



WPI



Device Design for Treatment of Benign Prostatic Hyperplasia

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by

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Abstract

The goal of this project was to design a device compatible with real time image guidance that will excavate prostate tissue encroaching on the urethra to treat benign prostatic hyperplasia (BPH). The device was designed to be inserted via catheter into the urethra and emplaced using image guidance. Based on the principles of rotational atherectomy, the device excavates prostate tissue by rotating a cylinder with adjustable blades. The design process required prototyping a device head, conducting testing for subsequent iterations and evaluating the final design. The results indicate the device head is fully functional and can consistently cut tissue. Therefore, we can conclude that the concept for this device has been proven.

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1. Introduction

The prostate is an important reproductive organ in males. The prostate grows continuously throughout a male's life, particularly in times of high hormonal excretion such as adolescence [1]. The continual growth of the prostate can eventually lead to benign prostatic hyperplasia (BPH) [1]. Symptoms are rarely noticed in men younger than 40, however up to 50% of all men experience moderate to severe symptoms by age 60, and up to 90% of all men by age 80 [2,3]. The transitional zone of the prostate directly surrounds the urethra. Its enlargement can directly restrict the urethra causing symptoms ranging from mild to severe. The most mild and common symptoms include urinary issues such as frequent urination and difficulty emptying the bladder [4]. Further symptoms include urinary tract infections, bladder and kidney stones, and possibly bladder and kidney damage in more severe cases [4].

For most patients, symptoms of BPH are not severe enough to be treated with surgical intervention [3]. The most common surgical procedure to treat BPH is the transurethral resection of the prostate (TURP). Approximately 150,000 TURP procedures are performed in the United States each year [2]. There are several drawbacks and limitations with this procedure which can cause complications and risks. Damage to the urethral sphincter during surgery is one of the most common complications which can lead to urinary incontinence. One study found this to occur in up to 8.4% of TURP procedures [5, 6]. Other complications due to TURP include bleeding, TUR syndrome, and incomplete resection, all of which could potentially be reduced with a device and procedure that is more accurate and offers a better view of the urological anatomy of the patient [7].

The purpose of this project is to design a novel device which adopts the principles of rotational atherectomy to operate under real time image guidance. This device will be used to safely resect prostate tissue from blocking the urethra, to treat BPH.

There are several important factors that must be considered for this device. First, the device must be compatible with the appropriate form of image guidance. The movement of the device also must be based on atherectomy. The device head itself must meet several requirements. The device head must be able to excavate prostate tissue consistently using extending and retracting rotating blades which operate safely when inside the body. The device also must be small enough to be inserted via catheter into the urethra.

Image guided surgery (IGS) has surged in popularity in the past several years and has been developed for numerous surgical procedures [8]. This technique allows for real time imaging through the tissue of the patients. The primary advantage in this technique is the increased field of view, offering a greater understanding of the surgical procedure with respect to surrounding tissue during operation. Fluoroscopy is a common approach to IGS and involves continuous imaging via X-ray to create a real time view of the patient's anatomy during surgery [8].

Atherectomy is a common endovascular surgical technique used to remove atherosclerosis from blood vessels in the body. Rotational atherectomy devices remove

obstructions from blood vessels by rotating either a directional blade, or a diamond studded device head at high speed [9]. There are several similarities between the function of a rotational atherectomy device and resection of the prostate. In both cases, a hollow cylinder is being blocked by obstructions which must be surgically removed. This will be investigated to determine if the principles of atherectomy can be applied to treat BPH.

This project intends to design a proof of concept device which can demonstrate the effectiveness and feasibility of the device to treat BPH. This design project will begin with background research of the anatomy of the prostate, BPH, current methods, image guidance and principles of atherectomy. Next, the project team will analyze the needs of the project and develop objectives and requirements based on the needs with input from advisors. Then the design process will begin with brainstorming and concept generation. Eventually design sketches will be turned into fully developed CAD models using SolidWorks. Alternative designs will be created, and advanced iterations will be prototyped using rapid prototyping. A final design will then be selected and evaluated in order to validate the product. Finally, conclusions will be drawn, and the team will make recommendations on the next steps for the device.

The need for an improved treatment for BPH is clear based on the large patient population and the pitfalls of current treatments. A novel approach using the widely accepted and successful principles of atherectomy and image guidance is necessary to treat patients of BPH more safely and consistently. Documenting the iterative process, creating a computerized model of the design, prototyping the final design, and testing the product will lead to a successful and revolutionary proof of concept device.

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2. Literature Review

This literature review provides the background knowledge necessary to understand the scope of the project. This review will overview the anatomy of the prostate, information on BPH, current treatments, image guidance, the principles of atherectomy, and the applications of atherectomy to this project.

2.1 Anatomy of the Prostate

The prostate is one of the most important organs in the male reproductive system. The organ is approximately the size of a walnut and is found within the male pelvis in front of the rectum, below the bladder. The top of the prostate, commonly referred to as the neck, rests against the bladder [1]. The lower part of the prostate, covered by the anterior fibromuscular stroma, is referred to as the apex. Most of the prostate is covered by a capsule which is composed of connective tissue and muscle fibers which can contract for the purpose of pushing seminal fluid into the urethra. The primary function of the prostate is the production of semen. The prostate produces prostatic fluid which aids in protecting and sustaining sperm. During sexual arousal, prostatic fluid is pushed into the urethra from seminal ducts to mix with sperm and form semen to be ejaculated from the urethra [1].

The prostate has four primary zones, the central zone, peripheral zone, anterior fibromuscular stroma zone, and the transition zone [2]. The central zone comprises approximately 25% of the prostate and surrounds the ejaculatory ducts. It is located between the transition zone and peripheral zone. The peripheral zone comprises approximately 65% of the prostate and contains most of the prostatic glandular tissue [3]. The anterior fibromuscular stroma zone located in the lower portion of the prostate, surrounds the apex and is made up of thick muscle fibers and connective tissues [1].

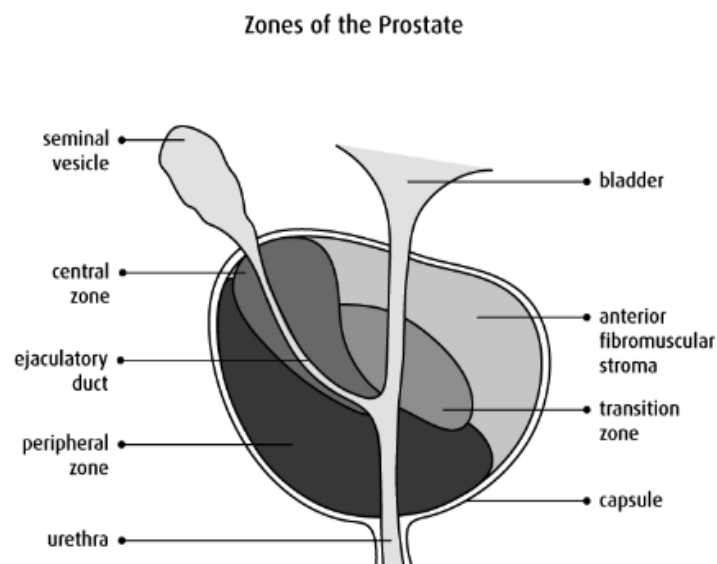


Figure 1: Prostate Structure and Zones [4]

The transition zone is the smallest zone and exists around the urethra. This area is the most prone to experience hypertrophy, enlargement due to increase in cell size, with old age. Figure 2 denotes the anatomy of a young male prior to transition zone hypertrophy (A) and that of someone who has experienced hypertrophy due to old age (B) [2, Fig. 2].

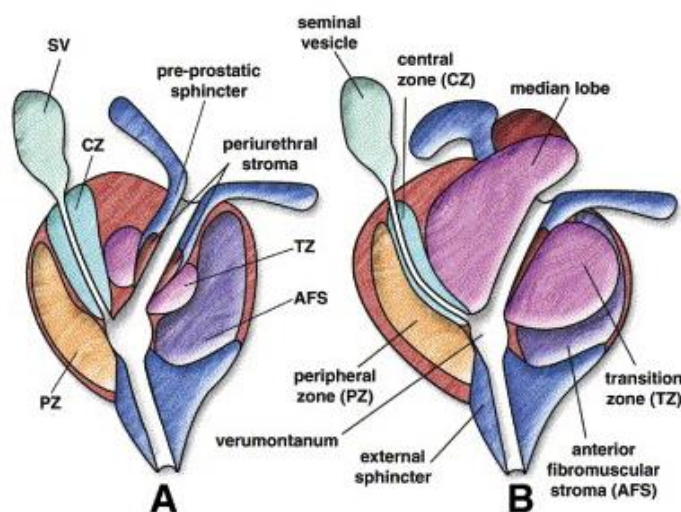


Figure 2: Transition Zone Hypertrophy Comparison [5]

The external urethral sphincter is not located within the prostate but is close in proximity. It is located directly below the prostate and made up of smooth muscle fibers. The main function of the external urethral sphincter is to control the excretion of urine from the bladder through the urethra [6].

2.2 Benign Prostatic Hyperplasia (BPH)

BPH is the enlargement of the prostate gland in males as a result of risk factors such as aging, family history, diabetes, heart disease, and lifestyle choices. While there is no scientific consensus regarding the cause of BPH, the condition has been primarily linked to aging [7].

The prostate undergoes growth during two main periods, puberty and early adulthood. During puberty, the prostate doubles in size. When men turn 25, the prostate typically continues to grow in another spurt. The second growth period takes place for the remainder of most male's lives which in turn can result in early symptoms of BPH by the age of 60 [8,9]. A major symptom of BPH is urinary problems caused by the enlarged prostate restricting the bladder. As depicted in Figure 3, this restriction of the bladder neck is caused by the enlarged transition zone of the prostate. [7, Fig. 3].

BPH

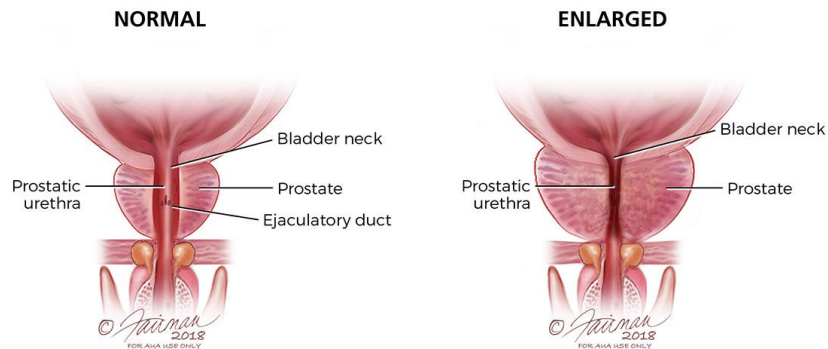


Figure 3: Enlarged Prostate Urethra Blockage [7]

BPH affects most males, especially later in life. The condition has been shown to manifest in over 50% of males over the age of 60 and 90% of those over the age of 80 [9]. The health effects of BPH can range from mild to severe. A constricted or blocked urethra can cause urinary tract infection, bladder or kidney stones, urinary retention, and a multitude of other problems. Some symptoms of BPH are urinary retention, increased frequency of urination, the inability to empty the bladder, and an inconsistent stream [7,8].

2.3 Current State of the Art Treatment for BPH

There are several current treatments for BPH. These treatments vary in terms of effectiveness, invasiveness, and recovery time. Two of the most widely used BPH treatments are transurethral microwave thermotherapy (TUMT) and transurethral resection of the prostate (TURP).

TUMT is a procedure where an intraurethral antenna is inserted into the urethra, emitting microwave radiation that destroys prostate tissue by exceeding the cytotoxic temperature threshold. Studies have shown that when the tissue is heated to a temperature over 45°C, coagulation necrosis occurs. There are two main factors to consider with TUMT, time and temperature. As the temperature increases, the time required to cause coagulation necrosis decreases. Thus, it is important when conducting this procedure to monitor the intraprostatic temperature to ensure the patient is not put at risk [10].

TURP is considered the current state of the art treatment. When conducting this surgical procedure, a urologist inserts a resectoscope through the tip of the penis and into the urethra. From there, the urologist uses telescopic image guidance to trim away prostate tissue that is interfering with urine flow through the urethra [11]. While TURP is more effective than other minimally invasive techniques (MIT), some of the downsides of the surgery include bleeding, occasional sexual dysfunction, and a reliance on anesthesia and hospitalization [10].

During TURP, the urologist telescopically guides a resectoscope while performing the procedure. Although the procedure is still effective, many complications have arisen regarding damage to the sphincter. When the resectoscope is inserted into the urethra, it is essential for it to be inserted far enough so that it does not damage the sphincter, but also that it does not go too far into the prostate and damage the bladder. Due to every prostate differing in size and composition, it can be difficult to assess how far the resectoscope must be inserted to perform the surgery properly. If a doctor does damage the sphincter with the resectoscope, it causes the patient to temporarily lose control of urinary function. In turn, the patient experiences immense discomfort and their recovery time increases [12, 13].

TUMT appeals to a wider range of patients because there are fewer risks associated when compared to TURP. TUMT is considered a minimally invasive therapy. TUMT and other minimally invasive therapies are often preferred to surgeries such as TURP because they have reduced procedural complications and offer a one-time therapy, although they are less effective. It is a tradeoff of efficacy for the purpose of reduced risk and complication during surgery [10].

2.4 Image Guidance

Image guidance is becoming increasingly prevalent in nearly every major surgical procedure. It allows the surgeon to operate using real time imaging to track the instrument in the body in relation to the anatomy and morphology of the patient. Typically, preoperative images are taken of the patient to help the surgeon gain a better understanding of the area in question and allow them to determine the best course of action prior to surgery. The combination of these features allows for increased surgical precision, which in turn minimizes the complications due to error and decreases the recovery time for the patient. There are a variety of different image guided techniques that are used in surgical procedures. Some of the most common techniques are CT, MRI, Ultrasound and fluoroscopy which are used based on the type of tissue being observed [14].

2.4.1 Fluoroscopy

Due to the nature of the urethra, prostate and surrounding soft tissues, fluoroscopy is the most viable option for the urological area of the body. Fluoroscopy is a specific type of medical imaging which uses x-ray technology. It works by rapidly taking x-ray images and stitching them together to form a continuous stream of images to give a two-dimensional real time video. In order for this method to be used successfully, a contrasting agent is introduced to the body so the area of operation can be more precisely visualized against the surrounding tissue [15]. Fluoroscopy imaging has many applications but is primarily used for cardiac catheterization, intravenous catheterization, biopsies and device guidance through the body. The main disadvantage with fluoroscopy is the extended exposure to x-ray radiation which could cause problems if numerous procedures are needed [16]. In order for fluoroscopy to be applied to prostate resection, a preoperative urethrogram must be performed in order to register the images.

A urethrogram is a procedure typically used to map out the patient's urethra to ensure it is not damaged or deformed. Using this technique allows the surgeon to gain an understanding of the patient's anatomy. This is done similarly to fluoroscopy, except a catheter is inserted into the

urethra, and a contrasting dye is injected through the tube into the bladder [17]. A urethrogram can also be used to localize the patient's external urethral sphincter.

2.5 Atherectomy

An atherectomy is a medical procedure used to treat coronary artery disease (CAD). CAD is caused by the buildup of plaque in the arteries transporting blood to and from the heart. Artery restriction can lead to heart attacks and even death and is the leading cause of death for men and women in the United States [18]. For years, the primary method of treatment was angioplasty, a balloon-like device that was inserted into the area of the artery where the blockage occurred. From here, it was inflated to expand the opening of the artery, and a stent was left in its place to hold that section of the artery open [19].

An atherectomy is performed by inserting a device intravenously, often through the common femoral artery, and snaking the device through the bloodstream until it reaches the blockage. Once the device is in the correct position, it will begin to cut or drill through the blockage to increase the blood flow capacity of the artery [20]. While each atherectomy device is inserted using the same method, there are typically three main types of device heads that can be used: transluminal, laser ablation and rotational.

The transluminal extraction device is one of the most uniquely designed. It has a long narrow shaft that has a rotating blade around the column. It is unique because this column is made from a flexible material which allows it to conform to the shape and tissue resistance that is associated with the coronary or peripheral arteries. In doing this, it allows the device to remove plaque buildup that can occur around corners or other areas that are difficult to access normally. This technology can be modified to be more compatible with the shape and tissue resistance of the urethra and is capable of being easily placed into the correct position. The one disadvantage to this design is its puncturing capabilities. While this will allow the rotating blade to be easily guided through the urethra with little damage to the surrounding tissue, it would have difficulty breaking through and drilling into the dense prostate tissue [21].

A laser ablation atherectomy device is unique because it uses heat to destroy the arterial blockage. The device produces a strong, focused, beam of light which vaporizes the arterial blockage when it comes in contact, returning normal blood flow [19]. Often, laser ablation burns unwanted tissue and causes scarring in the artery which can increase recovery time.

A rotational atherectomy device is the most common method used. It works by using a diamond-tipped rounded head, or a head with blades coming out the side which rotate at up to 150,000 rpm. When this device comes in contact with the blockage, it pulverizes the plaque to pieces which can be safely passed through the bloodstream, ultimately returning normal blood flow to the artery. The development and usage of the atherectomy method has greatly improved treatment of CAD, and the principles it uses can be translated and used in other medical applications [22].

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3. Project Strategy

Prior to starting the design process, a project strategy was developed in order to successfully meet the goals of this project.

3.1 Initial Client Statement

To develop a device to precisely resect prostate tissue using real time imaging with Ultrasound or CT guidance. The device will function using similar principles to an atherectomy device to treat benign prostatic hyperplasia (BPH). The target demographic of this project are those who suffer from BPH, males over the age of 60.

There were no technical restrictions in the initial client statement intentionally, as to not constrain an innovative solution early on. The initial areas of background research, and the preliminary client statement relied heavily on the guidance of Dr. Sarwat Hussain, the project advisor and a radiology professor at University of Massachusetts Medical School.

3.2 Design Requirements: Technical

The technical objectives for the development of this project were determined using the initial client statement and background information gathered from research. The most pertinent aspects of the project are defined in the primary objectives, and all other objectives are defined in secondary objectives.

Primary Objectives

The primary objectives for this project focus on the creation of a device to excavate excess prostate tissue in order to treat symptoms of BPH. By doing so, the device is intended to minimize complications and increase effectiveness of prostate resection.

- To create a device that functions under image guidance is most pertinent to our project, as ideal use is believed to reduce complications of the procedure and increase accuracy. Specifically, image guidance will allow a better perspective of the exact location of the device, and the prostate tissue, reducing the risk of disturbing other tissue such as the urethral sphincter. In order to accomplish this objective, the most capable and realistic imaging procedure must be selected for use. The device itself must also be able operate under image guidance effectively and be highly visible.
- To create a device based on the principles of atherectomy. This constraint was initially proposed by advisor Dr. Hussain and was initially believed to be a novel and more effective approach to prostate resection. The group will choose to design based on atherectomy principles because it is a successful surgical procedure which removes tissue at a similar scale. This can be achieved by adopting similar cutting or drilling mechanisms to the current state of the art methods like directional, rotational, and laser ablation. Another aspect of the atherectomy which can be translated to applications in the prostate is the method by which the device is snaked through the femoral artery. Once the device size is modified to be inserted into the urethra, the usage of a catheter followed by a guide wire could be implemented to mimic how it is currently performed. With some

modifications to size, compatibility to different areas of the body and a few other constraints, the principles and technology used in an atherectomy can be used to improve prostate resection procedures.

- To design a device head which safely and effectively removes prostate tissue after administration from a catheter inserted through the urethra. The scope of this project is primarily limited to the design of the device head due to time and resource constraints, mainly a lengthy development process.

Secondary Objectives

The secondary objectives focus on specific criteria that should be considered in a fully functioning device head prototype. These objectives are not as pertinent to the necessities of the project but should ideally be considered in the final design of the device.

- In order to safely be used as a surgical device, all the components of the device which will enter the body must be biocompatible to avoid any negative effects or complications due to material choice. Materials also must have mechanical properties which will function well beyond the capabilities necessary for the intended use of the device.
- To create a device which is accessible to areas where there is less medical infrastructure than the United States. This objective is somewhat inherent to the design, as several medical professionals of different specialty could be qualified to operate simple image guidance, reducing the need for a urologist to complete the surgery. Furthermore, the intent is to design a device which can be operated without the use of specialized components and diagnostic equipment.
- Excavated tissue must be disposed of safely and promptly after or during the procedure. Failure to do so would likely result in increased rates of infection. The device also must feature some way for the area to be flushed into the bladder during or after the procedure.
- The device also must be able to accommodate and function with a variety of urethra and prostate sizes. For this reason, the device should be adjustable or otherwise accommodate the anatomies of the vast majority of BPH patients.

Functions

The objectives of this project clearly outline the functions intended for the device. By accomplishing all primary and secondary objectives, the device will be considered fully functional. The primary intended use of the device is to be used in a surgical procedure to safely and effectively remove excess prostate tissue from the urethra to treat symptoms of BPH. The device will function by operating under live image guidance to precisely locate prostate tissue encroaching on the urethra. The device will function similarly to the principles of an atherectomy device as it excavates plaque from arteries but will be adapted to fit the unique needs of the prostate. The device will also allow for the disposal of excavated tissue safely to avoid risk of infection. The device will also accommodate different male anatomies by being adjustable.

Constraints

As a project, the two largest constraints are time and resources. As a majority of medical devices take years to design, develop, and gain approval, it is not likely that this device will be completely finalized by the end of the project term. Time constraints also make prototyping and ordering supplies difficult. The average time to have a device 3D printed is one week, however during peak times the wait for prints can easily reach three weeks. There are also resource constraints, as this project has limited funding, it will not be realistic to have parts professionally machined, and the team must devise the most cost-effective way to effectively complete the project. The specific device constraints will be outlined with the needs analysis in the design chapter.

3.3 Design Requirements: Standards

Due to the nature of this project, a minimally invasive surgical device, there are a specific set of standards which must be met. As this is a proof of concept device in its early conceptual stages, it is unlikely that all of these standards will be directly applicable to the device in its current form. However, it is important to form an understanding of the standards before beginning the design process.

Most of the standards for similar devices are regulated by The International Organization for Standardization (ISO) and The United States Food and Drug Administration (FDA). The predominate ISO standards we will have to follow are ISO 13485 and ISO 14971. ISO 13485 is an industry standard which defines requirements for a quality management system in the manufacturing of medical devices [1]. It lays out benchmarks that must be met for specified areas like the development, production, storage and distribution of these devices. ISO 14971 is a standard that defines applications of risk management to medical devices [2]. It also outlines requirements for *in vitro* diagnostic devices. Its primary purpose is to determine and analyze the potential risks that come with the use of the device and monitors the usefulness and effectiveness its controls. The FDA has a separate set of regulations that must be followed for the development and product of a medical device in the United States. Each organization or company must submit a Medical Device Listing (MDL) which gives a detailed description of a variety of things like manufacturers, repackagers and labelers, specification developers, and many other important entities that are requirement throughout the implementation process [3]. The FDA also has a set of standards called the Quality System Regulation (QS regulation). This outlines requirements that must be met and are used to benchmark the designing, purchasing, manufacturing, distribution, and storage of the device, as well as other facility requirements. This ensures the product comes from a clean, safe, and trustworthy environment with well documented methods [3].

3.4 Revised Client Statement

After conducting further research on BPH, image guidance, atherectomy, and state of the art methods for prostate tissue resection, our project focus and client statement have changed to be more precise. Upon speaking with Dr. Hussain (radiologist) and background research we decided to focus specifically on fluoroscopy (real time x-ray imaging), and urethrogram for

image guidance rather than Ultrasound and CT guidance. Dr. Hussain placed emphasis on combining the preoperative urethrograms images and real time x-ray screening for the purpose of increasing the safety of the procedure. It was decided that in doing so, the risk of damaging a patient’s external urethral sphincter would be greatly reduced. It would also make the treatment more accessible around the world by making it feasible for radiologists to perform. Further research into atherectomy devices brought insight into principles to adopt. For the needs of this project, rotational atherectomy, in which material is removed by a rotating device head, is believed to be the most applicable principle.

The aim of this project is to develop a device which adopts the principles of rotational atherectomy to operate under image guidance. This device will be used for prostate tissue resection in order to safely treat benign prostatic hyperplasia (BPH).

3.5 Management Approach

The final goal of this project is to develop a proof of concept device prototype which can remove prostate tissue by using rotational atherectomy principles. The overall management approach can be divided into four main categories; background research, idea generation, prototyping, and evaluation. First, the anatomy of the prostate and current procedures need to be examined and researched. After understanding the principles necessary to create a device, requirements and design constraints must be determined. These requirements will guide initial concepts and ideas which will then be assessed and prototyped. Lastly, a final design needs to be selected and its performance evaluated. The general work breakdown is outlined in Figure 4.

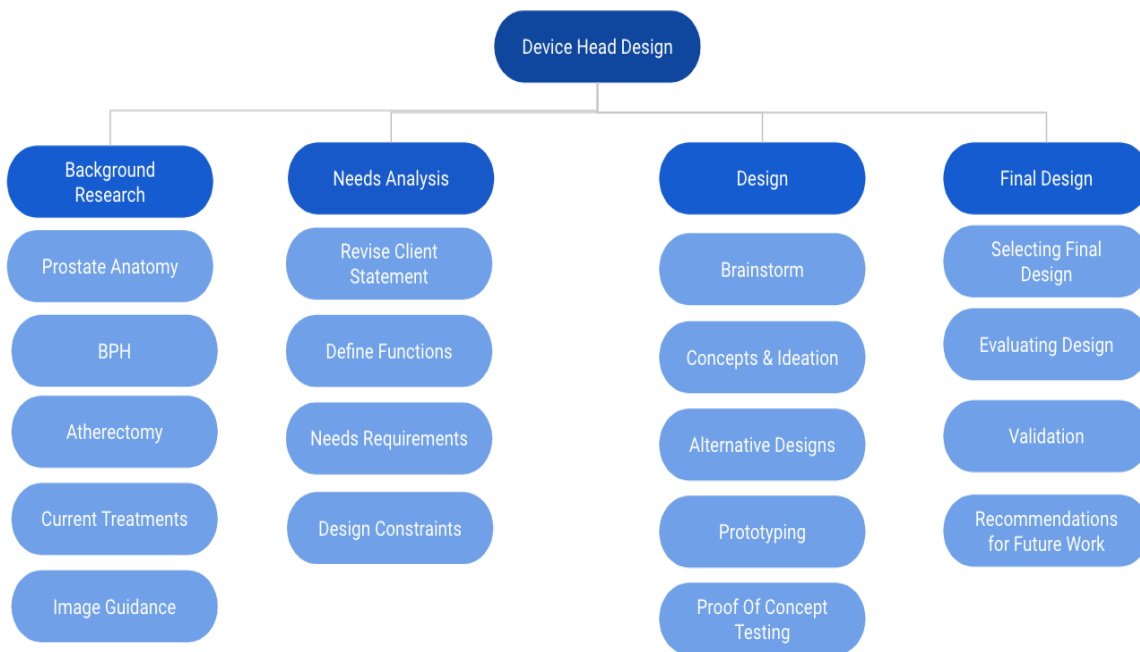


Figure 4: Work Breakdown Structure from Management Approach

Background Research

In order to understand the problem this project intends to solve, thorough background research must be conducted on areas pertinent to the success of the project. First the anatomy of the prostate and how it is affected by BPH will be investigated. The current treatments of BPH, with particular attention to the current gold standard, transurethral resection of prostate (TURP) will also be researched. The principles of atherectomy are to be researched to understand how to adapt the atherectomy device for the treatment of BPH. Finally, image guidance techniques will be researched in order to determine the appropriate method for the desired application.

Needs Analysis

Before moving forward with design and prototyping, a thorough needs analysis must be undergone in order to create criteria for the device. The functions of the device will need to first be confirmed based on background research and consultations with the sponsor. Based on desired functions, ranked needs criteria must be devised. This will serve to determine the importance of certain features and define the most necessary outcomes. Finally, precise constraints for the device must be defined in order to properly design the device.

Design

In the design stage of the project, the team will strive to create a working prototype which can meet all of the requirements and serve as the final design. This process will begin with a brainstorming phase where numerous approaches can be proposed before the design moves forward. Next, the most promising ideas will be conceptualized with basic sketches and dimensions. Alternative designs will be created, and the team must decide on the best design based on the requirements, feasibility, given resources, and time needed to develop. Designs will then be prototyped using CAD software (SolidWorks) and printed using a Form Labs 2 - 3D printer. A basic design of the device will be subjected to general testing in order to prove the concept is effective, and determine certain design aspects.

Final Design

The most promising design concept will be selected as the final design after prototyping and evaluation. This design will then be iterated to optimize and guarantee the needs of the project are met. Once the design is prototyped and fully functional, basic validation to prove functionality will be conducted. Finally, recommendations for improvements based on results will be given for future work.

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4. Design Process

Prior to beginning the design process, a needs analysis was conducted in order to identify the requirements necessary for a functional device. Once the needs were established, technical requirements and specifications were determined to guide the design iteration process. Preliminary design concepts were explored and discounted if they did not fit the needs previously outlined. In turn, these alternative designs laid the groundwork for the final device design.

4.1 Needs Analysis

Based on background research, and consultations with advisors and sponsors, the needs of the project were analyzed to create specific criteria necessary for a successful design.

General Needs

Pierces and Excavates Prostate Tissue: Taking into consideration that BPH is a condition which involves enlarged prostate and interferes with the urethra, it is crucial for this surgical device to have the ability to both pierce and excavate prostate tissue. The proposed method of accomplishing this need is by adopting the principles of rotational atherectomy- a rotating device which uses multiple blades to scrape away unwanted material.

Tissue Disposal: After excavating the tissue the device must also have a system in place to dispose of the tissue. Failure to properly dispose of and flush excavated tissue can result in infections and other medical complications.

Real Time Imaging: It is imperative for the operator of this procedure to be able to see the urological area precisely when treating BPH. The current gold standard device for this procedure uses telescopic guidance which provides a limited field of vision and leaves room for error during the procedure. Specifically, this imaging must be able to precisely locate the external urethral sphincter, bladder, urethra, and prostate. The device also must be visible in the image for successful guidance.

Biocompatibility: The entire device must not elicit an immune response from the body. Furthermore, any instrument which enters the body must be biocompatible and in line with FDA regulations.

Accessibility to Low Medical Infrastructure Areas: In discussing the deliverables of this project, it became evident that the procedure can not only be expensive, but also difficult to perform as it is currently only performed by urologists. The proposed solution is to design a device which can operate using x-ray image guidance. In turn, this would make the procedure more accessible to people around the world because with training, radiologists would also be able to perform the procedure.

Device Head Needs

Tissue Excavation: Tissue excavation is the primary objective of BPH treatment in order to prevent prostate tissue from encroaching on the urethra.

Blade Extension Mechanism: Each patient who requires BPH treatment presents a unique challenge. Every patient will have a different sized prostate and will need blades which cut to different depths. It is necessary for the blades of the device to be adjustable to multiple lengths. This extension mechanism must function inside the device head and give the doctor the ability to adjust blades as necessary.

Adjustable Extension: As previously explained, the primary surgical complication regarding BPH treatment is interference with the external urethral sphincter. To combat this, along with sphincter localization, the device must be capable of vertical adjustment in order to cater to the differing patient's prostate size.

Safety: The device must operate safely. Of primary concern, is a method to lock blades in place when inserting and removing the device.

Size: The final size of the device must be able to reasonably fit inside of a catheter to fit inside the urethra. The cutting edge of the device must not also be excessive in length, as this could result in unnecessary damage to surrounding tissue.

4.2 Technical Requirements & Specifications

After outlining the needs of the device, specific requirements and constraints for the device head were outlined and ranked with the advice of Dr. Hussain. With regards to the limited time frame of this project, requirements were ranked as either needs or wants; needs being must have primary design objectives which must be in the final product and wants being second objectives which should be in the final device if time permits.

The technical specifications of the device were based on consultations with Dr. Hussain, as well as background research to determine final dimensions. Current TURP resectoscopes range from 8.7-12.7 mm in diameter [1, 2]. It was thus imperative to constrain the diameter of the device to no larger than the current method. Including the thickness of the catheter which will be used to apply the device, 10 mm was set as the maximum diameter. For safety as well as practical concerns with the material strength, a minimum thickness of the device was set to be no less than 1 mm. This constraint will be updated once final materials are selected. Current rotational atherectomy devices can rotate over 250,000 rpm, however in this application, with mechanical parts, this speed could be dangerous. The current specification is to be tested for a standard DC motor which will rotate at minimum 2,000 RPM [3]. The length of resected prostate tissue varies patient to patient, however the length of the transition zone is approximately 25 mm [4]. For an increased safety factor, to decrease the risk of cutting surrounding tissue, the blade length has been restricted to 10mm. Finally, the device must be able to excavate the prostate tissue by scraping and cutting the tissue. The device must be able to exceed a puncture force of 20 N, the puncture force of actual prostate is likely similar to liver which is relatively lower [5]. However, the device will likely be tested on onions due to other similar properties which have a puncture resistance of around 20 N [6].

Table 1: Final Design Specifications

	Specification:	Need or Want:
Thickness	Device must be thick enough to withstand application (>1mm)	Want
Material	Biocompatible plastic or metal	Need
Mechanism of Motion	Controlled ex-vivo by external motor or manually	Want
Mechanism of Blade Motion	Controlled ex-vivo by external motor or manually	Want
Image guidance	Fluoroscopy	Need
Drill through prostate tissue	Puncture resistance above 20 N Cutting blade to scrape	Need
Insert into urethra	Diameter < 10mm	Need
Flexible	Allows device to move through small curved areas in urethra	Want
Sterilize drill and device	Single use device which is sterile to begin	Need
Device Coating	Lubricated for gentle motion in vivo	Want
Device Length	Cutting blades < 10 mm	Need
Rotation Speed	2000 rpm	Want

4.3 Conceptual Designs and Iterations

Preliminary Design Concepts

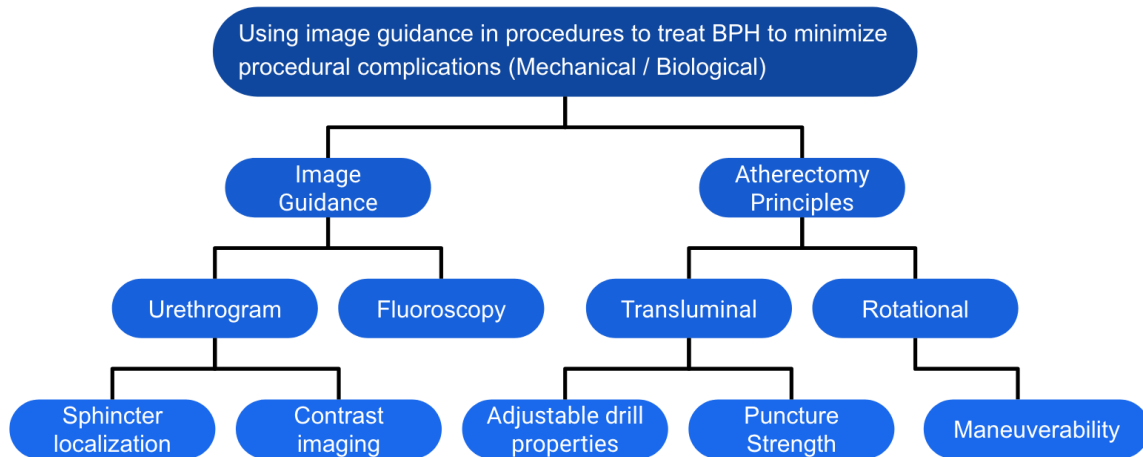


Figure 5: Preliminary Design Concept Map

The initial design process involved researching and making decisions for the basic principles of the novel device. Atherectomy principles were researched and compared in order to determine the most relevant and translatable method. It was determined that rotational atherectomy was the most applicable to the design, as it is the simplest mechanism and is the most likely to be effective when puncturing prostate tissue. The basic procedure for image guidance was also researched and determined with help using the expertise of Dr. Hussain. The urethrogram will serve as the preoperative image for the purpose of localizing the external urethral sphincter with contrast imaging. Once the preoperative image has been registered, the doctor will be able to develop the best surgical course of action prior to actually inserting the device into the urethra. The urethrogram is useful because it will ensure there is no interference with the device and the sphincter which could cause procedural complications. Next, the fluoroscopy will produce real time x-ray imaging in order to give the doctor a complete field of vision as they work to excavate the tissue that constricts the urethra.

Preliminary prototyping and brainstorming for the device head began with completing the needs analysis and technical specifications for this application. Much of the device design started with discussing these preliminary considerations with Dr. Hussain. Initial design sketches were created during brainstorming and concept generation. The primary goal of concept generation was to develop and model an enlarged prototype that could be printed on a 3D-printer. The biocompatibility of the device, and the actual size of the device would not be relevant at this point in the project. Generic straight razor blades were selected as the cutting blades due to their availability.

Initial designs and concepts focused first on understanding the geometry and angle of the blades. In the first modeled iteration, the overall shape and orientation of the blades were determined. The blades are oriented such that they protrude out of the device at a 30 degree with respect to the center.

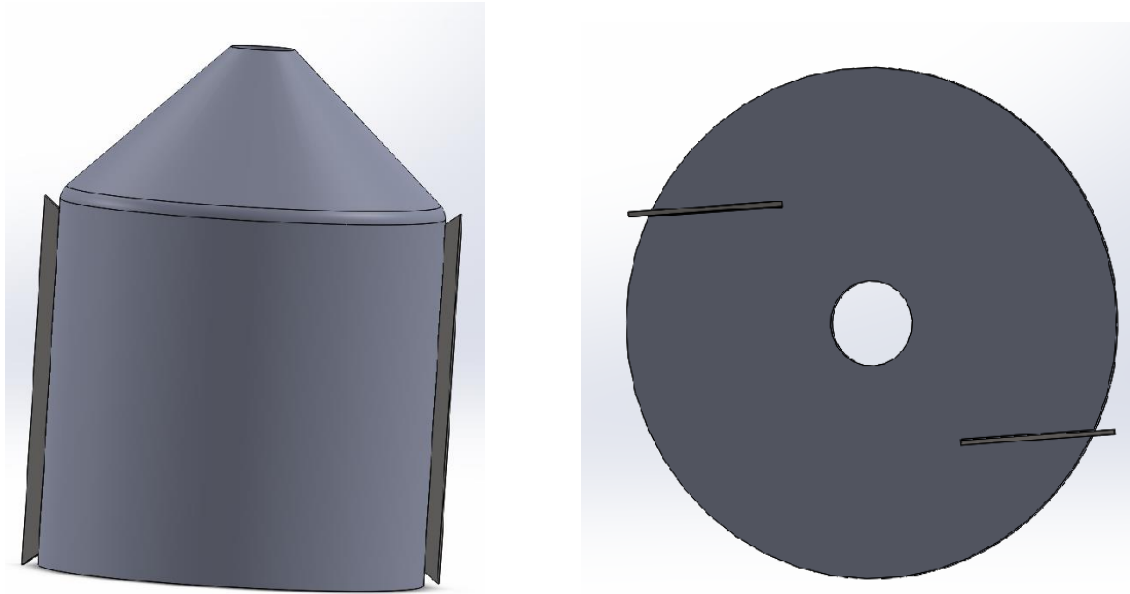


Figure 6: Preliminary Model

The first design intended to give a general shape and overall idea of the device head. It also served to test the tolerance and specifications of the printer and to determine the appropriate slots for the blades.

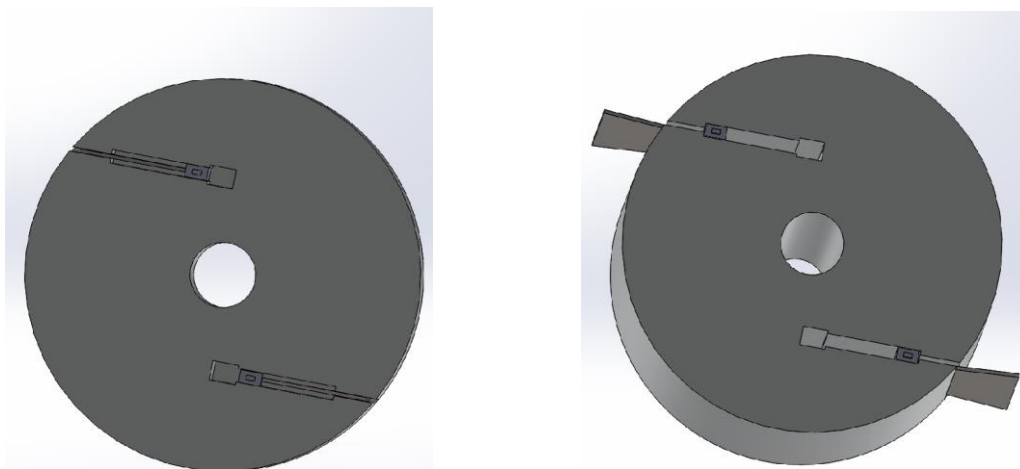


Figure 7: Secondary Model

In the second iteration, blade mounts were designed and fit into slots where the blades were joined initially. Once blades are attached to the mounts, they can be inserted into larger

opening of the slot. After the mounts are in the correct position, they can be pushed to the end of the slot near the surface.

After the second iteration, time was spent generating concepts for variable blade movement. Through brainstorming and concept design, numerous attempts and iterations were developed to satisfy the needs of the device head. From the start of the design, reliably extending and retracting the blades proved to be the most difficult aspect to design. This criterion is imperative to the design, as the blades must be retracted when inserted and removed and must be exposed while performing the procedure.

4.4 Alternative Designs

In preparation for the final design, a decision matrix was created to evaluate the nine most promising concepts and ideas for variable blade movement of the device head.

The group first agreed upon a set of criteria based on the needs of the device. It was decided to only select needs and wants relevant to the variable blade movement, and factors pertinent to a complete design. The criteria which were evaluated for each design can be found in Table 2. The weight for each criterion was debated and catered to this specific aspect of the design. From previous discussions, it was clear that the feasibility of manufacturing this mechanism is the greatest limiting factor, as there are numerous designs that work on a scaled-up model that would be impossible to make fit inside an 8-10mm shell. Next, the actual mechanism to extend the blade and blade holder was weighed the second highest. The mechanism to extend the device must be able to be controlled while the device is in motion. To satisfy this criterion, the mechanism must be controlled from outside the device head. The overall complexity of this mechanism, as well as its reliability are important factors; the design should strive to be as simplified and reliable as possible. The development time of the mechanism is also a major factor. For this design, a solution with short development time is preferred. Adjustable extension, and tissue excavation are also important factors. Furthermore, the top priority is to excavate tissue. Before full testing, it is unknown the best method for tissue excavation, however our accepted orientation from Dr. Hussain is our current gold standard and is preferred to any other orientation.

Table 2: Blade Design Criteria Evaluation

Criterion	Description	Weight
Extension Mechanism	How effective is the mechanism to move the blades in and out. How reliable is it? How complicated is it mechanically? Can it be operated while in use?	20%
Adjustable Extension	How adjustable are the blades? Are they on settings or finely adjustable?	15%
Tissue Excavation	Will this design impact the functionality of the blades (change of orientation)	15%
Tissue Disposal	Will the design impact how the tissue is flushed out? (by obstructing a catheter through the device)	10%
Manufacturing Feasibility	Is this design able to be manufactured with current resources? What tolerance is needed? Can this be made considering the final device is 8-10mm in diameter?	25%
Development Time	How long will this take to develop, model, fabricate, and test?	15%

A 0-4 fit scale was utilized: 0-No Fit, 1- Low Fit, 2- Fit, 3- Good Fit, and 4- Excellent fit. The weight of each criterion is multiplied for the fit rating and given a score. The score for each concept is added to the final score of the concept.

Overall the exercise proved useful, as the team was able to discuss strengths and limitations to each concept by using the requirements. It was clear from the discussion that several ideas were clearly infeasible and could immediately be removed from consideration. The centrifugal and magnetic ejector concepts were ranked the lowest concepts as they were not seen as feasible and their mechanism were ranked lower than the other designs. The umbrella, loaded spring, and side dial were all ranked somewhere in the middle of the concepts. Overall these designs had promising extension mechanisms and satisfied the needs of the project, but generally were either too complicated to be feasible in the final design or would take too long to develop for the scope of this project. The linear actuator and rotating gear matrix scored highly but were ultimately not chosen for the final design. The rotating gear matrix would be difficult to manufacture at scale, and if it were to work the parts would be intricate which makes them susceptible to breaking or becoming misaligned during normal use. The linear actuator concept is very strong; however we could not find a suitable model that could fit in the final design dimensions. The two highest scoring concepts also proved to be the most feasible and best overall designs based on the requirements and scope of the project. These two design concepts were both modeled and printed to be improved upon in future iterations.

Table 3: Blade Criteria Decision Model

Variable Blade Movement			Potential Solutions							
Decision Model			Motorized Gears		Mechanical Gears		Rotating Gear Matrix		Loaded Spring	
Criteria ID#	Criterion	Weight (%)	Rating	Score	Rating	Score	Rating	Score	Rating	Score
1	Extension Mechanism	20	Good Fit	60	Fit	40	Excellent Fit	80	Good Fit	60
2	Adjustable Extension	15	Excellent Fit	60	Good Fit	45	Excellent Fit	60	Low Fit	15
3	Tissue Excavation	15	Fit	30	Fit	30	Fit	30	Fit	30
4	Tissue Disposal	10	Fit	20	Fit	20	Low Fit	10	Fit	20
5	Manufacturing Feasibility	25	Good Fit	75	Fit	50	Low Fit	25	Low Fit	25
6	Development Time	15	Good Fit	45	Good Fit	45	Low Fit	15	Low Fit	15
		Total (%)		290		230		220		165

Side Dial		Magnetic Ejector		Umbrella		Linear Actuator		Centrifugal	
Rating	Score	Rating	Score	Rating	Score	Rating	Score	Rating	Score
Fit	40	Low Fit	20	Fit	40	Good Fit	60	Fit	40
Good Fit	45	Low Fit	15	Fit	30	Good Fit	45	Low Fit	15
Fit	30	Fit	30	Fit	30	Fit	30	Fit	30
Fit	20	Fit	20	Fit	20	Fit	20	Fit	20
Low Fit	25	No Fit	0	Low Fit	25	Low Fit	25	Low Fit	25
Good Fit	45	Fit	30	Low Fit	15	Good Fit	45	Low Fit	15
		205	115			160	225	145	

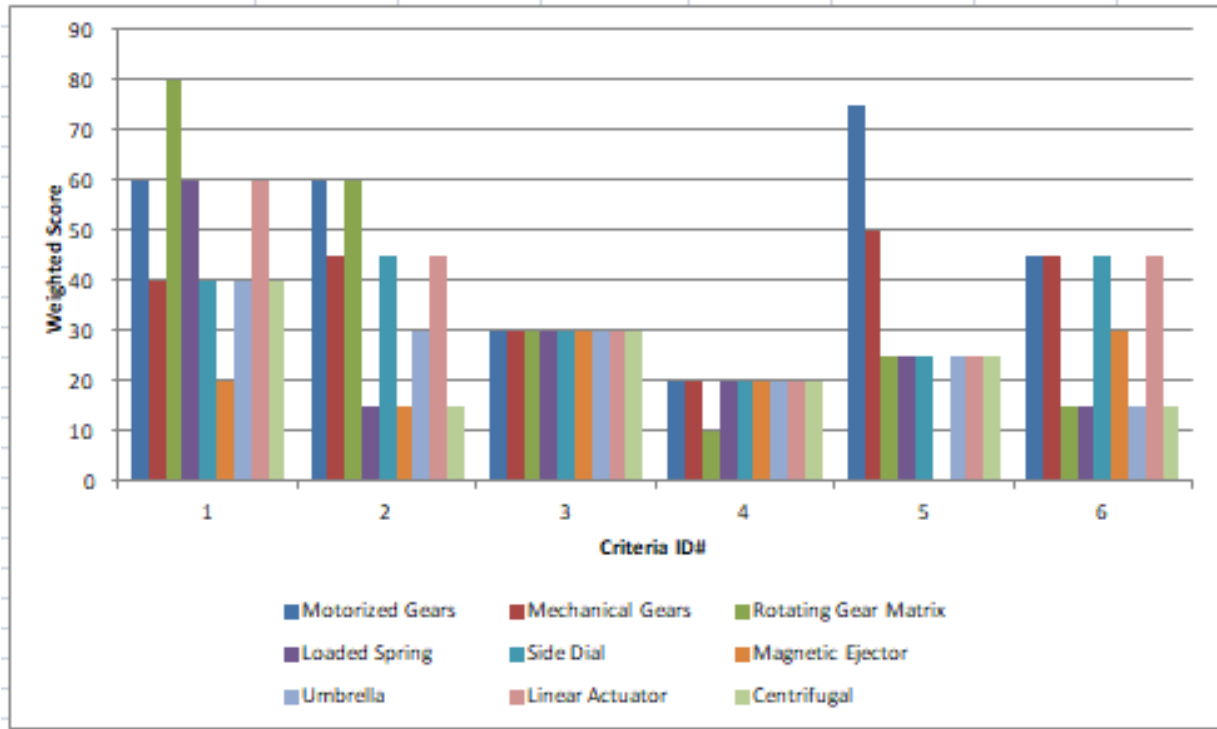


Figure 8: Blade Design Criteria Evaluation Graph

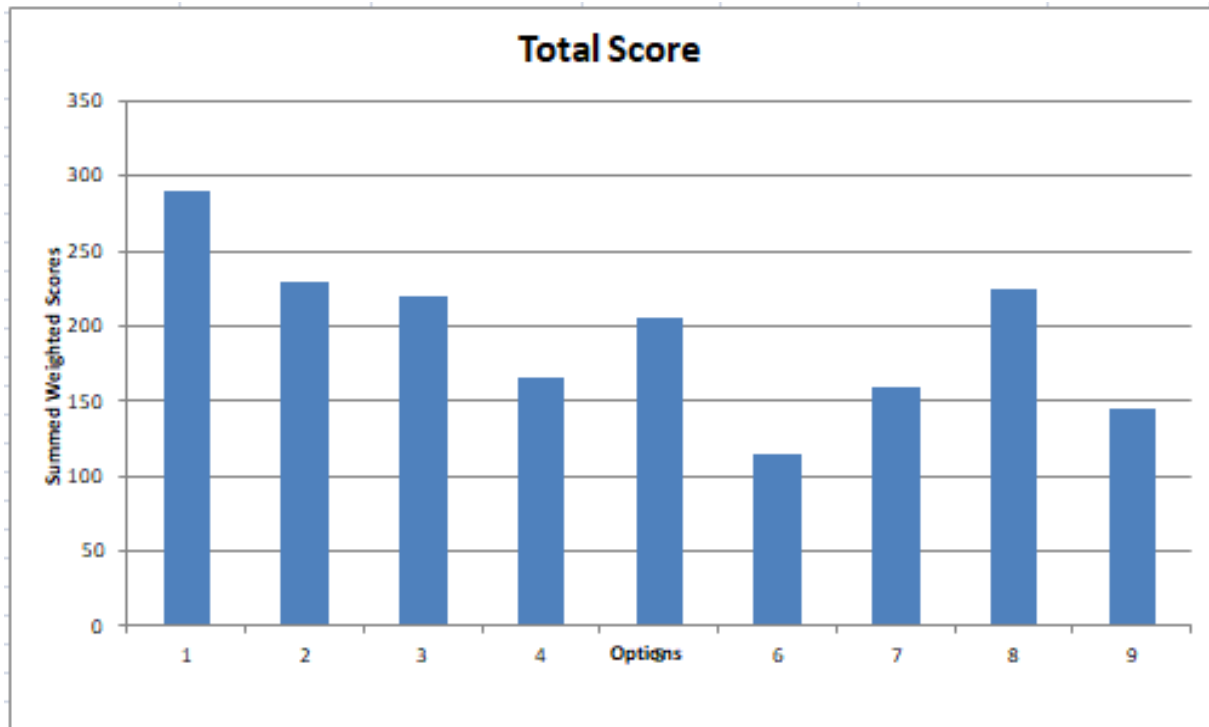


Figure 9: Blade Design Criteria Evaluation Chart

The blade extension designs were selected using the decision matrix detailed above. The two design ideas with the highest scores were the motorized gear and mechanical gear blade extenders. We chose to focus and further develop these designs, modeling them in SolidWorks with the goal to 3D print and test in the near future.

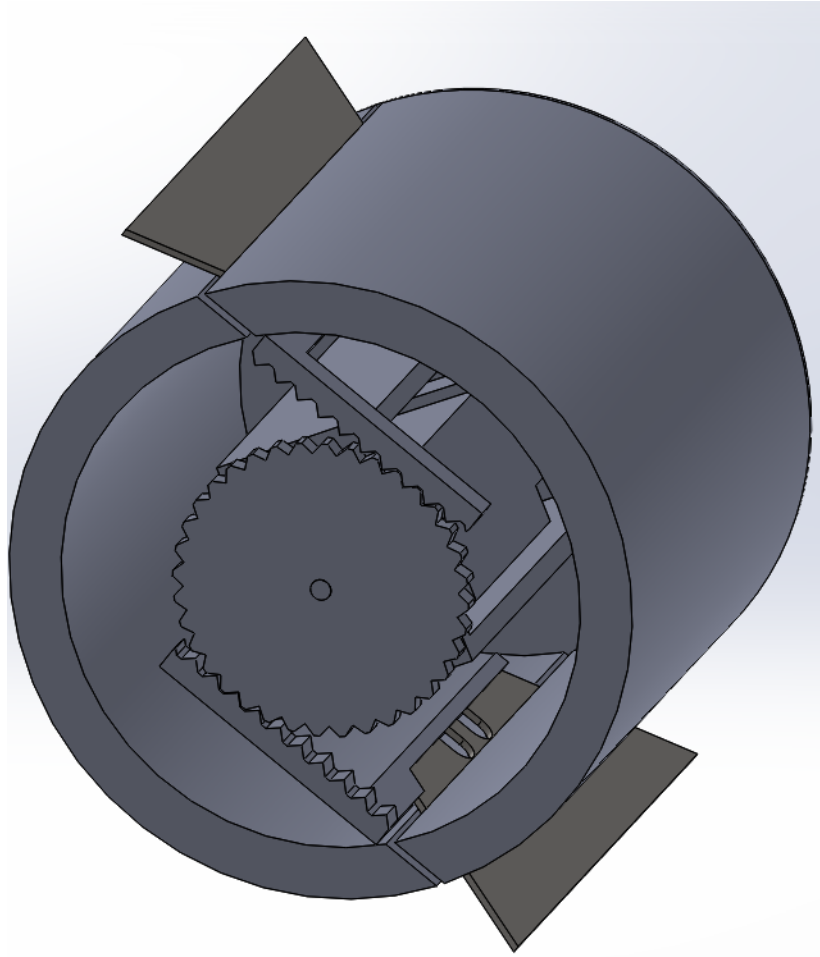


Figure 10: Motorized Gear Blade Extender

This blade extension design functions using one large central gear that is connected to a small 4 mm diameter bi-directional motor which is fastened securely to the bottom of the device head. The blades are mounted on a blade holder that contains a long arm with teeth that interlock with analogous teeth on the outer edge of the central gear. The teeth are designed to fit snugly to ensure that both blade holder arms extend the same distance. Once the motor begins to move, the central gear will spin which in turn extends the arms to the desired position. The direction of the motor can be changed as needed, so the blades will retract once cutting has finished.

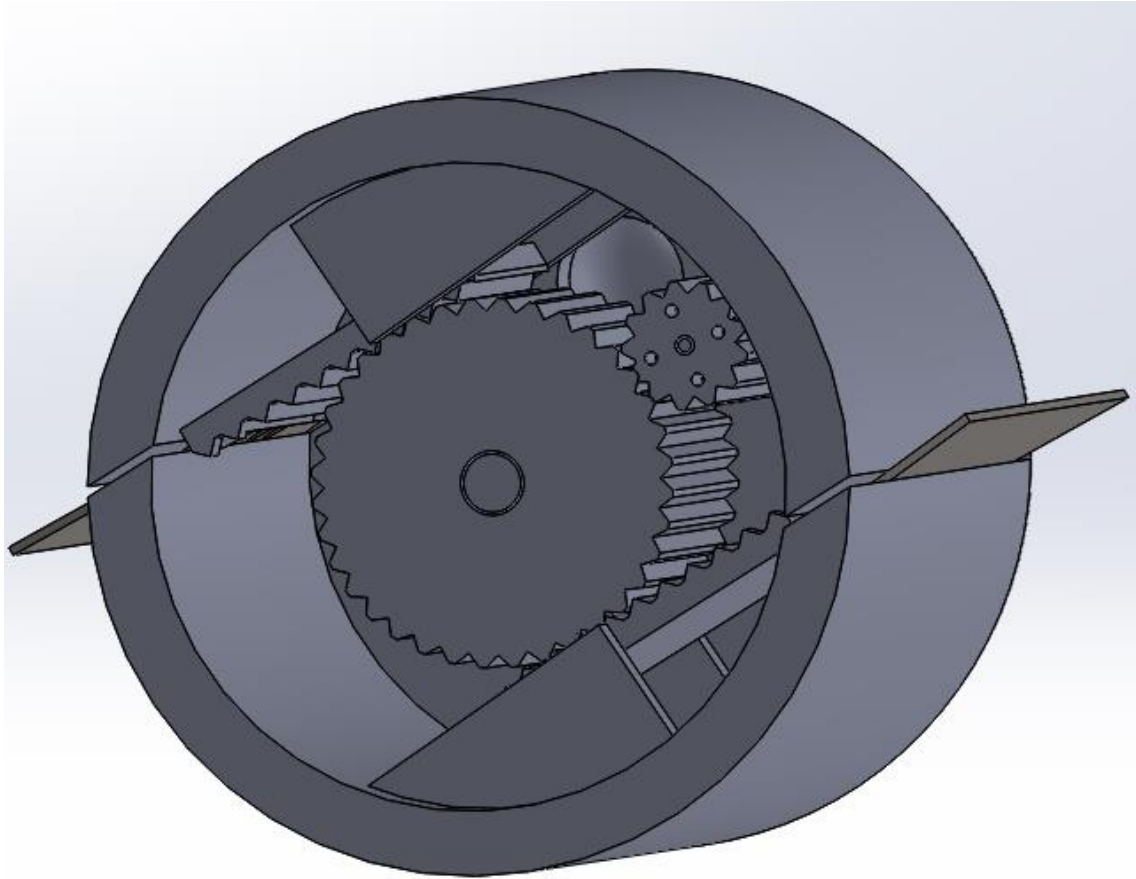


Figure 11: Mechanical Gear Blade Extender

In the next design, the device was updated based on feedback. Primarily, the motor was removed and replaced with a second gear to drive the blades in and out of the device. The blades are mounted on a blade holder that contains an arm with teeth that interlock with the outer edge of the central gear. Above the central gear, a second gear is placed interfacing with the central gear which will be manually rotated by the user from outside the body. One possible advantage of this design over the motorized version is that without a motor in the space, the gears can be much larger. This iteration of the device head also contains features to keep the gear holders in place. Due to the larger size of the blade holders, there is a greater chance that the blade holder will move causing the gears to become misaligned. On both versions, the hole at the center has been moved to allow a catheter to deliver saline through the tip of the device head.

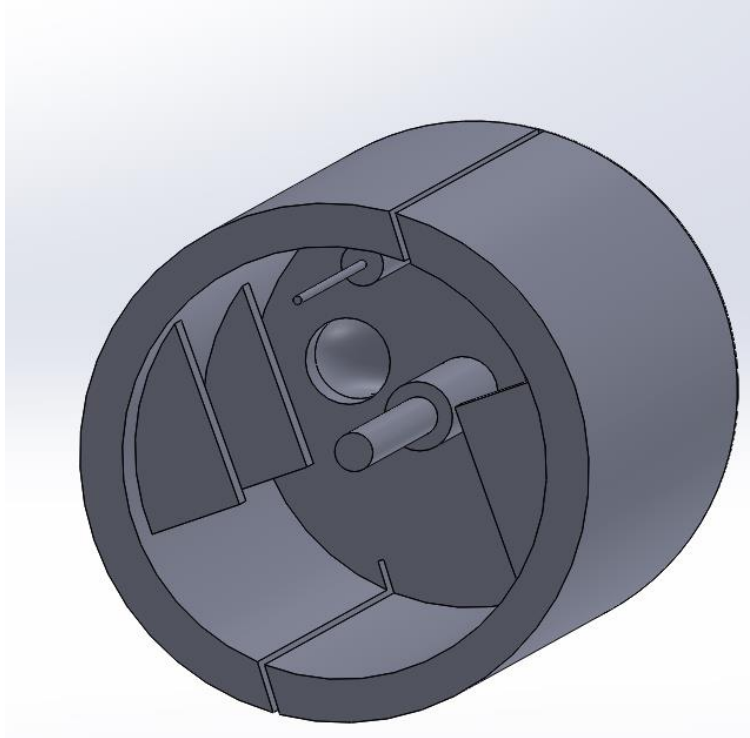


Figure 12: Manual Device Head

Both the motorized and mechanical blade extension designs feature an endcap which will be snugly placed on the bottom of the device head. This will ensure that all the inner parts remain enclosed in the device head. It also gives a point to rotate the device.

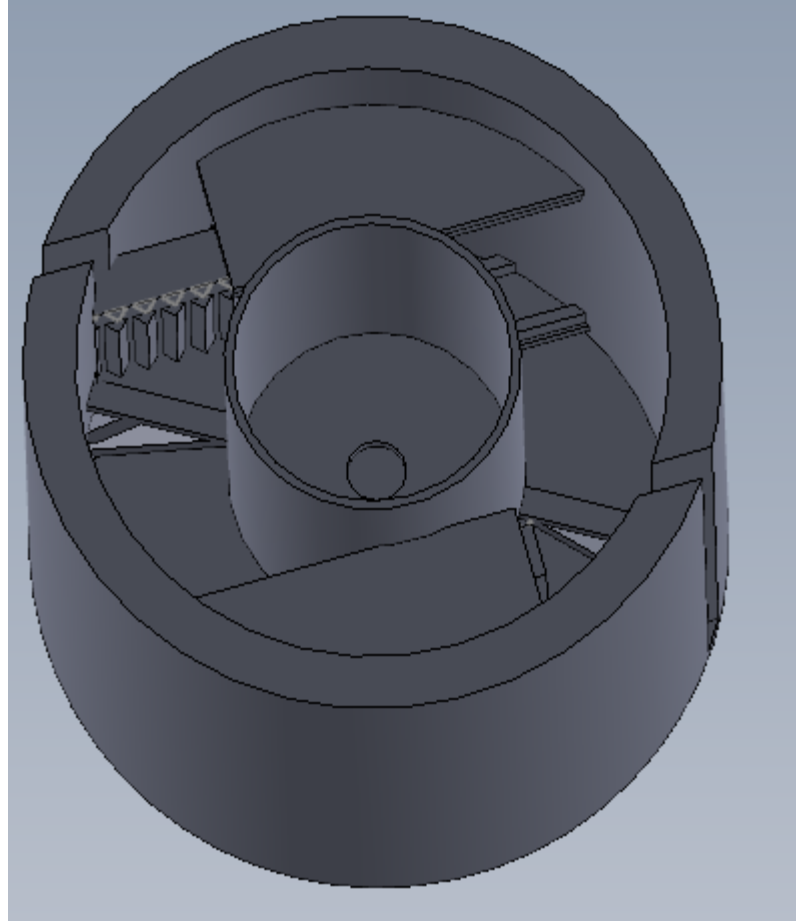


Figure 13: Improved Motorized Blade Extender

In this design the gear from the previous motorized blade extender was removed. The group determined the teeth on a gear 4 mm in diameter would be very likely to slip when rotating, and difficult to manufacture accurately. In order to solve this problem, the blade holder interfaces with a grooved track. A small motor has been specified which will be placed in the middle of the cone. The drive pin is inserted through the hole in the center, where a standard gear will be placed in between the motor and the hole. While this design eliminated the need for large gears in the device head, another problem was shortly identified. Using a motor would effectively move the blade holders in their track outward but doing this would cause us to turn a powerful motor on for a fraction of a second just to spin the center column a maximum of one quarter rotation. Typically, motors are designed to be consistently spinning for periods of time. In this design, the motor is not used effectively.

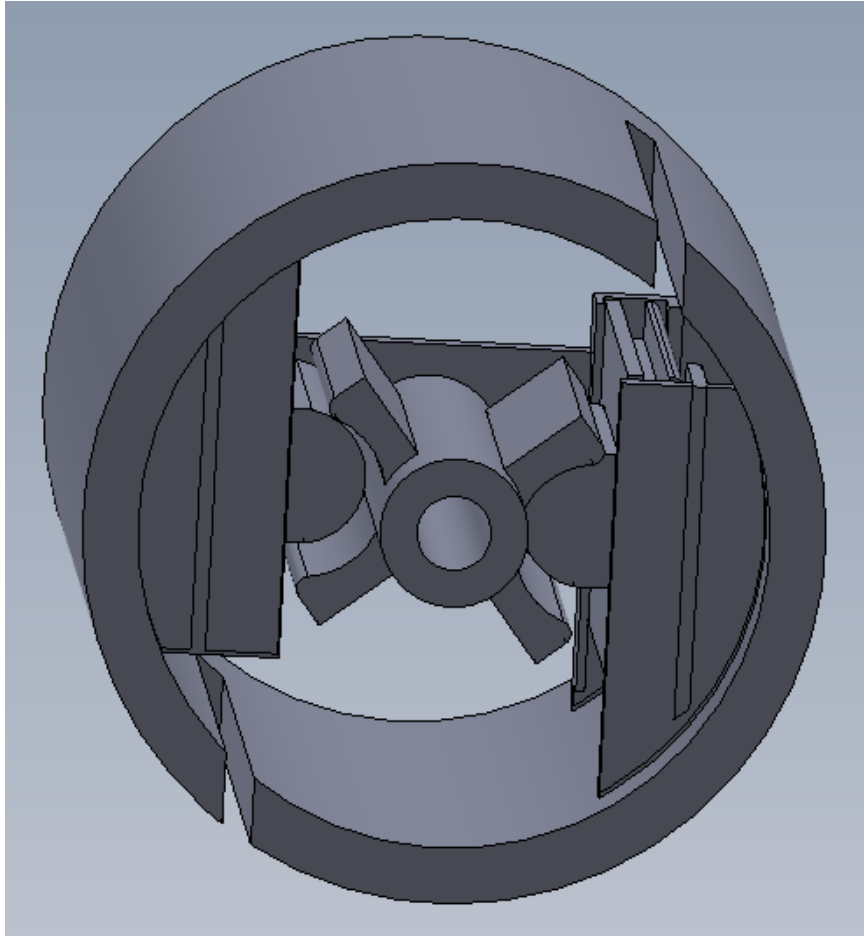


Figure 14: Improved Mechanical Blade Extender

The next major iteration aimed to solve issues with blade extension. This design completely reworked the method of blade extension by creating a custom part to replace the gear and motor. This part, referred to by the team as the swiffer, connects with semicircular notches to create a tight fit. As the swiffer part rotates its rounded extensions keep contact with the blade holders, ensuring a secure and smooth fit. The device head was also reworked in this design to give support for the swiffer part by creating a platform near the top of the device with a small pole to keep the swiffer balanced. An added advantage with this design, is an additional safety mechanism. During the design of this device, a flexible coaxial cable was selected which can be inserted into the swiffer, allowing its rotation to be locked. This design improves the overall safety of the device and provides a functional method to blade extension.

4.5 Final Design Selection

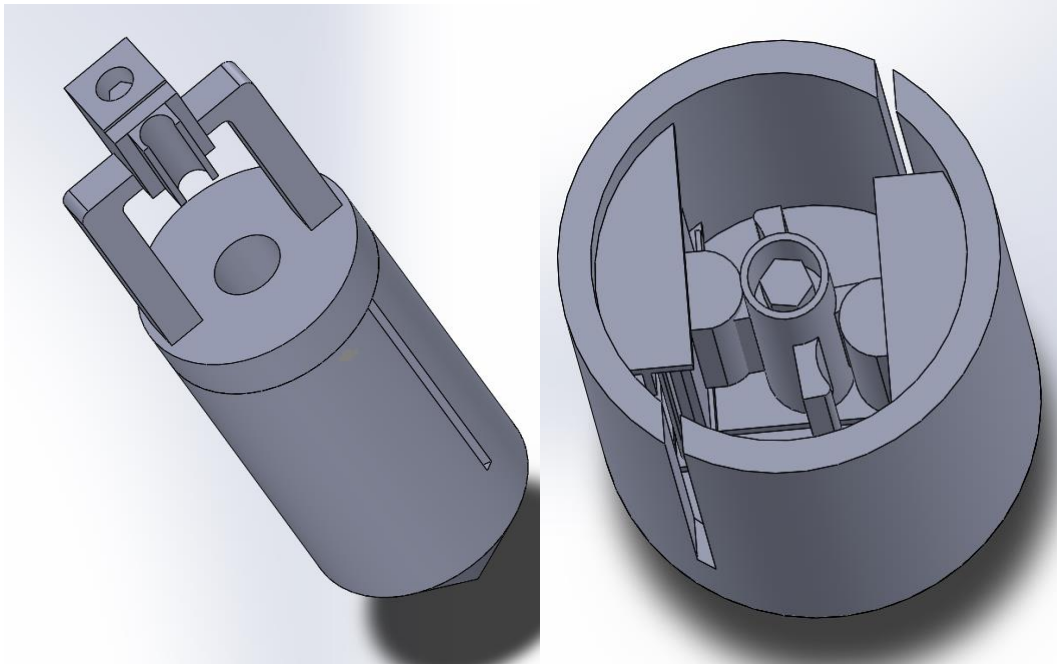


Figure 15: Final device head design

The final design improves on the previous iteration to meet the requirements of the project. In this design, the swiffer part is updated to interface with the coaxial cable. Overall, the device was refined in several small step iterations to improve the movement of the blade holders along the slots. A new part was created in order to rotate the entire device. This part is intended to interface with another coaxial cable which will be controlled externally from the patient. This new part interfaces with an updated bottom, attached by two holes which will serve as points of rotation. This part also allows passthrough for the cable from the swiffer, through the bottom and around the new part. Overall, this design combines the ideas from several iterations, and forms one fully functional device head which can effectively and safely rotate and extend blades to variable lengths.

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5. Design Verification

In order to verify the design of the device head, two tests were conducted during the design iteration process. First, a basic model of the device was tested in order to prove the concept and to determine settings for future iterations. The second test evaluated feasibility and consistency of the final design.

5.1 Initial Design Testing

After printing initial iterations and determining general device geometry and blade placement, initial tests were conducted in order to reach conclusions regarding blade settings for future iterations. Testing of the initial design played a major role when deciding the type of blade to be used for the final design as well as the cutting angle of the blades with respect to the center of the device head. There were two different blade types (Figure 16) and three blade angles (Figure 17) examined.

5.1.1 Material Selection

After consultation with Dr. Sarwat Hussain, raw onion was the suggested material for initial testing. Raw onion possesses material properties like that of prostate tissue. Extensive research into this suggestion shows the density of onion and prostate tissue to be nearly identical at 1.002 and 1.000 g/mL, respectively [1, 2]. Additionally, the elastic modulus of the onion is reportedly between 6.54 and 8.14 MPa [3]. In comparison to prostate tissue elastic modulus of 17.0 ± 9.0 kPa, an onion's stiffness is significantly higher [4]. In turn, if the device head is capable of cutting material with far greater resistance to elastic deformation, it will be able to easily cut away prostate tissue which possesses a considerably lower elastic modulus.

The second material chosen for testing was apple. Although the apple is much softer, it provides a control measure to properly evaluate results. Since testing on the apple and onion are conducted under the same conditions, conclusions can be drawn accordingly.

5.1.2 Blade Settings

Two different types of blades pictured in Figure 16 were evaluated in testing of the initial design. These blades are typically used for x-acto knives. The blades were cut to size for application to the prototype printed at 2x the scale of the actual device head size. The rounded blade covers more area but require more torque due to the increased friction. The straight blade does not cover as much area, in turn it does not require as much torque.



Figure 16: Blade Types

Three different blade angles were used in testing of the initial design. The prototypes were printed with slots at a 30°, 45°, and 55° with respect to the center of the device head as shown in Figure 17. Each prototype was evaluated on an apple and onion using both the straight and rounded blades.

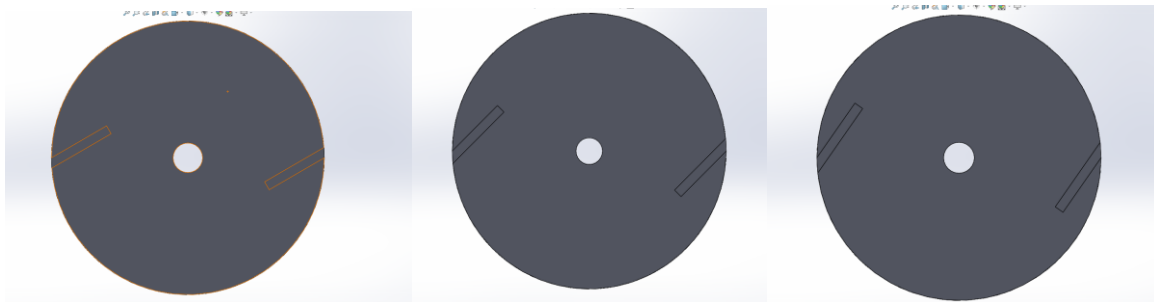


Figure 17: Blade Angles of Test Devices. From Left to Right 30°, 45°, 55°

5.1.3 Procedure

The testing procedure aimed to gain metrics regarding the device head's cut speed using varying blade settings. Ideally, it would have been the most useful to conduct initial design testing using an actual size prototype. Unfortunately, due to limited resources, inability to fasten blades to the actual size prototypes, and difficulty fixturing the device head to a drill bit, initial design testing was conducted on the 2x scaled up version of the device head as documented in Appendix A.1.

Materials used for preliminary testing were as follows:

- 1- Cordless drill
- 1- 5/64" bit
- 2- 30° prototypes
- 2- 45° prototypes
- 2- 55° prototypes
- 10- raw onions
- 10- raw apples
- 6- straight blades
- 6- rounded blades
- 1- Scale
- 1- Knife
- 1- Stopwatch
- 1- Digital Caliper
- 1- Safety Glasses

Procedure used for preliminary testing:

1. Cut small indent into apple/onion so that the conical top of the prototype is fully submerged in the apple/onion as demonstrated in Figure 18.



Figure 18: Initial Design Testing Procedure Step 1

2. Insert a pair of blades into the prototype such that they are only extended along the straight portion of the prototypes body, as demonstrated in Figure 19.

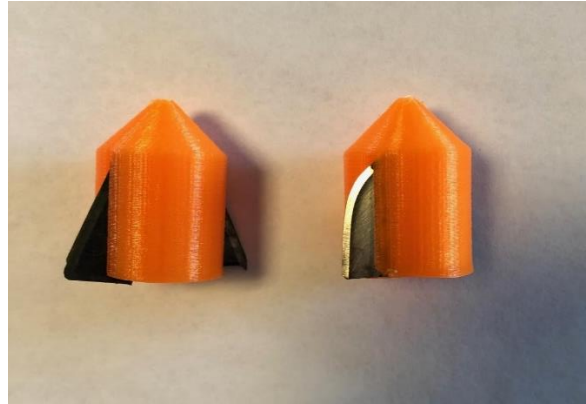


Figure 19: Initial Design Testing Procedure Step 2

3. Fixture a prototype to the drill bit. Drill approximately halfway through the center of the prototype's back.

4. Place the apple on the scale and the device head into the small cut on the apple/onion.

5. Press down on just the apple until the scale has an approximate reading of 25 lbs. as demonstrated in Figure 20 below.



Figure 20: Initial Design Testing Procedure Step 5

6. Once the scale consistently reads 25 lbs., simultaneously start the stopwatch while drilling and maintaining a constant downward force. Drill until the full body of the prototype is submerged in the apple/onion as demonstrated in Figure 21.

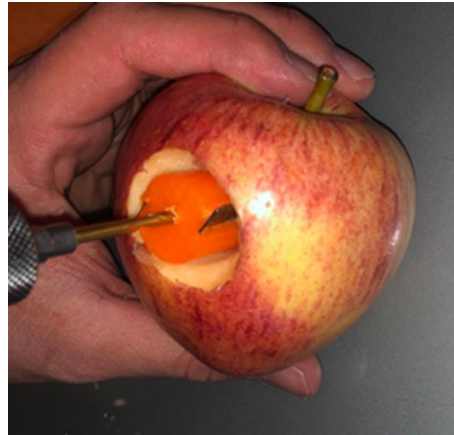


Figure 21: Initial Design Testing Procedure Step 6

- 7. Record the time it took for the device head to be fully submerged.
- 8. Repeat procedure for every combination of material, blade type and angle.

5.1.4 Results

The following results were used in order to evaluate the efficacy and settings of the initial device design:

Table 4: Cut Speed of Initial Design on Apple

Cut Speed of Device on Apple (mm/s)			
	30°	45°	55°
Straight	3.35	2.72	2.78
Rounded	3.56	2.74	2.86

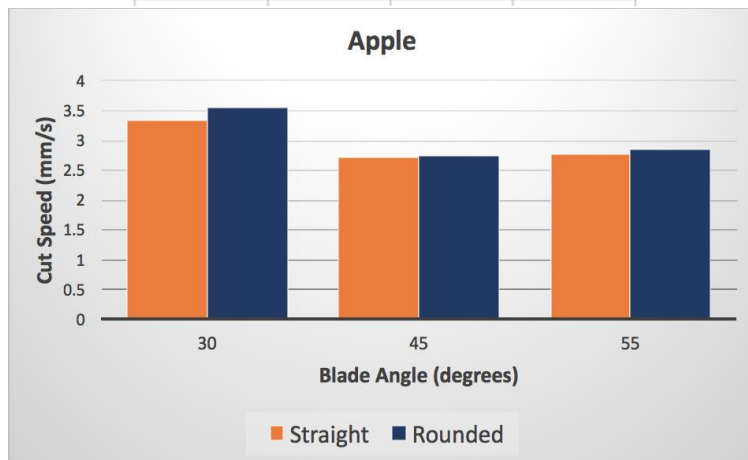


Figure 22: Cut Speed of Initial Design on Apple Bar Graph

Table 5: Cut Speed of Initial Design on Onion

Cut Speed of Device on Onion (mm/s)			
	30°	45°	55°
Straight	7.54	5.9	5.6
Rounded	8.77	4.63	4.83

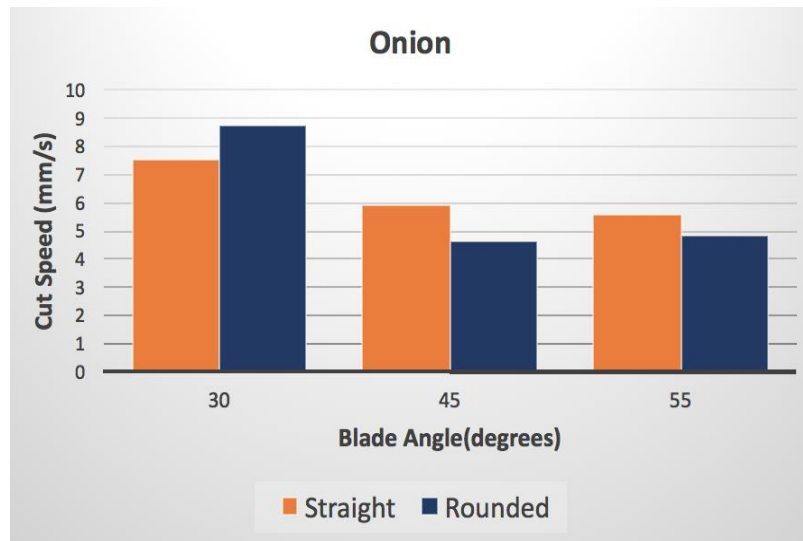


Figure 23: Cut Speed of Initial Design on Onion Bar Graph

From this data, it is important to note the 30° blade angle was the most successful in terms of cut speed. However, as can be seen from Figure 22 and 23 above, results regarding cut speed with respect to blade type are inconclusive as there is hardly any measured difference in cut speed.

5.2 Final Design Testing

After conducting testing on the initial design, a blade angle of 30° was chosen for the final design. Since the data was inconclusive regarding the blade type, straight blades were chosen due to their accessibility. These blade settings were applied to the final design for testing in order to determine efficacy and consistency of the final device head.

5.2.1 Material Selection

The chosen material for our final design was raw chicken breast. Similar to the onion and apple, raw chicken breast possesses a density of 1.15 g/mL which is close to that of prostate tissue [5]. Additionally, raw chicken breast has a much larger elastic modulus value of 2.62 MPa \pm 0.84 MPa in comparison to that of prostate tissue, 17.0 \pm 9.0 kPa [6, 2]. Again, if the final design is capable of cutting away material with far greater resistance to elastic deformation, it will be able to cut away material with a much lower stiffness value.

5.2.2 Procedure

After determining a final design, it was critical to conduct additional testing for 2 reasons. First, it was imperative to ensure the device could cut real tissue. Second, conditions were standardized in order to better understand consistency. This metric was important to evaluate because the TURP treatment experiences incomplete resection complications. By evaluating the consistency of our device design, we would be able to better understand improvements that could be made to avoid incomplete resection.

Materials used for final design testing were as follows:

- 1- Cordless drill
- 1- Hex drill bit
- 10- raw chicken breasts
- 2- straight blades
- 1- Roll of duct tape
- 1- Stopwatch
- 1- Digital Caliper
- 1- Safety Glasses
- Prototype body, head, back, back extension, blade holders, swiffer (Figure 24)

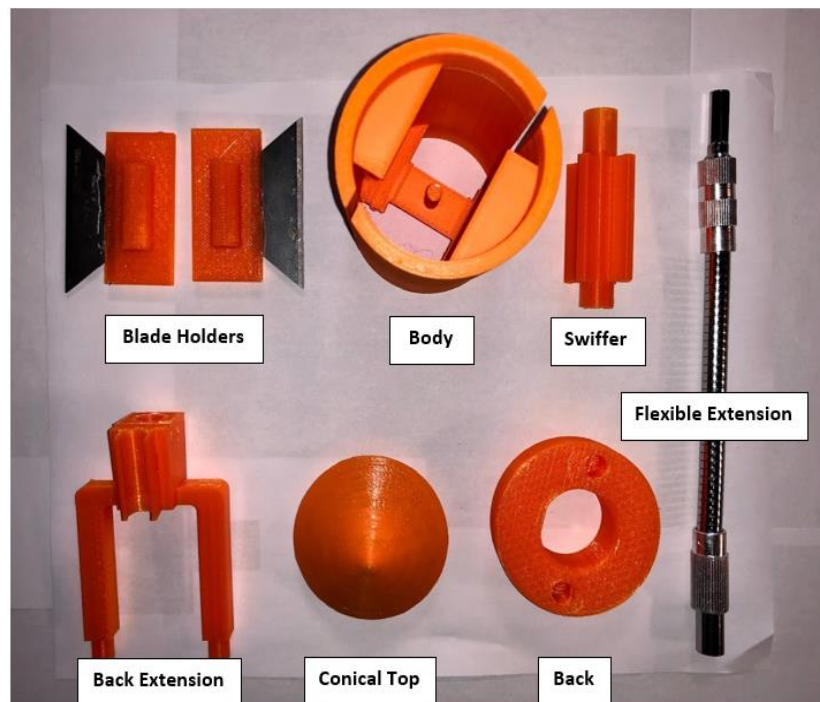


Figure 24: Deconstructed Final Device Design

Procedure used for final design testing is as follows:

1. Assemble the prototype as shown below in Fig. 25 (Do not attach flexible extension to back extension).

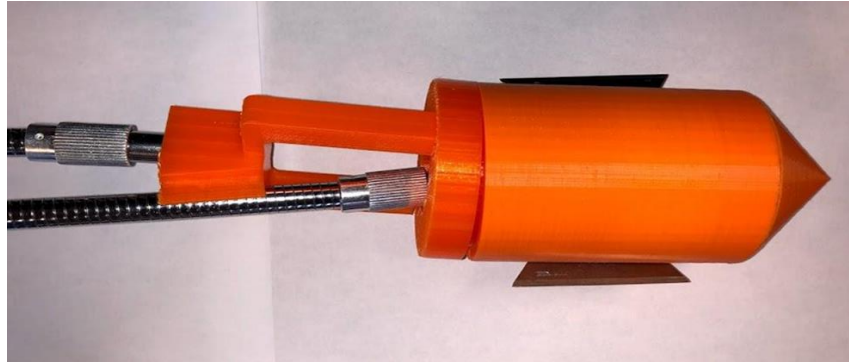


Figure 25: Fully Assembled Final Device Design

2. Secure the chicken breast to the table using duct tape.
3. Pre-measure the chicken breast in 3 different locations at the area of interest.
4. Fix the device head to the drill.
5. Start the stopwatch and begin drilling the chicken breast for the duration of 20 seconds.
6. Measure the cut depth of the chicken breast in 3 different locations at the area of interest (Figure 26).
7. Repeat procedure at least 15 times and record data.

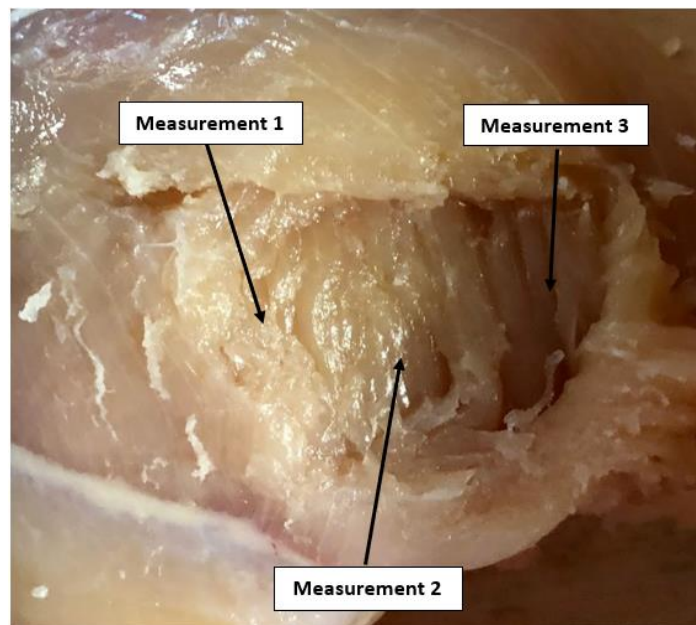


Figure 26: Post-trial Cut Depth Measurement on Raw Chicken Breast

5.2.3 Results

The following results were used in order to evaluate the feasibility and consistency of the final design:

Table 6: Cut Depth of Final Design on Raw Chicken Breast

Trial	Cut Depth (mm)	Mean	Difference	Mean	SD	2 tail values	
1	9.5	7.0625	2.4375	1.0375	0.7199537	-0.373609256	Low
2	6		1.0625			2.448609256	High
3	5.9		1.1625			95% confidence interval	
4	7.6		0.5375				
5	6.1		0.9625				
6	5.3		1.7625				
7	8.6		1.5375				
8	9.2		2.1375				
9	7.1		0.0375				
10	7.4		0.3375				
11	5.7		1.3625				
12	8.3		1.2375				
13	6.4		0.6625				
14	7.1		0.0375				
15	5.9		1.1625				
16	6.9		0.1625				

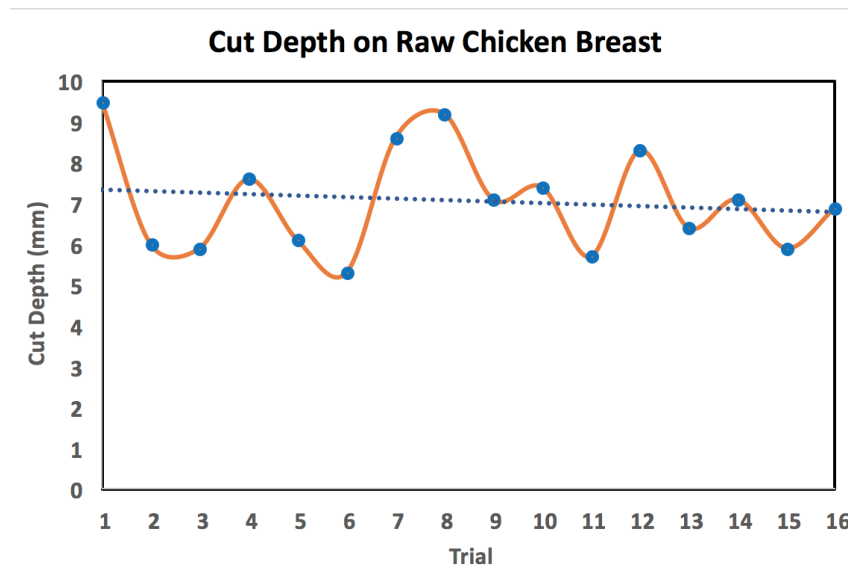


Figure 27: Cut Depth of Final Design on Raw Chicken Breast Scatter Plot

Testing the final design provided metrics regarding the consistency of the device head. After conducting a multitude of trials under a constant time duration of 20 seconds, the maximum and minimum cut depths were 9.5 and 6.7 mm, respectively. Thus, the final design averaged a cut depth of 7.06 mm with a standard deviation of 0.72 mm which is approximately a 10.2% error. The variance in this data can be attributed to the different sections of chicken breast used in testing.

In conducting a statistical analysis on the data to evaluate consistency, we developed a confidence interval based on the difference of each individual trial's cut depth with respect to the mean cut depth. Because the lower tail value of -0.374 is < 0 and the higher tail value of 2.45 is > 0 it is reasonable to assume with 95% confidence that our device's cut is consistent. However, we cannot conclusively say this data is significant due to the relatively small sample size and the variation in the sections of chicken breast used in testing. Qualitatively, the samples of chicken breast look consistent throughout each trial as depicted in Appendix B2.

5. References

- [1] Amer Eissa, Ayman. (2003). Physical and Mechanical Properties of Bulb Onions.
- [2] Torlakovic G, Grover VK. Easy method of assessing volume of prostate adenocarcinoma from estimated tumor area: using prostate tissue density to bridge gap between percentage involvement and tumor volume. *Croat Med J.* 2005;46(3):423–4288.
- [3] E. Cakir, F. Alayunt and K. Ozden , 2002. A Study on the Determination of Poisson’s Ratio and Modulus of Elasticity of Some Onion Varieties. *Asian Journal of Plant Sciences*, 1: 376-378.
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- [6] J. Poruthur, J. Tannir, A. Wu, and J. Wu, “Tensile Properties of Chicken Skin,” Oct. 1999.

6. Final Design and Validation

6.1 Economics

The results of this project, with further development, could significantly influence the medical industry. If the device were to be patented, tested, gain FDA approval, and manufactured to be sold by a medical company, it may prove to raise the stock of said company. This device will also aim to lower the cost of BPH treatment as it is expected to be more affordable than the TURP. With that being said, the success of the device in comparison to the current state of the art dictates the economic impact it may have in the future.

6.2 Environmental Impact

Given that the device would be manufactured using stainless steel, a material that is already produced and utilized in large quantities, it is safe to assume this project will have a very small, even negligible impact on the natural environment. All manufacturing processes will be streamlined and efficient as to not waste materials and burden the environment.

6.3 Societal Influence

If this device eventually proves to be more effective than the TURP, it would have an immense impact on society. If urologists and radiologists try the product and identify it as the new gold standard, word will spread, and more professionals will elect to perform the procedure in place of the TURP.

This product intends to improve the procedure to treat BPH. If this product makes it onto market, it will result in fewer complications. As this problem affects a majority of elderly men, this will hopefully have a positive impact on society as this age group will be healthier and not experience the symptoms of BPH.

6.4 Political Ramifications

Currently, treatments for BPH are only performed by urologists. Thus, treatment can be costly and inaccessible for people in remote areas of the world who do not have access to advanced medical treatment. If this device were to be manufactured to scale and compatible with real time image guidance as the project intends, the possibility of treatment would expand to more people throughout the world. In making the device compatible with x-ray imaging, radiologists would also be able to perform the surgery after training. Given that there are generally more radiologists than urologists, a higher demographic of patients would have access to treatment.

6.5 Ethical Concerns

Given the large population of people affected by BPH, a safer, more effective treatment that reduces recovery time has the potential of bettering the lives of countless ageing men suffering from the condition. The complications this treatment seeks to address will be essential in preventing not only symptoms related to BPH such as urinary retention, bladder stones and kidney damage, but also postoperative problems.

6.6 Health and Safety Issues

Since the current state of the art treatment for BPH operates under telescopic guidance, there are often surgical complications such as damage to the external urethral sphincter and incomplete resection. As this device would be compatible with real time image guidance, these procedural complications would be minimized. In turn, men would require less treatment and experience a shorter recovery time. This device would not only be more effective with advanced image guidance, but also safer for patients.

6.7 Manufacturability

A precision machine shop would most likely be the best way to manufacture this device design. The TURP method's resectoscope utilizes stainless steel which would still be a good material choice [1]. Although this project utilized 3D printers for all prototypes, this is not feasible on the much smaller scale required for the actual device head. Additionally, the time and money required to manufacture would not be ideal and the plastic (PLA) is likely not strong enough to withstand conditions of the procedures.

6. References

- [1] M. M. Issa, "Resectoscope Electrode Assembly with Simultaneous Cutting and Coagulation," 30-Nov-1999.

7. Discussion

The proposed device design outlined in this paper has proven to be successful by translating principles of image guidance and atherectomy to be used in the prostate. This device has also been successful cutting tissue like that of the prostate, with all the device head requirements getting completed in the process. The consistency of tissue cutting, and many other properties of the device were quantified and compared to the current state of the art.

7.1 Achieving Objectives

In the beginning of this project, the team set a variety of objectives that would be met by the end of the year. These include two major device objectives and specific device head objectives. After speaking with the stakeholders, the team determined the device would need to be operated under image guidance and be designed using principles of current atherectomy devices. In terms of the device head specifically, the device head would need to be able to excavate prostate tissue, be compatible with x-ray imaging techniques, contain a mechanical blade extension mechanism, contain safety features, and be less than 10 mm in diameter.

Throughout the process of collecting background information, the best image guidance method to be used with the device was frequently changed. Originally, the team thought that using CT or MRI methods would be the best for applications in the prostate, but this was later changed. Using stakeholder information from a practicing radiologist, the team chose to switch focus and use a combination of a urethrogram and fluoroscopy as the image guidance techniques in this project. This combination is the industry standard when operating on this area of the body. This combination of imaging techniques would allow the surgeon to take a preoperative image of the patient's specific anatomy and overlay it on a real time video of the device in the patient's body.

The device design of this project adopts principles of rotational atherectomy, a current widely used strategy to treat coronary artery disease. This application was used as inspiration for the design of the device in the project because it is a proven surgical method to remove tissue on a similar scale. Currently, rotational atherectomy devices use a diamond-embedded grinding head rotating at extremely high speeds to remove plaque from the artery. This concept was translated to the prostate by using a similar device head shape with blades on either side. From here, the device would spin at very high speeds and cut away prostate tissue encroaching the urethra.

Many of the device head objectives were met over the course of this project as well. It was tested that the simplified 2x scale device could successfully excavate an area of material from both an apple and an onion. These materials were used because they closely mimic the range of firmness of tissue in the prostate; showing the device should be able to cut prostate tissue. Next, the device had a mechanism that would allow the blades to be extended using a cable that would be externally rotated. The device was also integrated with a safety mechanism that would limit the extension distance of the blades and would be able to retract the blades at any point to mitigate unwanted tissue damage.

7.2 Comparison to Other Devices

The primary goal of this project was to create a device which improved the current prostate tissue resection method, the TURP. Our device improves upon this method by using real time image guidance, and more advanced tissue cutting techniques to reduce complications in surgery. Currently, the TURP uses telescopic guidance through a scope on the end of the device which only allows the surgeon to see what is directly in front of the cutting edge. Our device improves on this by combining urethrogram and fluoroscopy methods to create a real time X-ray movie where the surgeon can see the device moving in the patient's body. The TURP uses a device which has a scalpel blade on an arm that is moved around by the surgeon to scrap away encroaching tissue gradually; this often leads to sphincter damage and incomplete tissue resection. Our device improves upon this by rotating the device head with blades extended to consistently core out the entire area surrounding the urethra, rapidly removing the encroaching tissue.

7.3 Limitations

The biggest limitation for this project was the size constraint for the final device design. Since the final device would need to be inserted into the urethra, it would need to have a final diameter of 10 mm or less. This made it difficult to prototype and test out moving parts on the final scale due to the resources available to the group in this project. Due to the 3D printer and manufacturing capabilities, the group scaled the device diameter to 60 mm (6x), so the moving parts could be printed with accurate tolerances and then tested for efficacy.

Another limitation was the budget to complete this project. The group was not able to manufacture the final prototype at the desired size (10 mm) due to the cost for precision manufacturing. In order to get precise manufacturing, a high-power CNC machine would likely be needed, and the labor costs were out of the team's budget. The budget for this project also limited the materials which could be used to the prototype design and testing. Ideally the final device would be made from stainless steel and surgical scalpel blades instead of 3D printed PLA and x-acto blades due to their superior mechanical properties.

The testing of this design was another limitation of the project. It was difficult to design a test which accurately simulated drilling through part of the prostate. We were not able to use cadaver tissue in this project and were forced to find materials containing similar properties to the prostate. Ideally, the team would have been able to test the final design of the device using the final surgical materials on an actual prostate. The size of the prototypes also made it difficult to directly compare results to the final device.

8. Conclusions and Recommendations

Throughout the completion of this project the team was limited in a variety of aspects but was still able to design and test the prototype with the given resources. For this reason, the conclusions and recommendations for material selection, manufacturing processes, and future work will be outlined in this chapter.

8.1 Conclusions

In conclusion, the prostate tissue resection device was able to cut representative tissue samples consistently. A 60 mm scaled up model of the final 10 mm diameter device was 3D printed and tested under a multitude of conditions. Data from the initial and final design tests were collected and analyzed to draw meaningful conclusions regarding recommendations for the future. Using these results the team was able to improve the device head design in order to meet all design criteria.

8.2 Recommendations

Although the group spent considerable time conducting background research, designing and printing prototype iterations, and testing device designs, there is still a lot of work that needs to be done before this device could ever hit the market or be used to treat BPH. Future recommendations that are imperative to the success of this project moving forward are outlined below.

8.2.1 Material Selection

In the future the material used in the final device would change to improve the mechanical properties and efficacy of the device. Currently the device uses 3D printed polylactic acid (PLA) parts because of the ability to make rapid design iterations for a low cost. However, the final material used would likely be stainless steel which is a biocompatible metal that is known for its strong mechanical properties. This would allow the group to get better efficacy testing data as well as testing the compatibility of the device under x-ray guidance with the new material.

8.2.2 Manufacture to Scale

In the future, the 60 mm diameter device would need to be converted to its final intended size of 10 mm. This would require a high precision CNC machine to cut the surgical grade metal into moving parts at the correct scale. From here, the precise assembly of the separately created parts would be needed to ensure the entire device works as designed. This could be completed using similar high accuracy tools to that of a custom watchmaker.

8.2.3 Feasibility Tests at Scale

All of the feasibility tests conducted in this report would need to be repeated using the final size and material of the device to determine how the results would change. This would entail retesting the cut speed of the device on apples and onions, as well as consistency testing on real tissue substitutes like raw chicken breast or even cadaver tissue.

8.2.4 Intellectual Property

The group may pursue legal action to protect the device idea to ensure it is not replicated by the competition or copied in any way. There would need to be future testing required to prove that this device can function in a range of different scenarios necessary to truly patent it as a working medical device.

8.2.5 Clinical Trials

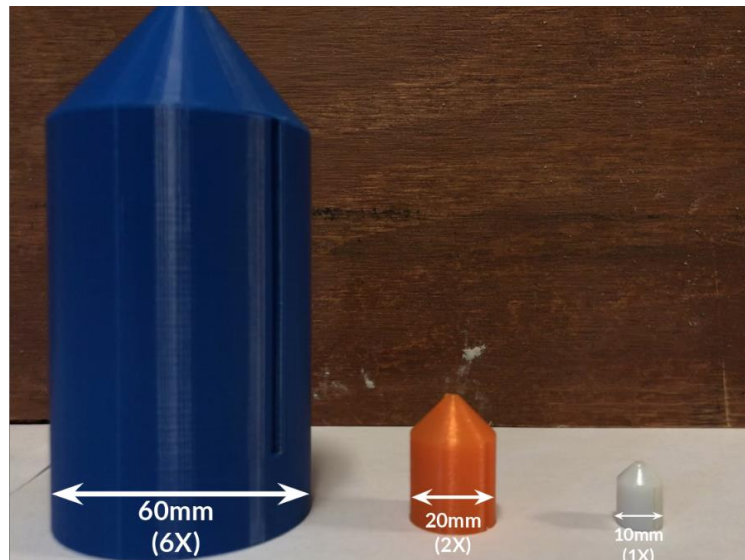
As with all medical devices, this device would need to undergo a series of clinical trials before it can be used on humans. These tests would likely be conducted on materials which resemble those of the involved tissues in surgery. Eventually, clinical trials would be run on smaller animals like rats or rabbits, until the technology could be trusted in larger animals like pigs and sheep. From here it would be tested in a subset of the human population before released as a trusted method of treatment for benign prostatic hyperplasia.

Appendix A: Supplemental Design Information

This section details additional information from the design process, including minor iterations and information not included in the body of the report.

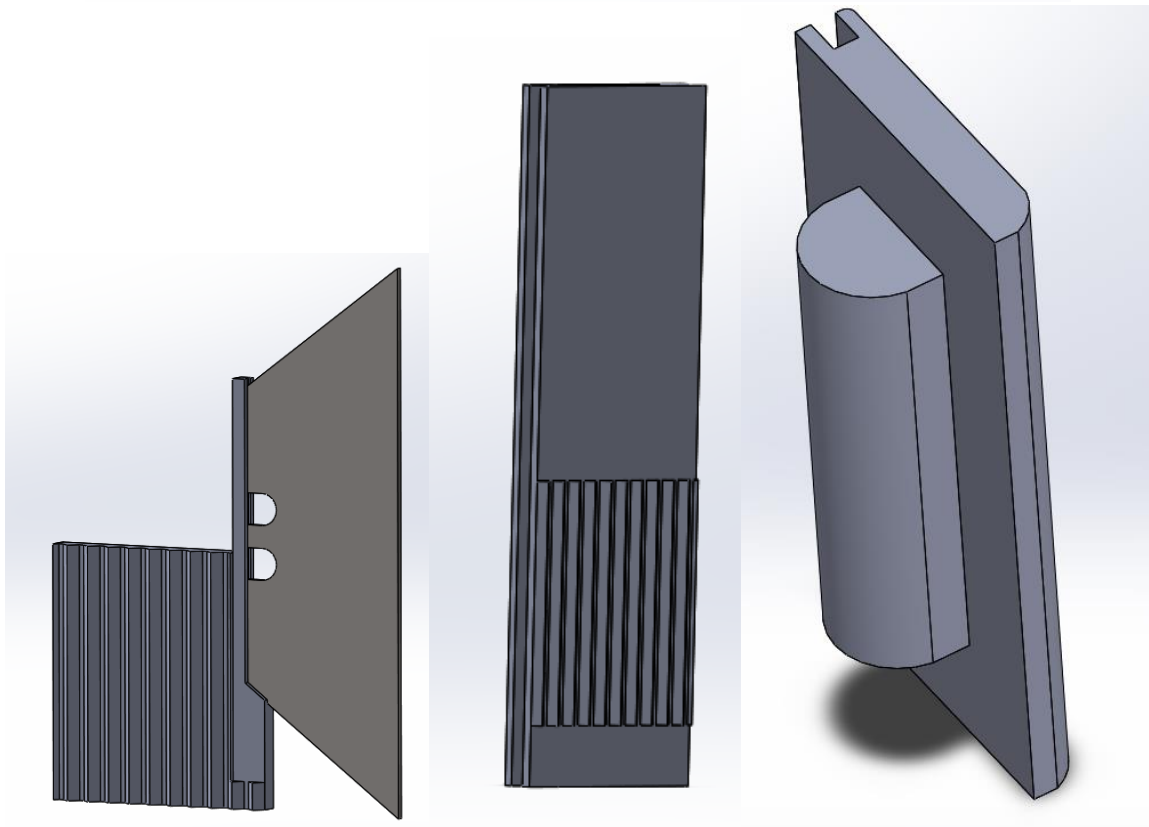
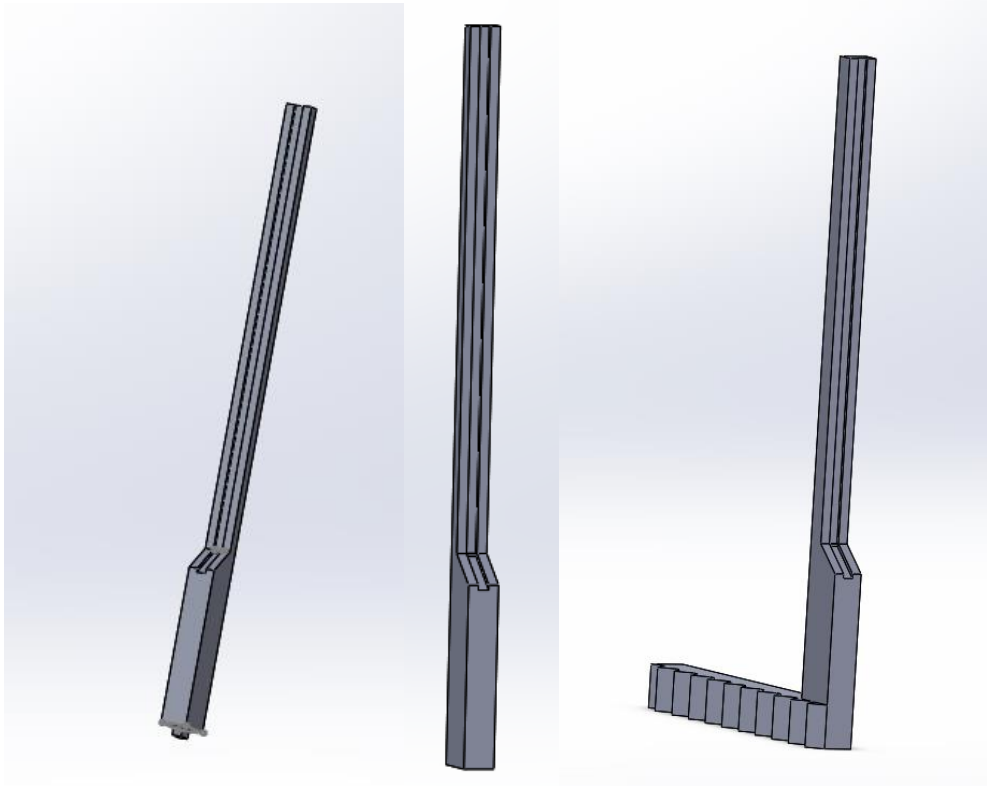
A.1 Scale of Device

The project team used three different sized devices during the design phase due to the high tolerance of 3D printers available and the high precision of the moving parts being designed. The final size of the device has been selected to be 10mm in diameter, however it was not feasible to 3D print moving parts at this scale. For purposes of initial testing, the 2X (20mm) device was used as this was the smallest device with the resolution to properly secure blades into slots. The 6X scale was used for all iterations with moving parts. To ensure correct tolerances in future work, all designs were first created at the 10mm scale, and then enlarged using the scale tool in SolidWorks.



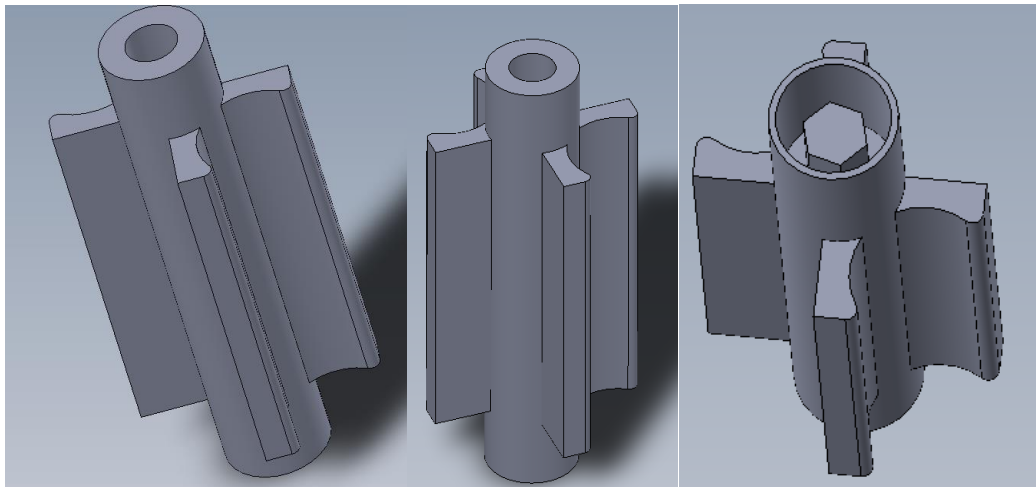
A.2 Blade Holder Revisions

The blade holder is adhered to the blades to be used in the device and interfaces with the extension mechanism to extend and retract the blades. In total, there were six major revisions to the blade holders, outlined from top left to right bottom below. The first revision reflects the second device revision in which there was no method to extend the blades. By the third revision, the blade holder was made into a rack for the central gear to extend and retract the gears. This idea was then iterated to be larger to make a better fit with the gears in the later revisions. By the final iterations of the full design, the gears from the blade holder were removed in favor of a extruded semicircular nub. This nub then interfaced with the swiffer part to form a tight connection, moving the blades in and out by turning the swiffer.



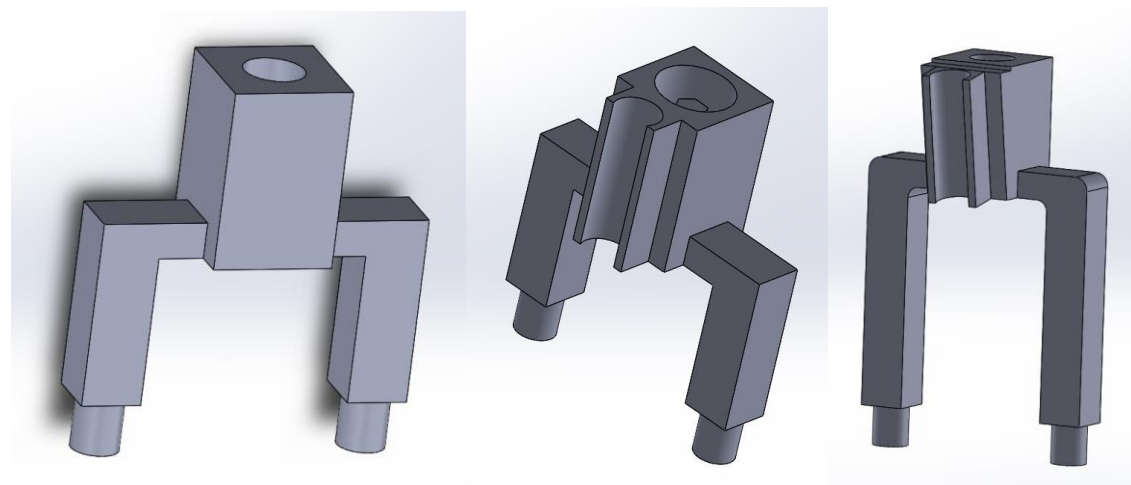
A.4 Swiffer Revisions

The swiffer connects to the base of the device head body, and interfaces with the blade holders. There were three primary design iterations for this part. In the first iteration a basic outline of the blade holder nubs was created. This was then improved in the second iteration to make the fit much closer to the blade holders. The height of the part was also reduced to make it easier to assemble. In the final design, a hex cutout was created to interface with the coaxial cable selected for the final design, the overall height again was also reduced to ease assembly.



A.5 Device Rotator Revisions

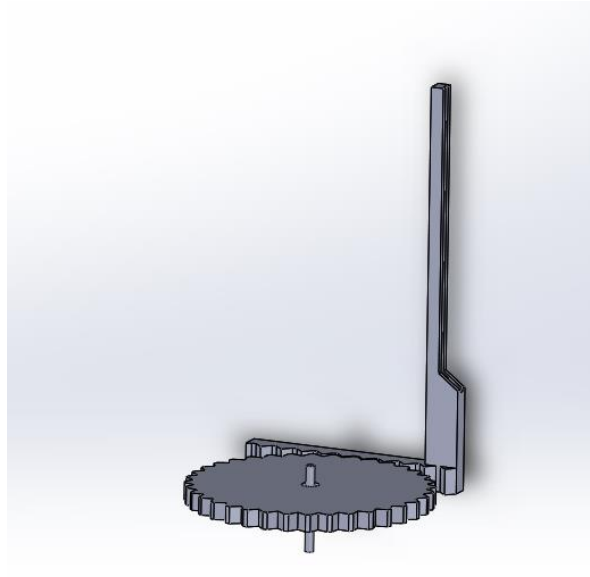
The device rotator connects to the bottom piece of the device to rotate the entire device head. Three major iterations were developed of this part. The first revision is very boxy and does not have a hex cutout to interface with the coaxial cable. In the second iteration a piece is created to fit the coaxial cable connected to the swiffer, and the top has a hex to snugly fit the coaxial cable meant to spin the device. In the final iteration, the length of the part was extended in order to compensate the cable for the swiffer. The part also improved the cable holder by putting it at an angle towards the middle of the device. In order to reduce stress concentrations at the sides of the part, the edges of the arms were also rounded.



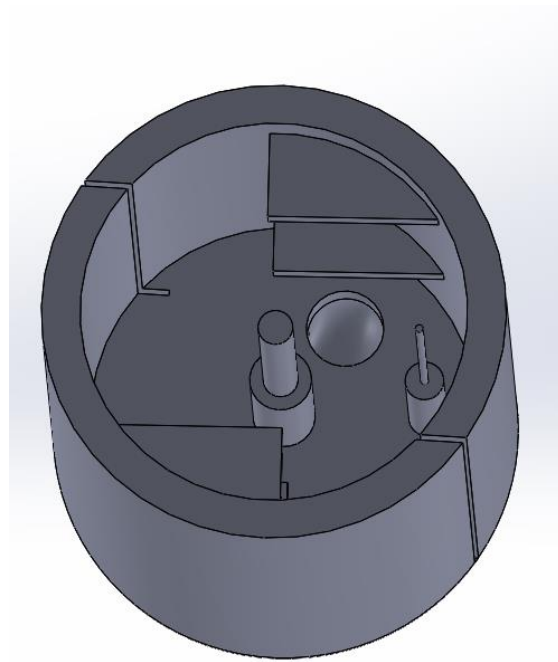
A.6 Other Revisions to Device Head and Assembly

The project team developed and modeled numerous iterations of the device head that were not included in the body of the report. Principally, there are three major steps that were not mentioned which proved to be major design innovations which were fully developed in later revisions.

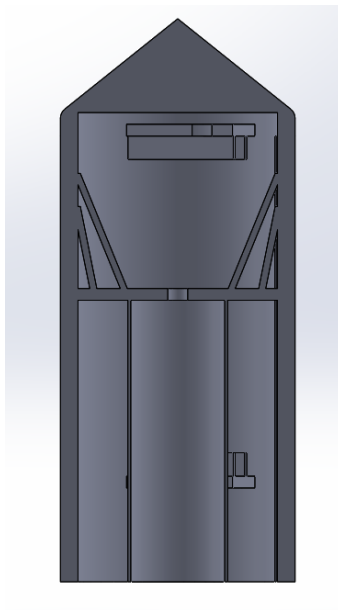
A set of custom gears were designed for specific use in the device head. One major limitation with designing in SolidWorks is the difficulty creating gears. As gears must have precise dimensions and pitch, they must be created very precisely in order to create gears from scratch in SolidWorks. An off the shelf gear could not be utilized as it needed to fit perfectly with the tracks of the blade holder. The creation of the gears was a major design breakthrough which allowed the team to progress several iterations.



The device was also significantly improved by creating mounts to hold the blade holders at a constant height. This was a major improvement from previous designs which relied on tension and tight tolerances to keep the blade holders in track with the gears.



Another major design innovation is demonstrated in the image below. After consulting experts at the WPI Rapid Prototyping Office, the overall method for design was changed to better reflect the capabilities of the 3D printer. Primarily the use of supports in the device head were employed to limit the amount of supports placed in the body.



Appendix B: Supplemental Testing Information

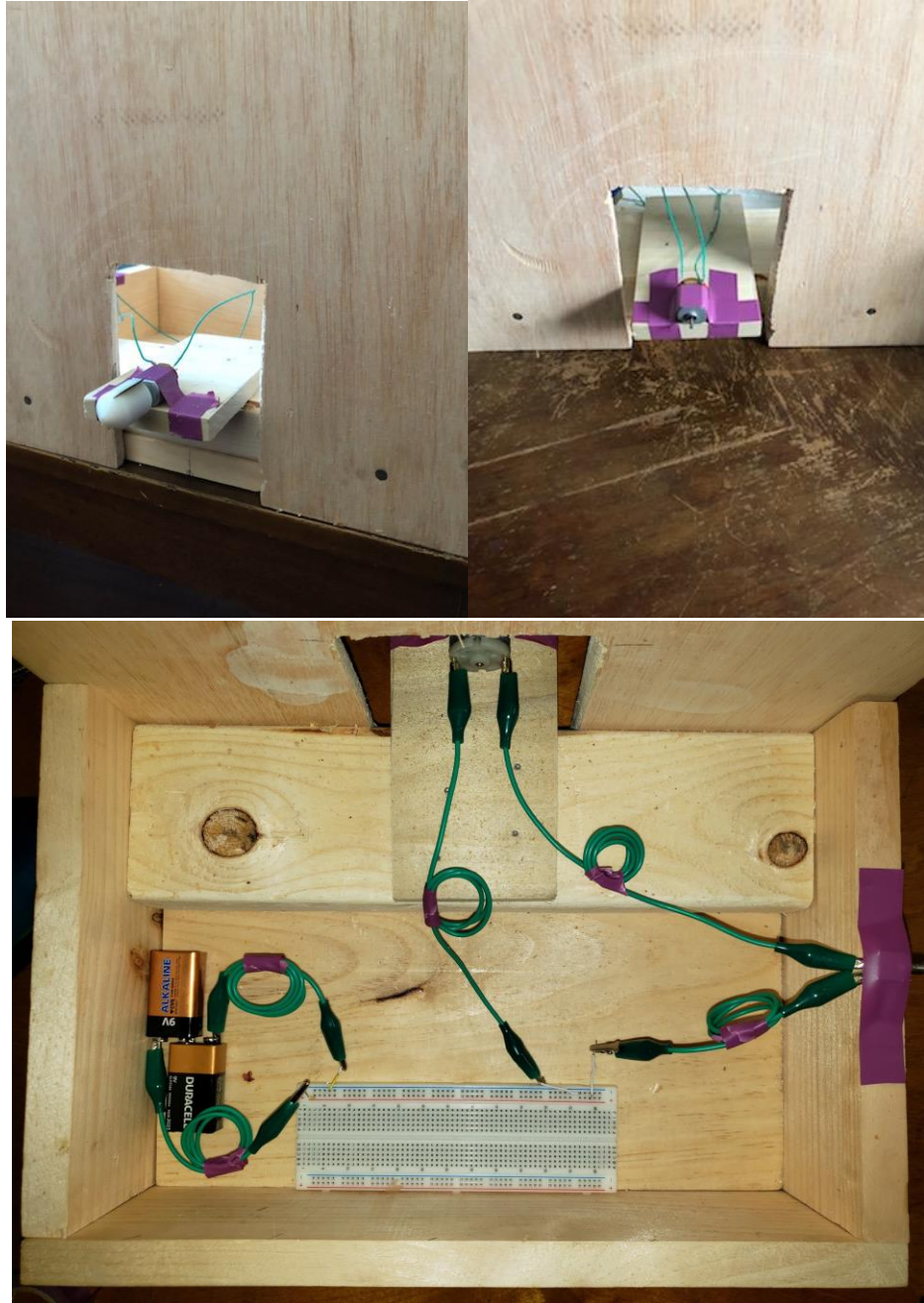
This section documents additional testing information that was left out of the body of the report. This information details the initial data, which was collected, and the initial testing apparatus used.

B.1 Initial Testing Setup and Data

The original testing setup that was used for the testing of the initial prototypes before the procedure was simplified using a mechanical drill. Below is the data set collected from this initial testing setup. In this procedure a wooden testing apparatus was created to hold a small DC motor in place. Behind the wooden guard piece, a breadboard was utilized in order to connect several batteries in series to a 3-way switch to the DC motor. This setup allowed the team to reverse the direction of the current, thus reversing the direction of the DC motor. This was necessary to determine if this motor could be utilized in the device body to extend and retract the blades. In this procedure, the same variables were tested on apples and onions. The intent was to measure the depth of cut at different time intervals on the surfaces of each material. Each material was held against the spinning device and measurements were taken using calipers.

The results of this data can be found below. After analyzing the results, there were clear limitations with this test method which led to major changes in the test procedure. One of the major limitations with this test is that the test material was not properly constrained, as the force pushed into the blades of the device corresponded to the overall cut depth of the material. It proved incredibly difficult to standardize a method to hold the material at constant force during this test. The motor and batteries of the device also were problematic as at several times the motor or batteries died mid test, or operated at reduced power which was not noticed until several tests had been conducted. Finally, the metric of cut depth proved to be ineffective at proving the concept of this device, as the cut depth eventually will be the exact length of the blades protruding from the device.

Trial #	Test Duration		Blade Type		Blade Orientation			Depth of Cut (mm)				Length of Cut (mm)			
	30 sec.	1 min.	Straight	Rounded	30°	45°	55°	Onion	Mean	Apple	Mean	Onion	Mean	Apple	Mean
1	X		X		X			6.46		12.75		26.65		29.97	
2	X		X		X			8.48	7.42	12.09	12.64	26.83	26.57	29.38	30.62
3	X		X		X			7.31		13.07		26.24		32.52	
1		X	X		X			6.93		16.82		27.14		32.89	
2		X	X		X			6.23	6.32	18.52	16.95	25.46	26.18	34.95	33.32
3		X	X		X			5.8		15.51		25.93		32.11	
1	X			X	X			9.1		13.2		27.64		33.14	
2	X			X	X			6.5	8.14	13.29	12.59	25.31	25.53	38.55	34.51
3	X			X	X			8.81		11.29		23.63		31.84	
1		X		X	X			7.86		18.61		25.55		33.56	
2		X		X	X			8.6	8.22	17.99	18.93	27.02	26.31	31.8	33.82
3		X		X	X			8.2		20.2		26.36		36.11	
1	X		X			X		5.01		17.41		22.12		31.55	
2	X		X			X		5.51	5.29	13.5	15.12	22.07	23.49	30.25	31.06
3	X		X			X		5.35		14.46		26.29		31.39	
1		X	X			X		9.22		16.24		22.63		30.15	
2		X	X			X		8.27	8.46	18.05	16.82	25.99	25.73	29.74	31.04
3		X	X			X		7.89		16.18		28.56		33.23	
1	X			X		X		4.31		16.76		20.11		33.12	
2	X			X		X		4.76	4.79	12.69	14.76	20.34	20.64	30.36	31.72
3	X			X		X		5.29		14.83		21.46		31.67	
1		X		X		X		4.74		19.09		22.05		32.51	
2		X		X		X		4.02	4.24	18.97	17.91	22.57	21.78	32.08	31.59
3		X		X		X		3.96		15.68		20.73		30.19	
1	X		X				X	5.52		18.82		23.8		32.14	
2	X		X				X	7.64	5.97	12.94	16.3	25.5	21.96	26.22	29.39
3	X		X				X	4.76		17.13		16.58		29.82	
1		X	X				X	12.13		24.7		34.18		31.31	
2		X	X				X	10.81	11.4	16.73	21.38	28.65	31.84	28.61	28.55
3		X	X				X	11.17		22.71		32.69		25.73	
1	X			X			X	6.32		8.58		28.45		31.76	
2	X			X			X	5.96	7.05	10.05	9.533	28.62	29.42	30.84	30.69
3	X			X			X	8.87		9.97		31.19		29.46	
1		X		X			X	6.45		15.94		24.18		28.98	
2		X		X			X	5.59	5.41	15.83	15.42	21.43	22.43	31.19	30.31
3		X		X			X	4.2		14.48		21.68		30.77	



B2. Final Testing Results - Qualitative

Below are the sections of chicken breast which were cut and measured to for the consistency results. Each chicken breast post cut was examined for qualitative consistency as well as quantitative. Each trial of the final testing is documented below.

