Applying an Innovative Idea to Kidney Stone Removal

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Background

Renal lithiasis, commonly referred to as "kidney stones" is a condition in which the urine composition crystallizes and cannot pass through the ureter, causing pain and discomfort. Renal lithiasis can be caused by diet, infection, reduced water retention, or hereditary disorders; each of which results in a distinct stone composition [1]. Stone compositions can vary between calcium oxalate, struvite, uric acid, and cystine[2]. Each stone type, however, provides the same pain to the patient and the same potential risk of blocking the urinary system.

Kidney stone symptoms may include but are not limited to: pain in the lower back, the presence of blood in the urine, cloudy or foul-smelling urine, and reduced amounts of urine [2]. It is expected that 1 in every 10 Americans will have kidney stones at some point in their life [3], totalling approximately 24 million men and women each year, primarily within ages ranging from 20-50 years old [4].

Once a patient is diagnosed with kidney stones, a urologist can suggest various methods of ablation and removal based on the location and size of the stones. Stones that are less than 5 mm are typically left in the body for patients to pass naturally, while stones within the 5-10 mm range are removed manually through the use of an extraction device. Stones that are greater than 10 mm, however, must be broken down so that they can either be passed naturally or surgically removed. These stones are broken down through lithotripsy, as seen in Figure 1, which is the fragmentation of stones either internally through the use of a laser, or externally through vibrational shock waves [3]. In order for the stones to be manually removed, a surgical procedure is performed.

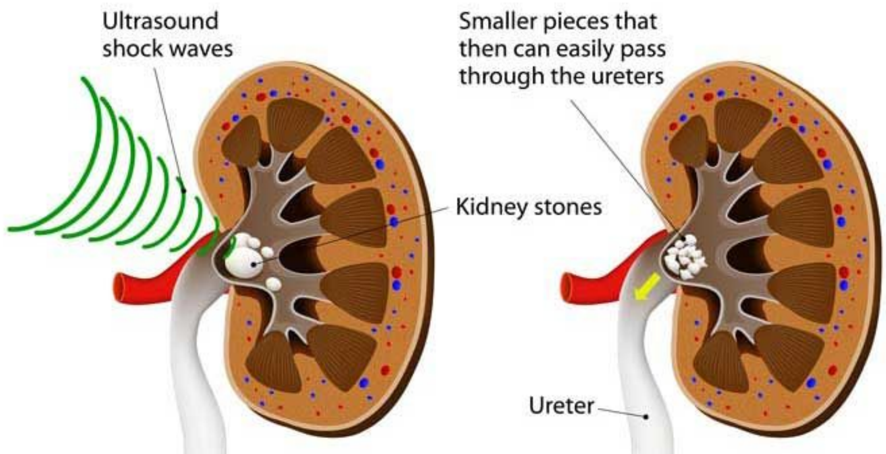

Figure 1. Diagram showing shock wave lithotripsy breaking down large stones in the kidney into fragments which can be more easily passed [3].

During the surgical removal of kidney stones, patients are under general anaesthesia. The procedure begins with the insertion of the ureteroscope through the urethra, bladder, and ureter, via the ureteral access sheath. The access sheath primarily aids with directing movement through the bladder and into the ureter. A ureteroscope is a long, thin device equipped with a light, a camera, and one or two lumens through which other tools can be inserted (Figure 2) [5]. The ureteroscope is used to detect stone placement and help the urologist visualize the urinary system. Once the access sheath has been inserted, lithotripsy is performed to break large stones into fragments. Once all stones are in the 1-10mm range, a basket is sent through the lumen in the ureteroscope and used to entrap and remove each individual stone.

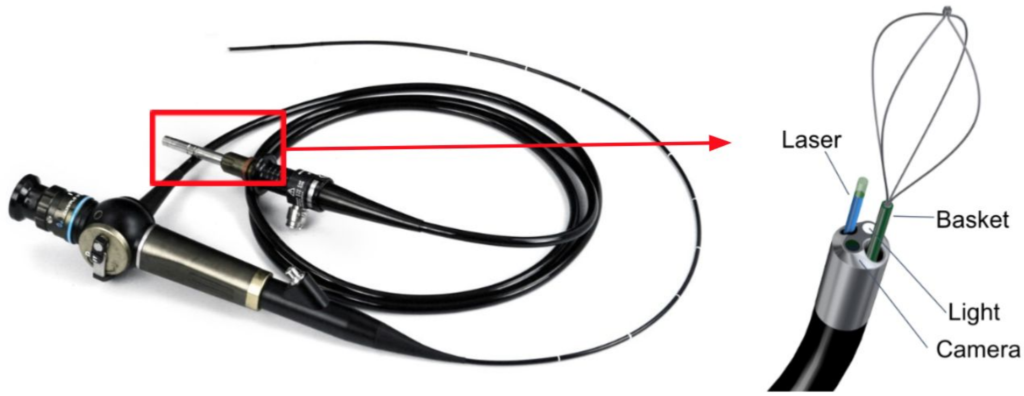

Figure 2. Ureteroscope with an enlarged image of the tip displaying the light and camera as well as the two lumens through which a laser and basket are inserted [5].

The extraction tools are generally made up of a flexible wire with a metal basket at the end [6]. There are multiple versions of these metal baskets, but they all have the same purpose: to entrap and remove stone fragments. These tools are very small and the diameter is generally recorded in the international unit of French (Fr), where one french unit is equivalent to three millimeters [7]. The baskets are retracted in a sheath upon entry into the body and, once near the targeted stone, they are expanded. Typically, they can range in size from 1-10 mm when expanded so that stones of various shapes and sizes are able to be entrapped.

These devices are typically made out of a nickel and titanium alloy called nitinol [8]. Nitinol is known for its hyper-elasticity and flexibility. These properties are important because they allow the baskets to completely retract into the sheath without fracture or deformation. Stainless steel was previously used, until 1994 when nitinol was first introduced [9]. This change in material greatly increased the flexibility and durability of the baskets, however, innovation in baskets has not changed much since then.

While baskets have been the predominant extraction tool for kidney stones, they have an inherent flaw in that they can only remove 1 stone, in the 5-10mm range, at a time. This slow removal rate contributes to the extended procedure length of about 60-90 minutes [10]. Since baskets can only remove 1 stone at a time, the entire device must be withdrawn from the body and reinserted for every individual stone. There are many different basket designs which are currently patented or sold, serving as prior art, however, as shown in Figure 3, the devices recently released are all baskets of some type which function in similar ways.

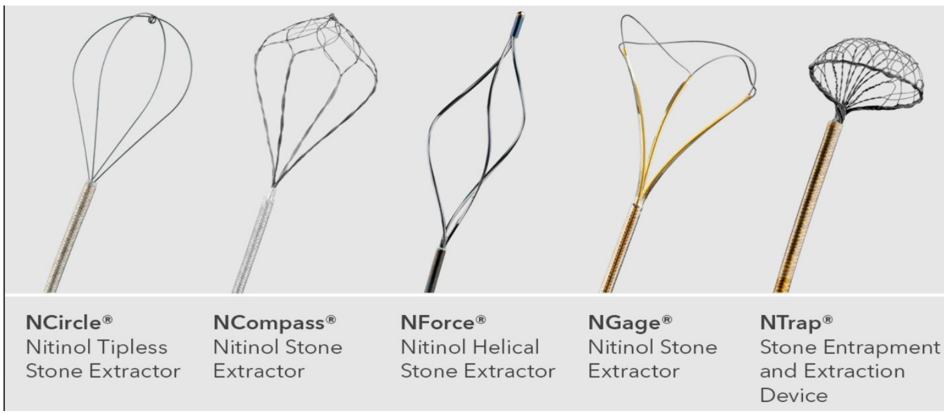

Figure 3. Recent stone extraction devices of Cook Medical [10].

Problem statement

Renal lithiasis, commonly known as kidney stones, is expected to affect 1 in 10 Americans at some point in their lifetime [3]. A urologist will often perform a ureteroscopic procedure to view and fragment stones present in the urinary system. While stones fragmented to a diameter less than 5mm can be passed naturally by the patient, fragments between 5-10mm must be removed manually using a kidney stone extraction device [10]. Current extraction devices are only able to extract 1-2 fragments at once, and the repetitive insertion and removal of these devices causes increased stress on the patient's body. **A kidney stone retrieval device that can successfully extract multiple stones, less than 5mm, at once can prevent the need to pass stones naturally; consequently decreasing**

patient recovery time compared to that of current devices, which are not designed to extract multiple stones.

Design Objectives

Table 1. Summarized Objective Tree, with primary objectives in bold, secondary objectives underlined, and tertiary objectives in italics.

<table>
<tr><td colspan="3">1. Efficient</td></tr>
<tr><td>1.1 <u>Ergonomic</u></td><td colspan="2">1.2 <u>Quickness of Extraction</u></td></tr>
<tr><td>1.1.1 Comfortable
1.1.2 Easy to Use</td><td colspan="2">1.2.1 Elastic
1.2.2 Flexible
1.2.3 Thin (diameter of head)</td></tr>
<tr><td colspan="3">2. Versatile</td></tr>
<tr><td>2.1 <u>Compatible with ureteroscope</u></td><td>2.2 <u>Compatible with different stone morphologies</u></td><td>2.3 <u>Long enough to reach in the kidney locations</u></td></tr>
<tr><td colspan="3">3. Safe</td></tr>
<tr><td>3.1 <u>Biocompatible</u></td><td colspan="2">3.2 <u>Externally smooth</u></td></tr>
</table>

Our proposed device has certain objectives that it must be able to fulfill, summarized in Table 1 (and Appendix A), and elaborated upon below.

1. Efficient- Our device will only be able to stand up against competition if it is able to achieve more in less time.

1.1 <u>Ergonomic</u>- The device handle should be easy to use and operate. An awkward or overcomplicated handle can inhibit the performance of the urologist.

1.1.1 *Comfortable* - The handle should provide adequate comfort for the urologist.

1.1.2 *Easy Control* - Urologists should find our device easy to use and control with minimal effort or training.

1.2 Quickness of Extraction **-** Current procedures use baskets which are only able to retrieve 1-2 stones at a time. By designing a device that can extract multiple stones at once, we can increase procedural efficiency.

1.2.1 *Elastic* - Our device's material composition must be able to remain in its elastic region while retrieving stones of different sizes, shapes and morphologies, meaning that it is not easily deformed and can "bounce back" to its original shape.

1.2.2 *Flexible* - Our device will be used through a ureteroscope, so the device must be equally as flexible as a ureteroscope.

1.2.3 *Thin (head diameter)* - The head of our device should be thin enough to enter through the urethra.

2. Versatile - The device should be able to operate in a number of different situations alongside other surgical tools, such as a ureteroscope or laser.

2.1 Compatible with ureteroscope - Our device must be able to operate with ureteroscopes, regardless of the kind.

2.2 Compatible with different stone morphologies - Urologists may use multiple baskets designed for specific stone morphologies and shapes. As a result, we aim to design a device that is able to extract stones of multiple shapes and sizes.

2.3 Long enough to reach locations - Current devices are sold in various lengths because they are specialized to retrieve stones in specific areas of the urinary system. We would like to design a solution that is long enough to retrieve stones from any location of the urinary system.

3. Safe - As with any medical device, safety is an extreme priority. Using our device must be completely safe for both the urologist and the patient.

3.1 <u>Biocompatible</u> - The design should be made of materials that do not cause a harmful reaction to living tissue.

3.2 <u>Externally Smooth</u> - The device should not have any sharp edges that can irritate living tissue.

Device Functions and Specifications

Table 3. List of functions along with the set metrics, unit of measurement, marginal, and ideal values. The marginal values were based off current devices [11].

Part of the device	Function	Metric	Unit	Marginal Value	Ideal Value
Head	Extract stones of various sizes	Size of stones	Millimeters	5-10	1-10
	Extract multiple stones at once	Maximum number of stones extracted in one motion	Binary	>2	>5
	Reach location of stone	Working length	Millimeters	650	650
Handle	Rotate the head	Deflection at tip	Degrees	270	300

A list of functions was compiled for our device (Appendix B). Our device must be able to extract multiple stones at once and also succeed regardless of the situation by obtaining stones of different chemical compositions, reaching the location of the stones, and extracting stones of various sizes. These functions were broken up based on the part of the device they relate to, and metrics were set for each of the measurable functions. The units of measurement were then set for each metric and the the marginal and ideal values were decided on. The functions were kept general so as not to restrict the design to a specific component.

Extract Stones of Various Sizes- This will be measured by size of successfully extracted stones. Since current devices are able to extract stones in the size range of 5-10 mm, that was set as the marginal value. Our device, however, aims to do better by extracting smaller stones as well. Instead of leaving stones less than 5 mm for the patient to pass naturally, we want to remove these as well, making our ideal range 1-10 mm. While these smaller stones *can* be passed naturally, it is still an extremely painful process that can take up to 22 days [12].

Extract Multiple Stones at Once- This will be measured by the diameter of our device. Current baskets have diameters anywhere from 10-15 mm [11]. Making the diameter larger will allow more stones to be entrapped at once. We aim to have a large diameter on our device, however, making the diameter too large will cause the ureter to be expanded quite a lot. Our ideal value was set to 15 mm so that it remains at the top of the range, however, does not cause the ureter to expand too much.

Reach Location of Stone- This will be measured by the working length of the device. Current technologies can be as long as 650 mm, and our device must be able to match that.

Rotate the Head- This will be measured by the rotation at the tip. The knob in the handle of the device will be used to rotate the head, and the measurement will be recorded in degrees. Current devices have a 270° rotation capability [10]. We plan to exceed that by making our device rotate 300°. This will make it easier for the urologist to grab hold of stones lodged in grooves of the kidney because they will be able to continue to rotate in the same direction if the stone is moved while it's being picked up.

Design Requirements

We have a total of 4 design requirements and have devised tests to ensure our prototype meets the requirements elaborated upon below.

Ergonomic - Categorized as a customer need, since the urologist's comfort is crucial for our device's success. We had 20 people hold our device and rate its comfort on a scale from 1-5 - 1 being very uncomfortable and 5 being extremely comfortable. The average ranking was a 4.6/5 which was above our "satisfactory" goal of a 3. When this test was repeated with the handle of a current device, the average ranking was only 2.6/5, showing the clear improvement in our new design.

Flexibility - Categorized as a customer need, since the device will be used inside a ureteroscope, and thus must have the flexibility of a ureteroscope, which is 270°. The device must match the flexibility of a ureteroscope so that it can reach all areas of the kidney. The prototype was placed on a flat surface, specifically on grid paper with an xy-graph. From the origin, we flexed the prototype clockwise and counterclockwise respectively until it reached 270° while remaining in its elastic region [13].

Extraction of Multiple Stones <5 mm- A core aspect of our design is the ability to extract multiple stones in the 1-5 mm range. The test elaborated under 'Validation of Design' was used to determine that our design can extract these small stones, and can extract multiple stones at once. If our standard for success was set at 3 stones and, since out device was able to extract more than 3 stones at once, it was deemed successful.

Device Diameter- Since the device will be used inside the urinary system, it must have a diameter less than or equal to the size of a dilated ureter. The ureter's diameter is 3 mm on average, but can decrease as it approaches the bladder. Furthermore, the ureter can be dilated during the procedure, increasing the diameter to about 5 mm. As a result, a device with a maximum diameter of 5 mm is suitable.

Documentation of the design

The proposed solution, named PureRemoval, incorporates a handle, basket, and adjustable balloon to achieve the objectives and functions of our design. A conceptual prototype of the device can be seen in Figure 4.

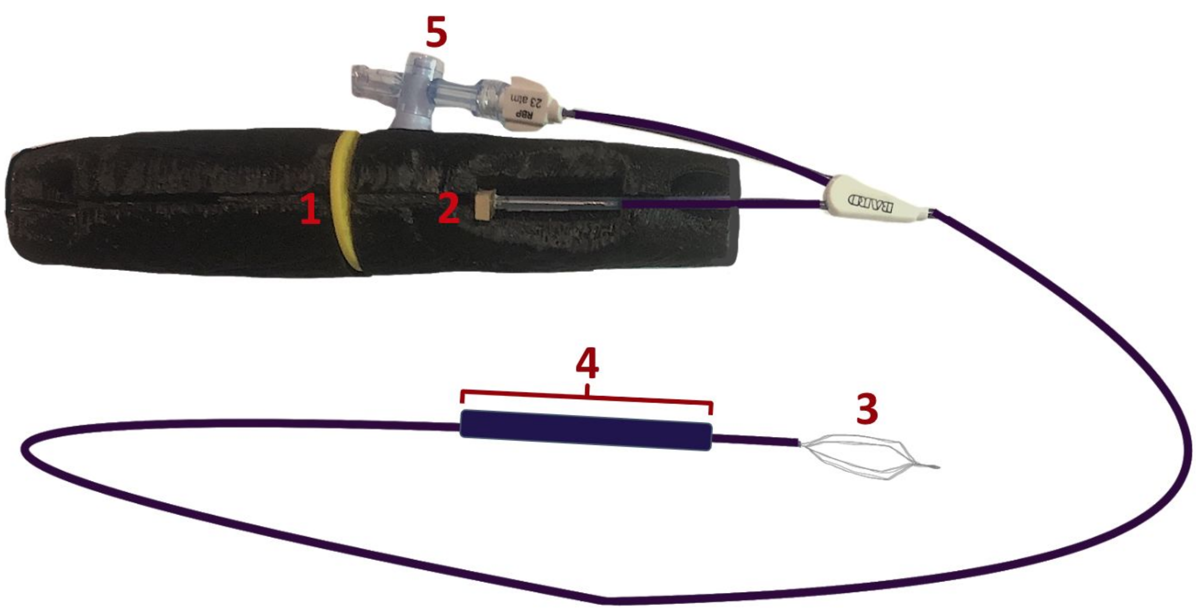

Figure 4. Prototype of PureRemoval. The design incorporates three main components: 1) Wheel-used to control rotation of basket 2) Slider-used to expand and contract the basket 3) Basket-made of nitinol and used to extract stones > 5mm or bring smaller stones into the ureter 4) Balloon- used to extract stones <5mm 5) Connection point for air syringe

Device Description

1. *Handle* - The handle is used as the primary interface between the urologist and the device.

1.1 Grip - The underside of the handle will have an ergonomic shape to comfortably rest in the surgeon's hand. This grip will allow the user to hold and control the device throughout the entire procedure and reduce muscle fatigue in extended procedures. This feature is not visible in Figure 3, but will be incorporated into the final prototype.

1.2 Wheel - A protruding wheel at the proximal end of the handle will be rotatable. This movement provides control of the basket through proportional rotation. The wheel can be rotated both clockwise and counterclockwise to accommodate for different stone orientations inside the body. The wheel is grooved to provide increased grip when the thumb is moved tangentially across the surface (Figure 4, part 1).

1.3 Slider - The sliding portion of the handle will control the expansion and retraction of the basket by manipulating plastic sheath surrounding the nitinol. The user's thumb will rest directly on top of the slider, which is embedded into tracks along the superior face of the handle. If the grooved slide is moved proximally, the connected sheath will move inward causing the basket to leave the sheath and expand, similar to current technology. When the slider is moved distally, the sheath can either completely cover the basket or partially constrict it to secure a kidney stone (Figure 4, part 2).

2. *Distal Basket* - The basket is used to remove kidney stones between 5 and 10mm in diameter (Figure 4, part 3).

2.1 Nitinol - The basket is made from nitinol, which is a Titanium-Nickel alloy known for its hyper-elasticity and flexibility. These properties allow the sheath to move completely over the basket without deformation or fracture. Upon retracting the sheath, the basket can expand and reorient into its original manufactured shape.

2.2 Shape - The basket head is made from four nitinol wires oriented in an overlapping, ovular, shape. The expanded diameter of the basket is 13mm. This will enable surgeons to entrap any stone less than 11 mm in width, which is the targeted range of our device.

3. *Balloon*- The adjustable balloon is the primary source of extracting kidney stones less than 5 mm in diameter (Figure 4, part 4).

3.1 Shape - The balloon is cylindrical in shape with a maximum diameter of 5mm. This shape prevents stones from slipping past the balloon as it is being pulled along the ureter walls and provides a safe stress distribution.

3.2 Polyethylene (PE) - PE is a lightweight, elastic, biocompatible polymer used in similar medical technologies, such as dilation balloons and catheters [12]. These properties will allow the device to inflate and deflate up to 5 mm on a patient to patient basis.

3.3 Air Syringe Connection Point - The device will be in the deflated state prior to insertion to the body. An air syringe connection point branching from the sheath is then used to adjust the size of the balloon based on the amount of air set in the syringe connected (Figure 4, part 5). Once in the extraction phase of the procedure, the balloon can be inflated to a pressure between 0-23 psi [13].

Stone Extraction Procedure Using Device

Similar to current basket designs, the proposed device would be inserted into the working channel of a ureteroscope. The ureteroscope and device would be guided through the urethra, bladder, and distal ureter via a ureteral access sheath. Once inside the ureter, the ureteroscope and PureRemoval would be inserted deep into the proximal ureter approaching the kidney.

Before this procedure even begins, the urologist would first detect the sizes of the stones, and would break down any stones greater than 10mm, by lithotripsy. Once all stones have been broken down to appropriate sizes (1-10mm), PureRemoval would be inserted and begin traveling towards the kidney. While traveling through the ureter, any large stones, obstructing the tube would be removed using the basket, and any stones less than 5mm in diameter would be gathered together (Figure 5 B) and removed using the balloon (Figure 5 C). To do this, the balloon portion of the device would be maneuvered upstream of the stones and inflated using the air syringe and internal valve on the handle. This inflation would seal the ureter walls and allow the urologist to pull the inflated device and ureteroscope out of the body, bringing any downstream stones along with it. This procedure would continue until the device makes its way to the kidney.

Once in the renal pelvis, the device's basket would be expanded using the slide on the handle to encompass a stone present in the kidney (Figure 5A). If needed, the urologist can use the wheel on the handle to rotate the basket into optimal position. The slider would then be used to contract the basket and secure the stone against the sheath. The entrapped stone and device would then be brought down into the lumen of the ureter for extraction. At this point, if the stone is less than 5mm, it would be released there for extraction using the balloon, and if the stone is greater than 5mm, it would be completely removed from the body by the basket. This procedure (Figure 5) would be repeated until all stones are out of the kidney.

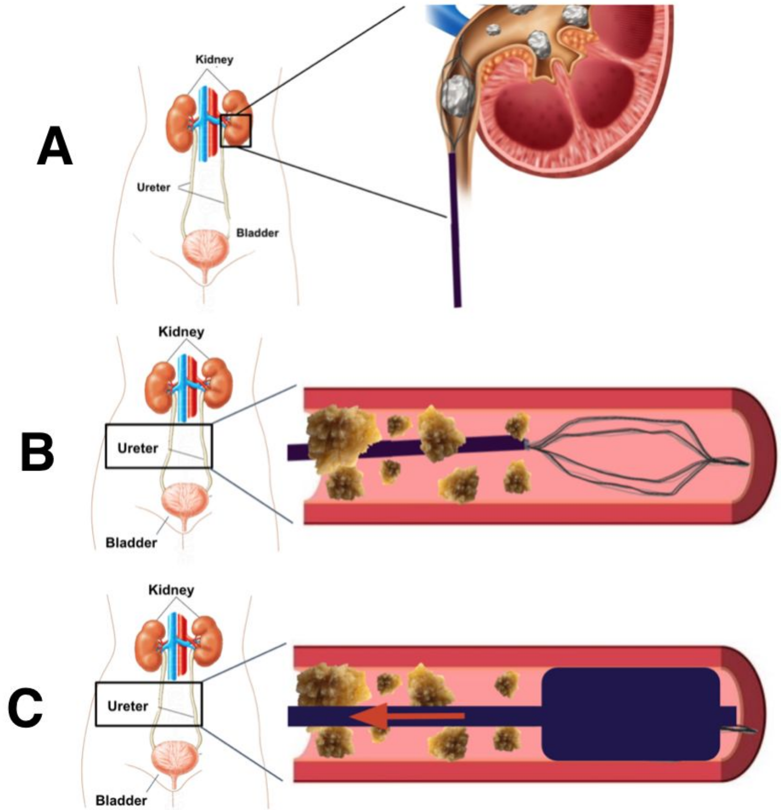

Figure 5. Procedure with PureRemoval. A) A large stone in the kidney being entrapped in the basket. This stone would then be removed entirely from the body. A stone <5mm would be entrapped in the same way and brought to the ureter for removal with the balloon. B) Stones <5mm in the ureter after being released from the basket. C) The balloon is inflated to seal the ureter and smaller stones are being forced out of the body as the device is pulled out.

Validation of Design

Upon completion of our prototype, the device was tested to ensure the objectives and functions were accomplished. To perform these tests, we created a mock kidney stone removal procedure using various materials. Three tests were performed which aligned with the three main steps of the extraction procedure. A survey of 20 participants was also conducted to assess the comfort and usability of our device.

1. *Testing Materials and Apparatus*

1.1 Ureter - Abrasion resistant polyurethane and translucent silicone were the two types of tubing used to model the ureter. Both tubings had an inner diameter of 5mm, which is the size of a dilated ureter [14]. While the mechanical properties of live tissue could not be simulated, the size of the tubing allowed us to test the functionality of our device on a 1:1 scale that accurately models the body.

1.2 Kidney Stones - Various types of small objects were used to simulate kidney stones. To model the inconsistent morphology of stones, a diverse array of objects between 1-10mm in diameter were acquired. Sprinkles, kosher salt, rock candy, plastic beads, and pebbles were the primary choice for testing and allowed us to model the calcium oxalate deposits found in patients.

1.3 Pathological Urinary System - Since kidney stones are often found in the ureter, several model stones were inserted into the plastic tubing to model a patient with this pathology. The tubing was ran under water to mimic the moist environment of live tissue. Up to five stones were then inserted into the tubing to prepare for testing. While these procedures use ureteroscopes to view the stones, the translucency of the tubing allowed us to conduct the tests manually.

2. *Validation Tests and Results* - Three tests were conducted to validate the functionality of our device. Each test was performed three times to ensure success. The results of these tests were binary, in the sense that the device could only pass or fail. While these results were qualitative, they still provide insight to the validity of our design. A full list results can be seen on Table 4.

2.1 Basket Functionality - To keep our device up to par with current technology, the basket on the distal end is used to entrap stones between 5-10mm in diameter. To test this, we assessed if the basket could expand out of the sheath, rotate via the wheel to an optimal angle, encircle the stone, and retract to secure. This test was successful in securing stones to validate the basket and inner mechanics of the handle.

2.2 Maneuvering in the Ureter - An important part of our modified extraction procedure is being able to move the device around stones inside the ureter. This movement allows the balloon to be upstream of the stones and in the correct position for inflation. Three stones between 1-5mm in diameter were successfully maneuvered past by the device.

2.3 Inflation and Extraction - Once the balloon was moved proximally past the stones in the ureter-tubing, it was inflated and pulled out of the body, bringing downstream stones out with it. The balloon was inflated with 0.8cc of air to occlude the tubing while still providing airflow. The test showed up to three stones could be removed per single extraction, which is advantageous compared to current procedures, which can only remove a single stone at a time.

Table 4. Validation Tests and Results. The three tests modeled the key steps in our modified procedure. “Success” implies the device was able to function properly and pass the validation test.

Validation Test	Result
Entrap stones between 5-10mm in diameter via the *Basket*	Success
Maneuver the device around stones inside the ureter	Success
Inflate the *Balloon* and extract downstream stones	Success

3. *Ergonomic Survey* - A 20 person survey was conducted to assess the comfort of the device. Since a urologist may have to hold PureRemoval for up to 90 minutes, we wanted to ensure minimal fatigue with an ergonomic grip. Participants were asked to hold the device, move the

slider and wheel, and rate their comfort on a scale of 1 to 5. A score of 1 means the participants were very dissatisfied, while a score of 5 indicates the handle felt ergonomic. A comparison was conducted by asking participants to repeat the survey while holding a competitor's device. Table 5 shows the average scores of both PureRemoval and the device from Cook Medical.

3.1 PureRemoval Survey Results - After holding PureRemoval and asked to scale its comfort from 1 to 5, the average score from 20 participants was a 4.6. The ergonomic shape and curvature allows for a comfortable grip around the device.

3.2 Cook Medical Survey Results - After holding a competitors device after holding PureRemoval and being asked to compare, the average score from 20 participants was 2.6. The small diameter of the handle led to an awkward grip around the device and was said to be uncomfortable by many participants.

Table 5. Survey Results of PureRemoval and Competitor's Device. 20 participants were asked to scale the comfort of both handles on a scale of 1-5. That score was then averaged for comparison.

Device	Average Score
PureRemoval	4.6/5
Cook Medical Extractor	2.6/5

Anticipated Regulatory Pathway

If we were to attempt to get FDA approval, PureRemoval would be classified as a Class II device posing only moderate risk to the patient. There are obvious risks associated with any technology that goes inside the human body, but our device certainly does not fall under the highest risk class. Our device would also require a 510(k) to show that it is substantially equivalent to predicated devices.

Analysis of 510(k) Pre-market Notification for Similar Device:

The pre-market notification analyzed was for the Wilson-Cook Mini Basket device - 510(k) number K182381 by Wilson-Cook Medical Inc 4900 Bethania Station Road Winston-Salem, NC 27105 as the applicant. The classification product code is LQR, meaning that the device is a biliary stone dislodger, falling under the category of biliary catheters and accessories. It was reviewed by the Gastroenterology/Urology panel, and has a regulation number of 876.5010, classifying it as a Class II device and identifying it as a tubular flexible device used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, or for preventing structure of the bile duct.

Substantial Equivalence:

The Wilson-Cook Mini Basket device is substantially equivalent to the Non-Lithotripsy Extraction Basket- cleared in March of 2018. These baskets have the same principles of operation, direct patient contacting materials, and fundamental technology. The main modification to the Wilson-Cook Mini Basket is the more specific intended use, the change in catheter diameter, and the dimensional changes to the basket. None of these changes raise any new questions of safety or effectiveness, therefore, it is substantially equivalent.

Summary of Device:

The Wilson-Cook Mini Basket is a single use basket which travels through the accessory channel of an endoscope. It is made out of metal wires in a helical design with a diameter of 5 Fr and a length of 182 cm. The catheter is made of Polytetrafluoroethylene and is 200 cm in length. The device was tested to demonstrate the basic performance of the device, and it was confirmed that the device is capable of removing biliary stones. The tests done were: tensile, functional, shelf-life, and stone and foreign body capture.

The FDA concluded that the risks associated with modifications made to this device from predicate devices were adequately addressed through the Design Control Process and do not affect the effectiveness of the device. Substantial equivalence was proved and the device received FDA approval.

The only differences that our capstone project might encounter during the process of receiving FDA approval would be to find predicate devices which use a balloon component. The basket design is very similar to that of current devices, so it will be simple to show equivalence, and the balloon design is also similar to those used in other procedures, however, we would have to prove the functionality of a balloon in the ureter. There are current devices which include balloon components in the ureter for dilation, we would just have to prove the intended use for biliary stone removal.

References

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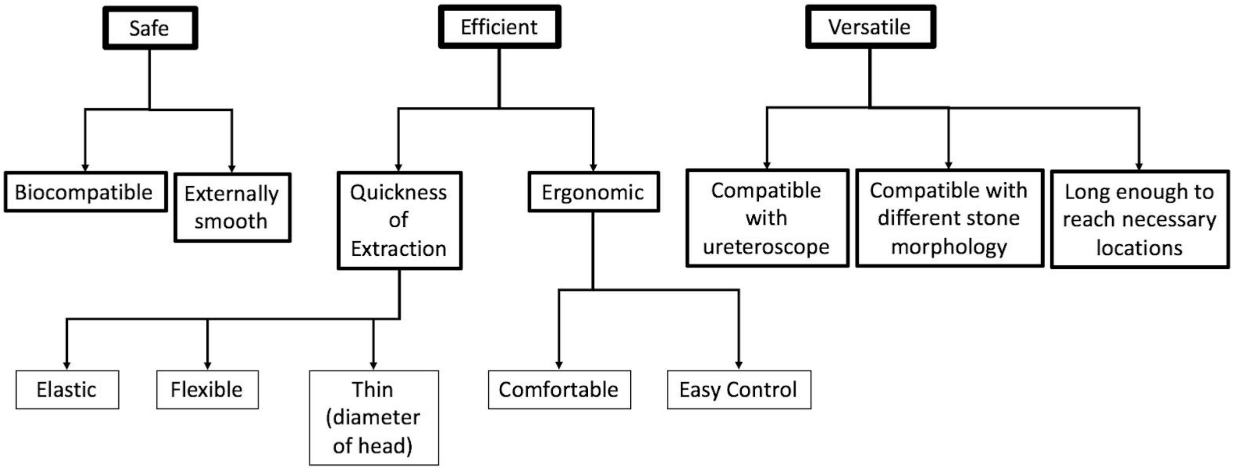
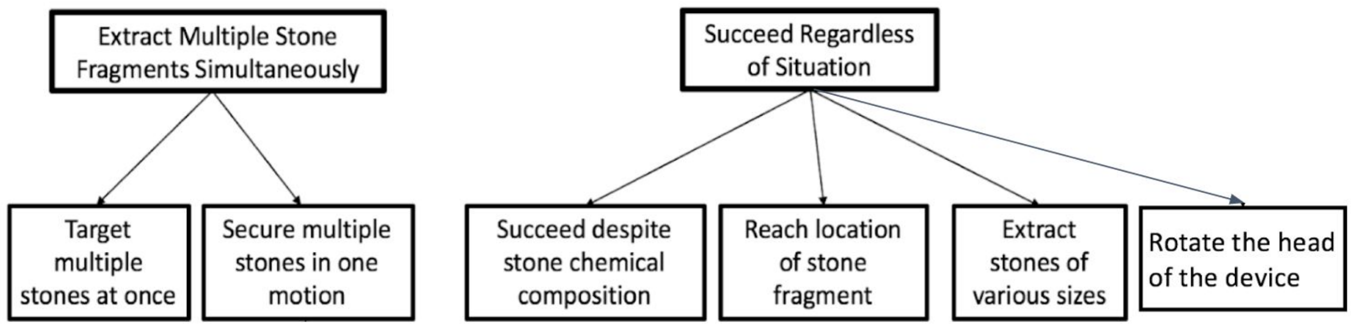
Appendices

Appendix A.



Design Objective Tree (A.1). A three level objective tree was created to outline the goals and objectives of our design.

Appendix B.



Function Tree Diagram (B.1). The tree above shows our two primary functions, with their associated secondary functions. We kept these in mind when deciding on our final design solutions and went over each function to ensure that our final solution will be able to successfully achieve each function.