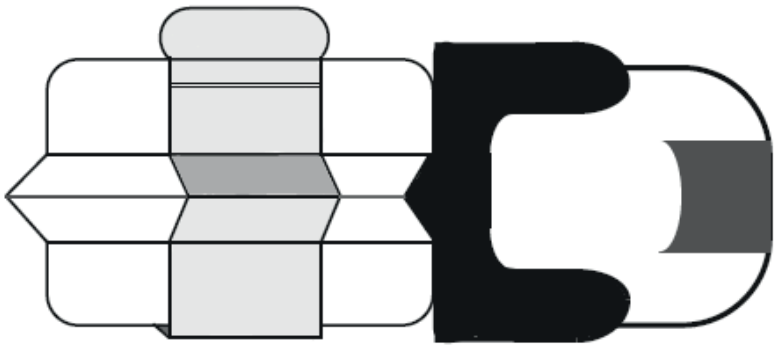




APPENDIX F.4: CONCEPT 3 - CLICK

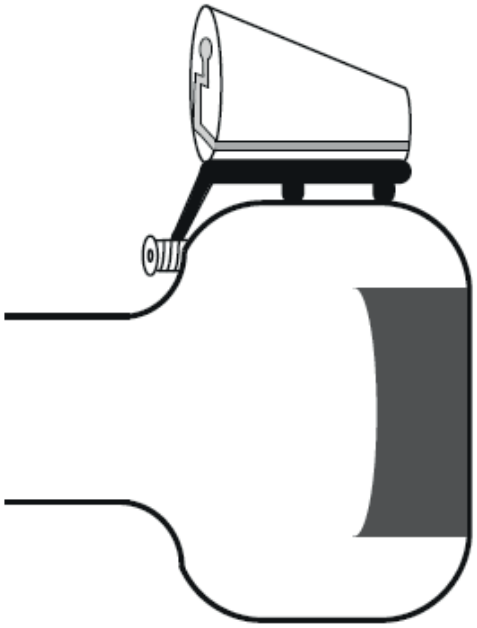
CONCEPT 3 'CLICK'

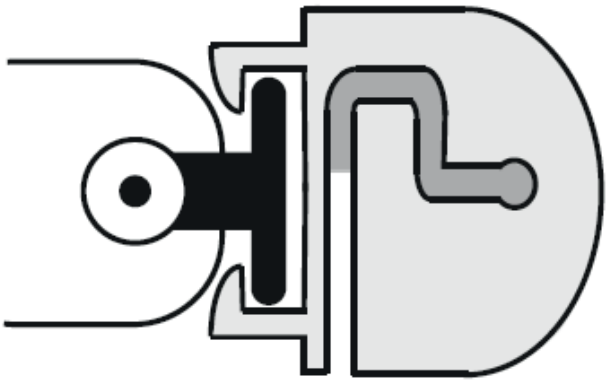




APPENDIX F.5: CONCEPT 2 - TURNER

CONCEPT 4
'MAZE'





APPENDIX G: THE DEFINED SCALE POSITIONS FOR EVERY WISH USED IN THE HARRIS PROFILE

Less as possible handlings needed to loosen the needle (e.g. hand movements)

-- More than two handlings
- Two handlings
+ One handling
++ Zero handlings

As less as possible parts

-- Four or more parts
- Three parts
+ Two parts
++ One part

Possibility of multiple angle orientations

-- Not one possibility to integrate multiple orientations
- Possibility of two angle orientations
+ Possibility of more angle orientations
++ Easy integration of multiple angle orientations

Speed of loosening needle, depending of amount of handlings per handling +1 sec, starting with 3 seconds as a ideal situation

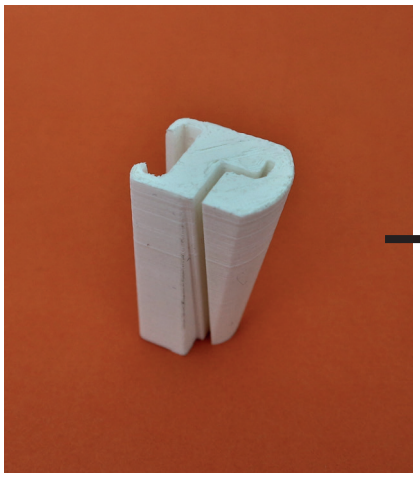
-- 6 Seconds
- 5 Seconds
+ 4 Seconds
++ 3 Seconds

Flat/small as possible, compatibility with the Verza

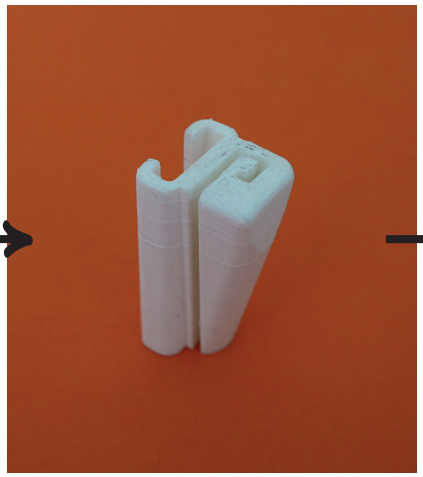
-- More than twice as large as the Verza
- Twice as large as the Verza
+ Compatible with the size of the Verza
++ Smaller than the Verza

APPENDIX H: ITERATION PROCESS OF THE USHIFT

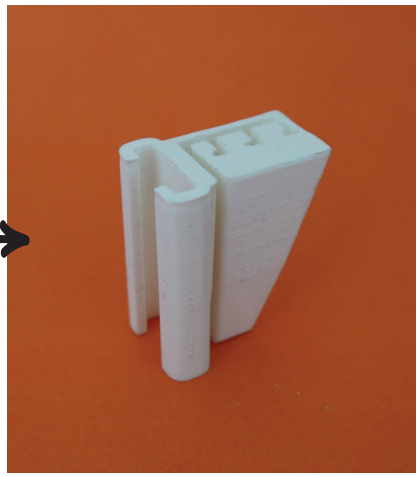
APPENDIX H.1: NEEDLE GUIDE DEVELOPMENT



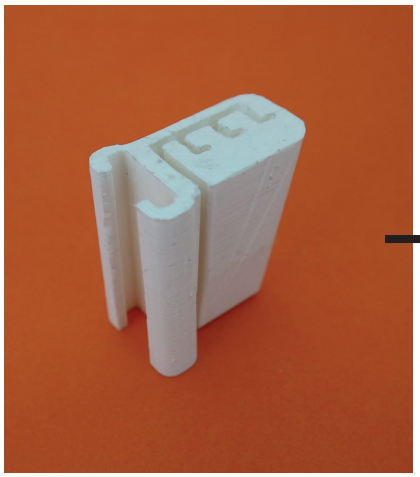
UShift prototype 1



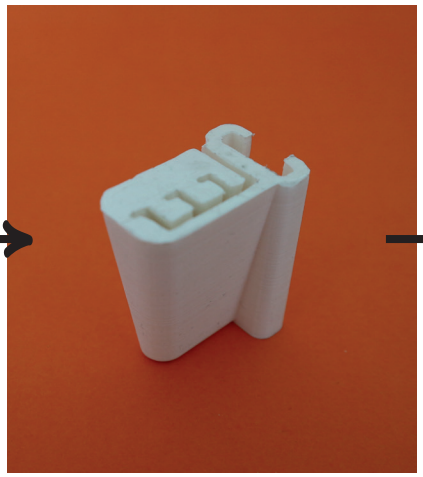
UShift prototype 2



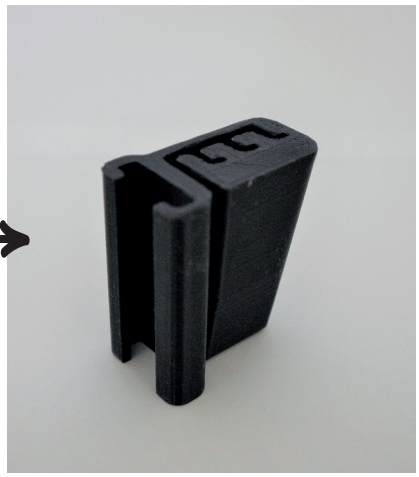
UShift prototype 3



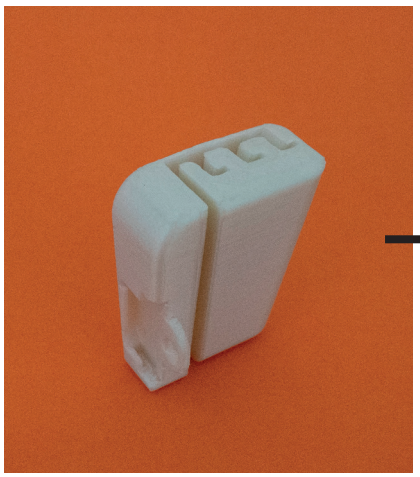
UShift prototype 4



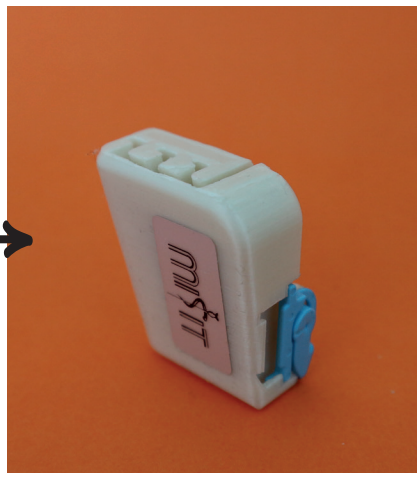
UShift prototype 5



UShift prototype 6



UShift prototype 7

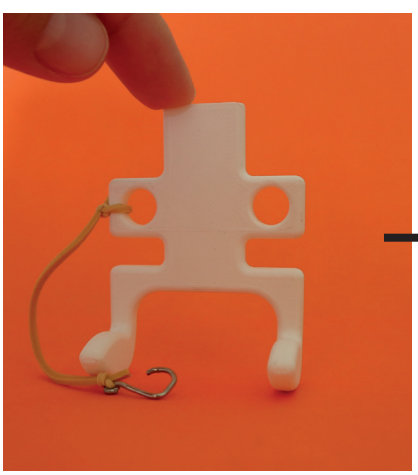


UShift prototype 8

Most important iteration steps:

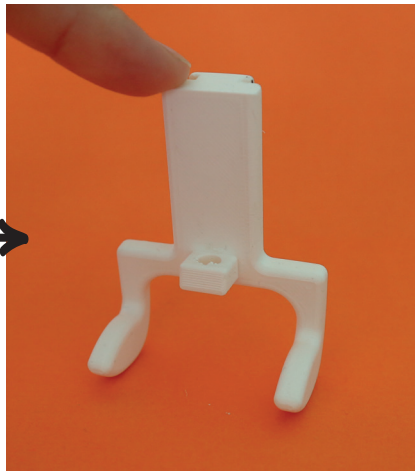
- The 'end'point of the path should be centred in the middle, otherwise the needle is out of plane
- Multiple angle orientations
- Rounding of edges
- Alignment of needlepaths within the guide, to reduce the fixtion points
- Attachment to bracket

APPENDIX H.2: NEEDLE GUIDE BRACKET DEVELOPMENT

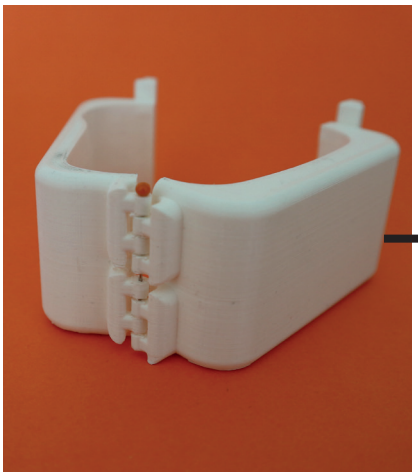


UShift bracket prototype 1

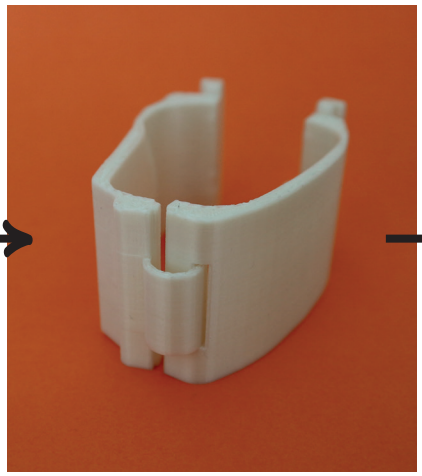
UShift bracket prototype 2



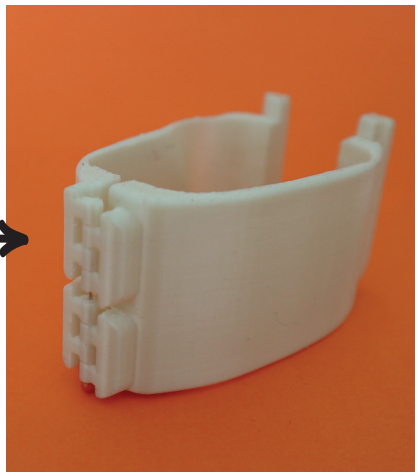
UShift bracket prototype 3



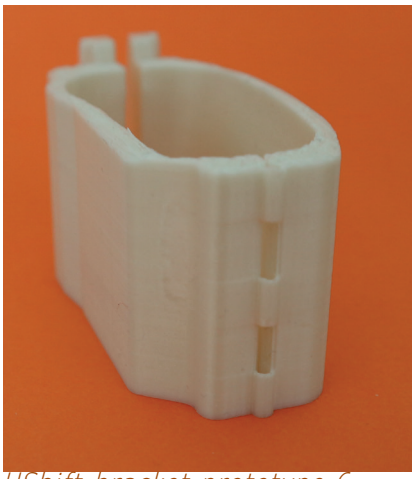
UShift bracket prototype 4



UShift bracket prototype 5



UShift bracket prototype 6

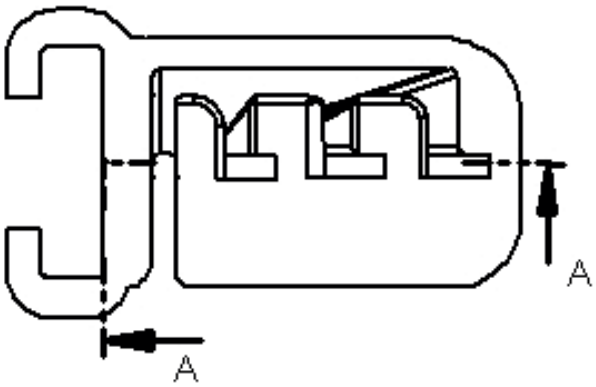


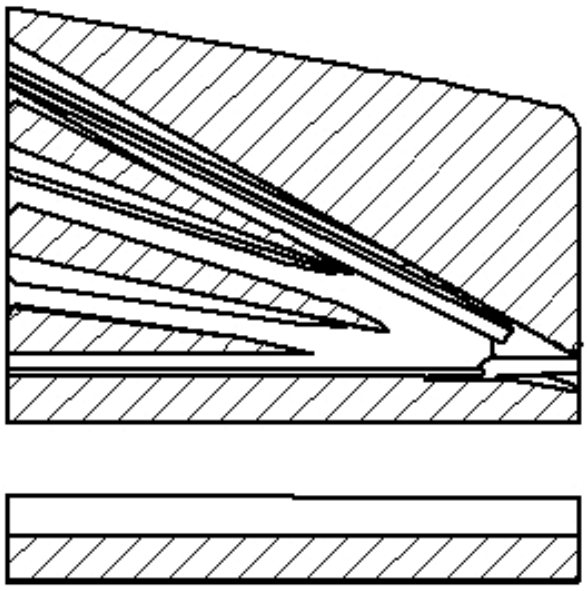
UShift bracket prototype 6

Most important iteration steps:

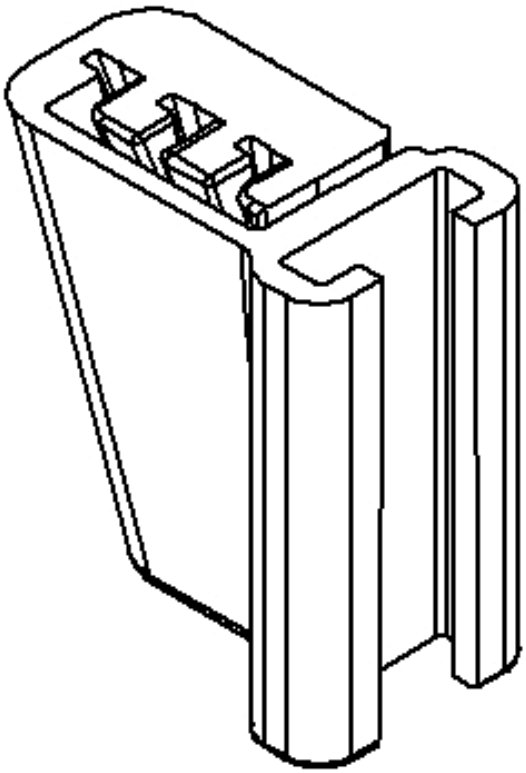
- Bracket with a clam mechanism on the side of the probe
- Bracket with a clip mechanism is introduced
- Narrow the size down of the bracket
- Keep the ergonomic aspects of the probe shape (thinner wall thickness)
- Try different hinge mechanisms

APPENDIX H.3: SOLIDWORKS TECHNICAL DRAWING FINAL CONCEPT USHIFT





SECTION A-A



DO NOT SCALE DRAWING REVISION

APPENDIX I: INTRODUCTION TEXT, INTERVIEW QUESTIONS USER DURING THE USER TEST AND THE RUN TABLE

APPENDIX I.1: INTRODUCTION TEXT USER TEST

WELCOME

at an experiment concerning a new needle guide concept; called UShift.

During this experiment you will do two similar tasks with two different needle guides. Please first read the description.

During the experiment imagine that the needle is a steerable needle. When you almost reach the target during puncturing, you want to adjust the direction of the needle. Because of this, you want to switch from guided puncturing to free-hand puncturing to have the needle better visualized.

Task 1
- First you will receive the Verza needle guide which will be connected to the probe
- Next, you are asked to insert the needle in the needle guide (position 2)
- Followed by puncturing towards the target which is placed somewhere in the middle of the specimen
- You will hear a sign, you are asked to switch from guided puncturing to free-hand puncturing
- Continue free-hand towards the target
- Once the target is reached you can withdraw the needle

Task 2
- First you will receive the UShift needle guide which will be connected to the probe
- Next, you are asked to insert the needle in the needle guide (hole 3)
- Followed by puncturing towards the target which is placed somewhere in the middle of the specimen
- You will hear a sign, you are asked to switch from guided puncturing to free-hand puncturing
- Continue free-hand towards the target
- Once the target is reached you can withdraw the needle

THANK YOU for participating!

APPENDIX I.2: QUESTIONNAIRE AS BASIS FOR THE INTERVIEWS

ENQUÊTE 1

1. Wat is je functie en hoe is echogeleid prikken hierbij betrokken?
   Radioloog Assisitent(e)

2. Hoeveel jaar prikervaring heb je ongeveer?
   …… jaar

3. Hoe vaak doe je een interventie waarbij echogeleid prikken bij betrokken is?
   ……. keer per week …… keer per dag

4. Hoe zou je je prik niveau beoordelen? Heb je meerdere pogingen nodig?
   Beginner – expert 1 - 2 - 3 - 4 - 5 Superfical – deep

5. Als je een interventie zoals RFA doet, prik je dan liever met een needle guide of free-hand?

   Needle guide Free-hand

ENQUÊTE 2

1. Welke naald heb je net als eerste gebruikt?

   Verza needle guide UShift needle guide

2. Vergelijk beide needle guides, welke vind jij beter?

   De wissel tussen needle guided naar free-hand prikken?
   Verza needle guide UShift needle guide

   De hoeveelheid handelingen om de taak te volbrengen?
   Verza needle guide UShift needle guide

3. Welke guide zou je kiezen voor een behandeling die vergelijkbaar is met RFA?

   Verza needle guide UShift needle guide

4. Wat is het grootste verschil tussen de twee guide denk je?

5. Zijn er nog overige opmerkingen?

APPENDIX I.3: RUN TABLE OF THE USER TEST

Participant	Needle guide to use first
1	UShift
2	Verza
3	Verza
4	Verza
5	Verza
6	Verza
7	UShift
8	UShift
9	UShift
10	UShift

APPENDIX J: TABLE WITH THE DATA OF THE TIME MEASUREMENTS

APPENDIX J.1: TIME TO REACH THE TARGET

	Time to reach the target UShift	Time to reach the target Verza	Order usage needle guide
Participant 1	12 sec	6 sec	UShift (1) - Verza (2)
Participant 2	5 sec	4 sec	Verza (1) – UShift (2)
Participant 3	4 sec	8 sec	Verza (1) – Ushift (2)
Participant 4	*N.A.*	*N.A.*	*Verza (1) – UShift (2)*
Participant 5	13 sec	17 sec	Verza (1) – Ushift (2)
Participant 6	13 sec	9 sec	Verza (1) – Ushift (2)
Average	9,4 sec	8,8 sec	

APPENDIX J.2: TIME TO SWITCH FROM GUIDED PUNCTURING TO FREE-HAND PUNCTURING

	Time to switch UShift 1st attempt	Time to switch UShift 2nd attempt	Time to switch Verza	Order usage needle guide
Participant 1	2,5 sec	N.A.	2,9 sec	UShift (2) - Verza (1)
Participant 2	1,6 sec	1,5 sec	2,1 sec	Verza (1) – UShift (2)
Participant 3	3,5 sec	2,9 sec	2,6 sec	Verza (1) – UShift (2)
Participant 4	*14,3 sec*	*N.A.*	*N.A.*	*Verza (1) – UShift (2)*
Participant 5	7,7 sec	4,0 sec	7,8 sec	Verza (1) – UShift (2)
Participant 6	5,8 sec	4,7 sec	4,7 sec	Verza (1) – UShift (2)
Average	4,2 sec	3,1 sec	4,0 sec	

APPENDIX K: VALIDATION OF REQUIREMENTS FOR THE USHIFT

1. Functional requirements:
   - 1.1 While inserted in the guide, the needle should not detach when not intended
     The needle cannot detach at an undesired moment, because the needle should follow very consciously a path and therefore it cannot go at an undesired moment.
   - 1.2 The needle should not deviate in the guide more than 0,5 mm when fixed in the guide
     Since the needle is 'fixed' in a small path, which has the same diameter as the needle, the needle only has 1 mm of moving space.
   - 1.3 The needle should be able to detach from the guide while the needle is inserted in the body
     The path has the height of the whole guide, the needle shaft can move through the path and because no interferences are present, the needle can detach when the needle is inserted in the body.
   - 1.4 The guide should have an attachment to a bracket
     Both the prototype and the final concept consist of an attachment possibility to different brackets.
   - 1.5 The guide should be as time efficient as the currently used Verza guide (not more than 25% slower)
     Considering the outcome of the user test, the Verza gained a time profit of 0,6 sec during targeting. The UShift was more time efficient (0,9 sec) during the switch of puncturing technique, which 23 % faster than the Verza.
   - 1.6 The guide should ease the switch from guided puncturing to free-hand puncturing
     According to experts using the UShift, the ease of use is increased and multiple advantages are noticed.

2. Clinical requirements:
   - 2.1 Sterilized production or sterilization possibilities afterwards
     Nowadays it is possible to 3D-print sterilized products, using a cleanroom. Also, the UShift can be casted, which can be sterilized afterwards.
   - 2.2 The use of the guide must be safe for the operators (e.g. no sharp edges or chance of breaking parts)
     The UShift does not contain any sharp edges, the corners are rounded. The UShift does not contain any fragile part and because of the absence of moving parts, the chance on breaking parts is reduced.

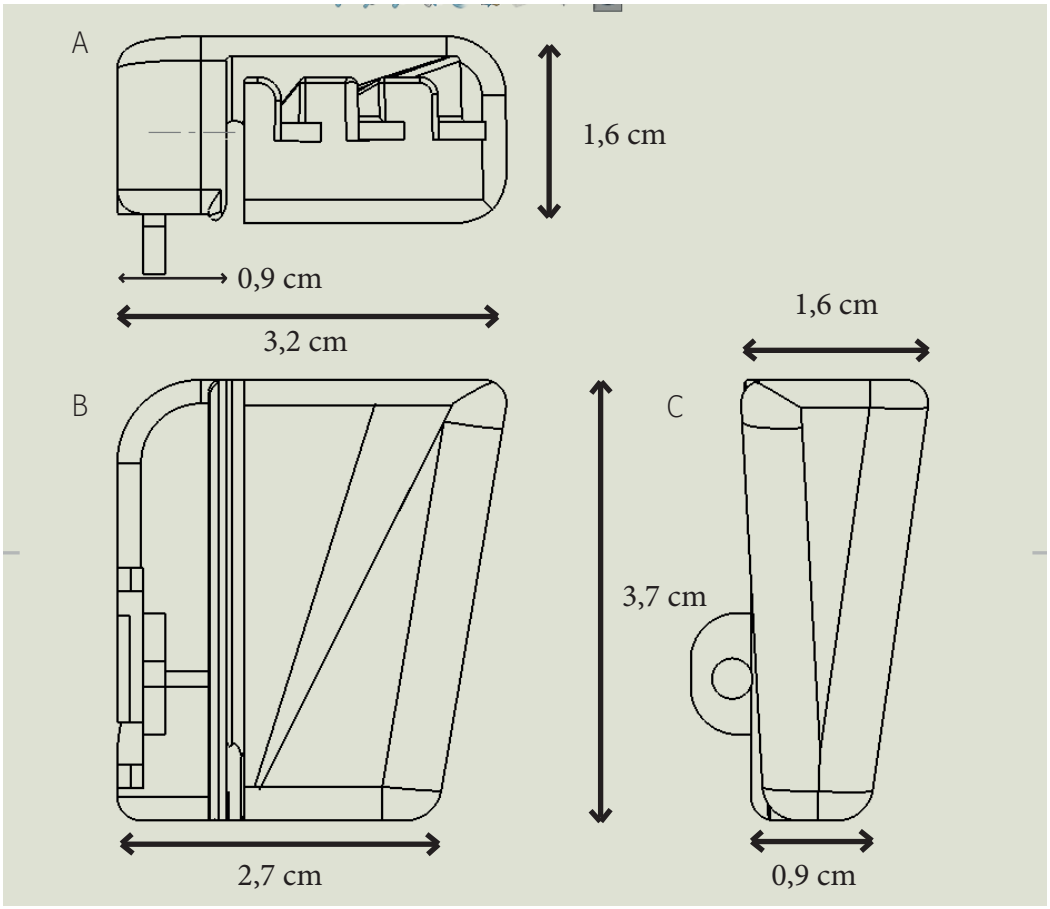
3. Cost and manufacturing requirements:
   - 3.1 The costs of the guide must be able to compete with existing guides
     Since the Verza needle guide has 8 components, which all need a mould, post-processing and assemblage to be produced. The UShift, which only consist of one piece is cheaper than the Verza guide.
   - 3.2 The guide should be manufactured such way that is cost-benefitable for a disposable product
     3D-printed is not a manufacturing method that is cost-beneficial for mass production. Therefore the UShift should be casted to allow mass production.

4. Physical requirements:
   - 4.1 The product cannot be higher than 4 cm and the maximum thickness is 2 cm
     The UShift has a height of 3,7 cm and the thickness is 1,6 cm.
   - 4.2 The product should not weight more than 10 gr
     The UShift has a weight of 7,8 grams
   - 4.3 The needle guide should be usable for both right- and lefthanded persons
     The user test shows that users can use both the hands for the needle manipulation or the probe. The needle can be manipulated to the front or to the back, is doesn't matter for the working principle.

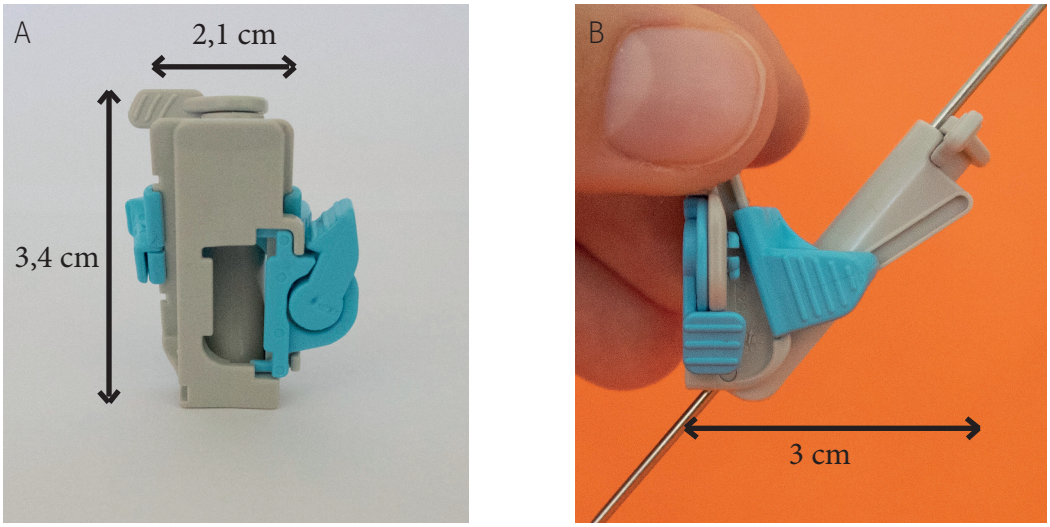
Wishes

1. As less as possible handlings to detach the needle from the needle guide
   Only one movement should be made to detach the needle.
2. As less as possible parts (assemblage)
   The final concept consists of 1 part.
3. At least two or more angle orientations possibilities
   The final concept contains three angles positions.
4. The loosening of the needle should be as fast as possible
   The loosening of the needle is 0,9 sec faster than the Verza, which is 22,5% faster. The average detach time is 3,1 sec.
5. The design should be as compact as possible
   This is a point of improvement, since the preference came to light with the user test.
6. Multiple needle diameters should fit the guide
   Multiple needle guides can be delivered/ordered for different ranges of needle diameters.
7. The device is disposable
   The UShift will be delivered as a sterilized package, directly available for use and is disposable.
8. As less as possible moving parts in the guide
   The final concept consists of one part with no moving parts.
9. The production should be as cheap as possible
   The prototype is made with 3D-printing, which is profitable for prototyping. The final concept will be casted.
10. Only one hand needed for manipulation
    The needle can be detached with one movement with the probe, to keep the needle in place. The hands are still placed on the probe and the needle. In fact, no hands are needed to detach, since the hands are not moved from their initial placement.
11. The insertion angle should correspond with the predetermined angle on the US
    When the UShift goes in production, the software can either be adjusted to the needle orientations, or the UShift can be slightly adjusted to for example the angles of the Verza guide.

APPENDIX K.1: DIMENSIONS OF THE USHIFT AND VERZA.



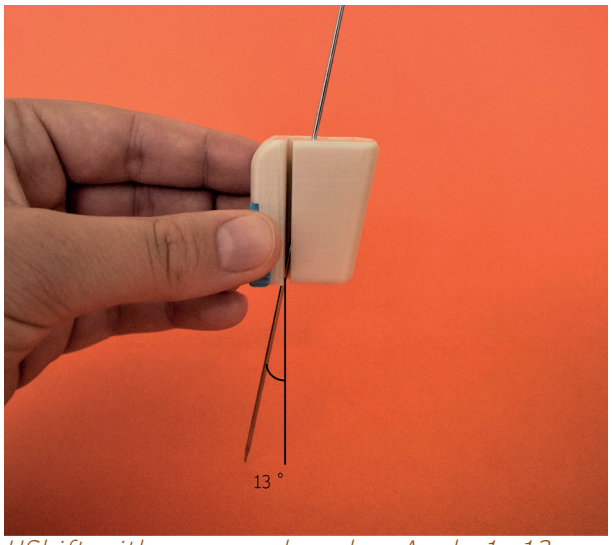
Dimensions UShift. A; top view, B; side view, C; front view.



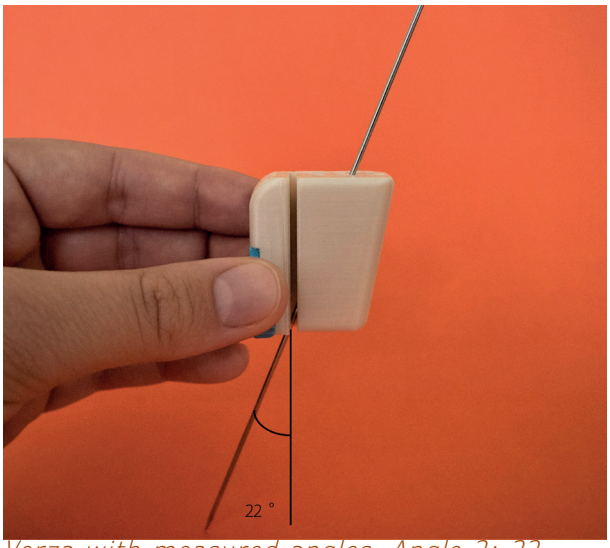
Dimensions Verza. A; back view, B; side view.

APPENDIX L: ANGLE ORIENTATIONS OF THE USHIFT AND VERZA

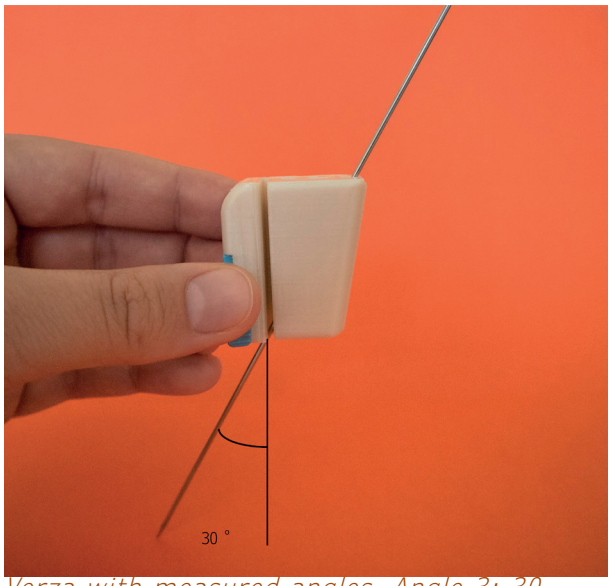
APPENDIX L.1: ANGLE ORIENTATIONS OF THE USHIFT



UShift with measured angles. Angle 1; 13 degrees.

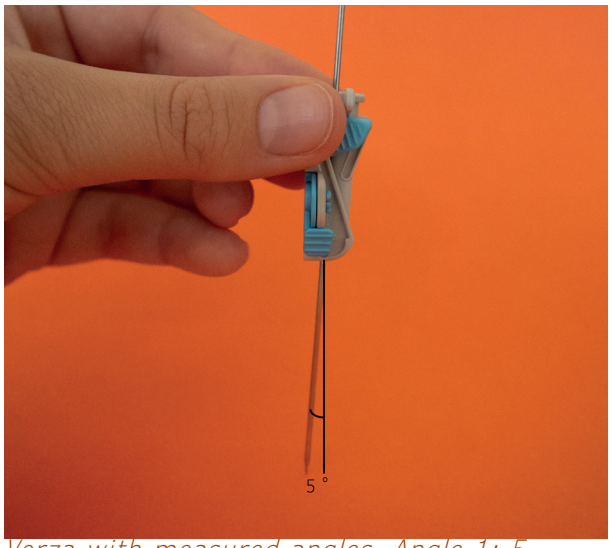


Verza with measured angles. Angle 2; 22 degrees.

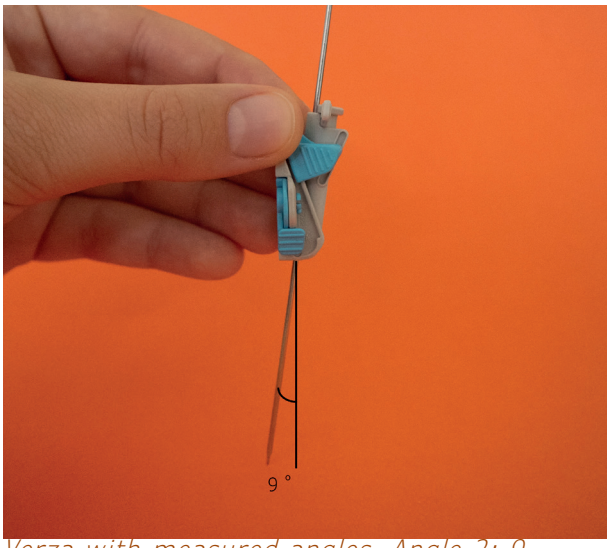


Verza with measured angles. Angle 3; 30 degrees.

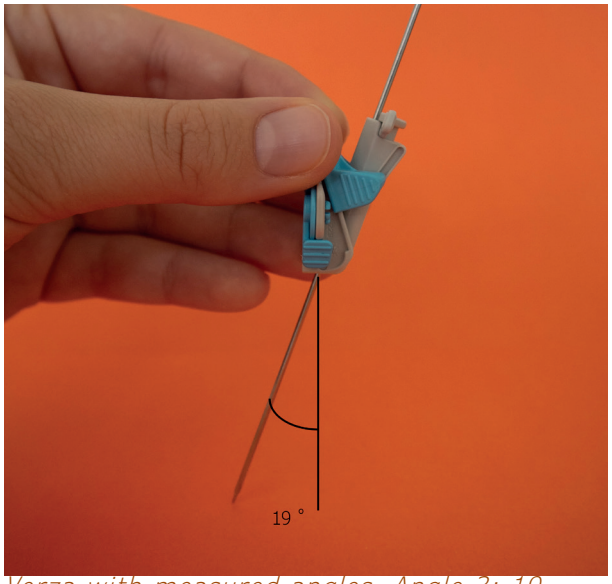
APPENDIX L.2: ANGLE ORIENTATIONS OF THE VERZA



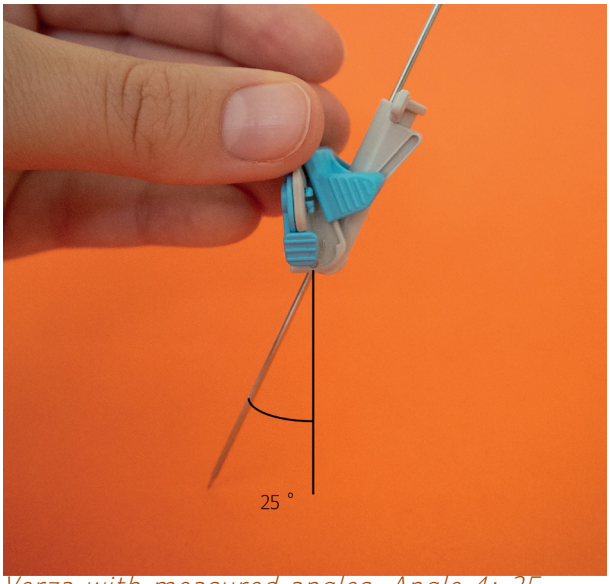
Verza with measured angles. Angle 1; 5 degrees.



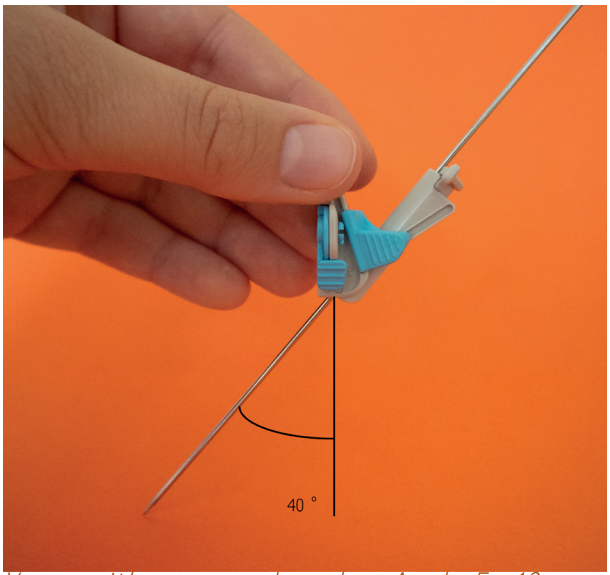
Verza with measured angles. Angle 2; 9 degrees.



Verza with measured angles. Angle 3; 19 degrees.



Verza with measured angles. Angle 4; 25 degrees.



Verza with measured angles. Angle 5; 40 degrees.