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Probe-Placement Fixture for Microwave Ablation

Final Report

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1. Abstract

Microwave ablation is a type of thermal therapy being used to treat the kidney, bone, liver, and lung cancer. Although this process has worked for these types of cancers, it is currently being researched in hopes of being a successful treatment for other types of cancer. Microwave ablation treatment denatures and destroys cancerous cells using the heat generated by microwaves. The power of microwaves is delivered to the cells through an antenna, and monitored through small temperature probes. This technique, if proven effective, would be a preferred method for future tumor treatments because it prevents many side effects that traditional treatments pose for many patients. The goal of this project is to design a fixture for microwave ablation probe placement that can be easily used by researchers during experimentation. In order to test the design, the probe-placement system will be tested using ex vivo mastectomy samples provided by a local hospital.

2. Introduction

2.1. Problem Statement

The problem that the client, Dr. Susan Hagness, has presented is that a probe-placement fixture is needed to hold the temperature probes and ablation antenna currently being used to test tissue samples. The current design takes an immense amount of time to set up, and take down. In order for this procedure to be successful, the entire procedure has to be less than 15 minutes, leaving roughly 2-3 minutes to set up our device. Although time is a pressing issue, the other problem is accuracy. In the current design, the antenna is held by a clamp, while the temperature probes are held up by the tissue conforming around them after they are inserted using hollow needles. Therefore, the probes are not guaranteed to be parallel while in the tissue and are not equidistant from each other.

2.2. Background

2.2.1 What is Microwave Ablation

Microwave ablation uses different intensities of electromagnetic energy to destroy cancer cells [1,2,3]. The heat generated by microwaves is transferred through a thin antenna, roughly 11-gauge (3.048 mm diameter) in size, that is inserted through the tissue [2]. The antenna is extremely small compared to previous treatments, so that the surgery itself is minimally invasive, and the patient will have a quicker and safer recovery [3]. As the energy is transferred through the antenna into the tissue, the malignant tumor cells are destroyed. The heating method for microwave ablation is different from radiowave ablation, a different clinically utilized method of tumor treatment [4,5]. Microwave radiation causes oscillation of polar molecules. This type of heating is called frictional heating, and radiowave radiation uses a different heating method called electric resistive heating. Since breast cancer tumors have such a high water concentration, the polar water molecules respond better to this type of heating. Other potential benefits of microwave ablation over radiowave ablation are smaller ablation zone, no grounding pad needed, and a shorter procedure [6].

In recent studies, different heating patterns were required for different types of cancer. System performance can vary widely, so it is critical that physicians understand the ablation-zone shapes and sizes created by different time and power combinations with a particular system [7]. The frequency is varied by the ablation zone, size of antenna orientation of the antenna, and the microwave frequency[8,10]. The orientation of the antenna is usually elongated in the vertical direction [9].

Some tumors required a high frequency of energy, while some cells required a lower frequency [10]. The different frequencies, therefore, have to be monitored for each specific case. Microwave ablation has been used, and was successful, for treatments of liver cancer[4, 11, 12, 25]. Tumors in the liver were able to be treated through microwave ablation techniques with a lesion no more than three centimeters in diameter [13,15]. Tumors like hepatocellular carcinoma (HCC) are treated through microwave ablation, because the microwaves exhibited are able to overcome the significant heat changes, therefore handling the high frequency of treatment of microwaves [14, 16, 17,25]. As a result, microwave ablation allows tumors to be treated using a minimally invasive technique, and allows the treatments to be performed in less time [3,18,19].

2.2.2 Implementing Microwave Ablation in Breast Cancer

In Dr. Hagness' research, she wanted to explore the possible effects of microwave ablation on various tissue types in hopes of applying it to different types of cancer. She and her team wanted to specifically do research on implementing microwave ablation in breast cancer. As mentioned before, different types of cancers required different types of treatment. Therefore, her team continued to work on this issue.

Her research showed that microwave ablation could possibly be implemented in breast cancer. She discovered that an issue in this treatment was the insertion of the antenna. In order to prevent damage to the tissue, the antenna would have to be small enough to be used to a minimally invasive incision [2,3,20, 21]. As a result, the original antenna was made narrower. In order to deliver enough treatment to the cells, a higher frequency of electromagnetic energy was used, and this also proved to deliver the same treatment before; by using a bigger antenna and lower frequency of energy[22, 23, 24].

After this discovery was made, Dr. Hagness and her team decided that it would be possible to deliver this treatment for breast cancer patients.

2.2.3 Current Procedure for Research

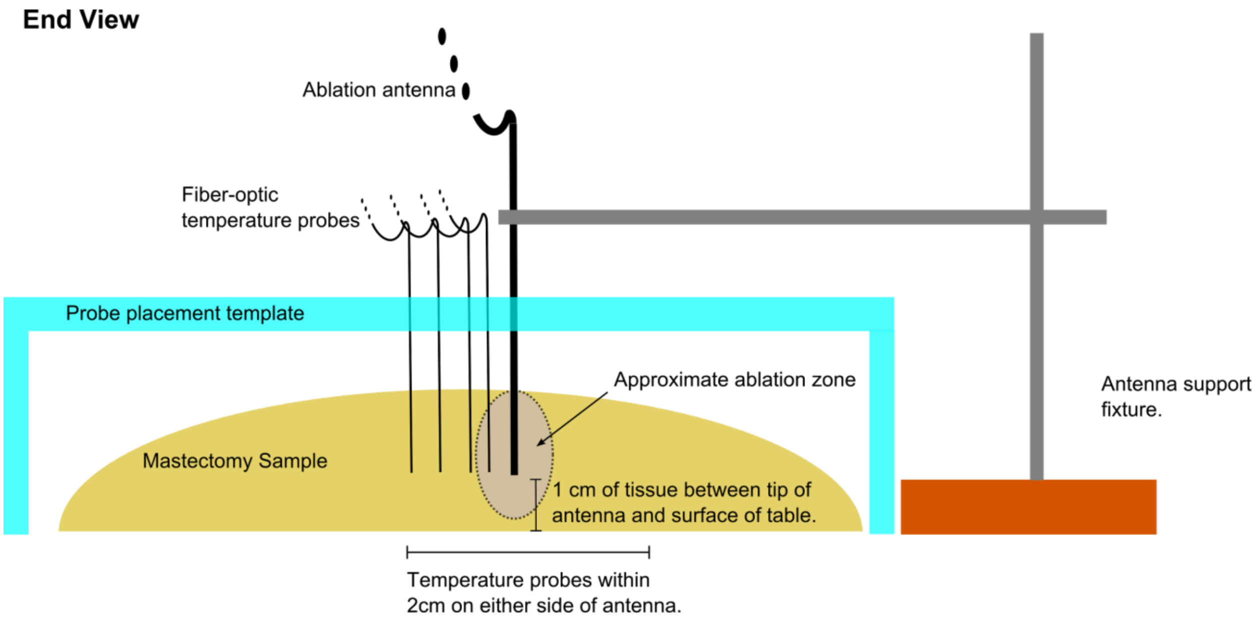
In order for microwave ablation to be implemented in breast cancer, an immense amount of research has to be done and many papers have to be done before to ensure that the team is operating within the bounds of the ethical standards. Currently, Dr. Hagness' lab has been working on testing microwave ablation using mastectomy samples provided by patients of the University of Wisconsin Hospital.

It was important for this to get approved so that mastectomy samples could be utilized for research [4]. Any research that is conducted that uses human samples is overseen by the American University's Institutional Review Board (IRB) [4]. This board protects the rights of all human participants, and ensures the welfare of any human samples taken. Since microwave ablation is being tested on human mastectomy samples, it was important to recognize these rights and ensure that the team was following all of the IRB's standards and procedures. Therefore, Dr. Hagness had to be approved for these conditions, since she would be using samples from patients at the University of Wisconsin Hospital.

Upon receiving approval from both the patient and the hospital to utilize a sample for their research, the team could begin testing the effects of microwave ablation. To monitor the temperature of the tissue during the procedure, four fiber-optic temperature probes are inserted into the issue using hollow needles. After insertion the needles must be removed from the tissue because they will interfere with the procedure. A small hole is drilled next to the temperature probes and the ablation antenna is inserted and is held in place by a clamp attached to a ring stand on the lab table. The temperature probes are roughly incremented within two centimeters of the ablation antenna. The probes need to be parallel, at the same depth, and inserted at fixed distances from one another for accurate results to be returned. The proper depth of the probes is within the active heating region of the ablation antenna which would be located roughly one centimeter above the surface of the table.

One of the main flaws with this procedure is the accuracy of the probes, and the time the procedure requires. Currently, the procedure takes a long time to set up and take down and this is problematic. It is important that the procedure does not take over 15 minutes, because having the tissue sample out in room temperature for that amount of time could damage the tissue. The probes are unguided when they are inserted which causes these accuracy issues. The temperature probes are not equal distance from each other or parallel to the antenna. The current procedure does not guarantee a proper depth for the probes, which would need to be within the 2 centimeter long active heating region of the antenna to return accurate results. The current procedure is depicted in Figure 1 below, and our client added the probe placement template to give us a general idea of what we would be creating for them. As seen in Figure 1 below, without the template, the temperature probes are not held by anything other than the tissue itself.

For this project, these issues were important to resolve to ensure success in receiving accurate results, and to ensure overall safety during research.



2.3. Product Design Specifications

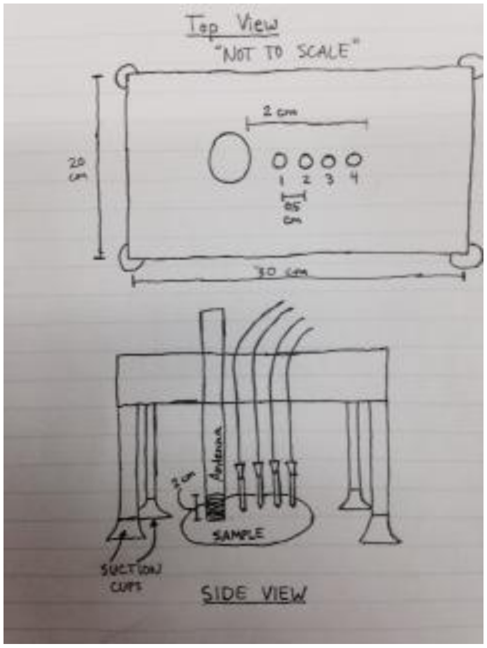
The client for this project, Dr. Susan Hagness, wanted the team to develop a fixture for placement of temperature probes to be used in microwave ablation. The temperature probes must be at known distances from the antennae (~0.5cm increments and all within 2cm of the antenna). The probes must be parallel to the ablation antenna and inserted at known depths within the mastectomy sample. The design must also not interfere with the the tissue sample undergoing ablation. The design should be easily set up and taken down, as the time frame for the ablation is limited . Achieving these goals will allow researchers to accurately measure the temperature induced by microwave ablation. Ultimately, accurate temperature readings ensure that the exposed tissue is not damaged.

2.4. Design Possibilities

The team explored three possible designs to fix the temperature probes at a known distance. It was suggested to use 3D printing or table top supports would be used to insert the temperature probes at known distances. The next section outlines the possible designs that the team explored.

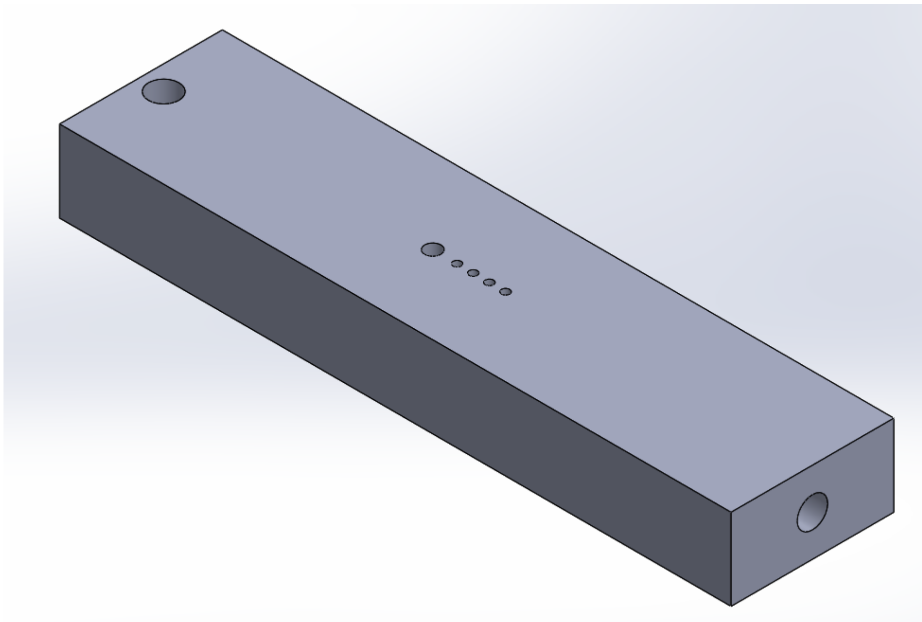
3. Designs

3.1 Design 1 – Table Top Stand



The first design is modeled after a table. We chose four legs for this design to give the table sturdiness and prevent as much tipping as possible. With dimensions of 20 cm wide, 30cm long, and 15 cm high the table design would allow for the mastectomy sample to sit underneath the table without the legs of the table touching the material. This is important because if the tissue is touched by anything other than the needles, antennae, and temperature probes, the tissue will not be able to be used again. Suction cups will be added to the feet of the table to stop the table from sliding or tipping over onto the the mastectomy sample and ruining its integrity for future research.

The top of the table design would be machined with one larger guide hole for the antenna, and four smaller holes with a diameter of 1.3mm that serve as rough guides for needle insertion and hold the needles once they have been removed from the tissue. Our client will simply need to place the larger hole for the antennae over ablation point, and then use the guide to place the antenna. They will then have to place the needles for the temperature probes by threading the fiber optic cable through the smaller holes. Unfortunately, the needles that puncture the holes for the temperature probes will still be placed by hand. The needles must be removed from the tissue to avoid false temperature readings. The smaller holes in the table top are to hold the needles once they are removed from the tissue.

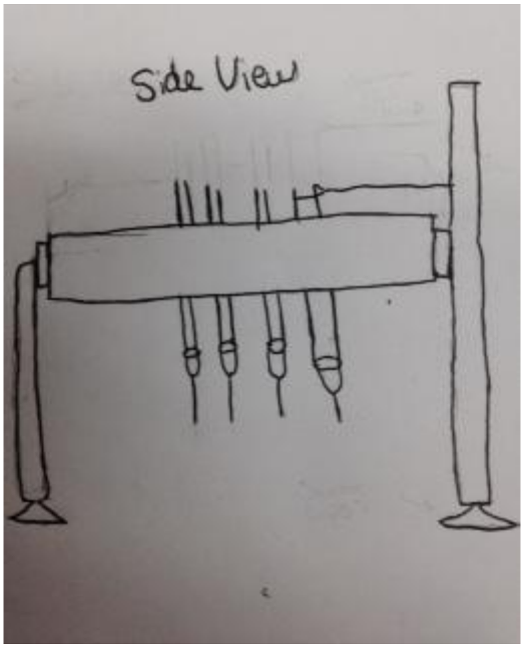


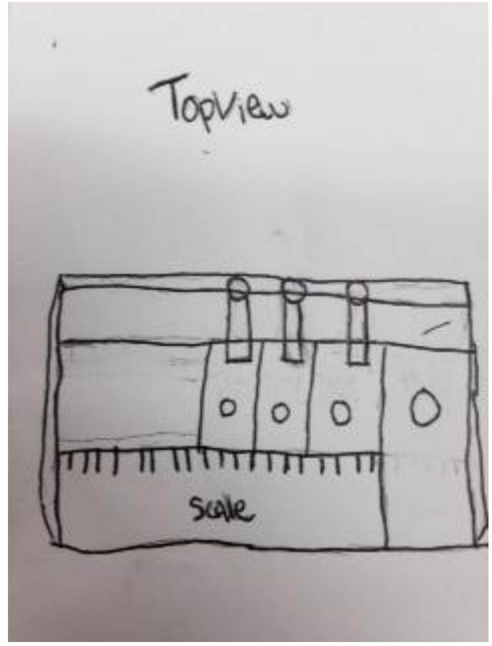
3.2 Design 2 – Clamp Stand Probe Fixture (3D-printed)

The second design is an accessory for common lab clamp stand. The hole located on the bottom right of the drawing will be threaded for a metal rod to be placed inside it. The rod will then be slid into a clamp on the clamp stand. After the measuring device is secured to the clamp stand, the device will sit over top of the tissue sample with the help of a support rod/level bar that will be in the hole on the far left of the drawing. The hole will be threaded, allowing for easy adjustability of the rod. The level bar can be adjusted to control the depth of the needle and the antenna in the sample since the dimensions of the tissue sample will be unknown until the procedure.

Once the clamp stand is set in place so the antenna guide(the larger hole) is over the site the ablation will occur and the level bar is set so the probes and the antenna will reach the correct depth in the tissue, the placement of the ablation antenna and the temperature probes can begin. First the researcher will place the needle needed into the large hole to make a guide hole for the ablation antenna. The ablation antenna can then be put into place. The antenna will be held at the correct height level via the use of a mini-clamp which allows the antenna to be attached to the body.

After the ablation antenna is in place, the needles for the temperature guides can be placed into the guide holes. The fiber optic cable with the temperature probes on the end can then be threaded through the hollow needle into the tissue sample. The needles can then be removed from the tissue sample to avoid tampering with the temperature readings. Once the needles have been removed, the procedure can begin.





3.3 Design 3 – Bridge Probe Guide

The final design is similar to the first design, but implements some new ideas to increase accuracy.

Instead of being a table, this design is called the bridge because it only has two legs. The tissue sits underneath the bridge the same way as it did with the table, keeping it safe. The suction cups are added to the base to help avoid tipping and to counteract the unstable nature of the two legged bridge. Once the probe is placed in the proper position for the procedure, the suction cups can be pushed tight to the table to lock the bridge in place.

The top view shows the adjustability of the probe placement. The holes for the temperature probes are machined through block that lie on sliders. The sliders can be slid along a rail system and clipped into place by weld clamps so they will not move when the needles are being placed. The scale will fixed on the structure so the researchers know which distance the probes are placed if they are adjusted. This adjustability allows for the researchers to collect different sets of data if they choose.

The needle insertion for the temperature probes will be guided. The researcher will place the guide needle for the ablation antenna through the guide hole for the antenna, remove the needle and replace it with the antenna just like with the table. The guide needles for the temperature probes will be placed into the tissue using the guide hole. The needles will be attached to hollow guide rods, similar to a gutted mechanical pencil. The guide rods ensure the temperature probes are placed parallel to the ablation antenna. The fiber optic cables can then be threaded through the needles to be placed into the tissue. Once the probes are in place, the needles can be removed and the researchers can begin their data collection.

3.4 Design Matrix

Design Criteria	Design 1 Table Top Support	Design 2 Clamp Stand Device	Design 3 Bridge Probe Guide
Efficacy and Accuracy (30)	10	30	20
Safety of Tissue (20)	18	16	12
Ease of Use/Set Up Time (20)	20	14	16
Adjustability (15)	1	10	8
Ease of Fabrication (10)	6	8	2
Cost (5)	5	2	3
Totals (100)	60	80	61

A design matrix (Figure 9) was created with the three aforementioned designs. Designs were ranked based on six categories in order of decreasing weight: efficacy and accuracy, safety of tissue, ease of use/set up time, adjustability, ease of fabrication, cost.

Efficacy and Accuracy was evaluated based on whether or not the temperature probes could be inserted at proper distances in the tissue. It was determined to be the highest weighted category, as the location of each temperature probe relative to the antennae needs to be precise. Specifically, the temperature probes need to be incremented at 0.5 cm intervals in the tissue sample. The Clamp Stand Device won this category with a maximum score, since it incorporates a level bar that ensure the probes are inserted at the proper depth (as well as location in the tissue). The Bridge Probe Guide finished with the second highest score in the this category, as it contains guides that ensure the proper placement of the temperature probes relative to the antennae. However, the Bridge design does not include a method for fixing the depth, thus it scored lower than the Clamp Stand Device. Finally, the Table Top device scored the lowest in this category, as it does not ensure that the temperature probes are placed at proper distances from the ablation antennae.

Safety of tissue was determined to be the second highest priority, and was gauged on whether or not the probe fixture device would interfere with the tissue sample. This category is relatively high in weight because the client requested that tissue samples not be contacted. In addition, contact with the tissue sample may cause any data obtained from testing to be skewed. The Table Top Support device scored the highest in this category, as this fixture is positioned high enough over the samples such that it would not contact it. In addition, the design features suction cups to keep the stand in place, thus preventing the device from sliding/falling into the tissue. The Clamp Stand probe fixture scored the second highest in this category. The Clamp Stand fixture would be secured via a screw to the clamp stand on one end, and by a measuring/support bar on the other. However, the clamp stand needs to be moved to the proper height, and could come in contact with the tissue if the operator is not careful. Lastly, the Bridge Probe Guide design score the lowest in this category, as it only contains two legs of support, causing it to be prone to fall over.

Ease of use/Set up time was determined to be of equal importance to the safety of the tissue. This is because the entire microwave ablation procedure takes about 15 minutes, thus leaving on 2-3 minutes for setup and takedown before the tissue is damaged. The Table Top Support design scored the highest in this category, as the setup includes placing the fixture device over the sample and inserting the antennae/probes into the sample. The second highest scoring device was the Bridge Probe Guide probe holder. This design requires slightly more time to set up: the device needs to be placed over the tissue, the probe holes need to be slide to the desired location and locked, and the antennae/probes inserted into the tissue through the guide holes. The lowest scoring design in this category was the Clamp Stand design. This design requires the highest amount of setup time: the fixture needs to be attached to the clamp stand, the clamp stand needs to be set to the proper height, and the probes/antennae need to be inserted into the tissue.

Adjustability was rated based on a device's capability to allow vertical flexibility. Since the horizontal distances to the probe are small, a device's adjustability in that direction was not as important. The device that rated the highest in this category was the Clamp Stand design. The Clamp Stand design can be adjusted via screw to best suit the tissue. In addition, this design includes an adjustable measuring bar, which allows control of the depth of the temperature probes. The Bridge Probe Guide design scored the second highest, as it allows the temperature probe holes to slide horizontally. However, this horizontal adjustability is not as important as the vertical adjustability of the Clamp Stand design. Finally, the Table Top Support design scored the lowest in the adjustability category as it contains no adjustable parts.

Ease of fabrication was the second lowest weighted category. Ease of fabrication basically measured how easily a device could be constructed. The highest scoring device in this category was the Clamp Stand design. The Clamp Stand design implements 3D printing in the manufacturing of the design, thus it does not require a high level of fabrication knowledge and skill. The second highest rated device in this category was the Table Top Support design. This design would require some level of machining of the guide holes, as well as insertion points for the legs. The suction cups would have needed to be attached to the legs as well. The lowest rated design in this category was the Bridge Probe Guide Design. This device scored the lowest mainly due to its implementation of rails and locks for the holes. While this is possible to construct, it is beyond the capabilities of a majority of the group members.

Cost was determined to be of the least importance in this experiment, as the budget of $150 would be an ample amount to create a device to fix the temperature probes. The design that scored the best in this category was the Table Top support design. This device requires a small amount of material to be used for the guide part of the design, as well as four legs and suction cups to hold the design in place. Since the amount of material required would be rather small, this design would not cost very much to construct. The next highest scoring design was the Bridge Probe Guide design. While this design is similar to the Table Top design, it would also require guides for the probes to be inserted, as well as clamps and a rail system for the adjustable holes. Finally, the Clamp Stand design scored the lowest, largely in part to the 3D printing aspect. The clamp stand and measuring/support bar would be rather inexpensive, however; we predicted that 3D printing would cost more than assembling the two other designs.

3.4 Material Matrix

Criteria	**HDPE**	**Acrylic**
Machinability (50)	**50**	**20**
Transparency (30)	**5**	**25**
Structural Integrity (10)	**8**	**6**
Cost (10)	**8**	**4**
TOTAL	**71**	**55**

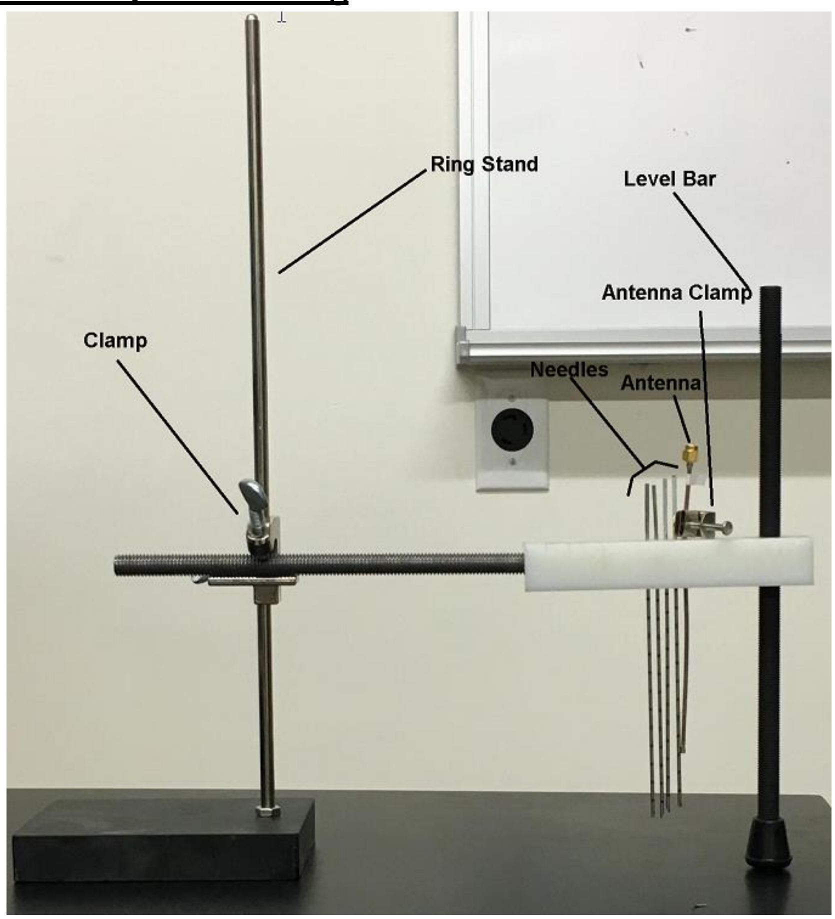
Machinability was determined to be the most important category for our material. The fabrication of a device with holes 5 mm apart requires a material that can be drilled into. High density polyethylene can be drill quite easily, without fear of damaging the material. Acrylic, on the other hand, runs the risk of cracking when being drilled into. Therefore, we rated HDPE higher than Acrylic.

Transparency was deemed to be the second most important category. Since the device is going to be used to insert temperature probes into a tissue sample from overhead, it would be a benefit to be able to see the temperature probe being inserted from above. This could ensure the accuracy of the fixture device. Acrylic is clear, and would be easy to see the tissue sample through. On the other hand, HDPE is not a clear material, and thus would not allow for overhead viewing.

Structural Integrity was determined to be the third most important category. It is crucial that this device does not give in, and maintains its intended form during the procedure. However, due to the light weights that are being dealt with, it highly unlikely that the device will lose its structural integrity. With that being so, High density polyethylene is a more versatile material, and thus received a higher rating.

Cost was determined to be the least important category, as either material runs for relatively cheap. The amount of material we plan on using for this device is miniscule compared to other projects. Thus, the cost plays a small factor in deciding which material we will pick. Overall, HDPE is slightly cheaper than its acrylic counterpart.

4. Experimental Setup and Testing



To test the final design, we used two experiments: one to test the efficiency/speed of setup, and one test the accuracy of the design.

The first experiment to test the timing of the design, involved a disassembled prototype, with the exception of the level bar being attached to the body of the device. For each trial the level bar started halfway on the fixture device, to allow for a consistent starting distance. After the timing started, the level bar was moved to the desired height. Once at the desired height, the device was attached to the clamp stand, and the needles and antennae were inserted into their corresponding holes. After the needles were inserted, the height of the device was adjusted to assure the needles were perpendicular to the table. The time was then recorded for multiple trials, at a variety of heights.

The speed experiment gave us a general sense of how long the device takes to set up. The major aspect absent from this experiment, was the insertion of the actual temperature probes into a tissue. Due to the lack of a mastectomy sample and probes, we could not account for the insertion time. Thus, the setup time obtained from experimentation would be an underestimate of the setup time during research.

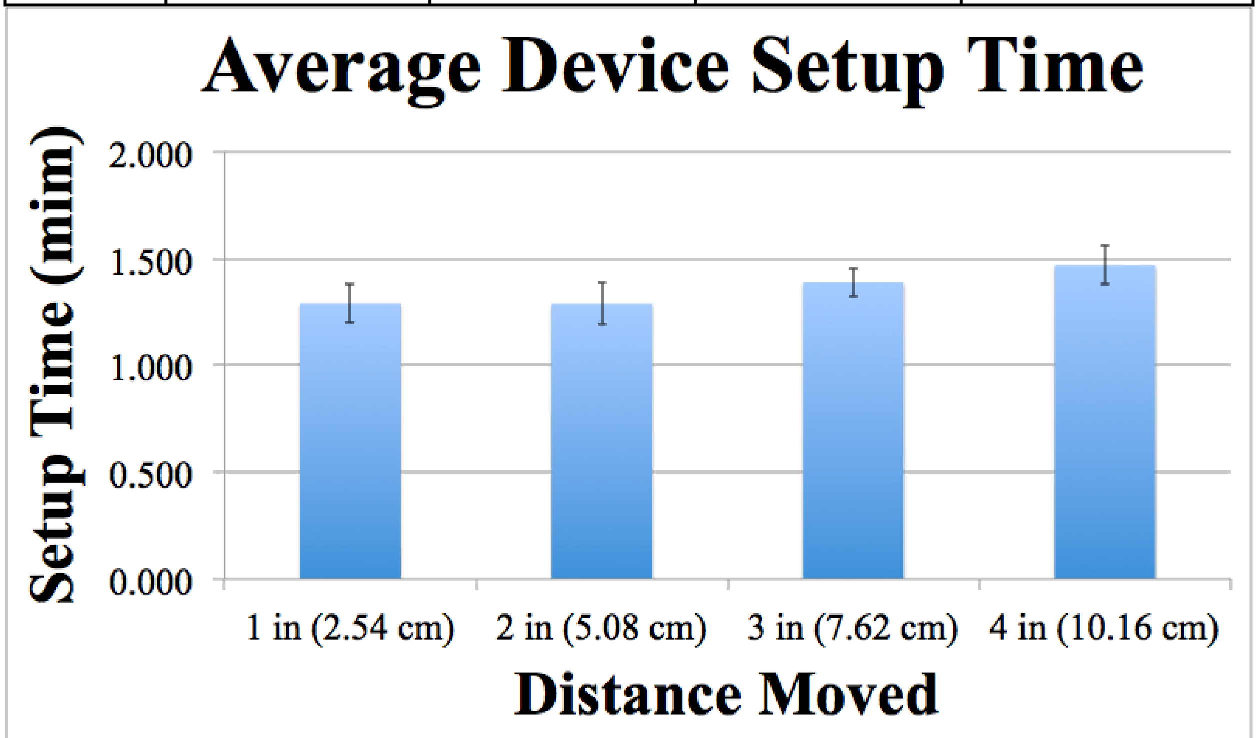
The second experiment we devised measured the accuracy of the inserted needles in relation to the antennae. To begin, the device's height was set to slightly less than the height of the antennae. Setting the device to this height meant the table supported the antennae as well as the needles. We then placed a sheet of paper underneath the device. After the paper was in position, a small amount of pressure was applied to the antennae and needles, leaving an imprint on the paper. The needles and antennae were removed, and the distance of the needle imprints were measured in relation to the antennae. To ensure the consistent readings, a needle's positions were rotated amongst the holes. This was done to account for any inconsistencies in the needle shape.

The accuracy experiment gave us a good idea as to the efficacy of our device. While this test measured the needle's location rather than the probe, the probes will be guided into place by the needles. The discrepancy between the needle's insertion point and the probe's will be very small. In addition, this test does not measure the accuracy of the height of the needles/probes. However, if needles of the same length are used, there will not be a difference in the depth of the probes.

5. Results and Analysis

The results of the speed test are as follows:

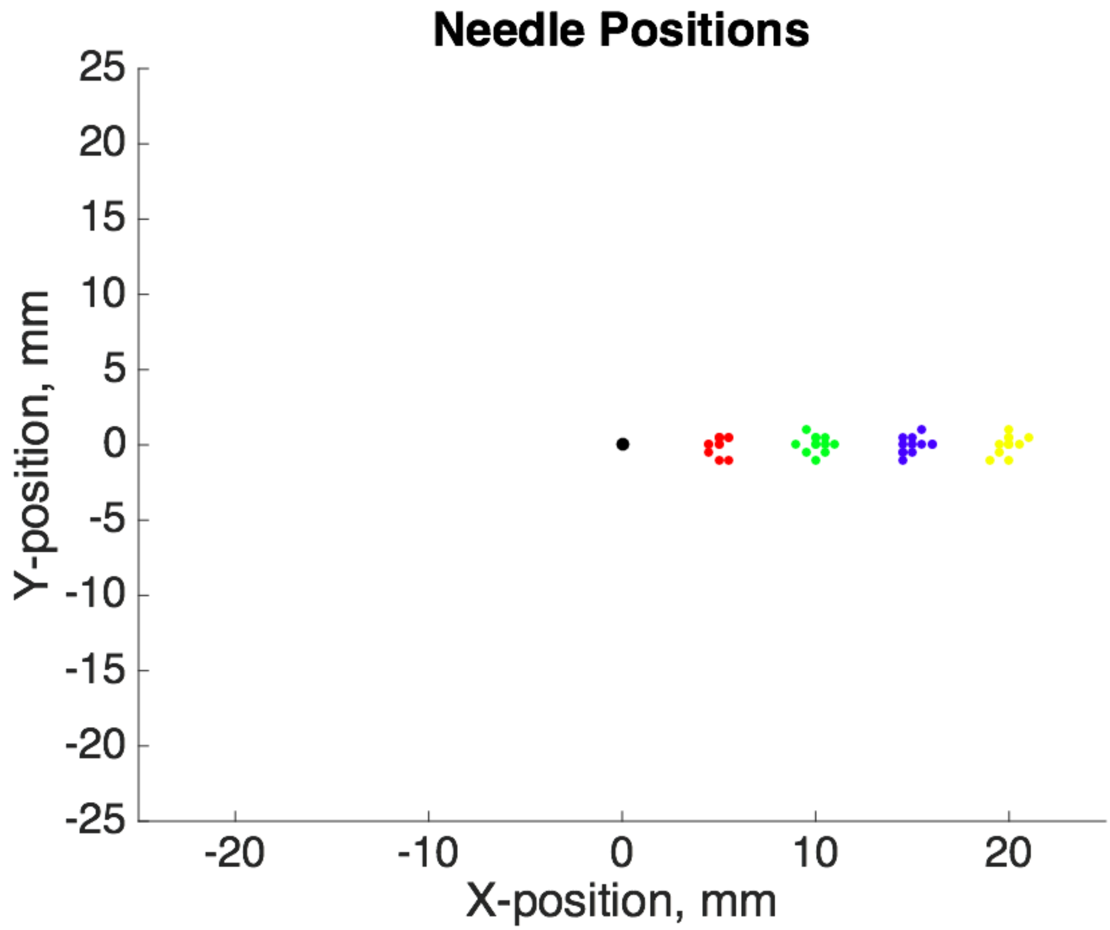
Minutes to Set up				
	1 in (2.54 cm)	2 in (5.08 cm)	3 in (7.62 cm)	4 in (10.16 cm)
Trial 1	1.186	1.392	1.371	1.567
Trial 2	1.354	1.275	1.460	1.454
Trial 3	1.329	1.200	1.333	1.388
Average	1.290	1.289	1.388	1.469



From the results of the speed test, it was determined that the device is capable of being set up in less than the desired two minute interval. Additional, the standard deviation of the results were very small, and thus these average setup times are what should normally be expected. As previously mentioned, timing did not account for the insertion of the probes into a tissue sample. Thus, the actual time will be longer from the measured time. However, the process of inserting the temperature probes merely includes sliding the probes into place through the needles. Thus, the actual setup time should still fall within the two minute interval. In addition, while moving the device to the proper height, we constantly checked the height with a ruler. This undoubtedly slowed down the setup time. Overall, the device is capable of being set up within the two minute interval.

The results of the accuracy test are as follows:

Distance from Antennae (mm)								
	Probe 1 X	Probe 1 Y	Probe 2 X	Probe 2 Y	Probe 3 X	Probe 3 Y	Probe 4 X	Probe 4 Y
Trial 1	5.50	0.50	10.00	-1.00	15.00	0.00	20.00	0.50
Trial 2	5.00	0.00	10.50	-0.50	15.50	1.00	19.50	0.00
Trial 3	4.50	-0.50	11.00	0.00	16.00	0.00	21.00	0.50
Trial 4	5.00	-1.00	10.00	0.50	14.50	0.50	20.00	-1.00
Trial 5	4.50	0.00	9.50	1.00	14.50	-0.50	20.50	0.00
Trial 6	5.00	0.00	10.00	0.50	15.50	0.00	20.00	1.00
Trial 7	5.00	0.50	10.00	0.00	15.00	0.50	20.00	0.50
Trial 8	5.50	0.50	10.50	0.50	16.00	0.00	20.00	0.00
Trial 9	5.50	-1.00	10.00	0.00	14.50	-1.00	19.50	-0.50
Trial 10	5.00	0.50	9.50	-0.50	14.50	-0.50	19.00	-1.00
Trial 11	5.00	0.50	10.50	0.00	14.50	0.00	20.00	0.00
Trial 12	4.50	0.00	9.00	0.00	15.00	-0.50	20.00	0.00
Average	5.00	0.00	10.04	0.04	15.04	-0.04	19.96	0.00



The results of the accuracy test show that the needle positions all fall within 1 mm of the intended location. The measuring was done to the nearest 0.5 mm, thus the measurements were not necessarily precise. However, the needles fall within a fair distance from the intended location. The discrepancy could have been caused by different geometry of the needles.

6. Future Work

The team plan needs to train the client in using the device to keep the process as fast as possible. The temperature probe placement device will be used is research by the client, hopefully giving the client more time to focus on research and less time on probe placement. The device will also help to increase the the accuracy of the probe placement, and therefore the temperature data obtained by the client. This device will help to further the research of microwave ablation of varying frequencies in breast cancer tissue. Using the results from the research, the client hopes to get closer to microwave ablation treatment of breast cancer clinically safe in years to come.

7. Conclusion

The team has been approached by Dr. Susan Hagness to develop a temperature probe fixture device to be used in microwave ablation research. In order to perform valid research on the effects of microwave ablation on the tissue, the temperature probes must be inserted into the tissue at known distances and depths in relation to the antenna. However, there is no available device that allows for the insertion of temperature probes at known distances from the antenna. Having a temperature-probe fixture device is a must if microwave ablation research wants to make any progress.

Specifically, the device needs to be able to fix four temperature probes at 0.5 cm increments from an antennae delivering energy to the tissue. The probe fixture needs to be setup and taken down quickly, as the timeframe for the entire microwave ablation experiment is fifteen minutes in order to preserve the mastectomy samples. The current method of approximating the distances by eye has proven to be inaccurate and ineffective in research. Thus, the team designed and fabricated a temperature probe fixture to ensure accurate tissue temperature readings.

8. Acknowledgements

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9. References

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10. Appendix

10.1. Product Design Specifications

Function:

Microwave ablation is a type of thermal therapy being used to treat the kidney, bone, liver, and lung cancer [g hwang, 1]. Although this process has worked for these types of cancers, it is currently being researched in hopes of being a successful treatment for other types of cancer. Microwave ablation treatment denatures and destroys cancerous cells by using the heat generated by microwaves [1]. The power of microwaves is delivered to the cells through an antenna, and monitored through small temperature probes. This technique, if proven effective, would be a preferred method for future tumor treatments because it prevents many side effects that traditional treatments pose for many patients.

The goal of this project is to design a fixture for microwave ablation probe placement that can be easily used by researchers can during experimentation. In order to test the design, the probe-placement system with be tested using ex vivo tissue from the liver.

Client Requirements:

- Operate quickly and efficiently due to the clients 15 minute time limit with the tissue sample.
- Must be able to easily maneuver and insert the temperature probes and antenna efficiently into the tissue sample.
- The mastectomy sample must remain in good condition after the experiment.
- Each probe has to be equally 0.5 cm apart, and 2 cm from the antenna in parallel. If possible, would like the option to make the distance variable.
- The probes perpendicular from the mastectomy sample, but would like the potential in from different angles is desired if possible.
- Maximum Diameter should be 20 cm to hold all of the temperature probes.

Design Requirements:

1. **Physical and Operational Characteristics**

   a. Performance requirements: The device must be able to insert a microwave ablation probe and fiber optic temperature probes into a mastectomy. The device must also be able to position the temperature probes an accurate distance from the ablation probe, while remaining at the same depth and parallel to the ablation probe.
   b. *Safety:* Our device must be functionally stable so it avoids all contact with the tissue. The mastectomy must remain intact and testable after the experiment is completed.
   c. *Accuracy and Reliability:* Design must function in a way that it can be used for numerous experiments to provide consistent and accurate results for the research assignment.
   d. Life in Service: Probe positioning device must be continuously effective throughout its implementation.
   e. Shelf Life: The probe positioning device must last for multiple years.
   f. Operating Environment: The device will be operated on a small lab table held at standard atmospheric conditions and temperature. The device will be positioned 10-25 cm above the mastectomy sample during the 15 minute procedure.
   g. Ergonomics: The device must be easy to use after a quick briefing. It must also be quickly assembled and disassembled.
   h. Size: The probe placement device must be able to fit on a small lab table approximately 120 cm by 120 cm and be no more than 10-25 cm above the mastectomy sample.
   i. Weight: The maximum weight of the device should not exceed five kilograms.
   j. Materials: The probe fixture must be sterilizable. Have access to sample antennas and fiber-optic probes.
   k. Aesthetics, Appearance, and Finish: Aesthetics and appearance of the design is not of particular importance.

2. **Production Characteristics:**

   a. Quantity: One fully operational probe-placement fixture will be produced.
   b. Target Product Cost: The budget is $150.

3. **Miscellaneous:**

   a. Standards and Specifications: No standards or approvals are required.
   b. Customer: The research team conducting the experiments must be able to use the device.
   c. Patient-related Concerns: The device must be sterilizable.
   d. Competition: There are currently no devices in the market that act as a probe placement fixture for microwave ablation.

2. Production Characteristics:

a. Quantity: One fully operational temperature probe-placement fixture.

b. Target Product Cost: The budget for this product is set at $150.

3. Miscellaneous:

a. Standards and Specifications: No standards or approvals are required.

b. Customer: Primarily researchers.

c. Patient-related Concerns: The temperature probe fixture has to be able to maintain the patient's mastectomy sample sterile.

d. Competition: Microwave ablation has been implemented in many cancer treatments such as cancer in the liver. Although, today, microwave ablation has not been an approved method of treatment for breast cancer. As a result, many researchers has been trying to implement this technique to be used to treat breast cancer.