Development of a ‘smart surgical instrument’

Assessing the feasibility of ultrasound integration into an ultrasonic scalpel

TU Delft

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by

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This thesis is confidential and cannot be made public until June 26, 2024.

Preface

This report presents the graduation research project that I performed at Delft University of Technology, at the department of BioMechanical Engineering. I chose my master-track BioMechanical Design because I want to bring the worlds of technology and healthcare closer together. This graduation project contributes to close this gap further.

I learned a lot about the technology of surgical instruments and sensing techniques and especially enjoyed the last part of the research project. The technologies came together and I could prove that integration of them in a smart surgical instrument could be valuable in multiple applications. While I know that scientific research is not typically a thing that I want to continue my career in, I am stronger motivated to continue on the interface of technology and healthcare.
On personal level, I learned that keeping focus is the most important aspect to get projects like this started and keep them running. Although I had problems in finding the right direction in the beginning of the project, I retook control at the end of the process.

First of all, I would like to thank Benno Hendriks, my thesis professor and main supervisor, for his endless patience in supervising this research and for his feedback and help in finding the right direction during the project. Secondly, I would like to thank Jenny Dankelman for reading my reports and organizational support. Furthermore, I want to thank Martin Pekař from Philips Research. Without his help the development of a functional prototype would not have been possible. Finally, I want to thank Daniëlle, Cor, Hanneke, Coen, Lizet and my friends for their helpful advices, continuous motivations and personal support during this graduation project.

I hope that this research project will contribute to the future improvement of surgical procedures, by further development of smart surgical instruments.

Abstract

Energy-based surgical instruments are increasingly used in laparoscopic surgical procedures. For example, the ultrasonic scalpel enables tissue coagulation and -cutting by transferring a mechanical vibration to the tissue. [1]–[3] Additionally, real-time sensing is implemented to improve the surgical procedures. Intraoperative ultrasonography is one of those real-time sensing techniques that allows the surgeon to visualize the anatomical surroundings of the surgical site. [4] Previous literature research has shown that integration of ultrasonography into the ultrasonic scalpel would be a promising direction for the development of a ‘smart surgical instrument’. [5] This research focusses on the integration of intraoperative ultrasonography into the ultrasonic scalpel.

Based on detailed analyses of the currently existing technology, several integration directions are developed. The integration of an existing ultrasound probe into the ultrasonic scalpel is tested in a series of experiments. A functional prototype is designed and manufactured in which the Philips Eagle Eye Platinum ultrasound catheter is integrated into a LOTUS Torsion ultrasonic scalpel. The performance of the separate ultrasound catheter is assessed using tissue phantom with inserted silicone distortions. This is followed by experiments to test the performance of the integrated catheter. Based on the experiment results, an improved prototype design is proposed.

The first proposed prototype design facilitates integration of the ultrasound catheter and the integrated Eagle Eye Platinum catheter covers the areas of interest in its field of view. It is shown that the tissue phantom that is grasped by the ultrasonic scalpel prototype can be assessed. Distortions in the tissue can be detected. Also sideward imaging, relevant during tumour-free margin measurements, is possible using the developed prototype.

Several problems were encountered during the experiments. The underlying causes are analysed and multiple solutions are recommended, leading to the proposal of an improved prototype design. It can be concluded that the integration of ultrasound imaging into the ultrasonic scalpel is a feasible direction for the development of a ‘smart surgical instrument’.

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1. Introduction

1.1. Research introduction

Energy application to treat wounds has been used for centuries. Heating stones to close open wounds and stop bleeding was the first 'method' used in energy-based surgery. In 1920, William T. Bovie developed the first energy-based surgical instrument, based on electricity. This electrosurgical knife, named after Bovie, transfers electrical energy to the human body and thereby enables the surgeon to coagulate or cut the tissue. Surgeries could be performed with less blood-loss, shorter recovery times and less risk of infections. Since then, development has continued and several energy-based surgical techniques are now available.

Another development in the operating room is real-time sensing. By applying real-time measurements intraoperatively, information about the surgical process and the operation site can be presented to the surgeon. It enables the surgeon to see which structures are below the tissue surface and guide the instruments, prevent damaging critical structures during the surgery and see or prevent complications during the surgery in an early stage.

A smart surgical instrument can combine the benefits of energy-based surgeries with the advantages of intra-operative sensing. Energy-based surgery yields effective surgeries with lower recovery times and low risks of infections. Real-time sensing could prevent lateral thermal damage, which is a common concern of energy-based surgery due to high energy levels. Additionally, the sensing technique can be valuable in guiding the instrument to the desired position.

As we look further into the future, the development of smart surgical instruments will be valuable for the entrance of completely robotic surgery into the clinic. Until now, robotic surgery has been implemented as telemanipulation; a surgeon performs the surgical procedure by manipulating the instruments through a console. A real robot should be able to make decisions independently and this requires sensing. A smart surgical instrument is potentially the first step towards automatic feedback, enabling the development of real robotic surgery.

The literature study that was conducted prior to this research project, presented an overview of the currently available surgical technique. [5] The study showed that the ultrasonic scalpel is a promising energy-based surgical instrument.
The literature study also included an overview of real-time intraoperative sensing techniques that could be integrated in the ultrasonic scalpel. Based on application field and working principle of the ultrasonic scalpel, ultrasonography has been selected as focus point for the development of a smart surgical instrument.

Following the conclusion of the literature study, this graduation project focusses on the integration of ultrasonography into the ultrasonic scalpel. Based on existing knowledge, an integration concept will be developed. Experiments will be performed to find out whether this integration concept is a feasible direction for the development of a smart surgical instrument.

1.2. Research questions

To guide the research process, several research questions have been formulated. The main research question is as follows:

How can ultrasonography be integrated into the ultrasonic scalpel to develop a 'smart surgical instrument'?

To answer this main research question, a set of sub-questions has been formulated. These questions define smaller areas of interest that will be combined to answer the main research question.

1. What are the detailed working principles of the ultrasonic scalpel and intraoperative ultrasonography?

2. Which solution direction is the most feasible for the development of a smart ultrasonic scalpel?
    a. Which solution directions are available?
    b. Which factors determine the feasibility of a concept?

3. Is the selected concept a feasible direction for the development of a smart ultrasonic scalpel?
    a. Which functionality of ultrasound sensing integration will be most useful for a surgeon?
    b. Which types of feedback would be the most useful during the surgical procedure?

1.3. Research framework & thesis outline

The development of a surgical instrument is a complicated process. Multiple phases are therefore combined in one research framework, which is also the basis for the outline of this thesis. This provides clear and separated sub-goals, which finally lead to a set of experiments. Using these experiments, the main research question will be answered. The findings can be used as a basis for further development of a smart ultrasonic scalpel, based on the integration of ultrasonography into the ultrasonic scalpel. An overview of the research framework is shown in Figure 1.

This thesis consists of multiple chapters that describe the process of the development of a smart ultrasonic scalpel.
Chapters 1 and 2 respectively give an introduction to this research project and an overview of the research framework and -methods.
In Chapter 3 the current technological backgrounds of the ultrasonic scalpel and ultrasonography are analysed.
The knowledge is used in the development of several integration directions, described in Chapter 4. This research focusses on one of these integration directions. In Chapters 5 to 9, the feasibility of this integration direction for further research and development of a smart instrument is assessed.
Chapter 10 contains an overall discussion of the research project and recommendations for further research. This report ends with an overall conclusion in Chapter 11.

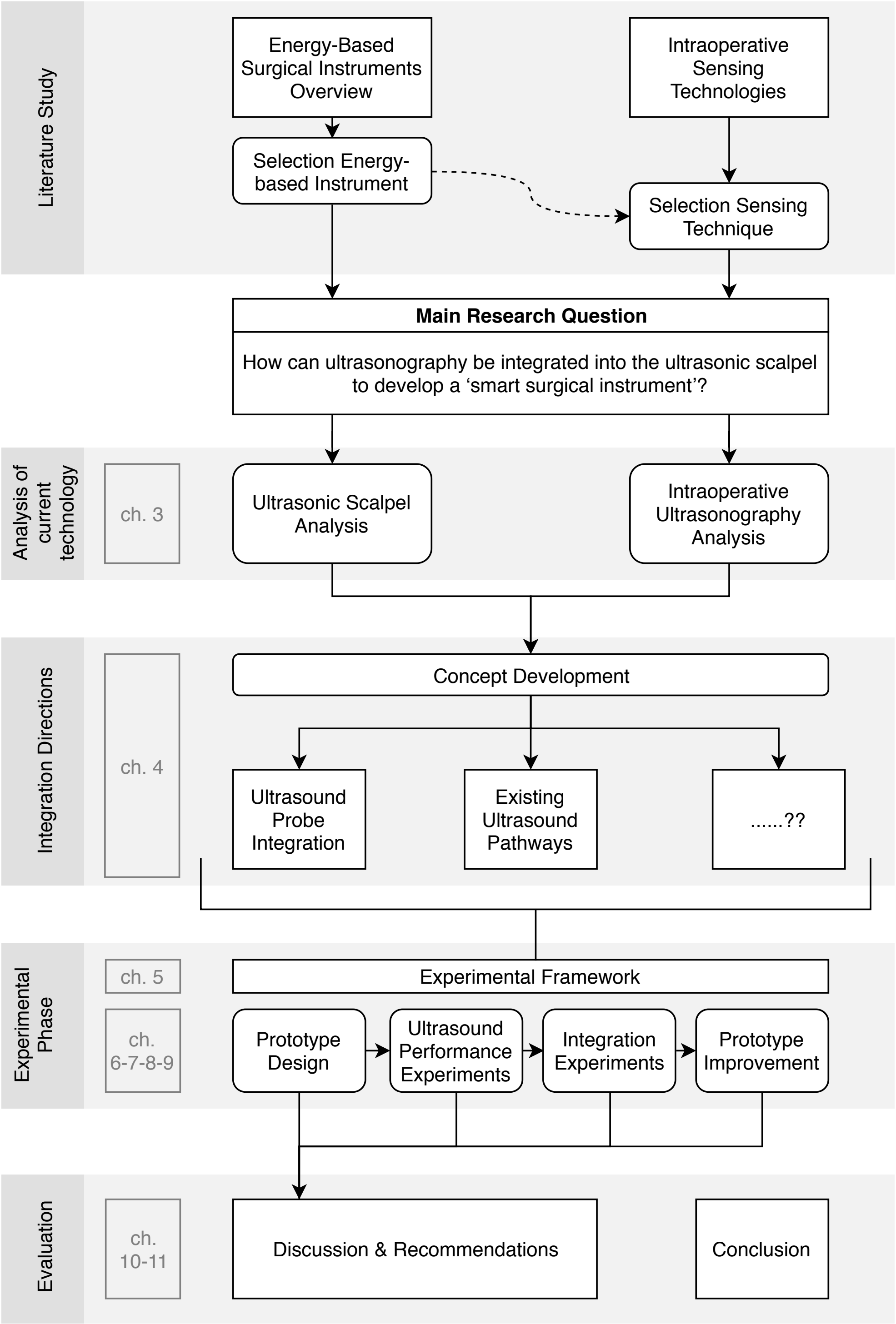


Figure 1: Overview of the research framework and thesis outline.

2. Research methods

In this chapter a description is given of the methods that are used to answer the research questions, stated in Section 1.2.

As was described in Section 1.3, a research framework will be the guideline for this research project. In the following sections, the methods of the different research phases will be explained in more detail.

2.1. Analysis of current technology

This research started with an analysis of the existing technology in the field of ultrasonic scalpels and ultrasonic sensing. The previously described literature study was used as a basis, but more extensive knowledge was required to adequately find out whether the development of a smart instrument would be feasible. Therefore, more in-depth research was conducted for both the ultrasonic scalpel and intraoperative ultrasonography.

A technical inspection of the scalpel has been performed. The scalpel was opened to find out which elements are present. The working principle of the scalpel was clarified. Furthermore, the exact dimensions could be measured and used as guidelines for design processes.

Also for intraoperative ultrasonography, the previous literature study is the basis of the analysis. The working principle of ultrasonography and the effect of frequency are described in more detail, based on additional literature research.

Furthermore, catalogues of ultrasound probes are consulted to get insight in the available techniques. A wide range of probes is available, so a selection based on size was made to make first selection on useful probes.

2.2. Integration directions

The next step in the research framework is the development of integration concepts that will result in a smart ultrasonic scalpel.

First, some boundaries are described to scope the concept development process and come up with useful applicable results.

Based on the elaborated descriptions of the ultrasonic scalpel and ultrasonography several integration directions came up that can be used to develop a smart ultrasonic scalpel. The integration directions are described and the special features are mentioned shortly.

The described integration directions are shortly evaluated to be able to provide the strengths and weaknesses of the integration directions. This information will be used in the feasibility study that will evaluate the integration directions more thoroughly.

2.3. Experimental phase

The final section of this thesis consists of a series of experiments in which the proposed integration directions are evaluated. The goal of this section is to provide a first series of tests to find out if one specific integration direction is feasible for the development of a smart ultrasonic scalpel. The methods used during the experiments will be described later.

Based on the experiments that will be performed, a design proposal for an improved prototype will be presented. Solving the problems that were encountered during the experiments will be the main goal of this design adjustment.

Phase 1

Concept development

3. Analysis of current technology

In the previous literature study, the ultrasonic scalpel has been shown to be a promising instrument for the development of a smart surgical instrument. Furthermore, ultrasonography and photoacoustic imaging were selected as promising sensing techniques for the development of a smart energy-based surgical instrument.
Based on the following aspects, ultrasonography has been selected as the focus sensing technique during this research project.

- Ultrasound imaging and the ultrasonic scalpel are based on the same basic working principle, synergy advantages could be reached.
- Ultrasonography is, compared to photoacoustic imaging, a flexible technique that can be easily adjusted to desired ranges and resolutions.
- Ultrasonography is an easy to use and cost-effective technique that is already commonly used in clinical practice.

As described in Section 2.1 the current technology is analysed in the fields of ultrasonic surgery and intraoperative ultrasonography.

3.1. Ultrasonic scalpel

Energy-based surgical instruments have been used for decades. They have the ability to coagulate the tissue and thereby prevent blood-loss during surgical procedures. The energy-based surgical instruments facilitate complicated surgical procedures, due the reduction of extensive blood-loss.

The use of ultrasonically activated scalpels was introduced in the early 1990s for coaptive coagulation and cutting of blood vessels and tissues. [1] In this period, monopolar electrosurgery used to be the standard method during surgical procedures. However, due to the risks associated with electrosurgery surgeons looked for alternatives. [6] One of those alternatives was found in the field of ultrasonic surgery: the use of surgical instruments transferring mechanical energy to the tissue in the form of a vibration. The main advantage that was found in ultrasonic surgery is that the desired effects like coagulating and cutting could be achieved at lower temperatures. This decreased the unwanted effects like thermal damage and tissue charring. [2]

Research on manufacturers websites and some market reports has led to the following list of well-known ultrasonic scalpel manufacturers:

- Ethicon Endosurgery
- Lotus Ultrasonic Scalpel
- Axon medical instruments
- Olympus medical systems
- Medtronic Covidien

The turnover that is achieved within a market, provides insight in the size and amount of use of a certain instrument. According to a market analysis, the global sales market for the ultrasonic scalpel is expected to grow to $4.6 bn in 2025, while its net worth was $2.3 bn in 2016. [7] Since $10-15 bn is mentioned in several market analyses as the global surgical instrument market size, it can be seen that the ultrasonic scalpel is a relatively well-received instrument in healthcare.

3.1.1. Tissue effects

The ultrasonic scalpel is capable of coagulating tissue, cutting tissue and sealing of blood vessels.

When the ultrasonic scalpel is used to coagulate tissue, the mechanical energy in the vibration is transferred to the tissue. The energy addition breaks the hydrogen bonds and destroys the extracellular matrix proteins. The proteins denature and form a gel, a sticky coagulum that is able to seal vessels or bleeding tissue. [1], [3] The threshold temperature for coagulation is at 63 °C, since that is the temperature the proteins start to denature. The hydrogen bonds are disrupted, leading to the uncoiling of the tertiary structure of the proteins. Usually, denaturation is complete at 80-100 °C. When the proteins cool down, the sticky coagulum is formed and seals the cut vessels. [2]

Research shows that the temperature rise of the tissue as a result of stress and friction of the ultrasonic scalpel is limited to 80 °C. Desiccation and tissue charring can thus be limited. Furthermore, the zone of thermal damage is limited, due to the low temperature. [2], [8]

When it comes to cutting, the ultrasonic scalpel shows two mechanisms: Cavitation & Power cutting. The cavitational effect is caused by the continuous pressure changes on both sides of the blade. This leads to intracellular water vaporizing at low temperatures, thereby rupturing the cells and facilitate precise cutting. Furthermore, the vaporizing water, due to cavitation, in between the tissue-planes, separates those planes and creates clear visibility of the cutting surface. The second effect is power cutting. The sharp blade vibrates at a 36 or 55.5 kHz frequency and thereby stretches cells beyond their elastic limit. This leads to breaking molecule bands, enabling separation of the tissue. This principle is mostly effective in protein-dense tissues like muscle. [2]

3.1.2. Instrument design

The regular set-up of an ultrasonically activated scalpel consists of a generator, a handpiece and a shaft with blade(s). The generator provides a current to the handpiece. The handpiece contains a stack of piezoelectric ceramics that provide a vibration under influence of the current. The vibration can be longitudinal or torsional. Different instrument manufacturers use a different set-up. A coupled amplifier amplifies the vibration and through a shaft, the vibration is transferred to the blade at the end of the instrument. Finally, the entire system vibrates harmonically at the desired frequency. Frequencies of 36 or 55.5 kHz are commonly used. [2], [9] The blade moves with an amplitude of approximately 80 µm. Maximum longitudinal displacement of the blade is 50 – 100 µm, which depends on the type of blade and the power level. [10]

Instruments for specific use in open surgeries are sold as well as designs for laparoscopic surgeries. Furthermore, the instruments are designed in pencil-shape as well as in shears-shape with the ultrasonic moving blade integrated in the shears tip. The blade can also have a specific shape or functionality based on its surgical application. [2] See Figure 2, Figure 3 and Figure 4 for examples of the different instruments.

Manufacturers often develop a series of scalpels using the ultrasonic coagulating and cutting technique. Different shaft lengths are desired for laparoscopic procedures, but also a version for open surgery is regularly offered.

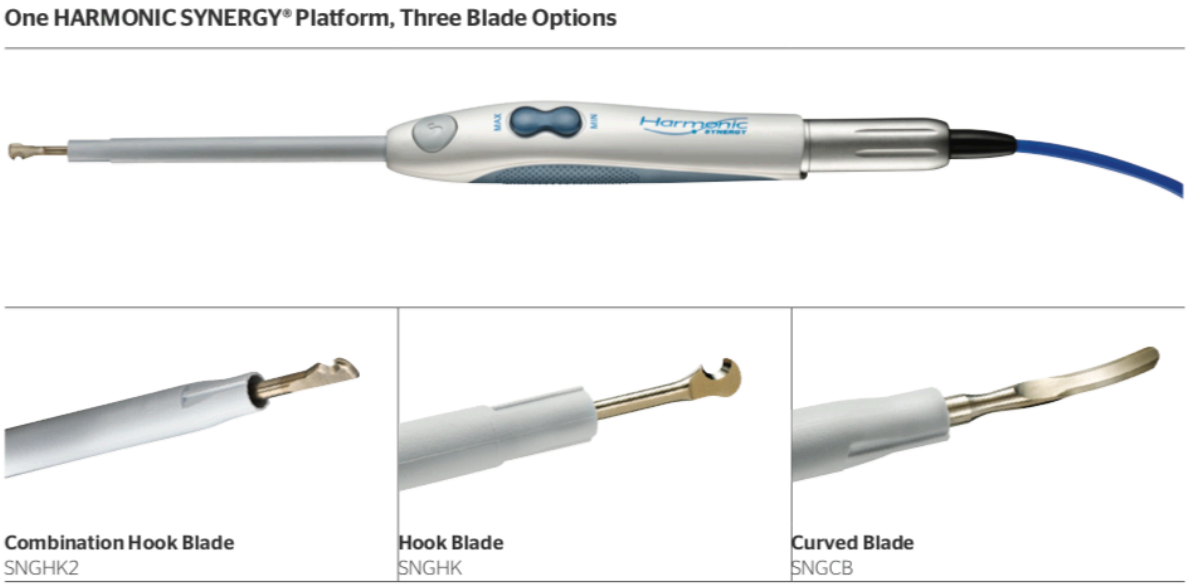


Figure 2: Harmonic Synergy ® with three different blade options, as an example of a pencil-like ultrasonic surgical instrument. Source: [11]

Figure 3: HARMONIC FOCUS™+ Shears, as an example of a shears-like ultrasonic surgical instrument, used in open surgeries. Source: [12]

Figure 4: Harmonic Ace®+7 shears, with advanced haemostasis, as an example of a shears-like ultrasonic surgical instrument. Source: [13]

The different parts of the ultrasonic scalpel will be described in more detail in the following sections. The generator, the active element, the waveguide, the blade and the other functionalities will be described in detail, to provide a good understanding of the technical aspects of the ultrasonic scalpel. Different instruments have been physically analysed to provide a thorough understanding of all components.

Generator

The generator of the system transforms the main power into the desired frequency and voltage output. Since the design is based on a natural frequency, the frequency of the input electricity is important. The power output can be chosen by the surgeon. A button is therefore provided on the handpiece, that transfers the signal to the generator. This trigger changes the power output to the handpiece and consequently the power transfer from the ultrasonic scalpel to the tissue. This will influence the cutting/coagulation speed.

Handpiece

The handpiece consists of the hand grip with activation buttons, a placeholder for the active element. Instruments designed for use in open surgeries can have a shears-like form or just have a blade attachment location.

Instruments designed for laparoscopic surgeries have a hollow tube attached to the handpiece that is used to activate the moving jaw.

Figure 5: Handpiece of the LOTUS Torsion ultrasonic scalpel, used for laparoscopic surgery.

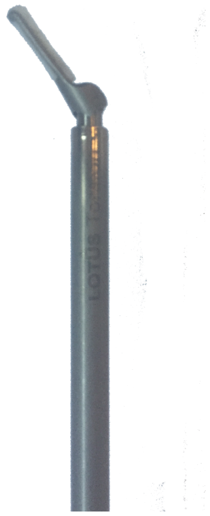


Figure 6: Moving jaw of the LOTUS Torsion ultrasonic scalpel.

Active element

The active element is the key part of the ultrasonic scalpel. The electrical energy coming from the generator is transferred into mechanical energy. A set of piezo-electric elements is located in the active element. Piezo-electric elements have the property that they expand when they are subjected to an electrical field. The piezo-electric materials are stacked in between metal elements. The piezo-electric stack needs to be activated on its resonance frequency, which is designed to be exactly the desired working frequency of the complete system.

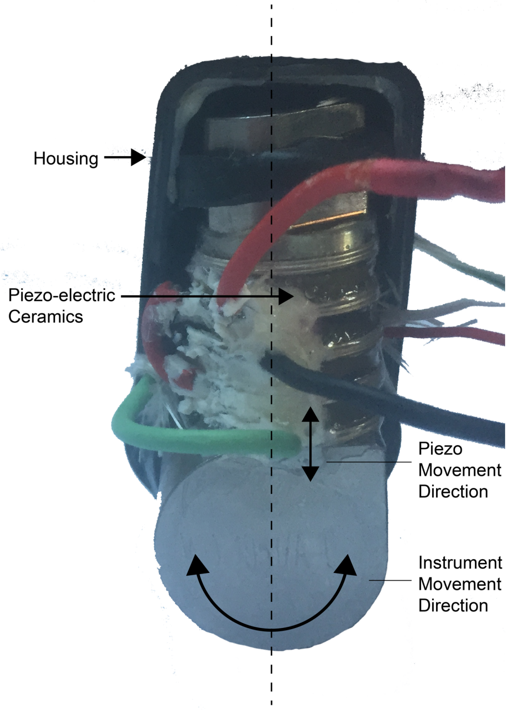


Figure 7: Active Element of the LOTUS Torsion ultrasonic scalpel. The blade moves in torsional direction, due to the a centrical alignment of the piezo-stack.

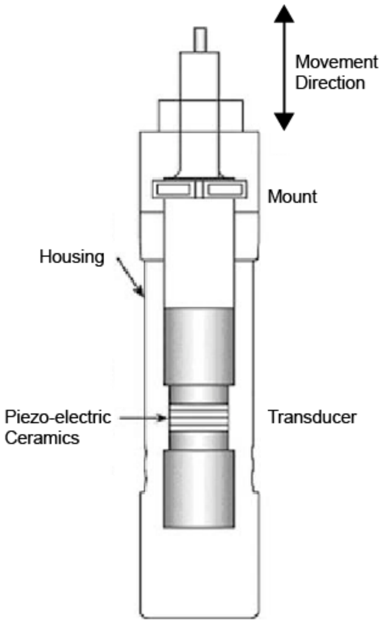


Figure 8: Active Element of the Harmonic Scalpel. The blade moves in longitudinal direction. Source: Adapted from [14].

Vibration amplifier

The vibration amplifier, also called horn, is a metal curved element in between the active element that generates the vibration and the blade or waveguide (depending on the type of instrument). The horn functions as an amplifier for the blade displacement. The cross-sectional area of the waveguide is decreased. The mechanical energy is thus transferred to a lower number of particles, leading to higher displacement velocities. This results in larger displacements at the distal end of the horn. [15]

Since the tissue effects are strongly related to the movement speed of the blade, the displacement is a relevant factor. [16]

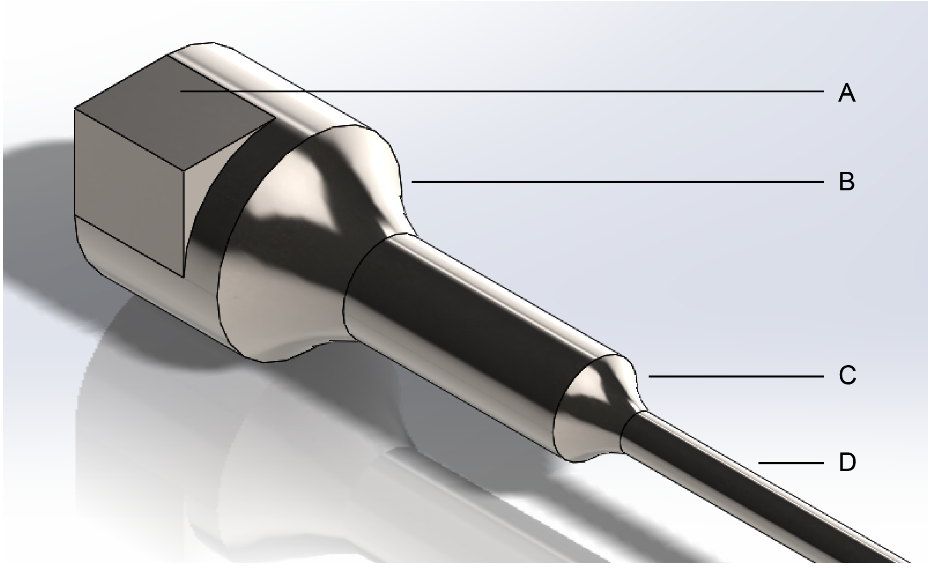


Figure 9: Image of waveguide 3D-model. A) Actuation surface. B) Horn 1. C) Horn 2. D) Waveguide.

Waveguide (laparoscopic instruments)

In laparoscopic instruments, the waveguide transfers the movement which is generated in the active element, to the blade. Depending on the type of instrument, the waveguide is fixed to the active element or to the handpiece.

The waveguide is a highly frequency-dependent part of the instrument. Since the instrument is designed to work at its resonance frequency, the waveguide needs to vibrate exactly in this frequency. This puts specific requirements on the length and diameter of the waveguide. The dimensions of the waveguide influence the wave node and antinode locations. The attachment points and the displacement of the tip need to be properly designed based on these locations.

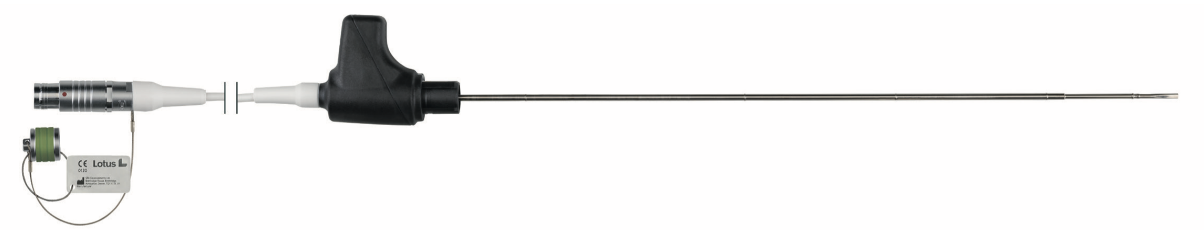


Figure 10: Active element of the LOTUS Torsional Ultrasonic Scalpel, with permanently attached waveguide and blade. Source: [17].

Blade

The blade is the final transfer of mechanical energy to the tissue. Different shapes are developed. Sharper blades have better cutting abilities, while wider blades do induce better haemostasis. This last ability is useful in for example liver surgery.

The instruments designed for open surgeries have even more variations in the blade designs. For example long thin blades, hooks and saw teeth are available to plug into the pencil like instruments.

Disposability vs. reusability

The ultrasonic scalpels regularly have reusable items that are cleaned (sterilization) after every surgery and some disposable parts that are only used a single time. In ultrasonic scalpels from all known manufacturers, the active element is the most expensive and sophisticated part of the instrument and is therefore reusable. The handpiece is disposable in all scalpels and delivered in a sterile package that can be opened in the operating room and connected to the active element and other reusable parts.

The LOTUS (Laparoscopic Operation by Torsional Ultrasound) Ultrasonic Scalpel is the only studied scalpel that has the waveguide and blade permanently attached to the active element. The active element and waveguide-blade assembly are suitable for sterilization and can be reused.

Other aspects

The ultrasonic scalpel has known multiple developments over the years, initiated by different manufacturers. The changes and the specific features of the scalpels can influence the sensing possibilities or requirements and are therefore described below.

- Medtronic developed their Covidien Sonicision™ ultrasonic scalpels being cordless. A rechargeable battery pack is included to drive the active element without a connection to a separate generator. [18]
- LOTUS designed an ultrasonic scalpel that vibrates differently from the other available scalpels. While most scalpels vibrate longitudinally, the LOTUS scalpels vibrate torsional. The energy dissipation is in this way more directed into the grasped tissue instead of in the tissue in front of the instrument. This leads to better surgical effects at lower power levels. [17], [19]
- Olympus Medical Systems has developed a combination-instrument: THUNDERBEAT. This instrument uses both ultrasonic vibrations and bipolar electrical energy to perform the surgical process. [20]

3.1.3. Application fields & procedures

From the broad search concerning the ultrasonic scalpel, several studies were specified on a certain application area. Additionally, several market analyses specified areas where the ultrasonic scalpel is used. [7]

It can be said that the ultrasonic scalpel is a widely used instrument in both open and laparoscopic surgical procedures. Areas of use are:

- Head- and neck surgery
- Ear-nose-throat (ENT)
- Liver/pancreas surgery
- Gastro-intestinal surgery
- Orthopaedic surgery
- Gynaecological surgery
- Urologic surgery
- Cardiac surgery
- General Surgery

Within the application fields, literature shows a lot of procedures that are performed using the ultrasonic scalpel technique.

Tissue dissection is the most common application for which the ultrasonic scalpel is selected, due to the optimal performance in combined coagulation and cutting. For example, tumour resection in different areas is a procedure in which the ultrasonic scalpel is commonly used. Cutting combined with coagulation results in less blood loss during such resections. The recovery time for the patient is thereby decreased.

Apart from tumour resections, other tissue resection procedures are performed using the ultrasonic scalpel. For example thyroidectomy, removal of the complete or a part of the thyroid in case of an enlarged gland, is a procedure in which the ultrasonic scalpel is used to resect non-tumour tissue. [21], [22]

During the above-mentioned procedures, the ultrasonic scalpel is used for the resection of tissue. The clearance of the target tissue from the surrounding tissues is also performed using the ultrasonic scalpel, to prevent blood loss and keep a clear view. Due to the recent introduction of the ultrasonic scalpel, not all surgeons use this instrument. For the surgeons using this instrument, it can be said that is a standard surgical tool during the complete procedure.

3.2. Intraoperative ultrasonography

Intraoperative Ultrasonography will be described in more detail in this chapter. The working principle, clinical use and the technical aspects of ultrasound imaging are explained.

3.2.1. Working principle

Sound at a frequency above the range that the human ear can register is called ultrasound. This starts from a frequency of approximately 20 kHz. Ultrasound Imaging is usually performed at a sound frequency of 1 – 20 MHz [23], [24]

Reflection of ultrasound waves in the tissue is the basis for ultrasound imaging. When two adjacent tissue layers have a different acoustic impedance, a part of the energy in the ultrasound pulse will be reflected at the interface and a part will be transmitted through the interface between the layers. See Figure 11 for a graphical representation of this process. The acoustic impedance is based on the material density and the velocity of the sound wave. This material property is a measure for the resistance of the material against the propagation of acoustic waves. When the difference between the acoustic impedance of the adjacent tissue layers is small, only a small part of the acoustic energy will be reflected. The rest will be transferred to the underlying tissue, meaning that the image can be extended. However, when a large difference in acoustic impedance occurs (e.g. at a bone-soft tissue interface), most of the energy will be reflected and the underlying structures disappear on the ultrasound image. This is called an acoustic shadow. [25]

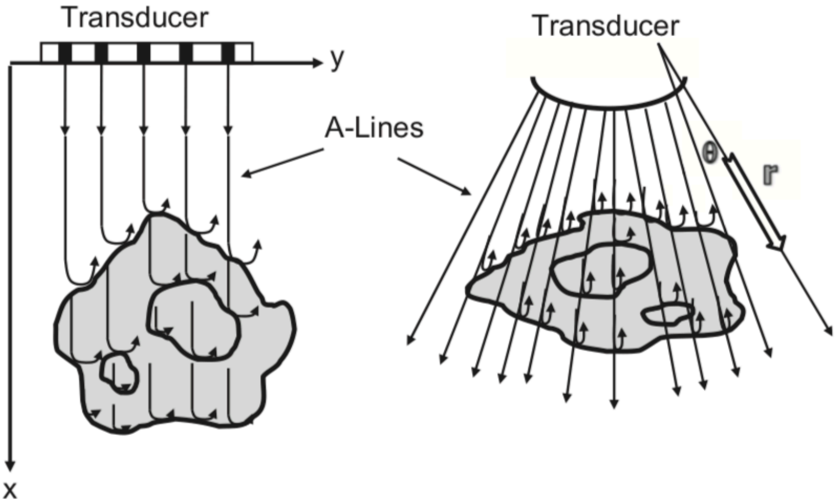


Figure 11: Ultrasound Imaging is based on the reflection of ultrasound pulses at interfaces between tissue layers with different acoustic impedances. Source: [26]

Ultrasound waves are transferred to the tissue in short pulses. The reflection of the pulses within the tissue is recorded at the transducer and an image can be generated. [27]
Based on the time of flight of the reflected acoustic pulse and the amplitude of the reflected waves, the imaging system can calculate the depth of the reflection surface. [23]

3.2.2. Resolution & penetration depth

As stated earlier, medical diagnostic ultrasound imaging is performed at frequencies from 1-20 MHz. The attenuation by the human soft tissues is roughly 0.5 dB/(MHz cm). The attenuation is proportional to the frequency: higher frequencies will have a faster decay of the signal because they are stronger attenuated by the tissue. This leads to a penetration depth of approximately 300-400 λ, meaning 20 cm for a 3 MHz transducer and 8 cm for a 7 MHz transducer. The higher the frequency, the shorter the wavelength will be and ultrasound imaging is thus performed at the highest frequency that can still reach the area of interest. [28] However, the frequency also influences the resolution that can be achieved in the ultrasound images. Mathematically, the axial resolution is half the pulse length. Since the pulse length consists of n times the wavelength, this wavelength determines the resolution: a shorter wavelength will lead to higher resolution. Since the wavelength and frequency are related following the equation

$$f = \frac{v}{\lambda}\,, \qquad (1)$$

where f is the frequency, v is the sound velocity through tissue and λ is the wavelength, the resolution increases when the frequency decreases. [29]

The lateral resolution, perpendicular to the ultrasound wave movement, depends on the width of the ultrasound beam. Close to the ultrasound transducer, the ultrasound waves interfere and fluctuations in the acoustic pressure occur. At a certain distance, the end of the near-field, a coherent ultrasonic wave-plane has been formed. The material particles do not transfer all their energy in the direction of the sound wave, but also in other directions, leading to divergence of the ultrasound beam. Since the lateral resolution depends on the width of the sound beam, the highest resolution is found at the end of the near field, where a coherent acoustic wave is present, without divergence of the ultrasound beam. [29]

3.2.3. Modes of ultrasound imaging

Different modes of operation are available within the ultrasound imaging technique.

A-mode ultrasound imaging is based on one element that transfers the ultrasound pulse to the tissue. The reflection of the pulse on the tissue reflectors is measured, filtered and presented as a line showing the amplitude of the reflection at a certain depth in the body. [26]

B-mode ultrasound imaging combines multiple “lines” of A-mode information (see Figure 11) and presents this in a brightness-scale in an image. B-mode is the most regular form of ultrasound. The amplitude of the reflection is shown as a greyscale brightness, with the strong reflectors very bright and the areas without reflection black. Since the tissue attenuates the sound waves, the deeper reflections have a lower amplitude. To compensate for this and get a readable image, a time-gain compensation is performed. A constant attenuation is assumed and the longer travelling reflections are multiplied with a specific factor to increase the amplitude. The spatial mapping is performed based on the travel time of the ultrasound pulse. It is assumed that the sound speed through the tissue is constant. [26], [27]

C-mode resembles a “regular” image. It gathers the reflection amplitudes at a certain depth, based on the travel time. By moving the transducer or the object, the reflection at this depth at multiple locations is gathered and a 2D orthogonal image can be created. [25]

M-mode shows the movement of a moving target, based on multiple subsequent A-mode scans. The reflection amplitudes are translated into grayscales and for every subsequent A-mode scan, the depth of the specific grey-scale is registered. In this way, the movement of the imaging target can be monitored over time. [26]

3.2.4. Ultrasound technology

The main part of an ultrasound system is the transducer. The transducer generates the ultrasound waves using specific elements, which will be described in more detail below. When the reflections arrive back at the transducer, the waves are transformed back into electrical energy and then processed by a computer. The active element in the transducer transfers the electrical energy into mechanical vibration. See Figure 12. [24]

To absorb the vibrations from the backside of the active element, a backing material is located there. The backing material absorbs the sound waves that are send backwards from the active element and decreases the ring-down time. After the current input, the vibration in the transducer element needs to damp out. If this takes longer, the pulse length of the transferred pulse will be longer and this leads to a lower axial resolution. [24]

An impedance matching layer is mounted in between the transducer elements and the tissue. Since the active element does not have an acoustic impedance in the same range as the tissue, a matching layer is added to increase the efficiency. If no matching layer would be applied, a lot of energy would be reflected and transferred into heat at the transducer-tissue interface. The thickness of this matching layer needs to be an odd multiple of $\lambda/4$ to have a maximum energy transfer from the active element to the tissue. The acoustic impedance of the matching layer should be the geometric mean of the acoustic impedances of the piezo-electric element and the tissue. The mathematical transfer function then provides perfect transmission of the ultrasonic waves. [24], [26], [30]

Piezo-electric vs capacitive transducers

Since the working principle of the ultrasound transducer relies on the active element, it is useful to get more in-depth knowledge on the working principle of this element.

Two basic principles are available to fabricate the transmitting and receiving active element of an ultrasound transducer: piezo-electric transducers or capacitive transducers.

The piezo-electric transducers contain an active element, based on a piezo-electric material. This material has the property to deform (shorten, elongate, shear) under the influence of electrical voltage over the two sides of the material. Applying a sinusoidal voltage to the piezo-electric material will lead to a vibration. The electrical energy is transferred into the mechanical energy in the vibration. Piezo-electric material also works vice-versa, when the ultrasound reflection is received back, the material will deform and thereby generate a voltage, see Figure 12. [24], [26]

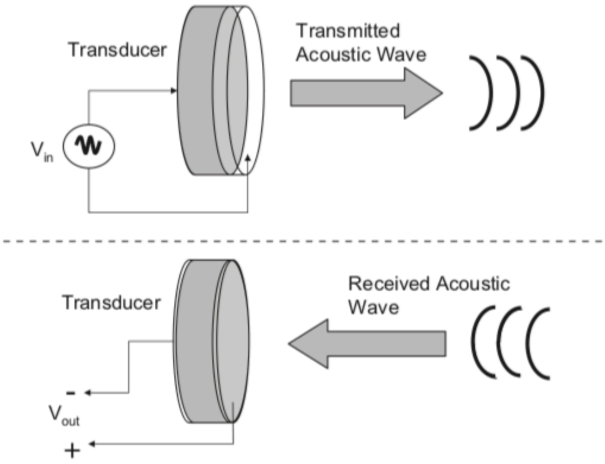


Figure 12: A piezo-electric material can operate as a transmitter (top) or as a receiver (bottom) Source: [26]

A recent development is the use of micromachined transducers. Especially the application of capacitive micromachined ultrasound transducers (CMUT) has emerged as an alternative for the use of piezoelectric material. A CMUT is basically a small capacitor with a fixed electrode at the bottom and a metalized membrane suspended above a cavity. When an AC voltage is applied, a vibration will occur and vice-versa, voltage will be generated when the capacitors change shape due to reflected sound waves. The CMUTs are fabricated using wafer-bonding technologies and micromachining techniques. [31], [32]

Two important advantages of CMUTs over piezoelectric elements are the efficiency and frequency range. Since the acoustic impedance of the CMUT matches the acoustic impedance of the soft tissue a lot better than piezo-electric materials, the efficiency of energy transfer is higher. Secondly, the frequency of CMUTs can be a lot higher (up to 60 MHz) than is possible with the use of piezo-electric materials (up to approximately 30 MHz). However, CMUT transducers also have some drawbacks. Due to acoustic cross-talk within the transducer, the sensitivity is lower than transducers with piezo-electric materials show. The cross-talk is caused by acoustic waves traveling through the membrane-water interface and by direct coupling of the separate elements. [31], [33]

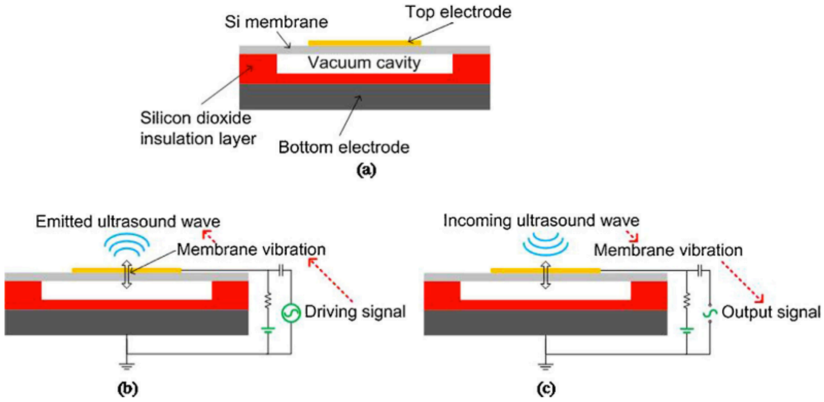


Figure 13: Schematic overview of the working principle of a Capacitive Micromachined Ultrasound Transducer (CMUT). Source: [34]

3.2.5. Clinical practice

Imaging

Intraoperative Ultrasonography is used in open surgeries (IOUS) and laparoscopic procedures (LUS). IOUS and LUS are used to create images at the point of operation and thereby define locations of lesions and prevent undesired damage.

Both in open and laparoscopic intraoperative ultrasound, the imaging can provide additional diagnostic information that was not available from the pre-operative scans. Furthermore, a procedure execution check can be performed by IOUS or LUS. [35]

Several authors have published articles in which they show the advantages and improved results, when intraoperative ultrasound imaging is used during surgery. The application areas contain among others brain & spine surgery and abdominal surgery. [35]–[37]

In for example pancreatic surgery, ultrasound imaging is being used for defining the stage and precise location of the lesions. Most of the times this can be done with high frequency transducers, packed in a sterile sheet with acoustic gel in it. When imaging through other organs, such as the liver or stomach is required, a lower frequency ultrasound transducer is required to increase the penetration depth. [38]

A relatively new application of ultrasound imaging is the intravascular ultrasound imaging. This concerns small ultrasound transducers that can be fed into blood vessels on a catheter guidewire to image the cross-sectional area of the blood vessels. New developments have shown methods to integrate ultrasound imaging in the already existing guidewire, to make this way of imaging even more easy to use during this type of interventions. [32] Since the penetration depth does not need to be large, high frequencies (25 - 40 MHz) are used in these catheter probes, to reach a high resolution. CMUT transducer development is a research area that could be advantageous for these catheter probes due to the small designs.

Temperature monitoring & tissue characterization

In the past decade ultrasonography have been used for temperature monitoring during radio frequent ablations. An increasing tissue temperature leads to a change in the speed of sound through the tissue and induces thermal expansion of the tissue. An echo time shift will occur which can be measured in the received ultrasound spectrum. [39] Experiments have shown the change of acoustic tissue parameters under influence of temperature changes, leading to temperature monitoring possibilities using ultrasound. [40], [41]

These acoustic properties can be the echo time shift, attenuation parameters, frequency shift, backscattering echo. Furthermore, image analysis of B-mode scans could provide temperature estimations. [42]

Using the temperature estimation could provide useful information about the progress of the coagulation plane, during the use of energy-based surgical instruments. Since proteins start to denature at a given temperature, the temperature spread can predict the coagulation progress through the tissue. [42], [43]

The mentioned acoustic parameters can, besides providing information on the tissue temperatures also help in identifying the tissue types or differentiate between healthy or diseased tissue. Both the B-mode scans as the raw ultrasound spectrum could provide such parameters. However, individual parameters do not normally correlate with diseased tissue or a specific tissue type. Multiple parameters should be combined in order to characterize a specific tissue type or distinguish healthy or diseased tissue. [44]

Existing ultrasound probes

A lot of ultrasound transducers have been developed over the years. The transducers differ in shape, size and proposed application area. To provide a clear overview, the available ultrasound transducers will be discussed in four categories:

- Regular
- Intraoperative
- Laparoscopic
- Special

The regular ultrasound transducers are used outside the body. The transducers provide a non-invasive manner of imaging that can be performed quickly. The transducers are used in a wide spectrum of applications and therefore a lot of different designs exist. The size of the imaged object determines the field of view and piezo-element configuration of the transducer. The frequency is chosen as such, that the resolution is as high as possible, while the ultrasound pulses still reach the imaged object. E.g. for cardiac imaging through the ribs, small transducers are used to avoid ultrasound blocking by the bones. The small array of piezo-elements is programmed as such that a sector area is covered. Thereby, a large area can be imaged through the relatively small entering area in between the ribs.

Intraoperative transducers are used directly on the imaged organ (see Figure 14, Top Left). Therefore, the penetration depth can be low and thus high frequencies can be used. By using a high frequency, a high resolution can be achieved.

Furthermore, the intraoperative transducers have special designs to reach difficult-access locations during the surgical procedure. They are smaller than the regular out-of-body ultrasound transducers. Some of the intraoperative ultrasound transducers have the possibility to rotate the imaging element, enabling imaging outside the line of sight of the surgeon.

The probes in the third category, the laparoscopic ultrasound transducers, are specifically designed for use in laparoscopic surgical procedures (see Figure 14, Top Right). The transducers therefore have to fulfil specific requirements. Dimensions are the most relevant criteria in this case, since the ultrasound transducer needs to enter the body through a trocar, with a maximum diameter of 12 mm in regular laparoscopic surgeries. The ultrasound instrument consists a long shaft and is sometimes equipped with a steerable tip on which the actual transducer is located. In this way, the ultrasound transducer can easily reach the desired imaging location, despite the fixed entering point and long rigid shaft. The laparoscopic probes mostly provide a sideward view.

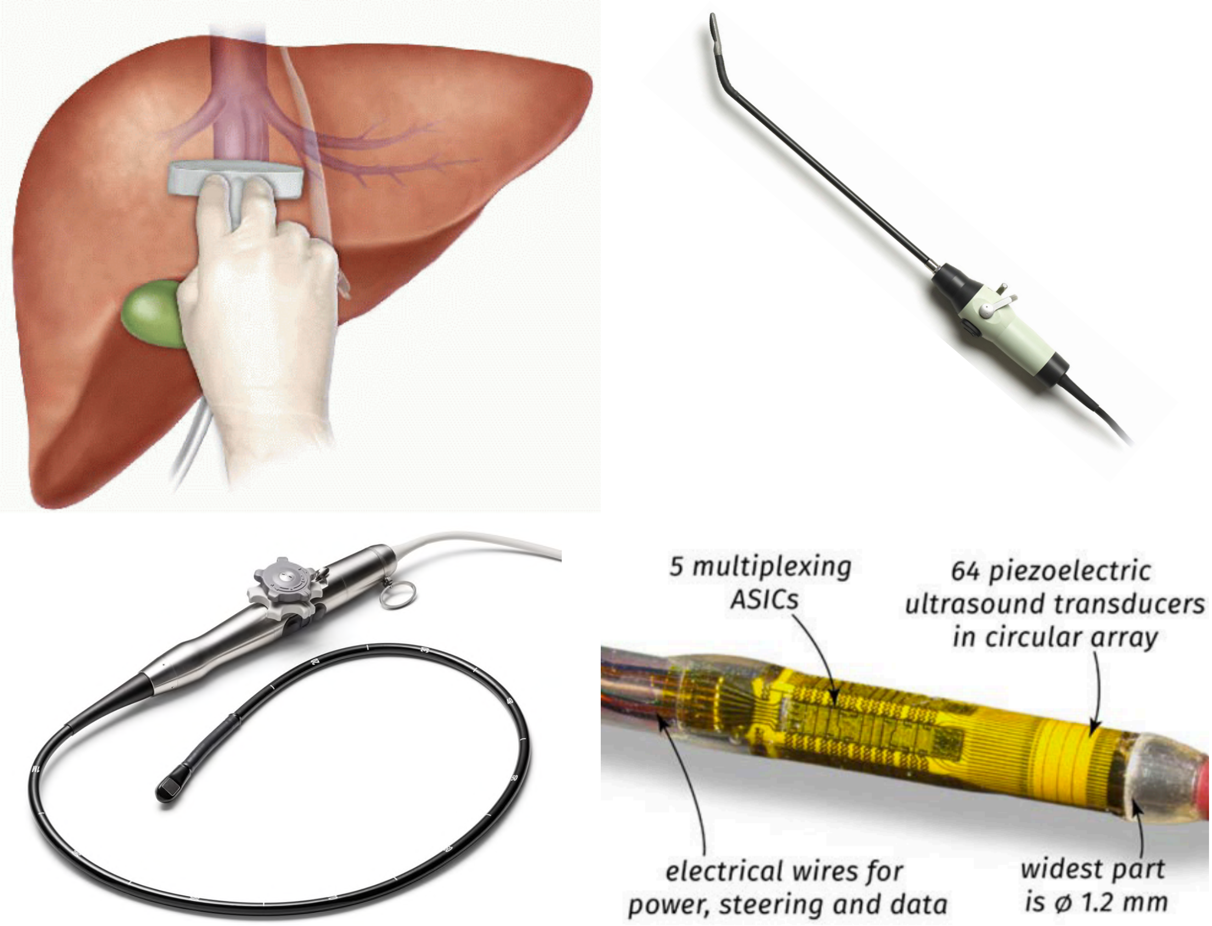


Figure 14: Four examples of different ultrasound transducers. Top Left: intraoperative ultrasound transducer. Source: [45]. *Top Right: laparoscopic ultrasound probe from BK Medical. Source:* [46]. *Bottom Left: transesophageal ultrasound probe from Philips. Source:* [47]. *Bottom Right: intravascular ultrasound catheter from Philips. Source:* [32].

Besides the three aforementioned categories, some special transducers are used in clinical practice. Firstly, special transducers can be used inside the body, through natural orifices. E.g. echocardiography can be performed with a transesophageal transducer (see Figure 14, Bottom Left) Through the esophagus, the heart can be approached from the backside which enables imaging of the heart through only thin tissue layers. The transesophageal probes have a sideward looking ultrasound array. Also transvaginal and transrectal ultrasound transducers are available and are used for imaging of e.g. the uterus or prostate. Bringing the transducer as close to the area of interest as possible facilitates the use of high frequency transducers, since the required penetration depth is low. This results in a high-resolution ultrasound image.

Secondly, the intravascular ultrasound techniques require special ultrasound transducers (see Figure 14, Bottom Right). The intravascular ultrasound transducers are very small, approximately 1 mm in diameter, and are fed through blood vessels. The transducer consists of a circular array of piezo-elements (e.g. or a rotating single piezo-element. This enables the probe to present the vessel walls in a cross-sectional image showing whether narrowing or irregularities in the blood vessel are present. The IVUS probes are operated at high frequencies (20-30 MHz) to provide a high image resolution.

4. Integration directions

The analyses of existing technology in the fields of the ultrasonic scalpel and intraoperative ultrasonography have been used as input for the synthesis process. In this process integration directions for the development of a smart ultrasonic scalpel have been formulated.

Synthesis scope

According to the previously performed literature study, the ultrasonic scalpel is an energy-based instrument that is likely to be used in the future due to several advantages. Ultrasonography has been shown to be a flexible, non-expensive technique that could add sensing to the ultrasonic scalpel.

Since the ultrasonic scalpel is a widely used surgical instrument, with a lot of applications, specific use areas have been chosen to focus the synthesis process. Laparoscopic use of the ultrasonic scalpel has more difficulties than use of the instrument in open surgeries, due to the lack of direct and clear view on the tissue. The synthesis of integration direction was therefore focussed on the use during laparoscopic surgical procedures.

Besides the added value in combining the two functionalities of surgical effect and sensing into one instrument, a more practical advantage for laparoscopic surgery is the reduction of the amount of body-entrances through trocars. Currently, two trocars are needed for real-time sensing: one for the surgical instrument and one for the sensing instrument. Combining these two into one instrument, makes these surgical procedures even more less invasive.

The applications of the ultrasonic scalpel and the possibilities that ultrasonography offers have led to the formulation of a goal that the 'smart instrument' should achieve. The integration of ultrasound sensing into the ultrasonic scalpel, should provide information on the surgical process (progress of cutting, coagulation progress, etc.) and/or on the environment of the surgical site (imaging).

The above described scope led to the following boundary list.

<u>From literature:</u>

- Ultrasonic scalpel working principle
  The ultrasonic scalpel will be used as the basis for the smart surgical instrument.
- Ultrasonography integration
  The smart instrument will be developed by integrating ultrasonography as sensing technique.

<u>Other boundaries:</u>

- Instrument Goal: process & environment monitoring
  The smart instrument should at least provide information on the surgical process and additionally on the environment of the surgical site.
- Laparoscopic use
  In this concept development phase, the focus is on the scalpels designed for laparoscopic use. The smart instrument has the most added value in these procedures compared to the open procedures, due to the limited view. Furthermore, trends show that open procedures are more and more transferred to laparoscopic surgical procedures.

4.1. Ultrasound probe integration

4.1.1. Concept explanation

The *Ultrasound probe integration* concept uses existing ultrasound transducers for the development of a smart surgical instrument. By integrating an ultrasound probe, the already existing sophisticated technology of ultrasound imaging can be used to gather information on the surgical process by imaging or determine tissue properties from the raw ultrasound data. Furthermore, the integrated transducer could provide information about the surrounding tissues and thereby help the surgeon.

The most basic form of feedback that the integrated ultrasound transducer could provide is a B-mode image. Based on this information the surgeon could prevent damage to critical structures or make sure that all relevant parts are dissected.

However, based on ultrasound data, also more detailed information could be made available. Since all tissues have a different composition, the propagation and reflection of the ultrasound pulses is different. From the raw data, the tissues might be characterized, when an appropriate algorithm is used. The same holds for tissue temperature, since the temperature influences the speed of sound through the tissue and thereby the measured data at the transducer.

Combining tissue characterization and temperature estimation facilitates monitoring of the coagulation front. This could prevent lateral thermal damage.

A more extended way of integration is a direct link of the raw ultrasound data, through a specifically designed algorithm, to the ultrasonic scalpel. In this way, the scalpel would be able to react automatically based on the ultrasound data.

4.1.2. Probe selection

A large variety of transducers is available for all kinds of different applications, as was already presented in Section 3.2.5. The probe needs to fulfil a certain set of requirements, based on the concept boundaries that are explained in the previous section. The probe requirements are:

- Probe capabilities
  The probe needs to enable the surgeon to gather information on the surgical process and/or the surrounding tissues. To provide information about the surgical process, the ultrasound transducer should be directed to the grasped tissue.

- Dimensions
  The dimensions are restricted to laparoscopic use. During laparoscopic surgeries, the ultrasonic scalpel is fed through the abdominal wall through a trocar. The trocars have inside diameters ranging from 5 to 12 mm.

From the available ultrasound probes, as presented in Section 3.2.5, only some probes fulfil the above described requirements. The category containing the “regular ultrasound transducers” does not fit in the dimensional requirement, related to the laparoscopic application and is therefore not investigated.

The intraoperative ultrasound transducers could be used for integration purposes. These transducers are specifically designed to image from the organ-surface. They have smaller transducer arrays that work on high frequency to reach high detail-levels in the images. Despite their smaller dimensions than regular ultrasound transducers, they still do not meet the requirements for laparoscopic dimensions.

The laparoscopic ultrasound transducers fulfil the requirements for the dimensions for laparoscopic surgery. These transducers are used in the same surgical field as the *smart ultrasonic scalpel.* However, since these ultrasound transducers are used stand-alone during the surgeries, they have been developed as a complete laparoscopic tool. They are built in shafts that are fed into the body through a trocar and sometimes have a steerable tip to reach the desired location. The complete off-the-shelf laparoscopic probe is not useful for integration into the scalpel. The ultrasound transducer itself, could be integrated. The dimensions of the transducer itself fit the requirements. With the right orientation of the transducer to the tissue that is grasped in the scalpel, this transducer could be used for the development of an ultrasonic scalpel.

In the category of the special ultrasound probes, several applications of ultrasound have been gathered. The probes that are used inside the body, through natural orifices (transvaginal, transrectal, transesophageal), have sector shaped ultrasound arrays. These transducers are designed for imaging of a large area of tissue (e.g. the complete heart), while in the *smart ultrasonic scalpel* small tissue parts need to be imaged in high detail levels. However, the transducers itself, disregarding their casings, could be useful since their dimensions fit the laparoscopic instrument.
The intravascular probes easily fit the dimensional requirement and could be integrated without any adjustments. Since the ultrasound array of this catheter probe is circular, a wide view of the area of interest could be imaged. Not only the tissue inside the grasper could be monitored, but also the tissue outside the grasper can be imaged. From the already existing ultrasound probes, this seems to be the only one enabling both process monitoring and providing information about the surrounding tissue.

4.1.3. Disposable/reusable instrument parts

Since the ultrasonic scalpels used in laparoscopic surgery, consist of different parts, several options are available for integration of an existing ultrasound probe. Most of the ultrasonic scalpels have a reusable generator and disposable handpiece with moving jaw, waveguide and blade. In some cases, the waveguide and blade are connected to the active element and also reusable. Integration of an existing ultrasound probe requires the possibility of sterilization, if located at a reusable part of the scalpel. If the probe is integrated in a disposable part, a disposable or reusable probe could be used. A disposable probe will increase the costs of the handpiece of the ultrasonic scalpel. A reusable probe will require a specific add-on possibility, since the handpiece of the ultrasonic scalpel is disposable.

4.1.4. Strengths & weaknesses

The *Ultrasound probe integration* concept has been evaluated and strengths and weaknesses are described below.

Strengths

+ Imaging options
  Existing ultrasound probes have sophisticated imaging possibilities. The technology already exists to retrieve a lot of information from the tissue.

+ Known technology
  The ultrasound technology behind the existing probes is designed and manufactured specifically for imaging. The use of ultrasound in this way has low risks of failure.

+ Known workflow
  The workflow of using ultrasound during a surgery is already known, since the information transfer to the surgeon is the same. Ultrasound-guided surgeries are common.

Weaknesses

- Integration in disposable parts
  The handpiece (including shaft & jaw), waveguide and blade are mostly single-use parts of the ultrasonic scalpel. If the transducer is integrated in a disposable part, a disposable transducer needs to be used or an add-on mechanism should be designed. This can facilitate the integration of a reusable transducer.

- Expensive
  Ultrasound probes are expensive, due to the highly sophisticated technology that is required to reach optimal image quality. The ultrasound probes are thus expensive add-ons to the ultrasonic scalpel, especially when disposable probes will be used.

- Too advanced instrument
  The ultrasound probes that are currently available are developed for highly sophisticated applications. A 'smart surgical instrument' could be developed using information of lower detail levels to provide useful information to the instrument and/or surgeon. High-level information could be too extensive for easy use in combination with the ultrasonic scalpel (e.g. in providing a feedback loop).

4.2. Existing ultrasonic pathways

Ultrasonography is based on echo recordings of a transmitted ultrasound pulse. The ultrasonic scalpel contains ultrasonic pathways in the instrument, to induce a vibration and transfer the mechanical energy to the tissue. These existing ultrasound pathways in the ultrasonic scalpel could also be used for sensing purposes. This concept is a synergy solution, using the same ultrasonic pathways in the ultrasonic scalpel for both inducing surgical effects and sensing purposes.

4.2.1. Concept explanation

As described in the previous chapters, ultrasonography uses piezo-electric ceramics to generate an ultrasound pulse. Besides the energy-transfer from electrical energy to mechanical energy (vibration), the piezo-electric elements also facilitate the transfer vice-versa. Any movement of the blade results in a deformation of the piezo-electric elements. These elements are thus subjected to strain and give a voltage change as output. This two-way working principle could also be used to facilitate measurements and gather information about the surgical process or surrounding tissues.

The ultrasonic scalpel is designed to vibrate at its natural frequency. Several measurement options, mostly based on this natural frequency, will be explained in Section 4.2.3 after a more detailed description of the principle of natural frequency change. The main principle of information gathering is visualized in Figure 15.

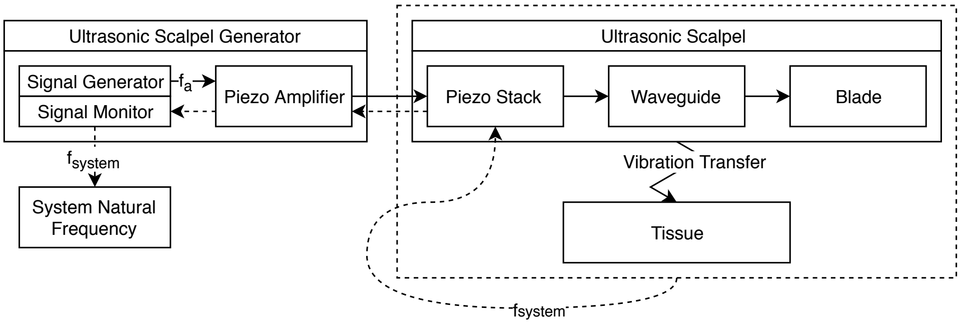


Figure 15: Block scheme of the Existing ultrasound pathways concept. 1) The system is activated at frequency f_a, 2) when a tissue is grasped, the total system has changed 3) the natural frequency of the system f_{system} (including the grasped tissue) can be monitored through the piezo elements and signal monitor.

4.2.2. Natural frequency

The ultrasonic scalpel is designed to vibrate harmonically at its natural frequency. Every system has its own natural frequency, in which resonance occurs if the system is activated at the same frequency. The vibration amplitude at the resonance frequency is the largest, relative to the amount of added energy to the system.

In this way, the largest blade movement can be achieved at the tip of the instrument. Large amplitudes of the blade movement lead, at the given operation frequency, to high-speed movement of the blade relative to the tissue. It is said that the cutting and coagulation effectivity of the scalpel is largely influenced by the movement speed of the blade. [16]

4.2.3. Measurement options

Multiple measurement options are available using the existing ultrasound pathways. With the existing ultrasound devices in the scalpel, vibrations can be induced, but also measured through the piezo-elements. Therefore, the system reaction can be determined which includes information on the tissue type that is grasped in the instrument. The three measurements listed below could provide useful information. These measurements will be explained in more detail.

- Natural frequency change
- Frequency response
- Ultrasound reflection

When a piece of tissue is grasped in between the vibrating blade and the jaw, the tissue has become a part of the total ‘system’. Since the system has changed, so has its natural frequency. The changed natural frequency could be determined through measurement of the voltage output of the piezo-electric elements, when the ultrasonic scalpel is not activated. By sensing an impulse signal into the system, it will start to vibrate in its natural frequency. The amount and direction of the natural frequency change could be a characterizing measure for the tissue type that is grasped. Based on the tissue properties and natural frequency shift, a reference database can be built over time, which will improve the performance of the system.

Normally, the ultrasonic scalpel is activated at its natural frequency, since the scalpel is designed to resonate in that frequency. However, it could be useful to activate the scalpel also at other frequencies, while grabbing a specific tissue type. The amplitude of vibration will change over the frequency spectrum. This can be measured by means of the piezo-voltage. Since the vibration amplitude will be the largest at the natural frequency, the natural frequency could be determined. The same information type (natural frequency shift) as when an impulse input is used can be derived. However, using the ‘sweeping frequency’ could give more useful information, since also the amplitudes at other frequencies than the natural frequency are recorded. A frequency – amplitude spectrum can be created, which might facilitate more detailed tissue characterization. See Figure 16 for an example of such a spectrum.

A next step could be to send an ultrasound pulse into the tissue and try to register the reflection of that repulse within the tissue. This is the basic technique of ultrasound imaging. At tissue borders of different acoustic impedances, the ultrasound pulse will be reflected and based on the travel-time the distance of the reflection surface can be calculated. The ultrasound wave frequency should be studied. To reach an acceptable resolution a frequency in the MHz range would be required, while the ultrasonic scalpel works at a natural frequency in de kHz range. However, activation at a frequency in the MHz range might provide useful pulses and reflection measurements.

Ultrasound imaging transducers commonly consist of an array of piezo-elements that send a pulse and receive the reflection. In this way, a grey-scale image can be projected, based on the received echoes. The application in the ultrasonic scalpel will not be as sophisticated as in ultrasound imaging equipment, due to the fact that the scalpel acts as only one element. The result will be an A-mode scan, showing the received echoes. However, using this information could prevent damage to surrounding tissues, since the relative distance can be detected. See Figure 17 for an example of a reflection measurement.

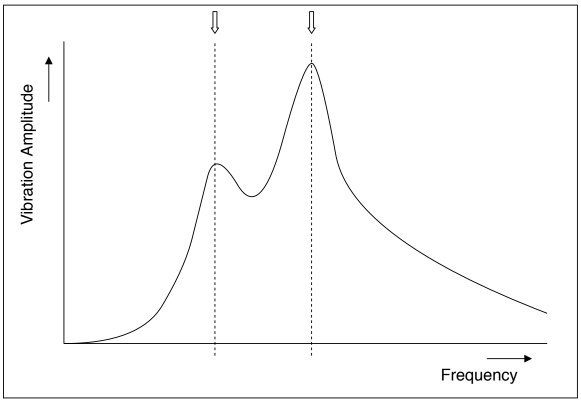


Figure 16: Example of a frequency spectrum that could be measured via the existing ultrasonic pathways. The white arrows show possibly characterizing features.

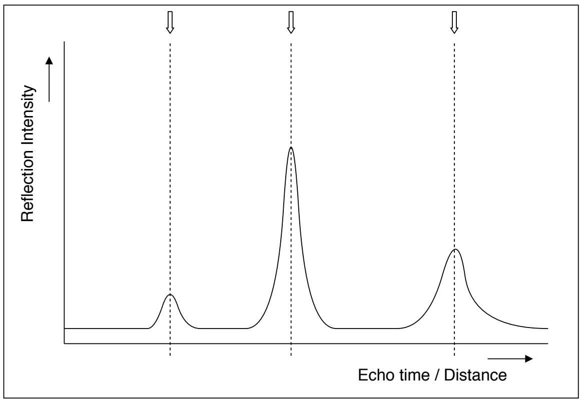


Figure 17: Example of a reflection measurement that could be measured via the existing ultrasonic pathways. The white arrows show reflection surfaces in the tissue.

4.2.4. Strengths & weaknesses

The *existing ultrasound pathways* concept has been evaluated and strengths and weaknesses are described below.

Strengths

\+ Synergy
The working principles of the ultrasonic scalpel and the measurement technique are combined in this concept. This could lead to synergy advantages. The measurement information is the same

\+ No extra devices
Since the existing ultrasound technology of the scalpel is being used as a sensing technique, no extra devices are required in the operating room when using the 'smart' ultrasonic scalpel.

\+ Cheap
No extra devices are required. Only monitoring of the voltage over the piezo-electric elements is needed to be able to record the frequencies and amplitudes of the system. The extra costs involved are limited.

Weaknesses

– No sophisticated imaging
Imaging with the quality of regular ultrasound imaging is not possible, due to the fact that only one active element is used.

– Frequency vs resolution
The ultrasonic scalpel is normally activated at frequencies in the 35-55 kHz range. Due to wavelength of the soundwaves, ultrasound imaging is performed using frequencies from 1-20 MHz. The higher the frequency, the smaller the wavelengths leading to a high resolution. Imaging/measuring reflections is only useful when the resolution is high enough to distinguish anatomical information.

4.3. Concept feasibility

Following the third sub-question of this research project, as formulated in Section 1.2, the feasibility of both concepts will be assessed. A set of criteria will be presented that will be used to determine the feasibility of a concept.

The factors that determine the feasibility of a concept are listed and explained in Table 1. The integration directions will be scored on these criteria. The scoring on these criteria will not be numerical. The current level of detail of the integration directions does not provide enough basis to numerically rate them. Therefore, an -/0/+ score will be used. It should be noted that this is subjective scoring by the author.

Criterion	**Description**
Surgical process information	The ability of the smart surgical instrument to provide information about the surgical process.
Surgical environment information	The ability of the smart surgical instrument to provide information about the environment of the instrument and the surgical site. ** This criterion is not assessed as a deciding factor for feasibility. Information about the surgical environment is considered a "nice-to-have".*
Manufacturability	The relative ease of manufacturing of a smart surgical instrument as proposed in the integration directions.
Workflow implication	The increase of workflow complexity that is related to the integration directions, relative to the use of the current ultrasonic scalpel. Large implications on the workflow lead to a lower score.

Table 1: Evaluation factors that determine the feasibility of the concepts.

The *Ultrasound probe integration* concept is definitely able to provide useful information about the surgical process and possibly also the surgical environment. If the currently existing state-of-the-art probes can be integrated, this will lead to useful new information during the surgical procedure.
It is assumed that integration of an existing probe is possible without extraordinary manufacturing issues. Only modifications to the existing ultrasonic scalpel are required.
No significant implications are expected in the workflow during the use of the ultrasonic scalpel. The use of ultrasound information (e.g. images) is already used a lot in the clinical field and this expertise can be used to present useful information to the surgeon.

The *Existing ultrasonic pathways* concept can provide information about the surgical process, based on the change of the natural frequency of the system.
However, the ultrasonic scalpel waveguide and blade act as one ultrasonic transducer element, which makes it more difficult to provide useful information about the surgical environment.
No modifications to the scalpel are required. Monitoring of vibration through piezo-electric elements is a common technique for which existing algorithms are available. This concept is thus very well manufacturable.
The information from the piezo-electric elements will need to be transferred into useful information for a surgeon. A strong analysis of the information transfer to the clinical personnel should be made in order to generate insights that are easy to interpret during the surgical procedure. When this can be achieved, the workflow will not significantly change.

The evaluation of the concepts described above is transferred into a score in Table 2.

Criterion	Ultrasound probe integration	Existing ultrasonic pathways
Surgical process information	+	+
Surgical environment information	+	-
Manufacturability	0	+
Workflow implication	0	0

Table 2: Scoring of integration direction on the different feasibility criteria.

Both concepts have their pros and cons, as was already described in Sections 4.1.4 and 4.2.4, but are expected to fulfil the requirements and wishes that were described in the synthesis scope and the feasibility criteria. As can be seen in the scoring table, the *Ultrasound probe integration* concept has the ability to provide surgical environment information, which is considered valuable.

At this point, both concepts are considered feasible, but it is most recommended to perform further research on the *Ultrasound probe integration* concept. The *Ultrasound probe integration* concept will be subjected to a series of experiments in the next phase of this research.

Phase 2

Experiments

5. Experimental framework

This chapter provides an overview of the steps that are taken in the experimental phase. The process is clearly presented and decisions that have been made are explained.

Due to time- and resource limitations, only one of the developed concepts is subjected to experiments. In Section 5.1, the selection of the chosen concept will be presented.

One application area of the ultrasonic scalpel has been selected to focus the experiments.
During the literature study, a set of articles out of a specific search query was read, to extend the knowledge about the ultrasonic scalpel. The articles all mentioned a specific application area or procedure of the ultrasonic scalpel and described the use of this type of instrument in that application. Thyroid surgery and tonsillectomy were the most present application fields of the ultrasonic scalpel, according to the selected set of articles. Liver surgery was also presented as a common application area for the ultrasonic scalpel.
Since in tonsillectomy and thyroid surgery the added value of real-time ultrasonography on the surgical site is less than it is for liver surgery, the latter was selected as specific application to focus on during the experiments. Section 5.2 will elaborate on the liver surgery and its relevant aspects for this experimental phase.

In Section 5.3, the set-up of the experiments will be described.

5.1. Concept selection

From the two integration directions, described in Chapter 4, one is chosen to assess the feasibility with a series of experiments. Both directions seem to be valuable for further research, with their own specific innovative elements. However, time-limitations and material availability caused the choice for only one experimental set-up.

The *Existing ultrasound pathways* was assessed as a promising concept, based on the strengths and weaknesses, described in Section 4.2.4. Modelling the complete waveguide has been proposed, but since no operational console for the ultrasonic scalpel was available, results from modelling could not be validated.
For the integration direction *Ultrasound probe integration,* material was available. Ultrasonic scalpels were present at Delft University of Technology and Philips Research could provide fully functional ultrasonography set-ups. Therefore, this integration direction is selected and a series of experiments is designed.

5.2. Liver surgery

As explained earlier, liver surgery is selected as focus application for the experimental phase. In this section, this application is described and an analysis is presented showing which elements are relevant to provide information about, using integrated ultrasonography.
A description of the most performed liver surgery procedure is given, to find out which elements of this procedure could be improved by the use of a *smart ultrasonic scalpel.*

Liver surgery is mostly performed for resecting malignancies from the organ. According to several studies on the indications for liver resections, hepatocellular carcinoma and colorectal cancer metastases are the main reasons for these resections. [48], [49] From the Dutch Cancer Registry, it can be found that colorectal cancer is the third most diagnosed type of cancer in The Netherlands, after skin- and breast cancer, with a number of 14.100 new diagnoses in 2018. Since in more than 50% of the cases also metastases in the liver exist, a very large group of patients undergoes liver resections. Hepatocellular carcinoma, a type of cancer that originates from the liver cells itself and is also be treated by tumour resections, is less common. [50] Following these statistics, the resection of colorectal cancer metastases from the liver is chosen as focus procedure in this experimental phase.

While surgical procedures on a lot of organs were already performed laparoscopically, this was still controversial for livery surgery. Due to fear for compromising the oncological resection, laparoscopic tumour resection in the liver was not regularly performed. Furthermore, factors as tumour-free margins and uncontrolled bleeding (out of view of the laparoscope) delayed the introduction of laparoscopy in this field. It was thought that measuring these margins and keep the cutting plane clear from the tumour was too difficult to perform in a laparoscopic procedure. However, the advantages in e.g. less blood loss, shorter hospital stay after the operation that are related to laparoscopic procedures are present. [51]–[53] With the ongoing developments in the technological field and proof of equality in multiple studies, it has been shown that no oncological disadvantages exist when laparoscopic liver resection is performed. Furthermore, the parallel treatments like chemotherapy have become better. Since lesions are already smaller under the influence of parallel treatments, laparoscopic is more reliable. It is therefore expected that laparoscopic resection of liver lesions will be the regular choice in the future. [48]–[50], [54]

5.2.1. Laparoscopic resection of colorectal cancer metastases

Liver resection is currently the standard technique that provides the most prolongation of the survival of patients with colorectal cancer metastases in the liver. [50]
Liver anatomy is described in segments, following a segmentation that Claude Couinaud developed. He presented eight functional segments of the liver and showed that this segmentation was based on vascular and biliary relationships within the liver and not based on external morphology. [55]

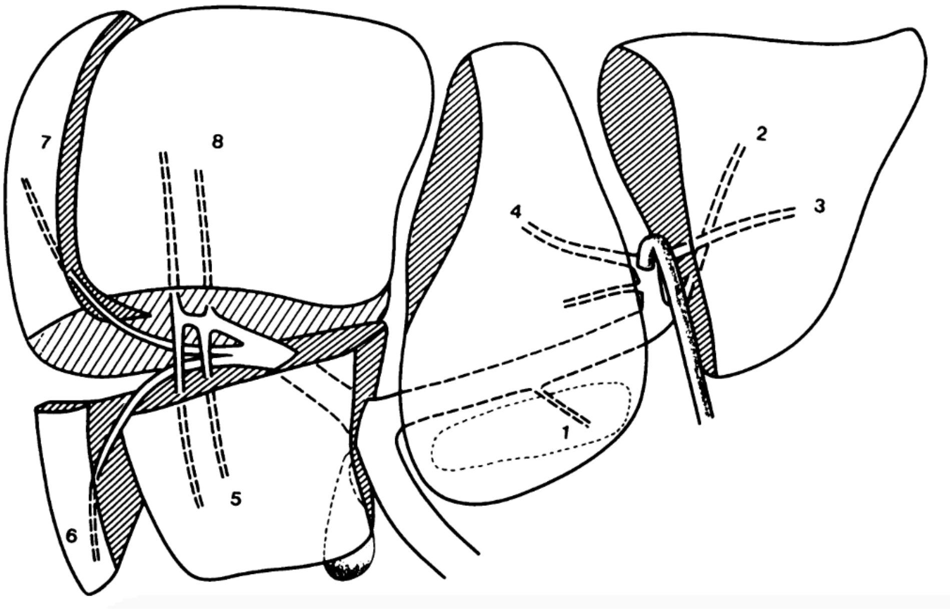


Figure 18: Liver segmentation following the standard of Claude Couinaud. Source: [56]

For liver resections, two methods exist: anatomical resection and wedge resection. In anatomical resections, one or multiple complete segment(s) from the Couinaud liver segmentation are resected. In a wedge resection, the functional segments of the liver are not followed and only the tumour cells including a margin of healthy liver are resected. Anatomical resection used to be the golden standard, due to indications that the recurrence rates of the tumours were lower. However, since a lot of liver tissue is removed when a complete liver segment is resected, the remaining part of the liver has more difficulties in growing back and perform the liver function. In wedge resections, where only the tumour is resected surrounded by a margin of healthy tissue to prevent remaining tumour-cells, more liver tissue can be saved. When resecting a tumour from the liver, it is important that a negative margin is achieved, meaning that the resected tumour is surrounded by healthy tissue. This ensures that no tumour-cells remain in the body. Tumour-free margins that surgeons hold on to, were set to 1 cm. Only if a tumour could be resected with at least 1 cm of tumour-free tissue, the tumour was assessed 'resectable' in wedge resection. However, studies have shown that the width of the tumour-free margin is not influencing the outcome after surgery. A tumour-free margin larger than 1 mm should be retained. [57], [58]

Multiple studies describe the use and advantages of the ultrasonic scalpel during liver resections. Due to the ability of sealing vessels, the use of the ultrasonic scalpel reduces blood loss in the strongly vascularized organ. The need to stop the inflow of blood to the liver, which was regularly done to limit the blood loss, is getting less. [59], [60]

The use of intraoperative ultrasonography is mentioned as valuable during liver resections.
Ultrasound imaging can assist in the determination of the liver segmentation. For example, the hepatic veins, dividing the different liver segments could be visualized using ultrasonography. [61], [62] Additionally, the surgical margins are less often invaded when intraoperative ultrasound is used. [52], [56], [59]
Especially during laparoscopic liver resections, intraoperative ultrasound has shown its added value. Intraoperative ultrasonography facilitates detection of additional lesions, small tumours that need to be resected as well, during the laparoscopic procedure despite missing visual and palpable feedback for the surgeon. [4], [35]

5.2.2. Impact of *smart ultrasonic scalpel*

When the *smart ultrasonic scalpel* will be developed, using the *ultrasound probe integration* concept, several aspects of liver resection can be improved. As is described in Section 5.2.1, the ultrasonic scalpel is a commonly used instrument for resecting tumours from the liver. Furthermore, ultrasound imaging can improve the orientation, segmentation and margin-assessment during resections of liver tumours.

Integrating these two functionalities will lead to improvements of the surgical process. The impact that the *smart ultrasonic scalpel* might have is described below.

Instrument changes

When ultrasound imaging is integrated into the ultrasonic scalpel, no separate instrument is required for imaging. During laparoscopic resection, this saves an incision making the procedure less invasive for the patient. Furthermore, the workflow for the operating team will be simpler. No change of instrument handling is required and the combination of different people steering multiple instruments will be less complicated.

Margin assessment

The assessment of tumour-free margins surrounding the tumour can be performed more easily. Effectively, the tumour-free margin sets the minimum distance between the tumour and the cutting instrument. When a stand-alone ultrasound probe is used, the distance between two elements needs to be assessed. The use of an integrated ultrasound probe enables precise measurements of the margin, using the scalpel itself as a reference.

For margin-assessment it is important that the line of sight of the ultrasound probe is open to the area of interest. When tissue is grasped, the sideward view presents the distance to the tumour. This line of sight needs to be present in the design. Given the fact that tumour-free margins need to be at least 1 mm, a penetration depth of 1 cm should be sufficient. [57], [58]

Real-time orientation

The use of a smart ultrasonic scalpel enables the surgeon to real-time image the surroundings of the surgical site and thereby orientate the ultrasonic scalpel. When resecting tumours from the liver, it is important to avoid critical vascular structures and follow the functional segment anatomy during anatomical resections. [61], [62]

When the grasped tissue, between the blade and jaw of the ultrasonic scalpel, can be imaged, damage to critical structures can be avoided, since they can be detected before activation of the scalpel. A view at the surrounding tissue is not only valuable during the use of the ultrasonic scalpel, but also using the scalpel as a laparoscopic ultrasound probe.

Instrument feedback

Future developments of integration of ultrasound into the ultrasonic scalpel might lead to direct feedback to the surgical instrument. Direct feedback could decrease the amount of energy that is transferred to the tissue, while the surgical effects are still achieved. This can improve the surgical procedure and influences the recovery of the patients.

In this thesis research, the focus will be mainly on the practical effects of imaging from the grasped tissue and surgical environment.

5.3. Experimental set-up

Firstly, the physical aspects of integrating an existing probe into the regularly used ultrasonic scalpels will be discussed. A prototype design will be proposed that enables the integration of ultrasonography into the ultrasonic scalpel. In this design process, the different design problems will be handled separately and design solutions are proposed. A final design will be proposed that will be used during the next steps in the experimental phase. It should be noted that a prototype design is presented and not a fully functional surgical device. The goal of the design process is to develop a simple and easy way to integrate an ultrasound probe into the ultrasonic scalpel.

Secondly, the performance of the selected existing ultrasound probe will be assessed, with a specific focus on the functionality that is required for a smart ultrasonic scalpel. The proposed prototype design is taken into account and the influences of integration on the performance of the ultrasound probe will be tested. In this way, the design is validated, before complete integration tests are performed.

Thirdly, the integration will be performed to test whether the proposed design and functionality of the ultrasound probe deliver promising results. Besides, the prototype will be assessed and design improvements and points of attention will be described that can be used as a basis for further research.

Based on the results of the experiments that are described above, an improved prototype will be presented. This adjusted prototype will solve the problems that were encountered during the experiments.

6. Prototype design

To test the feasibility of the integration of an existing ultrasound probe into the ultrasonic scalpel for the development of a smart ultrasonic scalpel, a first prototype will be developed. Experiments with an adjusted scalpel with integrated ultrasound transducer will be performed to find out if this is a feasible direction that should be further researched.
The design of the prototype starts with the statement of the design problem, sub-problems and related requirements that need to be imposed on the design. Several solutions are proposed, of which one will be selected to reach a functional prototype.

6.1. Problem analysis & design requirements

The design problem is split into several sub-problems. For all these sub-problems, solutions are presented. A final prototype design is presented from these set of solutions. The design problem is split into the following sub-problems:

- Transducer type, location & orientation
  The transducer type, location and orientation together define the field of view of the transducer. The areas of interest should be covered to provide useful information to the surgeon.

- Transducer attachment
  The attachment method of the transducer should not limit the performance of the ultrasonic scalpel or the functionality of the ultrasound transducer.

- Material choice
  The material choice is a relevant design problem. Ultrasound propagation and heat resistance need to be taken into account during the material selection.

- Data transfer
  A data cable needs to pass the skin alongside the shaft of the ultrasonic scalpel, since the instrument is used laparoscopically.

The above-mentioned sub-problems are separately discussed in Section 6.2 and solutions are presented.

Solutions for all sub-problems are subjected to a specific set of design requirements. These requirements are mostly related to the functionality of the ultrasonic scalpel and the added sensing-functionality that ultrasonography brings. The set of requirements is presented in Table 3.

Requirement	Description
Functionality ultrasonic scalpel	The functionality of the ultrasonic scalpel must not be influenced in any way by integration of an ultrasound probe. The tissue effects related to ultrasonic energy transfer and grasping functionality should not change.
Line of sight	The integrated ultrasound probe should at least facilitate imaging/recording of the grasped tissue. Second priority is sideward looking, in order to assess tumour-free margins. Third priority is a field of view that reaches surrounding tissues, enabling orientation and tissue assessment using the smart ultrasonic scalpel. See Figure 19 for a visual overview of the line of sight and prioritization.
Penetration depth	A penetration depth of at least 1 cm is required. The distance between the blade and jaw (Figure 19, annotation 1) is in open position not more than 1 cm. Margin assessment (Figure 19, annotation 2) can be performed sideward and requires approximately 1 cm of penetration depth. For orientation in the surgical field (Figure 19, annotation 3), a larger penetration depth could be valuable.
Dimensions	Outer diameter shaft: ≤ 10 mm The instrument needs to enter the body through a trocar (passing the skin) since it is used in laparoscopic surgery.
Heat resistance	The ultrasound transducer and attachment material should be able to withstand a temperature of 100 °C since this temperature can be reached when the ultrasonic scalpel is activated.

Table 3: Set of requirements that should be fulfilled by the prototype design.

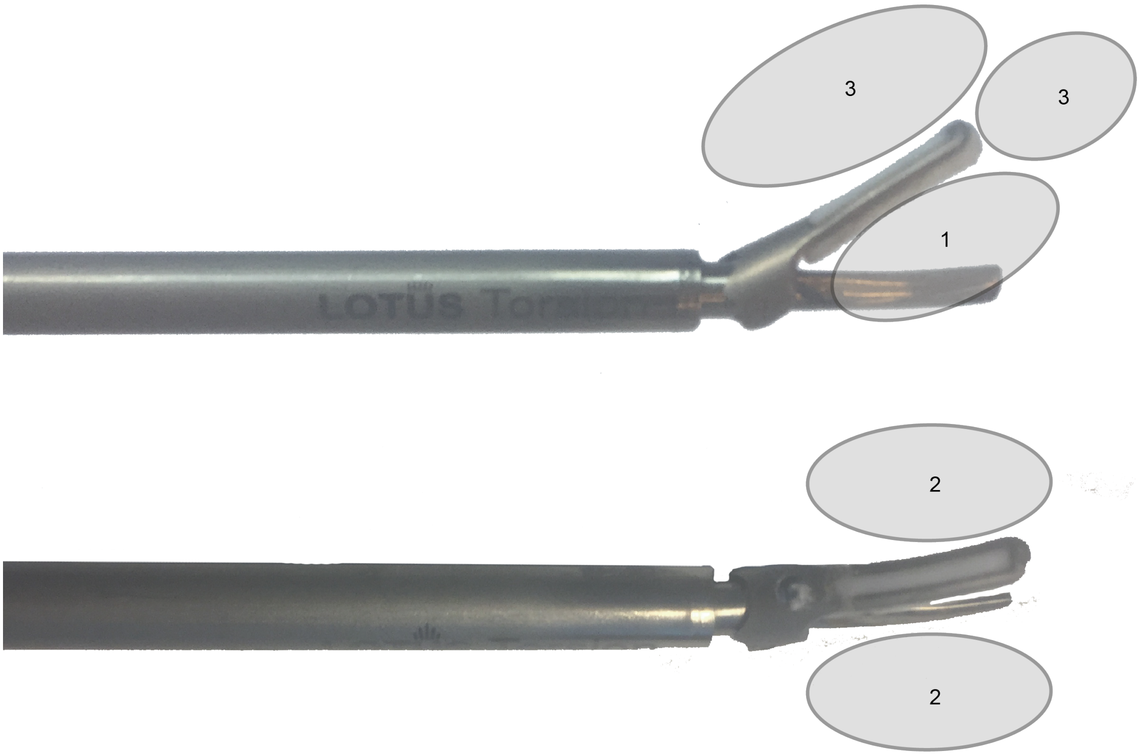


Figure 19: Areas of interest for assessment by ultrasonography. Top image is a side view, bottom image is a top view of the ultrasonic scalpel. Annotated areas in order of priority: 1) in between the vibrating blade and jaw to monitor the process. 2) surrounding tissue sideward of the blade and jaw. 3) surrounding tissue above and in front of moving jaw.

6.2. Design considerations

During the analysis of existing ultrasound transducers, several ultrasound probes have been found that could be used to integrate. The different options bring specific requirements for the probe location, orientation and attachment to the ultrasonic scalpel, in order to reach the best functionality. Furthermore, the cable to transfer the data needs to be positioned in such way that it does not influence the capabilities of the ultrasonic scalpel.

In the following sections, these issues are described and solutions are proposed.

Finally, some points of attention are described that could improve the functionality or should be kept in mind during the prototype development.

6.2.1. Transducer type

The type of probe that is used is strongly related to the probe location and -orientation that can be implemented.

Based on the overview, presented in Section 4.1.2, the laparoscopic ultrasound probes and intravascular probes are candidate probes to be integrated.

The laparoscopic ultrasound probes are designed for stand-alone use during laparoscopic surgeries and therefore have their own casing and sometimes steering mechanisms. These functional add-ons cannot be integrated. Only the transducer array itself could be integrated into the ultrasonic scalpel. The transducer has a field of view that is directed in one direction, but sideward-looking probes and forward-looking probes are available. The penetration depth differs from 15 to 90 mm. [63], [64]

The intravascular ultrasound probes (IVUS) are small enough to be completely integrated into the scalpel, since they have a diameter of 1-3 mm and a transducer length of less than 10 mm. The field of view of the intravascular ultrasound transducer is circular, with the imaging plane perpendicular to the catheter. The penetration depth ranges from 1 to 6 cm in each direction, leading to a circular cross-sectional image of 2 to 12 cm in diameter. [65], [66]

6.2.2. Transducer location

For every probe, the location and orientation of the transducer are a vital aspect influencing the functionality of the ultrasound integration. Given the functionality requirements, the transducers with a field of view in one direction, need to be located as such, that the tissue in the grasper can be imaged. Ultrasound probes containing a circular array can provide imaging of the tissue inside the grasper as well as information about the surrounding tissues.

For both transducer types, the moving jaw of the ultrasonic scalpel is the best possible integration location.

6.2.3. Transducer orientation

By gathering information from an array of ultrasound elements, the ultrasound systems provide 2D cross-sectional images. In order to be useful during the application of an ultrasonic scalpel, the orientation of the integrated ultrasound probe is a relevant design aspect.

The arrays that are sending ultrasound pulses in one direction could be oriented in such way that the image is built parallel to the moving jaw or perpendicular to the moving jaw. In both orientations, the transducer could be mounted with a sliding possibility to increase the field of view that can be covered. See Figure 20 for an overview on the field of view that will be reached with both orientations. It is noted that when the imaging plane is parallel to the jaw and blade of the ultrasonic scalpel, no sideward view is available. Margin assessment is then not possible.

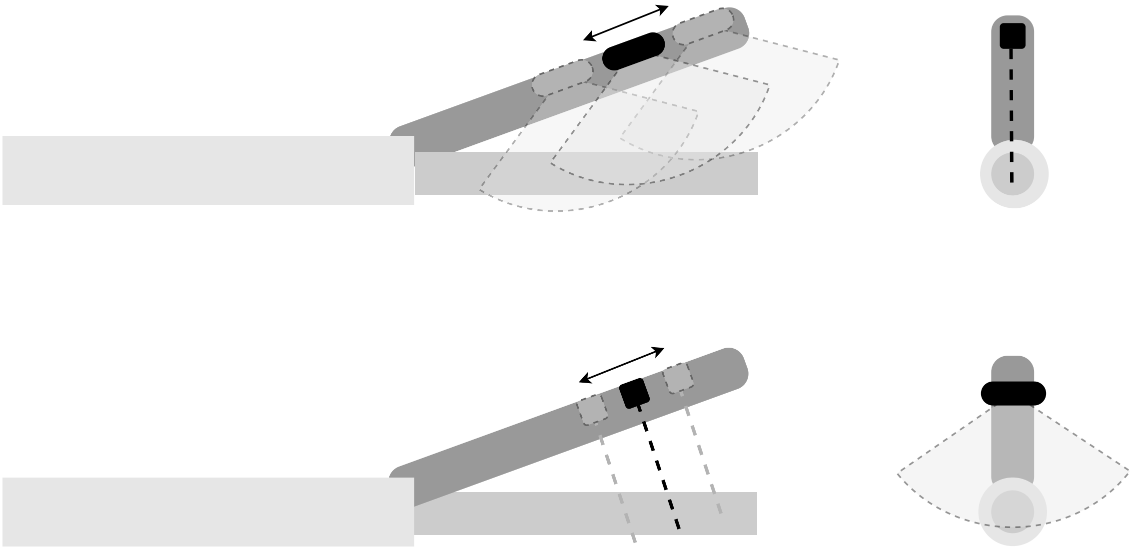


Figure 20: Orientation possibilities for mounting a laparoscopic ultrasound transducer (building image in one direction). Top Left: Side view of imaging plane parallel to scalpel jaw with sliding transducer. Top Right: Front view. Bottom Left: Side view of imaging plane perpendicular to scalpel jaw with sliding transducer. Bottom Right: Front view.

When a forward-looking laparoscopic transducer would be implemented, the orientation of the transducer could be changed in other planes. The array would look forward, out of the jaw, to provide images of the tissue in front of the instrument. Either the orientation can provide a large scope in the vertical direction or the transducer can provide a wide view in the horizontal direction. See Figure 21 for the difference in field of view of these orientation possibilities.
The use of a forward-looking transducer does not facilitate imaging of the grasped tissue. Additionally, the vertical orientation does not provide sideward imaging for margin-assessment. This ultrasound transducer does not fulfil the design requirements and is not further investigated.

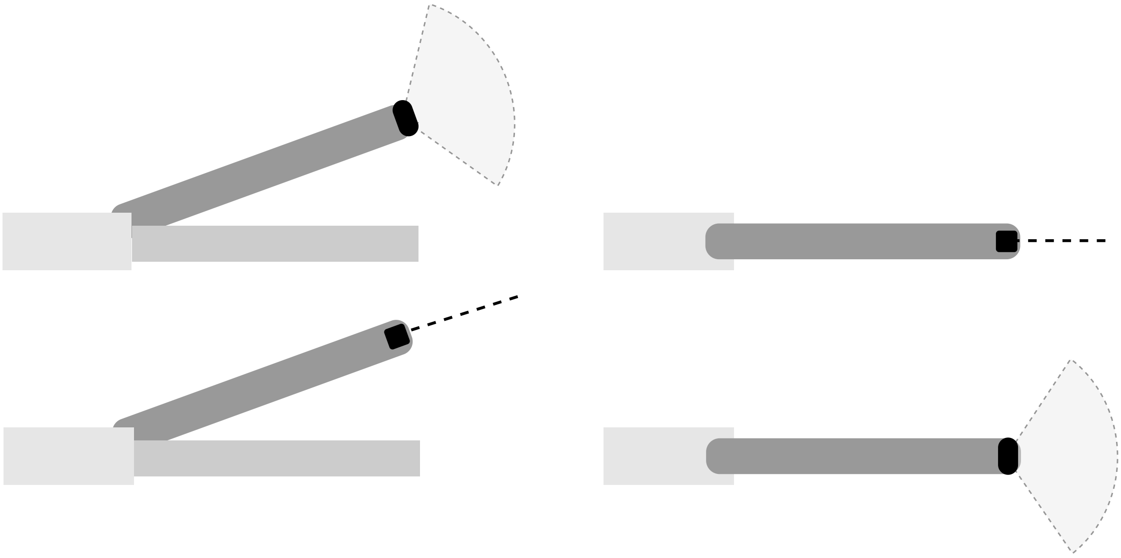


Figure 21: Orientation possibilities for mounting a forward-looking laparoscopic ultrasound transducer. Top Left: Side view of imaging plane parallel to jaw movement direction. Top Right: Top view of same configuration. Bottom Left: Side view of imaging plane perpendicular to jaw movement direction. Bottom Right: Top view of same configuration.

The circular arrays could also be oriented for imaging in a parallel manner relative to the jaw or in a perpendicular way. Figure 22 shows the implications that this choice will have on the imaging area. The application area of the current available catheter probes, creating a cross-sectional image of a blood vessel at a certain location, leads to a perpendicular imaging plane relative to the jaw. For an imaging plane parallel to the moving jaw the transducer array needs to be redesigned, in order to have the data transfer at another location. Since a parallel imaging plane does not provide sideward imaging, which is required for easy margin assessment, this option is not investigated further.

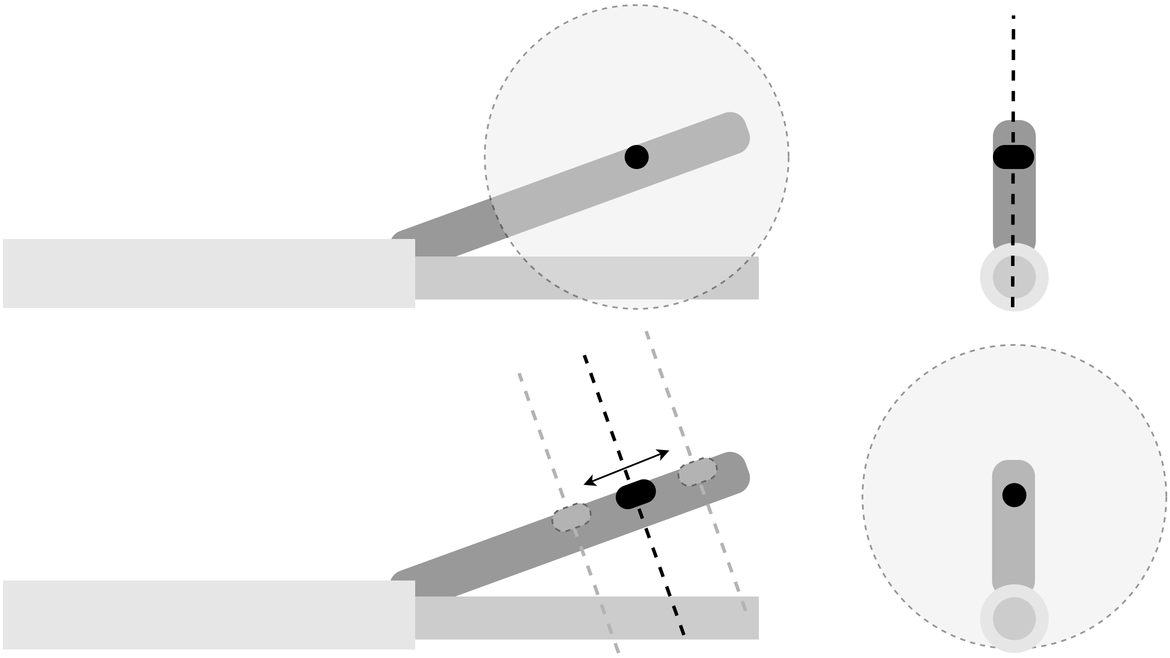


Figure 22: Orientation possibilities for mounting an intravascular ultrasound transducer (building circular image) Top Left: Side view of imaging plane parallel to scalpel jaw with sliding transducer. Top Right: Front view. Bottom Left: Side view of imaging plane perpendicular to scalpel jaw with sliding transducer. Bottom Right: Front view.

6.2.4. Transducer attachment

Given the attachment location at the moving jaw of the ultrasonic scalpel, several mounting options are proposed. First of all, the mounting principle should be as such, that the field of view of the transducer is not or as least as possible influenced.

For a one-direction transducer, a direct and fixed coupling to the moving jaw could be proposed. The plastic covering of the jaw, that normally enhances the grip on the grasped tissue, can be used as placeholder for the integrated ultrasound transducer.

The circular transducers require field of view in all directions. Therefore, the 'window' in the jaw which is normally used to attach the plastic cover should be opened, see Figure 23.

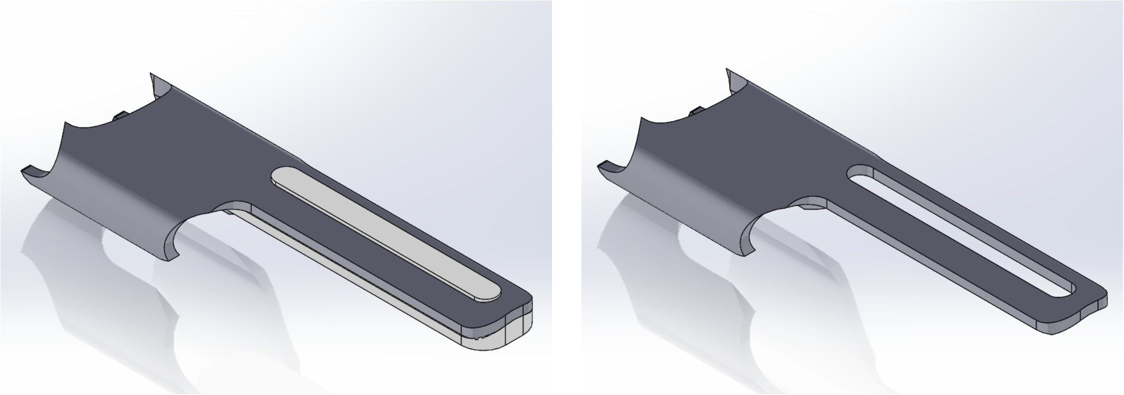


Figure 23: Left: jaw of the ultrasonic scalpel with plastic cover. Right: jaw of the ultrasonic scalpel with removed plastic cover, leaving a 'window'.

Three separate mounting approaches are proposed: Cover replacement, Transducer Socket, Guidewire.

In the *Cover replacement* option, the plastic cover on the jaw is replaced by a specifically designed transducer holder. The holder combines the functions of providing grip to the tissue and holding the transducer. The cover could be designed as a sterile barrier, meaning that the transducer does not touch the tissue directly and can be reused.

The *Transducer socket* does not require any adjustments to the current ultrasonic scalpel. A socket could be designed that fits on the jaw, including the plastic cover. The socket holds the transducer. For circular array transducers, it should be noted that the cover should either sufficiently transfer ultrasound or should be removed. Also this transducer socket can be designed with the additional purpose of a sterile barrier.

The *Guidewire* mounting is only available when an intravascular ultrasound probe is being selected. These probes are attached to a catheter that is fed through the blood vessels on a guidewire. This guidewire might also be used for the attachment of the catheter on the ultrasonic scalpel.

6.2.5. Material choice

The material that will be used to mount the catheter to the moving jaw of the ultrasonic scalpel must be able to withstand temperatures up to 100 ºC. This temperature can be reached in the tissue, when the ultrasonic scalpel is activated.

Furthermore, the material selection is relevant when the ultrasound signal needs to pass through it. To prevent reflection of the signal at the surface of the material, the material should have an acoustic impedance that is matching that of human tissue.

An appropriate choice could be silicone rubber. This material is often used as phantom material for ultrasonic phantoms since it matches the acoustic impedance of the tissue. Specific acoustic impedances close to 1.5 MRayl (the specific acoustic impedance of water) are presented in silicone rubber. [67], [68]

This material is also able to withstand temperatures up to 150 °C without noticeable changes in the material structure. For shorter use temperatures up to 200 °C and 300 °C do not cause alterations in the material. [69]

Another solution that could be selected is the use of existing ultrasound transducer covers. Covers for ultrasound transducer are commercially available. These thin balloon-like rubber covers are used to prevent direct contact between the human tissue and the transducer. Some of the covers facilitate introduction of coupling liquid within the cover. Acoustic coupling can be facilitated in larger areas, while imaging is performed with a small ultrasound transducer.

6.2.6. Data transfer

The data that is gathered at the ultrasound transducer needs to be transferred to a console outside the body in the operating room. A cable is required connecting the transducer and the console. This cable needs to pass the trocar, through which the ultrasonic scalpel is inserted in the body.

First proposed solution is to incorporate this data cable into the shaft of the ultrasonic scalpel. Several tubes are present that do not have another function than holding or moving the jaw which could be used to feed the cable through. However, this requires a redesign of the shaft of the ultrasonic scalpel to create space for a cable.

Another solution is to keep the data cable externally, through an additional small diameter tube that is separately connected to the shaft of the ultrasonic scalpel. Trocars exist in different diameters up to 12 mm, facilitating the entrance of the ultrasonic scalpel with an additional tube. This should not lead to problems introducing the ultrasonic scalpel.

6.2.7. Points of attention

Several points of attention have been noted during the development of the different design proposals presented in the previous sections. These aspects are relevant to keep in mind while developing and/or manufacturing a prototype, but even more when further research is performed.

Catheter rotation

This aspect is related to a circular array transducer. A circular array provides a circular cross-sectional image and the orientation relative to the ultrasonic scalpel can change without any notice. Only when the orientation is known, the information gathered from the images can be used effectively.

Since the jaw, to which the catheter is attached, is located in the field of view, these fixed elements could be used to rotate the image in the desired direction using image processing.

Sterile barrier

As is described in Section 4.1.3, the ultrasonic scalpel handpiece is disposable and thus only used one time. This part of the instrument is relatively cheap (€180-€250 according to online shops), meaning that the ultrasound transducer (manufacturing costs approximately €500 according to ultrasound experts) that will be integrated will increase the price dramatically. By developing an ultrasonic scalpel that has a covered path to introduce the ultrasonic transducer, contact with the tissue is prevented. In this way the catheter could be used multiple times, which will reduce the cost per surgery.

6.3. Final prototype design

The above described problem areas and proposed solutions, described in Section 6.2, have been analysed and used to develop a first prototype. It should be emphasized that this prototype is not a fully working ultrasonic scalpel with integrated ultrasonography. However, it does provide the possibility to perform experiments and find out whether ultrasonography integration would lead to useful insights for a surgeon.

The design decisions have been made with this experimental configuration in mind, see Table 4. For example, the transducer attachment to the moving jaw could be designed on more detail. But the selected solution in this prototype is easy, cheap and can provide a proof of principle of this prototype.

Design decisions	
Transducer type	Intravascular Ultrasound Transducer *An intravascular ultrasound catheter will be used. The circular array provides a wide imaging area and the dimensions fit the requirements to be integrated into the ultrasonic scalpel. The penetration depth might be too small to analyse all lesions, but at least the grasped tissue can be assessed and tumour-free margin assessments can be performed.* *In these current experiments, a Philips Eagle Eye Platinum transducer will be used.*
Transducer location	Moving jaw *The jaw of the scalpel is the location where the transducer can be mounted as close to the surgical site as possible. Furthermore, the possibility for imaging the surrounding area is available at this location. A mounting location of the catheter on top of the jaw is provided as well as a bottom mount inside the shears. A hole is drilled in the moving jaw of the ultrasonic scalpel to enable the catheter to be placed at the bottom of the jaw.*
Transducer orientation	Longitudinal (imaging plane perpendicular to blade) *The longitudinally oriented Eagle Eye Platinum catheter provides a wide field of view in all directions. Especially the downward and sideward field of view can be of great interest for surgeons: the grasped tissue can be assessed as well as the adjacent tissues (e.g. to ensure positive margins during tumour dissection).*
Transducer attachment	Transducer socket *A silicone tube with 2 mm inside diameter and a wall thickness of 0.3 mm will be used to mount the Eagle Eye Platinum catheter to the jaw of the ultrasonic scalpel. The wall thickness is chosen as low as possible (commercially available) to prevent ultrasound reflections between the inner and outer wall as much as possible. The tube fits around the jaw and mounts the catheter tightly to the jaw. The tube enables sliding of the catheter to increase the field of view. Additionally, this design option acts as a basic sterile barrier, enabling reuse of the ultrasound catheter.*

Material choice	Silicone rubber *Silicone rubber has an acoustic impedance that matches that of water and tissue, which minimizes the signal loss due to reflections at the silicone-tissue border. Furthermore, silicone rubber can withstand the high temperatures induced by the ultrasonic scalpel activation.* *The existing ultrasound transducer covering sheaths are only available for larger transducers. These sheaths do not fulfil the dimension requirements, needed to attach the ultrasound catheter on the jaw of the ultrasonic scalpel.*
Data transfer	Additional tube *An additional tube is attached to the shaft, feeding the cable from the transducer towards the handpiece of the ultrasonic scalpel. This part is not the first focus aspect and is therefore not assessed during the experiments.*

Table 4: Design decisions that are made in the final prototype design, in the problem areas that are described in Section 6.2.

The decisions described in Table 4 have led to a functional first prototype that can be used in experiments. See Figure 24 for schematic images of the prototype, with the ultrasound catheter mounted on the top and on the bottom of the moving jaw.
Figure 25 shows pictures of the first prototype.

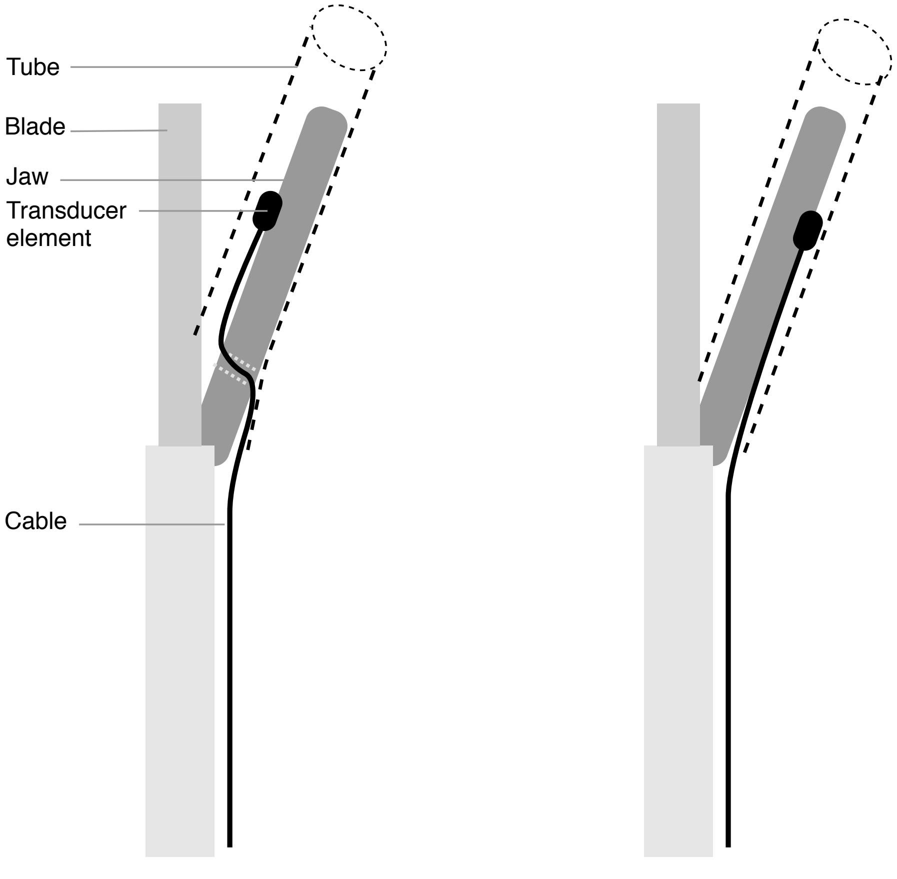


Figure 24: Schematic images of the prototype design with two mounting configurations of the ultrasound catheter. Left: ultrasound catheter mounted at the bottom of the jaw. Right: ultrasound catheter mounted on top of the jaw.

Figure 25: First prototype of the LOTUS ultrasonic scalpel with integrated Philips Eagle Eye Platinum ultrasound catheter. Left: ultrasound catheter mounted on the bottom of the moving jaw. Right: ultrasound catheter mounted on the top of the moving jaw.

7. Ultrasound performance experiments

Experiments are performed to find out what the capacities of the selected Eagle Eye Platinum catheter are, when this transducer is used in a completely different environment than its original application field.

7.1. Experiment introduction

The Eagle Eye Platinum catheter transducer is designed for use in blood vessels. The catheter is able to provide cross-sectional images of the vessel walls. When integrated, the environment of the catheter is different.

First of all, in the blood vessel the catheter is permanently surrounded by blood, enabling a perfect acoustic coupling to the vessel wall. During laparoscopic surgery, when the ultrasonic scalpel is used, the ultrasound transducer will directly touch the tissue and be surrounded by gasses, used to insufflate the abdomen.

Furthermore, the catheter is normally fed into the vessels and thus does not have any covering as it will encounter when integrated in the ultrasonic scalpel.

Lastly, due to the use of the ultrasonic scalpel, the temperature of the tissue increases, which might influence the imaging performance.

In this experiment, the imaging performance of the Eagle Eye Platinum transducer is assessed in an environment that simulates the surgical environment where the ultrasonic scalpel is used. Additionally, the basic influence of integration in the ultrasonic scalpel, due to covering of the catheter is tested.

7.2. Methods

The Philips Eagle Eye Platinum catheter is used in this experiment, coupled to the associated console. A field of view of 14 mm diameter is chosen. No further specific settings have been applied.

As a test specimen a tissue phantom has been used that was produced within the department of BioMechanical Engineering of Delft University of Technology. This phantom has approximately corresponding echogenic properties as human liver tissue. Two pieces of tissue phantom have been used in this stage.

Silicone lute pieces have been inserted in the tissue phantom, to find out whether the ultrasound catheter is able to record the ultrasound reflections from this surface. The lute was positioned at 5 mm from the surface of the phantom in Phantom 1, and at 2 mm from the surface in Phantom 2.

In the prototype, described in Section 6.3, the transducer is attached to the moving jaw by a silicon tube. To simulate this attachment, the aforementioned experiments are repeated while the transducer is covered with a silicone tube.

To have a reference regarding the acoustic transfer of the ultrasound waves into the tissue phantom, also one image is recorded with both the phantom and the catheter submerged in water. The water ensures acoustic coupling, as is the case in the catheter’s original application field; a blood vessel.

Table 5 shows an overview of the different experimental set-ups.

Figure 26 presents pictures of the experimental set-up and Figure 27 shows a schematic cross-sectional overview.

	Phantom 1		**Phantom 2**	
	Reference	*Lute at 5 mm*	*Reference*	*Lute at 2 mm*
Bare catheter	Image01	Image02	Image03	Image04
Catheter in tube	Image05	Image06	Image07	Image08
Bare catheter submerged	Image09	-	-	-

Table 5: Overview of experiment variables and recorded images in the Ultrasound Performance Experiments.

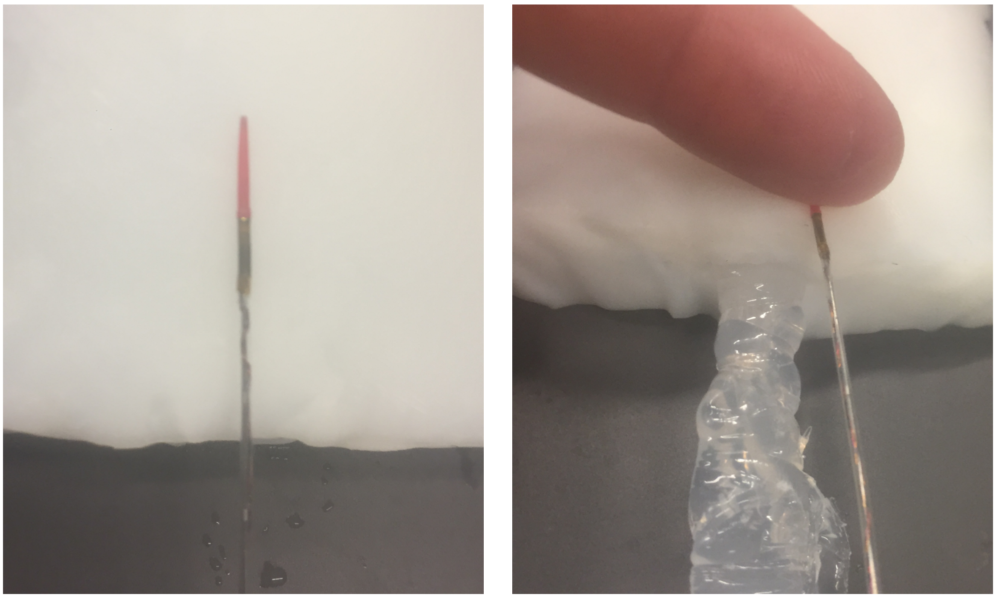


Figure 26: Images of the experimental set-up of the ultrasound performance experiments. Left: bare Eagle Eye Platinum catheter at the tissue phantom. Right: bare Eagle Eye Platinum catheter at the tissue phantom with silicone lute insertion.

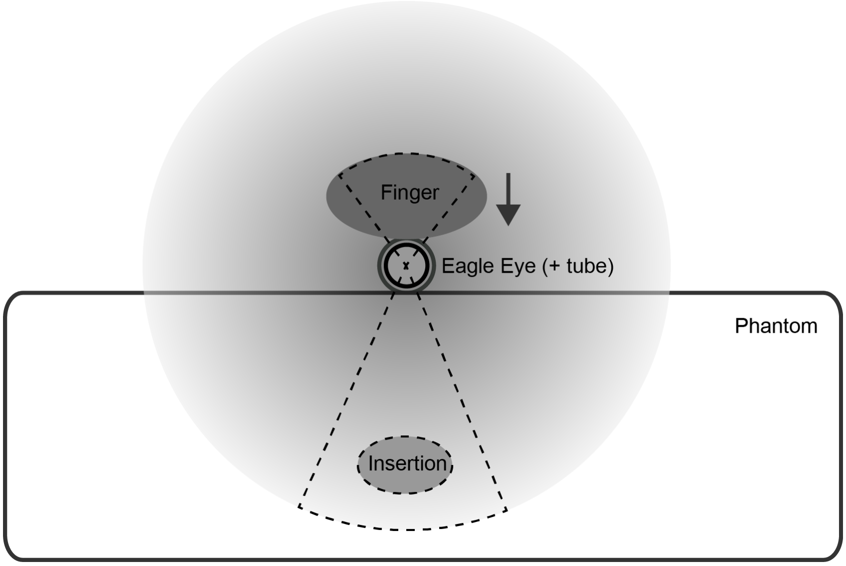


Figure 27: Schematic cross-section of experimental set-up. The shaded area is the field of view of the ultrasound catheter. Reflections are received from the dotted encircled areas.

7.3. Results

The experiments show that the reflection signal from the tissue phantom is only slightly reduced when no liquid is present that facilitates acoustic coupling. The image recorded with the phantom and catheter submerged in water, shows a wide view of the tissue phantom (2). The images recorded in open air only show the part of the phantom that is in direct contact with the ultrasound catheter. This image part does not differ a lot from the same area in the image recorded with the submerged catheter (2*) but misses some detailed structures (see Figure 28).

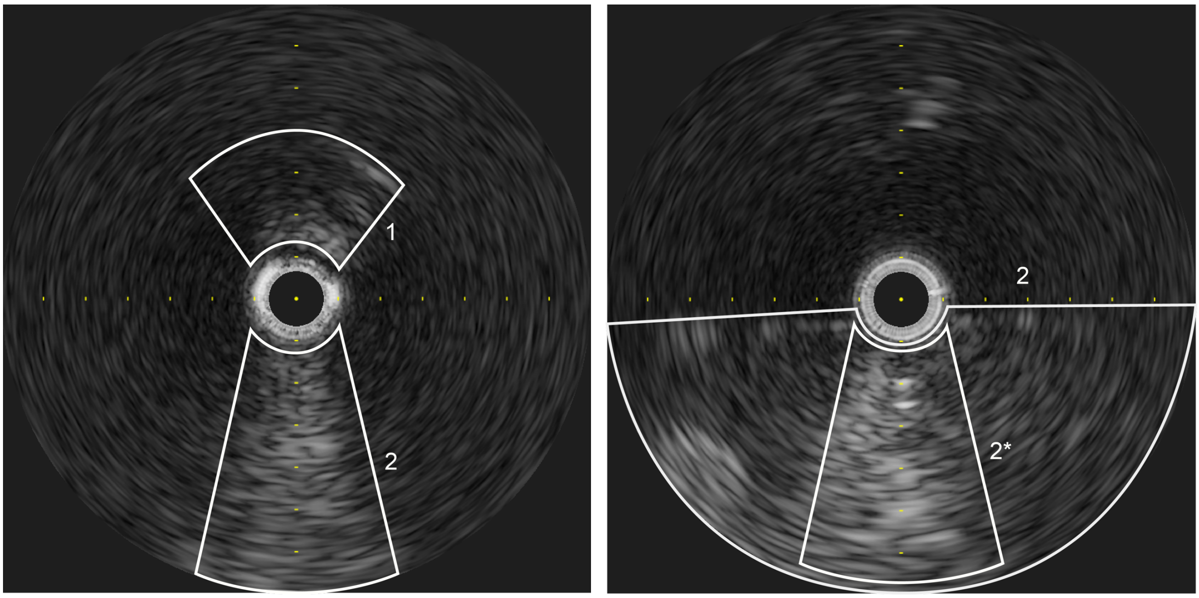


Figure 28: Images recorded with bare catheter on phantom 1 (Left) and phantom 1 while submerged in water (Right). Annotated areas: 1) finger holding catheter on phantom. 2) phantom. 2) phantom in direct contact with catheter.*

It has been found that the Eagle Eye Platinum catheter without the silicon tube is able to record images of the tissue phantom. Furthermore, the lute insertions could be detected at both depths of 2 mm and 5 mm. See Figure 29 for the recorded images of the phantom (2) and lute insertion at 5 mm (3).

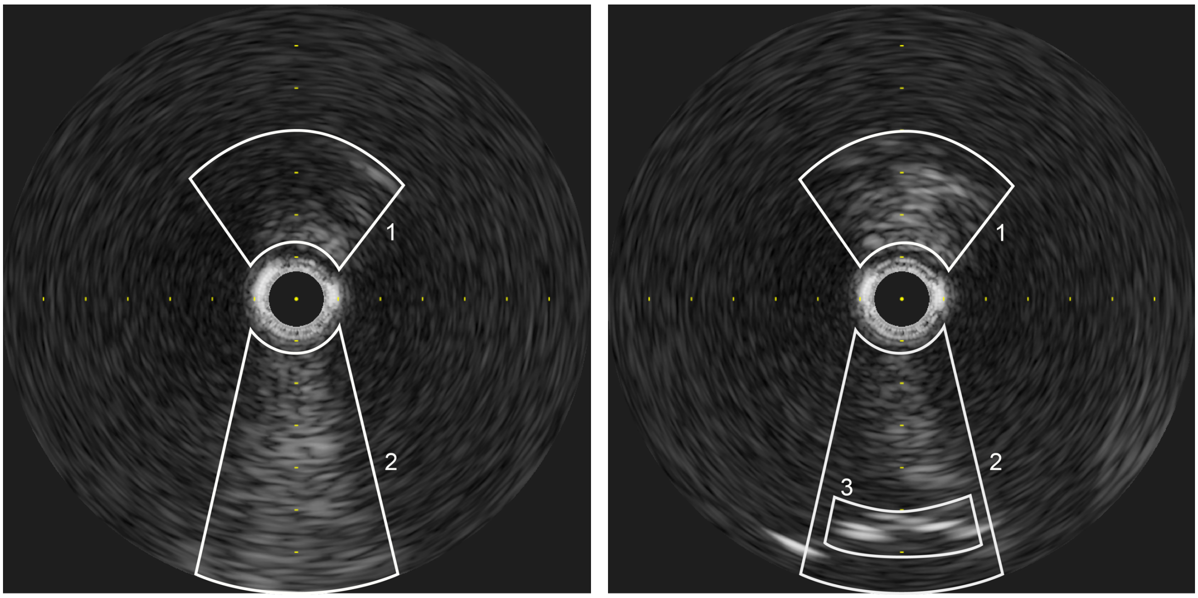


Figure 29: Images recorded with bare catheter on phantom 1 (Left) and phantom 1 with silicone lute insertion at 5 mm from the surface (Right). Annotated areas: 1) finger holding catheter on phantom. 2) phantom. 3) silicone lute insertion at 5 mm depth.

Also difficulties and points of attention are documented as results of these experiments.

- Applying force to the catheter on top of the tissue phantom was required to receive signal and recording an image.

When the silicone tube is covering the Eagle Eye Platinum catheter, the image quality lowers and recording of the tissue phantom is difficult. However, the lute insertions can still be discovered in the ultrasound images, at both depths of 2 mm and 5 mm. See Figure 30 for the recorded images of the phantom (2) and lute insertion at 2mm (3), with the catheter covered by a silicon tube (T).

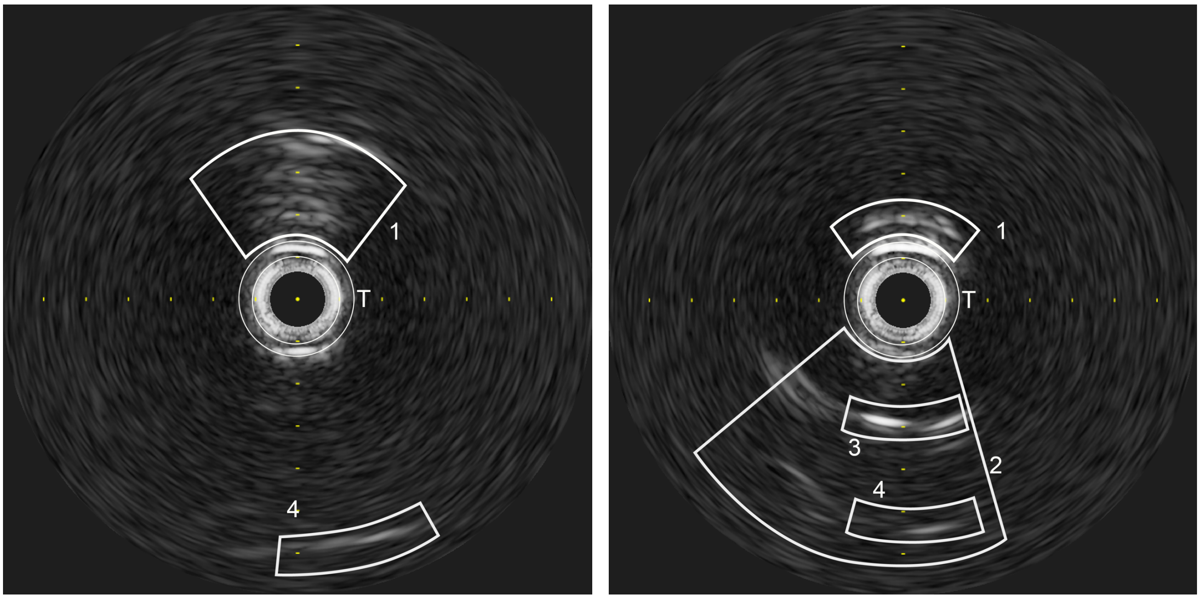


Figure 30: Images recorded with catheter in silicone tube on phantom 2 (Left) and phantom 2 with silicone lute insertion at 2 mm from the surface (Right). Annotated areas: T) reflections of the silicone tube. 1) finger holding catheter on phantom. 2) phantom. 3) silicone lute insertion at 2 mm depth. 4) bottom of phantom.

An overview of all recorded images can be found in Appendix 1.

7.4. Discussion

The experiments show that the Eagle Eye Platinum catheter is able to detect an insertion inside a tissue phantom. Without the perfect acoustic coupling to the tissue through the blood, in the catheter's regular application area, the phantom is visible and the silicone insertions are still clearly recognized in the images.
The silicone tube, covering the ultrasound transducer when it is integrated in the ultrasonic scalpel, influences the images significantly. The tissue phantom is hardly visible on the ultrasound images. However, the silicone insertions in the phantom can still be recognized.

The tissue phantom is recorded on the image (without the silicone tube covering the transducer), but pressure on the ultrasound transducer is required to be able to visualize the phantom. This seems to show that acoustic coupling is a key factor for proper imaging. Comparing the images that are recorded submerged in water with the images recorded in open air, it can be seen that sufficient acoustic coupling gives a better image quality. Especially smaller structures are better imaged with sufficient acoustic coupling. It is important to facilitate acoustic coupling during the integration of the ultrasound transducer into the ultrasonic scalpel. Pressure needs to be applied to record acceptable images or a liquid coupling medium needs to be present for more detailed imaging.

The silicone tube, covering the transducer, introduces problems based on signal strength. The silicone rubber already absorbs a part of the signal before it enters the tissue. Besides, due to the thickness of the rubber of 0.3 mm, the ultrasound waves reflect between the two borders. Multiple reflections are received at the ultrasound transducer, see Figure 31. These extra reflections are imaged as wider rings, due to the longer time of flight of these ultrasound pulses. This phenomenon excludes part of the image, since only reverberations are visible there, and reduces the signal that is transferred to the tissue even more.

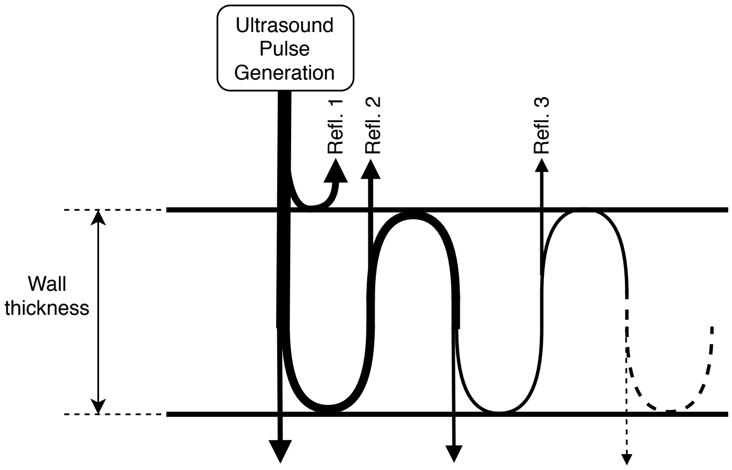


Figure 31: Visual explanation of the ultrasound wave reverberations in the wall of the silicone tube. Three reflections (or more) are received.

To prevent reverberation of the ultrasound waves in the wall of the silicone attachment material, a small wall thickness needs to be selected. When the wall thickness is reduced to a thickness smaller than the ultrasonic wavelength, the reverberation issues decrease.
Another solution is to abandon the concept of a sterile barrier to prevent contact between the tissue and the catheter, making it reusable. When contact is allowed, the silicone tube is not required since other methods can be developed to mount the catheter. For example, use of a guidewire as a rail seems to be a feasible option. Further investigation on this subjected is described in Chapter 9.

Concluding, it can be said that the Eagle Eye Platinum ultrasound catheter is able to provide useful images of tissue, even with reduced acoustic coupling due to the absence of coupling fluids. Also when a silicone rubber tube covers the ultrasound transducer, valuable information can be derived from the recorded images. However, the image quality is reduced due to the silicone cover of the transducer.

8. Integration experiments

The next step is to find out how integration of the catheter into the ultrasonic scalpel influences the performance of the ultrasound transducer.

8.1. Experiment introduction

In addition to the experiments in Chapter 7, a full integration of the ultrasound catheter into the ultrasonic scalpel is performed. The laparoscopic ultrasonic scalpel adds several other factors to the capabilities of the ultrasound transducer.

This experiment is performed to find out how the mounting of the catheter could be performed the best. Secondly, the practical usability of the integrated instrument will be tested. Since the Eagle Eye Platinum ultrasound catheter provides a circular cross-sectional image, both the area in between the blade and jaw and the area above and besides the jaw can be imaged. For a surgeon, this could provide useful information about the distance the instrument has to critical structures.

8.2. Methods

In this experiment the Eagle Eye Platinum catheter is integrated into the LOTUS Torsion ultrasonic scalpel. Again, a field of view of 14 mm is set for the Eagle Eye Platinum ultrasound catheter. No further specific settings have been applied.

Images without a test specimen have been recorded with the shear closed and opened (blade at 5 mm) submerged in water. Without the water, no acoustic coupling would be achieved and the blade would be invisible. The catheter is both mounted on top of the moving jaw and at the bottom of the jaw, see Figure 33 for a schematic overview.

For images with test specimens, the same test specimens as in the previous experiment have been used. However, since a different shape was required, a new part of the phantom (Phantom 3) has been used for the new images.

Also in this experiment silicone lute pieces have been inserted in the tissue phantom to assess the ability of the ultrasound transducer to detect the ultrasound reflections. The silicon lute pieces were inserted in Phantom 3 at a depth of approximately 4 mm.

The prototype as described in Section 6.3 has been used to mount the ultrasound catheter on the ultrasonic scalpel.

Two configurations of the ultrasonic scalpel, relative to the phantom have been assessed: grasped and tip-touch. See Figure 32 for photos of these configurations.

Table 6 shows an overview of the different experimental set-ups.

	No Phantom	**Phantom 3**	
		Reference	*Lute at 4 mm*
Blade open	Image10	-	-
Blade closed	Image11	-	-
Grasped	-	Image12	Image13
Tip Touch	-	Image14	Image15

Table 6: Overview of experiment variables and recorded images in the Integration Experiments.

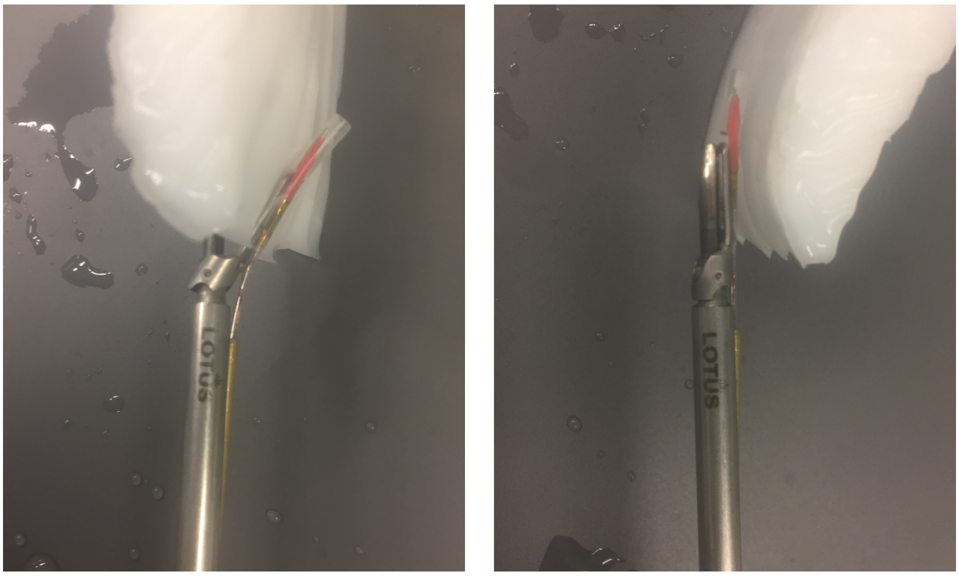
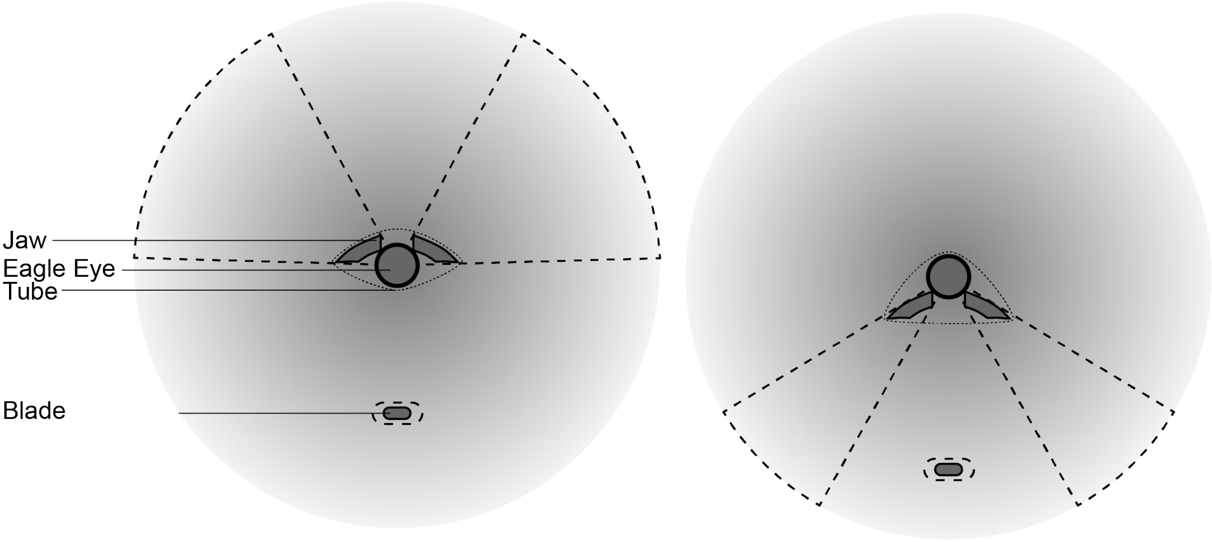


Figure 32: Images of the experimental set-up of the integration experiments. Left: tissue phantom grasped with ultrasonic scalpel. Right: tissue phantom tip-touched with ultrasonic scalpel.



Bottom configuration

Top configuration

Figure 33: Schematic cross-section of experimental set-up with the ultrasound catheter mounted at the bottom and at the top of the jaw. The shaded area is the field of view of the ultrasound catheter. Reflections are received from the dotted encircled areas.

8.3. Results

The first experiments that are performed prove that in integrated configuration, the Eagle Eye Platinum ultrasound catheter is able to provide images of the grasped and surrounding tissues. The ultrasonic scalpel parts do block a part of the field of view (Figure 34, annotation 1). Reverberations between the transducer and the strong reflecting jaw is visible. However, the interesting areas are still in sight. When the catheter is mounted on top of the moving jaw, the blade is visible through the “window” in the jaw and a large field of view to the top and sideward remains unaffected (Figure 34, Right). With the catheter mounted at the bottom of the jaw, inside the shear, the blade is visible and the field of view of the grasped tissue is wider, but the general sideward view is limited (Figure 34, Left), due to the wider reverberations of the jaw.

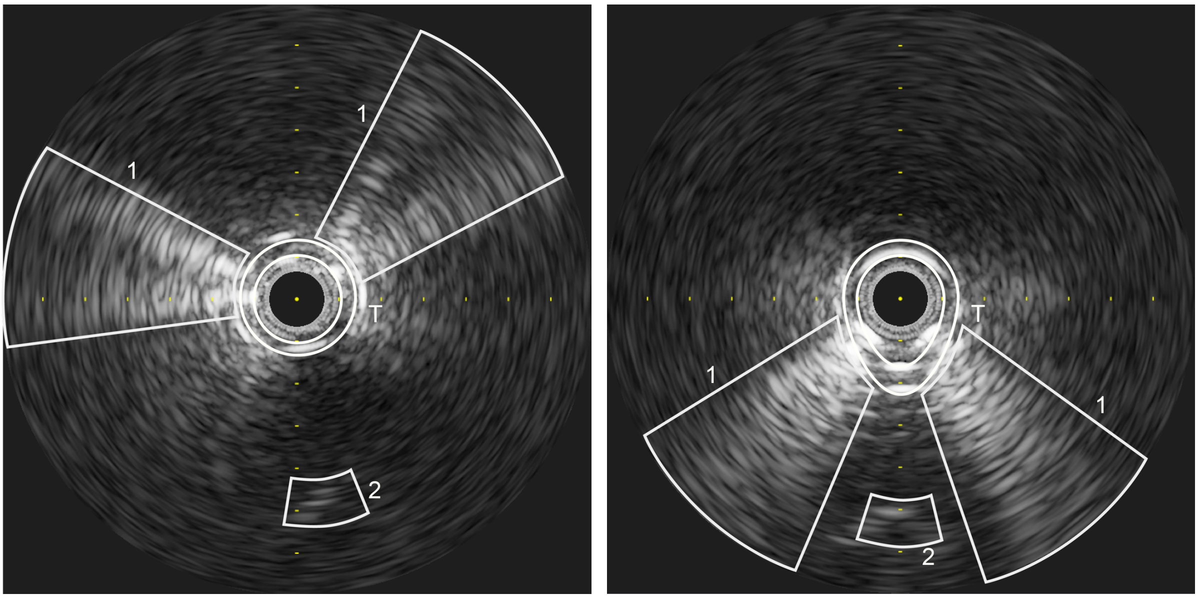


Figure 34: Images recorded with integrated catheter mounted on the bottom of the moving jaw (Left) and on top of the moving jaw (Right). Annotated areas: T) reflections of the silicone tube. 1) reverberations of steel sides of the moving jaw. 2) ultrasonic scalpel blade at 5 mm from the moving jaw.

Besides the images a specific insight has been found during these first experiments.

- The bottom mount of the catheter is possible, but not desirable. The catheter needs to be fed through a hole in the moving jaw. This induces stress in the stiffer parts of the catheter and continuous tension on the cables.

Based on the facts that the top mount of the catheter provides a wider field of view, especially in the sideward direction, and that the top mount avoids tension on the transducer and cables, the next experiments are carried out in the top-mount configuration.

When the phantom is grasped in between the ultrasonic blade and the moving jaw, the phantom is visible on the image (Figure 35, annotation 3). Also the blade is visible (Figure 35, annotation 2). Due to damage to the catheter, an image in which the phantom with inserted silicone lute is grasped could not be recorded. However, based on the results of the previous experiment series (Section 7.3) it could be assumed that the silicone lute insertion can be detected in a grasped phantom. On top of the catheter, reverberation artefacts from the silicone tube are visible.

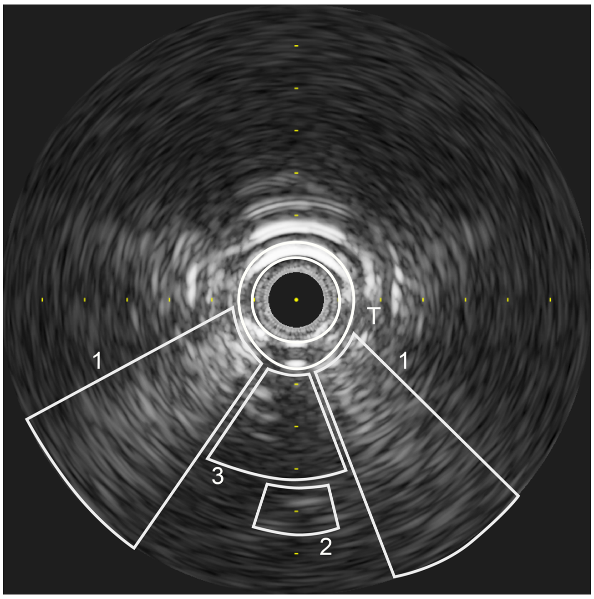


Figure 35: Images recorded with integrated catheter mounted on top of the moving jaw with phantom grasped between the ultrasonic scalpel blade and the moving jaw. Annotated areas: T) reflections of the silicone tube. 1) reverberations of steel sides of the moving jaw. 2) ultrasonic scalpel blade at 5 mm from the moving jaw. 3) phantom.

From the experiments with the integrated Eagle Eye Platinum catheter insight have been derived, besides the images.

- The mounting of the catheter with the silicone tube covers the jaw from which the regular cover is removed. The grasping experiments have shown that the silicone tube reduces the grip on the tissue phantom, making it difficult to grasp the phantom firmly.

In the tip-touch configuration (see Figure 32, Right) the phantom is visible (Figure 36, annotation 2). However, the signal strength is lower than when the phantom is grasped. The image with the phantom and silicone lute insertion could not be recorded, due to the damaged catheter. Based on the experiment in Chapter 7, it can be assumed that the silicone lute insertion can be detected in the tip-touch configuration.

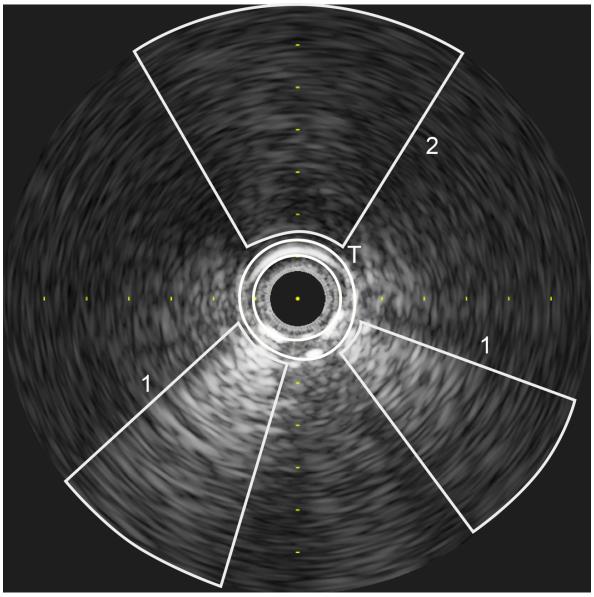


Figure 36: Images recorded with integrated catheter mounted on top of the moving jaw with phantom in the tip-touch configuration. Annotated areas: T) reflections of the silicone tube. 1) reverberations of steel sides of the moving jaw. 2) phantom.

An overview of all recorded images can be found in Appendix 2

8.4. Discussion

The experiments have shown that the integration influences the ultrasound performance, as was predicted. Due to reflection surfaces of the jaw and blade, extra reverberation noise is added to the image, limiting the field of view. The reverberation noise is caused by continuous reflection of the ultrasound waves between the strong reflective steel surfaces and the transducer. However, the field of view does still cover the areas of interest, enabling the integrated ultrasound probe to deliver valuable information about the grasped tissue and surrounding tissues to the surgeon.

In these experiments the mounting of the catheter on top of the jaw was used. Based on the first test, it was shown that this configuration leaves the best field of view to the top and sideward, while the grasped tissue can still be assessed. With the catheter mounted at the bottom of the jaw, within the shears of the scalpel, the field of view sideward is limited. This is caused by the bended shape of the jaw that covers the sideward line of sight.

The bottom mounting of the catheter has another problem: the catheter needs to be fed through a hole in the moving jaw. This requires bending of the catheter, that might get damaged after a few movements of the blade due to tension on the transducer and cable. Furthermore, inserting the catheter in the scalpel is practically more difficult when passing through the hole is required, due to the curvy path.

In order to improve the performance of the integrated ultrasound catheter but prevent damage and a limitation of the field of view it is recommended to redesign the moving jaw. When a wider window is incorporated in the jaw, the catheter will exactly fit in this window. In this way the shadows of the ultrasonic scalpel jaw in the ultrasound image can be minimized, leaving most of the field of view for useful imaging. Furthermore, continuous contact between the catheter and the jaw leading to friction can be prevented, minimizing the chance of transducer damage. The above discussed problems will be analysed and an improved prototype will be presented in Chapter 9.

In the tip-touch configuration, where the tissue is touched by the top of the moving jaw, the signal strength was lower than in the grasped configuration. As was already found in the previous experiments, the acoustic coupling is a critical aspect which is influenced by the pressure between the ultrasound transducer and the phantom. In the tip-touch configuration, the pressure on the tissue is lower than in the grasped configuration. This leads to lower signal strength and more difficulties in gathering useful information from the images recorded in the tip-touch configuration.

The fragility of the Eagle Eye Platinum ultrasound catheter has become clear. The catheter was getting damaged during the integration experiments. Some images could therefore not be recorded. The continuous contact between the steel jaw and the catheter and the movement of the jaw are probable causes. Reuse of an Eagle Eye Platinum ultrasound catheter does not seem to be realistic.

It can be concluded that the integration of the Eagle Eye Platinum ultrasound catheter into the ultrasonic scalpel can lead to valuable information for a surgeon. Distances to tumours can be measured and critical structures can be detected to prevent damage of improve the orientation during the surgical procedure. However, several aspects need improvements in the next steps towards a smart ultrasonic scalpel. The acoustic coupling needs to be improved and a mounting mechanism that influences the ultrasound performance less should be designed. In Chapter 9, some improvement proposals are described.

9. Prototype improvement

From the first experiment series described in the previous chapters, several problems could be derived. Solving these problems could lead to an improved prototype, providing better image quality and field of view. This will make it easier for the surgeon to retrieve useful information from the ultrasound images.

The problems that were discussed after the experiments can be summarized into the following main issues:

- Acoustic coupling
- Silicone tube reverberations

All these issues will be described in the following sections. Solutions to the problems are proposed and the recommended improvements are presented. An improved design is developed that will be shown in Section 9.3. The improved design will be discussed in Section 9.4.

9.1. Acoustic coupling

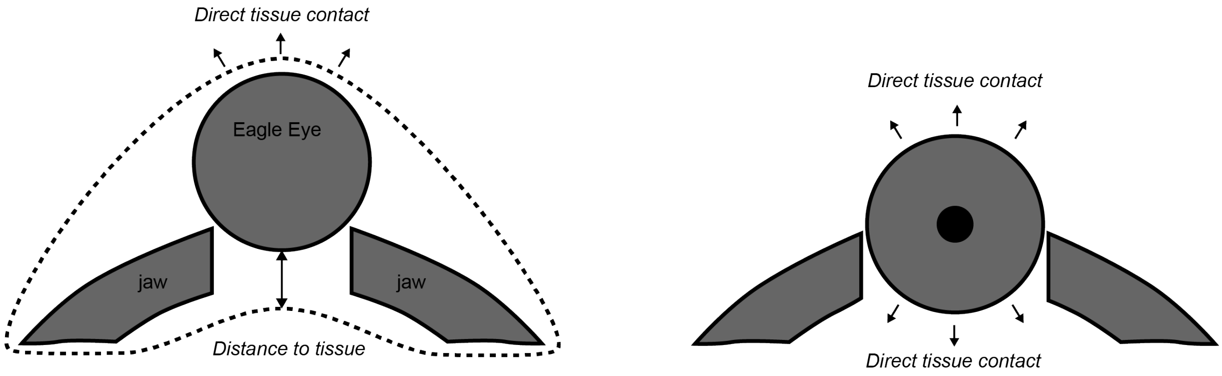
The acoustic coupling of the Eagle Eye Platinum ultrasound catheter is less when it is integrated in the ultrasonic scalpel than in its original application area, vascular ultrasonography. The lack of blood or liquid around the transducer leads to a decreased acoustic coupling to the tissue. However, the areas of interest are still visible and distortions can be detected.
Increasing the acoustic coupling would increase the image quality and thereby the effectiveness of the information that is provided to the surgeon.

Several solutions are proposed that will increase the acoustic coupling. These solutions are described in the following sections.

Redesign of jaw

A redesign of the jaw could lead to better acoustic coupling when the catheter can be located closer to the tissue. Direct contact would logically lead to the best acoustic coupling and when pressure could be applied between the transducer and the tissue, this might increase the coupling even further.
In the current design and the performed experiments, the catheter can be located on top of or at the bottom of the moving jaw. Due to fragility of the catheter and the better field of view, the top configuration was selected during the final stage of the experiments. However, the distance between the grasped tissue and the transducer was thereby increased.

A redesign of the moving jaw could provide the possibility to locate the ultrasound catheter in the middle of the jaw, by widening the ‘window’ in the jaw. Both the grasped tissue as the tip-touched tissue can be in direct contact with the ultrasound transducer. See Figure 37 for a schematic overview of the advantages that a new jaw design might bring.
A disadvantage of jaw redesign is that the ultrasonic scalpel instrument will have to be changed. This will increase the process difficulties and costs for the development of a smart ultrasonic scalpel.



Original jaw New designed jaw

Figure 37: Front view of the original jaw and a new designed jaw. The wider window allows the Eagle Eye Platinum ultrasound catheter to directly touch the tissue on top and at the bottom of the jaw.

Coupling gel/liquid

From the traditional abdominal ultrasonography, the concept of coupling gel could be used. Introducing an acoustic coupling medium between the transducer and the tissue will definitely increase the acoustic coupling and lead to better image quality.

However, it is unknown what the implications of coupling gel in an intraoperative area are. The sterility of the gel must be guaranteed and possible side-effects of coupling gel/liquid touching the organs should be investigated. Furthermore, a system needs to be designed to introduce this coupling gel/liquid at the tip of the ultrasonic scalpel.

Recommended solution

The use of a coupling gel or -liquid was not assumed to be feasible in the intraoperative laparoscopic application area, due to difficulties with direct in-body tissue contact and sterility. A redesign of the jaw is being proposed and will be explained in this Section 9.3.

9.2. Silicone tube attenuation & reverberations

During the experiments, it was found that the silicone tube that was used for mounting the catheter on the moving jaw of the scalpel led to attenuation and reflections of the ultrasonic waves. The attenuation reduces the ultrasound signal that reaches the tissue and thereby increases the difficulty of recognizing tissue characteristics.
The reflections within the silicone tube distort the image even more and make a part of the image unusable. Due to the thickness of the tube wall, the ultrasound waves are reflected back and forth between the borders. These reverberation artefacts show up in the image as rings, since the ultrasound waves travel longer.
The tube mount of the catheter was selected to create a sterile barrier around the catheter, making it available for reuse in multiple procedures.

Multiple solutions are proposed to decrease the attenuation- and reflection problems that are introduced by the silicon tube. These are described in the sections below.

Silicone tube adjustment

By decreasing the wall thickness of the silicon tube, the internal reflections can be minimized. Optimally, the thickness should be less than one wavelength of the ultrasound waves. This would prevent reverberation of the ultrasound waves within the silicone layer.

Furthermore, the composition of the material could influence the acoustic impedance. Specific focus on the composition might provide a better matching acoustic impedance to the tissue, leading to less reflections at the surface.

Changing the composition should be possible. However, thin silicone tubes in these dimensions are not commercially available. Furthermore, these thin tubes will be very fragile and damage easily, leading to a broken sterile barrier. It would then be impossible to reuse the catheter in multiple procedures.

New mounting mechanism

The use of a new mounting mechanism in which the silicone tube is not required would solve the problem completely. During regular use in vascular procedures, a guidewire is used to feed the catheter on. This guidewire could also be used as a guiding rail in the ultrasonic scalpel. No covering material around the ultrasound transducer will be present, leading to less signal loss.

The main disadvantage of this solution is the lack of a sterile barrier. The catheter will be in direct contact with the tissue and can therefore not be reused. This will increase the costs per procedure.

Recommended solution

The issues with the silicone tube (attenuation of signal and reverberations) have multiple solutions. Both the selection of a new silicon tube and a new mounting mechanism do not have significant disadvantages that influence the usability or performance of the instrument. Both solutions seem to be feasible to solve the problems.

The thin silicone tube and silicone composition are not further investigated in this project. This requires specific expertise on material fabrication, since silicone in such small thicknesses is not commercially available and should be specifically manufactured for this project.
The solution that is further elaborated is a new design of the jaw, that facilitates mounting of the catheter without the use of a silicone tube. This design is presented in Section 9.3.

9.3. New design of jaw

The jaw of the ultrasonic scalpel has been used in its original form during the experimental phase. Since adjustments to the design of the jaw could improve the performance of the integrated ultrasound catheter, a new design is proposed. This design is based on the integration of an Eagle Eye Platinum ultrasound catheter.

The original jaw is manufactured from a 5.0 mm diameter tube with wall thickness 0.40 mm. This basis is kept the same in the adjusted design to make sure that the manufacturability is not strongly influenced.

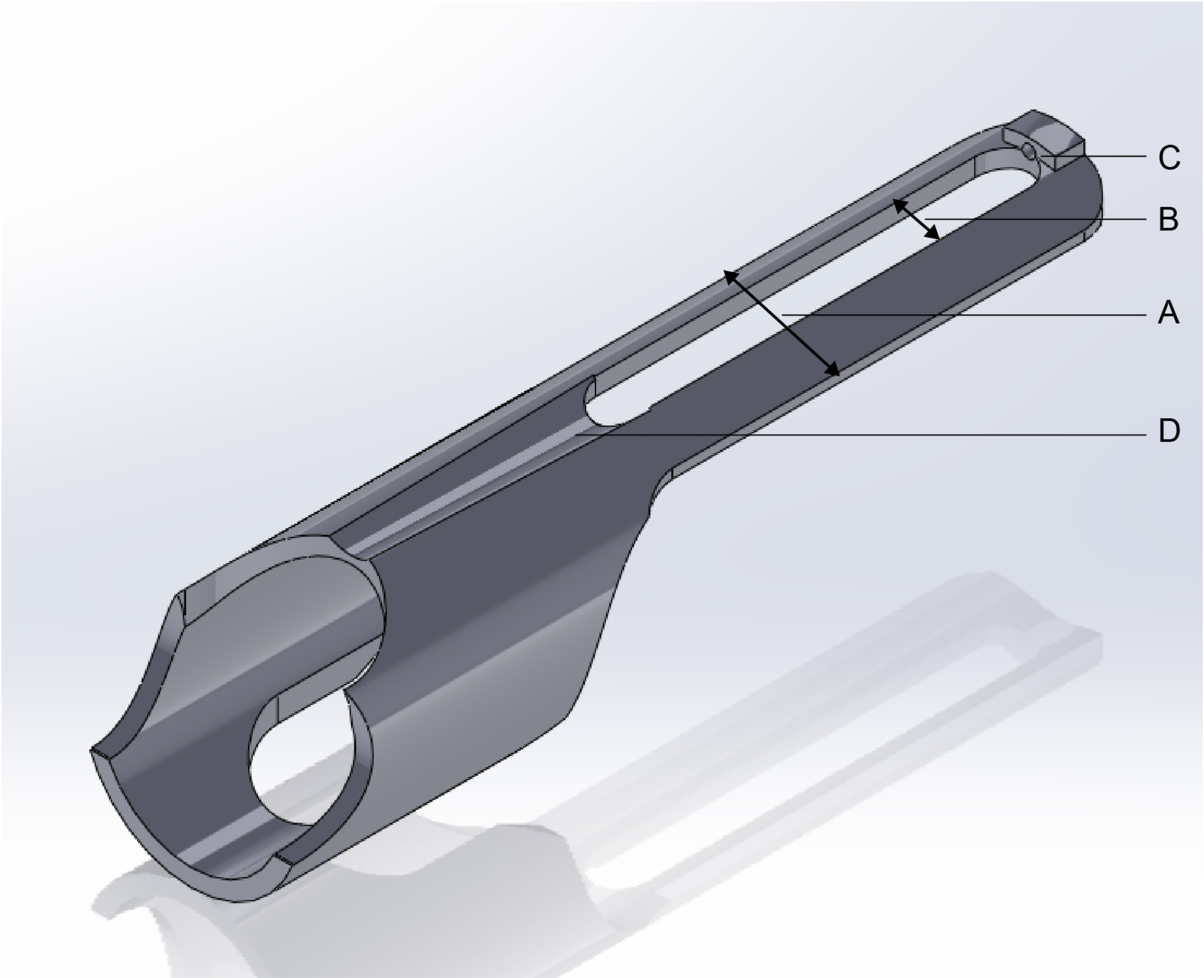


Figure 38: Adjusted design of the moving jaw of the ultrasonic scalpel. Annotated adjustments: A) larger width of the tip. B) larger width of the 'window'. C) hole in tip as placeholder for guidewire. D) cut-out in top surface for smooth path of catheter.

In the adjusted design, the tip has a larger width (Figure 38, annotation A). The original width was 2.8 mm and in the adjusted design a width of 3.2 mm is proposed. This gives room for a wider 'window'.

The 'window' in the jaw has a larger width. The original width was 1 mm and in the adjusted design a width of 1.25 mm is proposed (see Figure 38, annotation B). This enables the catheter to be located on the jaw, without continuously touching the steel and thereby preventing damage to the catheter. Furthermore, direct contact between the grasped tissue and the transducer is facilitated due to a closer attachment of the ultrasound catheter.

Sideward imaging is still possible, since the ultrasound elements left and right are not blocked by the jaw. This is valuable for tumour-free margin measurement during surgical tumour resections.

A hole is designed at the tip of the jaw as a placeholder for the guidewire that is used to mount the catheter (see Figure 38, annotation C and Figure 39). A placeholder is mounted to facilitate the attachment of the guidewire at the top surface of the jaw. Issues concerning signal attenuation and reverberation due to the silicone tube covering the transducer are now avoided. The guidewire should be positioned during fabrication of the jaw. By clamping, the guidewire can be fixated on its desired position.

A cut-out is made out of the top surface of the jaw (see Figure 38, annotation D). This facilitates a fluent path for the guidewire and catheter cable towards the tube along the scalpel shaft. The further configuration of the catheter cable is left out of the scope of this research. Both an integrated path through the shaft of the ultrasonic scalpel and an add-on tube attached to the shaft are possible. For the working principle and performance of the 'smart ultrasonic scalpel' the path of the cable is not relevant.

On the following pages, images of the adjusted design are presented.

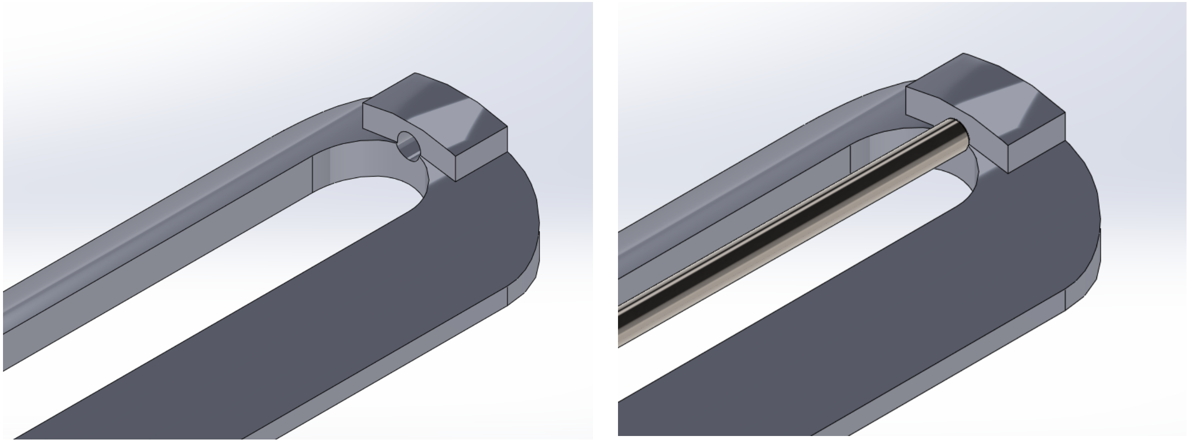


Figure 39: Hole in the tip of the moving jaw as a placeholder for the guidewire. Left: jaw without guidewire. Right: jaw with guidewire.

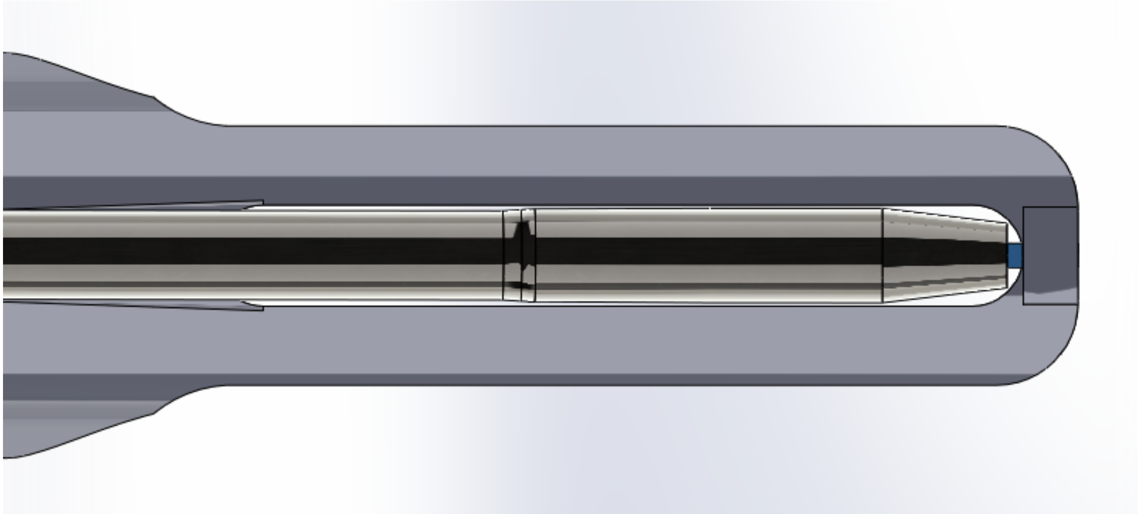


Figure 40: Top view of the adjusted jaw with integrated Eagle Eye Platinum ST catheter, mounted on a guidewire.

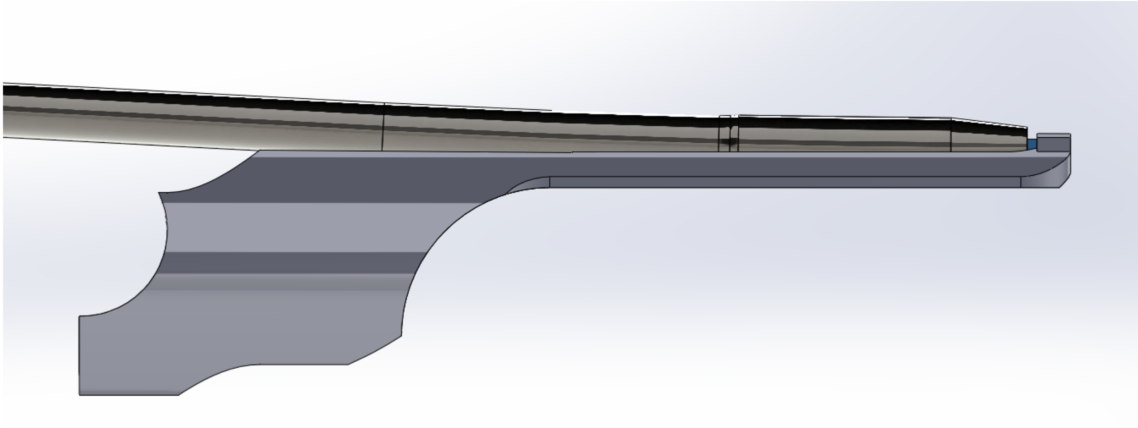


Figure 41: Side view of the adjusted jaw with integrated Eagle Eye Platinum ST catheter, mounted on a guidewire.

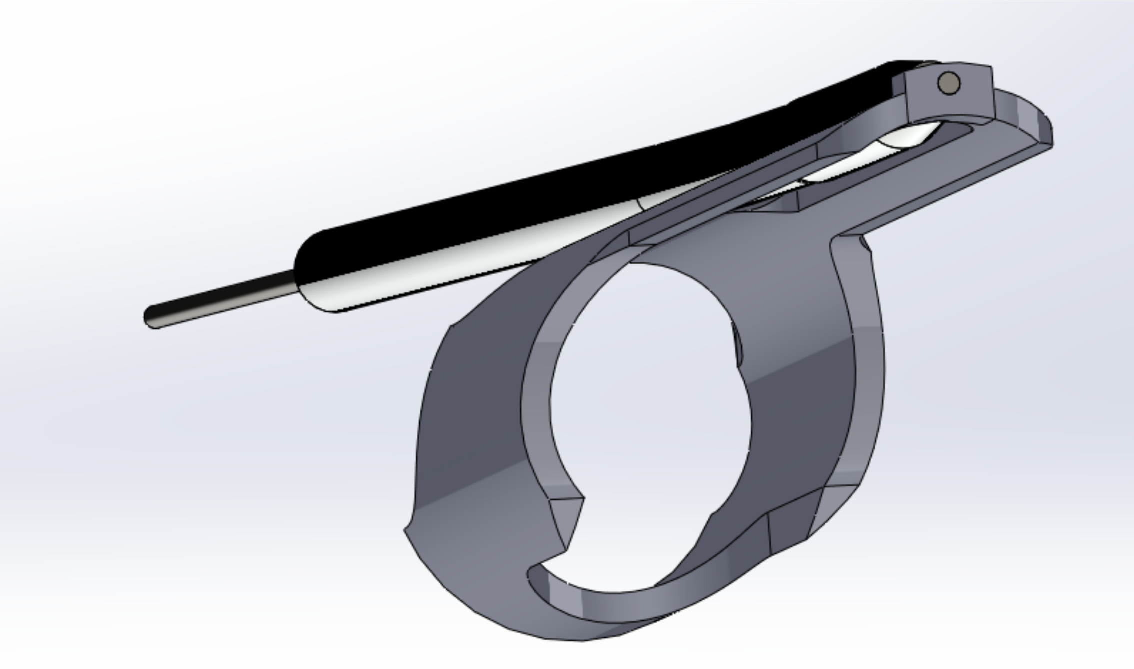


Figure 42: This bottom view shows that direct contact between the ultrasound transducer and the grasped tissue is facilitated.

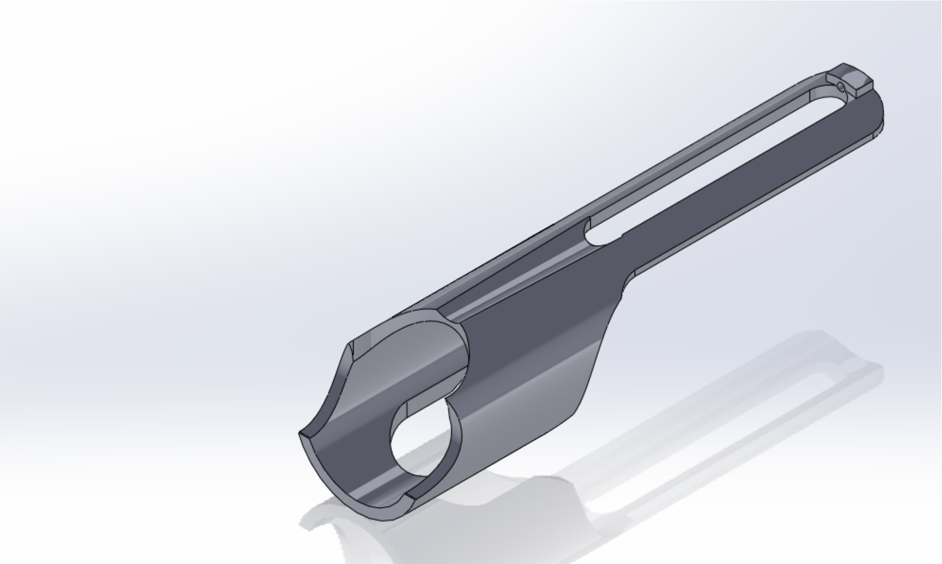


Figure 43: Adjusted jaw of the ultrasonic scalpel.

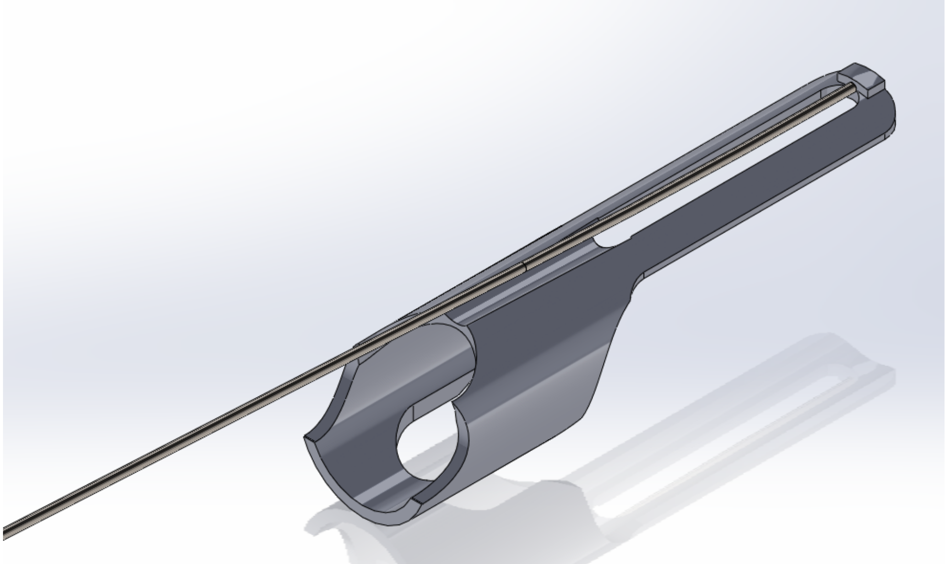


Figure 44: Adjusted jaw with guidewire to mount Eagle Eye Platinum ST catheter.

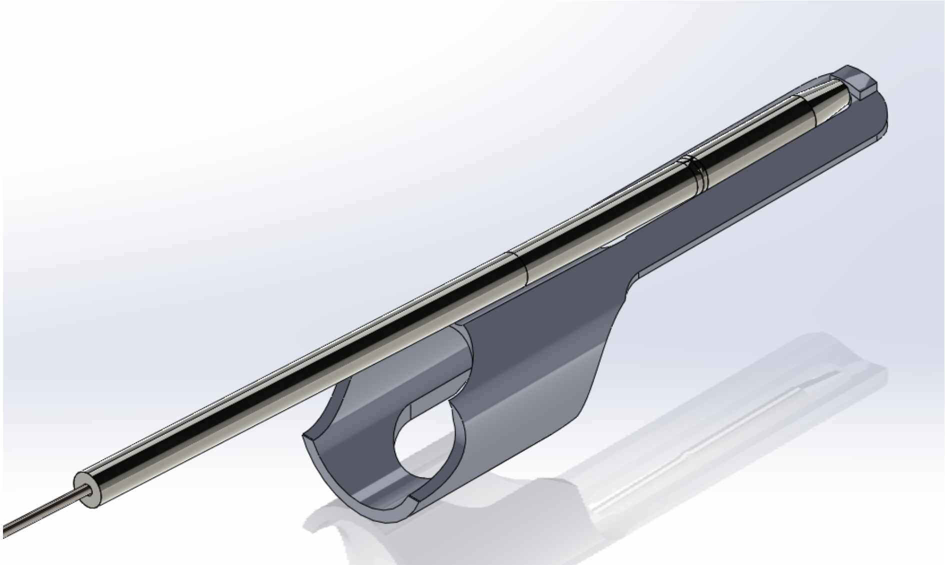


Figure 45: Adjusted jaw with Eagle Eye Platinum ST mounted on a guidewire.

9.4. Discussion

The design that was proposed in the previous section solves the problems that came up during the experimental phase. It is expected that the new design of the jaw will improve the performance of the integrated Eagle Eye Platinum ultrasound catheter. The acoustic coupling is expected to be better, due to direct contact with the tissue. This will increase the image quality and usability of the information.

However, it is important to also discuss the possible drawbacks and other points of attention of the new jaw design. These will be discussed below.

Ultrasonic scalpel functionality

The jaw is a part of the ultrasonic scalpel and the changed jaw could influence the functioning of the ultrasonic scalpel.

The basic function of the jaw, grasping the tissue is not expected to change. The new jaw can be manufactured from the same tube size as the original jaw and has the same length. The wider surface could possibly increase the grip on the tissue. It is not expected to negatively influence the grasping functionality.

The ultrasonic scalpel is activated at its natural frequency and works in resonance. A change of the design might also change this frequency. However, since the jaw is located on a separate tube and is thus no part of the vibrating system, the natural frequency of the ultrasonic scalpel will not be affected.

Alternative ultrasound transducers

The new design of the jaw is currently focussed on the Eagle Eye Platinum ultrasound catheter. This catheter was used during the experimental phase. The results were promising and therefore the prototype improvement is based on this transducer. However, more companies offer ultrasound catheters.

Boston Scientific manufactures two ultrasound catheters. The Opticross ultrasound catheter is almost the same as the Philips Eagle Eye Platinum catheter but works at a higher frequency of 60 MHz and has a smaller penetration depth. The iLab ultrasound catheter is a bit larger (diameter 2.8 mm) but works at a frequency of 9 MHz, resulting in a penetration depth of 6 cm and an imaging diameter of 12 cm. [66], [70] Especially the last mentioned catheter, Boston Scientific iLab, could be advantageous due to the larger imaging field. However, the integration needs significant design changes to the ultrasonic scalpel, due to the larger dimensions of the catheter, compared to the Philips Eagle Eye Platinum catheter.

In the next steps towards the development of a ‘smart surgical instrument’, these alternative ultrasound transducers can also be assessed.

10. Discussion & recommendations

In this chapter the conclusions that are drawn from this thesis, as well as the limitations that outline these conclusions will be discussed.
Additionally, several recommendations for further research will be presented based on the findings obtained from this current research project.

10.1. Overall discussion

The newly developed knowledge and design in this thesis research fill a gap in existing scientific research on several topics. These topics are discussed below.

Within this research project, a thorough analysis of the separate techniques of the ultrasonic scalpel and ultrasonography has been performed. Two promising integration directions were developed and one of them has been tested in a series of experiments. Liver resection was selected as the focus procedure for these experiments.

Feasibility of ultrasound integration in ultrasonic scalpel

The main conclusion that can be drawn from the experiments is that the integration of an existing ultrasound transducer into an ultrasonic scalpel is a feasible direction for the development of a *smart surgical instrument*. The desired field of view for the aforementioned liver resection procedures could be achieved. The ultrasound transducer was able to detect distortions in a liver issue phantom at relevant distances of 2 and 5 mm. Also when covered with a silicone tube, as is proposed in the first prototype, the phantom and insertions were detectable on the images.

Measurements that are commonly carried out in liver resections can be performed more easily with this integrated ultrasound transducer than with a separate laparoscopic ultrasound transducer. For example, tumour-free margins, that influence the tumour recurrence, can be measured from the instrument itself. This reduces the measurement actions, since only one point in the image needs to be detected to measure the tumour-free margin.

This research project has mainly focused on liver resection procedures. However, intraoperative ultrasonography has also been proven valuable in breast surgery, pancreas surgery and other abdominal procedures. [35], [71], [72] While not all of these procedures are performed laparoscopically, energy-based surgical instruments like the ultrasonic scalpel are often used. A smart ultrasonic scalpel, with integrated ultrasonography might therefore also be applicable and valuable in these application fields.

Prototype design

In the experimental phase of this research project a prototype has been developed. This first prototype facilitated the integration of the Eagle Eye Platinum catheter. The catheter could be reused, as it is not permanently fixed to the ultrasonic scalpel. Due to the fact that the handpiece, shaft and jaw of ultrasonic scalpels are disposable instrument parts, the ultrasound add-on possibility was assessed advantageous. To save costs, an integration method was developed in the first prototype that facilitates reuse of the catheter in multiple procedures. Using a silicone mounting tube, a sterile barrier was created to prevent contact between the ultrasound catheter and the transducer.
However, the silicone mounting tube that was used to attach the ultrasound catheter to the moving jaw decreased the image quality and overall performance of the ultrasound catheter substantially. Attenuation of the ultrasound signal and reverberations in the silicone wall led to an inferior image, compared to the images that could be recorded with the bare ultrasound catheter.

Based on the results that came forth from the experiments, a design improvement of the moving jaw of the ultrasonic scalpel has been proposed. In this redesign of the moving jaw, a mounting method is proposed without a silicone cover. This will increase the image quality, as was already found in the experiments.

Furthermore, this design shows that with little adjustments, a surgical instrument can be prepared for ultrasound integration using an ultrasound catheter. Since the instrument can still be used without integration of the ultrasound catheter, a surgeon can decide to add a catheter during the procedure. This choice can be made before or even during the surgical procedure. Permanent integration would lead to a large cost implication for the disposable handpiece of the ultrasonic scalpel. With the proposed design, a solution is presented that can make an ultrasonic scalpel ‘smart’ depending on the circumstances. Therefore, extra costs will only be made when also surgical improvements can be reached.

Type of ultrasound transducer

Multiple types of transducers are available. During the experiments in this thesis, the Eagle Eye Platinum ultrasound catheter was selected. Relevant in this selection were the dimensions of the transducer. Especially when focusing on laparoscopic procedures, the intravascular ultrasound catheters fit well.

Furthermore, the fact that these ultrasound catheters have a circular transducer and create a circular cross-sectional image is experienced as valuable. Integration into the jaw of the ultrasonic scalpel enables the user of the instrument to get a view in all relevant directions.

The use of an off-the-shelf ultrasound transducer was a specific choice. This enables a fast and focused approach to a fully functional smart instrument. The first step was to present a proof of concept. In the subsequent steps, the transducer might be refined based on specific demands from the clinical users.

The Eagle Eye Platinum ultrasound catheter provides a penetration depth of 10 mm in all directions, which is sufficient for instrument guidance during resection of a liver tumour. A tumour-free margin of several millimetres should be retained during the resections. [58], [73]

However, to detect deeper lesions or structures, a larger penetration depth might be convenient. Given the size of a regular liver, a penetration depth of multiple centimetres would be useful. Regular laparoscopic ultrasound transducers work at a frequency of 5-12 MHz and therefore provide a penetration depth of approximately 4-7 cm. [64], [74] Also ultrasound catheters with larger penetration depths are available. For example, the iLab catheter from Boston Scientific, provides 6 cm penetration depth and thus an imaging field of 12 cm. [66] Further research in the field of transducers with a larger penetration depth and with dimensions that still allow integration in a surgical instrument, is recommended.

Research contribution & future outlook

This research project contributes to a general change in the operating room. Minimally invasive surgery is still a growing field within the clinic. [75] Several research departments worldwide focus on this research area. The integration of a sensing technique into a laparoscopic surgical instrument like the ultrasonic scalpel can further improve this type of surgery. Besides the visual information from the laparoscope also intra-organ and surgical process-related information can now be presented to the surgeons.

To eventually reach the clinic, the ‘smart ultrasonic scalpel’ needs to be further developed. Existing technologies have been selected for the integration of ultrasonography into the ultrasonic scalpel. This could enable easy entering in the operating room in the future, since the existing technologies are already known by the users. However, more design iterations are required to end up with an instrument that delivers enough added value to be introduced in the operating room.

First, the proposed jaw design should be manufactured. Assessment of the improvements is then facilitated and a final design can be developed.
Additionally, in-depth evaluation of the clinical use of a *smart ultrasonic scalpel* needs to be done. This will provide insight in the users, their demands and wishes and the workflow in which the instrument will be used. The design of the instrument and selection of the ultrasound transducer can then be adjusted to the specific application field.

In the future, ongoing research can potentially enable direct feedback from sensing techniques to the surgical instrument. Further development of smart instrument might for example enable instruments to (de)activate itself based on feedback from the ultrasound measurements. Damage to critical structures or positive tumour-margins could then be prevented.
In needle-guidance research, ultrasound measurements are already used to automatically navigate needles to the desired position in the tissue. Following this development, automatic guidance of a surgical instrument based on the ultrasound measurements could be part of a future application of the ‘smart ultrasonic scalpel’. [76], [77]

10.2. Research limitations

A limitation of this research project is the experimental testing of only one of the two integration directions. Due to resource restrictions, no experimental set-up could be built for the *Existing ultrasound pathway* concept. When both concepts would have been subjected to experimental tests, a more complete overview of the possibilities and limits of ultrasound integration in the ultrasonic scalpel could have been provided. The use of existing ultrasonic pathways in the ultrasonic scalpel is still an interesting direction to investigate.

Due to the earlier described resource restrictions, no functional ultrasonic scalpel was available for the experimental phase. Therefore, integration of the ultrasound transducer could only be performed with the scalpel as a shape factor.
Further investigation of the effect of temperature rise on the ultrasound probe is still required. When the ultrasonic scalpel is activated the temperature of the tissue will increase. The transducer itself should be able to withstand this temperature rise. Based on the known components of the Eagle Eye Platinum ultrasound catheter, it is assumed that it would resist this temperature rise. However, the rise in temperature also influences the ultrasound imaging performance. Temperature influences the speed of sound through tissue and thus will have an effect on the images that can be recorded. [78], [79]
Due to the absence of a functional ultrasonic scalpel, the effect of the scalpel vibration on the imaging performance of the integrated ultrasound catheter could not be investigated. When the scalpel is activated, the blade vibration is transferred to the tissue and might interfere with the ultrasonic pulses that the ultrasound catheter is sending and receiving.

10.3. Recommendations

Both in the technical development of a ‘smart ultrasonic scalpel’ as in the wider application of this instrument, further research will be valuable.

First of all, further research on the mounting of the ultrasound transducer to the moving jaw of the ultrasonic scalpel should be performed. The proposed prototype design improvements should be transferred to a physical prototype. The performance of the proposed transducer attachment can then be assessed and compared with the currently available performance data. Additionally, the concept of a sterile barrier, that enables reusability of the transducer, needs more investigation. The composition and thickness of a cover material, related to optimal ultrasonic wave transfer to the tissue, are essential aspects for the development of a reusable ultrasound catheter integration.
The influence of the activated ultrasonic scalpel on the ultrasound imaging performance has not yet been investigated. It is recommended to perform research on the effects of tissue temperature and tissue vibration on the ultrasound imaging performance.

As was already described in the discussion, more research in the clinical field will be valuable. Workflow analyses and user research will provide more in-depth knowledge about the added value that the ‘smart surgical instrument’ could bring.

Further research could be performed in the direction of the *Existing ultrasound pathway* concept. Due to time- and resource limitations, this concept was not tested in experiments in this research project. Since the piezo-elements and controlling mechanisms are already present in the ultrasonic scalpel, investigation of possibilities to derive tissue characteristics from the tissue vibrations is recommended.

Lastly, a more in-depth research of the abilities of existing ultrasound probes can be valuable. Aspects such as tissue characterization and temperature estimation are possible using ultrasound sensing. Especially in combination with an energy-based surgical instrument such as an ultrasonic scalpel, these parameters are useful to present during a surgery. [80]

11. Conclusion

This report presented the research into the development of a smart surgical instrument; a surgical instrument with integrated sensing technique. In the previous literature study, the ultrasonic scalpel was selected as surgical instrument and ultrasonography as sensing technique to focus on. This research proposed multiple integration directions and assessed the feasibility of one of them.

The research questions, that were introduced in the Introduction of this thesis, will be answered. Several sub-questions have been formulated which will be answered. These answers together answer the main research question.

How can ultrasonography be integrated into the ultrasonic scalpel to develop a "smart surgical instrument"?

1. *What are the detailed working principles of the ultrasonic scalpel and intraoperative ultrasonography?*

The working principle of the ultrasonic scalpel is based on the transfer of mechanical energy to the human tissue. Due to the vibrations of the blade at a frequency of 36 or 55.5 kHz, the tissue is vibrated. Friction between the tissue cells lead to temperature increase, which causes the extracellular matrix proteins to denature. A sticky coagulum is formed that seals the blood vessels. Cutting of tissue with an ultrasonic scalpel relies on the principles of cavitation and power cutting. Cavitation is induced by the fast-changing pressure in the cells and leads to vaporization of the cell contents and cell explosion. Power cutting relies on the stretch of the cells beyond their elastic limit.
During the use of the ultrasonic scalpel, the tissue temperature does not exceed 80 °C. This reduces the lateral thermal damage and tissue desiccation, compared to other energy-based surgical instruments.
The vibrations are induced in the piezo-electric elements that are located in the active element of the scalpel. The elements are controlled by a generator console. The induced vibration is transferred through the horn, waveguide and blade to the tissue where the actual tissue effect takes place.

Ultrasonography also relies on a tissue vibration but usually operates in a different frequency spectrum of approximately 2-20 MHz. Ultrasound pulses are sent into the tissue and reflected at tissue boundaries when the acoustic impedance changes. The received echoes are transferred into grey-scale brightness and projected on a monitor. The relative distances of the reflection planes are calculated based on the amount of time between the pulse and the received echo.
The vibration pulses are usually generated by piezo-elements located in the transducer. Since piezo-electric elements also generate a voltage when they are subjected to a deformation, the reflected vibration can be recorded. Based on the application area of a transducer, a specific transducer design is required. Controlling the frequency is a relevant part of this design, since the frequency determines the penetration depth and the spatial resolution of ultrasound imaging.

Besides several modes of ultrasound imaging, also other information from the tissue can be gathered using the ultrasound sensing technique. Since tissues have different acoustic impedances and structures, tissue characterization is possible. Tissue temperature influences the speed of sound and can therefore also be estimated using ultrasound.
Following the wide application field of ultrasound, a lot of different ultrasound transducers are currently available. Four categories of probes can be distinguished based on their application: regular ultrasound probes (used outside the body), intraoperative ultrasound (open surgeries), laparoscopic ultrasound probes (laparoscopic surgeries) and special transducer. The last category contains for example the intravascular ultrasound catheters.

2. *Which solution direction is the most feasible one for the development of a smart ultrasonic scalpel?*

Based on the detailed working principles of the ultrasonic scalpel and ultrasonography, integration directions have been developed.

The *Ultrasound probe integration* concept is based on existing ultrasound probes that could be integrated in the ultrasonic scalpel. The imaging capabilities of the ultrasound transducer can be used real-time during surgical procedures. Besides, tissue characterization, which is already available in the existing ultrasound technology, can be used to help the surgeon. Strengths of this concept are the use of existing technology, leading to a familiar workflow and possibility to fully exploit the technological features of ultrasound. However, use of the sophisticated ultrasound transducers lead to a cost increase, especially when they need to be integrated in the disposable parts of the ultrasonic scalpel.

The *Existing ultrasonic pathways* concept uses the active element of the ultrasonic scalpel for the surgical process and for sensing. The ultrasonic scalpel is designed to vibrate in its natural frequency. The grasped tissue will influence the natural frequency and this change can be detected by monitoring the output voltage of the piezo-elements. Tissue characteristics can be derived from this information. Strengths of this concept are the synergy between the ultrasonic scalpel technique and ultrasonography. No extra devices are required which keep the costs low while improved surgical effects might be achieved. However, the ultrasonic scalpel is not designed for sensing purposes and therefore no sophisticated imaging is possible.

Based on the strengths and weaknesses of both concepts and a set of criteria, the feasibility of both concepts was assessed. Both integration directions are expected to fulfil the demands and are considered feasible. In this project, the *Ultrasound probe integration* concept is used during the experimental phase.

3. *Is the selected concept a feasible direction for the development of a smart ultrasonic scalpel?*

In the experimental phase, a set of experiments is performed to find out if the integration of ultrasonography into the ultrasonic scalpel would lead to useful feedback to the surgeon.
The results of the experiments show that the tissue phantom and silicone lute insertions can be detected, using an ultrasound catheter, despite the lack of acoustic coupling through a liquid. Also when the ultrasound catheter is covered, as was the case in the first prototype, the phantom and silicone lute insertion are visible on the ultrasound images.
The first prototype had its limitations but did proof that the relevant areas of interest are within the field of view of the ultrasound catheter. An improved prototype design is presented that solves the issues that were encountered during the experiments.
It can be concluded that an ultrasound transducer integrated into the ultrasonic scalpel could provide useful information and thereby support the performed procedures. Integration of ultrasonography into the ultrasonic scalpel is therefore considered a feasible direction for the development of a ‘smart surgical instrument’

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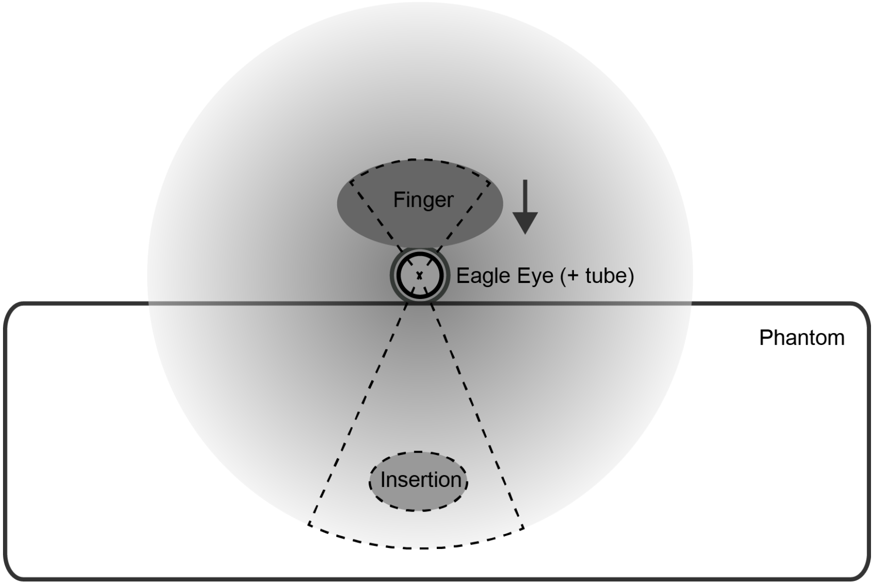
Appendix 1
Ultrasound performance experiments

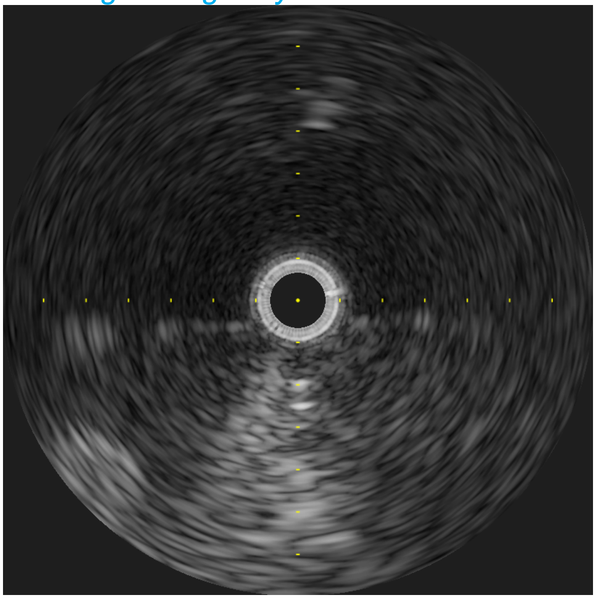
In this appendix, the complete overview of the recorded images in the ultrasound performance experiments (Chapter 7) is presented. Each image is presented two times: on the left side without annotations and on the right side with annotations.

Images of two phantoms and silicone lute insertions are presented recorded with the bare Eagle Eye Platinum ultrasound catheters. The second part shows the same images but recorded with the Eagle Eye Platinum ultrasound catheter covered with a silicone tube.

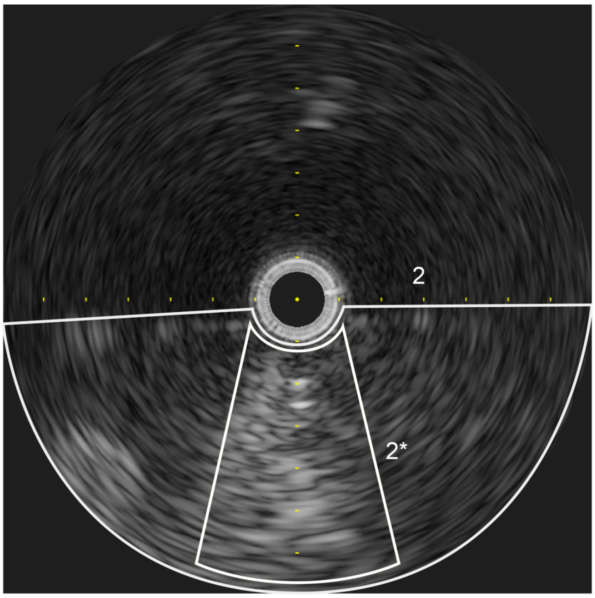


Schematic cross-section of experimental set-up. The shaded area is the field of view of the ultrasound catheter. Reflections are received from the dotted encircled areas.

Submerged Eagle Eye Platinum

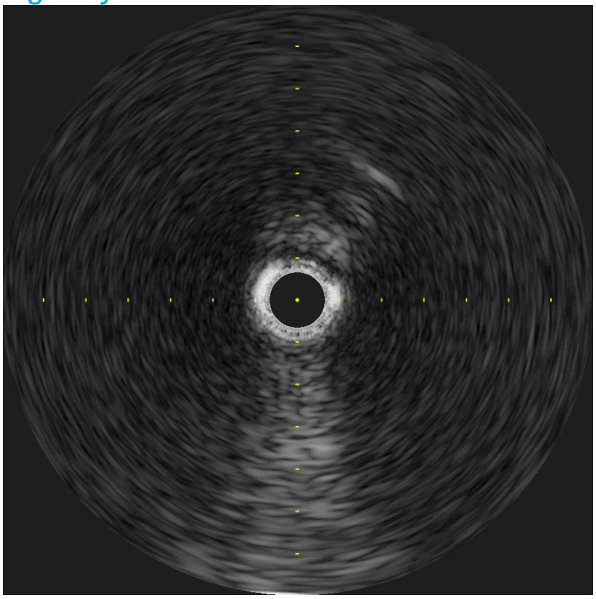


Submerged Eagle Eye Platinum Catheter
Phantom 1

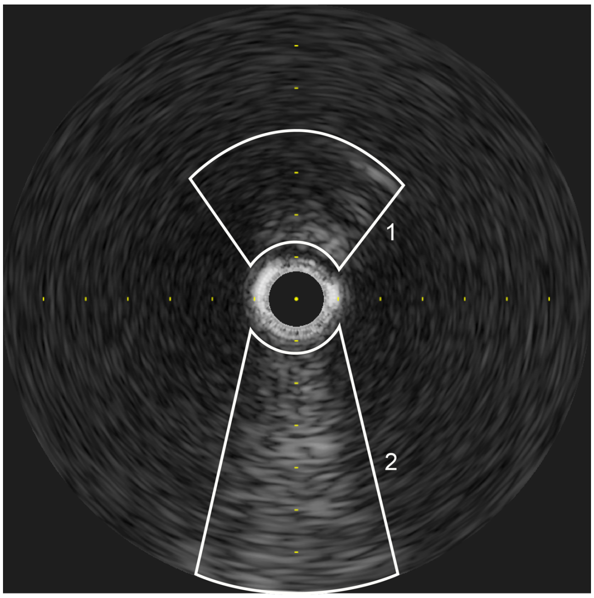


2) phantom 1, 2*) phantom 1 in direct contact with transducer

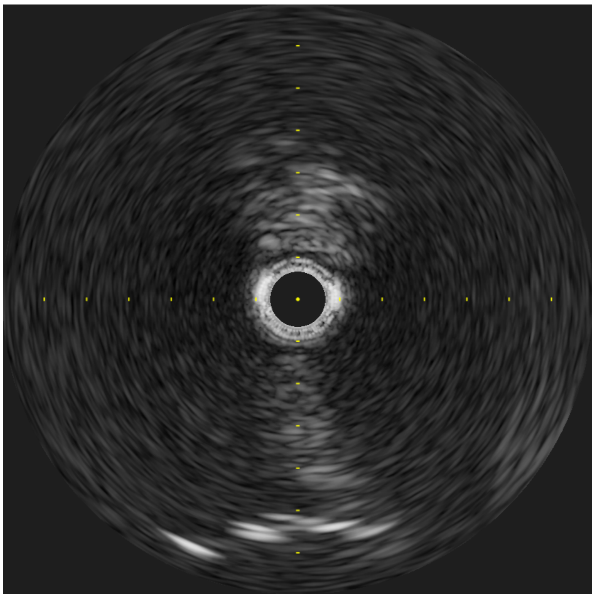
Eagle Eye Platinum



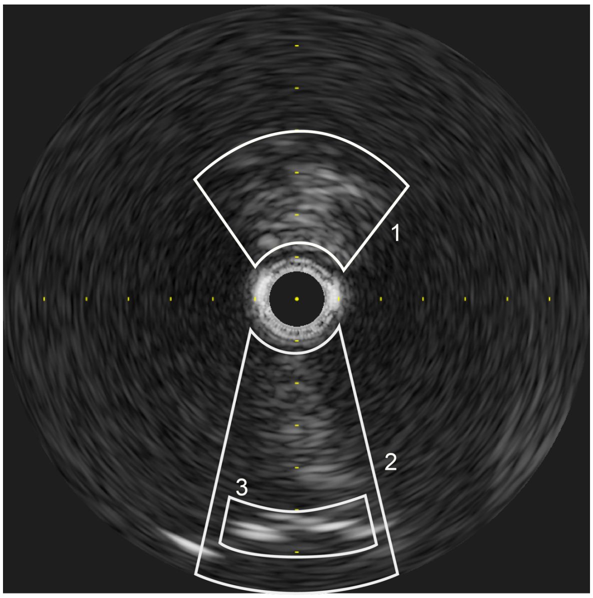
Bare Eagle Eye Platinum Catheter
Phantom 1



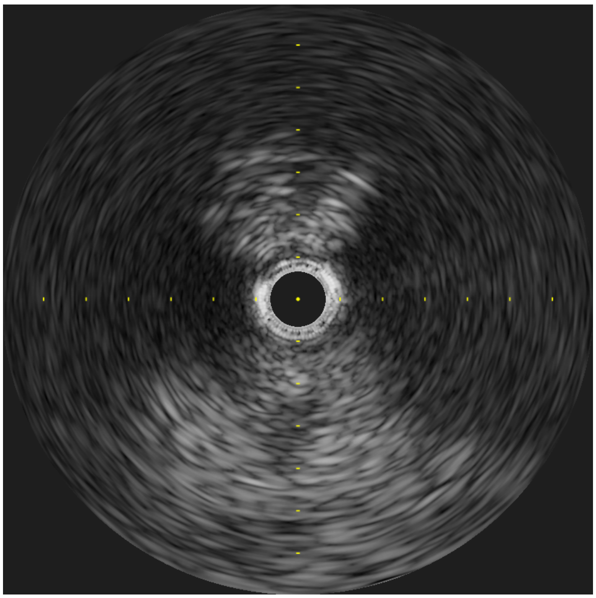
1) finger, 2) phantom 1



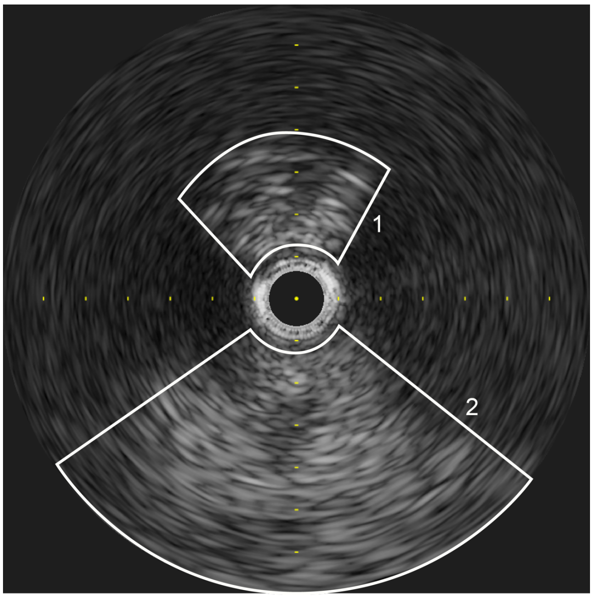
Bare Eagle Eye Platinum Catheter
Phantom 1 with silicone lute insertion at 5 mm



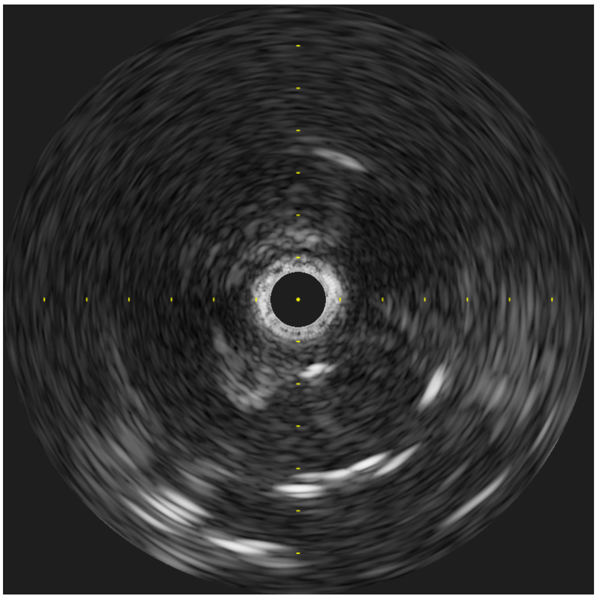
1) finger, 2) phantom 1, 3) silicone lute insertion



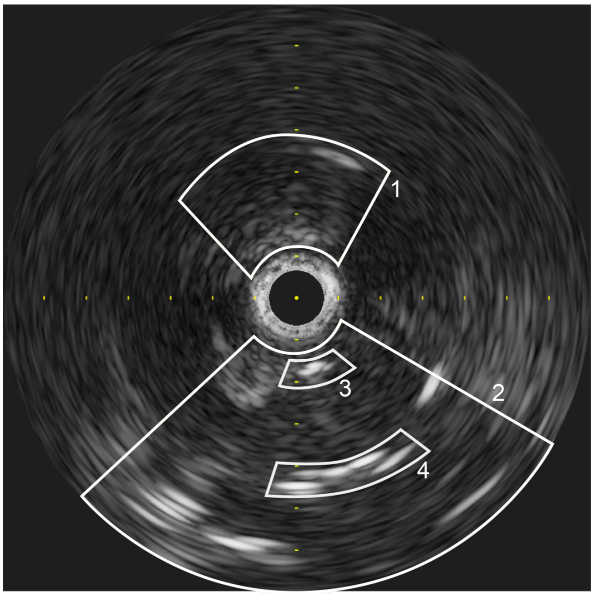
Bare Eagle Eye Platinum Catheter
Phantom 2



1) finger, 2) phantom 2

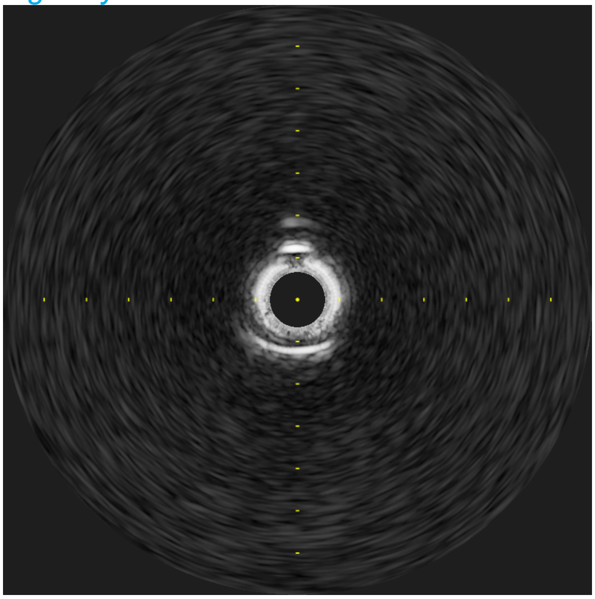


Bare Eagle Eye Platinum Catheter
Phantom 2 with silicone lute insertion at 2 mm

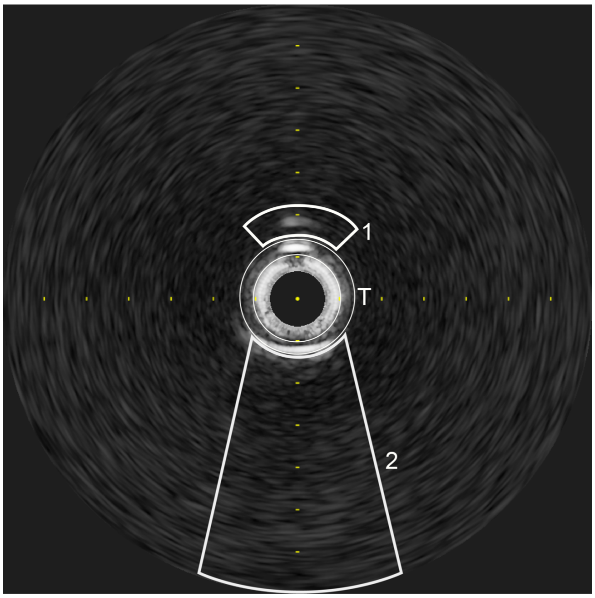


1) finger, 2) phantom 2, 3) silicone lute insertion, 4) bottom phantom surface

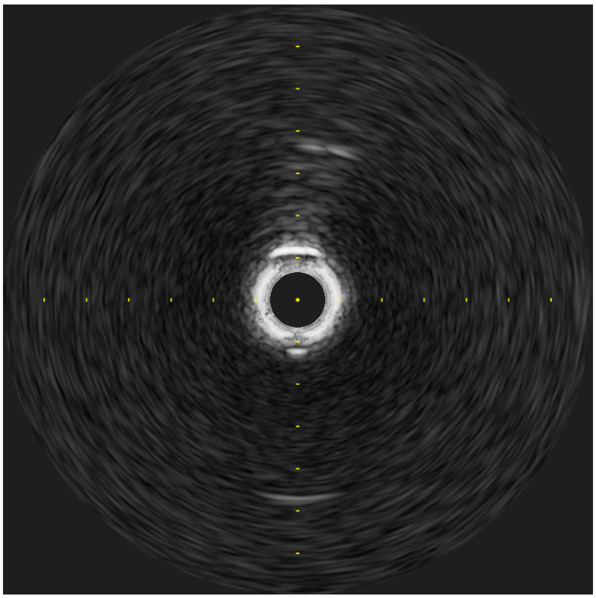
Eagle Eye Platinum covered with silicone tube



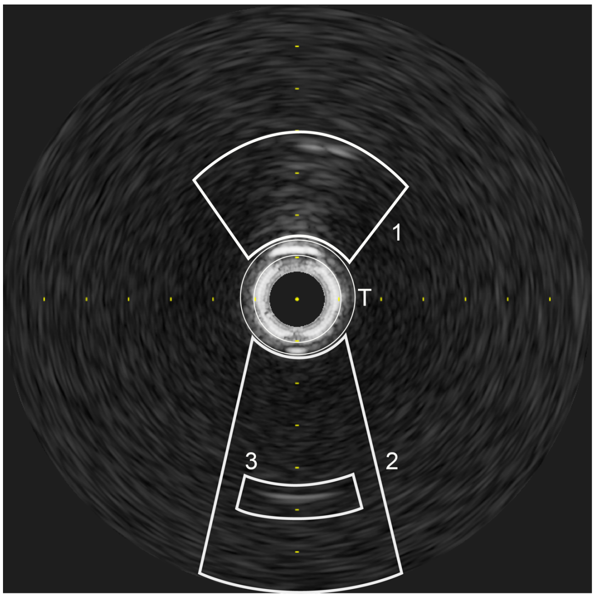
Eagle Eye Platinum Catheter covered with silicone tube
Phantom 1



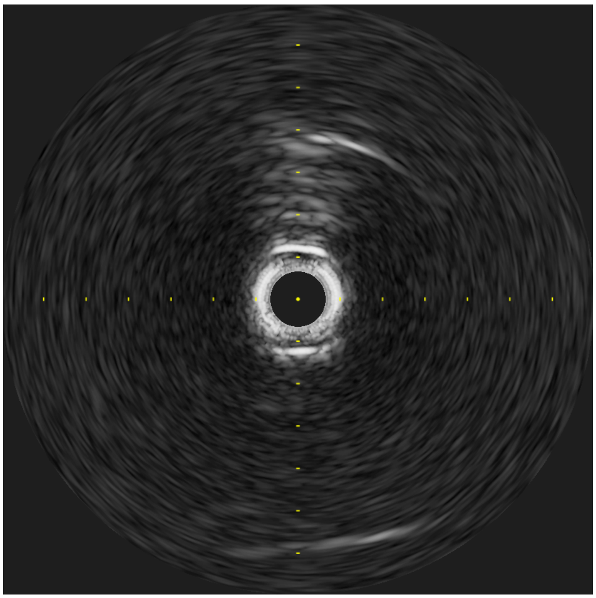
1) finger, 2) phantom 1



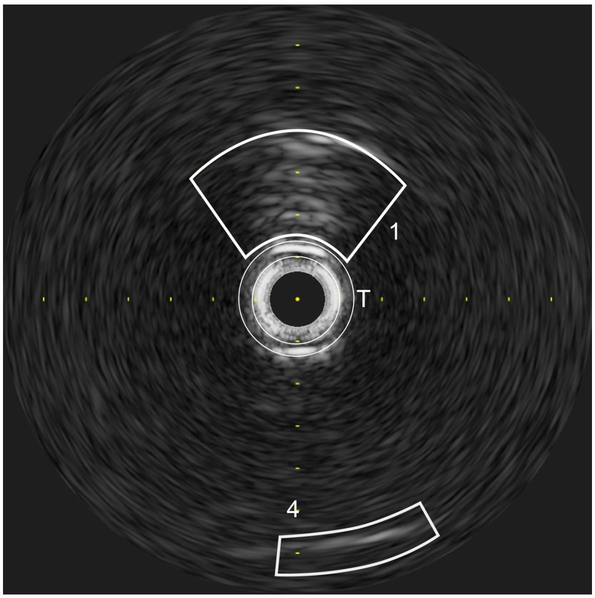
Eagle Eye Platinum Catheter covered with silicone tube
Phantom 1 with silicone lute insertion at 5 mm



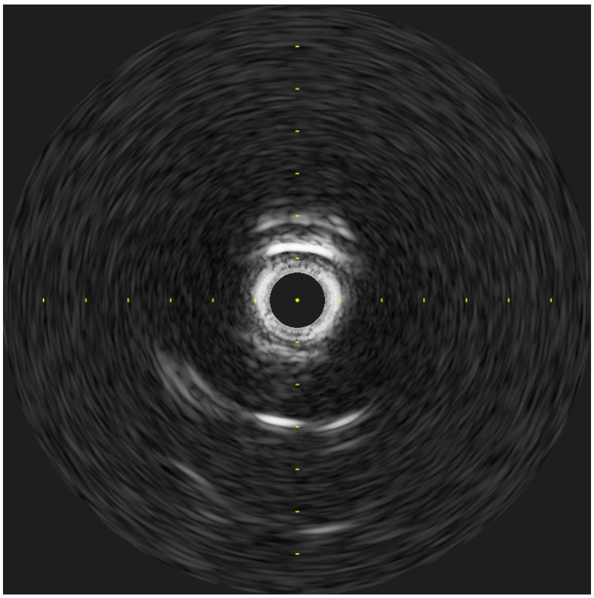
1) finger, 2) phantom 1, 3) silicone lute insertion



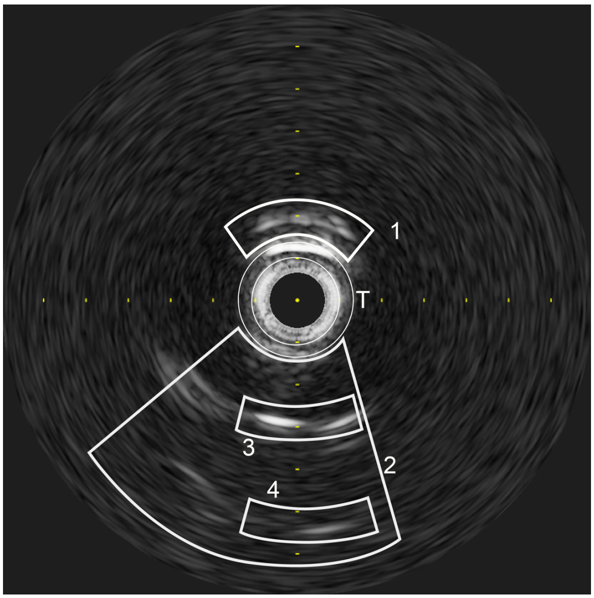
Eagle Eye Platinum Catheter covered with silicone tube
Phantom 2



1) finger, 4) bottom phantom surface



Eagle Eye Platinum Catheter covered with silicone tube
Phantom 2 with silicone lute insertion at 2 mm

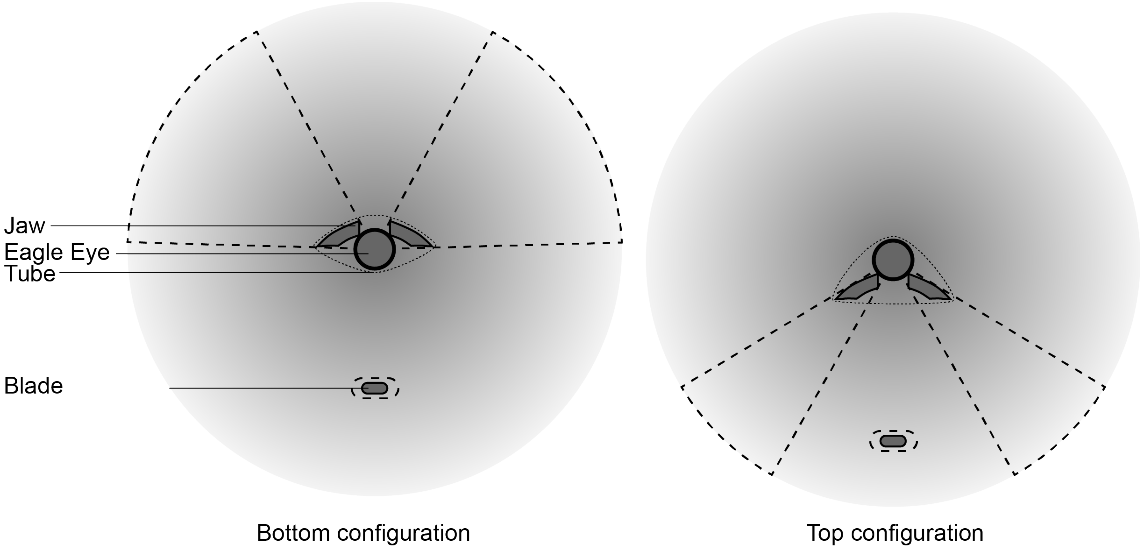


1) finger, 2) phantom 2, 3) silicone lute insertion, 4) bottom phantom surface

Appendix 2
Integration experiments

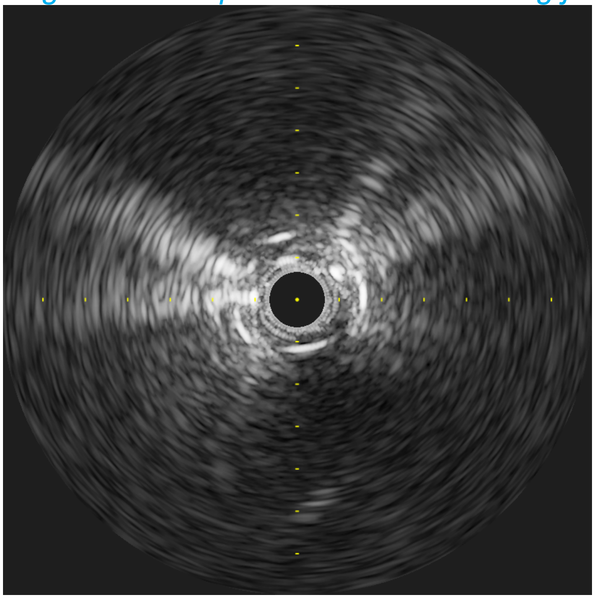
In this appendix, the complete overview of the recorded images in the integration experiments (Chapter 8) is presented. Each image is presented two times: on the left side without annotations and on the right side with annotations.

The first section of this appendix presents the images recorded with the top- and bottom configuration of the catheter. The second section shows the images of the grasped and tiptouched phantom.

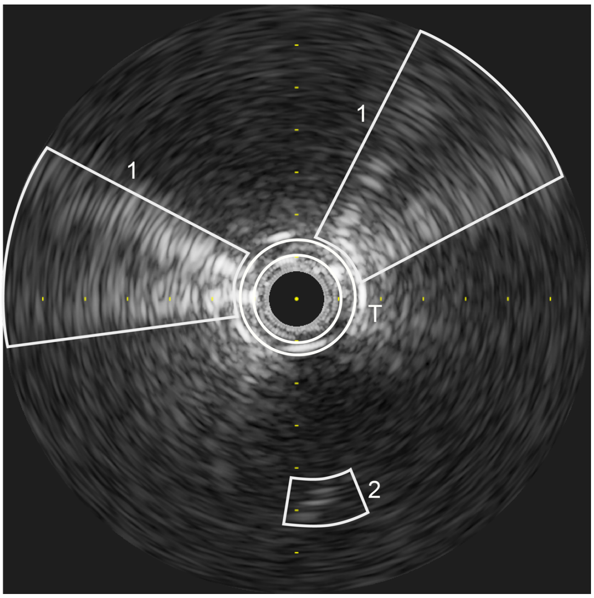


Schematic cross-section of experimental set-up. The shaded area is the field of view of the ultrasound catheter. Reflections are received from the dotted encircled areas.

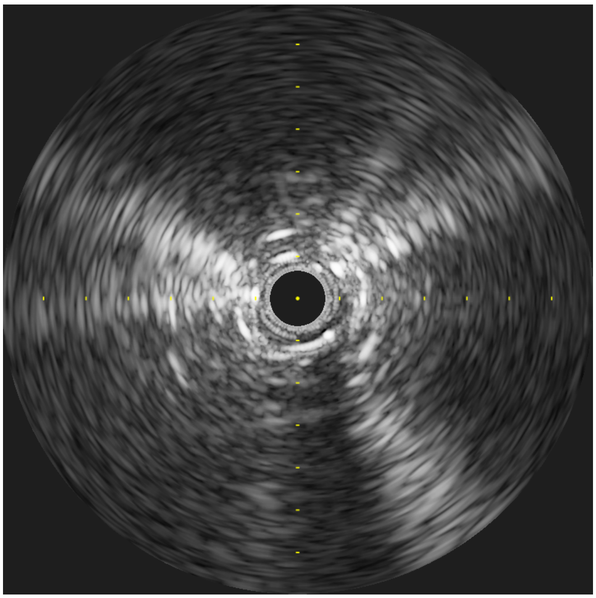
Integration on top and bottom of moving jaw



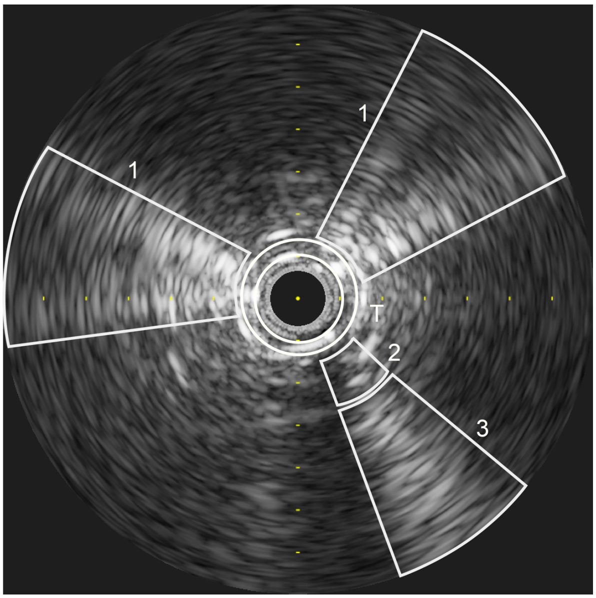
Eagle Eye mounted at the bottom of the moving jaw
Blade at 5 mm



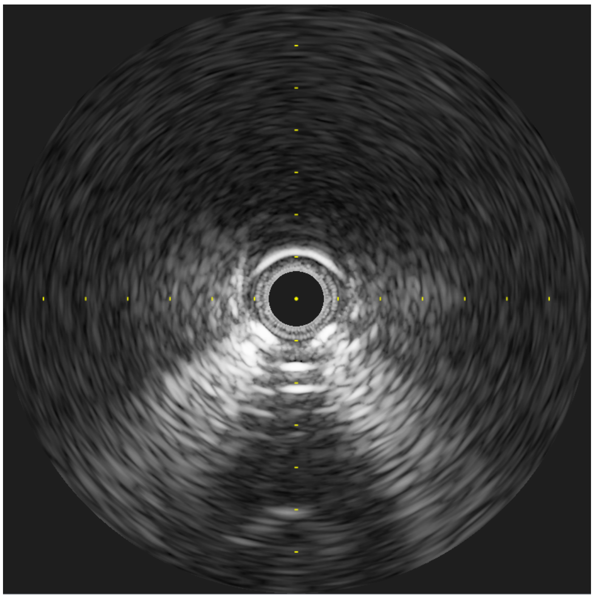
1) jaw reverberations, 2) blade



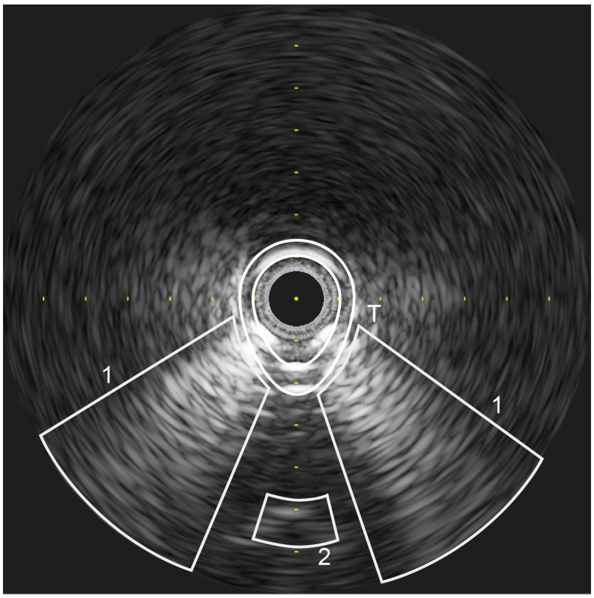
Eagle Eye mounted at the bottom of the moving jaw
Blade closed



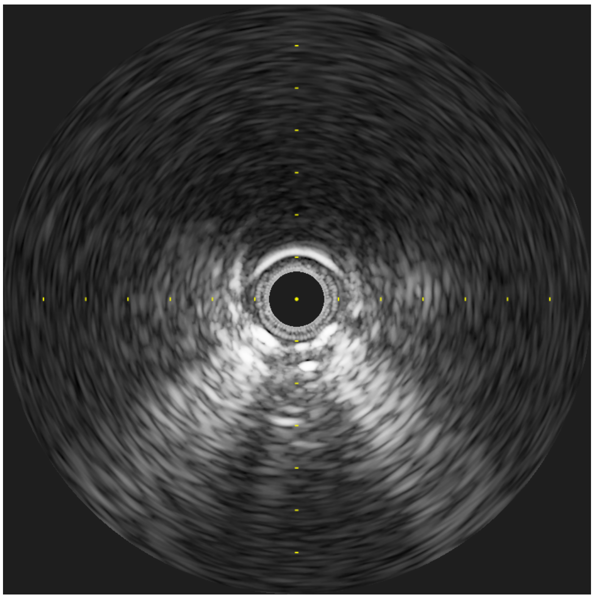
1) jaw reverberations, 2) blade, 3) blade reverberation



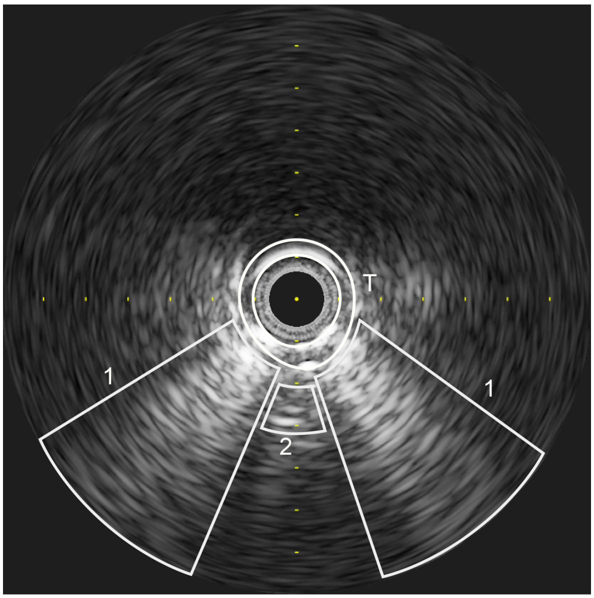
Eagle Eye mounted at the top of the moving jaw
Blade at 5 mm



1) jaw reverberations, 2) blade

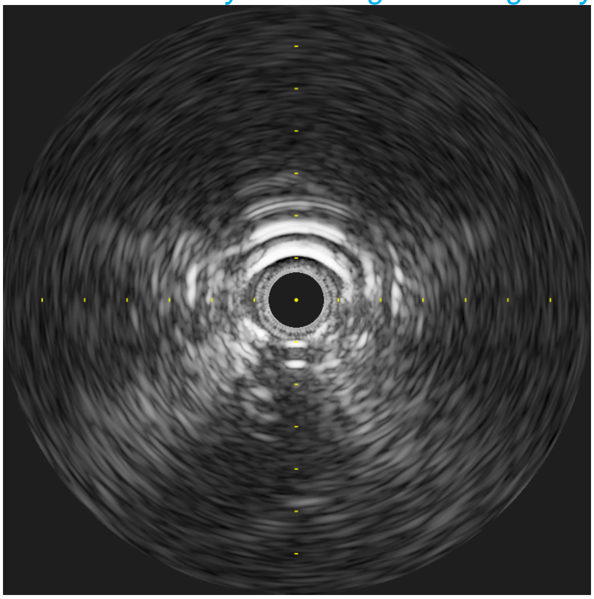


Eagle Eye mounted at the top of the moving jaw
Blade closed

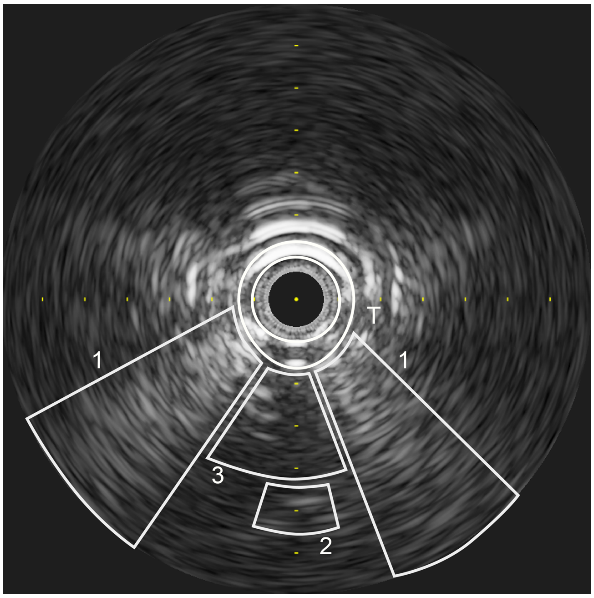


1) jaw reverberations, 2) blade

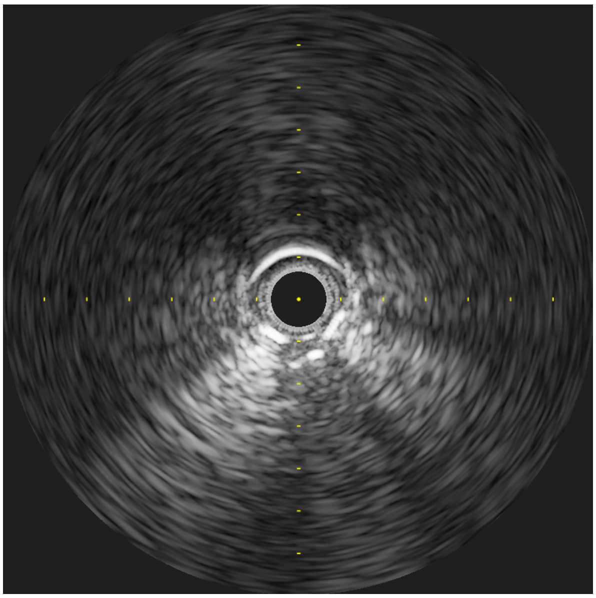
Phantom Visibility with integrated Eagle Eye Platinum catheter



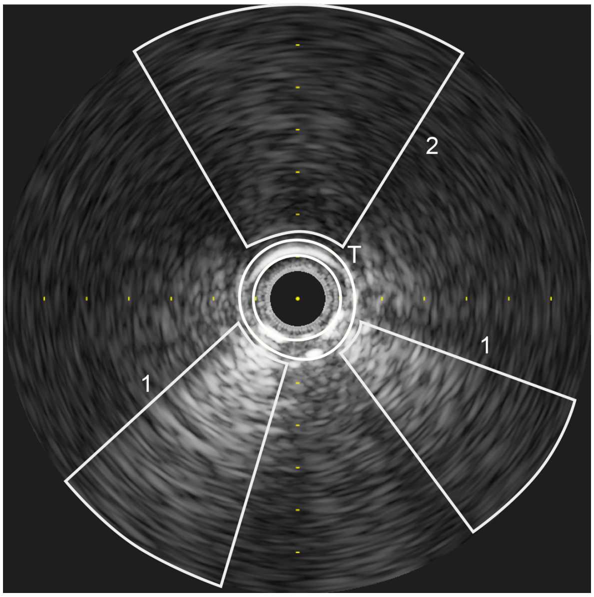
Eagle Eye mounted at the top of the moving jaw
Phantom 3 – Grasped (Blade 5 mm)



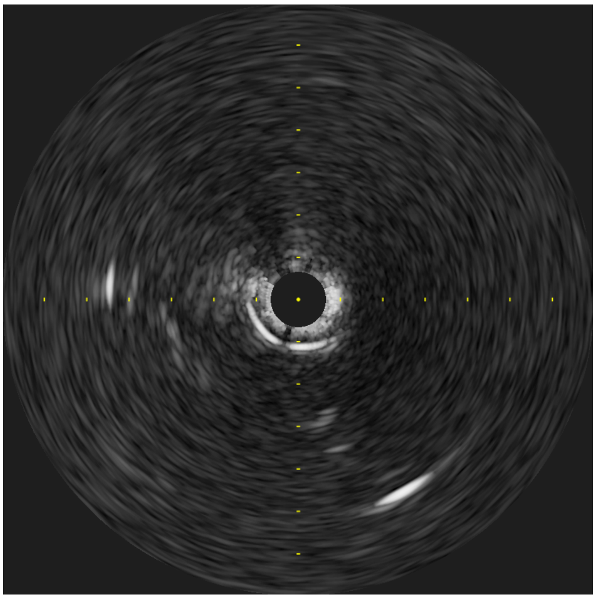
1) jaw reverberations, 2) blade, 3) phantom



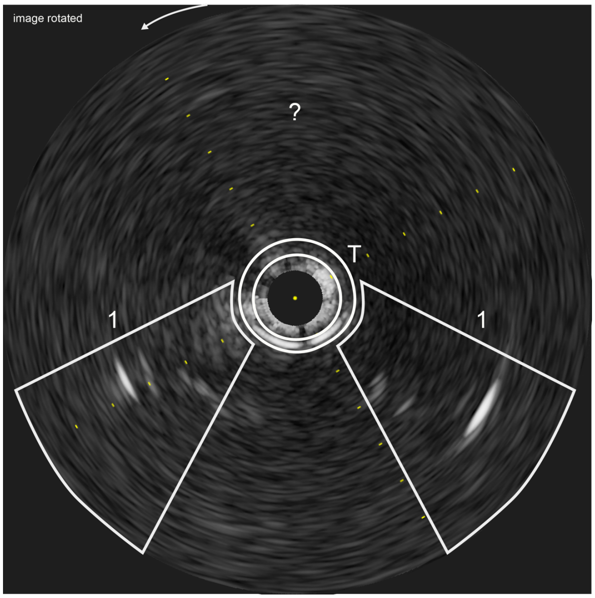
Eagle Eye mounted at the top of the moving jaw
Phantom 3 – Tip-touch



1) jaw reverberations, 2) phantom



Eagle Eye mounted at the top of the moving jaw
Phantom 3 with silicone lute insertion at 5 mm – Tip-touch



1) jaw reverberations, ?) expected location of phantom
It is expected that catheter was already damaged at this moment.