DESIGN OF A COMPLIANT MECHANISM RADIOFREQUENCY ABLATION PROBE TO TREAT PANCREATIC CARCINOMA

A Thesis in

Mechanical Engineering

by

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ABSTRACT

Pancreatic cancer is a deadly and difficult to treat disease affecting hundreds of thousands of patients globally every year. With difficult diagnosis and limited treatment options, the estimated five-year survival rate stands at a meager 5%. Radiofrequency ablation (RFA) is a recognized and well-established treatment option for other types of cancers such as hepatic and renal carcinomas, but is unsuitable in current form for the treatment of the pancreas. The goal of this research is to explore and model specially-shaped, deployable RFA probes introduced to the body via an endoscope. We propose a novel RFA probe, referred to as “the whisk design,” composed of superelastic nitinol to achieve adequate mechanical and ablative results. Modeling is pursued in two major areas.

First, mechanical modeling is pursued in ANSYS to determine the stress tolerance of the proposed design. The device is expected to undergo high amounts of stress prior to the insertion phase of use; therefore a finite element model was developed for this stage. Since the device has default-open geometry, the free elongation models displace it to a closed diameter capable of passing through the endoscope’s working channel. The design was a success and experienced a maximum Von Mises stress of 445 MPa in the narrow regions of the tines.

Secondly, the proposed design was analyzed for ablative potential utilizing the finite element software COMSOL. For these models, the interaction between an applied electric potential, temperature distribution, and necrosis zone (where cell death occurs) were studied. The model showed that the proposed device surpassed design goals in creating a necrosis zone of 3 centimeters with temperatures exceeding 50 °C. With finite element models completed successfully, alpha prototypes and design refinement can be performed in future studies.
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NOMENCLATURE

RFA = Radiofrequency Ablation
EUS = Endoscopic Ultrasonography
PC = Pancreatic Cancer
CT = Computed Tomography
MRI = Magnetic Resonance Imaging
IMRT = Intensity-Modulated Radiation Therapy
IGRT = Image-Guided Radiation Therapy
SABR = Stereotactic Ablative Body Radiotherapy
DNA = DeoxyriboNucleic Acid
RNA = RiboNucleic Acid
UGI = Upper Gastrointestinal
NOTES = Natural Orifice Transluminal Endoscopic Surgery
MW = Microwave
HAZ = Heat Affected Zone
SLM = Selective Laser Melting
ACKNOWLEDGMENTS

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Chapter 1

Background and Motivation

1.1 Introduction

Pancreatic cancer is an aggressive disease with a high mortality rate and few treatment options other than radiation therapy or resection surgery. Widely used in the treatment of carcinomas of other organs, radiofrequency ablation (RFA) is a recognized, well-established, and minimally invasive treatment option. However, in its current form, RFA is not yet applicable to treatment of pancreatic carcinoma. Through the use of a compliant mechanism constructed of superelastic nitinol, an RFA probe can be constructed which will be introduced and guided via endoscopic ultrasonography (EUS) into the pancreas.

The goal of this research is to develop finite element models to analyze performance of specially-shaped RFA probes. A compliant mechanism RFA probe, which resembles a kitchen whisk, is proposed to meet the high flexibility, biocompatibility, and ablation requirements of EUS-RFA. Finite element simulations are first developed for the mechanical deployment of several whisk configurations, which are further subdivided into the free elongation and the deployment into pancreatic tissue. Secondly, finite element simulations for the ablation within the pancreatic tissue are developed for each whisk configuration as well. Due to the superelastic effect of nitinol, the whisk can provide adequate radial deployment into the tissue, which further produces a nearly spherical ablation zone within the tissue.

1.2 Research Objectives

The objectives of this research include the design and analysis of a compliant mechanism, radiofrequency ablation probe using superelastic nitinol. The main research objectives are as follows:

1. Develop finite element models to predict the performance of the whisk design under three major conditions.
2. Analyze whisk configurations for mechanical loading and displacement in free elongation using superelastic nitinol.
3. Verify ablation modeling environment by replicating published results.
4. Analyze whisk configurations for ablation within pancreatic tissue.

1.3 Literature Review

This section will present related work on pancreatic cancer, radiofrequency ablation, endoscopic ultrasonography, superelastic nitinol, and compliant mechanisms.

1.3.1 Pancreatic Cancer

Pancreatic cancer (PC) is a deadly disease that is not fully understood. For a person born today, the lifetime risk of developing pancreatic cancer is approximately 1.27%; or, in other words, about 1 in 80 people will develop the disease [1]. PC is the tenth most common type of cancer and is the fourth most deadly [2-3]. In the United States, an estimated 37,000 new cases are diagnosed with approximately 30,000-35,000 deaths annually, with 227,000 deaths globally [1,3–5]. Because pancreatic cancer does not usually exhibit disease-specific symptoms until later stages, early diagnosis is difficult [1,6].

The cancer is generally understood to originate as pre-malignant lesions, which evolve into fully invasive cancer from an accumulation of gene mutations [3]. Several types of lesions, most typically pancreatic intraepithelial neoplasia, can evolve into the invasive cancer [3–5]. The genetic mutations that may signal the onset of pancreatic cancer, such as activation of the KRAS2 oncogene and inactivation of the tumor suppression gene CDKN2A for example, are some of the earliest detectable signs of cancer [3,5]. Figure 1-1 shows a diagram of the location of a typical pancreatic tumor.
along with a list of some of the typical genetic markers of the disease.

Figure 1-1 Tumor Diagram and Some Typical Genetic Markers [3]

Other than blood tests to check for disease markers, standard methods of diagnosis are based on imaging technologies and include computed tomography (CT), endoscopic ultrasound, and magnetic resonance imaging (MRI) [2]. However, these methods are used only after the patient is already experiencing symptoms, which in many cases indicates the disease is already progressed to a late stage [2]. Additionally, small lesions/tumors are hard to detect even under the imaging techniques discussed, and the smaller tumors are those that are more likely to be curable. Figure 1-2 shows the
progression of tumor size and the three definitions of “early” pancreatic cancer based on resectability, size, and curability.

![Diagram of pancreatic tumor size and three classification methods of “early” pancreatic cancer based on resectability, size, and curability]

Figure 1-2 Pancreatic tumor size and three classification methods of “early” pancreatic cancer based on resectability, size, and curability [1]

Once diagnosed, there are only two traditional treatment options for patients, resection surgery or radiation therapy. The more common method, resection surgery, is capable of removing tumors from the pancreatic head (pancreaticoduodenectomy) as well as from the body and tail (distal pancreatectomy) [7]. For patients capable of undergoing resection surgery, five-year survival rates are approximately 20% with a median survival of 17-18 months [7-8]. However, many patients exhibit unresectable tumors and are left with only radiation therapy as a treatment option. Common radiation therapies include intensity-modulated radiation therapy (IMRT), arc therapy, image-guided radiation therapy (IGRT), and stereotactic ablative body radiotherapy (SABR) [9]. However, several drawbacks face all radiation therapies. Target visualization during treatment, due to tumor size and movement during respiratory cycle, affects therapy accuracy. Additionally, the close proximity of other radiosensitive organs such as the liver and kidney can also lead to unintended toxicity doses to healthy tissue [9]. Median survival
times for patients undergoing radiation therapy range from 10-12 months \cite{7,9}. Low survival rates and side effects for the traditional treatment options underscore a need to develop more effective, less invasive treatment options.

1.3.2 Radiofrequency Ablation

A possibility for alternative treatment of pancreatic carcinomas lies in radiofrequency ablation or RFA. Radiofrequency ablation is a recognized and well-established treatment regimen for carcinomas of many organs through percutaneous or gastrointestinal endoluminal procedures \cite{10}. RFA works by applying an alternating, high frequency current to the tissue from the probe tip. This current usually is in the range of 450-550 kHz \cite{11–13}. As the current passes through the tissue, the ions attempt to change direction to match the current, causing frictional heating within the tissue. Figure 1-3 shows how a percutaneous RFA probe affects the ions within the tissue via the alternating current.

![Radiofrequency Ablation](image)

Figure 1-3 Effect of alternating current on tissue ions during percutaneous ablation procedure \cite{14}
The goal of RFA is to raise the temperature of the tissue above 50-60 °C [12,14]. Above those temperatures, cell proteins begin to denature, DNA and RNA are destroyed, and cell death occurs [14]. Depending on factors such as application time and RFA probe shape, the size of the necrosis region, the region where cell death has occurred, will vary; but generally is only 5-10 mm radially from the probe [11,14].

Percutaneous RFA procedures are typically used in conjunction with imaging techniques such as ultrasonography. Figure 1-4 shows how percutaneous RFA and ultrasonography are used in conjunction for treatment of a hepatic tumor.

Figure 1-4 (Top Left) Placement of percutaneous RFA probe and ultrasound probe relative to targeted tumor mass. (Top Right) Deployable probe placement within targeted tumor mass. (Bottom) Tumor mass after completion of RFA treatment with dashed line representing approximate necrosis zone. [14]

As can be seen in the bottom panel of Figure 1-4, the target zone for RFA procedures typically provides for a small margin of cell necrosis beyond the tumor to insure complete eradication of cancerous cells.

Because of its ability to precisely target tumorous tissue with minimal damage to surrounding tissue, RFA has been widely used in oncology for the treatment of such
organs as the lung, kidney, and breasts [11,15–17]. For example, percutaneous RFA for small kidney tumors has shown to be successful with a rate of 93.8% [15]. Table 1-1 lists some of the key values for the study presented by Joniau et al regarding renal RFA.

<table>
<thead>
<tr>
<th>Number of Patients</th>
<th>755</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Tumors Treated</td>
<td>868</td>
</tr>
<tr>
<td>Mean Patient Age</td>
<td>69.3 years</td>
</tr>
<tr>
<td>Mean Tumor Diameter</td>
<td>27.9 mm</td>
</tr>
<tr>
<td>Mean Success After First Ablation</td>
<td>86.9%</td>
</tr>
<tr>
<td>Mean Final Success</td>
<td>93.8%</td>
</tr>
</tbody>
</table>

Table 1-1 Key values for RFA treatment of small renal tumors as presented by Joniau et al [15]

Perhaps the most prevalent use of RFA to date is in the treatment of hepatic tumors via percutaneous, laparoscopic, or laparotomy (open) surgery procedures [14]. Varadarajulu et al have performed laboratory experiments on several Yorkshire pigs to determine efficacy and safety of RFA. In the pigs tested, tumor eradication was complete and no pigs showed any abscess or infection at time of euthanasia [18]. Furthermore, Curley has studied percutaneous and laparoscopic RFA of hepatic tumors in 100+ patients in several hospitals. His findings show that RFA has proven to be a useful alternative treatment for patients not meeting the criteria for resectability [14].

Though clinical trials have assessed the success or failure of RFA from the doctor’s standpoint, studies have also been pursued to characterize and model RFA and RFA probe design from an engineering standpoint. One aspect of these studies is seeking to better characterize the correlation between probe geometry, material properties, and the size of the necrosis zone. Two major studies published by both Chang and Nguyen make use of FEMLAB (COMSOL, Burlington, Massachusetts, USA), a multiphysics finite element software, to develop models accounting for temperature dependency of material parameters as well as perfusion (blood flow) in liver tissue, both of which can greatly affect the extent of tissue destruction achieved [12,19]. Figure 1-5 shows a comparison of several of the trials completed by Chang et al for temperature profiles generated during RFA in liver tissue.
As can be seen, the temperature dependency of the material parameters does not greatly affect the overall shape of the distribution. However, it does cause a slight increase in peak values. Conversely, the inclusion of perfusion into the finite element model greatly decreases the extent of heat absorbed by the tissue. In this case, the flowing blood acts as a heat sink and causes an approximately twenty degree drop in peak temperature and a visibly noticeable decrease in size of the area of tissue destruction. Chang and Nguyen’s studies attempt to allow surgeons a better prediction of clinical results before ever entering the operating room.

Like Chang’s, most studies to model RFA of hepatic tumors have focused on straight, rigid, percutaneous probes; however, deployable probes capable of creating larger, more uniform temperature distributions than their straight cousins are of great interest. One such deployable probe was investigated by Varadarajulu et al. In that study, a standard RFA probe was modified to include six retractable tines, making it appear like an “umbrella” [18]. Though the inclusion of deployable members increased...
the overall diameter of affected tissue, the irregular geometry of the array led to non-ideal shape for the necrosis zone. Since tumors typically appear spherical in shape, a probe should generate as nearly spherical necrosis zone as possible to most effectively eradicate tumorous cells.

All of these studies, however, are focused mainly on percutaneous probes. However, due to the obstruction of the pancreas by other organs, existing percutaneous RFA technology is ill-suited to the treatment of pancreatic carcinoma.

1.3.3 Endoscopic Ultrasonography

An endoscope is a highly flexible tool that allows doctors to visualize hollow organs in the body for diagnostic and therapeutic purposes. A common procedure performed using an endoscope is an upper gastrointestinal (UGI) endoscopy. A UGI endoscopy is a procedure where the doctor can inspect the interior lining of the esophagus, stomach, and the duodenum [20]. Endoscopes typically have one or more internal channels through which other surgical instruments can be passed. Figure 1-6 shows a diagram of the distal end of a typical endoscope.

![Diagram of Endoscope](image)

Figure 1-6 Distal end of a typical endoscope depicting major internal components including a working channel for surgical instruments [21]

Besides being used in diagnostic procedures, endoscopes can be used in other interventional surgical procedures, of which one major category is designated natural orifice transluminal endoscopic surgery (NOTES). NOTES is a surgical technique in
which abdominal operations are performed using an endoscope, which is passed through a natural orifice and then through an internal incision, thereby avoiding external incisions or scars [22]. The modern procedure that is officially deemed NOTES was introduced in 2005 by a group of members from the American Society of Gastrointestinal Endoscopy and the Society of American Gastrointestinal and Endoscopic Surgeons [23]. Laparoscopic surgeries already reduce the large incisions required by more traditional surgeries, however, NOTES has the potential to further reduce incisions by replacing laparoscopic procedures with its “incisionless” manner [24].

An example of a surgical procedure that can now be accomplished via the NOTES manner is transgastric gallbladder removal. The endoscope is passed through the patient’s mouth down the esophagus and into the stomach. From there, a small incision is made in the lining of the stomach through which the remainder of the procedure is performed [25-26]. Figure 1-7 shows the steps of said transgastric gallbladder removal.

Figure 1-7 Transgastric gallbladder removal surgery [26]
The less invasive approach offered by NOTES offers several benefits over other surgical methods including reduced pain, reduced risk of complications, and possible reduced care costs [23-24,27].

Another surgical use of endoscopes is EUS-guided ablation of tumors located within reach of the gastrointestinal tract. Various types of ablation technology have been investigated with the forerunners being cryoablation, microwave (MW) ablation, and radiofrequency ablation [28-29]. Figure 1-8 shows a typical use of an endoscope for ablating a tumor within the pancreas. Studies published by both Goldberg et al and Gaidhane et al have demonstrated proof of concept by testing EUS-RFA in porcine models [30-31].

Figure 1-8 Endoscope being used for ablation of a pancreatic mass under guidance of ultrasonography [10]

As demonstrated in Figure 1-8 and in the published studies, the current RFA technologies capable of being deployed via EUS use straight needle RFA probes [10,30-31]. Straight needles offer several limitations for complete eradication of cancerous cells in a single treatment session. First, straight probes tend to create necrosis zones that are elliptical in shape and limited in size (5-10 mm radially from probe) while pancreatic tumors tend to be larger and roughly spherical [11-12,14]. Though a promising technological advance, EUS-RFA is currently limited in efficacy due to a limited choice of RFA probes.
1.3.4 Superelastic Nitinol

Early in the 1960s, Buehler and Wiley developed a series of novel alloys composed of a mixture of nickel and titanium. The alloys were approximately 53% to 57% nickel by weight. A unique property of these alloys allows them to regain their original shape after a thermal cycle when severely deformed with residual strains of 8-15% [32]. Employees of the Naval Ordnance Laboratory, Buehler and Wiley named the alloys NiTiNOL [33].

As various researchers studied nitinol, two major effects of the nitinol came to be known as the shape memory effect and the superelastic effect [34]. The shape memory effect deals with deformation recovery during a thermal cycle. If the alloy is deformed at low temperatures, the deformation can be recovered by heating the alloy above a critical temperature. This recovery is enabled by a phase transformation between two crystal structures, martensite and austenite [35]. This phase transformation can be induced several ways, such as heating and applying load. Four critical temperatures are used to define the transformation: austenite start temperature, austenite finish temperature, martensite start temperature, and martensite finish temperature [34-35]. Figure 1-9 shows the microstructure during a typical phase transformation.
Figure 1-9 Microstructure during typical phase transformation in shape memory effect of nitinol [35]

Though the shape memory effect requires temperature variation to accomplish its effects, the superelastic effect of nitinol does not. However, the superelastic effect is only preserved at temperatures above the austenite finish temperature. In the superelastic effect, the phase transformation is induced by external loading or internal stress increase instead of temperature variation as in the shape memory effect. The superelastic effect allows for a large change in recoverable strain for a correspondingly small change in stress. Figure 1-10 shows the stress-strain relation in the superelastic effect up until the fracture point. Also on the figure are the phases that correspond to each section of loading.
Though the superelastic effect has no direct dependence on temperature, it is sensitive to the temperature at which the loading is occurring. For medical devices taking advantage of the superelastic effect, the working temperature, typically room or body temperature, should be above the austenite finish temperature [36]. Though this is true, the austenite finish temperature should also not deviate far from the working temperature because the superelastic effect only exists within a certain temperature range [37]. Figure 1-11 shows the stress-strain relations of superelastic nitinol for a series of temperatures. As can be seen, the superelastic effect begins to degrade at temperatures above 100 °C. The properties of nitinol, however, can be tweaked to the desired ranges by manipulating the ratio of nickel and titanium or by adding a third metal to the alloy [38].
Figure 1-11 Superelastic nitinol stress-strain relations at varying temperatures [37]

Another key aspect of nitinol is its biocompatibility, which is crucial for any material intended to be used in a biomedical capacity. Since its discovery, the biocompatibility of nitinol has been studied for various aspects. For example, one study looked into nitinol’s influence on the bio structure of a human cell culture. The leaching of nickel was detected during the experiment, but the dissolution level did not induce any negative toxic effects throughout the experimentation [39]. Further in vivo experiments determined that inflammation caused by the nitinol was similar to inflammation caused by stainless steel or Ti-6Al-4V, commonly used metals for other biomedical applications [40]. Lastly, the passive layer of titanium-oxide on the surface of nitinol can also help protect against corrosion and nickel oxidation [41-42]. Due to its superelastic effect and
its biocompatibility, nitinol is an ideal material choice for endoscopically deployed surgical devices.

1.3.5 Compliant Mechanisms

Taking advantage of the superelastic effect of nitinol, a compliant mechanism can be designed which will deploy into pancreatic tissue to create a more spherical necrosis zone during ablation. A compliant mechanism is commonly defined as a single-piece, flexible mechanism that transfers motion, force, or energy using the benefit of elastic deformation instead of conventional rigid body kinematic pairs [43-44]. Benefits of compliant mechanisms include lack of wear and backlash, zero necessary lubrication, and no required assembly [45]. Additionally, compliant mechanisms are capable of producing very precise motion, which is desirable for surgical devices [43].

Because of some of the benefits listed above, research has been pursued to develop small surgical tools for minimally invasive surgeries. Compliant mechanisms are especially suited to surgery via an endoscope, such as NOTES. Several of these devices have been previously developed in the Engineering Design Optimization Lab at The Pennsylvania State University [46–49]. Figure 1-12 shows a compliant, narrow-gauge forcep developed for use in NOTES.
The single-piece nature of compliant mechanisms is ideal for small-scale surgical applications [50]. If composed of a highly flexible material such as nitinol, compliant mechanisms are ideally suitable for adaptation into a deployable, EUS-guided, RFA probes.

### 1.4 Thesis Outline

This research is focused on design and analysis of a compliant mechanism, radiofrequency ablation probe constructed of nitinol. The remainder of the thesis is organized as follows.

In this thesis, Chapter 2 presents the design details of the RFA probe as well as discussing the various material models used in finite element simulation. First, a parametric model is built to represent the probe. Material models are discussed for the finite element simulations, namely the superelastic nitinol and the thermal/electrical properties for ablation.

Chapter 3 presents the mechanical modeling of the probe configurations. The setup for the models and the applied boundary conditions are first presented. Results are then presented for free elongation.
Chapter 4 presents the radiofrequency ablation modeling of the probe configurations. A verification of the modeling environment is provided first followed by a discussion of the model setup and applied boundary conditions. Results are then given for the ablation in pancreatic tissue.

Chapter 5 presents a summary of the work as well as major conclusions. It also presents contributions to the research and states several areas for potential future work.
Chapter 2

Design of Probe and Material Models

This chapter details the process of designing of the radiofrequency ablation probe and modeling the necessary materials. It describes the probe geometry as well as relevant material models used in the finite element simulations.

2.1 Design Concept

Through our collaboration with The Pennsylvania State University Hershey Medical Center, it was determined that an endoscopic ultrasonography (EUS)-guided radiofrequency ablation (RFA) probe was desired to deploy into the surrounding tissue. Additionally, the probe must be small enough to pass through a typical endoscopic working channel of approximately 1.8 mm in diameter. Finally, the force that the probe can withstand should be sufficient to prevent failure when the probe is deployed into tissue.

2.1.1 Probe Concept Generation

To meet the needs of the requirements developed in conjunction with the Hershey Medical center, three possible concepts were generated for probe geometries. The three concepts; referred to respectively as the whisk, squid, and coil design; each are capable of being deployed into the tissue via a different actuation method. Figure 2-1 shows the proposed whisk design in both the undeployed and deployed positions.
In this concept, the probe is actuated by applying an axial displacement to the probe tip which in turns bends and displaces the tines into the tissue. Furthermore, this concept is composed of a single piece of material with no hinges or joints to cause motion.

The second proposed concept, the squid device, works slightly differently than the whisk. For the squid, seen in Figure 2-2, the device is actuated by both axially displacing and twisting the base of the tines to allows the sharpened tips to pierce through the tissue. This design is composed of two parts, the tines with their base and a surrounding sheath.

Figure 2-1 The proposed whisk concept in the undeployed (top) and deployed (bottom) positions
Finally, the third proposed concept is the coil design. This utilizes a completely new actuation method from either of the previous designs. This design, seen in Figure 2-3, makes use of the shape memory effect of the nitinol. Instead of actuating into the tissue prior to ablation, the coil design performs both simultaneously. By using the heat generated during ablation, the coil design returns to its “memorized” deployed position while ablation occurs.
After consideration, however, the whisk design was chosen for detailed design and analysis. The following sections discuss this probe geometry in greater detail.

2.1.2 Geometric Model of Chosen Geometry

The whisk design was chosen based on its monolithic, compliant mechanism based geometry. The probe would be deployed through the working channel of a typical endoscope to the tumor site. Figure 2-1 shows an isometric view of the finalized, probe design.
The basic geometry of the RFA probe is seen in Figure 2-5. Eight design parameters are used to define the probe’s structure. These parameters include the outer radius ($R_o$), inner radius ($R_i$), tine radius ($R_t$), tine thickness ($t$), overall length ($L_o$), inner length ($L_i$), angle of tine sweep ($\theta$), and number of tines ($N$).

To be applicable for EUS-guided RFA, the outer radius of the probe must remain smaller than the working channel of the endoscope while in the undeployed position. A
schematic drawing with details of the geometry can be located in Appendix A: Schematic of Finalized Geometry.

2.1.2 Alternate Configurations

For this study, only the value of the parameter \( N \) was varied with all other parameters held equal between different configurations. The values for the seven constant parameters are listed below in Table 2-1. These values were determined from a mixture of design requirements and preliminary testing. The lengths and radii of the tube as well as the angle of the tines were based on available materials and parameters of the endoscopic working channel. The tine radius was chosen to maximize deflection into the tissue while keeping stress values below the chosen stress limit.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
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<td>( R_o )</td>
<td>0.9 mm</td>
</tr>
<tr>
<td>( R_i )</td>
<td>0.8 mm</td>
</tr>
<tr>
<td>( R_t )</td>
<td>3.9 mm</td>
</tr>
<tr>
<td>( t )</td>
<td>0.1 mm</td>
</tr>
<tr>
<td>( L_o )</td>
<td>26 mm</td>
</tr>
<tr>
<td>( L_i )</td>
<td>20 mm</td>
</tr>
<tr>
<td>( \theta )</td>
<td>15 degrees</td>
</tr>
</tbody>
</table>

Table 2-1 Geometric parameters that are held constant between different configurations

Additionally, in Figure 2-6, the six configurations are shown in isometric view for comparison between the variations. The minimum of four tines was chosen so that there would be at least one tine facing in each major direction. Conversely, the maximum of fifteen tines was chosen due to restriction on space. Any configuration using more than fifteen would encounter issues with overlapping and contacting tines. The design would not be able to actuate fully without deforming under self-contact. Therefore, values were chosen between 4 and 15 to be representative of possible solutions.
Figure 2-6 The six configurations investigated during this study. (Top row, left to right) 4-tine, 6-tine, and 8-tine configurations. (Bottom row, left to right) 10-tine, 12-tine, and 15-tine configurations.

2.2 Superelastic Material Model

The modeling of the non-linearity of nitinol will be discussed by first explaining the advances in material modeling techniques and common modeling usages. This will be followed by a description of the material model utilized in ANSYS 14.5.

2.2.1 Advances in Nitinol Modeling

The development of an accurate material model for superelastic nitinol has been the subject of study for many years. Early models made use of a one-dimensional, phenomenological characterization of pure tension [51-52]. The early models were eventually improved to be fully three-dimensional [53–56]. Additionally, numerical implementation methods were developed utilizing techniques from computational plasticity to aid in integrating the models computationally [57–60]. Recent advances in nitinol modeling have been incorporated into commercial finite element packages, such as ANSYS, based on the model developed by Auricchio and his group [56,61].

A common application using the advances in the material modeling of nitinol is artery stents [62-63]. The nitinol stent can withstand large deformation and is compressed to fit inside a small catheter. Figure 2-7 shows an example of a typical artery
Nitinol is further ideal for implantable devices, such as stents, because of its good biocompatibility.

![Nitinol stent for vascular support](image)

After being compressed into the catheter, the stent is inserted into the blood vessel at the location where the blood vessel has collapsed. Once in position, the stent is released. Due to the superelastic effect, the stent returns to its original shape thereby helping to support the artery wall [65].

2.2.2 Nitinol Model in ANSYS

In this research, ANSYS 14.5 (research version) is used for finite element analysis of mechanical modeling. The non-linear, superelastic model has already been embedded in ANSYS since its eighth version. ANSYS names the material model “shape memory alloy,” which is a misnomer, because it is only capable of modeling the superelastic effect of nitinol. Figure 2-8 shows a diagram that outlines the model in stress-strain form.
A total of eight parameters are required to fully describe the material as modeled in ANSYS. These parameters include Young’s modulus of Austenite ($E^A$), Poisson’s ratio ($\mu$), material response ratio between tension and compression ($\alpha$), maximum residual strain ($\bar{\varepsilon}_L$), starting stress value for the forward phase transformation ($\sigma_s^{AS}$), final stress value for the forward phase transformation ($\sigma_f^{AS}$), starting stress value for the reverse phase transformation ($\sigma_s^{SA}$), and final stress value for the reverse phase transformation ($\sigma_f^{SA}$). The values for these parameters can be obtained from a typical tension and compression test. However, as can be seen in Figure 2-5, the hysteresis loops between tension and compression are different [67-68].

In the ANSYS material model, this difference is accounted for by a single parameter $\alpha$. However, this only accounts for the difference in stress at the starting stress value for the forward phase transformation, shown in Equation (2-1) [69]. In this equation, $\sigma_c^{AS}$ is the initial value of the Austenite to Martensite phase transformation in compression and $\sigma_t^{AS}$ is the initial value of the Austenite to Martensite phase transformation in tension. The slopes are prescribed the same as the Young’s modulus of Austenite in tension [69].
\[ \alpha = \frac{\sigma^a_{\text{AS}} - \sigma^t_{\text{AS}}}{\sigma^a_{\text{AS}} + \sigma^t_{\text{AS}}} \] (2-1)

The values of the material model parameters were taken from tension and compression data provided by manufacturer NDC for previous work performed in the Engineering Design and Optimization Lab at The Pennsylvania State. Table 2-2 lists the values that were used in this research.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>( E^A )</td>
<td>44.0 GPa</td>
</tr>
<tr>
<td>( \mu )</td>
<td>0.3</td>
</tr>
<tr>
<td>( \sigma^a_{\text{AS}} )</td>
<td>440 MPa</td>
</tr>
<tr>
<td>( \sigma^t_{\text{AS}} )</td>
<td>472 MPa</td>
</tr>
<tr>
<td>( \sigma^a_{\text{SA}} )</td>
<td>218 MPa</td>
</tr>
<tr>
<td>( \sigma^t_{\text{SA}} )</td>
<td>206 MPa</td>
</tr>
<tr>
<td>( \bar{\varepsilon}_L )</td>
<td>0.045</td>
</tr>
<tr>
<td>( \alpha )</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 2-2 Material properties of nitinol at 22 °C used for ANSYS material model [69-70]

### 2.3 Ablation Material Models

For developing the finite element models capable of accurately modeling device-tissue interaction during ablation, several thermal and electric properties must be defined for both the nitinol and the pancreatic tissue. The key values needed by COMSOL to perform the simulations are density, heat capacity, thermal conductivity, and electrical conductivity. For the nitinol, material data as published by the Johnson Matthey Medical Components company, a supplier of nitinol wire to the medical device industry, is used [71]. Furthermore, experimental data of porcine pancreas as published by Saccomandi et al. is used [72]. Porcine pancreas is considered to act electrically and thermally similar to human tissue. Table 2-3 summarizes the key values utilized in the finite element model.

<table>
<thead>
<tr>
<th>Property</th>
<th>Nitinol</th>
<th>Pancreatic Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density (kg/m(^3))</td>
<td>6450</td>
<td>1040</td>
</tr>
<tr>
<td>Heat Capacity (J/kg-K)</td>
<td>836.8</td>
<td>3590</td>
</tr>
<tr>
<td>Thermal Conductivity (W/m-K)</td>
<td>18</td>
<td>0.5417</td>
</tr>
<tr>
<td>Electrical Conductivity (S/m)</td>
<td>1.25 x 106</td>
<td>0.148</td>
</tr>
</tbody>
</table>

Table 2-3 Material data utilized for nitinol and pancreatic tissue in ablation simulations [71-72]
2.4 Summary

This chapter presented the geometry with alternate configurations and the superelastic material model used in this research. It first presents the geometry of the proposed RFA probe in a parametric model and describes the six configurations studied in this research. Secondly, advances in computational material models for nitinol are discussed along with the chosen eight-parameter material model implemented in ANSYS. Finally, the material models chosen for both nitinol and pancreatic tissue in ablation are discussed with relevant properties stated.
Chapter 3

Mechanical Deployment Modeling

This chapter details the mechanical modeling of the proposed radiofrequency ablation probe. It first details the boundary conditions and geometry of the simulation performed for free elongation, which occurs prior to the surgical procedure. It then presents and discusses the key results of the model.

3.1 Free Elongation

The proposed geometry of the ablation probe is designed to be in a naturally open state, i.e. in the deployed state. Therefore, to pass the device successfully through the working channel of the endoscope, the device needs to be stretched and pre-stressed prior to operation. Because of the large stresses that occur during this segment, a finite element simulation is developed for each configuration to stretch the whisk shut.

ANSYS 14.5 is utilized to develop and perform the finite element simulations. This section details the geometry, applied boundary conditions, and results of the simulations that were run for each of the six configurations.

3.1.1 Simulation Geometry and Boundary Conditions

For the purpose of easing computational requirements, each model for free elongation is developed using half-symmetry in the model. Since the design is symmetric about the vertical plane that runs parallel to the whisk’s axis, a simplified model is imported into ANSYS for analysis. Figure 3-1 shows the geometry as imported.
Figure 3-1 Imported geometry utilizing half-symmetry for the 8-tine configuration

The geometry is meshed using Solid 20 node 186 elements with a global element size of 0.0001. Between the varying configurations, the total number of tetrahedral elements ranged from 30,535 to 91,769 elements.

There are two key boundary conditions applied to this model. The first is a displacement boundary condition applied to the surfaces of the whisk at the base (lower left region of Figure 3-1). These surfaces are considered fixed in all directions. The second boundary condition is also a displacement condition applied to all surfaces of the tip of the whisk (upper right of Figure 3-1). The value of the displacement was determined by drawing a correlation between the tines arc length and the horizontal distance between the base and tip. This value was found to be 0.00075 m away from the base.

To avoid element distortion, the simulation was solved over the time range zero to one seconds. In this way, the applied displacement was stepped in minimum increments of 0.01 s up to a maximum of 0.2 s at the discretion of the internal solver.
3.1.2 Simulation Results

The key value of interest in these simulations is the maximum Von Mises stress that occurs during elongation. As a design choice, a restriction on the geometry was chosen such that the maximum stress would not exceed 472 MPa (the austenite finish stress) in the superelastic model for nitinol. Figure 3-2 shows a contour plot of the 8-tine configuration for the Von Mises stress.

Since bending is the most significant method of loading in this design, the narrow regions at the base of the tines see the highest stress values. With the applied loads, this resulted in a peak value of 445 MPa for the Von Mises stress. Additionally, the stress distributions were completely smooth and indicated no areas where stress concentrations occurred. In Figure 3-3, a close-up of the base of the tine is showed, where the location of the maximum stress occurs.
Similar simulations are performed for each of the whisk configurations with key results summarized in Table 3-1. Despite varying geometry, the various configurations showed no differences in stress distributions. Since the highest stress values occurred in the top and bottom tines due to bending, which each configuration shares, the stresses carried by each configuration did not vary. For further images of the stress distributions of the other configurations, please refer to Appendix B: Complete Mechanical Modeling Results.

<table>
<thead>
<tr>
<th>Tine Number</th>
<th>Maximum Von Mises Stress (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>445</td>
</tr>
<tr>
<td>6</td>
<td>445</td>
</tr>
<tr>
<td>8</td>
<td>445</td>
</tr>
<tr>
<td>10</td>
<td>445</td>
</tr>
<tr>
<td>12</td>
<td>445</td>
</tr>
<tr>
<td>15</td>
<td>446</td>
</tr>
</tbody>
</table>

Table 3-1 Key results for mechanical modeling of elongation in air for all six configurations
Since keeping the peak stress below the design limit is a critical factor, several preliminary tests were performed on early variations of the whisk design which allowed iterative changes to the geometry to be made, achieving the stress goal. These early tests showed peak stress values ranging from 500-650 MPa Von Mises stress. The major factors that were varied were thickness of tine, width of the tine, and overall profile of the tine; however, the most significant of these factors was the thickness of each individual tine. The knowledge gained from these results allowed final adjustments to be made to the whisk design. By decreasing the tine thickness, the geometry was finalized with the stress value getting below the limit of 472 MPa.

3.2 Summary

In this chapter, the simulations and results for the mechanical modeling of free elongation are presented. First, the geometry of the simulation is presented using half-symmetry. Secondly, the mesh, boundary conditions, and solver time steps are discussed. Finally, the key stress results and distributions are presented and discussed.
Chapter 4

Radiofrequency Ablation Modeling

This chapter details the ablation modeling of the proposed radiofrequency ablation probe. It first details a simulation performed to compare the developed finite element model against results from literature. It then presents the model setup, boundary conditions, and results of ablation modeling.

4.1 Modeling Environment Verification

Though ANSYS 14.5 is adequate for modeling the mechanical deployment of the probe, it does not have the capacity to perform coupled simulations involving electrical and thermal interaction in biological tissue. Therefore, COMSOL Multiphysics Software v4.4 (COMSOL, Burlington, MA, USA) is utilized to analyze the ablation of tumorous tissue.

To test the modeling environment created in COMSOL, a replication of a study from literature is pursued. In a 2003 paper, I. Chang performed several finite element studies to investigate the effects of perfusion and temperature-dependent material properties on percutaneous radiofrequency ablation of the liver [12]. Chang’s model for no perfusion (a numerical method of accounting for blood flow) and constant conductivity is chosen to perform as validation.

4.1.1 Governing Equations

For the simulations, it is assumed that the wavelength of the frequency applied to the probe, typically 460-550 kHz, would be larger than the diameter of the probe [12]. This allows a quasi-static electrical model and solution utilizing Laplace’s equation as follows:

\[ \nabla \cdot (\sigma \nabla V) = 0 \quad (4-1) \]

where \( \nabla \) is the gradient operator \( (\nabla \phi = \frac{\partial \phi}{\partial x} + \frac{\partial \phi}{\partial y} + \frac{\partial \phi}{\partial z}) \), \( \sigma \) is the electrical conductivity \( (\text{S/m}) \), and \( V \) is the electric potential \( (\text{V}) \).
The thermal modeling is governed by a modified version of Pennes’ bioheat equation [12,19]:

\[ \rho c_p \frac{dT}{dt} = \nabla \cdot (k \nabla T) + \sigma |\nabla V|^2 + Q_{bio} \]  

(4-2)

where \( \rho \) is the density (kg/m\(^3\)), \( c_p \) is the heat capacity (J/kg-K), and \( k \) is the thermal conductivity (W/m-K). \( Q_{bio} \) contains the terms for the metabolic heat source and for heat loss due to perfusion, both of which are assumed negligible for this model.

### 4.1.2 Simulation Geometry and Boundary Conditions

The study used to compare the modeling environment involved a single, percutaneous, straight needle, radiofrequency probe embedded in a block of liver tissue. Figure 4-1 shows the image of the probe that is simulated in this model. The details of the needle tip are not designated in Figure 4-1 by Chang; so, for this simulation, it is assumed that the length of the taper is equal to the diameter of the needle, i.e. 0.15 cm.

![Figure 4-1 Geometry of probe as simulated in model verification](image)

The probe shown above is modeled such that the tip of the needle is the center of the model. The liver tissue was modeled as a cube of side length 12 cm. Figure 4-2 shows the overall geometry of the model including both the liver tissue block and probe.
There are two important boundary conditions for the thermal aspect. The first condition states that there is no heat transfer across the boundaries of the probe subject to the following equation:

$$-\mathbf{n} \cdot (-k \nabla T) = 0 \quad (4-3)$$

where $\mathbf{n}$ is the unit normal to the surface, $k$ is the thermal conductivity (W/m-K), $\nabla$ is the gradient operator ($\nabla \phi = \partial \phi / \partial x + \partial \phi / \partial y + \partial \phi / \partial z$), and $T$ is the temperature field (°C). The second key thermal boundary condition states that the outer boundaries of the model (i.e. the sides of the cube) are at ambient body temperature ($T_{\text{amb}} = 37$ °C).

On the electrical side, there are three key boundary conditions. The first condition states that a supplied voltage ($V_o = 20$ V) is applied to the bottom 2 cm of the
probe. Figure 4-3 shows a close-up of the geometry with the lower probe portions highlighted.

Figure 4-3 Model geometry highlighted purple to indicate lower 2 cm portion of probe

The second electrical boundary condition states that all external boundaries of the model (the six sides of the tissue box) are electrically grounded (\(V = 0 \text{ V}\)). Finally, the third boundary condition is applied to the upper portion of the probe. It indicates that the boundaries of the probe in that region are electrically insulated, i.e. subject to the following equation:

\[ \mathbf{n} \cdot (\sigma \mathbf{E}) = 0 \quad (4-4) \]

where \( \mathbf{n} \) is the unit normal to the surface, \( \sigma \) is the electrical conductivity (S/m), and \( \mathbf{E} \) is the electric field (V/m).

4.1.3 Simulation Results

This simulation is performed for a total ablation time of fifteen minutes. During the simulation, two key values are calculated and reported. The primary value of concern is the temperature distribution in the liver tissue. With the goal of RFA to heat tissue above the minimum temperature of 50 °C to be certain of cell death, for ten to fifteen minutes, temperature distributions are critical to determining efficacy of RFA treatment.
probes [12,73]. For the comparison simulation, a maximum temperature of 81.31 °C was achieved near the tip of the probe. Figure 4-4 shows the temperature distribution in the liver tissue. In the left panel are the results and scale as published by Chang, and in the right panel are the results and scale found in the verification simulation.

![Figure 4-4 Temperature distributions in liver tissue ablation after 15 minutes. (Left) Distribution as published by Chang [12]. (Right) Distribution from verification simulation](image)

Qualitatively, the results match up well in both shape and size to those published by Chang. Quantitatively, the peak temperature values show a discrepancy between the two simulations. This difference is discussed in more detail further in this section. Since effectiveness of RFA is often judged on the size of the necrosis zone, Figure 4-5 shows the extent of the simulation’s necrosis zone. The gold-colored, isothermic surface is the surface on which all elements achieved a temperature of 50 °C. For surgical planning purposes, it can be assumed that any tissue within that surface would be killed during the procedure.
Figure 4-5 Isotherm surface for 50 °C indicative of the size of the necrosis zone

For a straight needle RFA probe, the radius of the necrosis zone is typically expected to be approximately 1 cm from the surface of the probe [12]. The comparison simulation shows a necrosis zone with a radius of 1.04 cm at its widest point, matching well with theory.

The second key value calculated during simulation is the magnitude of the electric field in the tissue. The electric field is related to the efficiency of the ablation procedure in transmitting energy to the tissue. Figure 4-6 shows the electric field distributions in the tissue. The left panel displays the results and scale as published by Chang while the right panel displays the results and scale found in the verification simulation.
Figure 4-6 Electric field magnitude distributions in liver tissue ablation after 15 minutes. (Left) Distribution as published by Chang [12]. (Right) Distribution from verification simulation

Again, qualitatively, results show a similar distribution between the results published by Chang and the verification simulation. Table 4-1 lists the peak values for both temperature and electric field magnitude for both studies as well as the percent error between them.

<table>
<thead>
<tr>
<th></th>
<th>Chang</th>
<th>Current Study</th>
<th>% Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature (°C)</td>
<td>94</td>
<td>81.4</td>
<td>13.4</td>
</tr>
<tr>
<td>Electric Field</td>
<td>21165</td>
<td>25191</td>
<td>19.0</td>
</tr>
</tbody>
</table>

Table 4-1 Peak values for temperature and electric field magnitude for both studies [12]

There are two main reasons why quantitatively the simulation differs from the published results. First, Chang did not state the material properties used in his simulation for the RFA probe. For this simulation, it is assumed that the probe is made of nitinol, used in the whisk design, and the properties are defined as such. Secondly, Chang does not state for what time period he subjected his tissue to ablation. The comparison simulation assumes an ablation time of fifteen minutes. Given the assumptions made about the material properties and ablation time, it is concluded that the new COMSOL model is valid.
4.2 Model Setup and Boundary Conditions

This section describes the geometry and boundary conditions used in modeling ablation simulation. Six models are developed for each whisk configuration in COMSOL v4.4.

4.2.1 Model Geometry

Finite element models were next developed to simulate each configuration of the whisk design. Similar to the verification simulation, the whisk was encapsulated in a block of pancreatic tissue with the tip of the probe at the center of the geometry. The whisk geometry, as described in Section 2.1, was imported into the COMSOL software package. Figure 4-7 shows the geometry of the model for the 8-tine configuration. The whisk is located in the center of a block of tissue 5 cm wide by 5 cm long by 6.9 cm high. Additionally, a cylinder runs from the top of the whisk to the boundary of the model to simulate the attachment of the active probe to the remainder of the system.

Figure 4-7 Model geometry of 8-tine configuration for ablation simulation
4.2.2 Boundary Conditions

Boundary conditions applied the whisk models are similar to those applied to the verification simulation. The two key thermal boundary conditions are the same as previously specified. The first condition states that there is no heat transfer across the boundaries of the probe subject to the following equation:

\[-\mathbf{n} \cdot (-k \nabla T) = 0 \quad (4-5)\]

where \( \mathbf{n} \) is the unit normal to the surface, \( k \) is the thermal conductivity (W/m-K), \( \nabla \) is the gradient operator (\( \nabla \phi = \partial \phi / \partial x + \partial \phi / \partial y + \partial \phi / \partial z \)), and \( T \) is the temperature field (°C). The second key thermal boundary condition states that the outer boundaries of the model (i.e. the sides of the tissue block) are at ambient body temperature \( (T_{amb} = 37 \, ^\circ C) \).

Again, there are three key electrical boundary conditions. The first condition states that a supplied voltage \( (V_0 = 20 \, V) \) is applied to the active portion of the RFA probe. The active portion is the region of the probe including the tip, tines, and the section where the tines attach to the base, shown highlighted in purple in Figure 4-8 for the 8-tine configuration.

![Figure 4-8 Active portion of the whisk probe highlighted in purple in the 8-tine configuration](image)
The second electrical boundary condition states that the outer boundaries of the model are electrically grounded (V = 0 V). Finally, the third boundary condition is applied to the non-active portion of the probe. It indicates that the probe boundaries in this region are electrically insulated, i.e. subject to the following equation:

\[ n \cdot (\sigma E) = 0 \quad (4-6) \]

where \( n \) is the unit normal to the surface, \( \sigma \) is the electrical conductivity (S/m), and \( E \) is the electric field (V/m).

### 4.3 Model Results

The following section describes the results of the finite element analysis for RFA ablation of the six whisk configurations. The section is further broken down to give the thermal results first followed by the electrical results.

#### 4.3.1 Thermal Results

As described in Section 4.1.3, the key thermal result of interest in ablation is the distribution of temperature within the ablated tissue. For each whisk configuration, the temperature is tracked in each element. The goal of the radiofrequency ablation is to create a spherical zone of tissue that reaches a minimum temperature of 50 °C, which causes cell necrosis, at a diameter of 3 cm. This 3 cm zone allows for the destruction of a 2.5 cm diameter tumor plus a 0.5 cm margin to ensure complete tumor eradication.

Figure 4-9 shows the temperature distribution in tissue for the 8-tine configuration. The result is shown at a cross-section running through the center of the whisk. Also included in this figure is the maximum temperature achieved in this particular model. As can be seen, a temperature of 81.63 °C was achieved very near to the tip of the whisk.
Figure 4-9 Temperature distribution in pancreatic tissue for 8-tine configuration

The distribution reaches temperatures in excess of 75 °C in the regions near to the whisk itself, but drops off rapidly and smoothly as radial distance from the whisk increases, as expected. Figure 4-10 shows the three-dimensional model with an isothermic surface plotted for 50 °C, since this is a key threshold for cell death.
Figure 4-10 Isotherm for 50 °C indicating size of necrosis zone for 8-tine configuration

The necrosis zone generated by each configuration follows the general shape shown in Figure 4-10. Since one of the design criteria was to create a necrosis zone with a precise diameter of 3 cm, ablation times for each configuration were adjusted so that the necrosis zone achieved this requirement. Table 4-2 lists the values of maximum temperature and ablation time for each configuration.
As can be seen in the data, and visualized in Figure 4-11, the ablation time decreases rapidly as the number of tines increases. Since results show that the number of tines does not affect the stress distribution, it is recommended to choose a configuration with eight or greater tines to decrease surgical time and risk of complications.

Table 4-2 Significant thermal results for ablation modeling

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Maximum Temperature (°C)</th>
<th>Ablation Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-tine</td>
<td>83.81</td>
<td>970</td>
</tr>
<tr>
<td>6-tine</td>
<td>82.13</td>
<td>845</td>
</tr>
<tr>
<td>8-tine</td>
<td>81.63</td>
<td>800</td>
</tr>
<tr>
<td>10-tine</td>
<td>80.94</td>
<td>775</td>
</tr>
<tr>
<td>12-tine</td>
<td>80.78</td>
<td>762</td>
</tr>
<tr>
<td>15-tine</td>
<td>80.64</td>
<td>760</td>
</tr>
</tbody>
</table>

As evidenced by the results, the necrosis zone for the whisk design as it currently stands is not perfectly spherical, but is slightly ellipsoidal. There are several ways that the shape of the necrosis zone could be improved. First, one of the other two original concepts (the squid and the coil) could be modeled to determine if a more spherical zone is possible with that geometry. However, if the whisk is the preferred design, there are two possible geometric changes that could be made to improve it. If the overall length of the probe is shortened, the necrosis zone would become more spherical; but stress problems could arise during mechanical loading. Secondly, the current needle tip on top
of the probe causes non-symmetry in the temperature distribution. Redesigning this tip to promote symmetry will also improve.

Please refer to Appendix C: Complete Ablation Modeling Results for plots and distributions of the remaining configurations.

4.3.2 Electrical Results

The key electrical result of interest in ablation modeling is the magnitude of the electric field in the pancreatic tissue. As stated previously, the magnitude of the electric field in the tissue is a qualitative indicator of how uniformly the tissue ions are being heated. The distribution of the electric field is collected for each configuration. For example, Figure 4-11 shows the distribution for the 8-tine configuration.

Figure 4-12 Electric field magnitude distribution in pancreatic tissue for 8-tine configuration after 15 minutes of ablation
The distribution matches well with expected results. Intensity of the electric field is highest nearest to the probe itself. Again, as expected, the electric field appears to be inversely proportional to the square of the distance from the probe, falling off rapidly as you move away from the surface. For the 8-tine configuration, the maximum value is 271.66 V/m. Based on the results shown in Figure 4-12, several “hot spots” can be identified in the electric field distribution. These locations also correspond to areas with increased temperatures in the tissue. To overcome this challenge as well as additionally improve the shape of the necrosis zone, the method of applying the electric potential could be changed. Instead of applying it uniformly to all surfaces of the whisk, the whisk could be selectively insulated to generate an electric field more conducive to a spherical ablation zone while avoiding hot spots in the tissue. Table 4-3 lists the electrical results for each configuration. Refer to Appendix C for the plots of other configurations.

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Maximum Electric Field (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-tine</td>
<td>250.83</td>
</tr>
<tr>
<td>6-tine</td>
<td>265.19</td>
</tr>
<tr>
<td>8-tine</td>
<td>271.66</td>
</tr>
<tr>
<td>10-tine</td>
<td>274.87</td>
</tr>
<tr>
<td>12-tine</td>
<td>276.46</td>
</tr>
<tr>
<td>15-tine</td>
<td>275.95</td>
</tr>
</tbody>
</table>

Table 4-3 Significant electrical results for ablation modeling

4.3.3 Comparison to Existing Technology

For the sake of comparison, it was desired to determine how the proposed whisk design would compare against existing, straight needle RFA probes. Using almost the same model setup for the validation model (section 4.1), the time was adjusted until the necrosis zone of the straight needle probe was 3 cm in diameter. However, instead of the original liver material values, the pancreatic values used in the whisk simulation were used. Figure 4-13 shows a side-by-side view of the temperature distributions for both devices.
The two different probe types create similarly shaped necrosis zones which are slightly elliptical in shape. However, the two designs differ greatly in the time needed to achieve these results. For the whisk design, as reported previously, the design requires a procedure time of 800 s (13 min 20 s) to run to completion. For the straight needle probe, however, a total time of 2895 s (48 min 15 sec) is needed to achieve the same result. Since the standard procedure time for RFA is in the ten to fifteen minute range, the use of a non-deploying, straight needle RFA probe is untenable for tumors of the size desired to be treated in the pancreas via EUS.

4.4 Summary

This chapter presented the ablation modeling verification as well as the finite element models for each whisk configuration. It first presents the equations that govern the ablation finite element models. It then presents the geometry, boundary conditions, and results for the verification simulation. With verification completed successfully, model geometry and boundary conditions are presented for the ablation models for each whisk configuration. Finally, the thermal and electrical results are presented with a summation of key results.
Chapter 5

Conclusions, Recommendations, and Future Work

This thesis has presented design and analysis of specially-shaped, compliant mechanism, radiofrequency ablation probes. The goal of this work was to evaluate the design and performance of these probes that were created using superelastic nitinol. In order to accomplish this goal, a series of finite element simulations were developed to test each configuration for mechanical stress distributions and RF ablation within pancreatic tissue. The preceding chapters of this thesis have presented a review of the related existing work, relevant material models, and finite element simulations. This chapter will summarize the thesis, discuss the major conclusions drawn from the work, present the contributions made, and suggest possible future work.

5.1 Summary and Conclusions

First, a discussion of pancreatic cancer is presented. The growth from premalignant lesions into cancerous tumors, via gene mutations, is briefly mentioned. Additionally, existing diagnosis techniques are discussed, namely blood tests and imaging processes such as CT scans and endoscopic ultrasonography.

Radiofrequency ablation, a proposed alternative treatment which uses alternating current to agitate tissue ions, is then discussed. Clinical treatments of tumors, in organs such as the kidney and liver, show a good association between RFA and tumor eradication. Furthermore, computer simulations of RFA probes in the liver have correlated probe geometry and material properties to the size of the desired necrosis zone. Both the clinical trials and computer simulations demonstrate the effectiveness of RFA for treatment of malignant masses in oncology.

Endoscopic ultrasonography is then presented. A brief history of endoscopic procedures, most notably the NOTES methodology, are discussed as minimally invasive operations capable of facilitating a variety of medical procedures including various types of ablation. However, limitations of existing RFA technology that are compatible with EUS are discussed which point to a need for new probe designs.
The background and specifications of superelastic nitinol as used in this study are then presented. Nitinol, an alloy of nickel and titanium, was developed in the 1950s and was shown to have both shape memory and superelastic properties. The effect of interest in this study is the superelastic effect, where large recoverable strains occur with little increase in corresponding stress. Additionally, the temperature dependency of the superelastic effect and the biocompatibility of nitinol are also discussed.

Lastly, compliant mechanisms are introduced and discussed. Compliant mechanisms accomplish complex and precise motion without the need for multiple parts or joints, therefore making small scale surgical instruments much more practicable. Combined with superelastic nitinol, compliant mechanisms offer the ideal combination for EUS-guided RFA.

With the design goals determined, the concept geometry for the RFA probe was developed. The concept, resembling and referred to as the “whisk,” was developed in six configurations sharing multiple common geometric parameters. The configurations, with varying numbers of tines, were developed to give varying degrees of mechanical movement and ablative potential. With probes designed, the material models for the varying elements of the computer simulations were discussed. First, the specific parameters of a nitinol model were discussed as developed by Liu [Jeining thesis, NDC]. Primarily driven by four stress values corresponding to crystal phase transformations, the values allowed a pre-determined material model in ANSYS v14.5 to be utilized for the material model of the nitinol device. Additionally, the thermal and electrical properties of both nitinol and pancreatic tissue were presented, respectively based on values reported by JM Medical and Saccomandi et al. These material parameters, however, are not dependent on temperature. If temperature-dependency is not accounted for in the model, the corresponding peak values and size of the necrosis value will shrink slightly. Since the ablation simulations were performed to determine the time necessary to create a very precise necrosis zone, under-treatment of the tumor could occur allowing for relapse or spreading of the disease.

Computer simulations of the whisk were first developed to model the mechanical movement of the proposed design. The proposed design is sensitive to the method of meshing. Due to the narrow base of the tines and the fillets attaching the tines to the
base, the mesh size had to be chosen carefully to balance accurate results and computational time. As a result of experimentation with various meshes, the geometry itself was tweaked to remove problem areas and make a smooth mesh. Once the mesh was finalized, the free elongation simulations were run to determine the stress distribution in the material as a result of distending the whisk from its default-open position to a diameter capable of being passed through the endoscopic working channel. After being displaced, smooth Von Mises stress distributions were formed with a peak value of 445 MPa, for the 8-tine configuration, which was under the design limit of 472 MPa.

After mechanical modeling had been completed, the geometry was imported into COMSOL v4.4 for simulation of its ablative potential. Each configuration of the whisk was encased at the center of a block of tissue. Electric potential was applied to the tines and simulated for a total elapsed time of fifteen minutes. At the end of simulation, temperature profiles and ablation times were determined. Peak temperatures around 80 °C (well above the floor temperature of 50) were recorded across each configuration. Additionally, to achieve the 3 cm diameter necrosis zone, ablation times were determined with an average of 800 s (13 min 20 s) needed to achieve coagulation. Though a perfectly spherical necrosis zone was desired, the actual necrosis zone was slightly elliptical in shape with a slight non-axisymmetric portion due to the angled needle tip.

5.2 Contributions

This work has contributed to the design of a nitinol-based, compliant mechanism radiofrequency ablation probe deployed into the abdomen via an endoscope. In previous literature, superelastic nitinol, compliant mechanisms, and RFA probes have been presented. The proposed design, combining all three of these ideas, was successfully modeled with suitable material models and meshing approach determined. Two types of simulations, mechanical deployment and tissue ablation, were modeled in ANSYS and COMSOL respectively.

A novel, deployable RFA probe was designed, capable of being inserted into the abdomen through the 1.8 mm working channel of a standard endoscope. The design
utilized a compliant mechanism composed of superelastic nitinol to achieve deployment into pancreatic tissue. In the previous literature, no deployable probes were comprised of compliant mechanism and were based on multiple moving components. Furthermore, all existing deployable probes were rigid and designed to be used in laparoscopic procedures. The design was mechanically analyzed utilizing ANSYS v14.5, achieving acceptable Von Mises stress distributions.

Additionally, simulations were performed to determine the device’s ablative potential. In the previous literature, radiofrequency ablation probes were simulated to determine temperature distributions and sizes of necrosis zones. Due to its ability to deploy into the tissue, the design is capable of generating a nearly-spherical necrosis zone, ideal for combating tumors, of diameter in excess of three centimeters. In previous literature, endoscopically-deployed RFA probes were only capable of generating highly elliptical zones of a maximum diameter of a single centimeter. Therefore, the proposed design should allow for a more effective, novel treatment for aggressive carcinomas, namely cancers of the pancreas.

5.3 Recommendations for Future Work

This section will discuss areas where future work can be pursued to improve and further the results obtained during this study.

5.3.1 Alternate Geometric Variations

The current iteration of the whisk geometry has successfully met the mechanical loading design requirements. However, there is room for improvement in the design. Currently, the whisk is in its relaxed, default state when the tines are fully deployed i.e. there is no stress in the tines in this position. Because of this, high stresses are incurred during free elongation when it stretched to its closed position. Conversely, if the geometry had a default closed geometry, higher stresses would be incurred while deploying it into the open position within the tumor mass. To overcome both of these scenarios, it is recommended that a geometry with a default position halfway between
fully open and fully shut, which shall be referred to as a “neutral” position. This neutral position will minimize stress during both the free elongation and deployment stages, further reducing peak Von Mises stress values below the design limit of 472 MPa.

5.3.2 Deployment Models

One of the stages that the proposed device undergoes, after being inserted into the body, is deployment into tissue. During this stage, contact and applied displacements will cause high stresses to form in the whisk. In the present study, finite element models were not developed to account for this stage. By utilizing ANSYS, the proposed design can be modeled in a block of tissue and displaced to determine the corresponding Von Mises stress, which is likely to exceed the values found for the free elongation.

5.3.3 Viscoelastic Tissue Material Model

As part of developing the deployment simulations, an appropriate material model will need to be chosen to represent the pancreatic tissue’s mechanical response. As understanding and modeling of biological tissue has become more important to the medical industry, studies have been performed to develop appropriate material models to represent different types of tissue. Many studies have assumed a strict linear elastic response to loading [74–76]. However, in 1967, Y. Fung published results showing an exponential trend in material response data [77]. Based upon Fung’s work, studies began looking at non-linear material response models. For certain types of tissue, hyperelastic (superelastic) and hypoelastic (generalized hyperelastic) models showed good correlation to load data [78–80].

However, soft tissues like the liver and pancreas, exhibit many complex mechanical behaviors characterized by large strains, rate-sensitivity, hysteresis, solid/fluid behavior, residual stresses, and permanent deformations [81]. A viscoelastic material model best captures these various aspects, taking into account the rate of loading and viscous response of the tissue [82-83]. Based on these reasons, a viscoelastic model should be chosen to represent the pancreatic tissue in mechanical finite element models.
No data for models based upon pancreatic tissue were reported in literature, so a possible material model for a five-parameter Maxwell model based upon healthy liver tissue is demonstrated [83]. The parameters are listed in Table 2-3 that fit the following equation:

\[\sigma_a = \gamma_0 \sum_{i=1}^{5} \frac{\eta_i}{\lambda_i} e^{-t/\lambda_i}\]

based upon axial stress where \(\sigma_a\) is the axial stress, \(\gamma_0\) is the constant strain value, \(\eta_i\) and \(\lambda_i\) are the Maxwell parameters, and \(t\) is the time [83].

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(\lambda_1)</td>
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</tr>
<tr>
<td>(\lambda_2)</td>
<td>1</td>
</tr>
<tr>
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<td>(\eta_2)</td>
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<tr>
<td>(\eta_3)</td>
<td>1580.</td>
</tr>
<tr>
<td>(\eta_4)</td>
<td>52747</td>
</tr>
<tr>
<td>(\eta_5)</td>
<td>340520</td>
</tr>
</tbody>
</table>

Table 5-1 Parameter values for five-parameter Maxwell model for the viscoelastic material model [83]

However, there are two limitations to using the proposed material model or ones similar to it. First, the proposed model is based off of values obtained for liver tissue which will differ slightly from values for pancreatic tissue. Experimental results should be obtained to more accurately reproduce the environment that the device will encounter during surgery. Secondly, mechanical properties of healthy and tumorous tissue can be drastically different, with tumorous tissue expected to respond less to external simulation than healthy tissue though this difference is yet to be quantified [84]. To overcome these differences, artificially-induced tumors could be experimentally tested alongside the healthy tissue to fully understand the possible variations in tissue properties that might be encountered.

There is an additional consideration that should be mentioned concerning the material model to be chosen for the pancreatic tissue during mechanical modeling. For
the proposed model above and for similar published models, data was collected for high strain rates of several hundred millimeters per second. However, in the simulations presented in this thesis, applied strain rates are expected to be 1 mm/s. Because of the slow nature of the applied strain rates as currently utilized, the usage of a viscoelastic model may not be necessary. A quasi-static model could be assumed which would allow the use of a linear model for pancreatic tissue characteristics.

5.3.4 Contact Model

Additionally, in the proposed deployment models, contact will be designated between the device and the tissue. To model this contact, a contact pair can be created using ANSYS’s built-in contact modeler. Contact should be defined between the two volumes with the tissue domain chosen as the impacted volume and the probe domain chosen as the impacting volume. The mode of contact should be chosen as surface-to-surface. Additionally, a friction coefficient of 0.1 was prescribed based on existing studies of device-tissue interaction [85-86].

Preliminary contact models were developed as part of this research. However, errors were encountered that prevented results from being obtained. The major obstacle in the contact model involved the surfaces partially coming out of contact. A quarter of the way through solving, areas of the whisk would come out of contact with the surrounding tissue domain. To overcome this problem, it would be best to specify a boundary condition that prevents the surfaces from moving away from one another.

5.3.5 Physical Prototyping

A physical prototype and testing are also vital to verification of the computer simulations and for further refinement of the design. The computer simulations performed during this study show great promise for the proposed design, however, verification is needed before proceeding further. A physical prototype would allow for simple tension tests to aid in determining stresses encountered during service.

However, because of the scale of the device, concerns regarding manufacturing the device arise. One possible method of manufacturing involves shaping the device
from a stock piece of nitinol tubing using a laser micromachining. Complications, however, may arise using the laser cutter due to the heat affected zone (HAZ). Although the HAZ can be minimized by a variety of methods, such as flowing water, the effects on the material properties cannot be overlooked if the HAZ is large relative to the overall size [87]. Therefore, it might be beneficial to consider alternative methods of production such as additive manufacturing. Selective laser melting (SLM) is an example of a non-traditional additive manufacturing process. SLM works by melting powdered material with a laser into individual parts [88]. Regardless of manufacturing technique, the scale and sensitivity of the material properties pose a challenge to be overcome in future studies.
Appendix A: Schematic of Finalized Geometry

Figure A-1 Schematic drawing showing end view of finalized geometry. All length units are in mm.
Figure A-2 Schematic drawing showing side view of finalized whisk geometry. All length units are in mm.
Appendix B: Complete Mechanical Modeling Results

This appendix contains the relevant distributions and plots for the whisk configurations not displayed in chapter 3 of this thesis.

Figure B-1 Von Mises stress distribution in the 4-tine configuration
Figure B-2 Von Mises stress distribution in the 6-tine configuration
Figure B-3 Von Mises stress distribution in the 10-tine configuration
Figure B-4 Von Mises stress distribution in the 12-tine configuration
Figure B-5 Von Mises distribution in the 15-tine configuration
Appendix C: Complete Ablation Modeling Results

This appendix contains the relevant distributions and plots for the whisk configurations not displayed in chapter 4 of this thesis.

Figure C-1 Temperature distribution for the 4-tine configuration at end of ablation
Figure C-2 50 °C isotherm for the 4-tine configuration at end of ablation
Figure C-3 Electric field distribution for 4-tine configuration at end of ablation
Figure C-4 Temperature distribution for 6-tine configuration at end of ablation
Figure C-5 50 °C isotherm for the 6-tine configuration at end of ablation
Figure C-6 Electric field distribution for 4-tine configuration at end of ablation
Figure C-7 Temperature distribution for 10-tine configuration at end of ablation
Figure C-8 50 °C isotherm for the 10-tine configuration at end of ablation
Figure C-9 Electric field distribution for 10-tine configuration at end of ablation
Figure C-10 Temperature distribution for 12-tine configuration at end of ablation
Figure C-11 50 °C isotherm for the 12-tine configuration at end of ablation
Figure C-12 Electric field distribution for 12-tine configuration at end of ablation
Figure C-13 Temperature distribution for the 15-tine configuration at end of ablation
Figure C-14 50 °C isotherm for the 15-tine configuration at end of ablation
Figure C-15 Electric field distribution for the 15-tine configuration at end of ablation
Bibliography


[70] NDC, 2012, Nitinol Tube Tensile Test.


