Soft tissue dissection with an ultrasonic snare
and the quantification of thermal spread

Master thesis

N.J. van de Berg
December 4, 2011
Soft tissue dissection with an ultrasonic snare
and the quantification of thermal spread

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The master thesis that is lying in front of you is the result of an extensive research on ultrasonic soft tissue dissection techniques performed at the BioMedical Engineering department of the Delft University of Technology. Practically, this study has been divided in two sections, each consisting of several background and support chapters and working towards a set of final experiments, presented in respectively Chapter 5 and 10. The content of this thesis covers both the investigation and verification of a thermal spread protocol, and the feasibility study of ultrasonic tissue dissection by means of a flexible snare. Although chronologically these two subjects were covered in reverse order, they have been swapped around for a more coherent and readable text structure.

The initial goal of this thesis, the production of an ultrasonic snare, resulted from an autonomous proposition which found its inspiration during an earlier stage of the master trajectory. Herein, I was, together with a fellow student and friend Mart Gähler, allowed to work on a complex problem emerging directly from the clinical field. During this project, a close collaboration was established with gynecologists from the Bronovo Hospital and the Leiden University Medical Center, that eventually led to the production of a prototype solution. However, in some regards this prototype was purposely kept suboptimal and this stimulated me to continue my research. Additionally inspired by a monopolar dissection snare (very practical, but associated with a large thermal spread), the concept of developing an ultrasonic equivalent emerged.

Although the selection of a - to our university - new and challenging research field did, in my experience, provoke a lot of positive attention and goodwill from the people around me, the solitude in finding the proper means to actualizing my planned objectives, was sometimes found to be a challenge. Consequently, the performed research had its ups and downs and experimental delays were inevitable. Nonetheless, during the course of this thesis, some very interesting results (in my opinion) were obtained, upholding the morality and keeping the neighbors interested.

Audience and prerequisites

On behalf of the graduation requirements, two papers were extrapolated from this thesis. They can be found right after the content page and include brief and to the point descriptions of the two main research topics that were covered. It should
be noted that the content of these papers will largely, but not exclusively resemble
the content found in the associative thesis chapters (5, 8, and 10) and their discus-
sions (Chapter 6 and 11). The report does, however, present a more complete and
extensive overview of the performed work and the required preliminary studies.

Acknowledgment

Of course, this thesis could not have been completed the way it did without the
support of others. As a starter, I would like to thank my supervisors, Dr. John J.
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Nick J. van de Berg
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Articles
Thermal spread quantification method tested on the Lotus

Nick J. van de Berg, BioMedical Engineering, Delft University of Technology

December 2, 2011

1 Abstract

Thermal spread is the extend of lateral damage resulting from soft tissue dissection by means of an energetic surgical instrument. Both a true definition of this factor, and a consistent means to quantify it, are still lacking. This study attempts to standardize thermal spread by 1) listing the relevant medical, technical, and statistical parameters, 2) selecting a soft tissue substitute to reduce biological influences, and 3) testing the protocol by determining the thermal spread of the Lotus grasper.

Thermal spread was measured in a meat replacement product (quorn) by means of eight thermocouples. Spread of heat was determined as the distance between the instrument shaft and the 7.5°C isotherm. It was measured at 5 mm depth in the left (3.09 ± 0.637 mm), and right flank (2.70 ± 0.966 mm). In addition, two more depth levels were measured in the left flank, 2.5 mm (2.11±0.732 mm), and 7.5 mm (2.95±0.959 mm).

The thermal distribution of the Lotus obtained by this measuring technique was comprehensible and educative. The use of thermocouples seemed adequate, as spread could be measured in the deep direction, and sufficiently precise. The selected test material (quorn) was suboptimal from a mechanical viewpoint. This may have led to experimental uncertainties and an increased measurement variance.

2 Introduction

From a physiological viewpoint, thermal spread is of importance as it represents a quantitative measure of the endured procedural trauma by means of energetic dissection modalities, such as ultrasonic, bipolar, and plasma blades. The amount of thermal spread is therefore directly related to the recovery process of the patient. Thermally affected tissue structures - evoked by a hot scalpel - were found to have a reduced tensile strength for at least two weeks after the procedure [4]. Eventually, necrotic structures will decay and be removed by the body. As the amount of viable tissue around the wound decreases with increased thermal spread, complications with regard to wound closure (by means of sutures) can arise. One practical example is found during closure of the 'vaginal cuff' [4], the portion of the vaginal vault that remains open to the peritoneum after removal of the uterus.

When comparing published thermal spread values of energetic dissection techniques, a spread in data is found spanning a factor $10^4$, ranging from 2µm [9] to 25mm [2]. Although differences in spread can be expected due to varying mechanical, thermal, and chemical processes associated with each technique, the absence of a single standard to quantify this factor presumably plays a dominant role.

As an initial step to create a more thorough base for the evaluation of thermal spread, it is advised to admit all relevant information regarding medical, technical, and statistical research parameters. A summary of these
factors, revised from an earlier performed literature study [12], is presented below. It should be noted that many of these considerations deal with biological influences. This is comprehensible as the biological and chemical factors are typically the ones providing measurement variability. Mechanical factors are, however, often overlooked and not described adequately to allow experimental repetition.

### Medical parameters
- Tissue type – organic (species, organs) or phantom, constitution: water-, protein content (e.g. collagen, elastin), etc.
- Tissue integrity – medical conditions, in vivo, ex vivo, in vitro, freshness, preservation and storage, etc.
- Tissue evaluation – orientation, staining, used chemicals and tools, etc.

### Technical parameters
- Experimental method – fiber direction, tissue contact or distance to tissue, affected surface area, etc.
- Used instruments – working tips, sizes, diameters, personal modifications, etc.
- Energy levels – power setting, frequency, duration, speed, force, etc.

### Statistical parameters
- Groups – number of individuals, number of samples, subdivisions, etc.

### 3 Methods

A pilot study was performed to evaluate the thermal response of several marketed products as candidate soft tissue replacements. Material composition was chosen as a benchmark in this pilot as it represents the priorly available product information (the ingredients list). In particular, focus was put on the water, protein, and fat content of available products. Being the major constituents of tissue, these elements were assumed to largely define thermal conductivity. With the aid of nutritional data [1], Table 1 was constructed. Although, in total, many organic products were considered, it was found that only meat replacement products and cheeses were capable of approximating the desired composition.

Subsequently, the gross thermal and mechanical response of these materials was reproduced by cutting with a temperature tunable soldering iron, as shown in Fig. 1. It was considered likely that soft tissue will endure thermal damage, desiccate, and upon reaching high enough temperatures, carbonize. Actual cuts are not likely to result, for the same reason bipolar electrosurgical probes are good at heating and coagulating, but not at dissecting tissue [8]. In comparison, only quorn seemed to behave in an adequate manner. Most cheeses were found to melt, some test materials responded in a relatively coarse and crumbly manner (feta, tofu), and others were found to endure almost effortless smooth cuts (tempeh, panir, grill cheese).

The main difficulty in dealing with ex-vivo soft tissue samples lies in the time dependency of material properties in absence of a chemical balance due to the stagnation of metabolic processes. Quorn is a mechanically fabricated consumption product with a well defined composition and texture. After the production process, it is sold in a virtually stable state. With regard to preservation, a slow time dependent aging and possibly drying effect may come in play, in particular when the vacuum seal is broken. However, these changes can be
Table 1: Nutritional data of various organic products [1]. Information between brackets is obtained directly from the product ingredients list.

<table>
<thead>
<tr>
<th>Product</th>
<th>Water %</th>
<th>Protein %</th>
<th>Fat %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Porcine muscle, general</td>
<td>75.0</td>
<td>21.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Porc chop, raw</td>
<td>66.4</td>
<td>19.0</td>
<td>13.5</td>
</tr>
<tr>
<td>Meat replacement, raw avg.</td>
<td>63.8</td>
<td>18.4</td>
<td>7.2</td>
</tr>
<tr>
<td>Camembert 30+</td>
<td>61.0</td>
<td>23.5</td>
<td>13.5</td>
</tr>
<tr>
<td>Feta cheese</td>
<td>62.1</td>
<td>14.2(16.1)</td>
<td>21.5(22.6)</td>
</tr>
<tr>
<td>Mozzarella</td>
<td>56.9</td>
<td>20.0</td>
<td>16.5</td>
</tr>
<tr>
<td>Grill Cheese</td>
<td>−</td>
<td>−</td>
<td>−(&gt;43)</td>
</tr>
<tr>
<td>Tofu</td>
<td>57.1</td>
<td>19.3(10.5)</td>
<td>7.2(6.5)</td>
</tr>
<tr>
<td>Tempeh</td>
<td>69.2</td>
<td>12.0(19.5)</td>
<td>8.3(8)</td>
</tr>
<tr>
<td>Panir</td>
<td>−</td>
<td>−(15)</td>
<td>−(18)</td>
</tr>
<tr>
<td>Quorn</td>
<td>64.2</td>
<td>14(14.5)</td>
<td>2.6(6)</td>
</tr>
</tbody>
</table>

Figure 1: Visible response of various organic materials to thermal ‘cutting’ with a soldering iron.

easily omitted by trusting upon the manufacturers production standards and purchasing new samples for each experimental routine.

Thermal spread has on a frequent basis been quantified either by means of tissue staining and subsequent histological inspection [3, 5, 10], or by the application of thermocouples [7, 11]. The staining technique would, however, be ineffective due to the prior selection of a tissue substitute material. Therefore, the application of thermocouples seemed to be the most appropriate solution for this study. By positioning multiple thermocouples in the lateral and deep direction, it should be possible to generate a rough representation of the thermal spread in a 3-D space around the ultrasonic applicator.

An experimental setup was constructed, shown in Fig. 2 to dissect quorn samples by means of an ultrasonic grasper and subsequently measure the spread of heat. The input of this device is a 50 W, 36 kHz electrical signal provided by the corresponding generator (The Lotus LG-3 system). The produced setup consists of a tissue groove, covered with insulating tape in order to reduce heat dissipation to the aluminum ground plate. A tissue sample (quorn), with a thickness of ~10 mm, was placed inside this groove, in such a way that it would bridge the opening left for the (unmodified) Lotus grasper. The grasper was positioned sideways along the opening in the ground plate and moved forward against the tissue sample until the
beak was completely filled. Adjacent to the grasper, a small plate (printed circuit board) was bolted onto the ground plate. Its holes were found to be an exact match to the 1 mm thick thermocouples (TC Direct 408-201). This way, the thermocouples could be evenly spaced in a grid next to the ultrasonic grasper. The distance between the holes on the circuit board was 2.5 mm. Eight thermocouples were placed in a $3 \times 3$ grid, leaving the middle, most distal position open. The thermocouples were connected to two 4-channel thermocouple input modules (National Instruments) and subsequently led to a computer. Temperatures were measured with LabVIEW and processed in MATLAB.

During the experiments the grasper was closed to ensure tissue contact. The maximum on-time of the Lotus, approximately 22 s, was used to equalize ‘procedure’ time. After this, the Lotus generator produces a warning message and shuts down. In the meanwhile, temperature profiles were monitored on-line with a frame rate of 2 Hz. Once the tissue temperatures had reached a maximum at all locations (usually after $\sim$ 100 s), the recordings were terminated.

In total, 77 thermal spread measurements were conducted. They were divided over 4 positions around the Lotus grasper (at a penetration depth of 5 mm); left flank ($n = 25$), left top ($n = 10$), right flank ($n = 12$), and right top ($n = 10$), and 2 additional depths (measured at the left flank); 2.5 mm ($n = 10$) and 7.5 mm ($n = 10$). The difference between the left and right thermal spread was assessed by means of a student’s t-test and the three in-depth levels were evaluated by an analysis of variance (ANOVA) and subsequently a Tukey-Kramer evaluation to compare the estimated differences with the standard errors.

4 Results

Fig. 3 depicts the maximum temperature reached at each location around the grasper averaged over $n$. Both the 7.5°C and 10°C isotherms are shown. The distance of thermal spread is measured from the dotted gray lines which extend from the Lotus device shaft. Spread of heat up to the 7.5°C isotherm was determined for both the left and right flank. A single valued thermal spread estimate for each image was obtained by averaging the spread at the three horizontal line intersections (lines...
of thermocouple placement), see Fig. 3. This was done for all measurement and the mean and range are presented in Table 2. The student’s t-test provided a p-value of 0.22 for comparison of the left and right flank, which means the null hypothesis (the means of both measurements are equal) could not be rejected at a 5% significance level.

Thermographic representations of spread as a function of measurement depth (on the left flank) are presented in Fig. 4. The associative distances have been included in Table 2. Again the 7.5°C and 10°C isotherms are shown. A multiple comparison by means of an ANOVA test was performed, which resulted in a p value of 0.0035 (F = 6.48) and thereby demonstrated the likeliness that at least one thermal spread estimate differs from the rest. The Tukey-Kramer method was used to determine the lower bound, estimate, and upper bound for each comparison. The three estimates and the comparison intervals are shown. At a 5% significance level, the spread at 2.5 mm depth was found to differ significantly from both the 5 mm and 7.5 mm depths.

When regarding a single temperature - time (T-t) curve, the most illustrative example was produced by an incorrect measurement, shown in Fig. 5. During this trial, the ultrasonic activation button was accidentally released for a short moment. As a result, the on-time of the device could be extended by almost a factor 2. Consequently, higher temperatures were reached and a more distinct thermal profile with regard to the different locations was obtained. When regarding the temperature profiles in time, a heat conduction delay was observed. Between the near and far nodes (distance of 5 mm) a delay of ∼ 60 s between temperature maxima was not uncommon.

The on-time of the ultrasonic grasper is shown (Fig. 5) by the red or cyan thickened curve sections. It should be noted that these colors do not refer to the end temperatures of the sensors, but to the thermocouple input module to which they were connected.

![Figure 3: Average maximum lateral temperature increase (n = sample size) around the Lotus.](image)

![Figure 4: Top: thermographic representation of the average (n = sample size) maximum temperature increase at three depth levels. Bottom: estimates and comparison intervals according to the Tukey-Kramer method. Two groups have means significantly different from depth 2.5 mm.](image)
Table 2: Distance of thermal spread towards the $\Delta T = 7.5^\circ\text{C}$ isotherm.

<table>
<thead>
<tr>
<th>Location (depth)</th>
<th>n</th>
<th>Average distance (STD)</th>
<th>Range</th>
</tr>
</thead>
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<tr>
<td>Left flank (5 mm)</td>
<td>25</td>
<td>3.09(0.637) mm</td>
<td>1.85 – 4.56 mm</td>
</tr>
<tr>
<td>Right flank (5 mm)</td>
<td>12</td>
<td>2.70(0.966) mm</td>
<td>1.41 – 4.92 mm</td>
</tr>
<tr>
<td>Left flank (2.5 mm)</td>
<td>10</td>
<td>2.11(0.732) mm</td>
<td>1.25 – 3.66 mm</td>
</tr>
<tr>
<td>Left flank (7.5 mm)</td>
<td>10</td>
<td>2.95(0.959) mm</td>
<td>1.29 – 4.61 mm</td>
</tr>
</tbody>
</table>

Figure 5: Single $\Delta T$ - t measurement for (prolonged) heating by means of the Lotus torsion ultrasonic grasper. The active dissection time is shown by the red/cyan thickened curve section. The left top corner shows a thermographic illustration of the maximum temperatures reached at each node.

5 Conclusion

When evaluating the thermal spread around the Lotus grasper on a qualitative basis, a quite predictable behavior is found. The heat profile approximately follows the shape of the end effector. The average thermal spread is comparable in both the left and right lateral direction. On a quantitative basis, spread in quorn seems to be relatively low; elevations of 7.5$^\circ\text{C}$ above body temperature are not quickly detrimental for soft tissue. In addition, the variance in measured spread was not substantially below that obtained in soft tissue (e.g. [10]).

Upon evaluation of the in-depth spread during the dissection of a 10 mm thick tissue sample, the lateral spread at the top section is found to be smaller than at the middle and bottom sections. This can be easily understood by considering that the Lotus grasper only has one effective, vibrating side, which in this setup was held at the bottom of the tissue samples. Hence, the effective distance to the vibrational source at the top layers is greater than at bottom sections. This dependency was clearly observable thanks to the used thermocouples.

6 Discussion

Although a couple of critical remarks can and will be made regarding the completed experiments, the obtained results are considered adequate and sufficiently precise to describe many relevant factors regarding the thermal spread of the Lotus. It should be kept in mind that a higher accuracy would only be meaningful if the physician can actually work with that kind of precision in clinical practice. Demanding the physician to refrain from nearing delicate structures at 3.7 mm...
DISCUSSION

distance would only be useful to those who can visually distinguish and employ that constraint. In this regard, small differences in thermal spread among ultrasonic tools should not be considered a benchmark for device selection. Other factors, such as intuitive control, can be more meaningful and will possibly increase procedural safety to a much greater extend.

The importance of thermal spread should, however, not be underestimated as exemplified by the wound closure dilemma described in the introduction. The current status is that no consensus has been reached on how to quantify this factor. As a result, published values do tend to vary considerably. This is a serious concern as manufacturers often claim a reduction in thermal spread to be one of their strong assets. At this point it would theoretically be fairly easy to mislead the audience by presenting values in favor (or not) of a specific product by simple use of a different experimental routine. For this reason alone, the development of a thermal spread evaluation protocol should be encouraged.

One of the first factors that should be noted on behalf of the performed experiments is the discrepancy of determining thermal spread as the lateral distance from the Lotus waveguide, instead of the instrument tip. As shown in Fig. 3, spread is on average approximately a mm larger. However, the exact determination of spread from the irregularly shaped tip would quickly lead to errors due to instrument translations and rotations during use. The waveguide was considered a much more consistent and visually perceptive framework to start measuring.

Although the Lotus energy dispersion is limited by means of a maximum duration time, Fig. 5 clearly demonstrates the ease of cheating with this restriction by a short release of the activation button. If the procedural pause is short enough, this does not have to interfere with the thermal build up and high tissue temperatures can be reached.

One particular observed case of extreme temperatures (reaching a $\Delta T$ of almost 70°C) should be described. Although somewhat averaged out, its effect is still clearly visible in the right flank plot of Fig. 3 (left top corner). The individual measurement is shown in Fig. 6. A small tear around the associative thermocouple was observed. A possible, but not further explored and therefore provisional explanation would be that this gap fills itself with fluid, increasing the local conduction and convection of heat and possibly the generation of cavitation bubbles. Important to note is the possible risk of causing unintentional iatrogenic damage if resembling tears can be endured in soft tissue.

![Figure 6: Thermographic illustration of extreme thermal build up. For comparability, the temperature scale is left unchanged; all $\Delta T > 25$ are presented in red.](image)

Although a surrogate test material has been selected based upon the comparison of chemical composition and water content with respect to human tissue, the actual thermal properties of quorn have not been identified and a direct comparison of spread would be erroneous. However, it should be noted that this study is not aimed to quantify thermal spread in human tissue. Instead, it attempts to provide a basis for quantitative comparison of heat dissipation by different ultrasonic instruments. Equality of the relevant parameters and repeatability of the procedure are considered more important than the direct link to tissue damage in clinical practice.

In this regard, quorn may, however, be a suboptimal replacement material. Although
the chemical composition was obtained from the ingredients list, the reliability and precision of this information was not verified. A high diversity in composition may, just as it would in soft tissue, lead to an increased variance in mechanical and biological tissue properties. Whether the desired isolation of tissue parameters from the thermal spread quantification process has been realized, has therefore not been demonstrated. Tissue sample dependencies possibly still reflect in the measured variance.

In addition, the mechanical strength of quorn, though high compared to that of other tested materials, was considerably below that of muscular tissue. For this reason, it was found to be impossible to fully squeeze the grasper. As sustained contact with the test sample was considered a prime objective to ensure heat flow, contact forces remained somewhat variable during the experiments.

Although the selection of a non-living and chemically stable tissue substitute, being less dependent on preservation techniques, is still considered convenient for thermal spread evaluation, more suitable alternatives can possibly be found or individually developed.

As the link to clinical practice is considered less relevant, the application of the 7.5°C isotherm can be justified. This isotherm has no physiological meaning, but was merely used out of convenience as it was visible in the majority of the performed experiments. The few measurements (6) that did not contain the complete isotherm, were filled up with grid minima (1/2 dx) to determine the average. Although this approach inherently leads to an error, it was considered to give less bias than the complete removal of these low spread values. Due to the steep temperature incline close to the instrument, the missing isotherm coordinates had to be close to the grid (average ∆T at grid minima of missing coordinates was 6.4 ± 0.76°C).

In the performed experiments, use was made of thermocouples to measure tissue temperature at specific locations. The use of infrared cameras, or alternatively the employment of thermochromic surface layers, were opted as possible visualization techniques as well. Although these techniques would be non-invasive, they would require additional calibration steps in order to translate the produced color schemes to actual temperatures. Although they would allow full surface visualization - instead of the nodal measurements provided by thermocouples - they would be incapable of measuring in the deep direction. In addition, thermochromic inks or paints are usually applied to visualize color shifts at certain indicative trigger temperatures and not to display entire temperature ranges. With regard to the discovered depth dependency of thermal spread of the Lotus, the use of thermocouples seems appropriate.

As of yet, only one ultrasonic dissector has been studied. It may be required to repeat this study with the exact same techniques, but with another tissue substitute. Once an optimal tissue substitute has been found, more instruments should be evaluated by independent parties in order to assess experimental reproducibility and finally reach a thermal spread quantification standard.

References


Ultrasonic snare actuation by tagging on to the Lotus waveguide

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1 Abstract

The development of an ultrasonic dissection snare may be desirous for limiting thermal spread in a variety of surgical interventions. To test the operational feasibility of such an instrument, a preliminary study was performed. For the vibrational input, the Lotus Torsion system was used. The acoustics of this system had to be understood for an efficient transfer of energy to the snare.

In order to find the optimal location for snare actuation, a high speed camera was used to photograph the activated instrument. The standing wave in the Lotus was determined and a stainless steel snare was connected at the location of the first amplitude maximum (antinode). Subsequent dissection trials with an ultrasonic snare, making use of an experimental cheese model, initiated.

The Lotus was found to vibrate with a frequency of 36 kHz, a vibrational amplitude of \( \sim 100 \mu m \), and a wavelength of 4.3 cm. Although significant energetic losses were anticipated at the snare connection site, cutting potential was confirmed by a preliminary test. The stability of this configuration was, however, found to be limited, inhibiting further research on the associative tissue impact. Better results are anticipated upon individual development of an ultrasonic source, omitting the limitations posed by the Lotus system.

2 Introduction

Tissue dissection snares are convenient medical tools in a variety of clinical scenario's, ranging from the removal of colorectal polyps (polypectomy) to that of complete uteri (hysterectomy). Most often, these snares make use of cautery or monopolar electrosurgical energy to thermally affect tissue and cause it to separate. From an energetic point of view, more advanced techniques have been developed in the past decades, associated with less iatrogenic tissue damage \[2\], e.g. bipolar, plasma, and ultrasonic surgery. Up to this point, the embodiment of these techniques in a snare have, however, been unsuccessful.

The objective of this exploratory research is to test the feasibility of tissue dissection by means of an ultrasonic snare. A rational preliminary step would be to test the possibility of using an existing ultrasonic source as the vibrational input. For this purpose, the Lotus Torsion (LG-3) system was made available. This system is, however, controlled to operate under specific conditions, which have to be met and fully understood before an efficient transfer of energy can result. The remainder of this introduction covers the readily known information on the Lotus system and emphasizes the acoustic factors that should still be identified. Subsequent experiments will be described and performed to fill the missing gaps and eventually, ultrasonic snares will be connected to the Lotus waveguide to perform some initial snare dissection experiments.
2.1 The generator

The Lotus LG-3 ultrasonic system (SRA Developments) is a commonly used energetic source for soft tissue dissection by both the Bronovo Hospital and the Leiden University Medical Center. The generator of this system is required to provide the correct electric signal to the Lotus (piezoelectric) transducer. The output signal constitutes a sinusoidal wave of 36 kHz, associated with a relatively high voltage and low current as required by the transducer. The device has two intensity settings realized by altering the vibrational amplitude of the piezo. This stroke amplitude is directly coupled to the applied electrical amplitude (voltage), and hence to the electrical input power. The high level setting requires an electrical input of 50 W. It should be noted that this value deviates from the mechanical output power (mainly) due to the transducer’s efficiency or ‘coupling factor’.

2.2 The transducer

The transducer of the Lotus, shown in Fig. 1, is attached to a mount which connects to a waveguide, leading the vibrations directly to the working tip. The Lotus output consists of a torsional wave, whereas piezoelectric crystal deformations are generally extensional. As snare is typically designed to withstand stress conditions and not torsion, it would be beneficial to actualize a wave type conversion upon connecting the snare to the Lotus. This will be discussed later on. CT scans of the Lotus transducer were taken as a non-destructive means to visualize the underlying working mechanism, see Fig. 2. The transducer is shown as a bright, high density material, occasionally causing light scatter in the produced scans. The location of the stacked piezo elements is clearly visible. The mechanical conversion to torsion results from the engagement between the transducer output and an off-centered boring (with regard to the instrument centerline) in the mount. Finally, the vibrational amplitude is increased by several subsequent exponential horn segments.

Figure 1: The Lotus transducer, showing from left to right; the housing of the piezoelectric element and its mount, the torsional waveguide, and the instrument tip.

Figure 2: CT scans of the Lotus transducer. The rotational vibration of the waveguide is accomplished by an off-centered engagement, \( \Delta x \), between the piezostack and the mount. The acoustic horn is used to amplify this vibration.
Vibrations in the waveguide are typically characterized by an internal wave duality. The Lotus shaft contains a high frequency (36 kHz), time dependent harmonic wave of which the amplitude is spatially fixed and changes along the length of the waveguide. With other words; the Lotus embodies a standing wave, characterized by vibrational nodes (amplitude minima) and anti-nodes (amplitude maxima) along the shaft. Of course, the Lotus is constructed in such a way that the working tip coincides with the location of an anti-node.

Knowing that the Lotus shaft is made of a medical grade titanium alloy, the associative wavelength (distance between two nodes) can now be determined. For a bar of uniform cross section and no damping, the anti-resonance length, \( l \), can be calculated by Eq. 1. Here, \( f_n \) is the frequency, and \( c \) the speed of sound [4]. The Lotus provides a single sided vibrational output with a torsional wavelength equal to the anti-resonance length. This would approximately be 4.3 cm for a torsional (shear) speed of sound in titanium of 3125 m/s [2].

\[
l = \frac{n \cdot c}{4f_n}, \quad n = 2, 4, 6, \ldots \tag{1}
\]

The locations of wave amplitude optima (anti-nodes) need to be experimentally verified in order to ensure a maximal conversion of energy to the snare. Although a connection could be established at the working tip, this would introduce a large bending moment on the waveguide and transducer as the snare pulling force has its maximum arm. By using anti-nodes closer to the transducer housing, this factor can be reduced.

Henceforth, this article will be divided in two sections; the first describing the optimal location for a snare connection along the Lotus waveguide, and the second describing the actual connection and the subsequent initial dissection experiments.

3 Methods

3.1 Vibrational nodes in the Lotus

For the determination of nodes and anti-nodes in the shaft of the Lotus, the experimental setup shown in Fig. 3 was constructed. The shaft was covered with a marker grid of small indentations with a 1 mm spacing interval. A high speed camera (Photron FASTCAM-Ultima APX-RS) was connected to a focus mount (Rodenstock) with a 4x magnification and positioned above the shaft, zoomed in on each marker individually. A micrometer slider
(Thorlabs) was used to position the shaft relative to the camera view. The Lotus device was activated and the vibrating instrument was photographed at a frame rate of 100,000 fps with a resolution of 128 × 80 pixels. Due to the low exposure time, a high intensity external light source was needed to acquire sufficient contrast. For this purpose a slide projector was tilted and its continuous light source was bundled with a lens, placing the focal point on the shaft. Viewed from the high speed camera, the metallic shaft reflected a significant amount of light, whereas the marker pits remained dark.

As the Lotus vibrates with a frequency of 36 kHz, whereas frames were taken at a frequency of 100 kHz, approximately 3 images per wave were recorded. In order to capture the wave characteristics, many subsequent waves had to be evaluated. Of each marker a series of 300 photos (a little over 100 waves) was collected. Nodes of which the vibrational amplitude was observed to be near a maximum, were measured multiple times in both power levels of the Lotus transducer. MATLAB was used to filter out the noise in the images (using a hybrid median filter), convert the images to black and white only, sum up the black (0) or white (1) pixel values of the entire series, and calculate an averaged gray level per pixel. Pixels at boundary layers, among others caused by the indentations, translated due to the vibration. A gray border line appeared as pixels were found black in one photo, and white in the next. Under the assumption that, at some point during the 300 collected frames, the minimum and maximum displacement amplitude were approached, the width of this border was used as an indication for the vibrational amplitude.

With the aid of this experiment, the locations of vibrational anti-nodes was verified. The first available anti-node, as seen from the transducer, would acoustically and mechanically be optimal for connecting a snare.

3.2 Ultrasonic snare cutting

A stainless steel snare with a thickness of 0.6 mm was connected to the Lotus transducer. Although several techniques have been considered, the best results were eventually obtained by means of hard soldering the snare to a stainless steel thin ring surrounding the titanium waveguide of the Lotus. The ring, in its turn, was laser welded to the waveguide at the location of the first anti-node. As shown in Fig. 4, the vibrating snare was damped out at the top by means of a plastic stop, suspended by two leaf springs. Along the way, the snare dissects a cutting platform which was used to make contact with a test material. The original actuator of the Lotus was used to trigger the device.

4 Results

4.1 Vibrational nodes in the Lotus

The marker grid indentations administered to the Lotus waveguide are shown at the top of Fig. 5. Photo processing steps are visualized for three markers and the gray border lines, resulting from harmonic motions of the visible marker boundaries, are presented.
4.1 Vibrational nodes in the Lotus

Figure 5: Illustration of the standing wave in the Lotus. The shaft, shown at the top, was covered with markers (1 each mm). Of each marker 300 photos (a) were taken. After filtering out the noise (b), and converting the images to black-white only (c), the sum of the photo series was calculated pixelwise (black = 0, white = 1) and an average gray level was determined (d). Along the marker boundary a gray band appeared, of which the width was used as an approximation of the wave amplitude, $U$. A Fourier fit was used to create a sine through the measurement data.

The maximum vibrational amplitude was approximately $80 - 100 \mu m$. Competitive devices work with comparable wave amplitudes $[1]$. The first maximum was found at pit #13, the second at pit #56. Hence, the wavelength was found to be 4.3 cm, which is in accordance with the theoretical value derived in the introduction.

Now that the wave characteristics of the Lotus are known, it is possible to derive the mechanical output power and determine the energy efficiency of the device. At the location of an anti-node (amplitude maximum), the wave can be described by a sinusoid with a frequency of 36 kHz and an amplitude of 100$\mu m$ as was just determined. By subsequently taking the first and second order derivative of this wave function, the velocity and acceleration...
are given. The power required to perform this vibration also depends on the rotational inertia of the shaft. An estimate of this factor was established by means of using the CT scan footage to model the shaft in SolidWorks. With this information, the mechanical power was found to reach a maximum of 39.7 W, resembling a theoretical efficiency factor of 0.794 with regard to the 50 W electrical input signal. The ~20% power drop can mainly be attributed to losses of energy conversion by the transducer.

4.2 Ultrasonic snare cutting

Now that we know what kind of energy is delivered at the location of an anti-node, it is time to find out whether this energy can be successfully led through a snare to a more distal location in order to perform dissection experiments. A tissue holder was positioned on the cutting platform of Fig. 4. After activation of the Lotus, a tissue holder was used to slide and carefully press the tissue against the vibrating snare, see Fig. 7.

![Figure 7: Illustration of the ultrasonic dissection experiment. The tissue holder is positioned on top of the cutting platform. It contains a cheese sample and can slide towards the vibrating snare.](image)

During some preliminary tests, cheese was used as a tissue replacement. The snare was well capable of slicing through this substitute material, however, the metal backing surface of the tissue holder prevented full thickness dissection. Although the cutting process remained a manual task, an attempt was made to equalize the tissue dissection speed in order to minimize its influence on the extend of thermal spread. During the cutting experiment, videos were recorded in order to estimate the dissection time. Cutting times were found to be ~ 2 seconds for a contact length of 1.9 cm and a cutting depth of approximately 1 cm. More precise results could not yet be obtained as the weld between the connector ring and the waveguide broke at an early stage.

5 Conclusion

The identification of ultrasonic waves by means of high speed photography worked well and a suitable and sufficiently precise description of the resultant standing wave in the Lotus was obtained. The Lotus vibrates at a frequency of 36 kHz, has a vibrational amplitude of ~ 100 μm, a wavelength of 4.3 cm, and an output power of ~ 40 W. A simple verification experiment, realized by observing how dried Tipp-Ex crumbles down upon device activation, provided a crude confirmation of these results.

Although the feasibility of cutting with an ultrasonic snare was demonstrated, it should be noted that this result was hard-won. As will be elucidated in the discussion to follow, the adopted approach of modifying an existing ultrasonic instrument (although extremely educative) may not have been an optimal approach. The titanium waveguide of the Lotus was hard to work with both on a mechanical and acoustic level.

6 Discussion

Although the executed experiments illustrate the plausibility of transferring ultrasonic waves through a thin snare in order to mechanically disrupt tissue structures, they also show the required proficiency of managing this kind of energy in order to
create a working and stable end configuration. In order to exploit the mechanical benefits and strengths of a snare, extensional waves are desired and loads should be administered in the longitudinal direction. To achieve this, a torsion-to-extension wave type conversion is required. The simplest way to do this, is by actualizing a tangential connection between the waveguide and a snare. The necessity of literally leading and guiding harmonic waves through the subsequent materialistic elements of an ultrasonic tool, was illustrated by the fragility of the devised intermediate connector.

Ultrasonic waves propagating to the snare have to cross several boundary layers, including those of the snare connector. Waves can be heavily distorted by these material boundaries and the vibrational frequency, amplitude, phase, direction, and speed can alter. Waves can reflect at the acoustic interface and bounce back to the ‘source’ \( S \), or refract and penetrate the ‘load’ \( L \), traveling with a new velocity and direction \[3\]. The exact behavior largely relies on the acoustic match between the connected layers, and relates to the difference in acoustic resistance or impedance, \( Z_0 \). An acoustic match would result in little to no wave reflection. Acoustic impedance, in its turn depends on the density and vibrational speed of sound; \( Z_0 = \rho \cdot c \). The speed of sound in an isotropic solid is, however, dependent on the present wave type (here torsional and extensional) \[2\].

As titanium is a relatively light material, a good acoustic match should be sought in the selection of a high speed of sound. On a theoretic basis, the torsional (or shear \[2\]) speed of sound in a long rod is given by 
\[
c = \sqrt{\frac{Y}{\rho}}
\]
where \( Y \) is the Young’s modulus (the extensional speed of sound also comprises this elastic modulus dependency). With other words, a good acoustic match would go at the cost of material stiffness in the snare. For the current case, this would practically exclude all metals as snare materials. Although the selection of a matching material would help reduce acoustic losses and heat production at the snare connector, it would also complicate the prediction of remaining waves in the snare. During use, material strain would become quite large with respect to the vibrational amplitude, and the effective dissection potential might become irregular and difficult to assess.

For this reason, the choice was made to select a stiff and strong snare material, regardless of the associative acoustic losses. As a result, the experimental emphasis would shift from creating an efficient harmonic flow of waves into the cutting snare, to a more crude approach, actuating the snare as a whole and focusing on a minimal material strain.

For simplicity let’s consider a perfect conversion from a torsional to an extensional wave obtained by a direct connection between the titanium waveguide and stainless steel snare (so that only one boundary condition occurs). According to Eq. \[2\] using densities of 7870 and 4540 kg/m\(^3\) and speed of sound values of 5790 and 3125 m/s \[2\] for steel and titanium respectively, the reflection coefficient, \( \Gamma \), would be 0.53. With other words, during a direct and optimal conversion of energy in this setup, less than half the wave energy would be fed to the snare.

\[
\Gamma = \frac{Z_L - Z_S}{Z_L + Z_S}
\]

Although this approach was a logical preliminary step with regard to the architectural limitations while working with an existing instrument, it may, from an acoustic point of view, be considered somewhat bold and credulous. Although the snare did translate along with the vibrational input and tissue dissection was found to be feasible, the majority of the available energy was lost locally at the connection site, and failure of one of the intermediate structures resulted quickly.

In addition, due to the stiff construction, the snare and connector configuration will contribute to the moment of inertia of the total system, and thereby alter the Eigen frequency. As the piezoelectric element is
not excited with the right frequency, the vibrational amplitude will decrease. It was found that the addition of a rigidly fixed snare connector to the waveguide could result in an error and malfunction of the Lotus system. This presumably results from the generator’s control scheme, trying to regulate the voltage output across the piezoelectric element and compensate for the loss in vibrational amplitude. It is likely that this output voltage is limited for safety reasons. In any way, the set restrictions by the Lotus generator severely impeded the possibility of making any adaptations to the waveguide. Although a strong and lasting connection was desired, this had to be achieved with a virtually weightless configuration.

Looking back, a more credible approach - although costly and time consuming - would be the individual development of an ultrasonic transducer. By direct, in line coupling of the transducer output to an acoustic horn and the subsequent guidance of waves along this horn until the required snare diameter is reached, energetic losses may be reduced to a minimum. This way, a waveguide material of choice can be selected, the need for wave type conversion will be omitted, the amount of material boundaries will be reduced, and in general the acquisition of an acoustic match will be facilitated.

References


Introduction
Vibrations can be described as disturbances of particles, bodies, or entire systems of connected bodies from an equilibrium position. These disturbances are usually counteracted by restoring forces in such a way that a harmonic motion results. A common classification, based on the vibrational frequency spectrum, relates to the audibility of these harmonics in air - although they can propagate through any material. Frequencies above 20 kHz cannot be heard (by humans) and are consequently called ultrasound. In most mechanical designs vibrations are undesired as they produce, among others increased stresses, energy losses, mechanical wear, and material fatigue. In some cases, however, vibrations can be put to good use.

1.1 Introducing waves to the operating room

The first known medical example of an ultrasonic aspirator dates back to 1947 [75], when ultrasonic probes found their way to the field of dentistry to facilitate plaque removal. It wasn’t until 1967 that Kelman [68] started to experiment with this technique in other fields. He subsequently developed a method that is currently known as phacoemulsification, to emulsify the nucleus of the eye’s lens to remove cataracts. After that, developments in ultrasonic medicine went fast. In the past twenty years ultrasonic tools have evolved to precise and selective instruments that allow separation of specific tissue layers through the appropriate selection of operating frequency. Sound waves can even cut bone and mineral structures, while leaving soft tissue at rest [78].

Ultrasonic energy has a couple of advantages over other energetic soft tissue dissection techniques, such as bipolar electrosurgery and laser irradiation. Hemostasis is achieved at lower temperatures [34], ranging from 50 to 100 °C [42]. In addition, ultrasonic dissection is believed to cause less charring and smoke production [8, 42]. Coagulation foremost results in the direction of the applied force, whereas the lateral spread of energy is considered low [54]. This latter factor is often related to the formation of a zone of sustained thermal damage. This ‘thermal spread’ is on a frequent basis used to compare instrumental safety and will be discussed more explicitly in Chapter 3.
CHAPTER 1. GETTING ACQUAINTED WITH THE SUBJECT

1.2 Market pull for flexibility

The current emphasis on the laparoscopic market lies on the development of flexible and steerable instruments, giving the physician a larger working environment and possibly increasing procedural safety. As acoustic losses increase with a decreased material stiffness [26] (see also Appendix A), this development may be a potential pitfall for ultrasonic techniques. Current products all rely on long, stiff, and slender shafts (waveguides) to carry sound waves to distal tips. However, if some losses are acceptable and a flexible ultrasonic waveguide, or in extremity a flexible ultrasonic working tip can be produced, new doors will open for this energetic modality.

An example of a clinical case that would benefit from such an instrument, would be the hysterectomy - or uterus removal - procedure. Due to the procedural complexity, only 10% of all hysterectomy procedures are currently performed laparoscopically [76, 77]. Based on anatomical restrictions this could theoretically be 70% to 80% [17]. Decreasing the complexity brings advantages to both the gynecologist and patient. The procedure will become faster and cheaper, and as the high expertise demand tapers off, the risk on complications should decrease. An ultrasonic snare would be beneficial in this procedure as it could directly surround the uterus at its base, irrespective of its shape, size, and the presence of abnormal growths. By tightening and activating the snare, a fast and safe (well guided) uterus extirpation would be allowed. More background information on this medical scenario and the conjoined benefits of an ultrasonic snare are provided in Appendix B.

1.3 Research study objective

The main goal of this research study is to evaluate the feasibility of producing a flexible snare capable of conserving sufficient energy for soft tissue dissection at a remote distance. Such a snare may provide a safe and intuitive technique to simplify laparoscopic procedures, such as the hysterectomy procedure, and reduce their high expertise demand. When functional, the thermal spread (and other safety factors) of the vibrating snare should be evaluated. Its intuitive control should be assessed by means of experimental trials and questionnaires.

1.4 Thesis outline

This thesis is divided in two parts. Part I describes a protocol to evaluate thermal spread. Current techniques were found to lack coherence and experimental results appeared to deviate greatly. In order to demonstrate the effective safety of old and new energetic instruments by comparing their thermal impact, it would be convenient to have a standardized and repeatable quantification method.

Part II describes some initial steps in the development of an operative ultrasonic snare. It discusses relevant parameters for ultrasonic wave propagation, evaluates an available ultrasonic source, and considers the means to connect a snare to it. Some initial dissection trials were performed and suggestions were made for future research.
CHAPTER
TWO

ULTRASONIC HARDWARE & MEDICAL APPLICATIONS

In the last couple of decades, ultrasonic instruments have become an integral part of the surgical toolbox. A general description of acoustic waves and boundary interactions is provided by Appendix A. This chapter has a more practical focus and provides an overview of how ultrasonic waves are produced, in what way they are used in medicine, and what kind of interaction they invoke when brought in contact with biological tissue.

2.1 Ultrasonic transducers

Devices that are developed for the purpose of creating ultrasound are called ultrasonic transducers. By definition, a transducer is a device that converts one form of energy into another. An ultrasonic transducer converts (usually electrical) energy into mechanical energy in the form of vibrations, and vice versa. This can be achieved by means of the following principles [19]:

- The most familiar mechanical, gas driven, transducers is probably the dog whistle. Liquid driven transducers also exist and operates by driving a fluid through an orifice and over a thin blade, causing it to vibrate [52].

- Electrostriction is a property of virtually all dielectric materials which relates to the presence of randomly oriented electrical domains in the material. By the application of an external electric field these domains try to align and the specimen dimensions endure slight alterations. The resulting strain is proportional to the square of polarization. In practise this means the direction (sign) of the electric field does not affect the direction of strain.

- Magnetostriiction is found in ferromagnetic materials and presents the magnetic equivalent of electrostriction; the relation between magnetism and material strain. This was first described by Joule in 1842.

- Piezoelectricity was discovered in 1880 by the Curie brothers. It describes a relationship between electric polarization and mechanical strain. It differs from electrostriction in that the relation is linear instead of quadratic. Ergo, polarization and strain can change sign by inversion of the applied electric field.
The nature of piezoelectricity lies in the absence of a central symmetry of the crystal structure, leading to the formation of an electric dipole moment.

- **Piezomagnetism** presents a linear relation between magnetism and strain.

- **Electromagnetism** refers to the relation between electricity and magnetism, which can be used in conductive materials to generate vibrations by means of producing high frequency oscillating Lorentz forces (EMAT).

- Electromagnetic radiation in the form of short pulse, high peak power laser beams can generate regions of thermal expansion followed by a recoil effect, which induces ultrasonic vibrations in the material. In addition, this process can be associated with material evaporation and the local formation of plasma.

Since piezoelectric materials in general exhibit larger strains, are easier to work with (linear relation), and have a higher conversion efficiency [75], they are often preferred in practical applications.

### 2.1.1 Piezoelectric materials

There's a wide variety of natural and man-made materials exhibiting piezoelectric properties. Natural crystals, such as quartz, topaz, and tourmaline are well known for their piezoelectric behavior. Even organic materials, such as dried bone, may exhibit piezoelectricity to some extend ([Piezoelectricity, 1]). Man-made alternatives can be divided in crystals, ceramics, and polymers.

Some materials can not be obtained as extended single crystals, but only as powders [48]. Piezoelectric ceramics can be fabricated by sintering these powders at high temperatures, followed by a poling process. During this poling process the dielectric moment will be frozen in the ceramic structure by subsequently heating and cooling of the material under the constant application of a DC current.

For the production of piezoelectric high polymers, often found in the form of foils, a comparable polarization process is used. Either a stretching and subsequent polarization, or an electric discharge technique is used [48]. In the latter situation, the foil is placed between a conductive surface and a metal tip after which a high DC voltage is applied to produce an electric discharge.

A characteristic property of piezoelectric materials is the Curie temperature, above which the molecular structure modifies and the spontaneous internal polarization is lost. The Curie point of for instance quartz is reached at 573 °C [48].

### 2.1.2 Crystal structure

For simplicity, let's consider a typical single crystal configuration with its z-axis defined as the crystallographic axis connecting the two peaks, as shown in Fig. 2.1 [48]. The x-axis can be freely chosen perpendicular to the z-axis, since the material is isotropic in any plane perpendicular to the z-axis. The y-axis follows by producing a right-handed coordinate system. In red, an example of a piezoelectric crystal slab is shown. Due to the atomic structure, a quartz plate cut perpendicular to the z-axis will not exhibit piezoelectricity [48].
2.1. ULTRASONIC TRANSDUCERS

Figure 2.1: Illustration of a quartz crystal and its coordinate system. To the right, the influence of an electric current or mechanical force on a crystal slab is shown [19, 48].

2.1.3 Crystal in- and output

A piezoelectric transducer can be considered a 3-port network, including one electric port over the crystal and two acoustic ports, one on each vibrating surface, as shown on the right in Fig. 2.1. The crystal dielectric functions as a capacitor [64], allowing a potential difference to build up across the outer surfaces. This potential difference pulls at the crystal structure and generates a strain. By providing a high frequency alternating electric field to the crystal, vibrations with the same frequency are generated. The maximum electrical input depends among others on the specimen thickness and the selected material, e.g. the electrical impedance or resistance to alterations of current. To avoid overheating, and depolarization of the crystal, the average power dissipation should be limited and an appropriate waveform (voltage, pulses, duty cycle) should be chosen [64].

Besides this electrical limitation, the acoustic power output can be restricted by the chosen materials, the construction and mounting of the transducer, the media coupled to the transducer, the Q-factor, etc [48]. Unloaded piezoelectric generators operating at their resonance frequency may generate vibration amplitudes large enough to cause mechanical fracture of the transducer. Mechanical and dielectric losses may heat the transducer to the Curie point, and inhomogeneities caused by lattice imperfections, different packing densities in ceramics, and achieved levels of polarization, may result in additional material stresses.

One important characteristic of piezoelectric media is the coupling factor:

\[ k^2 \]

The piezoelectric coupling factor, \( k^2 \), is a measure of the efficiency of electrical-to-mechanical energy conversion, and vice versa. It is the ratio between the electrical (or mechanical) work done under ideal conditions and the total amount of stored energy from a mechanical (or electrical) source [19].
Chapter 2. Ultrasonic Hardware & Medical Applications

Figure 2.2: Work cycle of a piezoelectric element. Image adjusted from [19].

The choice of boundary conditions, e.g. how the transducer is mounted and in what directions strain can be endured, will influence the performed work and the coupling factor [19]. In the simplest situation, where stress is one dimensional and strain is small (linear relations), the working cycle of a piezoelectric element can be represented as in Fig. 2.2. When going from the resting position (a) to a situation stressed by an external force $F$, while keeping the electrodes short-circuited, both a mechanical and an electric displacement will build up according to the piezoelectric constitutive relations (see Table A.1) (b). After opening the circuit, and subsequently removing the external force, the mechanical displacement will be lost (c). The electric displacement, however, remains, and the electric field changes. By connecting the electrodes to an electric load, shown as a resistor in Fig. 2.2, the electric energy dissipates and the piezoelectric element will return to its resting position (d). As the area under the stress-strain curve represents the performed work, the piezoelectric coupling factor can be calculated from:

$$k^2 = \frac{W_1}{W_1 + W_2}$$  \hspace{1cm} (2.1)

Another often used configuration is obtained by considering a laterally clamped condition. This situation can be encountered when examining the behavior of a small volume whose thickness is equal to the piezoelectric element. This volume is surrounded by material regions that obstruct lateral movement. The encountered stress situation can not be considered one dimensional. The clamped situation should be regarded particularly for transducers with lateral dimensions much greater than the thickness, while operating in the thickness mode. The found efficiency is generally significantly lower than in the strain free situation.
2.1.4 Mechanical output adaptations

When working with ceramic piezoelectric elements, the lower laterally confined coupling factor can be avoided by the creation of a ceramic meshwork. Small volumes of ceramics with lateral dimensions less than a wavelength are surrounded by a compliant filling medium. As lateral movement is permitted, so is the usage of the unclamped coupling factor. Since the piezoelectric volume will decrease, an overall performance balance is, however, required to assess the most optimal configuration \[19\]. Several examples of two-phase ceramic composite structures, such as ceramic slabs, pillars, and particles, are discussed by Cobbold \[19\].

A practical solution to increase the capacitance of a piezoelectric transducer with relatively small cross sectional area is to stack several layers on top of each other, as shown in Fig. 2.3. The different layers are electrically connected in parallel, but operate acoustically in series \[19\]. Although this multilayer transducer configuration is associated with a decreased electrical impedance, the fabrication costs are significantly higher than for single-element devices.

\[ \text{Figure 2.3: Illustration of a) a pillar ceramic composite structure, b) a multilayer transducer, and c) an exponential velocity transformer, with the associative particle velocity.} \]

For the generation of even higher vibrational amplitudes, mechanical velocity transformers or horns can be applied. A horn basically consists of an inhomogeneous acoustical transmission line, i.e. a rod measuring half the wavelength, or an integer multiple of it, with a varying cross section along which the ratio of force and velocity varies as well. Commonly used materials are titanium or aluminum alloys \[26\]. Several profiles, such as stepped, conical, and exponential transformers have been discussed by Kuttruff \[48\].

Composites for high power applications usually have an axial boring with a bolt inside, connecting the element to its coupled medium. Depending on this coupled medium, the vibrational amplitude may be excessive and cause failure of for instance an adhesive bond. Furthermore, the piezoelectric material may be destroyed by high tensile stresses \[48\]. The axial fixation provides a static compressive stress within the transducer, which ensures that even at high amplitudes, the tensile stresses will not exceed this critical limit.
2.2 Ultrasonic tools in medicine

Ultrasonic devices used to dissect soft tissue structures in medicine frequently work by means of piezoelectricity and operate in the 23.5 - 55.5 kHz range [30]. The vibrational energy is led to the instrument tip and affects tissue by one of the following principles.

**Ultrasonic aspirator**  An ultrasonic transducer, operating between 23.5 to 25.0 kHz, is connected via a tube to a tapered hollow tip that serves as an aspirator. The longitudinal tip displacement ranges between 200 – 360 μm [30] and creates alternating pressure levels at the tissue interface. Cells are fragmented and tissue planes expanded as a result of cavitation bubble formation and implosion (see Section 2.3.3). Intense heat is released as the compressed gases escape. Low density structures such as adipose tissue and parenchyma are disrupted [54], while collagen structures are usually preserved. Current aspirators tend to have a low coagulating potential due to the narrow tissue contact and the cooling effect of saline irrigation.

**Ultrasonic scalpel**  The ultrasonic scalpel consists of stacked piezoelectric crystals. Mechanical vibrations are induced with a frequency of 23.5 to 55.5 kHz, having an amplitude between 50 and 200 μm [22, 30, 74]. The vibrations are conducted through an extending rod, the waveguide, to a hook, ball, or scissor blade [74]. The larger the contact surface with the tissue (blunt tip), the larger the hemostatic effect [30]. It has been demonstrated that the ultrasonic scalpel is capable of sealing vessels with a diameter up to 5 mm. A smaller contact surface (sharp tip) can be used for tissue dissection. Cutting efficiency depends on the used frequency and amplitude as well as the type of contact and the applied force [6].

**Ultrasonic snares**  In resemblance to the ultrasonic scalpel, a snare would probably rely largely on the direct vibrational impact and to some extent on cavitation. Although, to the author’s knowledge, no ultrasonic snare resection instruments have been marketed up to this day, the idea is not entirely new. By means of an on-line patent search, three distinct instrument designs were found. These devices were all designed for polyp removal in the intestines. They are shown in Fig. 2.4.

![Figure 2.4: Examples of readily patented ultrasonic snares; patent numbers a) US6231578, b) US5989264, and c) US6383194.](image-url)
2.3 Principles of cellular destruction

The piezoelectric transducer of an ultrasonic device transforms electrical energy into kinetic energy, which is delivered to the tissue at the instrument tip. Tissue dissection can be achieved by means of mechanical and thermal effects [18, 62]. In tissue with a high water content, the cavitation principle is dominant [68].

2.3.1 Tissue heating

Although macroscopic damage by ultrasonic heating is not necessarily evident [22], histological injuries might have occurred. The supplied energy can break tertiary hydrogen bonds between collagen and other extracellular matrix proteins and cause collagen denaturation [74]. This leads to the formation of a viscous, adhesive coagulum [8, 46] that can be used to seal blood vessels [34]. Sealing is characterized by homogenization of collagen, which leads to gland profile distortion, epithelium detachment, cell welding, nuclei lengthening and chromatin homogenization [39]. If enough energy is supplied, tissue and vessels at the application center will transform into an amorphous and condensed necrotic structure [74].

2.3.2 Tissue shearing

The direct mechanical or ‘jack hammer effect’ is generally attributed to the production of shear forces in soft tissue, caused by the variations in force level across a thin layer or boundary [62]. In addition, for hard materials such as bone, the fragmented particles may create an abrasive slurry at the probe-tissue interface which stimulates further material removal.

Mechanical effects are often tissue selective as the allowable vibrational insult depends on material strength [18, 62]. In this respect, foremost, the collagen network content, type, and organization is indicative. Structures with a high content are better preserved than those with little collagen.

2.3.3 Cavitation

Before the effect of cavitation (an indirect mechanical impact) in soft tissue is discussed, a short introduction to the subject is in order. A well written summary of sound induced cavitation, including many practical illustrations and examples, is provided by Kuttruff [48]. The general results of which are briefly discussed in the present section.

Any liquid in direct contact with a gas contains a certain amount of dissolved gas. When the pressure drops below the saturation pressure of the gas, small bubbles can appear at the locations of medium impurities. These sites, called ‘nuclei’, are often found at a solid boundary, e.g. a surface pit or scratch, or at a suspended particle. Normally, these microscopic gas bubbles are unstable and either surface due to buoyancy forces overcoming the liquid viscosity, or shrink due to continuous diffusion caused by their surface tension. In the latter case, the gas compresses, the density in the bubble increases, and the resulting progressive bubble collapse is characteristic for gaseous or soft cavitation.
If, on the other hand, the pressure drops below the vapor pressure of the liquid medium, vapor cavities can be formed which contain no or almost no dissolved gas. A reduction in bubble volume does not lead to compression, but to the immediate condensation of vapor, thereby keeping the cavity pressure constant. Due to the liquid inertia, the collapse or implosion of a vapor bubble occurs at an increasing speed and the effects are, in general, much more violent. This process is called hard or vaporous cavitation.

In practice, however, an intermediate situation is usually found where the bubble contains both gas and vapor. Upon implosion of the bubble, the compressed gas will store energy and effect a reversal of motion. The bubble will expand again and reach a new maximum diameter before it implodes a second time. Fig. 2.5 shows an experimental example of an artificially produced nearly gas free cavitation bubble in silicone oil. Several subsequent expansion and implosion steps are visible.

![Figure 2.5: Illustration of several subsequent expansion and implosion cycles of a cavitation bubble in silicone oil](image)

Under the influence of an ultrasonic source, bubbles perform harmonic radial oscillations with a similar frequency as the sound field. At high vibrational amplitudes, linearity is lost, and the bubble’s frequency spectrum will also contain multiples of the sound frequency. This is a discrete process where each vibrational component requires the amplitude of the sound pressure to exceed a successive threshold.

Besides the continuous, static dissipation of gas, ultrasonic waves introduce an additional dynamic component. As the bubble radius and surface area alternate by the vibration, so does the rate of diffusion. More gas will enter the bubble in the negative pressure phase, than is forced out in the positive phase. The rectified diffusion represents the net gas flow provided by both the static and dynamic component. At high vibrational amplitudes, the bubble can even experience a net growth. As
a result, the resonance frequency of the bubble decreases. Upon approaching the sound field frequency, this effect is strengthened. Eventually, the bubble either gets destroyed by the effect of its surface waves, or propelled out of the sound field by the sound pressure gradient. This effective ‘degassing’ process is a frequently used practical application of ultrasound in industry.

In reality, several or many cavitation bubbles will mutually influence each other. Bubble cohesion and even merging can result from displacement streams causing negative Bernoulli pressures between them. If merged bubbles grow larger than their ‘resonance size’, they may again disintegrate into smaller bubbles. In addition, the stream fields of imploding gas free cavities can interact with each other. If the radial symmetry with respect to the center of the cavity is lost, the bubbles will deform and thin liquid jets can be found shooting with high speed across the bubble.

During implosion, the reduction in bubble volume can lead to internal pressure increases with a factor $441 \times 10^3$. The local temperature can rise to as much as $12,000 \, \text{K}$. These extreme conditions lie at the basis of the emission of erosive shockwaves that damage nearby structures. After a surface area is initially affected, more cavitation nuclei will develop and the process tends to accelerate (Cavitation [1]).

It has been shown that the cavitation bubble behavior is highly sensitive to location and material type [62]. In clinical applications, it is often unclear whether cavitation occurs in the intra-cellular, extra-cellular or surrounding fluid. It is probable that cavitation causes cell fragmentation and destruction in a tissue structure, whereas in the surrounding medium, cavitation causes inefficient coupling and dissipation of energy [62].

2.4 Extend of damage

The precise mechanism for tissue removal and damage differs for individual specimens and is closely related to the mechanical, acoustic, and biological properties [62]. It has been established that the wave absorption parameter increases as a function of protein content and that, once more, collagen content is indicative [29]. The absorption in bone is considerably higher than in soft tissue [62]. As absorption is representative for the wave penetration depth, this subject has received considerable interest in the field of high frequency ultrasound imaging [29].

Throughout literature, large deviations in sustained tissue damage are found, ranging from a few millimeters [9, 39, 46] to one or more centimeters [22, 42, 74]. Fig. 2.6 shows the tissue temperature build up at various distances from the source, during and after heating for 15 s. As the temperature increase is steep, small changes in activation time can readily lead to large deviations in end temperature.

As can be seen by the in-vivo and in-vitro temperature distribution measurements, blood perfusion plays a crucial role in heat dissipation away from the tip. Hemostasis is achieved at relatively low temperatures [34] ranging from 50 to 100 °C [42], and dissection is associated with little charring and smoke production [8, 42] compared to electro- and laser surgery.
Figure 2.6: Temperature elevation vs. time at various distances, using the Harmonic Scalpel in lung tissue. Left: with blood perfusion (in-vivo), right: without blood perfusion (in-vitro). [46]
Part I

Standardization of thermal spread
CHAPTER THREE

THE NEED FOR A STANDARD

From a physiological perspective thermal spread is an important factor to examine as it is directly related to the endured trauma and the subsequent recovery of the patient. Thermally affected tissue structures (here evoked by a hot scalpel) were found to have reduced mechanical properties (e.g. tensile strength) for at least two weeks after the procedure [43]. In addition, necrotic structures will slowly decay and be removed by the body and the viable tissue around the wound, e.g. the ‘vaginal cuff’ in case of hysterectomy procedures, will decrease [31]. This can for instance complicate the preservation of wound closure by means of sutures.

The variability in thermal spread obtained after ultrasonic dissection was found to be considerable in Section 2.4. When comparing the thermal spread with different energetic dissection techniques (e.g. electrosurgery, laser surgery, plasma surgery) even more variables come into play and measurements have been found to vary with a factor $10^4$, ranging from 2 µm [65] to 25 mm [22]. This may indeed to some extend be attributed to the different mechanical, thermal, and chemical responses associated with the different techniques. However, it is also likely that the lack of coherence in the definition of ‘thermal spread’ and the absence of one standardized and controllable measurement technique plays its part.

Some papers report thermographic illustrations to define the spread [13, 51], assuming a temperature threshold above which damage results. Others use sensors, such as thermocouples, to determine tissue temperature at a specific distance [46, 70]. Sometimes even online MRI monitoring of the applied thermal dose is used [56]. Finally, an often used method to visualize specific chemical reagents or products that can be associated with the sustained damage is provided by tissue staining and subsequent histologic inspection [57, 58, 69, 84].

Table 3.1 provides a selection of thermal spread evaluations and comparisons encountered in literature. Whenever specified, the direction of measured spread, lateral or deep, is presented. One paper [38] contained a prototype device which has been excluded as the used energy modality was unclear (bipolar or plasma). The fact that the presented values are all in the same order of magnitude should probably (largely) be attributed to similarities in the applied evaluation technique. Each study made use of porcine tissue and all but one evaluated histology by means of hematoxylin and eosin (H&E) stains (a picrosirius red 34B stain was used in [79]).
CHAPTER 3. THE NEED FOR A STANDARD

Table 3.1: Average thermal spread measurements for different treatment techniques. All energetic dissection experiments were performed on porcine tissue and thermal spread was evaluated by means of tissue staining and subsequent histological inspection. ‘/’ means different instruments with the same energy type have been investigated, ‘-’ refers to multiple spread estimates obtained from a single instrument.

<table>
<thead>
<tr>
<th>Source</th>
<th>Tissue (direction)</th>
<th>Average thermal spread (mm)</th>
<th>Monopolar</th>
<th>Bip + mech*</th>
<th>Plasma</th>
<th>Ultrasonic</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002[28]</td>
<td>ureter</td>
<td>2.11</td>
<td>2.0 – 3.3</td>
<td>1.92</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2003[32]</td>
<td>artery</td>
<td>2.0 – 3.3</td>
<td>2.83/5.13</td>
<td>5.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2006[79]</td>
<td>peritoneum (lateral)</td>
<td>8.5</td>
<td>4.75</td>
<td>3.42/4.38</td>
<td>6.00</td>
<td></td>
</tr>
<tr>
<td>2007[38]</td>
<td>peritoneum (deep)</td>
<td>0.13</td>
<td>4.5</td>
<td>2.7/3.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007[69]</td>
<td>overall** (lateral)</td>
<td>5.9</td>
<td>4.5</td>
<td>0.3/0.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007[69]</td>
<td>overall** (deep)</td>
<td>7.0</td>
<td>6.3</td>
<td>2.8/4.3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Bip + mech* refers to a hybrid concept making use of both bipolar and mechanical energy. **‘overall’ provides the mean value for various tissue types.

Despite this effort to evaluate results from comparable experimental models, conclusive statements about the extend of thermal damage can not yet be made. Different tissue types have a different thermal response, e.g. connective tissue layers have a reduced thermal sensitivity [57]. Furthermore, differences in technical parameters such as power settings, application speeds, and forces have not yet been considered as they are often not described sufficiently. Recording of the application time is often forgotten of which the erroneous effect is sometimes acknowledged [69], and power settings are either expressed in the amount of ‘illuminated bars’ on the device [32] or completely left unmentioned [14, 28].

As an initial step to create a more thorough base for the evaluation of thermal spread, it is suggested to include all relevant information regarding the medical, technical, and statistical parameters of the experiment, as presented below (this list is revised from the earlier performed literature study [83]). It can be seen that a large part of these considerations deal with biological influences. This is logical, as the biological and chemical factors are typically the ones providing measurement variability. Mechanical factors are, however, often overlooked and not described sufficiently to allow experimental repetition.

Medical parameters

- **Tissue type** – organic (species, organs) or phantom, constitution: water-, protein content (e.g. collagen, elastin), etc.
- **Tissue integrity** – relevant medical conditions, in vivo, ex vivo, or in vitro, tissue freshness, preservation and storage techniques, etc.
- **Tissue evaluation** – orientation, staining, used tools and instruments, etc.
<table>
<thead>
<tr>
<th><strong>Technical parameters</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Experimental method – cutting orientation/fiber direction, tissue contact or distance to tissue, affected surface area, etc.</td>
</tr>
<tr>
<td>- Used instruments – working tips, sizes, diameters, personal modifications, etc.</td>
</tr>
<tr>
<td>- Energy levels – power setting, frequency, application time, speed, force, etc.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Statistical parameters</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Groups – number of individuals, number of samples, subdivisions, etc.</td>
</tr>
</tbody>
</table>
EXPERIMENTAL METHODS AND SETUP

The quality or neatness of a produced cut, for now interpreted as the resulting thermal spread at the dissection site, should be made comparable to that obtained by competitive techniques. In order to do this, the relevant free variables contributing to this factor should be identified and evaluated. An experimental framework, such as proposed in the previous chapter, would help reduce the amount of free variables by specifying and fixating as many factors as possible in a standardized protocol. This chapter attempts to construct this framework and apply it to one of the existing ultrasonic dissection tools.

4.1 Medical parameters

As illustrated in the introduction of this thesis, the hysterectomy procedure would be an archetypal medical situation that could benefit from ultrasonic snare resection. However, the selection of one particular tissue type might impede the generality of a thermal spread standard. Different instruments are used during different procedures on different tissue types. In addition, animal tissue tends to show large deviations from one specimen to the other as a result of variations in material constituents, concentrations, and isotropy (or in general; the absence of material homogeneity). In order to obtain coherent and repeatable test results, it may be interesting to broaden the scope and consider more (organic) materials.

4.1.1 Tissue type

As a basis for finding a suitable material substitute, some reference values regarding material properties would, however, be helpful. Data was collected on mechanical, acoustic, and thermal properties of various (bio-)material, as shown in Appendix C. Quantifications of cervical, uterine, vaginal wall, and ‘average’ soft tissue properties have been included where possible. In addition, estimates on the cervical water, collagen, and elastin content are shown.

As illustrated by the variability in these figures, and in particular by the mechanical properties, a single set of material characteristics that would reliably describe the thermal response, does not exist. Hence, the tissue properties presented in
Appendix C can merely provide an outline or frame of what would be desired. Therefore, the emphasis in finding a suitable test material should lie in the retrieval of a uniform and well known composition that provides experimental stability and repeatability, not in the exact matching of a specific set of properties. For this reason it may be interesting to regard materials other than animal tissue. Perhaps the biological variability can be isolated and removed from the experiment so that the resulting material response can be directly coupled to the distributed energy.

As, to the author’s knowledge, no marketed tissue phantoms exist for the purpose of conducting thermal experiments, two viable alternatives remain. A custom made phantom can either be designed and fabricated or an industrial surrogate material can be sought that agrees with the above confinements. A pilot study was performed to evaluate the thermal response of several marketed products. Material composition was chosen as a benchmark in this pilot as it represents the priorly available product information (the ingredients list). In particular, focus was put on the water, protein, and fat content of available products. Being the major constituents of tissue, these elements are assumed to largely define the thermal response.

With the aid of nutritional data [21], Table 4.1 was constructed. Although many organic products were considered, it was found that only meat replacement products and cheeses were capable of approximating the desired composition. Usually, the water content of surrogates was found relatively low as a consequence of the higher fat content, while purely muscular tissue tends to be very lean. In addition, it should be noted that the composition of marketed products can differ considerably from these tabular values. Apparently and perhaps within reason, the exact composition of these products is strongly branch dependent.

<table>
<thead>
<tr>
<th>Product</th>
<th>Water %</th>
<th>Protein %</th>
<th>Fat %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Porcine muscle, general</td>
<td>75.0</td>
<td>21.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Poc chop, unprepared</td>
<td>66.4</td>
<td>19.0</td>
<td>13.5</td>
</tr>
<tr>
<td>Meat replacement, raw avg.</td>
<td>63.8</td>
<td>18.4</td>
<td>7.2</td>
</tr>
<tr>
<td>Camembert 30+</td>
<td>61.0</td>
<td>23.5</td>
<td>13.5</td>
</tr>
<tr>
<td>Feta cheese</td>
<td>62.1</td>
<td>14.2(16.1)</td>
<td>21.5(22.6)</td>
</tr>
<tr>
<td>Mozzarella</td>
<td>56.9</td>
<td>20.0</td>
<td>16.5</td>
</tr>
<tr>
<td>Grill Cheese</td>
<td>-</td>
<td>-</td>
<td>- (&lt;43&gt;)</td>
</tr>
<tr>
<td>Tofu</td>
<td>57.1</td>
<td>19.3(10.5)</td>
<td>7.2(6.5)</td>
</tr>
<tr>
<td>Tempeh</td>
<td>69.2</td>
<td>12.0(19.5)</td>
<td>8.3(8)</td>
</tr>
<tr>
<td>Panir</td>
<td>-</td>
<td>- (15)</td>
<td>- (18)</td>
</tr>
<tr>
<td>Quorn</td>
<td>64.2</td>
<td>14(14.5)</td>
<td>2.6(6)</td>
</tr>
</tbody>
</table>

From this list several products were selected and purchased. Subsequently, the gross thermal response was reproduced with a temperature tunable soldering iron, as shown in Fig. 4.1.
Although soft tissue has not been included in this preliminary test, the effect of tissue heating has readily been studied by many (see also Section 2.3). Upon the application of a soldering iron, it is likely that tissue will withstand thermal damage, desiccate, and upon reaching high enough temperatures, carbonize. Actual cuts are not likely to result, for the same reason bipolar electrosurgical probes are good at heating and coagulating, but not at dissecting tissue [52]. In comparison, most cheeses were found to melt at higher temperatures, making the dissection process ‘reversible’ and the line of dissection unclear. On a thermal level this may influence heat propagation as the higher temperature liquid phase tends to flow and leap away. Feta cheese, grill cheese, and meat replacement products did not melt. However, the dissection of feta and tofu occurred in a relatively coarse and crumbly manner. This may refer to a more brittle material, whereas tissue tends to behave elastic. Large deviations in mechanical response may affect the dissection time and thereby the amount of dissipated heat. Tempeh, panir, and grill cheese did not melt and maintained a relatively smooth structure. However, tempeh contains large nutty parts, which introduce discontinuities in the tissue structure (affects tissue homogeneity). Heat did visibly affect quorn and resulted in a discoloration, but the soldering iron alone was insufficient to produce actual cuts. Apparently, the mechanical strength of this material is better than that of the other samples. For this reason quorn was selected as the most appropriate tissue substitute.

4.1.2 Tissue integrity

When dealing with ex-vivo animal tissue, the physical characteristics tend to undergo quick changes after the animal’s passing as the existing chemical and thermal balance is roughly disturbed. As a result, the exact material response will quickly lose its affinity with the in-vivo case, and perhaps more importantly, it will exhibit a strong time dependency. In general, storage methods, such as cooling or freezing techniques, or the regulation of water content by means of salt buffers [27], need to be considered in order to maintain the tissue’s structural and functional integrity [81]. Preservation techniques can, however, affect tissue integrity. Formalin can for
instance lead to tissue shrinkage \[82\] and thereby influence the measured distance. The selection of a non-living organic material will in this respect be advantageous. Quorn is a mechanically fabricated consumption product with a well defined composition. After the production process, it is sold in a virtually stable chemical state. A slow time dependent aging, and possibly drying effect may come in play, in particular when the vacuum seal is broken and the product is stored at suboptimal conditions. However, these changes can be easily omitted by trusting upon the manufacturers production standards and purchasing new samples for each experimental routine.

4.1.3 Tissue evaluation

Spread of damage should be evaluated in the lateral direction, perpendicular to the cut, as this represents the damage that remains after removal of a tissue structure (e.g. the vaginal cuff after removal of the uterus). A wide variety of evaluation techniques exists to assess thermal spread (see also \[83\]). One often applied technique for thermal spread evaluation in muscular structures is the microscopic evaluation of tissue processed by hematoxylin and eosin (H&E) stains. As thermal injury manifests by an eosinophilic homogenization of coagulative denaturized collagen \[82\], the H&E stain provides a useful indicator for the affected area.

As the current experiments will be performed on a meat replacement product, instead of actual muscular tissue, the standard staining techniques will be ineffective and histological evaluation seems to be an inappropriate approach. Instead, the use of thermocouples has been advocated on occasion to measure tissue temperature at a specific distance \[46, 70\]. This technique would be a useful alternative for the current test protocol. By using multiple thermocouples and positioning them in the lateral and deep direction, it should be possible to generate a rough representation of the thermal spread around the ultrasonic applicator.

<table>
<thead>
<tr>
<th>Table 4.2: Summary of selected medical parameters.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parameter choices</strong></td>
</tr>
<tr>
<td><strong>Tissue type</strong></td>
</tr>
<tr>
<td><strong>Tissue integrity</strong></td>
</tr>
<tr>
<td><strong>Tissue evaluation</strong></td>
</tr>
</tbody>
</table>

4.2 Mechanical parameters

Now that a tissue type is specified, the experimental methodology and the design of a suitable test setup should be discussed. This section also covers the used ultrasonic generator and dissector. In order to relate the measured spread to the actual spread in tissue, the selected dissector should be used in a similar fashion as would be the case in clinical practice. For this reason, instrumental modifications should be carefully described and justified.
4.2. MECHANICAL PARAMETERS

4.2.1 Experimental method

In equivalence to the cervical- and uterine wall anatomy, the tissue specimens to be dissected should be approximately 1 cm thick. Tissue fibers (when present) should be oriented in plane with the outer surface and orthogonal to the cutting instrument. The ultrasonic grasper should be placed over the tissue sample - so that its beak is completely filled - and squeezed tight during ultrasonic activation. Adjacent to the ultrasonic grasper, the thermocouples should be positioned. Procedural time and force should be kept constant during each trial in order to obtain comparable energy dissipation levels.

4.2.2 Used instruments and energy levels

Selection of a generator and transducer for the production of ultrasonic waves was largely determined by device availability. The Lotus torsion system (Lotus LG-3, SRA Developments) served as a basis for all experiments that follow. The piezoelectric stack of this device was designed for excitations by a 50 W input signal at 36 kHz. The longitudinal vibrations are subsequently converted to a torsional output in a titanium waveguide. The vibrational amplitude of the wave maxima, e.g. at the tip, was experimentally determined to be 80 – 100 µm (see Chapter 8 for these, and more experiments regarding the output characteristics of this device).

It was discovered that the Lotus system has a maximum on-time of ∼ 22 s, after which the generator produces a warning message and the signal output is terminated. This safety measure was used to equalize 'procedure' time.

A simple experiment was carried out to quantify the maximum closure force that can be delivered by the Lotus grasper. A force sensor (Futek LLB130) was placed inside the Lotus beak, and the maximum force was extrapolated by calibrating the sensor with the aid of several weight increments. Fig. 4.2 presents the results of this trial and provides a maximum force of ∼ 1150 gram.

![Figure 4.2: Relation between force sensor loading and sensor output, providing an estimate for the maximum grasping force of the Lotus.](image-url)
CHAPTER 4. EXPERIMENTAL METHODS AND SETUP

Table 4.3: Summary of selected mechanical parameters

<table>
<thead>
<tr>
<th>Parameter choices</th>
<th>Experimental method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 cm tissue sample thickness, equivalent to use in clinical practice</td>
</tr>
<tr>
<td>Used instruments</td>
<td>Lotus torsion LG-3</td>
</tr>
<tr>
<td>Vibration</td>
<td>Power = 50 W, frequency = 36 kHz, amplitude = (\sim 80-100\mu m)</td>
</tr>
<tr>
<td>Application factors</td>
<td>Duration = 22 s, force = (\sim 11.5) N</td>
</tr>
</tbody>
</table>

4.3 Statistical parameters

It would be desirable to attain some form of statistical foundation to relate the thermal spread of the Lotus to that of competitive designs.

4.3.1 Groups

As a starter, the spread of the readily available Lotus dissector should be evaluated. This will be done at different locations around the instrument to investigate the thermal profile and to assess heat buildup under particular experimental conditions. Thermal spread will be measured at four locations around the instrument and at three different depth levels.

4.3.2 Group size

In order to get a general idea of the required group size, a power analysis can be performed. In order to do this, an educated guess of the average thermal spread values and standard deviations is required. The thermal spread of an ultrasonic grasper is estimated to be \(3.4 \pm 1\) mm, based on the full thickness lateral spread measurements obtained from two different ultrasonic instruments [69]. It should be noted that these experiments were performed on porcine ureter samples processed with H&E stains. Although the effects in quorn may be completely different, this is as close of an estimate as can be obtained at this stage. Eventually, the thermal spread of the Lotus should be compared to that of another energetic dissection source. For this reason the second spread value was estimated to be \(4.8 \pm 1\) mm, which would be right between the other tested and commercially available energetic (but non-ultrasonic) dissection techniques evaluated in the same study [69].

Subsequently, a double sided t-test power calculation was performed in order to judge the required sample size (n) for these two normal distributions to be distinguished with significance (using the software package \(G^*\text{Power}\)). By selecting a power \((1 - \beta)\) of 0.95 with a significance level \((\alpha)\) of 0.05, the total sample size was found to be 30. This means that, under the made assumptions, at least 15 experiments with the original ultrasonic dissector and 15 experiments with a second device should be performed in order to proof a statistically significant difference between the measured spread estimates.

For the current experiments only the Lotus grasper will be used. Thermal spread will be evaluated at several locations around the instrument by means of the methods priorly described. Mostly due to the use of quorn as test material, it is expected that the variance in thermal spread will reduce, e.g. to \(\pm 0.5\) mm, which is already
achieved by one of the tested ultrasonic dissectors [69]. On forehand, no real difference in amplitude of spread around the Lotus is expected. As it is nearly impossible to experimentally proof similarity of two estimates (which would require a theoretical sample size of infinity), a minimum deviation that would still be allowable was specified. For convenience this distance was chosen to be 1 mm, stating that larger differences should in the very least be distinguishable. Performing a power analysis based on these criteria would require a minimum sample size of 8 for each subsequent group or location.

Table 4.4: Summary of selected statistical parameters

<table>
<thead>
<tr>
<th>Parameter choices</th>
<th>Groups</th>
<th>several locations around the instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group size</td>
<td>min. 8 samples per group, 15 for comparison with other instruments</td>
<td></td>
</tr>
</tbody>
</table>
THERMAL SPREAD MEASUREMENT

To test the previously proposed thermal spread evaluation technique, the Lotus ultrasonic torsion system was applied to dissect tissue samples. The associative temperature incline was measured as a function of time and position around the instrument and will be presented in this chapter.

5.1 Methods

The test setup is shown in Fig. 5.1. The tissue groove was covered with insulating tape in order to reduce heat dissipation to the aluminum ground plate. A tissue sample (quorn), with a thickness of 10 mm, was placed inside this groove, in such a way that it would bridge the opening left for the Lotus grasper. The grasper was positioned sideways along the opening in the ground plate and moved forward against the tissue sample until the beak was completely filled. Adjacent to the grasper, a small plate (printed circuit board) was bolted onto the ground plate. Its holes were found to be an exact match to the 1 mm thick thermocouples (TC Direct 408-201). This way, the thermocouples could be easily spaced in a grid next to the ultrasonic grasper. The distance between the holes on the circuit board was 2.5 mm. Eight thermocouples were positioned in a raster adjacent to the ultrasonic grasper and temperatures were recorded as a function of position and time.

Figure 5.1: Eight thermocouples were positioned in a raster adjacent to the ultrasonic grasper and temperatures were recorded as a function of position and time.
were placed in a 3x3 grid, leaving the middle, most distal position open. The thermocouples were connected to two 4-channel thermocouple input modules (National Instruments) and subsequently led to a computer. Temperatures were measured with LabVIEW and processed with MATLAB.

Before measuring, the thermocouples were lowered against the bottom of the sample groove, so they would evenly stick out 10 mm below the circuit board. They were subsequently fastened by means of glue. By positioning the circuit board as a whole at three different heights, respectively 2.5, 5, and 7.5 mm above the ground plate, the thermocouples were forced to penetrate the test samples with their remaining length (7.5, 5, or 2.5 mm). In addition, the circuit board was allowed to connect to the ground plate at four different locations; left or right, and besides or in front of the grasper, as shown in Fig. 5.2.

During the experiments the grasper was closed to ensure tissue contact. The maximum on-time of the Lotus, approximately 22 s, was used to equalize 'procedure' time. After the device turns off, the temperature profiles were monitored on-line with a frame rate of 2 Hz. Once the tissue temperatures had reached their maximum values at all locations (usually after ~ 100 s), the temperature recordings were terminated.

In total, 77 thermal spread measurements were conducted. They were divided over 4 positions around the Lotus grasper (at a penetration depth of 5 mm); left flank (n = 25), left top (n = 10), right flank (n = 12), and right top (n = 10), and 2 additional depths (measured at the left flank); 2.5 mm (n = 10) and 7.5 mm (n = 10). The difference between the left and right thermal spread was assessed by means of a student's t-test and the three in-depth levels were evaluated by an analysis of variance (ANOVA) and subsequently a Tukey-Kramer evaluation to compare the estimated differences with the standard errors.

5.2 Results

Fig. 5.2 depicts the maximum temperature reached at each location around the grasper averaged over n. Both the 7.5°C and 10°C isotherms are shown. The distance between two thermocouples is presented by dx. The distance of thermal spread is measured from the dotted gray lines which extend from the Lotus device shaft.

When regarding a single temperature - time (T-t) curve, the most illustrative example was produced by an incorrect measurement, shown in
During this trial, the ultrasonic activation button was accidentally released for a short moment. As a result, the on-time of the device could be extended by almost a factor 2. Consequently, higher temperatures were reached and a more distinct thermal profile with regard to the different locations was obtained. The on-time of the ultrasonic grasper is shown by the thickened curve sections.

The lateral distance between the 7.5°C isotherm and the Lotus shaft (see the dotted vertical lines in Fig. 5.2) was determined for both the left and right flank. A single valued thermal spread estimate was calculated by taking the mean of the distances at which the isotherm intersects the three horizontal lines (see Fig. 5.3) at which thermocouples were placed. This was done for all measurement and the average thermal spread plus range are presented in Table 5.1. The student’s t-test provided a p-value of 0.22 for the comparison between the left and right flank, which means the null hypothesis (the means of both measurements are equal) cannot be rejected at the 5% significance level with the currently retrieved data.

<table>
<thead>
<tr>
<th>Location (depth)</th>
<th>n</th>
<th>Average distance (STD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left flank (5 mm)</td>
<td>25</td>
<td>3.09(0.637) mm</td>
<td>1.85 – 4.56 mm</td>
</tr>
<tr>
<td>Right flank (5 mm)</td>
<td>12</td>
<td>2.70(0.966) mm</td>
<td>1.41 – 4.92 mm</td>
</tr>
<tr>
<td>Left flank (2.5 mm)</td>
<td>10</td>
<td>2.11(0.732) mm</td>
<td>1.25 – 3.66 mm</td>
</tr>
<tr>
<td>Left flank (7.5 mm)</td>
<td>10</td>
<td>2.95(0.959) mm</td>
<td>1.29 – 4.61 mm</td>
</tr>
</tbody>
</table>

Thermographic representations of thermal spread as a function of measurement depth (on the left flank) are shown in Fig. 5.4 and the measured distances have been included in Table 5.1. Again the 7.5°C and 10°C isotherms are shown. A multiple comparison by means of an ANOVA test was performed, which resulted in a p value of 0.0035 (F = 6.48) and thereby demonstrated the likeliness of at least one thermal spread estimate to differ from the rest. The boxplots shown in Fig. 5.5
CHAPTER 5. THERMAL SPREAD MEASUREMENT

Figure 5.4: Thermographic representation of the averaged (n = sample size) maximum in-depth temperature increase at three depth levels.

(left) present the data of these estimates and the associative notches illustrate the comparison intervals. As the 2.5 mm depth comparison interval does not overlap the other two intervals, it can be expected that this estimate is the one deviating from the rest. The Tukey-Kramer method was used to determine the lower bound, estimate, and upper bound for each comparison. Fig. 5.5 (right) displays a graph of all three estimates and the comparison intervals according to this method. At a 5% significance level, the thermal spread at 2.5 mm depth was found to differ significantly from both the 5 and 7.5 mm depths.

Figure 5.5: Left: boxplot resulting from ANOVA showing the lateral thermal spread as a function of sensor penetration depth. The comparison interval (notch in the boxplot) at 7.5 mm depth extends beyond the upper quartile of the drawn box, resulting in the plotted shape. Right: Tukey-Kramer estimates and comparison intervals, demonstrating the difference between the 2.5 and 5 mm depths, and the 2.5 and 7.5 mm depths.

5.3 Conclusion

When evaluating the thermal spread around the ultrasonic grasper on a qualitative basis, a quite predictable behavior is found. The heat profile approximately follows the shape of the end effector. The averaged thermal spread is comparable in both the left and right lateral direction. On a quantitative basis, the thermal spread
in quorn seems to be relatively low; elevations of 7.5°C above body temperature are not quickly detrimental for soft tissue. On the other hand, a steep slope in temperature is found upon approaching the grasper and higher level isotherms won’t be located far. In addition, the variance in measured spread was not substantially below that in soft tissue (e.g. [69]) and the selection of quorn as tissue substitute should be carefully reassessed. When regarding the temperature profiles in time, a heat conduction delay is observed. Between the near and far nodes (distance of 5 mm) a delay of \( \sim 60 \) s between temperature maxima is not uncommon.

Upon evaluation of the in-depth spread during the dissection of a 10 mm thick tissue sample, the lateral spread at the top section is found to be smaller than at the middle and bottom sections. This can be easily understood by considering that the Lotus grasper only has one effective, vibrating side, which in this setup was held at the bottom of the tissue samples. Hence, the effective distance to the vibrational source at the top layers is greater than at bottom sections. This dependency was clearly observable thanks to the use of thermocouples.

### 5.4 Discussion

One of the first factors that should be noted is the discrepancy of determining thermal spread as the lateral distance from the Lotus waveguide, instead of the instrument tip. As shown in Fig. 5.2, spread is on average approximately a mm larger. However, the exact determination of spread from the irregularly shaped tip would quickly lead to errors due to slight instrument translations and rotations during use. The waveguide was considered a more rigid and more-over visible framework to start measuring.

Although the Lotus energy dispersion is limited by means of a maximum duration time, Fig. 5.3 clearly demonstrates the ease of cheating with this restriction by a short release of the activation button. If the procedural pause is short enough, this does not have to interfere with the thermal build up and high tissue temperatures can be reached.

One particular observed case of extreme temperatures (reaching a \( \Delta T \) of almost 70°C) should be described. Although somewhat averaged out, its effect is still clearly visible in the right flank plot of Fig. 5.2 (left top corner). A small tear around the associative thermocouple was observed. A possible, but not further explored and therefore provisional explanation would be that this gap fills itself with fluid, increasing the local conduction and convection of heat and possibly the generation of cavitation bubbles. The resulting thermograph is shown in Fig. 5.6.

The higher water content in soft tissue may therefore also suggest an additional explanation for the discrepancy in thermal spread between soft tissue and quorn. Important to note is the possible risk of causing unintentional iatrogenic damage if resembling tears can be endured by soft tissue.

Although a surrogate material has been selected based upon the comparison of chemical composition and water content with respect to human tissue, the actual
thermal properties of quorn have not been identified and a direct comparison of spread would be erroneous. It should be noted that this is of less relevance as this study is not aimed to quantify thermal spread in human tissue in the first place. Instead, it attempts to provide a basis for quantitative comparison of heat dissipation by different ultrasonic instruments. Equality of the relevant parameters and repeatability of the procedure were considered more important than the direct link to tissue damage in clinical practice.

With a similar argument, the application of the $7.5^\circ C$ isotherm can be justified; this isotherm has no physiological meaning, but was merely used out of convenience as it was visible in the majority of the performed experiments. The few measurements (6) that did not contain the complete isotherm, were filled up with minimum x-coordinates (1.25) to determine the average spread. Although this approach has led to a measurement error, it was considered to give less bias than the complete removal of these low spread values. Due to the steep temperature incline close to the instrument, the missing coordinates had to be close to the grid (average $\Delta T$ at adjacent nodes under $7.5^\circ C$ was $6.4 \pm 0.76^\circ C$).

With the hardware restriction of possessing two thermocouple input modules, this error could have been omitted by either measuring closer to the ultrasonic tip or by evaluating a lower $\Delta T$ isotherm. However, these solutions have their downsides. Measuring closer to the instrument may result in accidental tip contact, possibly leading to device malfunction. In addition, nearby measurement data appeared to be more irregular and susceptible to local contact differences. Although some short tests were performed with other grids (not $3 \times 3$), these either quickly extended beyond the zone of perceptible ‘action’ (having large blue areas in the thermographic plots) or required a significant amount of data interpolation in order to fill up the full temperature matrix for the surface plot. Interpolation of data was found to be risky as the direction of the temperature gradient deviates both in time and among experiments due to contact differences. This would require the acquisition of individual and time dependent interpolation function for each measurement grid.

One of the main aspects leading to variance in thermal spread was tissue contact. The mechanical strength of quorn was observed to be less than that of muscular tissue and it was found to be impossible to fully squeeze the grasper. As the maintenance of tissue contact was considered a prime objective to ensure heat flow, contact force remained variable. This may have affected heat production and caused variance in the measured data (which was higher than anticipated).

As thermal conduction is proportional to the temperature difference between two connected items (Fourier's law), identical energy dissipation by an ultrasonic source may lead to a different $\Delta T$ and thermal spread in the same tissue sample, but at another start temperature. The use of temperature increase ($\Delta T$) instead of true temperature ($T$) should in this respect be considered a regretful, but necessary loss of information required to prevent misinterpretation of data due to room temperature fluctuations (on average $23.7 \pm 1.4^\circ C$, $n = 616$). It should, however, be noted that the resulting error in thermal spread due to these fluctuations is relatively small because of the high ultrasonic end effector temperature (the variance in $\Delta T$ will still be low). This aspect may, however, become an issue upon the direct substitution of presented spread values in a clinical case, at body temperatures.
Although a couple of critical remarks (see also Section 5.4) can and should be made regarding the completed experiments, the obtained results are considered adequate and sufficiently precise to describe many relevant factors regarding the thermal spread of the Lotus. It should be kept in mind that a higher accuracy would only be meaningful if the physician can actually work with that kind of precision in clinical practice. Demanding the physician to refrain from nearing delicate structures at 3.7 mm distance would only be useful to those who can visually distinguish and employ that constraint. In this regard, small differences in thermal spread among ultrasonic tools should not be considered a benchmark for device selection. Other factors, such as intuitive control, can be more meaningful and will possibly increase procedural safety to a much greater extend.

The importance of thermal spread should, however, not be underestimated as exemplified by the wound closure dilemma in Chapter 3. However, the current status is that no consensus has been reached on how to quantify thermal spread. As a result, published values do tend to vary considerably. This is a serious concern as many manufacturers claim a reduction in thermal spread to be one of their strong assets. At this point it would theoretically be fairly easy to mislead the majority of an audience by presenting values in favor (or not) of a specific product by simple use of a different experimental routine. For this reason alone, the development of a thermal spread evaluation protocol should be encouraged. Although the priorly described protocol could present a basis for such a routine, several aspects may still be improved. As of yet, only one ultrasonic dissector has been studied. In order to assess experimental reproducibility and reach a standard, more instruments should be evaluated by independent parties.

In the currently performed experiments, thermocouples were used to measure tissue temperature at specific locations. This technique was selected because it had been used in advance in several research studies [46, 70]. The use of infrared cameras, or alternatively the employment of thermochromic surface layers, were opted as possible visualization techniques as well. Although these techniques would be non-invasive, they would require additional calibration steps in order to translate the produced color schemes to actual temperatures. Although they would allow full surface visualization - instead of the nodal measurements provided by thermo-
couples - they would be incapable of measuring in the deep direction. In addition, thermochromic inks or paints are usually applied to obtain color shifts at certain indicative trigger temperatures and not to visualize an entire range of temperatures. Reviewing the discovered depth dependency in the dissected tissue samples, the use of thermocouples seemed appropriate.

Although the selection of a non-living test material, being more stable in time and less dependent on preservation techniques, is still considered a convenient choice for thermal spread evaluation, an optimal substitute was not found in the selection of quorn. Although the strength of quorn seemed relatively high compared to that of other considered materials, it is nowhere near that of biological tissue. The Lotus grasper was even capable of dissecting these samples without the use of ultrasonic energy. As a result, the grasping force and consequently, the amount of dissipated heat could not be held constant. This may have led to an increased variance in the obtained spread values. In addition, quorn (in contrast to the blocks of cheese or other meat substitutes) was sold in pre-shaped form, complicating the retrieval of sufficiently large test samples. Perhaps an appropriate solution can be found in the production of some sort of reinforced gel or other type of individually developed material.
Part II

Development of an ultrasonic snare
ULTRASONIC SNARE CONSIDERATIONS

Optimal dissection would require a swift and smooth motion resulting in a clean, non bleeding cut with minimal spread of damage to surrounding structures. Fig. 2.6 shows how the temperature increase in tissue depends on procedure time. Damage decreases as dissection speed is increased and procedure time is reduced, while procedural safety is maintained. As procedure time largely relies on device employment, both efficient and intuitive controlled design are important. However, in this preliminary stage, only the (mechanical) design aspects that will influence cutting efficiency, e.g. the operational frequency, area of contact, stroke amplitude, and applied force [86], will be discussed.

7.1 Frequency and amplitude

![Graph showing predicted reaction force on a cutting blade for several vibration amplitudes at 35 kHz.](image)

Ultrasonic trials on a mild cheddar cheese model have shown that especially the blade tip amplitude is indicative for the effective cutting force. Fig. 7.1 provides a finite element prediction of the positive relation between the blade tip amplitude and the peak-to-peak oscillating force [49]. An initial force peak can be recognized before the first node unbinds (crack initiation). In a homogeneous material, the dissection force will eventually plateau to a steady-state situation.
CHAPTER 7. ULTRASONIC SNARE CONSIDERATIONS

As the material fragmentation rate is a direct function of the stroke amplitude [18], it is important to enhance the stroke of the ultrasonic tip. Mechanical means to do this have been readily discussed in Section 2.1.4 and comprise the stacking of multiple piezoelectric elements and the implementation of an acoustic horn.

As the wave amplitude was kept constant, it was found that the operational frequency had a negligible effect on the oscillating force [49]. Nonetheless, this does not mean that operational frequency does not affect the dissection potential. As discussed in Section 2.3, destruction of tissue can be achieved by means of mechanical, thermal, and cavitation effects. The mechanical effect depends on the oscillating force, but also on other factors, such as contact geometry and intensity. In addition, the cavitation and thermal effects will likely change with frequency. In particular, the extend of cavitation was found to be tissue dependent, and changes with density [54] and water content. It is expected that the tissue selective dissection ability of ultrasonic devices should be attributed to the choice in frequency [78].

![Figure 7.2: Input admittance amplitude for various tissue loads. The vertical line indicates the unloaded resonance frequency [86].](image)

In addition, an external load has been found to affect the operative performance [62]. During use, the (anti-)resonant frequency, admittance, reflection factor, and electromechanical coupling coefficient of the combined system tend to deviate from unloaded operation in plain air [86]. As piezoelectric transducers are used near their resonance frequency, the loaded situation leads to a reduced vibrational amplitude and output power [86]. For soft tissues, such as fat, muscle, liver, skin, and cartilage, the resonance frequency of the total system is lowered, whereas application on bone tends to increase the frequency, as shown in Fig. 7.2 [86]. These discrepancies can, however, be compensated for by regulating the generator frequency during the procedure [62]. Some ultrasonic generators are to some extent capable of auto-tuning and thereby compensating for this autonomously [26].
7.2 Snare characteristics

It has been shown that size and sharpness of the working tip in ultrasonic applications are indicative for the tissue response. A sharp tip leads to tissue dissection, whereas a blunt tip primarily causes coagulation [46]. The appropriate choice of contact is of fundamental importance to realize an adequate reaction. The contact characteristics of an ultrasonic snare deviate notably from the usually considered blade model. Although both methods employ a line contact, the effects of snare radius (edge sharpness), length, and other geometrical factors influence the transmission and propagation of waves and should be regarded.

7.2.1 Length

Whenever an ultrasonic transducer is coupled to a close by - with regard to the vibrational wavelength - instrument tool tip, the input and output waves are strongly related. However, when an intermediate medium (waveguide) is used to transfer the waves to a more distal tip, i.e. as is the case for long laparoscopic instruments, the wave characteristics of the intermediate medium should be considered. A standing wave will develop [4] which exhibits regions of compression and strain related to the harmonic resonance and anti-resonance lengths. Therefore, vibrational amplitude and cutting efficiency will not be constant over the waveguide length and the placement of harmonic nodes needs to be considered carefully to optimize performance at the tool tip. Dependent on the selected material and dimensions, a similar response may possibly result in an ultrasonically activated snare.

Fig. 7.3 illustrates the distal output displacement amplitude in a nitinol (Nickel-Titanium or NiTi) wave guide as a function of length [26]. For a bar of uniform cross section and no damping, the anti resonance length, \( l \), can be calculated by Eq. 7.1. Here, \( f_n \) is the frequency, and \( c \) the speed of sound [61]. The available Lotus system provides a single sided vibrational output with a torsional wavelength equal to the anti-resonance length. This would approximately be 4.3 cm for a torsional (shear) speed of sound in titanium of 3125 m/s [33].

\[
l = \frac{n \cdot c}{4f_n}, \quad n = 2, 4, 6, \ldots
\]  

(7.1)

Besides the wavy character of the displacement amplitude, considerable attenuation losses are seen in Fig. 7.3. Even for relatively short waveguide lengths, damping effects are evident from the peak-to-peak displacement amplitude [26]. It was shown that these attenuation effects can be somewhat relieved by the use of tapered wires [61], resulting in an amplification effect at each taper point (the acoustic horn principle). In addition, the lower distal mass aids in minimizing inertia. The locations of the wave amplitude maxima and the stress concentrations at the taper points can be optimized by controlling the section lengths with regard to the (anti-)resonance distance.
CHAPTER 7. ULTRASONIC SNARE CONSIDERATIONS

7.2.2 Geometry

Tip-tissue interaction is largely dependent on the shape of the end effector \[62\]. Ultrasonic energy can either be concentrated on a specific site or dispersed over a larger area, dependent on the desired tissue effect. Wire thickness should be regarded in analogy to the cutting edge radius of a blade. It is evident that blades are generally sharper, and have smaller contact areas than wires. On the other hand, ultrasonic graspers, capable of dissecting soft tissue, do not necessarily have a sharp edge. In any way, the trade-off between cutting and coagulating, but also mechanical aspects such as snare strength and flexibility, complicate the optimization of snare thickness and should be carefully assessed.

In order to focus the ultrasonic energy dissipated by a snare, it might be possible to adjust the snare’s geometry by means of incorporating a specific surface roughness or an external profile. Perhaps triangular or square cross sections, or the incorporation of a screw profile would be beneficial. It should, however, be kept in mind that such modifications will alter the snare’s mechanical behavior and strength. Procedural safety should be reevaluated as new hazards, e.g. abrasion, can emerge. As the vibrational amplitude is relatively small \((\sim 100\mu m)\), it is difficult to predict the effects of such alterations on the dissection speed analytically and experimental trials would be in order.

7.2.3 Material

So far, the list of material demands for suitable soft tissue snare resection has been growing steadily. The material selected for ultrasonic cutting blades usually has
7.3. APPLIED FORCE

A high strength and toughness \cite{55}. The snare strength should be high enough to allow the operator to exert external forces on it without causing material failure. If the snare length requires the consideration of internally propagating waves, the acoustic properties need to be matched with those of the ultrasonic source \cite{55} in order to obtain a high Q factor and thereby efficient transfer of energy. In order to benefit from the snare removal technique, the snare needs to be flexible. In addition, the snare needs to be thick enough to produce a coagulum and arrest internal bleedings, but as thin as possible to decrease the contact area and speed up the procedure. Finally, the snare should not corrode, release allergens, or result in any other additional safety risks when exposed to the environment of the human body.

7.3 Applied force

It has been shown that forces exerted on the tissue structure increase with increased cutting edge radius and cutting depth \cite{73}. The required force for cutting ductile film is found to decrease with increased operational speed, as the sustained deformation reduces \cite{73}. Since soft tissue is highly susceptible to deformation, it can be posited that the employment of an external force during ultrasonic snare resection may accelerate the procedure. Especially the ‘jack hammer effect’ of the ultrasonic effector is deemed to increase in significance. This can for instance be achieved by increasing the suction level during ultrasonic aspiration \cite{62}, or by tightening a snare around the tissue structure in case of an ultrasonic loop. It should, however, be kept in mind that both the snare and the piezoelectric transducer have a finite strength and are susceptible to failure as external forces become excessive.
8.1 The generator

The generator is required to provide the correct electric signal to the piezoelectric transducer. The Lotus generator is depicted in Fig. 8.1. The output signal constitutes a sinusoidal wave of 36 kHz associated with a relatively high voltage and low current as required by the transducer. The device has two intensity settings realized by altering the vibrational amplitude of the piezo. This stroke amplitude is directly related to the applied electrical amplitude (voltage) of the input signal and hence to the electrical input power. The high level setting requires an electrical input of 50 W. It should be noted that this value deviates from the mechanical output power (mainly) due to the transducer’s coupling factor (see Section 2.1.3).
8.2 The transducer

The transducer of the Lotus, shown in Fig. 8.2, is attached to a mount which connects to a waveguide, leading the ultrasonic vibrations directly to the working tip. The Lotus output consists of a torsional wave, which is unusual as crystal deformations are extensional. How this vibration is generated and applied will be discussed in the remainder of this section.

Figure 8.2: The Lotus transducer, showing from left to right; the housing of the piezoelectric element and its mount, the torsional waveguide, and the instrument tip.

As an initial step to analyze the piezoelectric transducer, the CT scans shown in Fig. 8.3 were taken. They clearly show the internal construction and allowed an initial non-destructive evaluation of the device.

Figure 8.3: CT scans of the Lotus transducer. The bright white surface depicts the piezoelectric stack. The rotational vibration of the waveguide is accomplished by an off-centered engagement between the transducer and mount. The acoustic horn is used to amplify this vibration.
8.2. THE TRANSDUCER

The piezoelectric transducer is shown as a bright, high density material, occasionally causing light scatter in the produced scans. The location and direction of the stacked piezo elements are clearly visible. The mechanical conversion to torsion results from the engagement between the transducer output and an off-centered boring (with regard to the instrument centerline) in the mount. The vibrational amplitude is increased by several subsequent exponential horn sections.

![Figure 8.4: The housing of the Lotus transducer was opened after careful inspection of the CT scans.](image)

With the aid of these scans, a safe technique to open the transducer housing without damaging the piezo elements was investigated and subsequently executed. Although the possible means to directly tap into the longitudinal vibration of the piezoelectric element was investigated, it soon became apparent that the risk of irreversibly damaging the transducer upon further disassembly would be substantial and that continuation in this approach should be carefully reconsidered. In addition, the original amplitude would probably be low due to the absence of a matching acoustic horn. Horn designs are typically based on the associative vibrational wavelength [48] and this variable differs for the torsional and longitudinal case. Although it would be possible to individually design and fabricate a new horn for longitudinal use, it seemed wise and time saving to rely on the expertise of the manufacturing company by tapping into the vibrational output of the waveguide after amplification.

This choice resulted in two additional aspects that had to be considered. At this point, a wave mode conversion from longitudinal to torsion took place. Snares are, however, typically designed to withstand stress conditions and not torsion. Hence, it would be preferred to reverse the wave conversion in order to benefit from the snare’s mechanical strength. Several methods have been examined to convert the Lotus energy and produce extensional waves in the snare (see Appendix D).

In addition, the locations of wave amplitude optima (anti-nodes) in the waveguide need to be experimentally verified in order to ensure a maximal conversion of energy. Although the snare could be connected to the working tip, where it is reasonable to expect the vibrational amplitude to have a maximum, this would introduce an unnecessarily large bending force on the waveguide and transducer as the snare pulling force has its maximum arm. By using earlier anti-nodes along the waveguide, this factor should be reduced.
8.2.1 Determination of vibrational nodes in the Lotus

For the determination of nodes and anti-nodes in the shaft of the Lotus, the experimental setup shown in Fig. 8.5 was constructed. The shaft was covered with a marker grid of small indentations with a 1 mm spacing interval as shown in Fig. 8.6. A high speed camera (Photron FASTCAM-Ultima APX-RS) was connected to a focus mount (Rodenstock) with a 4× magnification and positioned above the shaft, zoomed in on each marker individually. A micrometer slider (Thorlabs) was used to position the shaft relative to the camera view. The Lotus device was activated and the vibrating instrument was photographed at a frame rate of 100,000 fps with a resolution of 128 × 80 pixels. Due to the low exposure time, a high intensity external light source was needed to acquire sufficient contrast. For this purpose a slide projector was tilted and its continuous light source was bundled with a lens, placing the focal point on the shaft. Viewed from the high speed camera, the metallic shaft reflected a significant amount of light, whereas the marker pits remained dark.

As the Lotus vibrates with a frequency of 36 kHz, whereas frames were taken at a frequency of 100 kHz, approximately 3 images per wave were recorded. In order to capture the wave characteristics, many subsequent waves had to be evaluated. Of each marker a series of 300 photos (a little over 100 waves) was collected. Nodes of which the vibrational amplitude was observed to be near a maximum, were measured multiple times in both power levels of the Lotus transducer. MATLAB was used to filter out the noise in the images (using a hybrid median filter), convert the images to black and white only, sum up the black (0) or white (1) pixel values of the entire series, and calculate an averaged gray level per pixel. Pixels at boundary layers, among others caused by the indentations, translated due to the vibration. A gray border line appeared as pixels were found black in one photo, and white in the next. Under the assumption that, at some point during the 300 collected frames,
8.2. THE TRANSDUCER

Figure 8.6: Illustration of the standing wave in the Lotus. The shaft, shown at the top, was covered with markers (1 each mm). Of each marker 300 photos (a) were taken. After filtering out the noise (b), and converting the images to black-white only (c), the sum of the photo series was calculated pixelwise (black = 0, white = 1) and an average gray level was determined (d). Along the marker boundary a gray band appeared, of which the width was used as an approximation of the wave amplitude, U. A Fourier fit was used to create a sine through the measurement data.

the minimum and maximum displacement amplitude were approached, the width of this border was used as an indication for the vibrational amplitude.

At this point, the wave amplitude is expressed as an amount of pixels. In order to roughly relate this to an actual distance, several indentation radii were measured under a digital microscope (Keyence, VHX-100). The obtained values were used as a reference to determine the wave amplitude, U (µm), as shown in Fig. 8.7. The amplitude was plotted as a function of the shaft length (bottom of Fig. 8.6) and a basic Fourier fit was used to visualize the wave.

Figure 8.7: Microscope measurements were used to relate the wave amplitude to the marker diameter.

The maximum vibrational amplitude was approximately 80 – 100 µm. Compet-itive devices work with comparable wave amplitudes [4]. The first maximum was found at pit #13, the second at pit #56. Hence, the wavelength was found to be 4.3 cm, which is in accordance with the theoretical value obtained in Section 7.2.1.
8.2.2 Reverse verification of energy flow and power

Now that the wave characteristics of the Lotus are known, it is possible to derive the mechanical output power and determine the energy efficiency of the device. The Lotus shaft essentially embodies a wave inside a wave; it contains a high frequency, time dependent wave of which the amplitude is described by a standing wave along the shaft, see Fig. 8.6. Hence, at the location of an anti-node (amplitude maximum), the wave can be described by a sinusoid with a frequency of 36 kHz and an amplitude of 100 µm as depicted at the top of Fig. 8.8. By subsequently taking the first and second order derivative of this function, the velocity and acceleration are given. The power required to perform this vibration also depends on the rotational inertia of the shaft. An estimate of this factor was established by means of using the CT scan footage to model the shaft in SolidWorks, as shown in Fig. 8.9.

![Figure 8.8](image1)

**Figure 8.8:** Model of the Lotus wave at an anti-node.

![Figure 8.9](image2)

**Figure 8.9:** SolidWorks model of the Lotus shaft used to approximate the rotational moment of inertia.

The power curve provided by Fig. 8.10 represents the undamped situation at an anti-node. Would this condition be supplemented on the entire shaft, an infinitely stiff, undamped, vibrating structure would be modeled. In reality, a balance exists between forward- and reflected waves leading to a suboptimal situation of cancelling waves and system damping in the bulk of the device. Although a complex mass-spring-damper system would be required to fully model this system, the current focus lies on the evaluation of energy flow at the location of an anti-node. Therefore, the simplified stiff model is assumed to be adequate and sufficient to approximate the local output power. The red, solid line represents the absolute power distribution, as direction dependencies introduced by velocity and acceleration vectors are of no importance when describing the energy dissipation. The mechanical power reaches a maximum of 39.7 W, which resembles a theoretical efficiency factor of 0.794 with regard to the 50 W electrical input signal. The ~20% power drop can mainly be attributed to losses in energy conversion. The power curve falls back to zero whenever either the velocity or the acceleration vector switches sign.

![Figure 8.10](image3)

**Figure 8.10:** Output power of the Lotus shaft at the location of its maximum amplitude.
ULTRASONIC SNARE SELECTION

Although many variables will likely affect cutting efficiency, the ones related to snare selection are easily amendable and will therefore have a considerable influence on the direction and continuation of this research field. Material selection of the ultrasonic resection snare is a crucial development step. The material selection procedure developed by Michael F. Ashby [7] provides a useful structural routine to retrieve the most suitable material for a specific task. The CES edu software package was used for the subsequent evaluation. The four main steps of this approach are defined as 1) the translation of design criteria, 2) the screening of materials using the set constraints, 3) the ranking of found alternatives, and 4) the retrieval of supportive information.

9.1 Translation of design criteria

The main function of an ultrasonic snare is the transfer of acoustic energy. This can either be achieved by allowing wave propagation from a harmonically vibrating source, or by perturbing the snare as a whole. In short, these two alternatives differ in the snare’s molecular lattice response. During wave propagation, the molecules themselves resonate about their equilibrium position, whereas during perturbation the internal structure remains rigid. In order to keep energy losses low, the first situation would require an acoustic match between the snare material and that of the acoustic source. The second situation would require a stiffness high enough to prevent significant losses of the vibrational input due to elastic deformations; i.e. the elongation caused by a maximum snare load should be low compared to the vibrational amplitude.

During wave propagation in a snare, the development of a standing wave existing of wave nodes and anti-nodes should be considered. Displacement at the nodes will be at a minimum, whereas anti-nodes exhibit displacement maxima. This would suggest differences in cutting efficiency along the snare’s length. In addition, focus was put on the development of extensional waves in the snare, whereas the Lotus applies torsional waves. Exact acoustic matching of the in-and output during wave propagation from the waveguide to the snare is complicated by wave type dependencies of the material’s acoustic properties (e.g. the speed of sound in one
material is different for the torsional and extensional case). The speed of sound in isotropic solids is roughly a factor two larger for extensional waves than for torsion\[33\], and is proportional to the ratio between Young’s modulus, $Y$, and density, $\rho$, ($\sqrt{Y/\rho}$). An acoustic match would require similarity of acoustic impedance, $Z_0 = \rho \cdot c$, of the two connected materials, see Section A.4. As titanium is a relatively light material, this would require a very low Young’s modulus of the complementary material. Practically, this would exclude all metals. These theoretical disadvantages have led to an initial favor for the stiff, ultrasonically perturbed snare concept, taking some heat production due to acoustic losses for granted.

The snare should be able to withstand an external force caused by the accumulative influence of applied snare tension and friction resulting from tissue contact in a linear elastic manner. The resulting elongation should be low compared to the perturbation amplitude. Therefore, a high elastic modulus is required. Finally, the snare material should not interfere with the human body in a toxic, corrosive, or otherwise chemical manner. The objective of the current evaluation is therefore to find a biocompatible material with a high stiffness and yield strength. Design factors, constraints, and (partially) free variables are presented in Table 9.1.

### Table 9.1: The functions, objectives, constraints, and free variables of an ultrasonic activated snare.

<table>
<thead>
<tr>
<th>Function</th>
<th>Efficient transfer of acoustic energy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives</td>
<td>Find a stiff, biocompatible snare material</td>
</tr>
<tr>
<td>Constraints</td>
<td>Snare length 150 mm</td>
</tr>
<tr>
<td></td>
<td>Minimum bending radius 12.5 mm</td>
</tr>
<tr>
<td></td>
<td>Snare cross-section profile Round</td>
</tr>
<tr>
<td>Free variables</td>
<td>Material selection Biocompatible</td>
</tr>
<tr>
<td></td>
<td>Snare thickness range 0.1 – 1 mm</td>
</tr>
</tbody>
</table>

The importance of cutting edge radius on the blade ‘sharpness’ was demonstrated by McCarthy et al\[53\]. In particular, the cutting force and the crack initiation peak, as shown in Fig. 7.1, are affected by this parameter. During the use of an ultrasonic tool, the importance of this parameter is evident as it directly affects the dispersed energy density. Pure cutting is achieved by means of a sharp edged blade, such as a modified no. 15 blade \[4\]. Sharp blades typically have a cutting tip radius around 1 $\mu$m \[53\]. Pure coagulation is achieved by a flat surface. In practice, large radii (several mm) ball type probes are used. An ultrasonic snare should have a radius located between these two ultimates to allow both dissection and coagulation. Snare thickness is initially considered a free variable between give and take 0.1 – 1 mm. Several mechanical factors, including the strain and bending radius are thickness dependent and should be evaluated. As a benchmark for the bending radius, the outer radius (12.5 mm) of a prototype instrument for uterus extirpation (described in Appendix B.6) was used. The ultrasonic snare would theoretically be a useful addition to this device. As the retrieval of an infinitely stiff material is unrealistic, the snare elongation will be bound to increase with snare length due to the development of internal strain. For the current purpose, the evaluation of a short snare length is preferred. Using the same prototype as a dimensional reference, the minimum snare length capable of surrounding a 1 cm thick tissue layer around

...
9.2 Screening of Material Database

this instrument, would be 141.4 mm (2\pi r). A snare length of 150 mm is selected.

As for the snare profile, initial focus will be on simple round wires. At a later stage it might be interesting to look into alternative configurations. The cross sectional area of a snare with a radius of 0.4 mm is approximately 0.5 mm$^2$ ($A = \pi r^2$). Accordingly, a titanium snare with a yield strength of 830 MPa, could elastically support forces up to 417 N ($F = \sigma_y A$). The material stiffness $k$ is obtained by:

$$k = \frac{AE}{L}$$

(9.1)

Where $E$ is the material's elastic modulus and $L$ is the length. Before filling in this formula, the mechanical setup, as shown in Fig. 9.1 should be considered. As the snare is actuated on both sides, surrounds the tissue, and is loaded halfway its length, for simplicity let's consider a symmetrical case with two snares of length $L$ half the snare length, loaded with a force $F/2$ at the end.

The stiffness of a single titanium snare ($E \approx 110$ GPa), according to Eq.9.1 would be $\sim 737$ kN/m. A force $F$ of 834 N (417 N per snare) would lead to yielding and a snare elongation, $x$, of 0.57 mm ($x = F/k$). It should, however, be mentioned that an external force of this magnitude would probably have no trouble dissecting tissue even without the addition of ultrasonic energy. The application of a force of 20N ($F = 10$N), would lead to an elongation $x$ of 13.6\mu m, an approximate factor 7 smaller than the vibrational wave amplitude of the Lotus.

Up to this point, the flexibility of the snare has not yet been regarded. In the simplified situation of pure bending, the snare will deform by means of compression in one side and tension in the other. Hence, the elastic modulus is indicative for the desired behavior. In addition, bending is dependent on the cross sectional shape, as expressed by the bending moment of inertia $I$. For a round snare, this factor is provided by $I = \pi r^4/4$. This means the 'ease of bending' of a snare with a radius varying between 0.1 and 1 mm could be manipulated by a factor 10,000, making the effect of material choice (elastic modulus) in this respect relatively small.

### 9.2 Screening of Material Database

Although titanium has just been used as an example to evaluate the feasibility of some of the set constraints, it is imperative to perform this material selection procedure with an unbiased perspective. During the material screening process, a pre-selection is made based on the elimination of candidates with attributes that
lie outside the set constraints. In the current situation all biocompatible materials should be considered, the rest can be excluded. With the available software package this was approximated by placing some strict limitations on the material’s durability with regard to contact with water, salts, weak acids and alkalis, and organic solvents. In order to limit the search results to materials that can be produced as wire, a shape factor value of 1 was given. Finally, to further reduce the results, a restriction to the minimum yield strength and Young’s modulus was set to respectively 100 MPa and 100 GPa.

9.3 Ranking of suitable options

Materials that have passed the screening step should subsequently be ranked. A ‘criterion of excellence’ should be defined in order to optimize material attributes for the specified application. As was mentioned, the current evaluation should focus on finding a suitable material with a high stiffness. However, Eq. 9.1 illustrates the dependence of snare stiffness on dimensional aspects, such as cross sectional area.

![Figure 9.2: Young's modulus vs. yield strength for various materials, shape factor = 1](image_url)
and length. The elastic modulus in this equation would therefore be a better optimization criteria. As a second axis for the material selection plot the yield strength was chosen, although an initial filter readily eliminated low strength materials in the screening step. Fig. 9.2 provides the Young’s modulus plotted against yield strength for various materials.

The top materials include variations on Nickel-Cr-Co alloys, tantalum alloys, and stainless steel. The mechanical properties of which are presented in Table 9.2.

<table>
<thead>
<tr>
<th>Name</th>
<th>Young’s modulus (GPa)</th>
<th>Yield strength (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nickel-Cr-Co-Mo alloy</td>
<td>215 – 225</td>
<td>1800 – 2100</td>
</tr>
<tr>
<td>Tantalum-tungsten alloy</td>
<td>190 – 210</td>
<td>990 – 1210</td>
</tr>
<tr>
<td>Stainless steel martensitic</td>
<td>190 – 210</td>
<td>620 – 690</td>
</tr>
</tbody>
</table>

It can be seen that the difference in Young’s moduli among these materials is relatively low. Due to the common availability and low costs of stainless steel, this material is selected for initial experiments. If the resulting snares are too large, the use of other alloys can always be explored.

9.4 Retrieval of supportive information

To finalize the selection procedure, the material reputation and credibility should be evaluated. As a matter of fact, several individual constituents of the top three materials are frequently encountered in biomechanical design.

Cobalt-chromium alloys have been used in dental and orthopedic applications for decades, e.g. in the contact surface of prosthetic bearings. They are radiopaque and MRI-compatible and generally appreciated for their high elastic modulus [50].

A more recent application of these alloys is in the development of ultra-thin struts in stents. The addition of nickel to this alloy, as suggested by the Ashby results, should be carefully evaluated. Nickel containing materials in the medical field have been a frequent point of discussion due to the apparent toxicity of this component (e.g. in nitinol). Several surface treatment techniques have however been developed to decrease the chance of nickel ion release.

Tantalum has an excellent corrosion resistance due to the formation of a highly stable surface oxide layer. It is occasionally used to coat stainless steel in order to enhance the biocompatibility [50]. It is non-ferromagnetic and therefore compatible with MRI techniques. Due to its high density it is also very suitable for the production of fluoroscopic röntgen images.

Stainless steel, with or without coating, is probably the most commonly used metal for medical instruments. It is generally considered to have an excellent corrosion resistance, although for long term applications a coating would be desired to prevent triggering of the local immune response due to the slow release of chemical impurities such as nickel, chromate, and molybdenum [50].
ULTRASONIC SNARE CUTTING

Now that there is sufficient understanding of the available ultrasonic source, the relevant wave propagation characteristics, and the desired snare parameters, a test setup can be constructed. The preliminary results of ultrasonic cutting experiments with a snare are presented in this chapter.

10.1 Methods

A stainless steel snare with a thickness of 0.6 mm was connected to the Lotus transducer. This connection was achieved by means of hard soldering the snare to a stainless steel thin ring surrounding the titanium waveguide of the transducer. The ring was laser welded to the waveguide at the location of the first anti-node. As shown in Fig. 10.1, the vibrating snare was damped out at the top by means of a plastic stop suspended with two leaf springs. Along the way, the snare dissects a cutting platform which was used to make contact with the test material. The original actuator of the Lotus was used to trigger the device.

![Figure 10.1: Overview of the experimental ultrasonic snare dissection test setup.](image-url)
10.2 Results

After activation of the Lotus, a tissue holder was used to slide and carefully press the tissue sample against the vibrating snare, as shown in Fig. 10.2.

![Figure 10.2: Illustration of the ultrasonic dissection experiment. The tissue holder is positioned on top of the cutting platform. It contains a cheese sample and can slide towards the vibrating snare.](image)

During some preliminary tests, cheese was used as a tissue substitute. The snare was well capable of slicing through the tissue layers, however, the metal backing surface of the tissue holder prevented full thickness dissection. During some cutting experiment videos were recorded to estimate the dissection time so that this factor could eventually be kept constant and not interfere with the extend of thermal spread. Cutting times were found to be \( \sim 2 \) seconds for a snare contact length of \( 1.9 \text{ cm} \) and a cutting depth of approximately \( 1 \text{ cm} \). More precise results could not yet be obtained as the weld between the connector ring and the waveguide broke early.

10.3 Conclusion

Although the feasibility of cutting with an ultrasonic snare was demonstrated by this small experiment, it should be noted that this result was hard-won. As will be elucidated in the discussion to follow, the adopted approach of modifying an existing ultrasonic source (although extremely educative) may not have been the right approach. The titanium waveguide of the Lotus is hard to work with both on a mechanical and acoustic level.

10.4 Discussion

As the right stainless steel snare was not directly available, a short initial test was performed with a braided \( 7 \times 7 \) snare. As expected, it was discovered that braided snares are not suitable for transferring ultrasonic energy. Although their flexibility
would increase the maneuverability during operation, the individual strands were triggered independently and internal friction led to a rapid dissipation of energy. The braided snare was found to reach red hot temperatures near the connector, tissue dissection was not possible, and snare failure resulted quickly.

In Section 9.1, the choice was made to develop a stiff structure which is perturbed by the ultrasonic waveguide. This way, the (complex) retrieval of an acoustically matching material was omitted, taking some energetic losses for granted. Ultrasonic waves propagating to the snare have to cross several boundary layers, including those of the intermediate connector. As covered in Appendix A.4, waves can be heavily distorted by these material boundaries. For simplicity let’s consider a perfect conversion from a torsional to an extensional wave obtained by a direct connection between the titanium waveguide and stainless steel snare (so that only one boundary condition occurs). According to Eq. A.10, using densities of 7870 and 4540 kg/m$^3$ and speed of sound values of 5790 and 3125 m/s [33] for steel and titanium respectively, the reflection coefficient would be 0.53. With other words, during a direct and optimal conversion in this setup, less than half the wave energy would be fed to the snare.

Although the selection of a less stiff (non-metallic), acoustically matching material would help reduce the energetic losses and thereby the heat production at the material boundary, this would also increase the attenuation in the snare and complicate the prediction of remaining waves due to external loads. During use, the material strain would become quite large with respect to the vibrational amplitude, and the effective dissection potential might become irregular and difficult to assess.

However, in the present setup, a lot of heat was dissipated at a relatively small contact surface, making this connection very fragile. Many connector designs have been constructed and tested, as discussed in Appendix D, but none were found resistive enough to sustain multiple trials and eventually allow some degree of thermal spread evaluation.

In addition, the stiff configuration will contribute to the moment of inertia. The addition of a mass will alter the Eigen frequency of the total system. As the piezoelectric element is not excited with the right frequency, the vibrational amplitude will rapidly decrease. It was found that the addition of a rigidly fixed snare connector to the waveguide could result in an error and malfunction of the Lotus generator. This presumably results from the generator’s control scheme trying to regulate the voltage output across the piezoelectric element and thereby trying to compensate for the loss in vibrational amplitude. It is likely that this output voltage is limited for safety reasons. In any way, the set restrictions by the Lotus generator severely impeded the possibility of making any adaptations to the waveguide. Although a strong and lasting connection was desired, this had to be achieved with an almost weightless configuration. Up to this point, no suitable solution to this problem has been found.
DISCUSSION AND FUTURE WORK

Although the executed experiments presented in the previous chapter illustrate the plausibility of transferring ultrasonic waves through a thin snare in order to mechanically disrupt tissue structures, they also show the required proficiency of managing this kind of high level energy in order to, ultimately, create a working and stable end configuration. The necessity of literally leading and guiding ultrasonic waves through the subsequent elements of a design, with the intention of minimizing energy losses and local heat build up, was elucidated by the fragility of the snare connector. Although the considered approach of creating a stiff structure that vibrates along with the waveguide was a logical preliminary step with regard to the architectural limitations while working with an existing instrument, this approach may, from an acoustic point of view, be considered somewhat bold and credulous. Although the snare did translate along with the vibrational input, the majority of the available energy was lost locally at the connection site, whereas during wave transmittance in the snare, the same energy would be dissipated more evenly along its length. With regard to the required wave type conversion and the retrieval of acoustic compliance with the titanium waveguide, the efficient conduction of waves in this setup should be considered ambitious in the least.

Looking back, a more credible approach - although costly and time consuming - would be the individual development of an ultrasonic transducer. By direct, in line coupling of the transducer output to an acoustic horn and the subsequent guidance of waves along this horn until the required snare diameter is reached (by making several subsequent exponential steps towards this decreased diameter), energetic losses may be reduced to a minimum. This way, a waveguide material of choice can be selected, the need for wave type conversion will be omitted, the amount of material boundaries will be reduced, and in general the acquisition of an acoustic match will be facilitated.
In conclusion of this thesis, the contribution of the performed research studies, should be discussed in light of the current, clinical state of affairs. As an illustrative example to do so, the frequently used monopolar dissection loop (e.g. the LiNA loop) could be considered. This instrument provides a simple and intuitive solution to a hand full of medical procedures that require the resection of a tissue mass. The LiNA loop, in particular, was developed to facilitate uterus resection from the vaginal wall during the hysterectomy procedure (see Appendix B). A downside of the used monopolar electrosurgical technique, is the excessive tissue damage (thermal spread) that remains after the procedure. As a result, wound closure by means of suturing of the remaining viable tissue structures may be complicated, as was priorly described in Chapter 3.

Alignment of studies

From an energetic point of view, more advanced soft tissue dissection techniques have been developed in the last couple of decades. These techniques include bipolar electrosurgery, plasma surgery, and ultrasonic surgery, and are generally associated with a decreased thermal spread [83]. The embodiment of these energetic modalities in a tissue dissection snare have, however, up to this day, been unsuccessful. In line with this observation, both the development of a standardized technique to quantify thermal spread and the evaluation of possible means to actualize an ultrasonic dissection snare, can be justified.

Once a fully operational ultrasonic snare is obtained, the associative thermal spread should be evaluated in accordance to a standardized measurement protocol. In case the resulting spread is equal or lower than that of competitive tools, the direct operational benefit of a flexible snare could be explored and a variety of applications could be proposed, including that of uterus resection during laparoscopically assisted vaginal hysterectomy.
Appendices
Before a design can be made to test the feasibility of an ultrasonic snare, some basic knowledge on the generation of high frequency vibrations and their propagation through a medium is required.

Vibrating structures introduce waves in surrounding media. Whenever these vibrations are located within the right frequency domain, they can be intercepted by the human ear as sounds. Waves traveling at frequencies below the lower hearing limit are called infrasound (<20 Hz), whereas those above the upper limit (>20 kHz) are referred to as ultrasound. The frequency range of ultrasound extends to very high values. A theoretical maximum would relate to the discrete (atomic) nature of the material through which a wave propagates. To be more precise; the minimal wavelength is proportional to the acoustic modes and spacing of the quantum particle-phonon-lattice of the material. Frequencies up to $10^{12}$ Hz have been generated by means of piezoelectricity [16].

Ultrasonic vibrations are used in numerous practical applications. Although the terms are often used interchangeably, a distinction can be made between ultrasound and ultrasonic techniques. Ultrasound is primarily used for imaging, material examination (non-destructive testing), and diagnostics, whereas ultrasonics are generally used for energy transfer and the subsequent disruption of a material structure. Examples of ultrasonic applications are welding, milling, cleaning, and cell disintegration.

### A.1 Wavetypes

As a starter, some basic aspects of the propagating ultrasonic wave are discussed. In contrast to the propagation of electromagnetic waves, e.g. visible light, sound needs an elastic medium, such as a liquid or solid, to travel. Fig. A.1 illustrates typical waves in a two dimensional (2D) plane. Their wavelength $\lambda$, and amplitude $u$, are depicted. The period $T$ represents the time it takes to travel the distance of one wavelength, and the frequency $f$ is defined as the amount of passing waves per second; $f = 1/T$. The wave velocity $c$ is constant in a perfectly elastic material at a given temperature and pressure. It is calculated by:

$$c = \frac{\lambda}{T} = \lambda \cdot f$$  \hspace{1cm} (A.1)
Some commonly found wavetypes are:

- The **extensional** or longitudinal wave, as shown in Fig. A.1a. It vibrates in the same direction it travels. In mechanical terms the longitudinal wave is also frequently referred to as a compressional wave.

- The **shear** or transverse wave, where the particle motion is perpendicular to the direction of propagation, is shown in Fig. A.1b.

- The **Rayleigh** wave, which is a combination of compressional and shear waves. Rayleigh waves are often referred to as surface waves, as their penetration depth in a 3D configuration approximates one wavelength [64]. As shown in Fig. A.1c, the displacement amplitude decreases exponentially towards the interior of the body [45].

- The **Lamb** or plate wave, which is found in media with a thickness much smaller than the present wavelengths. The wave can be considered a superposition of Rayleigh waves with similar amplitudes at both plate surfaces. Depending on whether these waves have an equal or opposite phase, two wave modalities are possible, as shown in Fig. A.2a,b.

- The **torsional** wave, which is a purely transverse wave modality found in thin rods. In this mode, adjacent cross sections of the rod are rotated with respect to each other, as shown in Fig. A.2c.

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**Figure A.1:** Illustration of a) longitudinal, b) transverse, and c) Rayleigh waves in a 2D plane.

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**Figure A.2:** Illustration of a) extensional (quasilongitudinal), and b) bending Lamb waves in a plate and c) torsional waves in a rod.
Propagation speed in a material relies on the wavetype \cite{33}. The occurring wavetypes depend on the kind of excitation, the medium geometry, and its mechanical properties. Liquid media with moderate viscosities for instance cannot support shear waves. Solid media can be subjected to complex wave combinations. This is particularly true for anisotropic materials where the elastic constants, as well as many other physical properties, depend on specimen orientation \cite{48}.

\section*{A.2 Acoustic attenuation}

As sound travels through a medium, its intensity diminishes with distance. Ideally, the sound pressure only weakens due to spreading of the wave. In practice, however, signal deteriorating factors, such as diffraction, scatter, and absorption play a significant role \cite{64}. Other factors are viscous losses, thermal conduction (nonadiabatic processes), unequal thermal expansion of neighboring grains due to their axes being rotated with respect to each other, and sound induced changes of state, e.g. crystallization \cite{43}. The combined effect of these factors is referred to as attenuation (dB), which can be calculated by:

\begin{equation}
\text{Attenuation} = \alpha \cdot l \cdot f, \tag{A.2}
\end{equation}

where $\alpha$ is the attenuation coefficient, $l$ the traveled distance, and $f$ the frequency.

The **attenuation coefficient**, $\alpha$, quantifies how strong the transmitted sound wave amplitude decreases in a given medium for a specific frequency.

For attenuation measurements, the signal’s quality factor or Q-factor can be used. The Q-factor is a measure of signal damping and represents the mechanical effects and losses on the stability of the vibrational frequency; or $Q = f_0 / \Delta f = \omega_0 / 2\alpha$, where $f_0$ is the resonant frequency, $\Delta f$ the bandwidth, $\omega_0$ the angular resonant frequency, and $\alpha$ the signal attenuation.

\section*{A.3 Constitutive relations}

Under the assumption of small deformations, it can be derived from classic material strength theory, that strain ($s$) is linearly proportional to stress ($\sigma$) and that the elastic modulus ($E$) relates the two.

When dealing with piezoelectric materials, electric influences, such as piezoelectric stiffening, alter the material’s behavior. The constitutive relations conform the mechanical and piezoelectric effects \cite{48} are presented in Table A.1.

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|}
\hline
Mechanical & stress, $\sigma$ & strain, $s$ & interrelation \\
& $\sigma = \frac{F}{A}$ & $s = \frac{l-l_0}{l_0}$ & $\sigma = E \cdot s$ \\
\hline
Piezoelectric & stress, $\sigma$ & electric displacement, $D$ & \\
& $\sigma = K_E \cdot s - e \cdot E$ & $D = \varepsilon_s \cdot E + e \cdot s$ & \\
\hline
\end{tabular}
\caption{Mechanical and piezoelectric constitutive relations \cite{48}, where $F$ is the force, $A$ the surface area, $l$ the length, and $l_0$ the initial length.}
\end{table}
The first part of the piezoelectric constitutive expressions results from plain mechanics. The stress resulting from the deformed piezoelectric element is only significant in the thickness direction, described by strain $s$. Hence, under a constant field strength $E$, $K_E$ presents the elastic modulus of the material. Likewise, under the assumption of a constant strain, $\epsilon_s$ represents the dielectric constant (relative permittivity) of the piezo element.

Under the influence of an electric field strength $E$, a dipole is created with an associative electric displacement, $D$ (charge density per surface area). The material deforms and the resulting strain, $s$, leads to an internal stress, $\sigma$. By defining a piezoelectric constant, $e$ (N/Vm), the second part of the constitutive equations can be formulated:

$$\sigma = -e \cdot E$$  \hspace{1cm} (A.3)
$$D = e \cdot s,$$  \hspace{1cm} (A.4)

Sometimes the piezoelectric modulus, $d$, is used, which provides the following relations:

$$\sigma = D/d$$  \hspace{1cm} (A.5)
$$s = -d \cdot E$$  \hspace{1cm} (A.6)

For the purpose of relating the piezoelectric constant and modulus, a stiffness value, $c$, needs to be introduced. Stiffness, as usual, relates the stress and strain; $\sigma = c \cdot s$. This leads to:

$$d = e \cdot c^{-1}$$  \hspace{1cm} (A.7)

When extending the previous equations to the full (3D) situation, linear matrix algebra comes into play, e.g. when each stress component is related to each electric field component, a large (18 component) piezoelectric constant matrix arises [18], see Eq. A.8. To clarify the full representation of the first piezoelectric constitutive relation (the second relation can be constructed in a similar manner), a redefinition of the coordinate indices is useful:

$$xx = 1 \hspace{0.5cm} yy = 2 \hspace{0.5cm} zz = 3 \hspace{0.5cm} yz = 4 \hspace{0.5cm} xz = 5 \hspace{0.5cm} xy = 6$$

Since the properties in the $xy$ direction can be considered similar to those in the $yx$ direction [18], only 3 shear factors remain. Therefore, indices $1 - 3$ represent the normal, and $4 - 6$ the shear orientations. When leaving out the subscript, $E$, in the elastic constants, the first piezoelectric constitutive relation can be written as [19]:

$$\begin{bmatrix}
\sigma_1 \\
\sigma_2 \\
\sigma_3 \\
\vdots \\
\sigma_6 
\end{bmatrix} = 
\begin{bmatrix}
K_{11} & K_{21} & K_{31} & \cdots & K_{51} \\
K_{12} & K_{22} & K_{32} & \cdots & K_{52} \\
K_{13} & K_{23} & K_{33} & \cdots & K_{53} \\
\vdots & \vdots & \vdots & \ddots & \vdots \\
K_{16} & K_{26} & K_{36} & \cdots & K_{66}
\end{bmatrix}
\begin{bmatrix}
s_1 \\
s_2 \\
s_3 \\
\vdots \\
s_6
\end{bmatrix} - 
\begin{bmatrix}
e_{11} & e_{21} & e_{31} \\
e_{12} & e_{22} & e_{32} \\
e_{13} & e_{23} & e_{33} \\
\vdots & \vdots & \vdots \\
e_{16} & e_{26} & e_{36}
\end{bmatrix}
\begin{bmatrix}
E_1 \\
E_2 \\
E_3
\end{bmatrix}
\hspace{1cm} (A.8)
Fortunately, many of the constants or moduli from these matrices will turn out to be insignificant (zero) or equal in value due to symmetries in the crystal structure [19]. The amount of independent coefficients largely depends on the symmetry planes - the way the crystal is shaped, oriented, polarized, and the way the electrodes are placed [48]. For a cubic, isotropic crystal, the amount of independent elastic constants even reduces to two. The stiffness matrix would then look like:

\[
\begin{bmatrix}
K_{11} & K_{12} & K_{12} & 0 & 0 & 0 \\
K_{12} & K_{11} & K_{12} & 0 & 0 & 0 \\
K_{12} & K_{12} & K_{11} & 0 & 0 & 0 \\
0 & 0 & 0 & K_{44} & 0 & 0 \\
0 & 0 & 0 & 0 & K_{44} & 0 \\
0 & 0 & 0 & 0 & 0 & K_{44}
\end{bmatrix} \tag{A.9}
\]

Where \(K_{12}\) is interrelated with the other 2 coefficients; \(K_{12} = K_{11} - 2 \cdot K_{44}\). The remaining constants are called the Lamé constants; \(\lambda = K_{12}\), and \(\mu = K_{44}\) [44].

Most ultrasonic transducers are designed in such a way that one particular direction is given preference to all others, so that one particular piezo constant is the deciding one [48]. Although it cannot be completely excluded that other, undesired transducer processes take place as well, these are usually considered side effects and they are often neglected.

### A.4 Material boundaries

So far, the production of ultrasound, the propagation through a material, and the influence of attenuating factors have been discussed. One other major factor leading to energy losses is the propagation from one medium into the other. When this happens, the frequency, amplitude, phase, direction, and speed of the wave can alter. As illustrated in Fig. A.3, waves can reflect at the acoustic interface and bounce back to the ‘source’, or refract and penetrate the ‘load’, traveling with a new velocity and direction [44]. The boundary behavior of a wave largely depends on the difference in the acoustic resistance or impedance of the two connected layers.

![Figure A.3: General case of boundary reflection and refraction at the interface between two media.](image)
The acoustic impedance, $Z$ (N·s·m$^{-2}$), of a material is the opposition of its particles to sound induced displacements [64]. The specific acoustic impedance, $z$, is the ratio between the effective sound pressure and the particle velocity at a single frequency; $z = p/v$. For a plane wave traveling in the forward direction, the characteristic acoustic impedance, $Z_0$, represents a material property defined by the product of its density ($\rho$) and speed of sound ($c$); $Z_0 = \rho \cdot c$.

Especially when waves are transmitted from one state of matter into another, e.g. from a solid to a liquid, the difference in acoustic impedance can be large. A reflection coefficient, $\Gamma$, describes the amplitude ratio of the reflected and incident wave as a function of acoustic impedance of the source ($S$) and load ($L$) [16]:

$$\Gamma = \frac{Z_L - Z_S}{Z_L + Z_S}$$  \hspace{1cm} \text{(A.10)}

It should be apparent that the proper material selection is a crucial step in the development of a wave carrying structure connected to a transducer. Since a piezoelectric transducer has two acoustic ports, both faces of the crystal need to be regarded.

If only one side of the transducer is used, a ‘backing material’ is often added to absorb the energy radiating from the back. The back side can also be left unloaded, in which case $Z_L$ is approximately zero [48], and according to Eq. A.10 most wave energy would reflect.

Waves in the forward direction propagate through the instrument to the tool tip. It is convenient to use a material with an acoustic impedance closely related to that of the transducer to reduce the energy loss by wave reflection. At the tip of the instrument, wave propagation can be a bit more complex. For a proper design, information is required on the load and the acoustic properties of the external environment. During ultrasound imaging techniques, piezoelectric polymers are of special interest as their characteristic impedance lies considerably closer to that of soft tissue than when ceramics are used [19].

In many cases, the surrounding medium consists of a gas or liquid of which the density greatly deviates from the acoustic source. Matching between two media of widely different impedances can be obtained by the appropriate selection of an intermediate layer [44]. It can be shown that the ideal matching layer has a thickness of $\frac{1}{4}$th the sound wavelength $\lambda$, and an impedance equal to the geometric mean of the two media [10]. As a consequence, an optimal match only occurs for one frequency (for which $d = \frac{\lambda}{4}$). Typically, the larger the impedance mismatch, the narrower the frequency bandwidth for which reasonable wave propagation can be reached.

One last effect that should be discussed is mode conversion. When an incident longitudinal wave travels from a liquid to a solid, at an angle of incidence, $\theta_i$, that exceeds a material specific critical value, the resulting wave in the solid is purely transverse. Conversion of wavetype may also result from the internal reflection of sound at a free surface if the solid has a Poisson constant below 0.263 [48].
CLINICAL RELEVANCE: THE HYSTERECTOMY PROCEDURE

B.1 The uterus removal procedure

The medical term for a uterus removal procedure is ‘hysterectomy’. Occasionally, the term uterus extirpation is used in analogy. This procedure, with an annual occurrence of over 16,000 times in the Netherlands (1998) [11, 80] and approximately 600,000 times in the USA [70, 85], is besides cesarean delivery the most frequent major surgical intervention performed on women [80, 85]. Although a decreasing trend was witnessed during the period 1991 – 1998, due to the emergence of alternative uterus preserving methods, such as medication and new endoscopic techniques [80] (e.g. endometrial resection [3]), see Fig. B.1 [12], these alternatives only form a substitute for a part of all indications leading to hysterectomy. The procedure will likely continue to be performed on a large scale. The lifetime risk for a woman to experience a hysterectomy procedure varies considerably on a geographical basis; ranging from 30% in the USA, 20% in the UK, to 12% in the Netherlands, and 10% in Sweden. The peak age at which hysterectomies are performed occurs during the menopause (age 45 to 49), although the procedure remains common practice up to a high age, see Fig. B.2 [3].

Figure B.1: Occurrence of different types of hysterectomy during 1991 – 1998 in the Netherlands [12]
APPENDIX B. CLINICAL RELEVANCE; THE HYSTERECTOMY PROCEDURE

Hysterectomy is often performed to improve the quality of life, rather than to cure life-threatening conditions [76]. The most common indications for hysterectomy procedures are pelvic pain or pressure and abnormal bleeding. These symptoms often result from pelvic organ prolapse, uterine fibroids, and sometimes malignancies of the uterus or ovaries [11], such as endometrial cancers. Although legitimate concerns exist that, especially in the USA, the hysterectomy procedure may be overused [85], it has also been shown that it can present an ideal solution for a lot of discomfort among women [80]. Significant post-procedural improvements in all three aspects of a person’s health; symptoms, psychological functioning, and quality of life, were demonstrated [45, 76]. Pelvic pain, dyspareunia, and fatigue complaints were significantly reduced after hysterectomy [76].

B.2 Uterus proportions

The uterus is a hollow, inverted pear shaped organ with the size of a fist. The actual size of the uterus, especially in the presence of a medical condition, can deviate quite a bit. An average diameter of 11 cm (ranging between 5 – 17 cm) was found among 512 women who underwent a hysterectomy procedure [60]. The weight of the uterus was found to be $292.9 \pm 206.3$ g [17]. The maximum specimen weight in this study was in excess of 1 kg. It should be noted that these values represent a group of removed uteri. Normal, healthy uteri have a considerably smaller size and weight.

B.3 Procedural classification

There are many types of hysterectomy techniques in use today. In order to comprehend the procedure’s illustrative value for the current thesis, some basic knowledge on the different techniques and terminology is useful.

B.3.1 Total or subtotal hysterectomy

Based on the patient’s disorder, a method of approach for the hysterectomy procedure is chosen. During total hysterectomy, the uterus and cervix are completely
B.3. PROCEDURAL CLASSIFICATION

removed at the location of the fornix, see Fig. B.3. When a cancer is present, this approach is often the method of choice. Sometimes the ovaries need to be removed in addition, e.g. for patients with endometriosis. In the extreme case, radical hysterectomy is performed, where the uterus, cervix, top of the vagina, ovaries, fallopian tubes, lymph nodes, lymph channels, and tissue in the pelvic cavity that surrounds the cervix, need to be removed.

It should be noted that the ovaries play an important role in maintaining the body’s hormone balance even after the menopause [67]. Estrogen has been shown to lower the chance of sustaining among others osteoporosis and heart disease. Testosterone, also produced by the ovaries, in addition prevents muscle loss and directly affects the brain, increasing libido. Although surrogate hormones exist, it has been shown that merely 30% of the patients will actually take them [67]. It is therefore advised to preserve the ovaries whenever possible.

In some cases it might be possible to preserve the cervix by performing a subtotal or supracervical hysterectomy. This reduces the risk of ureter, bladder, or intestine injury during the procedure and decreases blood loss. However, the remaining part of the cervix can be more susceptible to the development or spread of cancer [67].

Figure B.3: Anatomy of the vagina, uterus, and ovaries, showing the dissection lines of total, and subtotal (supracervical) hysterectomy [2].

B.3.2 Abdominal, vaginal, or laparoscopic hysterectomy

There's a wide variety of routes by which a hysterectomy procedure can be performed. Grossly, the procedure can be carried out through the abdomen (abdominal hysterectomy, AH) or the vagina (VH). The right approach is determined by among others the size and the descensus of the uterus, the space of the vaginal orifice, the necessity to inspect the abdominal area, and the skills of the operator [80]. As the vaginal approach is associated with a shorter operation time and lower costs, with a comparable risk for complications, it is usually preferred [11, 80]. This difference was readily recognized by Doyen (1859 – 1916) in the year 1900. He posed:

“No man can call himself a gynecologist, until he can perform a vaginal hysterectomy” [80].

The vaginal approach is, however, restricted by some anatomical factors. Whenever, excessively large uteri or a limited vaginal capacities is encountered, the procedural complexity rapidly grows.
Large geographical fluctuations can again be witnessed when comparing the amount of vaginal versus abdominal hysterectomies performed. In the Netherlands approximately 50% of all hysterectomies are performed vaginally. In Sweden, the UK, and the USA, this is respectively 5%, 30%, and 20% [11, 80].

For several decades, hysterectomy procedures can additionally be performed by means of laparoscopy (laparoscopic hysterectomy, LH). This approach accounts for approximately 10% of all hysterectomy procedures performed [76, 77]. LH is considerably more complex than both the abdominal and vaginal alternatives [77]. Surgeons beginning with the technique will experience a learning curve, initially associated with a larger operation time and a higher rate of complications compared to VH and AH [17, 60]. Major complications of total laparoscopic hysterectomy (TLH) are urinary tract lesions [77]. However, when the technique is mastered, LH does have several advantages. Compared to the abdominal approach, it is associated with a reduction in pain, a shorter hospital stay and a reduced recovery time [17]. Although the vaginal approach can still be considered least invasive, the applicability of LH is less restricted to anatomical factors [17]. Whenever the expertise is present, approximately 70% to 80% of all hysterectomies could be performed by TLH and it is believed that the surgical outcome can approach that of VH [17]. Additionally, the laparoscopic approach allows the inspection of the intra-abdominal situs and the performance of other operational steps in case of pathologies [77]. Although a midway is found in the introduction of laparoscopic assisted vaginal hysterectomy (LAVH), the technical and anatomical limitations of VH remain.

B.4 Procedural steps

Before providing an in-depth disclosure on the uterus removal technique under evaluation in this thesis, it would be convenient to start with a brief description of existing instruments and techniques. Actual design descriptions are omitted; instead, only the effective goals and outputs of the devices are described.

B.4.1 Uterus mobilization

A uterus mobilizer is a simple but valuable asset, used to move around the uterus in the abdominal cavity during TLH. It is introduced vaginally and enters the uterus through the cervix. It can be used to stretch up ligaments and thereby facilitates their dissection. It also allows the gynecologist to get a better view of the abdominal and uterine tissue structures, and enhances the accessibility of dissection lines.

There are many uterine mobilizers currently on the market. Most of them operate by means of a parallelogram mechanism, where the hand piece and working tip of the instrument preserve a similar direction. The working tip is often screwed – or by other means invasively connected – to the uterus, thereby allowing the uterus to adopt a desirable orientation. A second tube sometimes covers the instrument and includes a wider – sometimes conical – section, which functions as a fornix presenter from an endoscopic viewpoint. The fornix presenter provides a hard backing surface for uterus resection with laparoscopic tools.
B.4.2 Uterus resection

The uterine ligaments, blood vessels, fallopian tubes, and the uterine base or cervix need to be dissected in order to loosen the organ in its entirety. For safety reasons blades and knives are less frequently used in laparoscopy. Energetic dissection modalities, e.g. electrosurgical tools, can be switched on and off and have the advantage of producing heat, thereby enabling simultaneous coagulation of structures. The maintenance of hemostasis not only helps in reducing the procedural blood loss, it also upholds the endoscopic view for the operator.

For the performance of a uterus resection, the choice of equipment largely depends on experience and personal preference. Academic fundamentals often find their reflection in this choice and the used equipment varies considerably among hospitals. Popular instruments are ultrasonic blades, and electrosurgical graspers or snares. There are, however, many more energetic dissection modalities available.

A review of literature was performed to evaluate the usage of monopolar electrosurgery, bipolar electrosurgery, plasma surgery, ultrasonic cutting, laser surgery, and waterjet cutting, during hysterectomy [83]. In addition, a combination of bipolar electrical and mechanical energy, obtained through a squeezing motion, was considered. Vaginal wall tissue was chosen as reference material. The efficacy of these dissection modalities was analyzed on behalf of the following criteria:

- Soft tissue dissection ability
- Hemostatic ability
- Operational safety
  - Tissue Selectivity
  - Thermal spread
  - Gas production
  - Additional risks
- Vessel sealing ability

Each of the dissection techniques was graded with a value between 1 and 3 according to these criteria. If the technique did not abide to a criterion the value 0 was given. Table B.1 provides an overview of the obtained results and is completed with a ‘knifes and blades’ category. Although some trends were visible in the ‘thermal spread’ evaluation (monopolar electrosurgery is for instance associated with a large area of thermal damage), huge differences were found among research studies, and this criterion was left unrated. Instead, a protocol was suggested which should result in a better alignment of the scientific approach and hopefully a better consistency in future results.
### Table B.1: Evaluation of several dissection modalities according to multiple performance criteria.

<table>
<thead>
<tr>
<th>Dissection ability</th>
<th>Hemostatic ability</th>
<th>Safety factors</th>
<th>Tissue selectivity</th>
<th>Gas production</th>
<th>Overall safety</th>
<th>Sealing ability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knife / blade</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Monopolar</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Bipolar</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Bip + mech (^1)</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Plasma surgery</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2 – 3</td>
</tr>
<tr>
<td>Ultrasonic cutting</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>? (^3)</td>
<td>2</td>
<td>1 – 2</td>
</tr>
<tr>
<td>Laser surgery</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>0 (^4)</td>
</tr>
<tr>
<td>Waterjet cutting</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^1\) ‘Bip + mech’ refers to dissection with both bipolar and mechanical energy.

\(^2\) It should be noted that a high score in this category is unwanted, whereas high scores in the other categories are desirable.

\(^3\) Gas production is present during ultrasonic cutting. However, there are some differences in the concentration, composition and the size of the produced particles. The result of which on the patient’s and operator’s health is unknown.

\(^4\) Sealing is only possible with a squeezing motion, heat administration alone is not sufficient.

#### B.4.3 Uterus removal

After the uterus is cut loose it has to be removed from the abdominal cavity. The surgical approach is largely indicative for the method of removal. During abdominal hysterectomy, the uterus is removed through the incision. A vaginal hysterectomy makes use of the vaginal cavity to extract the uterus. In addition, laparoscopic hysterectomy often attempts to use a similar vaginal approach.

It is apparent that the uterus dimensions and characteristics play an important role in selecting the right approach. Especially for large uteri, the removal can be problematic. Several techniques have been developed to facilitate the removal of large uteri.

**Hemisection** or bisection is often used to divide the uterus in the sagittal plane towards the fundus. Both halves can subsequently be delivered through the vagina.

**Morcellation** provides an alternative method for uterus removal in case further descensus and a subsequent vaginal approach is not achievable. The term morcellation is generally used to refer to the manual debulking of tissue, e.g. with a knife, followed by a piecemeal removal. Many morcellators, often making use of motorized rotating blades, have been developed to this purpose. Occasionally, other power
sources, such as electrosurgery or plasma surgery are used. A comparative overview
of existing morcellators, written by Arkenbout et al.\cite{5}, elaborates on the different
techniques, their morcellation rates, and their trends.

**Myomectomy** refers to the removal of myomas or fibroids, which might significantly reduce the total uterus size. For this reason, myomectomies are frequently performed in combination with uterus bisection or morcellation.

### B.5 Questionnaire

A questionnaire was composed and administered by Dr. J. Rhemrev among 26 laparoscopic specialists, divided between experienced gynecologists (18) and novices or fellows (8). The opinion on the current hysterectomy procedure and its difficulties was analyzed. Some results are shown in Table B.2. As not all questions could be answered by all specialists, $n$ indicates the number of answers obtained.

**Table B.2:** Average results of a subjective evaluation of the hysterectomy procedure held among 26 trained laparoscopic specialists.

<table>
<thead>
<tr>
<th></th>
<th>Gynecologists ($n$)</th>
<th>Novices ($n$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual ≠ hysterectomies</td>
<td>428 – 523 (15)</td>
<td>-</td>
</tr>
<tr>
<td>of which open</td>
<td>22% (12)</td>
<td>-</td>
</tr>
<tr>
<td>of which laparoscopic</td>
<td>59% (13)</td>
<td>-</td>
</tr>
<tr>
<td>of which vaginal</td>
<td>19% (11)</td>
<td>-</td>
</tr>
<tr>
<td>Procedure time estimate</td>
<td>73 – 158 (14)</td>
<td>100 – 190 (3)</td>
</tr>
<tr>
<td>[range, min]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uterus separation time</td>
<td>15 – 32 (13)</td>
<td>23 – 42 (3)</td>
</tr>
<tr>
<td>estimate [range, min]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLH complexity score</td>
<td>2.6 ± 1.09 (14)</td>
<td>4.6 ± 0.46 (6)</td>
</tr>
<tr>
<td>[value: 1-5]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

It was found that the current laparoscopic hysterectomy procedure is relatively complex to learn. Even for adept gynecologists the procedure can be quite time consuming. In particular the resection of the uterus from the cervix can be troublesome. This procedural step was found to consume over 20\% of the total time.

From an anatomical point of view it can be understood that the resection of the uterus from the vaginal wall or cervix is a time consuming and challenging step in the field of laparoscopic gynecology. The uterus is located between several delicate organs, such as the bladder, intestines, and rectum. Fig. B.4 illustrates the top view of the uterus positioned in the abdomen as would be obtained through an endoscope. The textbook illustration on the left also shows the dissection lines behind the uterus. Although instruments exist that allow a certain degree of uterus mobilization (see Section B.4.1), a complete view of the dissection line can in reality rarely be obtained. Often, the gynecologist is forced to proceed dissecting the uterus through an existing incision instead of positioning the blade on the plain tissue surface. Especially in the presence of uterine fibroids, movement of the uterus can be impeded, and the gynecologist’s view can be obstructed. Blood and smoke, released in the abdominal cavity, will only aggravate this situation.
B.6 MobiSep

In an earlier phase of the master program BioMedical Engineering at the Delft University of Technology, a medical instrument was developed in close cooperation with two gynecologists, Prof. dr. F.W. Jansen (LUMC) and Dr. J. Rhenrev (Bronovo Hospital). This device, called the ‘MobiSep’, has the dimensions and shape of a fornix presenter, as used in combination with a uterus mobilizer. The MobiSep was, however, designed to perform one of the most challenging steps during the hysterectomy procedure; the dissection of the uterus at its base. The device requires an initial incision through the fornix, obtained with laparoscopic assistance, in order to introduce the head of the device into the abdominal cavity. A subsequent combination of device rotation and the manual control of a blade would allow uterus dissection from the vaginal wall. Fig. B.5 displays the MobiSep, including from left to right; the blade box, shaft, air seal, and actuation mechanism.

This first prototype of the MobiSep served as a proof-of-principle design, leaving significant room for improvement by means of incorporating a more elegant, smoother, and safer embodiment. It did, however, serve its purpose and demonstrated a remarkable decrease in tissue dissection time in a basic test setup. On average, merely 102 seconds were needed to produce a full circular cut in a tubular sutured piece of meat [25]. It should, however, be mentioned that a one on one comparison of this time with the surgical situation would be erroneous. Although a vaginal approach was chosen and therefore a laparoscopic box trainer was no prerequisite, the used setup did provide better visual feedback as would be obtained in-vivo. In addition, the MobiSep makes use of blades to dissect the tissue. This was a logical design choice for a proof-of-principle concept, as other energetic modalities would greatly complicate prototype fabrication. However, in the operating room uterus resection goes hand in hand with the production of hemostasis and this combined effort would definitely require more time.
Despite these differences, the prototype showed a great potential to facilitate and speed up the hysterectomy procedure. From an anatomical point of view this would be related to the chosen vaginal approach. The desired line of dissection is directly accessible, while other tissue structures are shielded by the blade box head.

### B.6.1 Consolidation of information

Although the vaginal approach for uterus resection shows great potential to simplify the hysterectomy procedure, the MobiSep still has some shortcomings. The device has no potential to coagulate, and the design is still somewhat robust and stiff. The review of literature covered in Section B.4.2 suggests the use of either ultrasonic cutting or plasma surgery as an energetic means to incorporate coagulation.

During the analysis of existing uterus resection techniques, an interesting group of solutions was formed by monopolar snares (e.g. the LiNA loop). These snares can be pulled tight around the uterus and, by means of monopolar electrosurgical energy, cut through the tissue layers, producing a coagulum along the way. Although monopolar energy administration is associated with a large thermal spread, the resilient, safe, and intuitive character of this technique is remarkable.

What if this approach could be combined with ultrasonic energy? Can a resilient wire under tension vibrate at ultrasonic speeds? Could this technique be incorporated in a vaginal approach during a hysterectomy procedure?

The wire would be vaginally introduced to the cervix by leading it through the MobiSep. By means of a needle puncture or with the aid of laparoscopic tools the wire would have to enter the abdominal cavity. It would be pulled around the uterus, independent of its shape, and tightened on the MobiSep body. The bulky bladebox would become redundant and perhaps a self-centering profile for the snare could be placed on the shaft. Actuation would be performed at the distal end of the device. The ultrasonic energy would dissect the uterine or cervical tissue and a coagulum would be produced. Thermal spread and smoke production would likely be reduced compared to the monopolar method.
Beneath the basement membrane of the vaginal wall, a well vascularized structure of fibrous tissue and smooth muscle layers is found. The female genital tract is a muscular organ with smooth muscles arranged primarily in a circular or spiral order and at a deeper level also in the longitudinal direction along the tract [47]. The remaining connective tissue layers can be characterized as loose tissue consisting of collagen, elastin and reticulin fibers and a hydrophilic gel called the ground substance. In the vaginal wall, the ground substance dominates as the ratio of ground substance to fiber elements is $1.5 : 1$ [24].

In contrast to the vaginal wall, the cervix is made of a somewhat stiffer material. Although the water content is still high ($75 - 80\%$ [37]), primarily the constitution of the ‘dry weight’ differs. The concentration of the insoluble elastin of the dry, defatted cervix tissue was found to be approximately $1.4\%$, whereas the total collagen weight was estimated between $64.3\%$ and $72.4\%$ [41]. The smooth muscle content of the cervix would be approximately $10 - 15\%$. In order to find material that behaves similar to ultrasonic perturbations, a better insight in the acoustic, mechanical, and thermal properties of the cervix would be useful. Information on this structure is, however, sparse and occasionally vaginal wall or uterine tissue had to be considered for an approximation.

As opposed to ultrasound imaging, acoustic energy is meant to dissipate right at the instrument tip boundary. Although wave attenuation measurements have been performed for various tissue types, including the uterine and vaginal wall [40], this property is excluded from the current evaluation as it is frequency dependent and measurements are usually performed for the evaluation of high frequency ultrasound imaging techniques. Other acoustic properties of various (bio)materials are listed in Table C.1 [40, 66].
Table C.1: Acoustic properties of various materials [40, 66]. Speed of sound values are given for longitudinal waves only.

<table>
<thead>
<tr>
<th>Material</th>
<th>Density, ( \rho ) (kg/m(^3))</th>
<th>Speed of sound, ( c ) (m/s)</th>
<th>Acoustic Impedance, ( Z_0 ) (N·s/m(^3))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>1000</td>
<td>1480</td>
<td>( 1.48 \cdot 10^6 )</td>
</tr>
<tr>
<td>Vaginal wall</td>
<td>990</td>
<td>1540</td>
<td>( 1.529 \cdot 10^6 )</td>
</tr>
<tr>
<td>Uterus</td>
<td>1040</td>
<td>1629</td>
<td>( 1.694 \cdot 10^6 )</td>
</tr>
<tr>
<td>Soft tissue</td>
<td>1010 – 1060</td>
<td>1540</td>
<td>( 1.63 \cdot 10^6 )</td>
</tr>
<tr>
<td>Bone (compact)</td>
<td>1800 – 2100</td>
<td>4080</td>
<td>( 7.80 \cdot 10^6 )</td>
</tr>
<tr>
<td>Stainless steel</td>
<td>7930</td>
<td>5800</td>
<td>( 45.76 \cdot 10^6 )</td>
</tr>
</tbody>
</table>

The mechanical and thermal tissue properties are shown in Table C.2 [83]. Large deviations were encountered as literature tends to evaluate medical conditions, such as pregnancies or pathologies (e.g. pelvic organ prolapse). Chemical reactions caused by the immune response and alterations in the hormone balance (with age, pregnancy, or phase of the estrous cycle [10]) can strongly affect the soft tissue composition. Especially pregnancy has been shown to affect the cervical tissue integrity [59, 72]. Mechanical loads over time can result in direction dependent fiber alignment and development rates, resulting in material anisotropy. All in all, it is advised to treat these bio-material properties with caution.

Table C.2: Mechanical and thermal properties of various materials.

**Mechanical properties** [71, 72, 83]

<table>
<thead>
<tr>
<th>Material</th>
<th>Ultimate strength (MPa)</th>
<th>Stiffness (MPa)</th>
<th>Ductility (-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal wall</td>
<td>0.27 – 8.4</td>
<td>1.73 – 18.7</td>
<td>0.06 – 0.92</td>
</tr>
<tr>
<td>Cervix (non-pregnant)</td>
<td>3.14</td>
<td>?</td>
<td>0.61</td>
</tr>
<tr>
<td>Bone (compact)</td>
<td>70 – 150</td>
<td>15.000 – 30.000</td>
<td>0 – 0.08</td>
</tr>
<tr>
<td>Stainless steel</td>
<td>600</td>
<td>210.000</td>
<td>0.55</td>
</tr>
</tbody>
</table>

**Thermal properties** [15, 20, 96, 83]. 1 Thermal conductivity; 2 Both immobilized and free water. 3 Compact bone

<table>
<thead>
<tr>
<th>Material</th>
<th>Th. conductivity (W/K·m)</th>
<th>Blood flow (ml/g·min)</th>
<th>Water content (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water 1</td>
<td>0.6</td>
<td>–</td>
<td>100</td>
</tr>
<tr>
<td>Muscle</td>
<td>0.51 – 0.62</td>
<td>0.018 – 0.03</td>
<td>70 – 78 2</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.542</td>
<td>?</td>
<td>81.6</td>
</tr>
<tr>
<td>Bone</td>
<td>0.53 – 0.58 3</td>
<td>0.117</td>
<td>12 – 15</td>
</tr>
<tr>
<td>Stainless steel 1</td>
<td>12 – 45</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>
Although the individual development of a piezoelectric system for the direct and smooth transition of longitudinal ultrasonic waves to a cutting snare would be possible, such a project would be too large and expensive to fit in the framework of a master thesis assignment. One of the largest expenditures would be the acquisition of a signal generator to actuate the high demanding piezoelectric elements. It was therefore considered convenient to borrow and apply the generator of an existing ultrasonic source, such as the Lotus system.

However, the Lotus operates with a rotational vibration, whereas longitudinal waves would be more convenient in a snare. The most logical initial step would be to try and modify the existing instrument by realizing a rotational-to-translational wave conversion. The Lotus is, however, controlled to operate under specific conditions which have to be met by the transducer. The Lotus instrument was designed to have its Eigen frequency at 36 kHz. Hence, the required voltage to maintain a vibration at this frequency is at a minimum. By changing the system load, the rotational moment of inertia and thereby the Eigen frequency of the system changes. As a result, the voltage required to produce the 36 kHz vibration rapidly increases. Most likely, a maximum voltage has been set as a system safety measure, e.g. to prevent overheating of the transducer. In practice, this means that large system modifications will not be accepted by the available generator.

D.1 Theory

One of the most important aspects in the design of a rotational-to-translational wave converter is the impact of shaft radius on the circumferential displacement (wave amplitude). Initially, one might expect an increase in diameter to result in a proportional amplitude increase. However, this relation only holds if an external torque would lead to a similar angle of twist in both the small and large radius shaft-section. The fact that acoustic horns are developed to increase wave speed and amplitude by means of a decreasing shaft radius suggests the opposite. It can indeed be shown that the angle of twist is strongly reduced with increasing shaft radius. Fig. [D.1] illustrates a homogeneous, linear elastic shaft under torque with a varying radius along its length, resembling an acoustic horn. When isolating
APPENDIX D. WAVE TYPE CONVERSION

Figure D.1: Illustration of a shaft with circular cross section that gradually varies along its length.

A differential disk of thickness $dx$ at a distance $x$, the local shear strain $\gamma$ at an arbitrary radius, $r$, can be visualized. For small angles, the angle of twist, $d\phi$ can be related to shear by the formula [35]:

$$d\phi = \frac{\gamma dx}{r}$$

(D.1)

By applying Hooke’s law, $\gamma = \tau/G$, and expressing the shear stress as a function of the applied torque, $\tau = T(x)r/J(x)$, this equation can be rewritten as:

$$d\phi = \frac{T(x)}{J(x)G}dx$$

(D.2)

Where $T(x)$ is the internal torque, and $J(x)$ the polar moment of inertia at an arbitrary position, $x$, and $G$ is the material’s shear modulus of elasticity. For a cylindrical shaft with radius, $r$, the polar moment of inertia can be expressed as $J = \pi r^4/2$. With other words; due to the strong increase in shaft inertia, the angle of twist and the circumferential displacement are severely reduced by increasing the shaft radius.

D.2 Practice

This theory shows that even the slightest alteration of the waveguide’s geometry can strongly interfere with the rotational inertia and thereby with the desired vibrational output. This was found to be a major complicating factor in practice as it would require the formation of a rigid and robust connection with minimal modifications to the device. Therefore, the wave type converter, i.e. the connection between the cutting snare and the waveguide, needs to be very compact and preferably non-invasive and needs to sustain high energy densities and possibly temperatures. Although a satisfactory connection, strong enough to allow full evaluation of the ultrasonic cutting snare’s thermal damage pattern, has not yet been obtained, the remainder of this chapter is included for the interested reader and contains an overview of the realized connection efforts.
D.2.1 Snare clamping

As a first attempt to connect the snare to the device shaft, a small converter was constructed which was shape locked and clamped to the waveguide by means of bolts and nuts. The clamp was bend out of plate material to keep everything as thin and light as possible and to prevent further development of waves inside the converter. Fig. D.2 shows a photo of this clamp. The construction was made relatively stiff in the torsional wave direction to ensure a pure translation of the cutting snare.

![SolidWorks model of the wave converter clamp and photograph of the actual constructed clamp.](image)

It turned out that this construction caused the generator to produce an error. Apparently, the added mass (2.2 g) was readily enough to alter the system dynamics and Eigen frequency in such a way that the generator voltage output had to exceed the set limitation, in order to produce the desired waves in the waveguide.

D.2.2 Snare piercing

It was speculated that drilling a small hole in the waveguide, just enough to be filled with the snare, would be the least disturbing connection when considering the system mass. The snare was subsequently bend upwards, tangent to the waveguide in such a way that a similar orientation results as shown for the clamp in Fig. D.2.

It was found that the removal of material from the Lotus shaft disrupts the propagating waves. A clear audible sound was produced by the Lotus (lower harmonics of the 36 kHz signal), probably due to partial wave reflection at the newly created material boundaries. Although the device remained fully operative, a durable solution was not found. The introduced snare snapped after only seconds at the edge of the drilled hole, probably due to material fatigue. Even when a protective tube was placed between the hole and snare in order to increase the bend radius and reduce the edge sharpness, the construction was unstable. Eventually the hole was filled up again with titanium by means of a small laser weld.

D.2.3 Snare gluing

A much simpler and more direct connection method subsequently evaluated was the winding of a snare around the waveguide in combination with a glue. As the snare was not led across any sharp edges and had a bending radius larger than 4mm (shaft diameter), this setup was deemed to be more durable.
However, the device temperature was found to exceed the maximum temperature of most available glue types and the connected snare quickly detached from the waveguide. In addition the steel windings around the instrument shaft were found to be damaging to the titanium waveguide.

**D.2.4 Snare soldering**

As the Lotus waveguide consist of high grade titanium it was found that direct silver (hard) soldering was no option as the solder did not attach to the surface.

**D.2.5 Partial wave damping**

As the priorly discussed connection types all seemed to be disrupted by a local, high energy density contact surface, partial damping of the outgoing wave was considered as an alternative to improve the construction’s durability. O-rings were placed between the shaft and the snare connector, as shown in Fig. D.3, reducing the rigidity of the construction. Of course, from an acoustic point of view, this method would result in a bad acoustic match and a high wave reflection coefficient. It was merely presumed that some energy would remain to produce snare vibrations and experimental trials would have to demonstrate the actual outcome. Although this connection seemed to be more stable and stayed in tact for a significant time, it was found that the damping factor was detrimental for wave propagation. The o-ring and connector were found to heat up considerably and the end effector (snare) was found unable to produce cuts.

![Figure D.3: Illustration of a damped connection between the Lotus waveguide and the dissection snare.](image)

**D.2.6 Snare welding**

Subsequently a thin, stainless steel ring on which a snare could be connected, e.g. by means of hard soldering, was laser welded to the titanium shaft. For this a full circumferential contact weld was used. Welding the snare directly to the instrument (without intermediate ring) might have been a solution, but as earlier experiments articulated the delicacy of the snare, this seemed to be a laborious and invasive option to the Lotus waveguide (each lase does afflict damage). The small, stainless steel surface would provide a very light, and more easily amendable working environment for new connection types, such as the priorly discussed hard soldering technique.
All in all, this method turned out to be operational and the snare was found to be able to cut through a couple of plastic and cheese types, see Chapter [10]. However, as anticipated, the snare did snap every once in a while and had to be replaced. This complicated the actual commencement of thermal spread evaluation experiments. After several runs, also the laser weld broke and the intermediate ring detached from the waveguide. Several subsequent attempts to reconnect the ring were carried out, but none seemed to be as strong and lasting as the initial construction.

D.2.7 Shrink fitting

One last attempt to provide a firm connection between the waveguide and the intermediate ring was actualized by means of shrink fitting. The ultrasonic waveguide was cooled down with liquid nitrogen, while the connector ring was heated. Due to the relative shrinking and expanding of the different parts it was possible to position a stainless steel ring with a smaller inner diameter over the waveguide with a larger outer diameter. Upon reaching an equilibrium temperature a strong bond between the two parts was produced. However, also in this case the connection only held temporarily and eventually the ring detached.
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[1] Online Encyclopedia, en.wikipedia.org, search term can be found in the reference.


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