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Uniflow: a collapsible prostatic stent to treat the symptoms of benign prostatic hyperplasia

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Uniflow: A Collapsible Prostatic Stent to Treat the Symptoms of Benign Prostatic Hyperplasia

by

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SENIOR DESIGN PROJECT REPORT

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Uniflow: A Collapsible Prostatic Stent to Treat the Symptoms of Benign Prostatic Hyperplasia

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ABSTRACT

BPH is a widespread problem that currently does not have any highly effective and cheap solutions. We propose a solution involving a collapsible and durable stent for insertion in to the urethra to aid in urination by opening the urethra only when needed.

ACKNOWLEDGEMENTS

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Plasma Surface Treatment

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1. Introduction

1.1 Background

Benign prostatic hyperplasia (BPH), otherwise known as an enlarged prostate, affects 23 million people a year (Urologix). The prostate, a male reproductive gland, produces fluid that carries sperm during ejaculation. It surrounds the urethra, the tube leading from the bladder to the tip of the penis, which expels urine from the body. As men age, the prostate continues to grow, applying pressure to the urethra and narrowing the channel for the urine to pass through. This leads to not only urination problems in older men, but can also cause issues with thickening of the bladder tissue.

Though the cause of the BPH is unknown, it is believed to be linked to hormonal imbalances caused by aging and the testicles. This has been observed through the reduction of prostate size after testicle removal, as well as the absence of BPH in men who lost their testicles at a young age (Zieve).

The symptoms of BPH include dribbling during urination, weak urine stream, as well as a slowed or delayed start to the urination process. Frequent urination, urinary retention, pain while urinating and a strong and sudden urge are all common symptoms of men suffering from BPH. Incontinence and even erectile dysfunction can also be caused by this enlarging of the prostate (Zieve).

1.2 Problem Statement and Goals

BPH is a widespread problem that currently does not have any highly effective and cheap solutions. We propose a solution involving a collapsible and durable stent for insertion in to the urethra to aid in urination by opening the urethra only when needed.

2. System-Level Summary

2.1 Systems-Level Overview

The Uniflow system will be composed of the stent, and the catheter system that deploys the stent. The main function and purpose of the stent is to maintain strength of shape while being able to open and close, mimicking the function of the urethra.

2.2 System Sketches

Preliminary Sketches

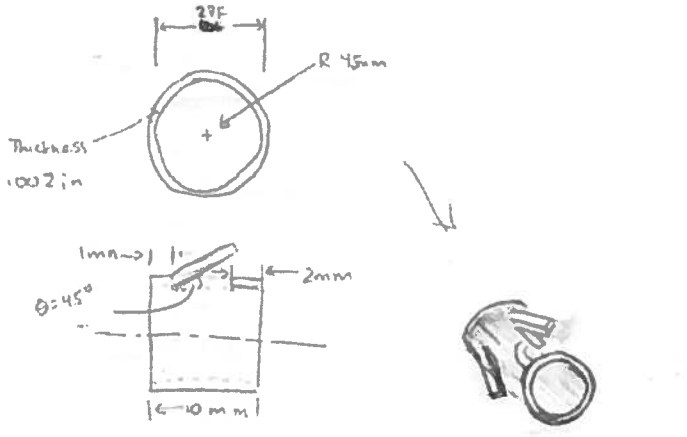


Figure 2.1

2.3 Customer needs and system level requirements

The use of either a non-metallic or non-degrading stent would be ideal in prevention of urethral stent degradation. This could also be a drug-eluting stent that targets prostate cells and curbs expansion and growth of the prostate. Over time this form of stent would ideally degrade and disappear from the body. This type of stent however does not address the problem of keeping the urethra open. A collapsible stent would be able to address this problem. A collapsible stent that is able to lay flat without urine flow and yet expand to the ideal size of the urethra during urination is the ideal goal of our project. This type of stent would need to be made of either a metal or other material that is

durable enough to last but also has the capability of collapsing to prevent pain in the patient. This could either be done with an expansion due to increase of pressure from the bladder, high salt content in the urine, or temperature in the urine. The stent would also need to be small enough for delivery through the penis, and short enough to not cause discomfort and yet still be effective.

2.4 Benchmarking results

Table 1. Benchmarking results

	Size	Site	Post Procedure	Length (hr)	Mechanism	Back to Normal	Anesthesia
Laser	10F	In hospital	Cath - 2 days	1-2 hours	Ablation	4 -5 days	General
Urolume	24F	In hospital	NONE	15 minutes	NO	1 wk	General or Local
TUNA	20F	In office	Cath – 3 days	1 hour	Ablation	48 hours	General
TUMP	20F	In office	Cath – 4-7days	2 hours	Ablation	1 wk	General
Steam	20F	In office	Cath - 5 days	1 hour	Ablation	1 wk	General
Urolift	20F	In hospital	Cath - 2 days	1 hour	NO	2 days	General Prostatic Block
TURP	27F	In hospital	Cath - 4-7 days	1-1.5 hours	NO	1 wk	General or Spinal
Uniflow	**20F**	**In hospital**	**NONE**	**15 minutes**	**NO**	**1 wk**	**Local**

The Green Light Laser Therapy is the current gold standard for treatment of BPH. It uses a laser to heat up the prostatic tissue and ablate tissue away (AMS). The laser cuts tissue away and cauterizes the tissue to prevent bleeding. Although this procedure is very effective at relieving the symptoms of BPH it can have unwanted side effects. This procedure results in the destruction of the internal sphincter, which is between the bladder and the prostate. A normally functioning internal sphincter will close when there is an ejaculation and cause the semen to flow down the urethra. When this sphincter is destroyed the semen shoots into the bladder, which is called retrograde ejaculation.

The Urolume is the only prostatic stent that has been approved by the FDA. Originally it was a very popular option for treating BPH, but patients experienced many complications with the device, which is why no one recommends it anymore. The diameter of the Urolume is 45 F or 15 mm, which is 6 mm larger than the average prostatic urethra (AMS). This caused serious discomfort for patients, which would lead to its removal. The Urolume is also difficult to remove due to tissue in growth through the mesh and calcification of the metal.

Transurethral resection of the prostate (TURP) is the former gold standard for treatment of BPH. It consisted of cutting tissue away with a hot knife. This procedure allowed for a large opening to be made in the prostatic urethra. This procedure along with many of the procedures for treatment of BPH can be very scary for men to undergo. Many men do not seek treatment because the treatment options seem threatening.

2.5 Functional Analysis

Uniflow has three subsystems, stent deployment, stent neck, and collapsibility mechanism. Subsystem one, stent deployment, involves the process of delivery by catheter. This system will be incorporated from current catheter deployment procedures. The second subsystem of the device is the stent neck, which can be seen in the system sketches of Section 2.2. Anchoring to the bladder neck and support are the two goals of the stent neck. Subsystem 3 is the collapsibility mechanism, which consists of the spring and sleeve attached to the stent neck.

2.5.1 Stent Deployment

The deployment aspect of our collapsible stent will be adapted from current stent implantation and deployment procedures. This process however will be slightly different due to the different design of our stent. Rather than using the same method as mesh stents to expand and lock the stent in place, we will have to insert the stent neck in place while it maintains its final shape and size.

2.5.2 Stent Neck

This part provides structure and stability to the stent and is composed of a small nitnol tube. Being only 10mm in total length the stent neck is inserted in to the neck of the bladder where it is anchored and provides support for the remaining part of the stent. The neck is also coated in parylene-c to counteract any possible corrosion that the urine would cause.

2.5.3 Collapsibility Mechanism

The third part of the Uniflow, the collapsibility mechanism, consists of an insertion area on the stent neck and the nitinol wire that makes up the remaining 20mm of the stent. The wire is first baked in to a spring shape. The nitinol wire is placed in to a hook created in the surface of the stent neck, both of which are plasma treated to allow for better adhesion of the nitinol wire and polyester sleeve enclosing the wire. The wire is then soldered in place. As urine flows through the stent neck and through the wire the spring expands causing the urethra to expand as well.

2.6 Key Systems Level issues

Upon researching and discussing the design and materials that we are using to create Uniflow, the team encountered a few issues and had to explore and design alternatives that will ultimately lead to a better product upon prototyping and testing. The challenges we have faced so far are described in the subsystem chapters.

2.7 Team Project Management

2.7.1 Challenges and Risks

Our stent will have to overcome a number of risks and problems in order for it to properly function. The first major problem we may see is the anchoring of the stent. This is a process that we hope can be achieved with little to no initial pain. This is also highly important because the system must be effective. If the stent does not anchor properly it may become dislodged. This not only would require removal of the stent, but would also cause the patient a great amount of unneeded pain and discomfort. As well as the anchoring system, the collapsing mechanism may also be a problem area for our

product. There are issues of tissue growth or calcification. Though these may be great for aiding in the anchoring of the stent they could become problematic if they were to interrupt the collapsing mechanism. This would not only defeat the purpose of our collapsing stent but could permanently force open the urethra. Pressure of the stent could also be an issue. We must design the stent to emit pressure on the urethra that is enough to force open the channel, but cannot apply too much force that would cause pain to the patient.

Manufacturability is another issue that our product may face. Our prostatic stent will be about one inch long. The size alone could cause difficulty in manufacturing. The other issue is the collapsibility mechanism. Depending upon how intricate and complex our collapsibility mechanism could be, the stent could be even more difficult to manufacture.

2.7.2 Budget

The budget for our product mostly consists of material purchases for testing and manufacture of our product. The largest portion of our budget is for the manufacturing of our stent product, with our hopes being to manufacture three prototypes.

Table 2. Budget Proposal

Material	Cost	Quantity
.1-.2mm Nitinol Sheets	$500	1
Polymer Sheets	$500	1
Other Test materials	$500	1
Material Total	$1,500	1
Items		
Stents	$250/unit	2
Incubator Trips		
Stent Cutting	$500	1
Graphic		
Animation	$500	1
Poster	$20	1
Catheter system	1000$	1

Total Cost	$3000

2.7.3 Timeline

Currently we have mostly been on schedule with regards to our timeline. We are moving through the final selection process of our material and will have that finalized by the end of this quarter. Winter quarter we will be finalizing our Solidworks designs and collapsibility mechanism. By the end of the quarter we will have our full design and model testing complete. By the beginning of spring quarter we aim to have our working prototypes complete and conduct in-vitro testing with these prototypes for at least a month before our design presentation.

2.7.4 Design Process

Uniflow was designed because alternative treatment options for BPH can have serious unwanted side effects. The Urolume, a prostatic stent, had the potential to minimize side effects and effectively treat BPH, but due to design flaws in the Urolume, it is not used anymore. Some of the problems associated with the Urolume are that it is uncomfortable, it gets dislodged, and it is very hard to remove. We addressed the issue of patients experiencing discomfort with a stent by making the radius of the stent equal to the radius of the average prostatic urethra. Uniflow will be anchored in the bladder neck where it will be less likely to be dislodged. The Urolume was made out of a metal mesh that would allow the prostate to grow through the mesh, and stent would become embedded in the prostate. The metal mesh also became calcified in the urethra due to the salty conditions of urine. A combination of the stent being embedded and calcified in the urethra makes it very hard for it to be removed. Uniflow has a sleeve around the stent that will prevent tissue in growth and calcification of the metal.

2.7.5 Risks and Mitigations

Throughout the design and development of our product, there were many risks that had to be considered. Some of these risks included a lack of funding, inability to purchase desired quantities of the materials, poor performance of our selected materials and design flaws. These problems either have arisen or may arise at some point and we must not only acknowledge this but also find a way to combat or prevent these problems.

Our first risk we would have to overcome would be proper funding for the production and promotion of Uniflow. So far this has not been an issue as we have either received our needed funding for development or have already been in possession of our needed materials. For future expansion and development however, we will need to seek further funding through venture capitalists. Currently we have had issues in constructing our prototypes out of the proper materials due to the necessity to purchase excess amounts of the material that we currently do not need.

Poor performance of our selected materials may also arise as we move through the development and testing stages for Uniflow. This could either be from the durability of our materials or possibly the affects they may have on the human body. Design flaws may also be an issue. These could either be the issues with the functionality and effectiveness of the mechanisms we have or possibly the shape and anchoring mechanisms. Only through thorough testing and analysis will we are able to determine which materials and designs provide the best and most effective product.

2.7.6 Team Management

For an effective approach to team management we have distributed the work in order for each person to properly utilize their best skills and qualities. Since there are three members comprising our senior design group, we have split the work evenly by subject as well as strength in order to create a highly efficient and effective team.

Our primary consultant for any issues, questions, or concerns will be Mr. Gerardo Noriega, our faculty advisor. If there are any more direct university issues then we will

be consulting our department chair, Professor Yan. Finally, if any conflicts or problems present themselves within our group we plan on meeting, discussing these problems, and creating new plans of action to prevent the reoccurrence of these issues.

3. Subsystem 1

System Overview

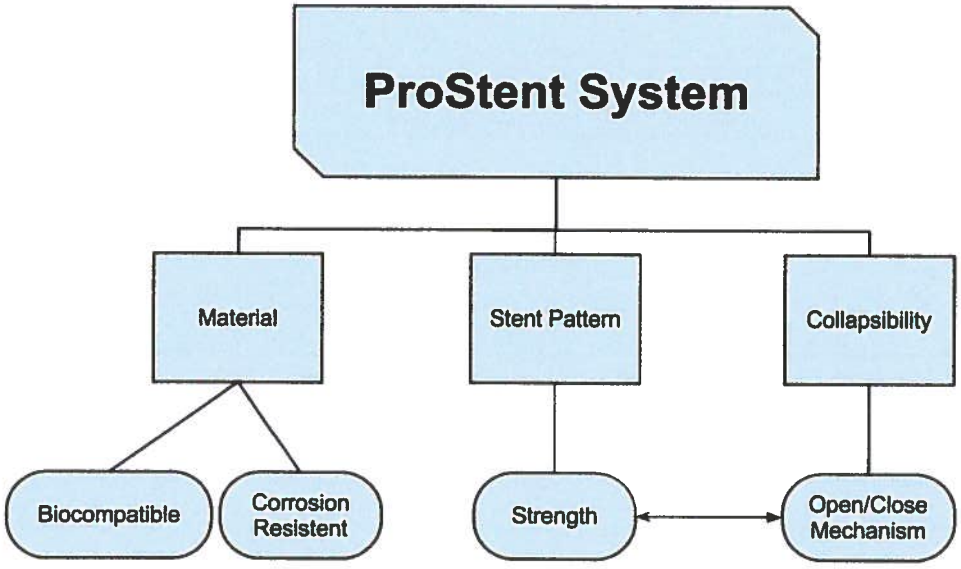


Figure 3.1

3.1 Deployment Subsystem

The deployment subsystem manages how the doctor will insert and anchor the device into the patient. This will be achieved by use of a catheter inserted into the urethra of the penis. First a local anesthetic will be applied to the urethra in order to take away any minor discomfort. Once inserted, the catheter will travel back into the bladder where a saline balloon will be pumped up to anchor the catheter. Once the catheter is anchored, the stent will travel through the catheter until it reaches the span of the prostate. This catheter will have channels to collect urine while the patient is undergoing the procedure. Here, the doctor will expand the stent and then anchor it using the mechanism designed. After deployment the catheter will be removed out of the penis and disposed of.

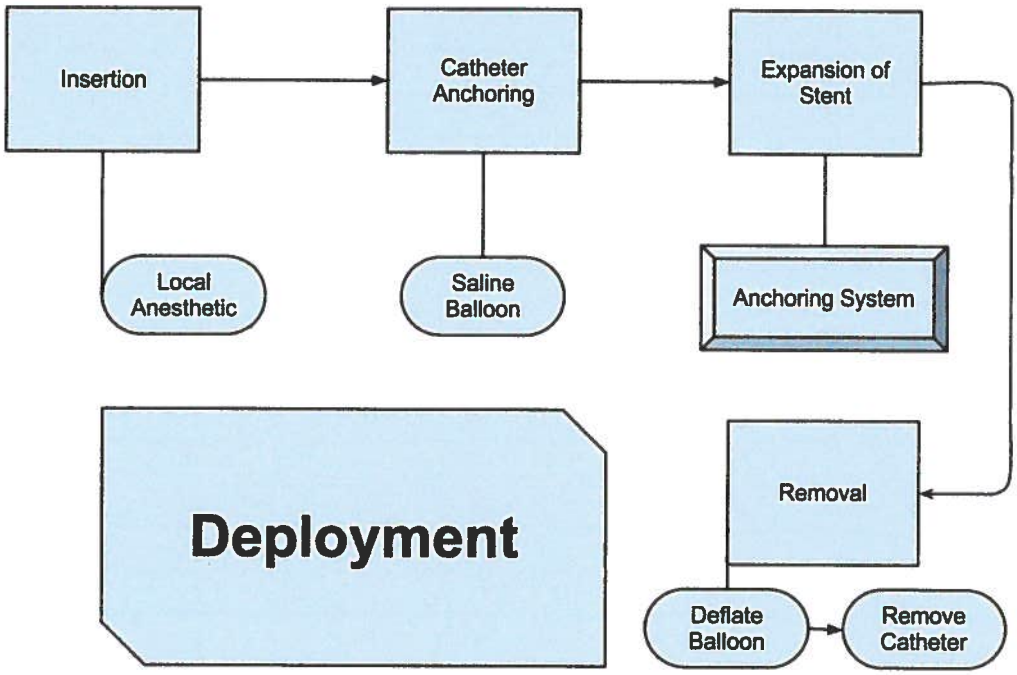


Figure 3.2

3.2 Options & Trade Summary

3.2.1 Catheter: Options/ Trades

Through the development and design process of our stent we needed to establish a method for insertion and implantation of the Uniflow. We have chosen a catheter to implement the deployment of our stent. Catheters have a successful history of not only stent deployment but also in urethral insertion. The use of a catheter appears to be the ideal fit for a minimally invasive implantation.

3.2.2 Deployment: Options/ Trades

Rather than create a new method and system, we have chosen to implement a catheter for implantation. This catheter would work similarly to current coronary stents. The smaller differences caused by our anchoring system will force us to slightly alter this implantation method over the course of our product development. Currently we are looking in to a balloon inflation type system and insertion of the stent neck in to the bladder neck for anchoring purposes.

3.3 Subsystem Design Description

3.3.1 Catheter

The catheter design will be based solely on current catheter technologies used for stent deployment in other regions of the body. Slight alterations may be needed and will be made throughout the development and testing stages.

3.3.2 Deployment

Uniflow deployment will initially be attempted with the use of a balloon catheter and inflation process. However with the rigid stent neck and anchoring systems this may be more difficult to achieve and thus will require alterations and upgrades through a rigorous testing process.

4. Subsystem 2

4.1 Stent Subsystem

Our second subsystem is the stent. First, we need to select a material that is strong, biocompatible, and corrosion resistant. We have narrowed our material down to the metals tantalum, titanium, and nitinol.

Table 3. Material Selection

Metal	Flexibility	Corrosion Resistance	Fatigue Strength	BioInert	Cost
Nickel Titanium (Nitinol)	Very Good	Good	Good	Yes	Low-Mid
Titanium	Good	Good	Very Good	Yes	Low
Tantalum	Good	Very Good (Surface Oxide layer)	Very Good	Yes	High

In addition to selecting a material for our stent, we must have a strong pattern that can support the pressure of the prostate. Our pattern must also be able to collapse when there is no urine flow and expand when there is urine flow. We must find a mechanism that will expand the stent when there is flow through it. Our mechanism might be a regulated by the pressure increase in the urethra when there is flow through it. We have also discussed using manual pump that would expand the stent when prompted.

4.2 Options & Trade Summary

4.2.1 Stent Neck: Options/ Trades

Within our initial designs a stent neck was not present but rather the use of an entire mesh style stent. Through further research we discovered that this design within the urethra had many flaws and thus a neck was designed in to our system.

4.2.2 Anchoring Mechanism: Options/ Trades

Anchoring can be achieved in only a few ways. First of all, the stent may be anchored by having a large enough width at the proximal end in which the stent is anchored by the bladder opening. Another anchoring option is giving the stent a fish hook type function that will minimally pierce the walls of the urethra, therefore anchoring it.

4.2.3 Collapsibility Mechanism: Options/ Trades

The collapsibility mechanism is another function that has undergone design and mechanism changes through the life of Uniflow. Initially this was going to be achieved through alteration of a mesh stent to allow it to fully collapse and expand. However, this idea was altered along with the creation of the stent neck in favor of a spring type system.

4.2.4 Sleeve: Options/ Trades

The sleeve of our stent was not introduced until the switch from a mesh design to our current design was implemented. We had a few different choices of sleeve material ranging in price, and ease of availability.

4.2.5 Materials: Options/ Trades

There are many different biomaterials that our group has considered for the stent system. The three best choices have been Titanium, Tantalum, and Nitinol. If we refer to Figure 1, we conclude that although tantalum would be the best option, Titanium offers the best function for the relative price.

4.3 Subsystem Design Description

4.3.1 Neck

The neck of the stent will be made of a nitinol tube 10mm in length with a thickness of .02 in and radius of 27 French (F). The neck provides the structural support for the stent and also houses the anchoring mechanism. Cut in to the side of the neck is a groove for the nitniol wire insertion. This acts as the housing for the collapsibility mechanism. The tube is plasma treated to allow better adhesion of the wire and sleeve, and is coated in parylene-c for protection from the urine.

4.3.2 Anchoring

The anchoring system comprises three anchors that are placed equidistance around the circumference of the nitinol tube. The neck of the stent is then placed in to the bladder neck where the anchors will hold the stent in place. The anchor flaps come out at a 45 degree angle from the tube and are 2mm in length.

4.3.3 Collapsibility

A nitinol wire .01 in thick and the neck tube comprise the collapsibility mechanism of Uniflow. The nitinol wire is baked in to a spiral shape in order to act similar to a spring. The nitinol wire is inserted into the precut groove of the neck, adding a mechanical aspect to secure the wire. It is also aided in it's adherence from the previous plasma treatment of the tube and wire, as well as soldering of the wire. The wire is then placed inside a sleeve for protection. As urine flows through the neck and the sleeve, the pressure exerted by the urine flow forces open the nitinol wire, widening the urethral opening and allowing for better urine flow for the patient.

4.3.4 Sleeve

The sleeve is placed around the nitinol wire to ensure it will be protected from the urine and can also resist the in growth of tissue which could affect performance of the stent. Unlike the neck tube, parylene-c can not be used for the nitinol wire due to the restriction of movement it would cause, thus a bio-inert sleeve was implemented. Polyeurathane was chosen as our sleeve material due to its accessibility and previous successful uses during implantation.

5. System Integration

5.1 Test

In order to test our system integration, a simple test of connectivity to the catheter will be applied. The test will determine if the stent can be compacted and delivered down the tube of the catheter and then deployed out the end. Bench top tests will be able to determine the integration and delivery of our stent.

6. Engineering Standards and Constraints

6.1 Health

Health and safety is by far the most important standard that we must put our project up against. As an implantable medical device, Uniflow must be a safe product that does not cause health issues within the patient. Not only would this cause issues in selling the product but more importantly it would endanger the customer. Our goal is to improve the health of our customers making the safety of our prostatic stent a top priority. If we seek out FDA approval for our 510(k) product, it must meet the most stringent health and safety standards. The main goal of Uniflow is to relive the customer of pain and improve the quality of life, a goal that stays a priority throughout development and design of our product.

6.2 Economics

Economics is another constraint that we may face in our project. Currently our hope is to not only create safer and more efficient alternative to current BPH treatments and surgeries, but also one that is more affordable. Not only will this allow our product to be competitive and hopefully successful in market, but it would also be a great alternative to the much more expensive alternatives. The largest problem with BPH is currently its lack of diagnosis. We believe this is caused by a combination of a few things, but mostly in the invasiveness and drastic surgeries of alternative procedures, and the expensive costs of these treatments. With a cheaper, safer, and more effective alternative, Uniflow not only would be highly competitive but also would be much cheaper.

6.3 Social

Socially BPH is a problem for many of the men who are affected by the disease. Many of the symptoms, such as incontinence or frequent urination can cause awkward social interactions. It can also cause an older man to wake up to urinate multiple times per night, causing him to be more tired during the day. These can all lead to numerous social issues, a large part of the disease. Through production and development of a safe and effective product we hope to overcome these social issues in junction with the physical aspects of the disease.

6.4 Manufacturability

Ethics also affect our project, though not in as direct a way as some of the above examples. However, ethics is still very important, especially to our product development. With our goal being to create a prostatic stent that is safe and works effectively, we must not cut corners and compromise our design. This may be brought on if we begin to run out of time, or possibly money, especially if this becomes a product that we hope to maximize profit with.

6.5 Ethical

Manufacturability is also very important, especially in its aspect of cost, as well as size. Our product is going to be relatively small, around two to three centimeters in length and could possibly have a highly intricate mechanism that allows for collapsibility. Not only must we not make a product that is too complex to create and make a reality, but we also do not want it to be expensive. In order for people to see Uniflow as a viable alternative it must be affordable, something that could become harder to do if the manufacturing costs are high, causing the cost difference to be passed on to the customer.

7. Summary and Conclusions

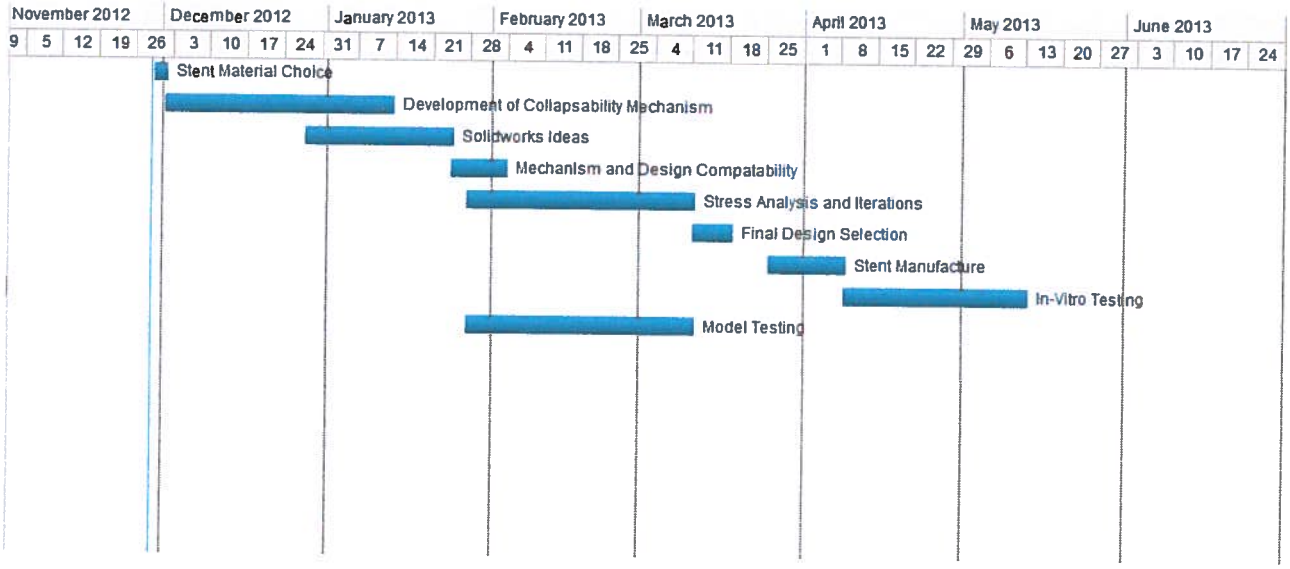
7.1 Summary

Our goal for this project is to make a collapsible stent to treat benign prostatic hyperplasia. We want out stent to collapse when there is no urine flow through the urethra and to expand when there is urine flow. The mechanism for which the stent will collapse and expand is still being discussed.

Our team is currently researching other market products as well as the anatomy and physiology of the urinary tract so that we may have a full understanding of the affected area and other types of treatments. Our aim is to produce a preliminary design within a couple weeks. This first iteration would include our stent shape, a test material and stent pattern. After initial iterations our goal is to seek clinical input to further iterate our product before we are ready for testing. Continuing this process through much iteration of materials, designs, and patterns would hopefully produce a successful and market ready product.

7.2 Timeline

Table 4. Timeline



7.3 Future Work

In the future we would like to build more prototypes of our stent and do more bench testing. Through bench testing we would like to finalize our anchoring subsystem. We would also like to perform corrosion tests on our stent with the parylene C coated on the

nitinol and strength test the entire stent. We would like to move from bench testing to animal trials and ultimately to FDA approval. In addition of further testing and FDA approval we would like to file for a provisional patent. Once we finish our bench testing we will file for a patent.

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9. Appendices

Appendix A: Design Information

Appendix A-1: Questionnaire and Response of Gerardo Noriega

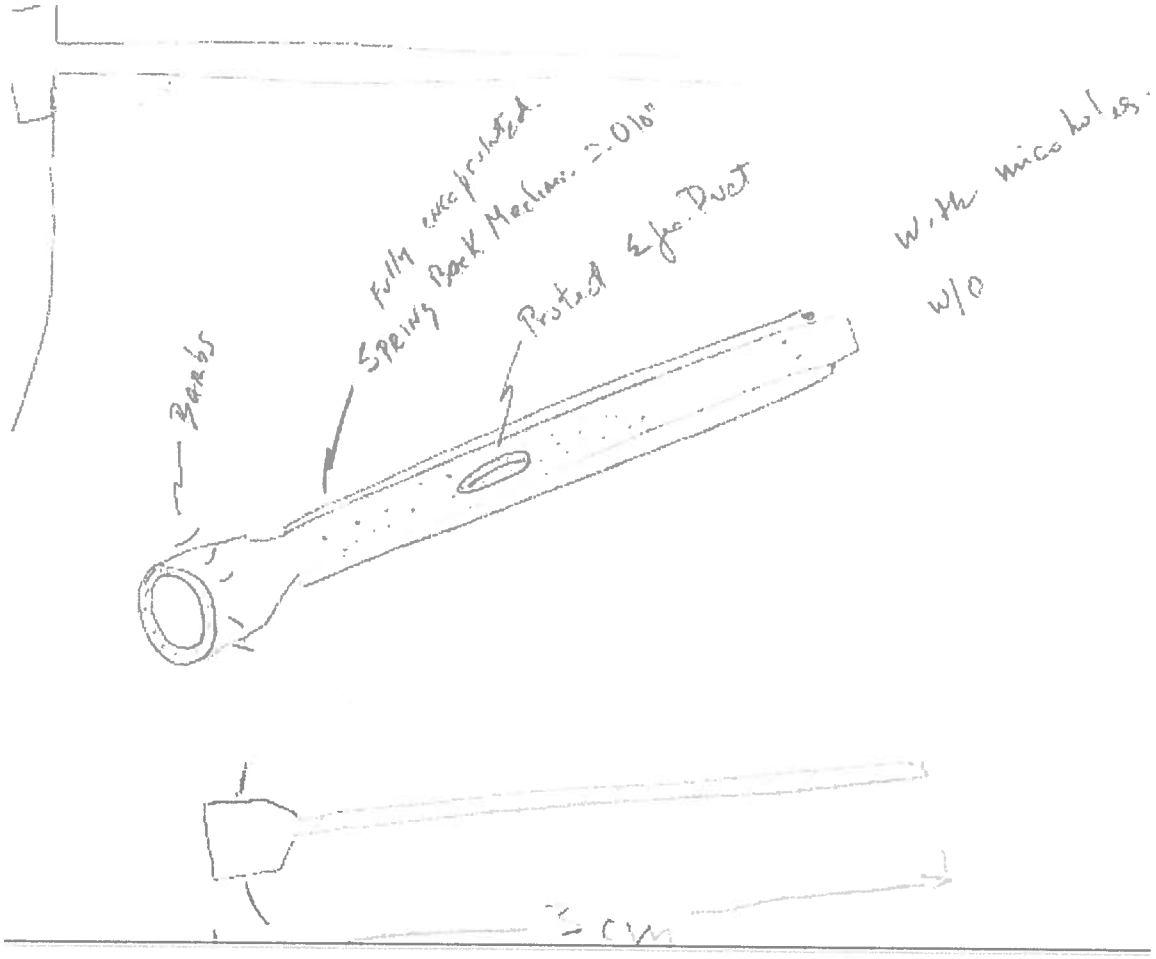
- What design aspect could make males more likely to visit their doctor about this problem?
- If the patients are able to feel or touch the device, the anxiety seems to decrease. Therefore, if the patient is allowed to see and touch the product before the procedure, they are more likely to continue.
- Besides getting males to visit their doctor, what is the most difficult part of treating BPH?
- The side effects are the most difficult. There are currently no products that do not carry some sort of side effect.
- What are the current leading treatments for BPH?
- Green Light laser, TURP, RF ablation, ballooning, stenting, and medications are the treatments that are currently leading the device market for BPH.
- Do you think a collapsible stent could solve problems with current stent systems?
- Yes! It can work because it would mimic the normal functions of the urethra and the closer we get to normal function, the better the device will be.
- How do you envision a collapsible stent competing in the BPH device market?
- Very good, it would be simple, safe, non invasive. No ballooning post treatment is great, positive feature of the stent.
- What are the biggest obstacles in bringing this product to market?
- They are many other competing therapies and that makes it more difficult in selling the ideas to the investors. However, its simplicity will be a attractive quality to doctors as there will be minimal teaching to using the device.
- Do you see any problems with a device like this being approved by the FDA?
- No, they should have no trouble because there are current products like this on the market.

Appendix B: Design Analysis

Appendix B-1: Preliminary and Alternate Sketches

Below are some preliminary sketches and alternate sketches when we started the project. They develop from figuring out how to make a stent mimic urethral function to anchoring mechanism to dimensions.

a)



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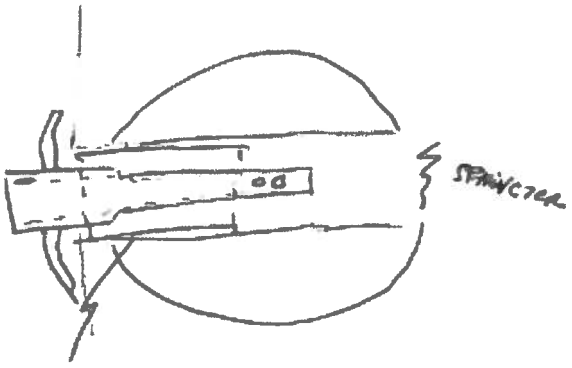
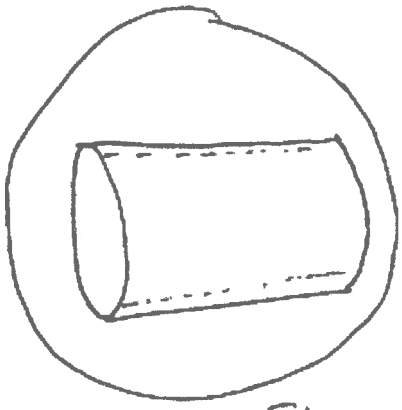


DETAIL A



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1

Sleeve -

DETAIL "A"

c)

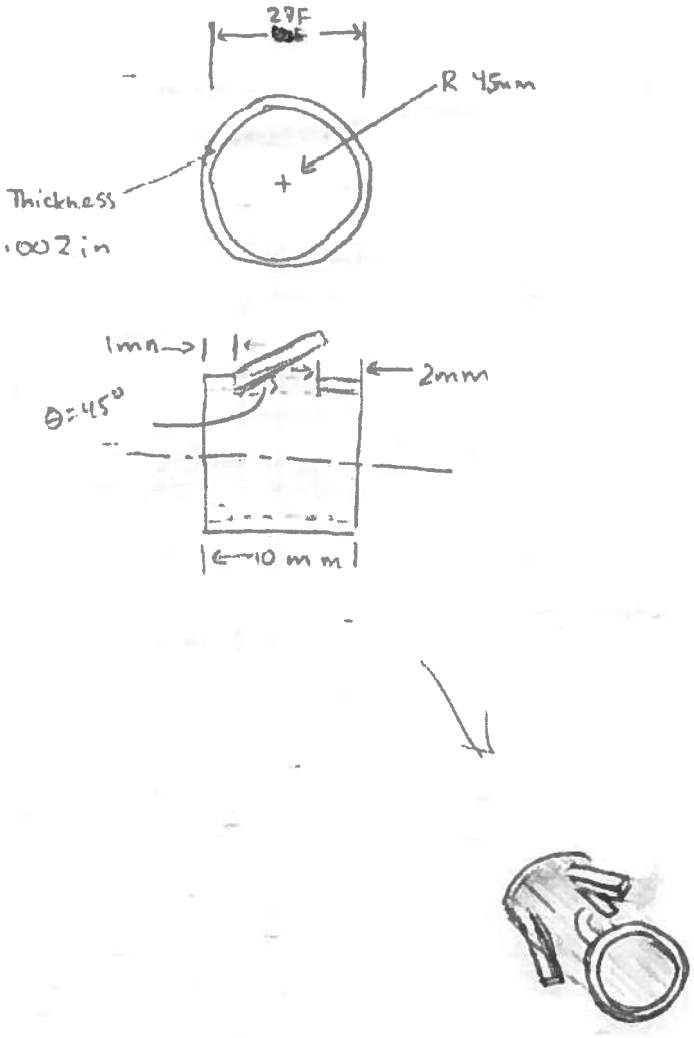

Figure A1(a-c) Preliminary sketches