Prostate Cutting Device

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Abstract

Prostate cancer is a prominent problem among aging males in the United States. Our client Dr. Wei Huang works as a pathologist at the UW hospital diagnosing biopsied prostate samples. To expedite and improve the process of extracting slices from the biopsied prostate, Dr. Huang would like us to design a prostate cutting apparatus that would secure the tissue during cutting as well as allow for 3 mm slices to be extracted. After many modifications, our team has constructed a prostate cutting device that can secure the prostate while it is being accurately cut into 3mm slices.

Introduction

One in six American men over the age of 50 is affected by prostate cancer, equating to approximately 2 million American men (Prostate Cancer Foundation). New cases are diagnosed every 2.7 minutes and death due to prostate cancer complications occurs every 19 minutes (Prostate Cancer Foundation). Prostate cancer poses a significant problem for a considerable portion of the population. The best way to avoid complications due to prostate cancer is to diagnose and treat it early. For this reason, pathological analysis of prostate tissue is critical, and streamlining the analysis process is a major concern.

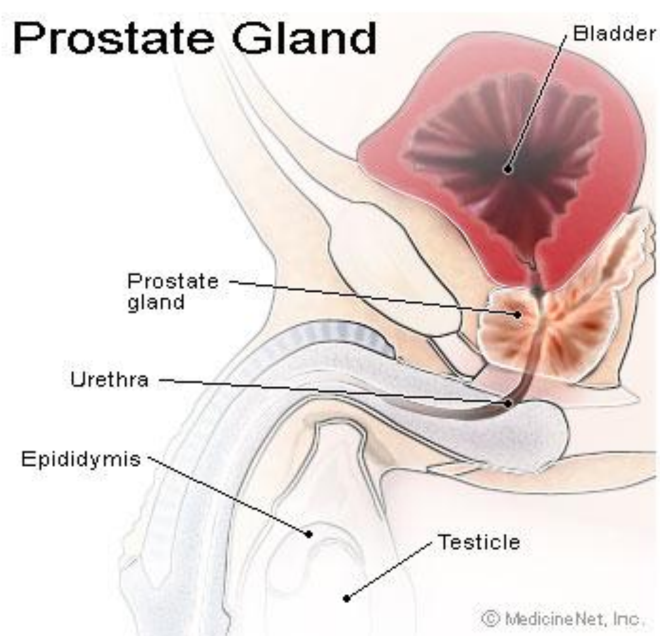

Figure 1: Prostate schematic
http://www.medicinenet.com/prostate_cancer/article.htm#_Toc498458211

Background

Prostate Function

The prostate is a gland located directly beneath the bladder in men (Fig. 1). More specifically, it is located at the base or outlet of the urinary bladder and surrounds the first portion of the urethra. Due to this strategic placement, the prostate assists in controlling urination by directly pressing or squeezing the portion of the urethra that it surrounds. In addition, the prostate plays a role in the male reproductive system. The prostate secretes fluid that contributes to semen volume. This fluid is slightly alkaline in pH to neutralize the acidity of the vaginal tract and prolong the life of sperm. Lastly, nerves running alongside the prostate are responsible for controlling erectile function.

Prostate Cancer

When a population of cells within the prostate grows uncontrollably, normal cell proliferation is disrupted and tumors can form (Fig. 2). The spread and continual growth of cancer cells within the prostate takes place at a relatively slow rate, normally requiring a substantial amount of time before the cancer spreads from the prostate to other areas of the body. This continual growth of cells can enlarge a normal 20 to 30 gram prostate up to 100 grams (Prostate Physiology). This enlargement, as would be expected, causes many problems and

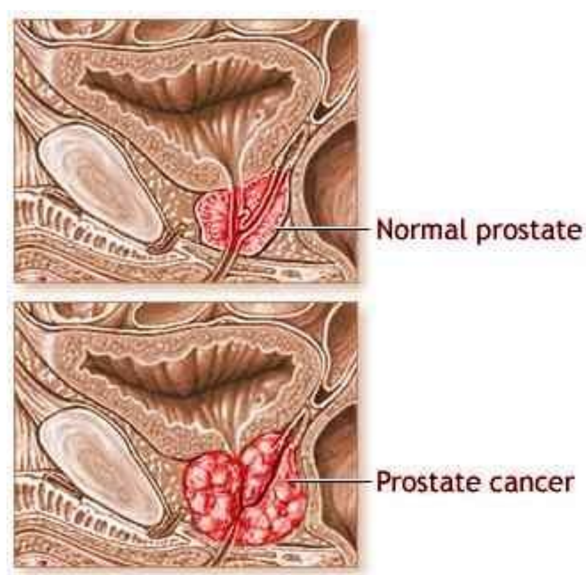

Figure 2: Normal prostate vs. cancerous prostate tissue size
http://catherinemaname.files.wordpress.com/2009/02/prostate-cancer3.jpg

complications. It is unknown what causes prostate cancer but a few contributors thought to be responsible are advancing age, genetics, hormonal influences, and environmental factors such as toxins, chemicals, and industrial products (Medicine.net). Treatments for prostate cancer include surgery, radiation therapy, hormonal therapy, cryotherapy, chemotherapy, or in some cases, a combination of these treatments (Medicine.net). The employment of these treatments results in a very high cure rate, meaning many individuals treated will be in full remission within five years. However, there are a certain percentage of cases that result in death. The National Cancer Institute estimated that prostate cancer caused approximately 27,360 deaths in the year 2009 (National Cancer Institute). Therefore, early diagnosis and treatment are important to promote survival of those afflicted with prostate cancer.

Pathological Analysis

Doctor Wei Huang from the Department of Pathology at the University of Wisconsin Hospital is involved with the clinical research and diagnosis of prostate cancer. She and her colleagues perform a diagnostic process in a series of steps to accurately analyze and diagnose cancerous tissue. First, the prostate is biopsied or fully removed. Prostates are generally biopsied for diagnostic cases or fully removed for research cases. If fully removed, the prostate is dyed for orientation purposes. The

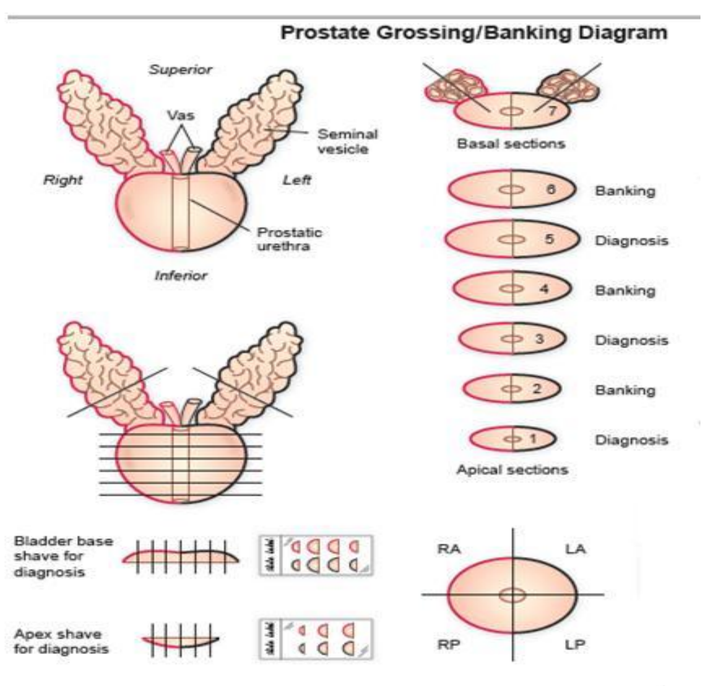

Figure 3: Prostate grossing diagram (From Client)

right side is dyed red and the left side black. Using a scalpel, a series of horizontal free-hand slices are subsequently made, with each slice approximately 3 mm in thickness (Fig 3). From these slices, the odd numbered selections are submitted for fixation and bathed in formalin for 2-3 hours. They are then divided into 4 quadrants for processing and embedding allowing for the immediate analysis and diagnosis of the tissue at hand. The even numbered slices are divided into four quadrants and frozen. The frozen tissue blocks are then stored individually in a plastic bag at -80˚C and are stained with hematoxylin eosine for evaluation. After fixation, designated slices can be embedded in paraffin and sliced using a microtome, resulting in the construction of microscope slides from each quadrant for evaluation. Overall, this process allows for the best chance of correct diagnosis of the type, spread, and severity of prostate cancer in an individual.

Problem Statement

Prostate cancer affects 1 out of 6 men in the United States. In order to properly diagnose this cancer, analysis must be performed on a biopsied or excised prostate. A major problem during analysis of samples is obtaining fresh, thin slices from the biopsied tissue. Our goal is to fabricate a device that secures the prostate while a pathologist slices 3mm segments. We propose a device that contains a measurement grid allowing the physician or pathologist to easily dissect the prostate into the 3mm slices. We also propose an adjustable device to accommodate varying prostate sizes. Eventually, this device could be used to cut and examine tissues other than the prostate.

Problem Overview

Currently, the method used to extract samples from the dissected prostate is to manually cut ‘thin’ slices from the prostate sample with one hand while holding the sample stationary with the other. As would be expected, this method is neither accurate nor precise, and novice pathologists have an especially difficult time extracting slices without damaging the prostate. Our client would like us to design a cutting device that will hold the prostate tissue stationary and provide a means of efficiently extracting 3 mm slices from the tissue.

Problem Motivation

The motivation behind this project is to provide physicians with a simple, more reliable way to cut accurate, intact prostate tissue slices. In order to detect the spread and severity of prostate cancer, it is important to maintain the integrity of the margin of the prostate. The margin is the outermost layer of the tissue surrounding the prostate. By examining this layer, pathologists are able to determine whether prostate cancer has metastasized. Any damage to the margin of the sample impedes the ability of the pathologist to make an accurate diagnosis. The current method used for cutting the prostate results in a high probability of margin damage, and our device's main purpose will be to stabilize the prostate to make it easier to cut without incurring damage.

Design Constraints

One of the main purposes of the device is to secure the biopsied prostate while it is being cut. As prostate samples can significantly vary in size, our device must be able to lock prostates of all reasonable sizes, from 20 to 100 grams. While keeping the sample stationary, our device must not cause any damage to the tissue, such as tearing, puncturing or deforming.

After securing the prostate, the pathologist will dissect 3-4 slices from the tissue. A main concern for this project is accuracy; the slices should be as close to 3 mm as possible while maintaining the integrity of the tissue. As this design is to be used in a lab setting, it is necessary for it to be sterilized in the same manner as the other lab equipment. Our client's lab uses an autoclave oven; therefore, the material components of our device must be able to withstand the high temperatures and pressures associated with autoclave cleaning without developing any conformational changes or damage. Also, the material of the design must have a long lifespan without rusting or degrading, as the device must be used 3-4 times a week for up to five years.

Our client also emphasized that the device should be manually operated and easy to use. It should cut the prostate slices relatively quickly, taking about five minutes to cut up to eight slices. One of the more obvious problems with the current method of cutting samples by hand is safety - our design should significantly reduce the likelihood of pathologists accidently cutting themselves while extracting slices. As a final constraint, our client allotted us a budget of $500 - $1000 to produce one functional prototype to be used in the lab at the end of the semester, so we must keep this factor in mind as we make choices regarding the final design.

Current Devices

The current method used to obtain prostate slices is cutting by hand. The prostate is held to the cutting surface with one hand while it is being cut at an approximate width with the other. This method is open to error in sample size and uniformity.

Competition

We are not aware of any other devices used to cut prostate tissue. A device exists that is used to slice mouse brain samples (Zivic Instruments) in a similar manner, but its dimensions are fixed and this device could not be utilized for cutting prostate tissue.

Potential Designs

Snap-On Slider

The first design tackles the issue of securing the prostate by using a sliding-wall mechanism (Fig 4). Running along the sides of the base, there will be tracks which the sliding wall snaps into, allowing it to slide to secure the prostate. The prostate will first be placed inside the cutter against the stationary wall, and the moving wall will slide along the track until it clamps the prostate. The wall will lock into place during cutting, adding an additional measure of security. Locking will occur on the aforementioned sliding track, most likely with a screw mechanism or clamp.

This design also incorporates removable blade guides which help guide the scalpel to cut 3 mm slices. These attach orthogonally to the moving and stationary walls, on the outside of the sliding mechanism. These guides will align with grooves in the base to ensure the scalpel cuts through the tissue completely. Like the sliding wall, the exact mechanism of attaching the guides to the base is uncertain. Removable guides would make it possible for varying widths of tissue to be cut. For example, one could use the 3 mm blade guides to cut prostate, and then attach blade guides of a different width to cut different tissue. In addition, any cleaning aside from autoclaving that needs to be

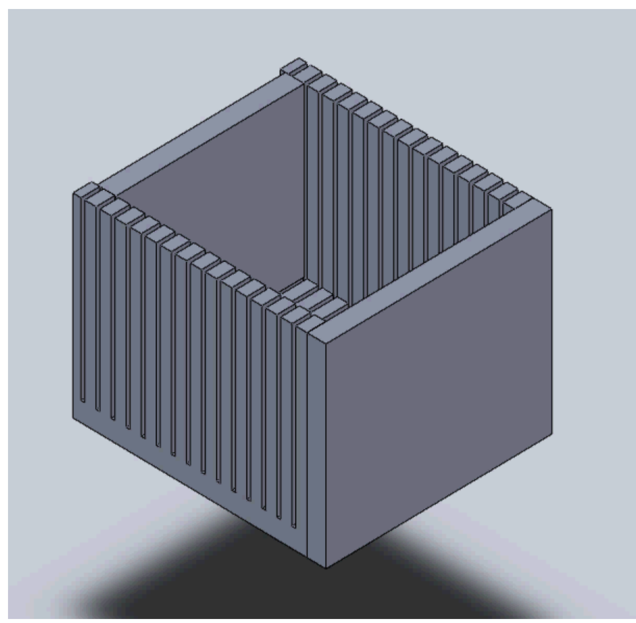

Figure 4: Snap-on slider design

done between uses will be easier if the guides are detachable. The detachable guides could be secured permanently if the snap-on design proved too difficult to implement.

Finally, although this design will be the easiest to fabricate, it does not conform to the shape of the prostate. Because the design entails two flat planes pushing on opposite sides of a spherical prostate, there may be some potential clamping problems. For instance, the prostate may deform if it is clamped too tightly or may slip out of the cutter if it is not clamped tightly enough, making it more difficult to slice.

C-Clamp Cutter

The second design utilizes a modified c-clamp to secure the prostate. This design is adjustable to accommodate different sizes of prostates, which can range from 20 to 100 grams in size. In contrast to the sliding wall, the c-clamp cutter has a movable guide and a stationary clamping apparatus. This clamping mechanism will better conform to the spherical shape of the prostate than the wall of the first design, facilitating easier clamping. Running along the base of the clamp (Fig 5) is a single mobile blade guide which lies tangent to the prostate, ensuring a straight horizontal slice is cut. Since there are measurements on the side of the clamp, the guide can be shifted to the appropriate position according to these hash marks and the prostate can be sliced at the desired thickness.

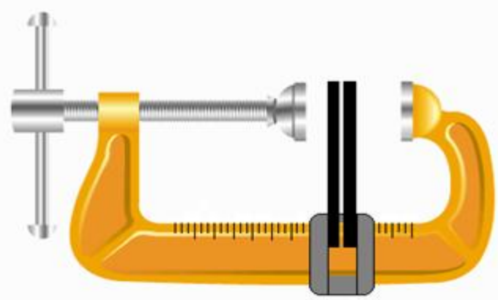

Figure 5: C-Clamp cutter design

Though the variability of thicknesses can be achieved on the c-clamp cutter without additional parts, this design does have drawbacks. When the prostate is cut, there is no way to keep the slices secured. It is possible that after being cut they may be damaged by the pressure of the clamp, or fall into an unsterile area. Also, since the prostate is suspended, it will require re-clamping after each slice is made. Though only 3-4 slices are cut at a time, the process of clamping and re-clamping may be tedious. Finally because the c-clamp is not self-supporting, additions will be necessary in order for this design to be viable on a cutting table or similar surface.

2-Comb Scoop

In this design, two contoured combs cradle and secure the prostate (Fig 6). One comb is stationary while the other slides into place along a track in the base. The translating comb will be able to lock into place with a screw or clamp, much like the translating wall in the sliding wall design. Both combs have 1 mm slits that guide the scalpel during cutting, separated by 3mm solid sections. This will allow 3 mm sections of prostate to be sliced. The stationary sides along the track are the same height as the combs to prevent the prostate from sliding out of the holder during cutting.

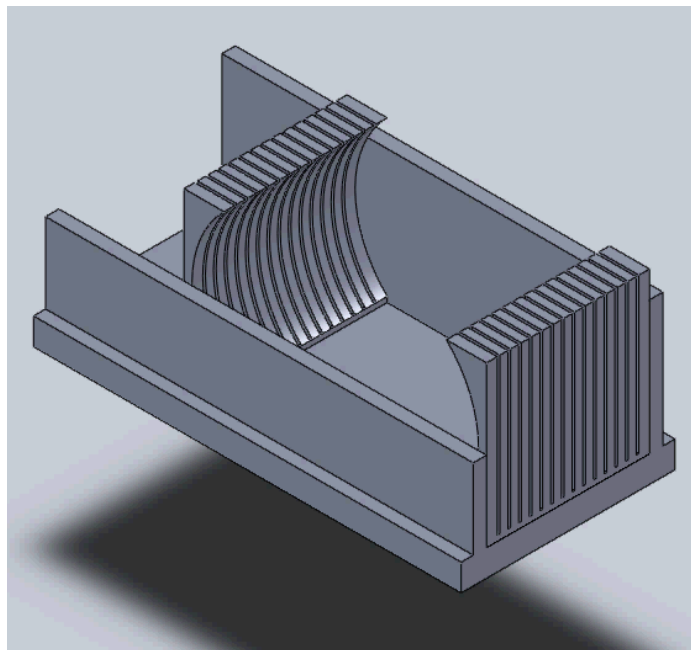

Figure 6: Two-comb scoop design

This design is more stable and secure than the other two designs. However, there are still some issues with this design. The slits in the combs cannot extend all the way to the base without compromising the integrity of the comb. This may make it difficult to cut all the way through the tissue. For this reason, it may be necessary to place gauze or a spacer underneath the prostate to lift it and cut all the way through the tissue.

Design Matrix

We evaluated each of the three designs using a design matrix (Fig 7) with categories of: safety, ease of use, ease of construction, aesthetics, precision, security, and cost. We valued ease of use, precision, and clamping security higher than the other categories because these will be most important to the success of the design.

	Safety (10)	**Ease of Use (20)**	**Ease of Construction (15)**	**Aesthetics (5)**	**Precision (25)**	**Security (20)**	**Cost (5)**	**Total (100)**
Snap-On Slider	9	16	12	5	23	15	3	**83**
2-Comb Scoop	9	17	7	5	23	19	3	**83**
C-Clamp Cutter	5	12	11	4	19	12	5	68

Figure 7: Design Matrix

Final Design

Accessory Clamp

Our client would also like our team to fabricate an accessory clamp (Fig 8) in addition to the prostate cutting device. After each 3mm slice of the prostate is cut, it is fixed in formaldehyde which can cause tissue deformation. We have fabricated a device that mimics a 3-ring binder, in which each of the 3mm slices of the prostate can be placed and then clamped down. The material has holes evenly and strategically placed to allow for maximum diffusion of the formaldehyde solution during fixation. This will allow for the margin to be preserved and for the overall shape of the prostate to stay intact for diagnostic purposes

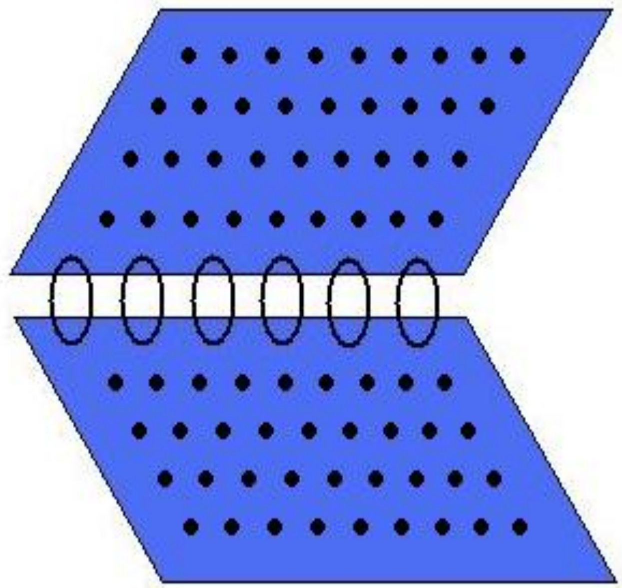

Figure 8: Accessory Clamp Design Schematic

Prostate Cutter

The design matrix resulted in a tie between the top two design options. The final design selected was the snap on slider, selected after receiving client feedback about both designs. Due to the complexity and size of the design, our group decided to contract

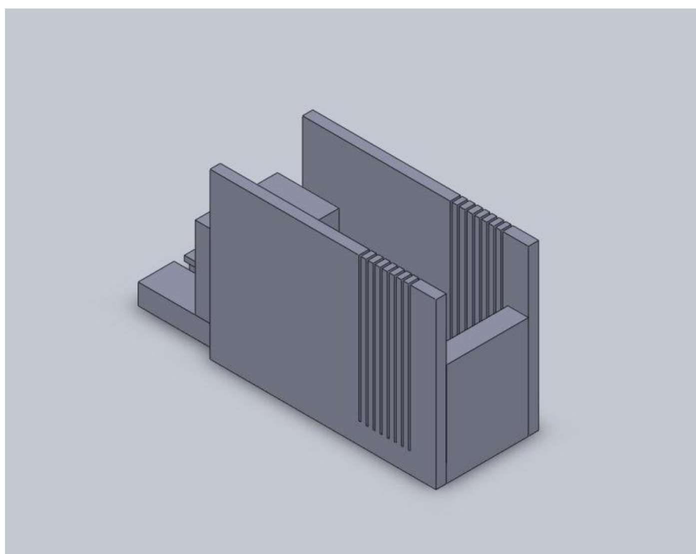

Figure 9: Final Design

out our design and have it professionally constructed to improve the quality of the final product. After some market research, our team selected the Tosa Tool Company to fabricate our design (Fig 9).

Some changes were made to the design to reduce the fabrication costs and improve its stability. The final design features a 1.5" long sliding side that moves along a t-track in the base, as seen in a cut-away of the final design (Fig 10). The length of the sliding side was increased to enhance the stability of the side and prevent it from wobbling. The sliding side locks in place with a hexagonal bolt and a wing-nut. The head of the hexagonal bolt is also located in the t-track, and the bolt extends through the sliding side to the top of the piece. The wing-nut then tightens onto the bolt, securing the sliding side to the base.

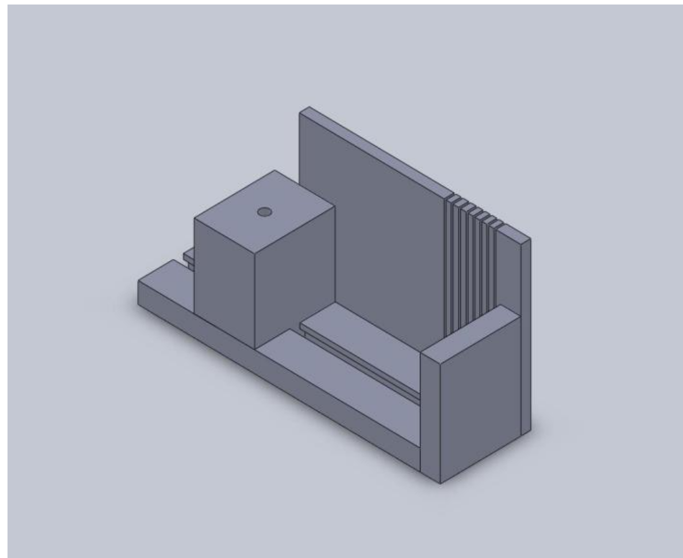

Figure 10: Cut away of final design

On either side of the base, two sides have slits spaced 0.125" apart (approx 3mm). These slits are 0.0469" = 3/64" wide (approx. the width of the scalpel blade). Rather than placing slits completely along the length of each side, our team economically chose to put only eight slits in each side. This is the maximum number of slices a pathologist must make at any one time from a single prostate. The final feature of the design is a stationary side opposite the sliding side which serves as a barrier against which the prostate may be secured.

The entire device is fabricated out of AISI-SAE 6061 Aluminum. This metal is rigid and can withstand the high temperature and pressure of autoclaving. The pieces of the design are secured together with bolts. Due to price and feasibility constraints, there are no removable pieces in this iteration of the design, although it could be adapted to cut other sizes of tissue with additional side pieces that would likely be easy to interchange.

Full schematics and diagrams of the individual parts of the design can be found in Appendix C – Design Schematics.

Testing

Material Durability

The durability and degradation of the polycarbonate was tested by placing the material in a container filled with a 10% neutral buffered formalin solution. Data was collected qualitatively by bending the material (Fig 11) over a period of 12 hours at intervals of: 15 minutes, 30 minutes, one hour, two hours and 12 hours. Although the appearance of the material remained constant, the rigidity of the material increased after two hours and further increased overnight. This could be due to suspected leaching of plasticizers over long time intervals.

Figure 11 Material Durability Testing - bending the polycarbonate to assess its rigidity

Tissue Fixation

For testing purposes, our client suggested we mimic the tissue of the prostate by using a piece of lean meat, such as chicken. To test the efficacy of the accessory clamp, two 3-mm slices were placed between the two polycarbonate plates of our accessory clamp. The accessory clamp was then placed in the 10% neutral buffered formalin solution. The clamped tissue in the formalin solution was compared to the unclamped tissue in formalin and to a control of raw chicken (Fig 12). Each of the slices was relatively the same size and weight, and was monitored over a period of 2 hours. There was no physical difference in the fixation of the tissue in the accessory clamp compared to the tissue in the formalin solution. The chicken that was unclamped did not lay flat after the fixation period, and the accessory clamp solved this problem. For the given fixation time period and the material used, the accessory clamp adequately allows diffusion of the 10% formalin solution to the entire tissue.

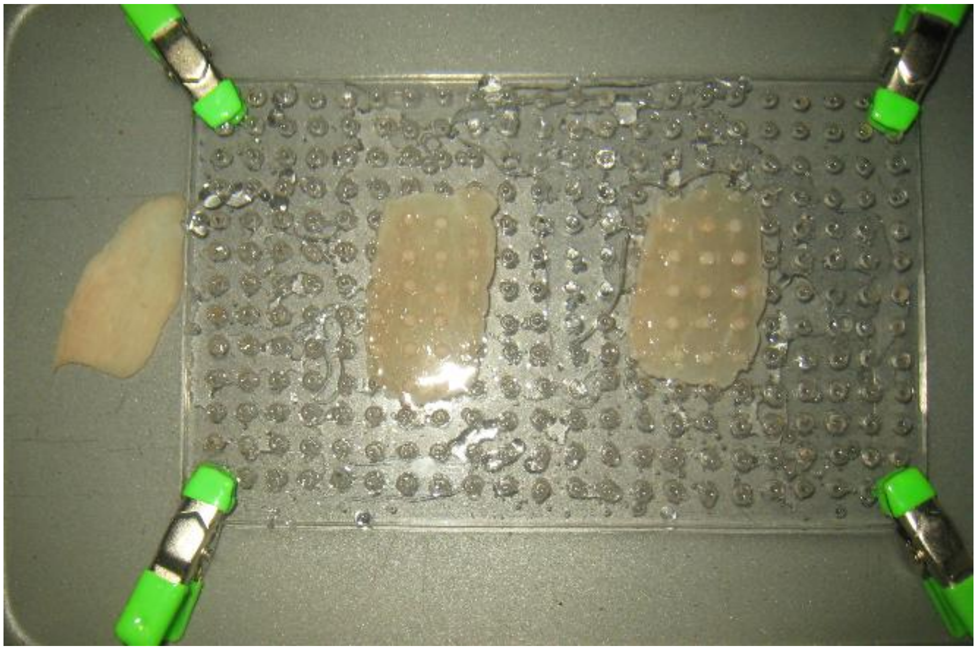

Figure 12 Tissue Fixation testing of tissue. Left - unclamped chicken in formalin. Right - Accessory clamp with clamped chicken in formalin

Slice Accuracy Testing

Slice accuracy was tested qualitatively with two different tissues – chicken and steak. The goal of this test was to determine whether the prostate cutter performs as intended by cutting accurate 3 mm slices of tissue. It was first tested with raw chicken as with the previous fixation test. Though the chicken was very soft, we were eventually able to achieve accurate slices by clamping the tissue very firmly in place. It was discovered that if the tissue was not clamped tightly enough, it had the potential to move and was sliced less accurately. Because the chicken was somewhat softer than expected (and therefore dissimilar to prostate consistency) steak was used as a substitute. It was found that this was much easier to cut than chicken, even without clamping the tissue very firmly.

The tests that were performed on the two tissues are encouraging – not only did the device achieve accurate and repeatable slices, but it did so with different tissue consistencies. This suggests our device has the ability to handle variation between prostates and an ability to easily cut other tissues. However, one drawback was observed. It was often difficult to cut completely through the tissue and completely separate adjacent slices. This led to pulling at the tissue to achieve separate slices. It was anticipated that this could be a problem in early brainstorming sessions, and we concluded that it would be easy to place a piece of gauze or cutting board underneath the tissue so that it could be cut all the way through. Aside from this small adjustment, based on preliminary testing it appears that the device works accurately as intended; however, we have yet to test the prostate cutting device on an actual prostate, the tissue it is designed to slice.

Future Work

Prostate Testing

Throughout the testing phases of our accessory clamp and final design assembly, raw chicken was used to mimic the material properties of a prostate. While this served our purposes for initial testing, it will be necessary to use our finished product with an actual excised prostate. There are multiple reasons to take this extra step and insure that our device works as intended. First, there may be unseen challenges that exist when cutting the prostate. We assume the tissue of prostate to be near that of raw chicken or steak; the tissues will likely behave somewhat differently. Adjustments may be made in how the prostate is cut or how tightly it can be clamped. Second, there are precautions that must be taken while cutting the prostate that which were not necessary during the initial testing phase. For example, the entire capsule and margin of the prostate must be intact throughout the cutting process, and it is possible that cutting or clamping methods may have to change in order to ensure the integrity of the specimen. In short, prostate testing is crucial to the success of this device and will be the last step before delivering a finished product to our client.

Physician Testing

In order to facilitate the successful use of this device in practical medical applications, it first must be tested with physicians who plan to use it on a daily or weekly basis. Since the team has been working on this project for an entire semester, we know the subtle details of how it operates successfully. When faced with this new device having no prior knowledge or experience with it, a physician may not know how to operate it initially. To facilitate this learning process, we have created a brief instructional video that demonstrates basic operation of the device. This visual tutorial should provide all the necessary information to begin slicing prostates in accurate 3 mm slices.

There is also a need to gauge physician satisfaction while using this device. Our hope is that this device greatly improves both the efficacy and efficiency of slicing prostates for pathological analysis; however, if this is not the case, then the design will need to be modified. Testing the device with a physician will not only confirm that we have designed a quality product, but will also allow us to gain insight regarding whether our prostate cutter has the potential to be mass-produced and patented.

Instructional Video

As our device is intended as a tool for pathologists, it was decided that some form of instructions should be provided to our client to facilitate the use and effectiveness of the completed prototype as it is used in its intended setting. While a manual or pamphlet may have sufficed, we determined that a visual demonstration of the correct operation of the prototype would be more effective in teaching users how to properly operate the device. Using a video camera procured by the biomedical engineering department, our team recorded an instructional video displaying the proper operation of the prostate cutting device. The video is approximately 3 minutes in length, and provides pathologists with simple, straightforward instructions on how to use the device. Using steak as a substitute for prostate tissue, the video demonstrates how to properly place and secure a sample in the device, then slice thin sections of tissue by gliding a blade through the partitioned segments.

Additionally, a simple demonstration of the accessory clamp is included, instructing viewers on how to place, secure, and clamp the dissected segments of tissue into the clamp before placing the mechanism into the fixative solution. Once our device is delivered to our client, we would like her and her team of pathologists to watch the video before attempting to use the device. Based on their response to the video and how well they are able to utilize the cutting device, we may choose to modify our instructional video or add written directions to ensure proper use of the final design.

Patenting & Marketability

Our client has made it clear to us that she intends to pursue a patent on the prostate cutter device after receiving it and gaining experience using it. She has mentioned that there is a substantial need for a device like this; however, before pursuing a patent, the topic of marketability must first be considered. An important factor in determining the marketability of a product is assessing its demand. It can be assumed that this device will be used specifically for pathology, which narrows down its user base. However, it has the potential to cut different types of tissues, as demonstrated with our initial testing using chicken and steak. Therefore, its use can be expanded to other realms of the biomedical sciences where tissue preparation is prevalent, perhaps for surgical applications.

Cost is important when considering patenting a device. The price of this prototype was $520, a large sum of money for a tool that has such a specific function. We believe this cost would be drastically reduced if the prostate cutter were mass-produced. The parts of the assembly are relatively simple. The slits require precision machining, but there are no curved edges or very difficult cutting patterns. Every feature on the device can be modeled as a 2D shape with variable thickness. These features easily translate to mass-production, a strategy that would ideally reduce the cost of the product so that the prostate cutter becomes an obtainable device in hospitals all over the United States.

Ethical Considerations

There are some ethical considerations associated with the implementation and utilization of the prostate cutting design. This first of these considerations is safety. Although our design does not have high safety risks involved, it does require precise handling of a scalpel blade. There is a slight possibility that pathologists could injure themselves while slicing tissue samples with this device. However, our design is extremely safe when compared to current slicing methods which utilize unconstrained scalpel movements close to the fingers. Another concern associated with the design is the lack of precision involved in tissue slicing. During use of the prostate cutting device, tissue samples are not entirely secured and move slightly during slicing with the scalpel blade. This movement could cause the margin or other distinguishing tissue features could be considerably altered. With a considerable or even slight alteration to the tested specimen, an inaccurate diagnosis could be made. However, because the current method of tissue slicing also presents the risk of margin and tissue damage, our device should pose no additional danger.

Conclusions

Correctly diagnosing prostate cancer is vital to the health of men who suffer from this condition. To ensure correct diagnosis, the processes of pathological analysis must be efficient and accurate. The prostate cutting device fills this unique and important need because it allows prostate slice to be cut accurately at a precise thickness of 3mm for pathological analysis. From preliminary tests with prostate tissue substitutes such as raw chicken and steak, the Prostate Cutting Device appears to serve its function of repeatedly and accurately cutting 3 mm slices of tissue. However, it remains to be seen how well the prostate cutter actually handles its intended tissue, an excised prostate. Future tests will confirm whether or not the device achieves our client's expectations. Depending on how well the Prostate Cutting Device preserves the margin and other distinguishing features of prostate tissue, changes may have to be made to ensure that this device successfully fulfills its role in assisting pathology.

Appendix A – References

1. Prostate Cancer Foundation
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6. National Cancer Institute http://www.cancer.gov/cancertopics/types/prostate

7. Zivic Institutes http://www.zivicinstruments.com/

Appendix B – Product Design Specifications

Problem Statement:

Prostate cancer affects 1 out of 6 men in the United States. In order to properly diagnose this cancer, analysis must be performed on a biopsied or excised prostate. A major problem during analysis of samples is obtaining fresh thin slices from the biopsied tissue. Our goal is to fabricate a device that secures the prostate while the physician or pathologist slices 3mm segments. We propose a device that contains a measurement grid allowing the physician or pathologist to easily dissect the prostate into the 3mm slices. We also propose an adjustable device to accommodate varying prostate sizes. Eventually, this device could be used to cut and examine tissues other than the prostate

Client requirements:

- Must be able to be sterilized.
- Must be able to cut prostate in 3 mm slices.
- Must provide a guide for cutting prostate.
- Must not damage the margin or capsule of the prostate.
- Must be manually operated, not automatic.
- Must be size adjustable.
- Must be less than $500-$1000.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: Will be used for 10-15 minutes while cutting prostate. The device will need to be sterilized between uses to prevent cross contamination. May be used multiple times a day.

b. *Safety*: Must provide a guide to cut prostate without harming physician.

c. *Accuracy and Reliability*: Must be able to adjust to differently sized prostates. Normal prostates are 5x4x4cm, but can be larger if diseased. Should accurately and repeatably be able to cut 3mm sections of the prostate.

d. *Life in Service*: Reusable, must be able to be used multiple times a day/week.

e. *Shelf Life*: There are no degradable components to our design. Theoretically the device should have an indefinite shelf life when properly stored.

f. *Operating Environment*: The device will be operated in a hospital. It needs to be sterile to avoid cross-contamination. It should be easy to clean and sterilize.

g. *Ergonomics*: Should be easy to operate by one moderately experienced pathology lab technician.

h. *Size*: There should be guides for cutting 3mm slices precisely. If the device is applied to cut other types of tissue, different sized guides will need to be engineered. The device should easily fit on a narrow lab counter top. The device may be mounted on countertop.

i. *Weight*: The device should be small and easy to lift, not exceeding 10 lbs.

j. *Materials*: The material used should not pit or rust easily. It should also be easy to sterilize. It should not be magnetic in order to avoid any unnecessary interactions with the carbon steel blade or any of the other materials in the pathology lab.

k. *Aesthetics, Appearance, and Finish*: Aesthetically pleasing. Appearance isn't really an issue, it should be free of rough edges and sleek for safety.

2. Production Characteristics

a. *Quantity*: 1 deliverable.

b. *Target Product Cost*: Up to $500-$1000.

3. Miscellaneous

a. *Standards and Specifications*: Must be approved for safety and function by the lab technicians utilizing the device.

b. *Customer/Patient related concerns*: Not applicable, device does not come in direct contact with patient.

d. *Competition*: There is currently no product made specifically for prostate cutting. There is a similar product on the market for cutting mouse brains.

Appendix C – Design Schematics (All units are in inches)

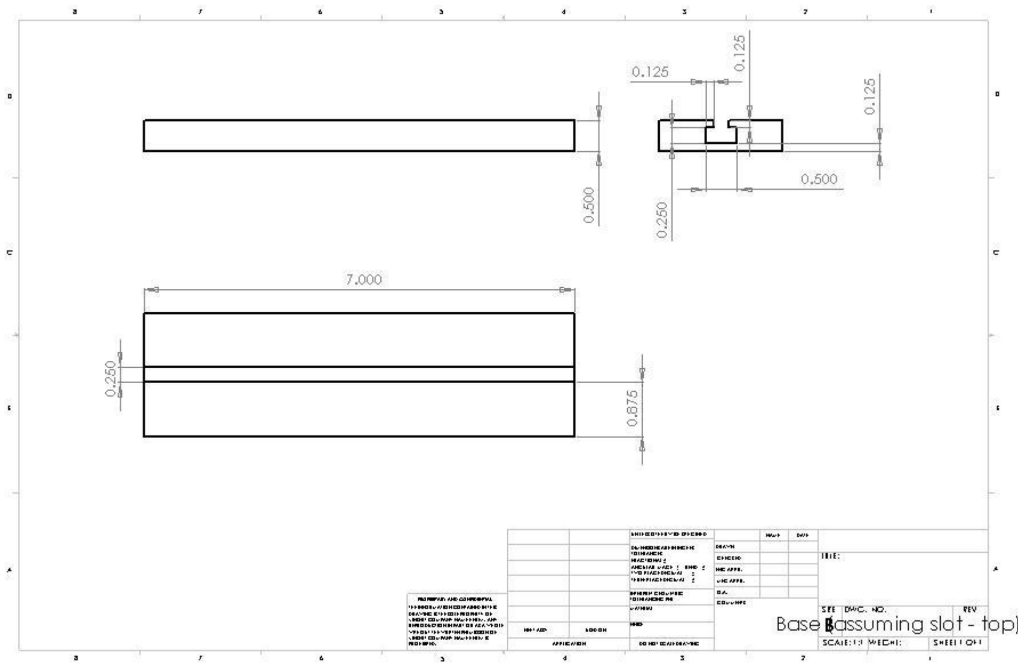

Figure 13 Base dimensions

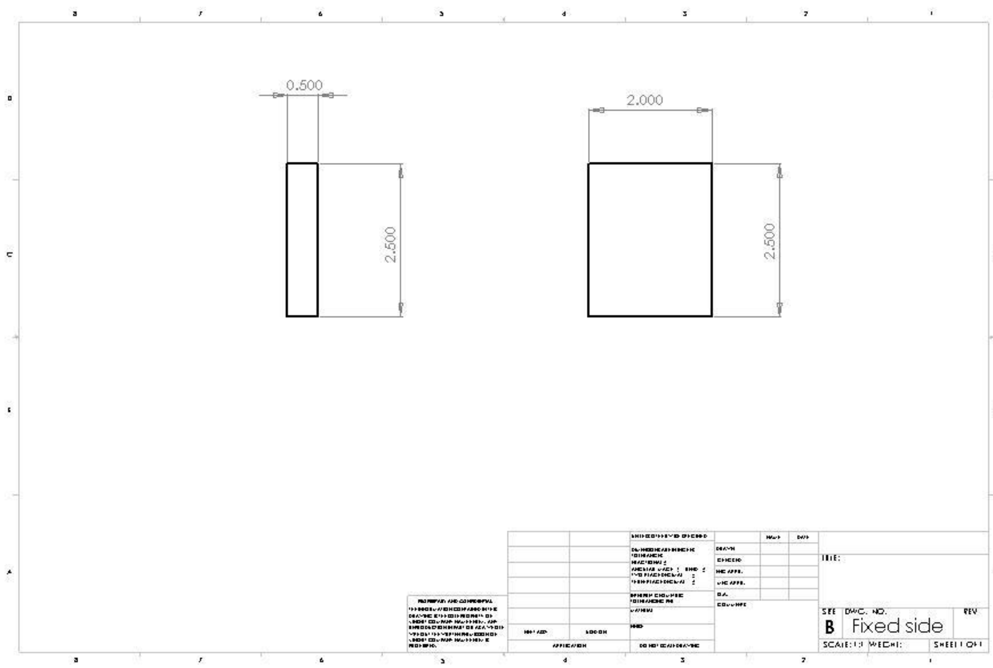

Figure 14 Fixed side dimensions

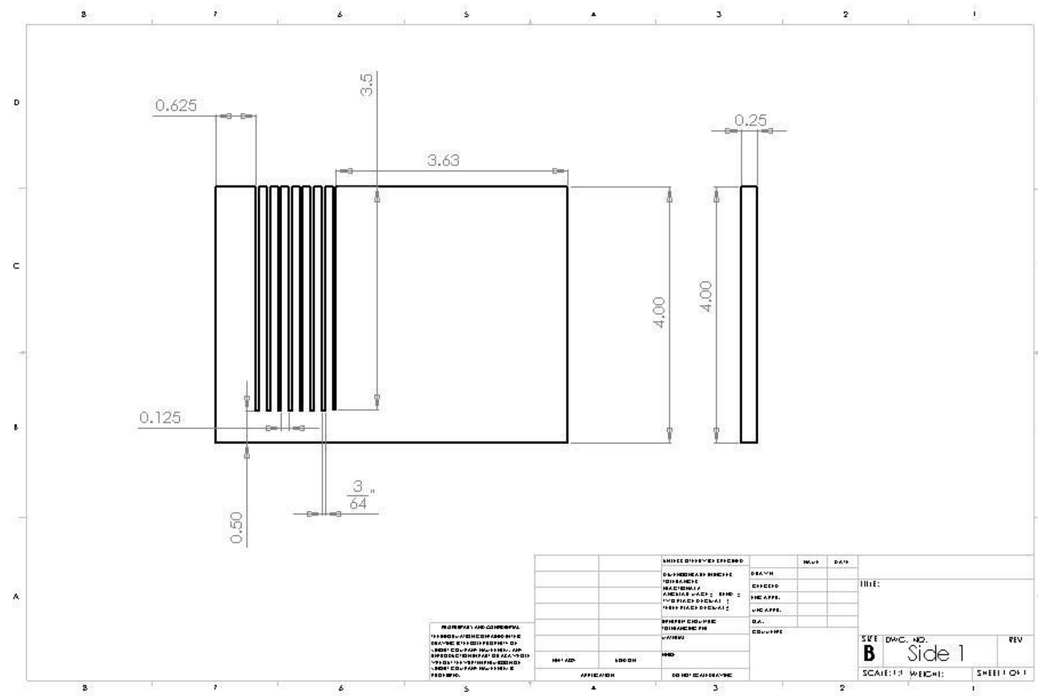

Figure 15 Slitted side 1 dimensions

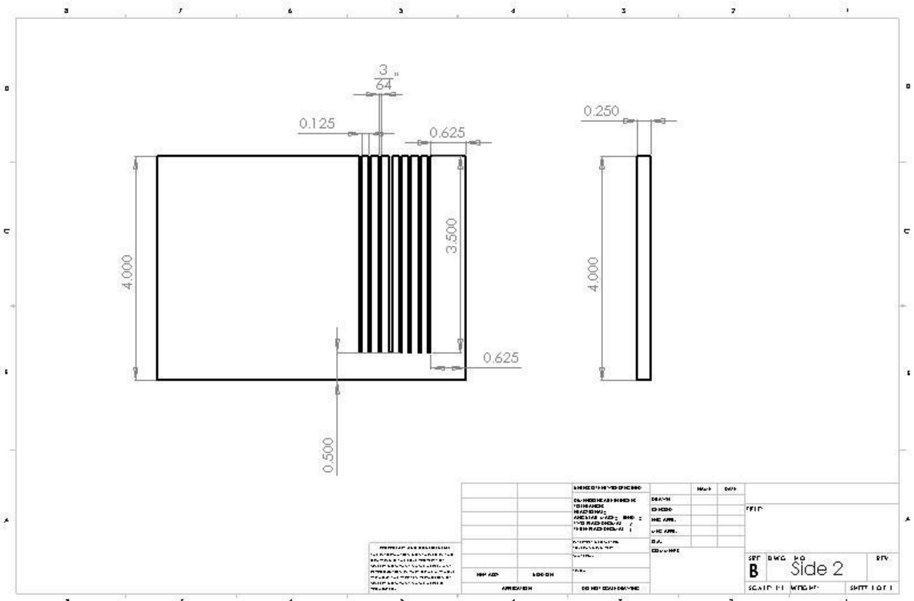

Figure 7 Slitted side 2 dimensions

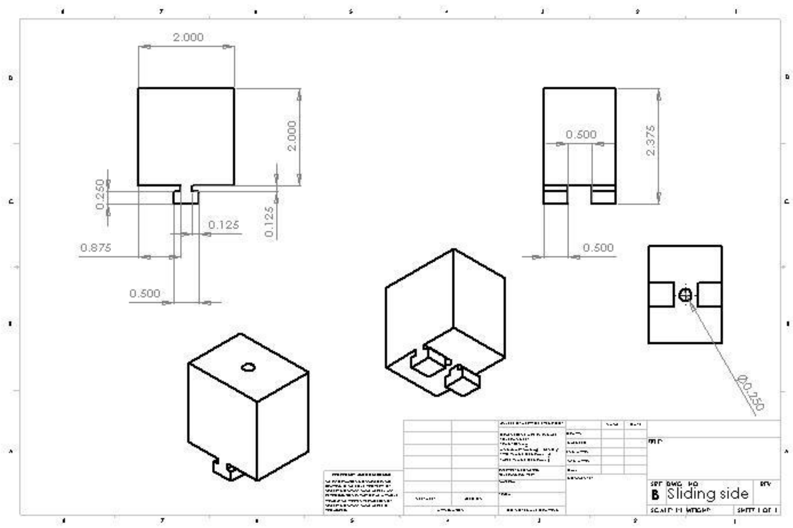

Figure 17 Sliding side dimensions