DESIGN OF A WIRELESS URETEROPYELOSCOPE

by

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Declaration

I, Mkhokheli Ncube, declare that this thesis is my own work. Where material generated by other researchers is included, the parties and/or material are indicated in the acknowledgements or references as appropriate.

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Abstract

Ureteroscopy is a form of endoscopy that concerns itself with the urinary system. Flexible ureteropyeloscopes are instruments used to access the urinary system for diagnostic and therapeutic procedures. An average ureteropyeloscope requires a repair for every 3 to 13 hours of use, or alternatively 6 to 15 procedures. Therefore, there is a need to increase the durability of the ureteropyeloscope to lower the frequency of repairs required. In addition, the number of cables in the workspace needs to be reduced for improved handling by the clinician.

The present study details the design of an ureteropyeloscope, which is modelled after currently existing instruments. Current endoscopes use fibre-optics for lighting area of interest as well as image acquisition. However, the ureteropyeloscope discussed was developed with a camera at the distal end of the insertion tube as its image acquisition system. The images captured were transmitted to a monitor for viewing via a wireless transmission module. The ureteropyeloscope discussed in the study was aimed at increasing the durability of the deflection unit of the ureteropyeloscope, with primary component made of nitinol, and reducing the number of cables around the workstation by using wireless means to transmit images from image acquisition system to monitor.

The durability of the ureteropyeloscope was tested *in-silico* using CAD models developed using SolidWorks 2013. Durability tests were done for static loading and fatigue loading and the major test component being the tubular bending mechanism made of nitinol. For static loading four different loading set-ups were used for simulating loading on the bending sleeve. The loading set-ups were assumed to be offset axial, perpendicular loading, a combination of axial and perpendicular loading and torque loading. From the loading simulations it was noted that perpendicular loading caused the most amount of stress at the region of failure with 3.82 GPa, whilst the least was experienced by torque loading at 2.26GPa. In reality, these values of stress will not be reached because of nitinol phase transformation that would make it easier to deform."

For fatigue loading the damage undergone by the designed ureteropyeloscope after single use, which was assumed to be 1000 cycles, is 0.83%. This was 2.4 times more durable than previous designs discussed by Afane et al. (2000). For the designed ureteropyeloscope failure occurred after 12000 cycles which was a 100% increase in durability towards fatigue failure for the design discussed by Lei & Du, (2010).Compared with Afane et al. 2000 findings on durability the designed ureteropyeloscope is 4 times as durable because the Afane et al (2000) ureteropyeloscopes were assumed to failed at 3000 cycles. The fatigue durability of the ureteropyeloscope was doubled by the design discussed compared to currently used ureteropyeloscopes.

The wireless video transmission system was also developed to aid in the transmission of the captured images from the distal end of the ureteropyeloscope to the viewing monitor. A prototype of the wireless video transmission system was made to test the concept of wireless video transmission for the ureteropyeloscope. The developed prototype used the same concepts by different components to those specified for the final product. The wireless transmission of the images was successful with no noise due to wireless transmission. Real-time image transmission was achieved between the camera and computer screen.

Components manufacturability was tested through SolidWorks 2013 'Design for Manufacture module' (DFMXpress). The DFMXpress simulated how components could be made using a specified process with specified materials. Hence manufacturability was defined as assessment of the component design through a chosen manufacturing process. Manufacturability tests were run for all components and all components passed the test. However, some components, such as the steel cable connection system and irrigation-instrument channel connection system, were noted to require micro-scale manufacturing due to their size.

The bending sleeve had an increased fatigue durability theoretically compared to previous designs. The success in wireless video transmission meant that the number of cables around the workspace is reducible by using a wireless video system instead of fibre-optic based systems. Design components of the ureteropyeloscope were found to be manufacturable. The initial prototyping of the ureteropyeloscope was instrumental in specifying the materials used in the next prototype development with customised wireless circuitry, and components manufactured to design specifications.

Keywords: *Ureteropyeloscope, design, prototype, bending sleeve, simulations, wireless transmission*

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Chapter 1: INTRODUCTION

Endoscopy is a technique used by clinicians to visualize the interior of a hollow body organ (Baillie, 1992; Bosco et al., 2003; Ginsberg, Kochman, Norton, & Gostout, 2005; Mao, Feng, & Cheng, 2011). The visualisation helps clinicians with the observation of the organs to aid detection of any abnormalities in the organs or diseases that may affect them. Endoscopy has been increasing especially in the abdominal region, for diagnosis or for intervention procedures because of its minimally invasive nature (Bosco et al., 2003; Botaitis et al., 2012).

The advances in technology have seen both the medical profession and patients gaining more confidence in the use of the endoscopy. This has been due to the compactness of the endoscopes, which has made them less invasive. Patients have gained even more confidence on endoscopy since the inception of disposable endoscopes (Croffie et al., 2005). Endoscopes have grown in their popularity because they can access areas in the human body which were previously deemed inaccessible. This feature provides the endoscopes with a great potential for use in surgical procedures. Another bonus with endoscopic procedures is that the patients have shorter hospital stays, and the rate of complications after the procedures are reduced in the case of laparoscopies cholecystectomy (Botaitis et al., 2012).

Ureteroscopy is an endoscopic procedure which is undertaken to help treat people with urological diseases (Lei & Du, 2010). It is concerned with the endoscopic treatment of the urinary system that includes the kidneys, the renal pelvis, the ureter, the bladder and the urethra. Bagley (1987) describes ureteroscopy as a “retrograde endoscopic procedure with an endoscope passed through the lower urinary tract into the ureter and calyceal system”. The term pyelo means renal pelvis (Terris, Cherukuri, & Jadick, 2013). Hence, ureteropyeloscopy is the endoscopic procedure to treat urological diseases within the renal pelvis and Figure 1 shows a picture of an ureteropyeloscope.

Figure 1: A typical flexible ureteroscope ("Northwoods Urology," 2013).

Ureteropyeloscopy is used in two ways. Firstly, to visualise the urinary tract or parts thereof for diagnostic purposes. In this case, the ureteropyeloscope is inserted into the urinary system to diagnose a diseased region or to inspect tissues. Secondly, the ureteropyeloscopy is used for intervention procedures or therapeutic procedures, whereby the ureteropyeloscope and its accessory instruments are used to aid a surgical procedure being carried out. These procedures vary from kidney stone removal to biopsies. In the case of intervention procedures, the clinician would require prior knowledge of what the patient's problem is foregoing the procedure, what they are looking for or wanting to achieve.

1.1 Problem description

Proper diagnosis of diseases and infected areas using ureteroscopic procedures depend on three aspects of the ureteropyeloscope. The first aspect is the imaging system upon which the image quality and clarity of area being viewed relies on. The second aspect is the bending mechanism of the ureteropyeloscope that governs the active bending and the flexibility of the ureteropyeloscope to navigate torturous anatomy as well as the guiding of the image acquisition system at the tip of the ureteropyeloscope to the area of interest. The last aspect is the presence of accessory channels, which are used for the passing of irrigants and accessory instruments to the distal end of the insertion tube. The instrument and irrigation channels may be combined in a single channel in some in some ureteropyeloscopes and separate in others.

Lei & Du, (2010) state that a repair of an ureteropyeloscope is required after 6 to 15 procedures or 3 to 12 hours for an ureteropyeloscope. A study by Afane et al. (2000) shows that for an average ureteropyeloscope, a repair is required between every 3 to 13 hours of use and they claim that the most fragile part of the ureteroscope is the deflection unit. Furthermore, Afane et al. (2000) state that the active deflection was seen to deteriorate by between 2% to 28% after consecutive uses. This implies that if any other parts do not fail, the ureteroscope will be used for between 4 and 50 procedures. The repairs of ureteropyeloscope “due to poor or complete loss of deflection” constitute a large percentage of repairs, 40% of repairs according to Afane et al., (2000).

The length of an average intervention procedure was assumed to be 2 hours. The bending section of the ureteropyeloscope was also assumed to undergo 1000 cycles of deflection during intervention procedures (assuming the clinician uses the angulation system every 10 seconds for navigation). The hours of use of the ureteropyeloscope per surgery and hours of use of the ureteropyeloscope between two consecutive repairs show that some ureteropyeloscopes may be used once between two consecutive repairs. Increasing the number of cycles the deflection unit can endure increased the durability of the deflection unit. Therefore, an increase in the durability of the deflection unit reduces the need for frequent repairs due to the damage to the deflection unit.

The mode of failure of the deflection unit is not discussed in literature and it was assumed that it was due to either static or fatigue failure of the actual bending mechanism. With that assumption, the design and tests, which were done to address the issue of durability, were approached from the static and fatigue loading of the bending sleeve, which is the major component that facilitates the bending of the ureteropyeloscope. The study at hand focused on the design and testing of the bending mechanism of the ureteropyeloscope.

The image transmission system used for ureteropyeloscopes is based on fibre-optics technology. These image transmission systems must be used in conjunction with lighting bundles, which provide lighting for the area of interest. The light is shone on the area of interest, reflected from tissue and is then picked up by the fibre-optics and transmitted to the monitor for viewing. The connection between the image acquisition device at the distal end of the insertion tube and the monitor is through fibre-optic cables and requires a separate light cord (Buscarini & Conlin, 2008).

The cables for light and image transmission present a problem in the handling of the ureteropyeloscopes, as there are other cables and pipes in proximity. The other cables close by are for the irrigation channel and instrument channel (if it is separate from the irrigation channel). Reduction of the number of cables around the workspace makes the handling of the ureteropyeloscope comfortable.

The study at hand aimed to design and develop a flexible ureteropyeloscope with improved durability, and decreased number of cables around the workstation. The components specified for the design had their manufacturing processes simulated *in-silico* in SolidWorks 2013 using methods that were applicable to produce them. An increase in the durability of the ureteropyeloscope will help in the reduction of the frequency of repairs over time or increase the number of procedures undertaken between repairs.

Reduction of repairs implies that the ureteropyeloscope is available for use more compared to ureteropyeloscopes that need frequent repairs. Other benefits of increasing the durability of the ureteropyeloscope are the direct decrease in the cost of repairs over time whilst increasing the number of uses between repairs lowers the cost of repairs per use, and in turn, this helps in saving running costs of the procedure.

1.2 Significance of problem

A continuous improvement of surgical instruments is necessary to address the issues and problems current instruments have. The current ureteropyeloscope have low durability (needing repairs for every 6 to 15 undertaken) that influences the number of repairs, and use fibre-optics, which relies on a physical cable to transmit light and captured information, and their presence does not give optimal handling of the ureteropyeloscope. The ureteropyeloscope discussed here aims to increase the durability of the bending mechanism responsible for the insertion tube angulation and improve the user experience of handling the ureteropyeloscope by using a wireless system for image transmission to the monitor.

Improved durability means lowered maintenance costs for a given time and more availability of the ureteropyeloscope. On average an ureteropyeloscope is used between 6 to 15 procedures or 3 to 12 hours before it requires repairing and maintenance (Lei & Du, 2010). The most durable ureteropyeloscopes last for 25 procedures before repairs are necessary (Buscarini & Conlin, 2008) and if durability of the ureteropyeloscopes is increased, need for repairs would decrease. Durability does not solely depend on the bending mechanism or deflection system only, but also on other factors such as the irrigation channel and user handling (Landman & Clayman, 2003). However, increasing the durability of the bending mechanism is likely to increase the durability of the whole ureteroscope because according to Afane et al., (2000) forty percent of repairs of ureteropyeloscope are "due to poor or complete loss of deflection" by the bending mechanism.

The ability to change the insertion tube of an endoscope increases its efficiency, whether it is disposable or must be sterilised separately from the control section before next use. With respect to disposability, being able to detach the insertion tube from the control section implies that the clinicians can dispose of fewer parts, hence saving on non-disposed parts. Concerning sterilisation, if the insertion tube is detached from the control section, it can then be taken to be sterilised because of contact with the patient whilst the control section is cleaned quickly, sterilised and reused separately. This would help deal with delays associated with cleaning and sterilisation of the ureteroscopes described by Oskin, Maclean, Asselin, Obrien, Zappia, (2013). Similar modularised designs for endoscopes may be transposable for robotic surgical instruments.

A market need for locally manufactured medical devices exists in South Africa due to the increase in endoscopy use in emerging economies. As South Africa develops, more people would become richer and be able to afford healthcare and endoscopy facilitates quicker procedures with shorter hospital stays. Confidence gained in endoscopic surgeries primarily due to the minimally invasive nature would translate into an increased need for endoscopic equipment within South Africa as it is counted among emerging economies ("Flexible endoscopes market outlookin BRICS to 2017," 2012). The expertise of the design and production of the endoscopes is very important because it enables the local manufacture of endoscopes. Locally manufactured endoscopes are likely to be cheaper because of elimination of extra costs such as import and duty costs. Another benefit for a locally based market is employment creation and money saving by eliminating import duty and transport costs. Therefore, the study is a part of a bigger picture, which is a quest for developing locally manufactured surgical devices.

The ideas contained within this project addresses issues of durability of the ureteroscopes used in urology intervention procedures. These ideas are exportable to other fields of endoscopy such as gastroscopy, colonoscopy and so on. It is also desirable to increase the durability of all other forms of endoscopes. Hence, ideas and methods discussed here to increase accessibility and durability could be used also as stepping stones in other areas to make the endoscopes smaller. Therefore, the problem being tackled here can be taken as a model problem for general endoscopies at large.

The minimally invasive nature of endoscopies means that the procedure has fewer and/or shorter incisions made by the clinician. This means that patients can recover more quickly than those who undergo open surgery. Faster recovery implies that patients have shorter stays at the hospital after the procedure. According to Lei & Du, (2010), patients are able to go home after one or two days after the procedure. This is very important in two ways. One, it helps the patient save money due to a shorter stay at the hospital (assuming that endoscopies cost the same as open surgeries) and two, this means that the hospital can attend to more patients. Therefore, research in the field of endoscopy to further knowledge and improve designs is necessary.

Endoscopic procedures have lower rates of complication after the procedure is undertaken compared to open surgeries. This is the result of the fact that endoscopies are less dangerous and less invasive. Thus, less money is spent treating complications resulting from initial surgery, and less time is spent dealing with the complications. Therefore, it can be concluded that endoscopies are more efficient than open surgeries in terms of time and money (Botaitis et al., 2012; Lei & Du, 2010).

1.3 Objectives of the study

The main objective of the study is the design and development of an ureteropyeloscope and the assessment of its manufacturability. The study focuses on the design and modelling of an ureteropyeloscope with specific objectives that are:

1. Designing and testing a bending mechanism to increase the durability of the ureteropyeloscope. The main test component being the NiTinol tubular structure which controls the bending mechanism
2. Designing a wireless image transmission system to decrease the number of cables around the working station
3. Assessing the manufacturability of the components of the ureteropyeloscope

The design, modelling and manufacturability study of the ureteropyeloscope provides the information required to ascertain the feasibility to make ureteropyeloscopes and it also highlights the challenges faced throughout the process within South African. The ureteropyeloscope is benchmarked using currently existing endoscopes, and user requirements and desired improvements acquired from a clinician, a frequent endoscope user. A prototype was developed to aid the study of the design and assess manufacturability.

Increasing the durability of the angulation system would increase the durability of the ureteropyeloscope. The designed angulation system underwent *in-silico* tests to verify that the design met the requirements and to test for increase in durability. However, the prototype of the ureteropyeloscope did not allow for the testing of the angulation tube because the focus of the prototype was on development of a wireless video transmission system.

The reduction of the number of cables was done was through introduction of wireless transmission of the video. The study focused on the feasibility of using the wireless transmission method for ureteropyeloscopes in conjunction with using CCDs rather than fibre-optics for transmission. The possibility of using different cameras was explored and technological advantages and downfalls of each compared. Choices of different transmission methods were investigated and the one deemed most appropriate for application was chosen.

1.4 Limitations of the study

Modelling and simulations of components was done using SolidWorks 2013 Student Edition. This package did not have some modules, for example, the SolidWorks Simulation Premium that enables more accurate modelling for nonlinear materials such as the NiTinol used for the bending sleeve. The bending simulations done on the nitinol bending sleeve are done using linear materials and are not as accurate as using the actual nonlinear properties of the nitinol.

Manufacturing technology required to manufacture or assemble some of the parts of the ureteropyeloscope were beyond the financial means of the project. Some parts required micro-scale production for full functionality but since this was the first stage of the design, a cheap substitute method was used. Manufacturing of medical grade devices requires adherence to strict standards about the manufacturing environment, particularly for invasive medical devices such as the one being developed.

Phantom trials to validate the image quality captured by the image transmission system were not carried out. The development stage at which the design of the ureteropyeloscope is on did not allow for the phantom trials to be carried out. This was due to the mechanical design, which was limited by prototyping means, not being fully functional. However, the phantom trials were deemed necessary in the validation of the image quality and the navigation of the ureteropyeloscope up the anatomy.

Chapter 2: LITERATURE REVIEW

Patients have gained confidence in endoscopy due to its minimally invasive nature (Botaitis et al., 2012; Croffie et al., 2005; "Endoscopy will become one of the fastest growing sectors in the medical device industry," 2012). The increase in the patient base of endoscopy has resulted in the rapid growth in the use endoscopy and has been regarded as the fastest growing medical device sector ("Endoscopy will become one of the fastest growing sectors in the medical device industry," 2012). One of the reasons of the increase of use of endoscopy is claimed to be treatment of age-related disorders such as cancer and arthritis as the report by Global Data points ("Flexible endoscopes market outlookin BRICS to 2017," 2012). The same report also states that mortality rate can be reduced by up to 90% due to early disease screening using endoscopes.

It is important for a developing country like South Africa to take advantage of gaining knowledge of the workings of endoscopes and move to manufacturing its own. This would have many benefits including employment creation, shorter turnaround times for repairs, decrease in the money spent on imports, and probably increase in better healthcare. This chapter is concerned with research on currently used endoscopes, ureteroscopes in particular. It seeks to present information found on best design practices of ureteroscopes, interpret them, and define how they are applied to the objectives of the study at hand to generate a solution.

2.1 Kidney stone access

Flexible ureterorenoscopes, as Bach, Geavlete, Herrmann, and Gross (2008) calls them, could offer "access to almost every point within the collecting system". This is very important because kidney stones may occur at any point along the urinary system. Unlike nephrolithotomy, (shown in Figure 2 next page) flexible ureteroscopes do not make any incision on the kidney tissue to access the calyceal system but rather the access to the calyceal system is via the ureter. Nephrolithotomy offers access to the calyceal system via an incision made on the kidney tissue ("Stone Disease Minimally Invasive Stone Surgery," 2013).

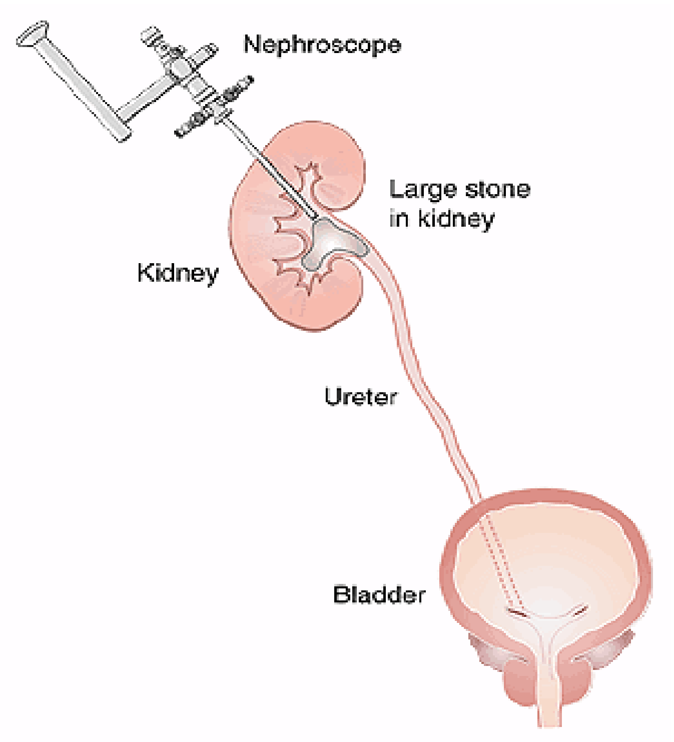


Figure 2: Nephrolithotomy illustrating the nephroscope accessing the kidney stones in the pyelum ("Stone Disease: Minimally invasive stone surgery," 2010)

The insertion tube (part of the ureteroscope that accesses the patient) is introduced into the patient via a cut made on the belly button, which is a natural orifice. Another cut is then made on the bladder to enter the bladder. Once the tip of the insertion tube is in the bladder it is navigated towards the ureter, where it is introduced and pushed up. Once the tip is in the ureter, the insertion tube is pushed in to access the calyceal system, or wherever the kidney stones maybe located. Figure 3 illustrates the insertion of a flexible ureteroscope juxtaposed to the use of a rigid ureteroscope ("Urology: Ureteroscopy," 2010).

The distal end of the insertion tube has been introduced all the way to the renal pelvis and a kidney stone located ("Urology: Ureteroscopy," 2010). Prior to use of flexible ureteroscope (shown in use in Figure 3a), rigid ureteroscopes were used and an example of such ureteroscope is shown in Figure 3b accessing a stone in the ureter. The rigid ureteroscope is introduced into the ureter via the urethra past the bladder in a similar way mentioned for the flexible ureteroscope. This procedure is highly uncomfortable as it forces the anatomy to accommodate the instrument and that is why flexible ureteroscopy is preferred over rigid.

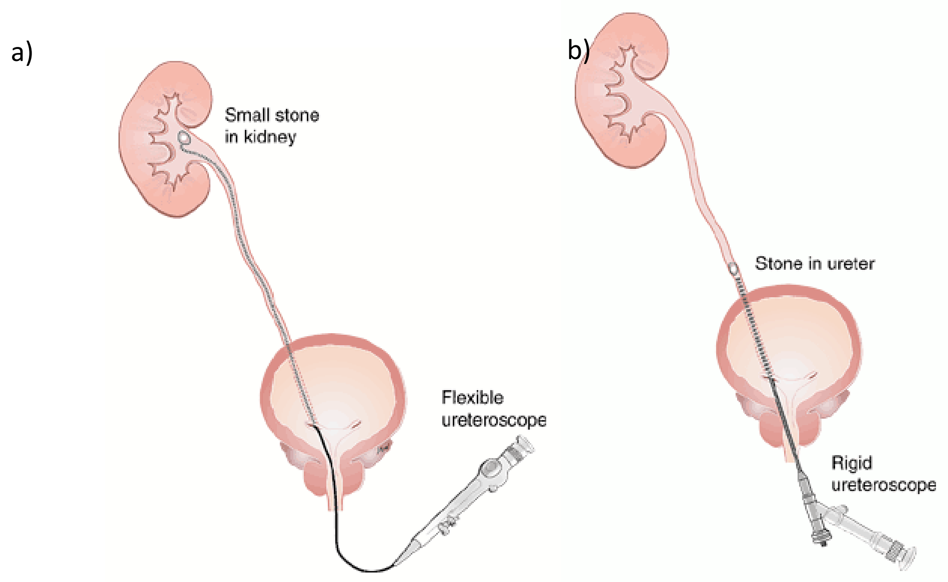


Figure 3: Illustration of access of the urinary system by a) flexible ureteroscope and b)rigid ureteroscope both via bladder ("Urology: Ureteroscopy," 2010)

The ureteroscope has either light bundles or LEDs on the distal tip to illuminate the internal structures to find where the ureter is. If a clinician accesses the bladder via the urethra with no incisions, the procedure is called cystoscopy and not ureteroscopy (Pilcher, 1911). This procedure concerns itself with examination of the urethra and bladder only.

For flexible ureteroscopes, the navigation of the insertion tube into the urinary system relies on the size of the insertion tube, image quality to direct navigation, flexibility of the tube, and torqueability of the insertion tube. If the size of the insertion tube is larger than the ureter, it means that the dilation of the ureter is required. This causes the procedure to take a longer time than when no dilation is needed. A good image is required to navigate the insertion tube in the urinary system. Neglecting dilation and having a poor image system may result in trauma. Flexibility is necessary to facilitate the tube to navigate the winding anatomy.

According to Ginsberg et al. 2005 torqueability assists in making sure the thrust forces exerted are effected to the distal end, as well as ensuring that a twist in the proximal end is carried all the way to the distal, producing a one-to-one twist ratio. The discussion of torqueability carried out by Ginsberg et al. 2005 is for gastrointestinal endoscopes, however, the same torque transmission is required for ureteroscopes as well (Ginsberg et al., 2005).

The ureter is the defining feature in the urinary system of how big the insertion tube can be. This is because the ureter is the smallest anatomical structure in terms of diameter in the urinary system. The mean diameter of the ureter is taken to be 3.4 ± 0.61mm, whilst the range of the diameter is from 1.9mm to 5.3mm (Song, Cho, & Kim, 2010). Song et al., (2010) also state that a previous study had found that the mean diameter was 1.8 ± 0.9mm and this may be attributed to the "variations in measuring the exact diameter of the ureter in its course of peristalsis". Inserting a big insertion tube requires dilation of the ureter prior to insertion, otherwise the ureter may undergo trauma.

The length on the insertion tube is also dependent on the route taken (whether inserted via urethra or straight to the bladder), length of the ureter and all the other urinary system parts such as size of bladder. The ureter is the longest and most significant part in terms of how long the insertion tube can be. According to Song et al., (2010) the mean length of the ureter is 226.8 ± 20.8 mm. The range of length varies from 175mm to 286mm (Song et al., 2010). To be able to access the whole urinary system, the length of the insertion tube must then be longer than the anatomy to ensure reach of all anatomy involved.

The location of the kidney stones affects the use of the ureteroscope. If the kidney stones are located in the ureter, there is hardly any need for active instrument deflection to access the kidney stones whilst if the stones occur in the lower pole calyx of the kidney active deflection and even secondary deflection is mandatory (Bach et al., 2008). Secondary deflection is the bending at a second site controlled by the clinician.

2.2 Mechanical properties of ureteroscopes

Ureteroscopes are surgical precision instruments because the space they function in is very small. The ureter is not more than 5.5mm in diameter and any damage caused to the tissue will cause patient discomfort. Size and control of the distal end of the instrument used is very critical for optimised functioning of the ureteropyeloscope. These two properties help influence the design and technology applied in the development of the ureteroscope.

The mechanical properties of ureteroscopes govern the efficacy and the efficiency of the procedure. A study done by Grasso and Bagley (1998) to compare different ureteroscopes was instrumental in identifying important properties. Table 1 shown on the next page shows the properties compared by the study. The important characteristics noted were diameter of the insertion tube, length of the insertion tube, size of the working channel/instrument channel, irrigation channel (in some cases the working channel is used for irrigation) and most importantly the achievable deflection.

Table 1: **Specifications of ureteropyeloscopes used in study by Grasso and Bagley.** (Grasso & Bagley, 1998)

	Storz 11274AA	Olympus ACMI AUR 7	Wolf 7325.171	Mitsubishi 971101	Olympus URF-P2Y
Diameter (Fr)					
Distal end	7.5	7.4	7.5	7.9	6.9/8.4
Body	8.2	7.5	7.5	7.9	8.4
Optics					
Field of view(deg)	70	80	60	70	90
Angle of view(deg)	0	12	0	0	0
Focus depth (mm)	2-50	2-50	3-30	3.5	1.7-50
Optical bundle	Standard	Standard	Fused-quartz	Fused-quartz	Standard
Pixels/bundle	3000	3400	5000	6000	5500
Working channel diameter (Fr)	3.6	3.6	3.6	3.6	3.6
Deflection					
Active(down/up)	170/120	160/120	160/130	134/170	100/180
Logical	+	+	+	+	-
Secondary	+	+	+	+	+

A study done by Buscarini and Conlin (2008) provides an update of currently available ureteroscopes. Table 2 shows primary characteristics of an ureteroscope drawn up by Buscarini and Conlin (2008) which verifies the importance of characteristics chosen by Grasso and Bagley (1998). The three major classifications that the properties mentioned fall into are (1) size of insertion tube, (2) deflection of the active tip and (3) the viewing of the area of interest. It can be inferred from these studies that these classifications are the critical ones for the design of ureteroscopes.

Table 2: Mechanical properties of some of commonly used ureteroscopes adapted from Buscarini & Conlin (2008).

Model of ureteroscopes	Distal end diameter	Length of insertion tube	Working channel	Irrigation	Deflection
Invisio ® DUR ®-D Digital Flexible Ureteroscope	3.1mm	65cm	3.6Fr (1.2mm)		
DUR®-8 Elite	8.7Fr insertion tube that has two locations of active deflection.	64cm which is smooth and lubricious for ease of insertion	3.6Fr made smooth and lubricious for ease of instrument insertion	Same as working channel but only when using a 3Fr instrument	
DUR®-8	8.7Fr which is bevelled at the tip (6.8Fr) for smooth insertion and no dilation needed	65mm cable deflection compensation	3.6Fr with lubricious surface for ease of passage for instruments		
AUR™-7	7.5Fr diameter which gradually increases to 11Fr.	65cm with has dual active deflection	3.6Fr	Simultaneously used with the working channel	160 down 120 up

Studies done by Abdelshehid et al., (2005) and Chiu et al. (2003) sought to outline the differences between deflection, irrigation and optical characteristics of some ureteroscopes that were commercially available at the time of their study. Similar to studies by Grasso and Bagley (1998) and Buscarini and Conlin (2008), the studies by Abdelshehid et al. (2005) and Chiu et al. (2003) also have detailed specifications of ureteroscopes used. Abdelshehid et al. (2005) measured and compared the following properties in endoscopes of the same generation: (1) deflection of the active deflection, (2) irrigation flow rates, (3) distortion of the images captured, (4) resolution of the images and (5) light transmission for illumination of the area of interest. Chiu et al. (2003) compared "new flexible ureteroscopes with prior models to determine whether engineering" advancements had overcome problems of smaller working channels impairing irrigant flow.

The dimensions of the distal end of the insertion tube are usually given using the French scale, which is used mostly for endoscopes and catheters. According to this scale, 3 French units make up 1 mm (Foster, 2002). Using this ratio it can be seen from Table 1 that all the ureteroscopes have a distal end diameter less than 3mm, which is very small for incorporating a camera but large from a ureter size point of view.

2.2.1.1 Bending properties

The active bending of the distal end of the insertion is important to facilitate the access to otherwise inaccessible regions of the calyceal system. To access the calyx of the lower pole, a secondary bending mechanism is implemented (Bach et al., 2008). The secondary bending mechanism is achieved by the tube passively buckling at a set point as the primary active bending mechanism reaches its maximum bending angle (Rajamahanty & Grasso, 2008).

There are currently ureteroscopes that can bend up to 270 degrees at a single point in either direction (Abdelshehid et al., 2005; Rajamahanty & Grasso, 2008). This means that there is no need for secondary bending as the active primary bending meets the required angle for bending. However, having secondary bending which can be actively controlled like the one found in a patent by Grabover et al. (2004) means that the ureteropyeloscope has more agility to reach even anatomical regions which require highly specialised bending (Grabover et al., 2004). Figure 4 on the next page shows the modes of bending available for the patented ureteropyeloscope. This also introduces more parts for the new mechanism and increases the size of the insertion tube. The trade-off between the specialisation and size is a critical and for the study at hand, a smaller size is preferable.

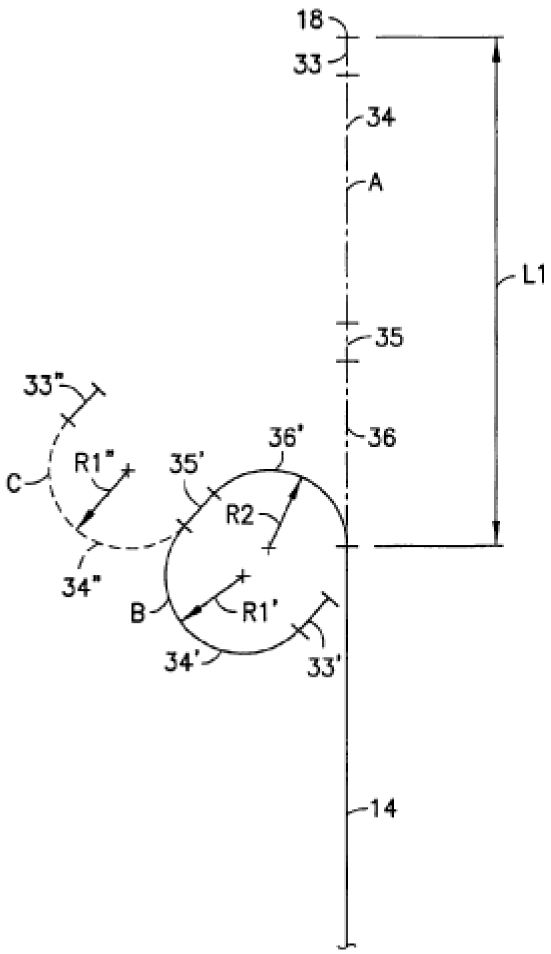


Figure 4: Primary and secondary active deflection with the primary deflection in two directions (Grabover et al., 2004).

2.2.1.2 Irrigation channel and accessory instruments

Accessory instruments are critical in intervention procedures and their use is inevitable, hence necessitating a need for an instrument channel. Bach et al. (2008) through their study on working tools in flexible ureteroscopes imply that in some cases the accessory channel has a dual purpose, also being used as an irrigation channel. Use of accessory instruments results in diminished irrigation flow rate; and this might impair the vision for optic-fibre based visualization systems for the ureteroscope. In addition, when an accessory instrument is used there is a loss of deflection in the ureteroscope and this might impair the ability of the clinician to reach certain points of the urinary system.

The ureteroscope is used with accessory instruments in some cases of intervention procedures. These accessory instruments aid the procedure by providing extra functionality to the ureteroscope, which it does not have inherently. Accessory instruments have a range of functions, ranging from aiding in the dilation of the ureter to carrying out procedures, such as biopsies, and also being used as retrieval devices after a biopsy is carried out (Baillie, 1992; Somogyi et al., 2007).

According to Somogyi et al. (2007), guide wires “are used to achieve or maintain access to a lumen or cavity and to facilitate advancement of various devices”. Their application is in both diagnostic and therapeutic endoscopy. There are differences in the guide wires used for gaining access to a lumen and those used to advance devices such as stents and dilators, amongst many devices. The insertion tube must be able to take into account the fact that there are different types of guide wires. For example, there are ones for gaining access and others for device advancement. Access guide wires have slippery and flexible tips to avoid perforating the anatomy, whilst the advancement guide wires work best when they are stiff and taut, to minimise lateral deviation (Somogyi et al., 2007).

Lithotripsy is a medical procedure used to break down stones in the kidney, bladder or ureter, by using shock waves. The stones are then passed out of the body in urine by the patient. Lithotripsy uses a lithotripter, which is the device that directs the shock waves at a stone to break it down. A lithotripter is a very important accessory device because some kidney stones cannot be retrieved from the kidney due to their size. Hence, breaking them down into smaller pieces for the stones to pass in urine is the best treatment. It is necessary that the ureteropyeloscope is able to accommodate the use of a lithotripter. Intracorporeal lithotripsy is by far the most common ureteroscopic procedure according to Rajamahanty and Grasso (2008).

Endoscopic retrieval devices are used to aid removal of objects from the area of working. The objects needing removing are polyps and foreign bodies. Devices used to carry out the removal include forceps, graspers, baskets, snares, and nets. The choice of which device is used depends on the size and shape of the object being retrieved (Diehl et al., 2009). Even though Diehl et al., (2009) discuss retrieval devices for gastrointestinal endoscopy, the same principles apply in ureteroscopy. Retrieval devices are designed to pass through the channel of the endoscope and the channel sizes between gastrointestinal endoscopy and ureteroscopy are different. The size of the retrieval devices available also dictates the size of the insertion tube because the devices pass through the channel in the insertion tube.

2.3 Durability of Ureteroscopes

2.3.1 Repair and maintenance

The effectiveness of ureteroscopes has benefited from miniaturization due to technological advancements, but the fragility of ureteroscopes has also increased due to the miniaturization. Increase in fragility (decrease in durability) results in high cost of repairs. One of the most common causes of failures in flexible ureteroscopes is the damage of the working channel by the ureteroscope accessories (Buscarini & Conlin, 2008). An experimental model of studying the physical damage incurred by the working channel developed by Seto, Ishiura, Egawa, Komatsu and Namiki (2006) concluded that insertion of working instruments should be done with great care, as the working channel may be damaged through the process of insertion (Seto et al., 2006).

Table 3: Table sowing repair costs for flexible ureteroscopes

Manufacturers' specifications of flexible ureteroscopes						
	ACMI DUR-8 Elite	**Storz 11278A Au**	**Storz 11274A Au**	**ACMI Dur-8**	**Wolf 9F**	**Olympus URF-P3**
Warranty period (yr)	1	1	1	1	1	1
Cost of repair of deflection (USD)	550	500	500	550	4,195	5,965
Time to repair deflection (days)	2	7	7	2	1	2
Cost of repair of optics (USD)	5,900	5,850	3,995	5,900	4,195	5,965
Time to repair optics (days)	1	1	1	1	1	1

Repairs and maintenance of flexible ureteroscopes depends on the care the clinician takes when using the ureteroscope. Repair costs differ between manufacturers and depend on the damage incurred. The most expensive component to repair is the fibre optic component (Chiu et al., 2003). This may be because slight damage to fibre-optic cable renders the component unusable due to reliability required by ureteroscopes. The cost of repairs of the deflection mechanism, according to Chiu et al. (2003), ranged from US$500 to US$5,985 while the costs of repairing the fibre optic component range from US$3,995 to US$5,985 over year. Table 3 shows a table adapted from the study by Chiu et al (2003) with costs of repairs.

According to Afane et al., (2000), 40% of repairs of the ureteropyeloscopes were "due to poor or complete loss of deflection" because the most fragile part of the ureteroscope is the deflection unit. The ureteroscopes used in the study by Afane et al. (2000) were the same as those used by Chiu et al. (2003) and the results showed that the repairs of these ureteroscopes is required after 6-15 uses only. However, a study by Landman et al. 2003 states that 70% of repairs were for the working channel and this was caused by user error such as improper application.

Reviewing the foregoing literature on the important characteristics of the ureteroscopes, it is evident that the two most important characteristics that affect durability are the deflection unit and the working channel. Increase in the durability of the deflection unit would result in fewer repairs due to poor or loss of deflection. On the other hand, the repairs caused by damage to the working channel can be lowered by training of clinicians on proper use of accessory instruments to minimise user error.

2.3.2 Current bending mechanisms

There are two types of flexible ureteroscopes, passive deflectable and active deflectable ureteroscopes according to Bagley (1987). The differences in the two are in the amount of area accessed, fragility and cost. Generally, passive deflectable ureteroscopes access less areas of the urinary system ("viewing only portions of the ureter renal pelvis and in some cases the upper part of the infundibula"), are more robust, and less expansive. On contrary, active deflectable ureteroscopes have the capability to gain access to the entire urinary system, are more fragile and more expensive (Bagley, 1987).

There are two ways in which the ureteroscope deflects in the urinary system. One way is passive deflection in which the ureteroscope is guided by the anatomy. The second way is the active deflection whereby the clinician using the ureteroscope can dictate the tip movement via cables connected to a knob or a lever. Lei & Du, 2010 state that active bending is controlled bending whilst passive bending is induced bending. They classify bending into three distinct categories: primary active, secondary active and secondary passive bending. Secondary active is “achieved by the endoscope passively buckling at a particular designated point along the shaft” due to primary active bending (Rajamahanty & Grasso, 2008).

Adding the function of being able to actively deflect an endoscope expanded the use of ureteroscopes from diagnostic one to a range of complex minimally invasive intervention procedures Rajamahanty & Grasso (2008) state. The angle of deflection of the distal end of the ureteroscope is governed by the bending mechanism used. The bending mechanism of the ureteroscope is the one that allows the clinician to manoeuvre the tip, as they will. This facilitates the access into the intrarenal collecting system even up to the calyx of the lower pole. The angle of deflection is controlled by a pair of wires or cables, which are directly connected to a lever/knob on the control section of the ureteroscope. The loci of the tip are governed by how far the tip is from the bending section, the bending radius, as well as the control of the bending.

To fully access the lower pole calyx, the active deflection must be capable of reaching the required angles. The angle of deflection is governed by the ureterofundibular angle of the kidney (Lei & Du, 2010). Figure 5 below shows where the ureterofundibular angle may be found relative to the ureter and the kidney. This angle ranges from 140 degrees to 175 degrees. Hence ureteroscopes are designed to reach 175 degrees of active bending. A critical aspect not documented or discussed in any literature alongside the ureterofundibular angle is the radius of deflection. The ureterofundibular angle is important for the active bending required; it is the one that governs how much the ureteroscope must be deflected to access the lower pole calyx. The lack of documentation of the ureterofundibular angle may be because this varies drastically according to individuals. This leaves the maximum attainable angle through the tip deflection to the designer’s discretion.

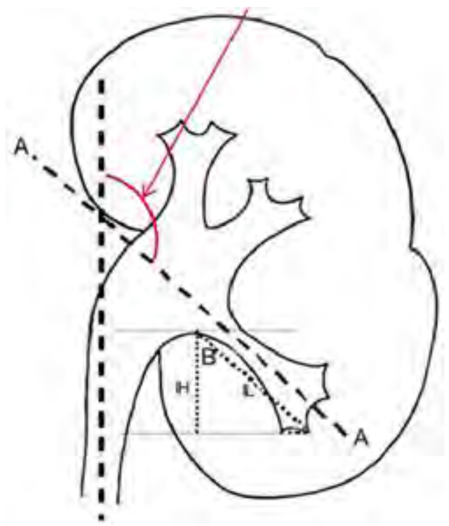


Figure 5: The ureterofundibular angle (adapted from Lei and Du, 2010)

Secondary deflection is further bending induced by primary bending (Lei & Du, 2010). Secondary deflection is passive and is proximal to the control section, compared to the primary bending. Access to the lower pole calyx has been made possible by the presence of secondary deflection, which allows the tip of ureteroscopes to be positioned in the lower calyx (Grasso & Bagley, 1998). This lower calyx is the most difficult region to access via retrograde endoscopes (Bagley, 1987).

Bending moments and forces required to bend insertion tubes are not documented or discussed in literature. This may be because the literature dealing with design of ureteroscopes focuses more on the impact of the design on the procedure rather than the design of the ureteroscope itself. Literature that discusses the mathematics and design of the bending mechanism seldom balances the mechanics with the choice of materials used.

2.3.2.1 Vertebrae type mechanism

The vertebra type mechanism shown in Figure 6, on the next page, works in the same manner as the human backbone. From literature searches on the different bending mechanisms, it was found to be the most common amongst gastroscopes and colonoscopes. Designs of endoscopes examined on patents mostly used this mechanism up until recently, when the tubular mechanism discussed later became common.

The mechanism uses small pivoting between two adjacent sections or vertebrae to deflect. The accumulated small deflections over many sections sum up to a large deflection. The final deflection is dependent on the number of sections present, the relative deflection between any two sections and how long each section is. This mechanism is most used for gastroscopes and colonoscopes, mainly because of the bulky nature its design. Gastroscopes and colonoscopes are large in design and navigate large anatomy with no sharp turnings, hence the mechanism applicable (Ginsberg et al., 2005). For small instruments this method of angulation is not the most space efficient with regards to turning radius.

The use of several segments joined together to make bending possible implies that the manufacturing of such a system is potentially expensive. The number of sections and the coupling mechanism, which requires assembly of the segments precisely, suggest the high cost of the system. Due to the size the ureteroscopes, the machining and joining of the sections to make pivots is likely to be expensive if this mechanism is used for ureteroscopes.

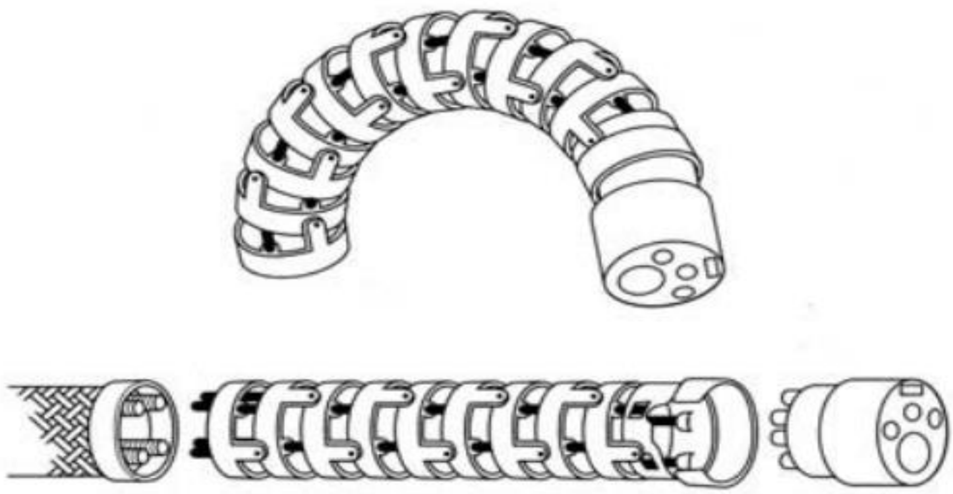


Figure 6: An illustration of a vertebrae bending mechanism ("How It Works: The Angulation System," 2012)

Durability of the ureteroscopes can be assumed to significantly rely on the bending mechanism if used correctly. The vertebrae type of bending mechanism relies on many parts, which results in increased chance to fail, and decreased durability. Therefore increasing the durability of ureteroscopes can be undertaken by increasing the durability of the bending section.

2.3.2.2 Pivot pin mechanism

The pivot pin mechanism is analogous to the vertebrae mechanism and can be taken as an upgrade of it. However, the pivot pin mechanism has sections with smaller thicknesses and different profiles. The way the mechanism functions resembles a vertebrae type mechanism in that the two adjacent sections have a pivot in between them and the distal section pivots relative to the proximal section. The difference, however, is the amount of pivoting between two sections. Figure 7 depicts the bending of a pivot pin mechanism. This can be compared to Figure 6 (above) for notable differences. The pivot pin mechanism also can navigate smaller radii compared to vertebrae type mechanisms because of the larger pivoting radii between two sections.

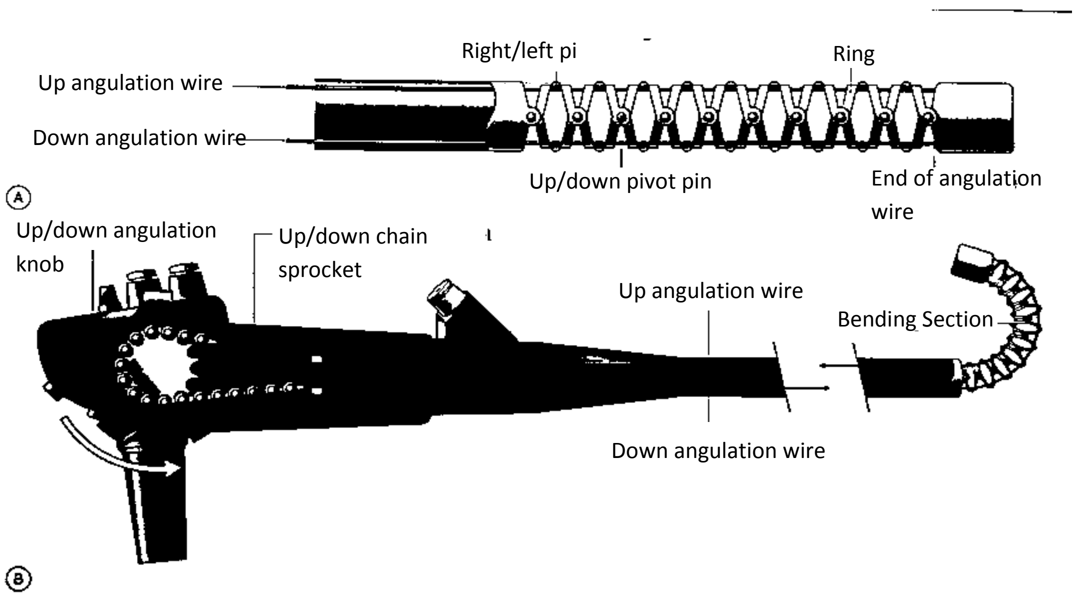


Figure 7: The pin pivot mechanism used in some flexible endoscopes. (Ginsberg et al., 2005)

The durability of the pivot pin mechanism is improved compared to that of the vertebrae type mechanism. This may be due to the enriched manufacturing technologies involved in the pivot pin mechanism. Similar to the vertebrae type mechanism, the pivot pin mechanism has many sections joined together. Damage between two sections would render the whole tube defective.

2.3.2.3 Shape alloys micro-sensor system

Shape alloys micro-sensor deflection mechanism used by MicroFlex endoscopes, is claimed to be ultra-flexible, digitally-controlled and allows for minimally invasive sinus diagnosis and surgery (Kopelove, 2006). This system was in design phase in 2006. A “proof of concept” is either still to be produced, or has been produced but is not documented or available in public domain. The size of the insertion tubes is very small, having diameters of 3mm and 1mm. The size of the endoscope facilitates access to areas which were previously inaccessible and allows for visualization of the tissues. The development of this bending and imaging system resulted from in technological innovation in actuation, sensing, control and assembly.

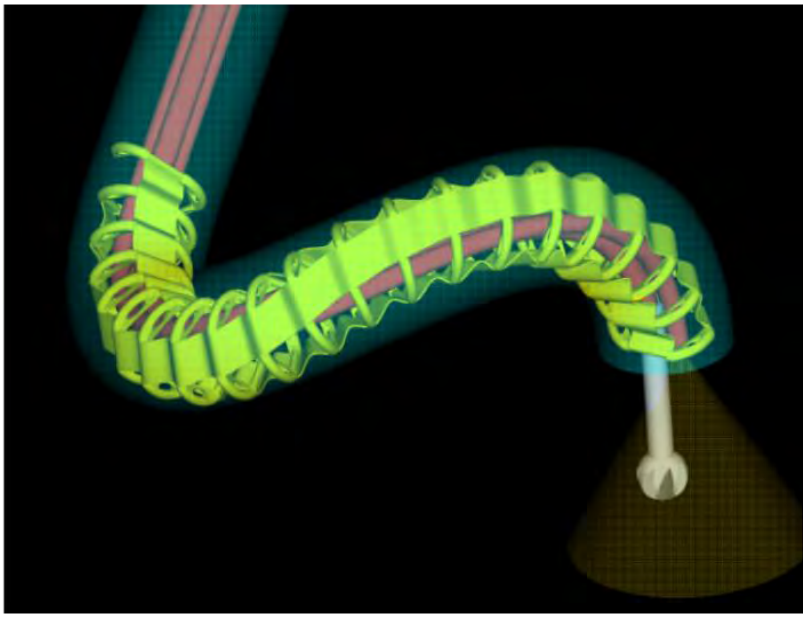


Figure 8: Shape alloy micro-sensor system design to be used for sinus surgery (Kopelove, 2006)

The durability of this system can only be discussed theoretically because there are no known existing models of the mechanism that have been tested. From Figure 8 it is seen that the design of the bending section is composed of small rings joined together by a strip of what can be presumed to be the shape alloy metal. The sophistication of the design with shape alloy micro-sensors and the bending seen on Figure 8 suggests a high cost for manufacturing.

2.3.2.4 Tubular mechanism

The tubular mechanism uses a single tubular structure having cuts along its length to accommodate bending without bulging of material. Shown in Figure 9 is an example of such a tubular structure from a design by Grabover et al. (2004). The mechanism relies on the bending of the tube, which is made from highly elastic material. Most of these mechanisms use shape memory alloy material such as Tinel or Nitinol which behave like super springs and has higher deflection compared to other metals (Grabover et al., 2004; Konstorum & Grabover, 2004). Gilbertson (2000) discusses how superelasticity and the phase transformation link and how that all play a role in the functioning of the tube. An example of such a tube is shown in Figure 9 next page.

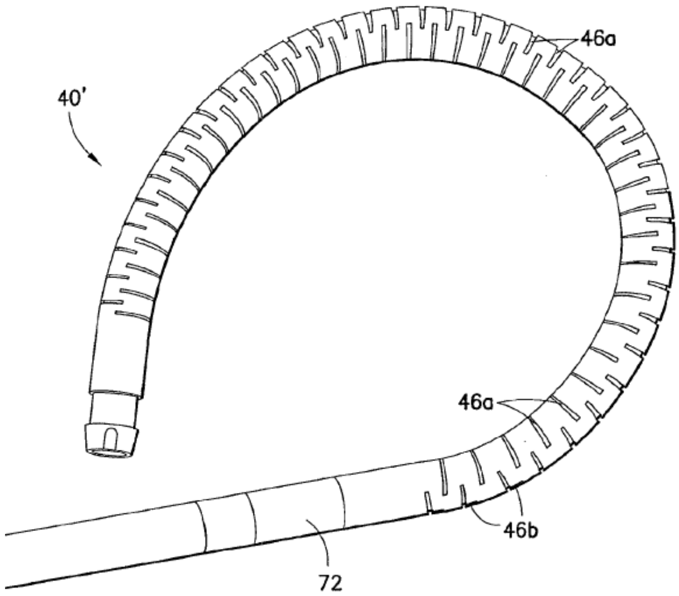


Figure 9: The tubular mechanism presented for patenting by Grabover et al. (2004)

Making a single tube with cuts is easier than the vertebrae type mechanism and pivot pin mechanism. The manufacturing of the tubular mechanism can be assumed cheaper due to the simplicity of the design. However, the material used for the tubular mechanism is more expensive than the one used for vertebrae and pivot pin mechanisms. Damage to the tube can also render the whole tube unusable, but the replacement of such a mechanism is seemingly easier. Furthermore, the mechanism can have smaller sizes due to its manufacture process (because of the absence of assembling of parts).

2.3.2.5 Compression spring mechanism

The use of a compression spring as a means of directing angulation is the simplest form which can be applied. However, the control of the bending of the spring is not as easy as in other designs. Singular plane spring deflection has to be carefully managed. As the spring is bent for angulation it also compresses and this has to be accounted for in the design. The great advantage of the compression spring mechanism is the reduction in actuating parts. The spring deformation is controlled by two braided steel cables which are attached antagonistically.

The study by Jong Yoon et al., (2013) seeks to integrate a modular articulable imaging device with a tele-operated surgical robot. The articulation of the distal insertion tube for anatomy navigation is carried out through a compression coil spring and two steel cables attached to the periphery of the spring as shown in Figure 10. The steel cables can be pulled and released to subject the compression coil under an axial resultant force and an axial bending moment which results in the spring being compressed or extended. The exact mechanics of the bending of the spring are further discussed in Appendix A.

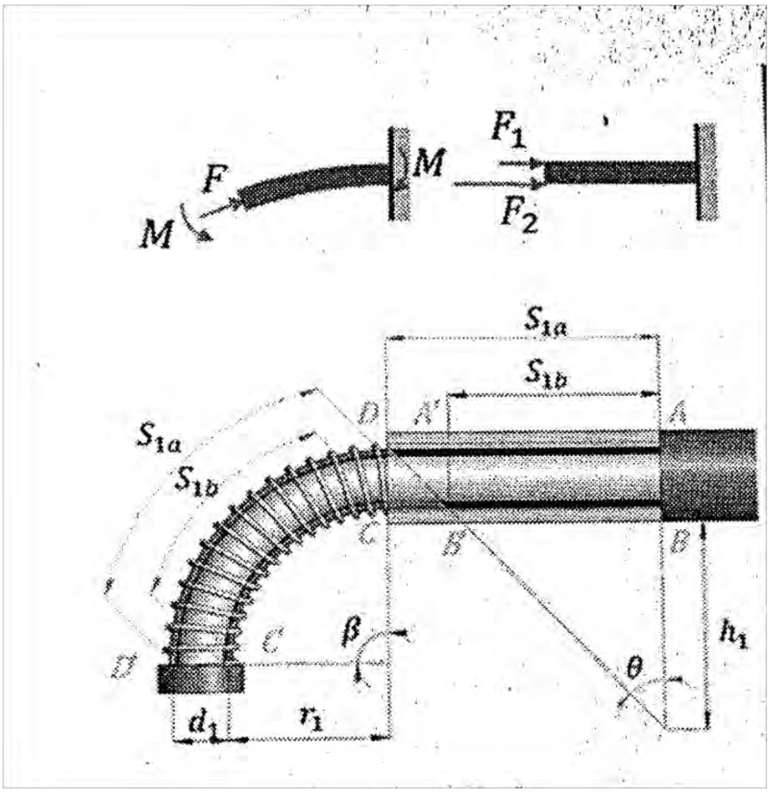


Figure 10: The compression spring mechanism prototype that seeks to integrate articulable imaging devices and tele-operated surgical robots (Jong Yoon et al., 2013)

The design of the preliminary system by Jong Yoon et al. (2013) has an inner lumen with a 3.5mm diameter for the insertion of an imaging device. The size of the lumen is large enough to accommodate some modern endoscope cameras as will be discussed in the next section (Imaging systems). The spring is used in compression state even prior to applying the forces that cause angulation. Its initial length is 100mm but when in use it is 60mm. The bending forces are applied to this precompressed length.

The size and complexity of designs varies according to the technology used. The vertebrae type of angulation system is most common in large diameter endoscopes whist small diameter endoscope use the tubular mechanism. Since the ureteroscope being designed is a small diameter endoscope which requires fine control of the bending, using the tubular mechanism or a variation of it is logical. Increased durability is assumed for tubular mechanism because of fewer parts than the vertebrae type mechanism. The compression spring mechanism simplifies the design but for highly controlled bending it introduces new parts which are counterproductive when it comes to space allocation for the size of the ureteroscope being designed.

2.4 Imaging Systems and Wireless Image Transmission

"For sufficient stone workup, excellent visualization is mandatory" according to Bach et al. (2008). Therefore, the image quality is the one of the major components of an endoscope, which determines whether it is useful or useless. The clearer the images are the better the quality of the diagnosis because the clinician is able to give a precise diagnosis without speculation. Since image capture is closely linked to image transmission both will be discussed in this section.

2.4.1 Image capturing systems

The traditional endoscopes capture images by "use of fibre-optics for light and video transmission" (Chan, Meng, & Wang, 2005). However, more recently endoscopes have been equipped with image sensors at their distal ends. The image sensors work in conjunction with LEDs, which provide lighting, a lens that helps which the focusing on the area of interest and occasionally a wireless transmitter. Chan et al. (2005) state that the four key components of a wireless image capturing system are: (1) a video camera, (2) radio frequency (RF) modulator (3) an antenna, and (4) a lighting system. The key components described above are in relation to capsule endoscopy but are also highly applicable to video ureteroscopy.

An image sensor is fitted at the distal end of the ureteroscope. The image sensor or video camera can either be analogue or digital. Chan et al. (2005) declare that the major advantage of digital cameras over analogue cameras is that digital cameras can be smaller. This becomes a very important factor in the choice of camera because space is a major constraint in the design of the insertion tube. The insertion tube is aimed to be as small as possible to avoid the process of dilation and avoid trauma to the anatomy at all costs.

Digital cameras also provide high resolution images and low power consumption, whilst analogue cameras are extremely easy to interface with output monitor. Even though the digital cameras are found in smaller sizes they require more processing of the output signal due to the various output digital formats. Analogue cameras have a single pin output, whereas in digital cameras the signal is outputted in parallel by either one 4-pin or 8-pin configuration, depending on the design.

Table 4: Table of comparison between digital and analogue cameras (adapted from Chan et al., 2005).

	Digital cameras	**Analogue cameras**
Size	Small	Large
Resolution	High resolution	Medium
Power consumption	Low	High
Circuit Interfacing	Complicated	Simple
Output	Either 4-pin or 8 pin	1-pin
Output formats	More than one format	One format only

Lighting is very critical for visualisation of the area of interest. As previously stated, the traditional way of illuminating the area of interest is via fibre-optics. When using video-enabled endoscopes the lighting is done by LEDs fitted at the distal end of the insertion tube. Three parameters to consider for the lighting system and circuitry thereof involved are (1) pulsing frequency, (2) duty cycle of pulses and (3) the forward current of LEDs (Chan et al., 2005). Duty cycle is describe as the percentage in which a signal is active over one period and forward LED current is the flowing from the anode to the cathode of the LED providing sufficient current to power the LED on. The pulsing frequency of lower than 3 kHz causes flashes in the video. The duty cycle and forward current of LEDs affect the brightness of the video. For optimal results the duty cycle should be low, while maintaining a high forward current of the LEDs.

Charge coupled device (CCDs) and complementary metal oxide semiconductor (CMOS) image sensors are technologies used to capture images digitally. They both convert light into electric charge and then into electric signals even though they differ in their mechanism to do so (Inspection Optimax Imaging Measurement, 2013). CCDs have a better image quality compared to CMOS. However, CMOS have lower power consumption, camera-on-chip integration and low manufacturing costs (Litwiller, 2005). CCDs are used in most cases where high quality images with excellent light sensitivity is required ("Camera Technologies CCD OR CMOS," 2013).

The size of the imaging system is one of the major constraints when designing endoscopes. Chan et al. (2005) state that size was one of the two constraints when prototyping the wireless capsule. The size of the ureteropyeloscope is highly dependant on the imaging technology used as well as the lighting system employed. Lighting is very important, as it is there to illuminate the area of interest. Hence, it should be bright enough to provide clarity in the region being viewed. From previous studies, by Grasso and Bagley (1998) and Buscarini and Conlin (2008), on the size of the insertion tubes it is shown that the diameter cannot be larger than 10Fr, which is 3.3mm.

2.4.2 Endoscopic cameras

Currently the smallest endoscopic camera is said to be the 1.2mm camera made by Medigus ("Medigus micro-camera catalog," 2013). The size of the camera makes it possible to incorporate it at the distal end of the insertion tube for at least a diagnostic ureteropyeloscope. With distal end diameters of 6.9 to 8.4Fr, which translates to 2.3 to 2.8mm, such small cameras make it possible for camera technology to compete with fibre-optic technology, which is prevalent in ureteropyeloscope due to compactness and ease of fitting in the insertion tube distal end. Figure 11 below illustrates the size of the camera and the fact that is it claimed to be 1.20 millimetres.

Figure 11: Depiction of how small the 1.20mm camera is. ("Medigus micro-camera catalog," 2013)

The technical specifications of the 1.20mm camera are very impressive for a camera of its size. The field of view (FOV) of the camera is 100 degrees and provides high quality images as claimed by the manufacturers. The depth of field is 5mm to 50mm and the default optical distance is 10mm. The optimal focal distance can be adjusted as needed by the user during the manufacturing of the camera and can be put in the range of 5mm to 20mm. The camera cable is 0.58mm but can also be provided in the diameter of 0.52, as need be, and is usually provided in 2m lengths but can be provided in 10m as well.

An HD Rainbow video processor processes the image captured by the camera, which is a DSP-based platform. The images are in HD format. The video processor is encased in a hand held device with a touch screen control panel. The control panel is user-friendly with various controls including image optimization. The video processor also has improved algorithms for image-correction, colour-correction, brightness enhancement, image enlargement capability (three image size options) and different masking options (square/round shaped image). However, for illumination the camera does not have LEDs around it, it uses a white light source just like fibre optic endoscopes. The typically used light sources are LED or Xenon.

From the same series there is a 1.8mm and a 3mm camera, which are also used for endoscopic purposes. The specifications are different and the 3mm version has a square version of 3mm x 3mm and has a 140 degree FOV. The video processor used for the 3mm x 3mm camera is also different and also provides a PAL S-video and Composite output options. The depth of field ranges from 5mm to 100mm and the optimal focus is pegged at 20mm (but just like the 1.2mm camera the optimal focus can be modified on manufacturing is desired). The output is not HDMI like the 1.2mm camera but is S-video or composite PAL.

The pricing for the 1.2mm camera is US$10,860 and this includes the camera and the HD Rainbow video processor. The camera and the cable cost $1,200 and it can be seen that the expensive component is the video processor. This may be due to the fact that it has so many features which facilitate acquisition and conversion of images to high quality HD images. The 3mm x 3mm CCD camera costs US$3,400, its video processor costs the same amount, and therefore the total cost of the system is US$6,800.

BC Tech of Santa Cruz, California in the United States also has a design of a small endoscopic video camera (Ostrovsky, 2012). The video camera is aimed at being integratable into small systems. The camera is also designed to be disposable. The resolution of the camera is 400 by 400 and provides high quality images with a frame capture rate of 30fps. The illumination on areas of interest is done by LEDs, which are located around the camera to give a maximum 3mm diameter. Figure 12 shows the camera and an ant to illustrate how small the camera is.

Figure 12: An image illustrating how small a BC Tech camera is (Ostrovsky, 2012)

2.4.3 Image transmission properties

Real-time image viewing is a basic requirement and this can be carried out in two ways (1) wired transmission, or (2) wireless transmission. Real-time viewing is a must due to the nature of use of the instrument being designed. In an attempt to increase the ease of use by decreasing wires around the workspace, wireless transmission is chosen over wired transmission for the study.

Wireless transmission of images in endoscopy is not a novel idea. Gastrointestinal endoscopy has been researching telemetric endoscopy as early as 1957 (Thoné et al., 2009). Several designs have been developed but all of them use a similar principle that involves the camera capturing an image or a video signal, which is then taken into the radio frequency modulator and amplifier to be converted into a RF signal, which can be then transmitted by the antenna. The signal is then received by the receiver and decoded back into an image or video signal, which is viewed on a monitor (Chan et al., 2005). Figure 13 below shows the schematic diagram of the signal flow.

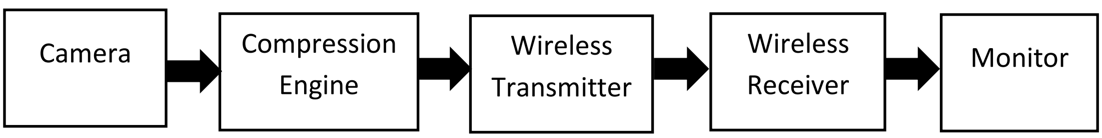


Figure 13: schematic diagram of video transmission (adapted from (Chan et al., 2005)**)**

Chan et al. (2005) identified the frequency of transmission as a main constraint alongside the size of imaging system. A rule of thumb for transmission was that the frequency of 1GHz must not to be exceeded in capsule endoscopy. This is because above this frequency the human body tissue would then absorb most radiation energy, as the transmitter would be contained within the human body during transmission. This does not apply to the ureteroscopy as the transmitter is housed on the handle of the ureteroscope and would not be inside the human body. This results in the fact that higher frequencies can be used.

Signals are transmitted as either analogue or digital. There are several means to transmit the signal analogue-wise, but the simplest way is using a TV modulator, which works through an amplitude modulation (AM) scheme to convert the video to radio frequency (RF) signal for transmission. A monitor picks up the transmitted RF signal where the video is displayed. Evidently, no extra circuitry (special or external) is needed to display the video on the receiving end. In contrast, digital video transmitters are developed for specific industrial, scientific or medical applications.

Commercially available cameras for endoscopy with data being transmitted via Bluetooth at a frame rate of 2 frames per second (fps) and a resolution of 256×256, should at least transfer data at 1MBps to achieve real-time viewing (Miaou, Jeng, Tsung, Hsiao, & Lin, 2006). At least 4MBps is required if the camera resolution is 512 x 512 while maintaining data transmitted at 2fps. Increasing the frame rate to 30fps results in the required data rate being 15MBps. Any data rate above 1MBps cannot be supported via Bluetooth 2.0 or Infrared 1.1 and even then the distance of transmission is very short (maximum range of about a meter).

Data rate heavily depends on the resolution of the video camera. For wired endoscopes, a high definition camera with a resolution of 1920x1080 and providing 30fps is commercially available (Thoné et al., 2009). If this endoscope were converted to wireless transmission the data rate required would be 78MBps and that is very costly to implement both financially as well as in terms of power. The study done by Chan et al. (2005) shows that digital transmitters have very slow data rates and could not carry digital video data of at least 3MBps. Transmitters designed with high data rates are deemed not applicable to capsule endoscopy (procedure that uses a tiny wireless camera in form of a pill to take pictures of the digestive tract) due energy absorption by human body tissue. The high data rate transmitters operate at gigahertz frequency range and are developed for wireless LAN and Bluetooth applications. The data rate transmission required by 10fps is 3.84MBps (Thoné et al., 2009).

Data rate is reduced by image compression. "Image compression removes visually redundant information from a picture or video, without exaggerated loss of detail or introduction of compression artefacts" (Thoné et al., 2009). Thoné et al. (2009) claim that 20-fold compression of a video which required 3.84MBps can be reduced to 1.5MBps. The compression cuts the data rate by more than half. Compression may reduce the data rate but it also introduces a need for RAM (which requires space and power). The trade-off between compression and presence of RAM is to be critically considered. Figure 14 shows a block diagram of the video transmission in the case of a compression engine.

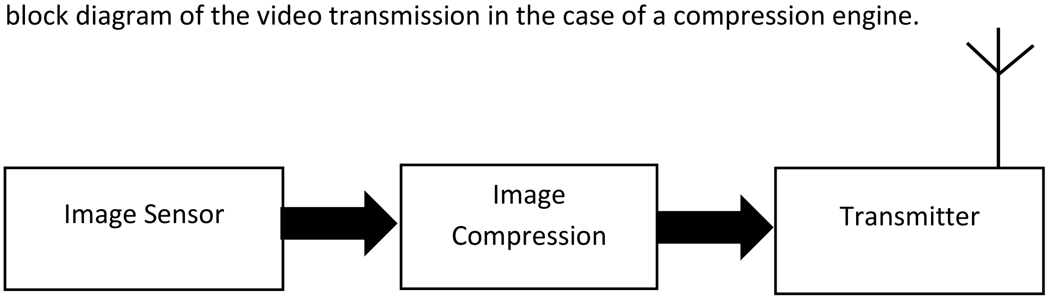


Figure 14: Block diagram highlighting where a compression would fit in when applied.

Antennas provide a means of signal transmission to a receiver or a TV monitor for video viewing. A helical antenna was chosen in the study done by Chan et al., (2005) due to its compactness and size. The decision was arrived at considering different types of antennas even though it is not stated how many. The antenna was 8mm in diameter and the radiation frequency used was 800MHz. It is very important to note at this point that the study Chan et al. (2005) did was for image transmission for real time viewing of the gastrointestinal tract.

Output signals from the study by Chan et al. (2005) were found to have noise due to wireless transmission. This noise was found to be able to be filtered at the receiving end by either a circuit technique or image processing technique.

2.5 Materials for Components

Biocompatibility is the interaction of the living organism or tissue with a medical device, component or components of the device without the device being toxic or injuring the living organism or tissue. Biocompatible material does not injure or cause immunological rejection by the living organism or tissue by its introduction. "In a regulatory sense, biocompatibility is tested to determine the potential toxicity resulting from bodily contact with a material or medical device" (Paleos, 2012). Biocompatibility is vital for medical devices and the evaluation of both local and systemic reactions must be carried out. A systemic reaction affects parts of the body beyond the local part that contacted the material or device.

For medical devices, there are different requirements to be met dependant on how the device is used. Biocompatibility is mostly concerned with how the introduction of the material into human body disturbs or affects the normal functions of the human body. Some of these effects are basic such as irritation, sensitization, as well as cytotoxicity (Upman & Charton, n.d.).

Cleanability and sterilisability of the ureteropyeloscopes are very important to avoid cases of cross contamination of patients undergoing endoscopic procedures. To avoid cross contamination between patients, endoscopes are cleaned, disinfected and sterilised between each patient use (Pennsylvania Patient Safety Advisory, 2010). Serious patient infection or even death may result due to exposure of patients to bloodborne pathogens from another patient.

Basic steps to get an ureteroscope ready for next procedure are (1), precleaning using enzymatic detergent to wipe endoscope exterior and flush channels. (2), leak testing to check for damages that it may have incurred during use (highly relevant for channels). (3) manual cleaning done by removal of all debris by scrubbing the endoscope in an enzymatic detergent as well as brushing, aspirating and flushing the channels either with the detergents or water and (4) high-level disinfection and sterilisation, which can be done manually, or by an endoscope reprocessor. The materials used for the ureteropyeloscope must be durable enough to withstand all the processes undergone during preparation for use.

The process internationally recognised for choosing material is the one defined by Food & Drug Administration, United States of America. The flow diagram, Figure 15 shown next page, highlights the process. The flow diagram shown below used in conjunction with the Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" would provide the best material choice if applied correctly.

It is very important to realise that the study aims for the highest quality of design and material choice for the prototype but because the design is in its infancy, hence medical grade materials will be stipulated for the 3D design but not for the prototype. The prototype uses a different, cheap and more accessible material.

It is apparent that between flexible ureteroscopy and rigid ureteroscopy, flexible ureteroscopy is the preferred procedure. This is because of lowered cost of patient treatment, shorter hospital stays and less tissue scarring left on the patient. The shift from rigid ureteroscope to flexible ureteroscope is imperative for better health care for kidney stone treatment. The procedure to remove kidney stones requires use of accessory instruments, a lithotripter in particular. Use of other accessory instruments should be accommodated but is not of primary importance in the case of kidney stone removal using a lithotripter.

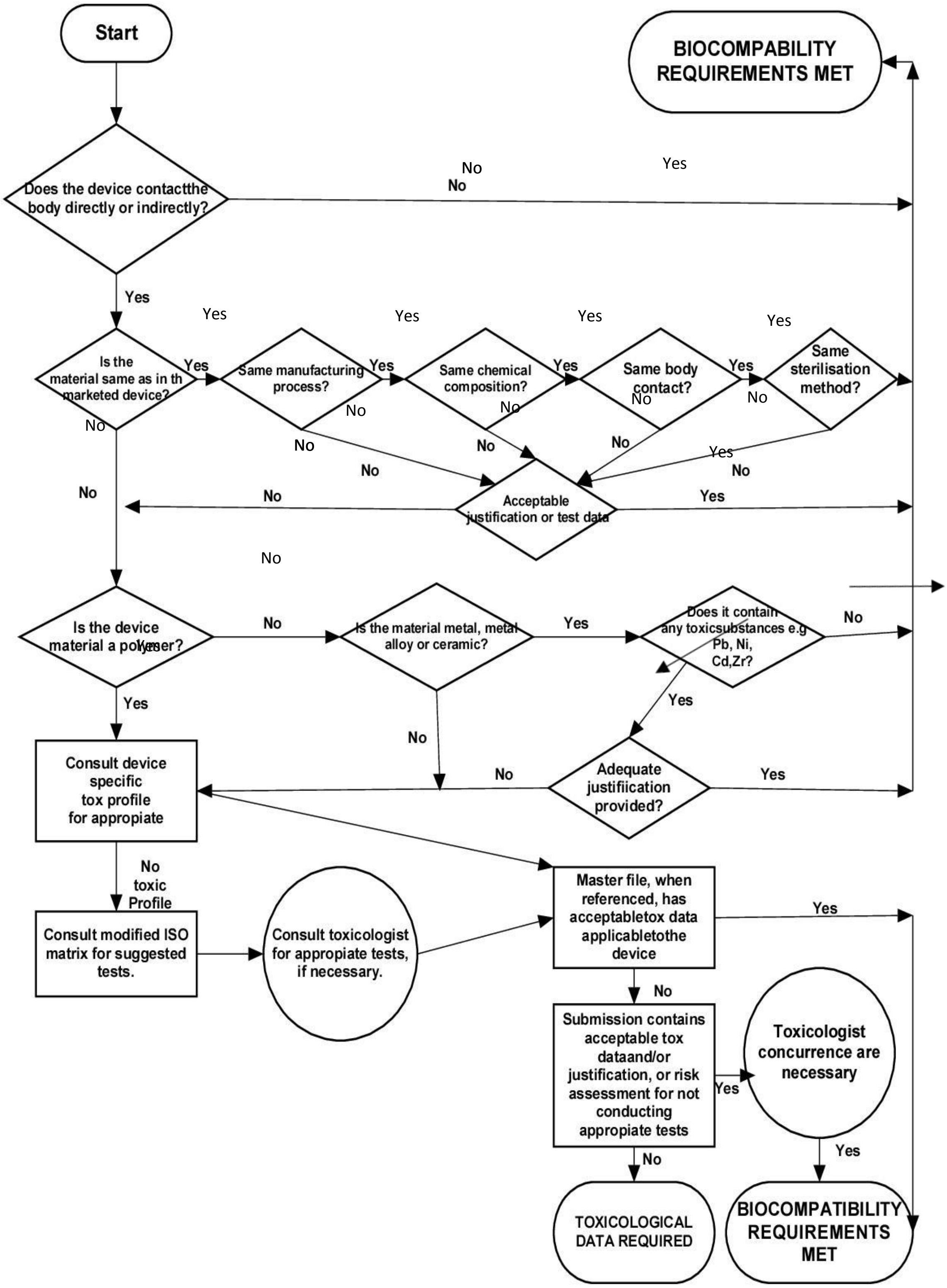


Figure 15: A flow diagram detailing how to determine is the material chosen is biocompatible.

Chapter 3: DESIGN METHODOLOGY

The process of product development is not linear but rather comes about by a sequence of processes that are repeatable at certain stages and culminate in the final product. However, for the study at hand a sequence of processes to develop a product was decided upon by author and is described in this chapter. This chapter deals with the methods undertaken in the design of the ureteropyeloscope, the stages undertaken in the testing of durability of the angulation system, wireless video transmission system and assessment of manufacturability.

3.1 Derivation of Design Specifications

3.1.1 Assumptions

Any design is a product of engineering assumptions, mathematical models of analysis and knowledge of material application. The assumptions drawn up for the ureteropyeloscope were based on current designs and those found in literature pertaining characteristics desired by clinicians. According to Blake (1966) the choice of applicable mathematical models and assumptions hang on comprehensive knowledge of the theoretical design principles, experience and creative imagination. Mathematical models used for the design at hand were derived from already existing designs. The assumptions made and models used were to ascertain that the design at hand would approximate operation of current designs.

According to Blake, (1966) almost every engineering problem has many solutions. This implies that when design decisions are made a rationale must be supplied as to why a given solution was chosen. The design decisions such as environment of use influence the size, geometry and material of the finished item amongst other factors otherwise they are constrained by the same parameters (Blake, 1966).In this study, the device size and geometry was determined by the anatomy that the device navigates. The materials used for the design were governed by the application of the device; the device materials were specified to be biocompatible, low cost and easily available in South Africa.

Solutions to some problems are merely improvement on existing ones not necessarily new solutions. The design of the ureteropyeloscope fell under the category of implementing improvements on existing solutions and not creating a new solution. The design of the ureteropyeloscope discussed was based on previous designs to ensure clinicians' approval from a functional and ergonomic perspective. *In-silico* tests carried out were assumed to approximate the working conditions of the ureteropyeloscope otherwise stated.

3.1.2 Design Specifications

Product requirement specification, a critical document of what a design artefact must be and do, was drawn up to ensure that the product developed met the clinician's requirements. The document drawn up for the requirements of the designed ureteropyeloscope featured functional and performance requirements. Amongst some of the functional requirements were the need for the ureteropyeloscope to capture real-time images, and supply of power to the device for the duration of the procedure. Some of the performance requirements were that the ureteropyeloscope must be waterproof. (See Appendix A.1 for the full Product Requirements Specification).

The design specifications of the ureteropyeloscope were formulated to ascertain meeting of specific design needs. The specifications were based on the clinicians' desired needs and engineering influences such as available technologies for manufacturing and materials. Table A.1 in Appendix A.2 shows the tabulation of the design specifications alongside some of the major components of ureteropyeloscope and what materials are used in the manufacture of those components. Moreover, the design specification was used to clearly state the function of the device being designed, who the users are, what the device is used for, where it would be used as well as what it would look like.

3.1.3 Design and functional analysis

The ureteropyeloscope was broken down into three major functional subsystems. Each subsystem carried out specific functions that enabled the ureteropyeloscope to function optimally. The subsystems were (1) wireless video transmission subsystem, (2) instrument and irrigation subsystem and (3) angulation control subsystem. Figure 16 below depicts the breakdown of the ureteropyeloscope into its different subsystems and the constituents of each subsystem. The wireless video transmission subsystem has the further following subsystems (1) lighting system, (2) image capture, and (3) image transmission. The instrument and irrigation subsystem was involved in the introduction of accessories necessary for intervention procedures as well as introduction of lubricant and water for irrigation. The angulation control subsystem's role was to facilitate the manoeuvring of the ureteropyeloscope in the human anatomy.

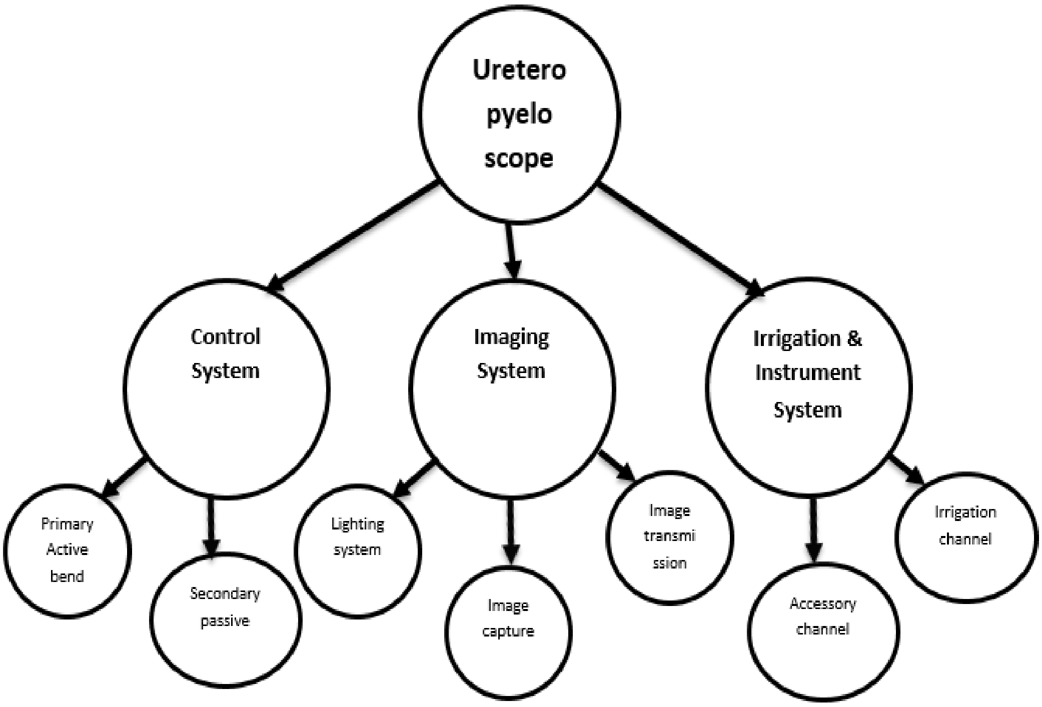


Figure 16: Design analysis in a diagrammatic expression

The flow of information, masses and forces through the ureteropyeloscopes was vital to the design and for optimal control of these components; and the way they flow from one subsystem to other was defined by use of a functional analysis. Figure A.1 (see Appendix A.3) shows the functional analysis of the ureteropyeloscope and the relationship between some of the major components of the ureteropyeloscope, the forces applied and images captured.

3.1.4 Benchmarking and design specification

The relationship between customer needs and engineering properties of the ureteropyeloscope was established and illustrated through drawing up of a house of quality or the Quality Function Deployment (QFD). These relationships were also compared to the currently existing ureteroscopes, and the attributes compared were those which clinicians deemed important. The order of importance of the attributes was decided upon by using information found during literature survey and ureteropyeloscope design analysis. Attributes, such as maximum angle of deflection and radius of deflection amongst others, were found to be common in studies regarding ureteroscope properties such as the studies done by Abdelshehid et al., (2005), Grasso and Bagley, (1998), and Rajamahanty and Grasso, (2008).

From the QFD (see Appendix A.3), it was deduced that the most important characteristic of the ureteropyeloscope was the maximum angle of deflection and the second most important characteristic was the instrument channel alongside the irrigation channel. Data transmission rate was the most important characteristics of the imaging system. Frame capture rate was noted to be more important than the resolution of the image capture device. However, it was asserted that the study at hand did not focus on increasing the maximum bending angle but merely use previously prescribed angles.

The ureteroscopes used for benchmarking use fibre-optics as a means to illuminate and capture the image of the area of interest. The imaging system prescribed by clinicians for the design was required to use video capture techniques and not fibre optics. The benchmarking between these two different methods of image acquisition was based on image quality or resolution, size of imaging system, frame capture rate and data transmission rate. For data transmission rate it was required that each system be able to provide real-time viewing.

The design specifications were drawn up to ascertain that the specific needs of the clinician are met by the design. The specifications were based on the clinicians' desired needs and engineering influences such as available technologies for manufacturing and materials. The tabulation of the design specifications alongside some of the major components of ureteropyeloscope and what materials are used in the manufacture of those components is shown in Table A.2 (see Appendix A.4). Moreover, the design specification was used to provide the function of the device being designed, who the users would be, what the device would be used for, where it would be used as well as what it would look like.

3.2 Design of the ureteropyeloscope

The ureteropyeloscope design was an integration of subsystems, in which each subsystem carries out specific tasks. SolidWorks 2013 was used in the 3D modelling of components and system. The relationships between subsystems were described concisely so that when the subsystem components are defined, their function made apparent and how the components interact with each other. The interaction of the components within a subsystem was critical to define properly because failure to define the interaction may result in failure to implement the interaction, which in turn affects the functionality of system.

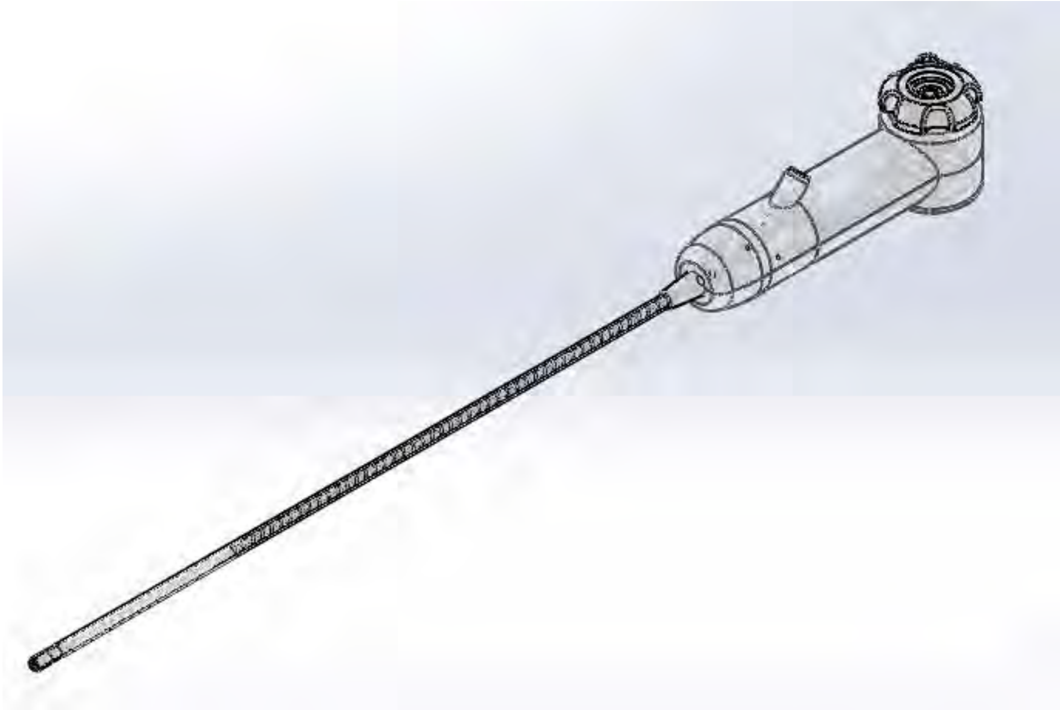


Figure 17: The design of the ureteropyeloscope

Figure 17 above shows the design of the ureteropyeloscope. Figure 18 next page shows the ureteropyeloscope 3D model in exploded view with insertion tube is not fully shown. The ureteropyeloscope was developed in subsystems as previously mentioned, this means that each subsystem had a function to carry out, the subsystems are shown in Figure 16, and these are angulation control system, wireless video transmission subsystem and the irrigation-instrument subsystem. The function and design of each subsystem is discussed in the following sections.

The working simulations tests were the tests of the ureteropyeloscope done *in-silico* to verify if the desired design outcomes were met and the design specifications adhered to. The three major tests done for the ureteropyeloscope were the bending of the distal end of the insertion tube, the ability to lock the tip in a specific position and the leakage tests. The leakage tests involved the protection of the electrical component of the ureteropyeloscope from fluids outside infiltrating into the inside of the ureteropyeloscope during sterilisation and the analysis of the irrigant flow through the irrigation/instrument channel and are also discussed in detail in following sections.

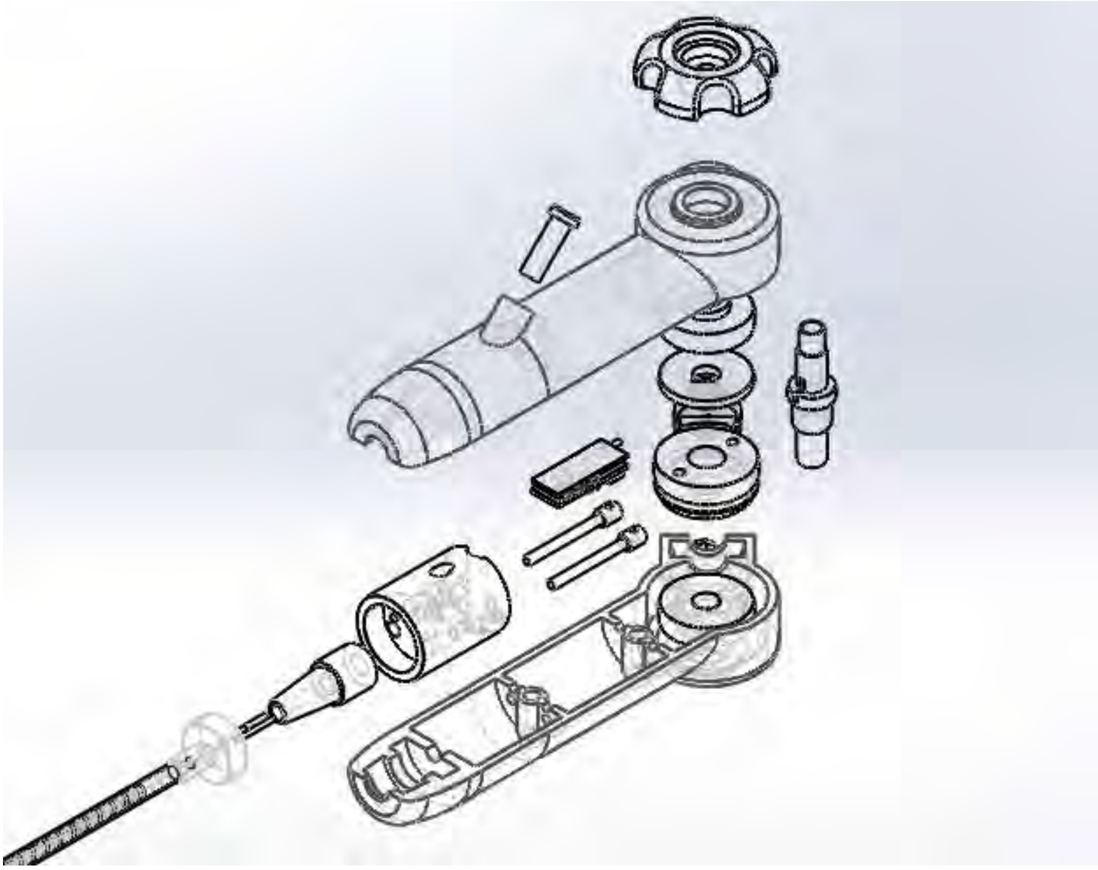


Figure 18: Illustration of the exploded view of the ureteropyeloscope to show different subsystem

3.2.1 Angulation control subsystem

The angulation control subsystem as the name suggests was the subsystem that was responsible for the actuation of the tip to direct its path and line of vision during use. This subsystem enabled the clinician to navigate the anatomy during the introduction of the insertion tube into the urinary system, as well as aid in focusing on the diseased area for diagnosis. The subsystem comprised of two mechanisms that help guide how much the distal tip of the insertion tube angulates and has other components for structural support. The two mechanisms of angulation are discussed in detail in the following sections as well as the major components each mechanism.

3.2.1.1 Active bending control mechanism

The angulation control subsystem was responsible for the manipulation of the insertion tube helping with its navigation through the bladder, up the ureter and subsequently into the kidneys. The command of the tip had to be very precise to avoid unintentional damage to tissue during navigation. The active bending mechanism was the most crucial mechanism of the ureteropyeloscope because this mechanism made it possible to navigate the anatomy without causing damage to the anatomy of the patient. The bending of the tip of the insertion tube was carried out through turning the angulation knob (labelled A in Figure 19) that is connected to the distal of the insertion tubes via cables, which in turn directs the line of view of the distal end. The cables are wound around the cable wheel (labelled C in Figure 19), and the angulation knob was connected to the cable wheel by the angulation shaft B.

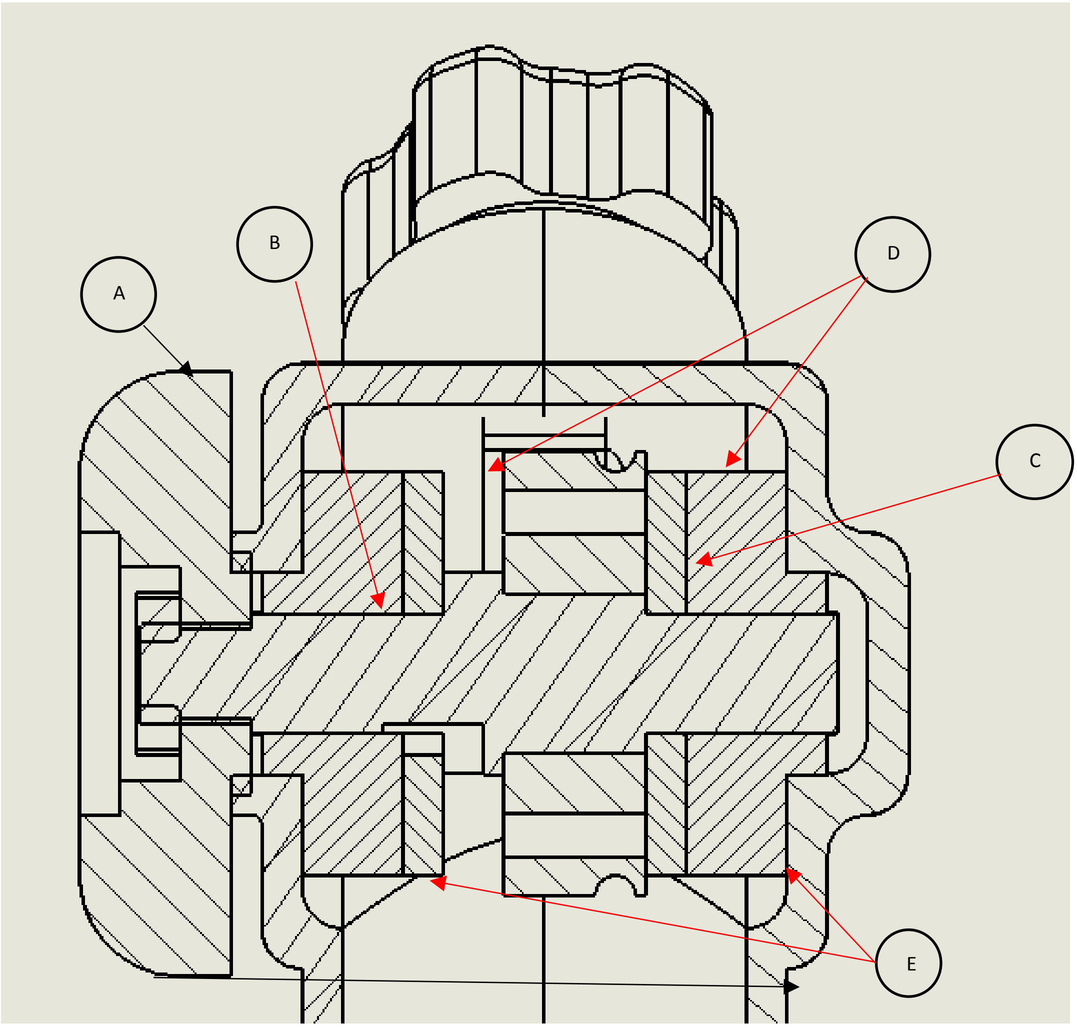


Figure 19: A cross-sectional view showing the interaction of the angulation knob, knob shaft and the friction plates

Fine control of the tip was required, meaning all jerky movements had to be eliminated, and it was done so by incorporating a brake system that when applied slowed down motion of the shaft rotation. The shaft (labelled B in Figure 19) connected to the knob (labelled A) was equipped with two friction plates (labelled D), which were in contact with another pair of friction plates fixed onto the control section case (labelled E) fixed to the casing. The friction between the surfaces regulated the relative rotational movements between the two friction plates. The mechanism shown did not hinder motion but merely regulated it, avoiding sudden movements of the tip in the event of the lock mechanism failure.

From benchmarking, positive logical turning of the tip was more preferable. One way to ensure that the system had positive correlation between the bending of the tip and the knob was to use of a pulley system. The knob to control the distal end of the insertion tube is designed in a positive logical sense meaning that turning the knob clockwise causes the tip to bend towards the right side. This provides a means to use the ureteropyeloscope intuitively.

The major components of this mechanism were the angulation knob, steel cables and the bending sleeve with was responsible for the localised angulation of the insertion tube. It provided a region where the bending could be controlled. The distal part of the bending sleeve had steel cables attached so that when the cables were pulled the bending sleeve angulated. The steel cables were attached to the angulation shaft via the cable wheel, which is joined to the knob to make the angulation possible. See Appendix C.1 for detailed active bending mechanism control components

The insertion tube distal end bending was tested *in-silico* to ascertain that the required angulation angle is achieved. The bending section has two primary layers, which are the bending sleeve and the outer tube cover. The test was carried out using SolidWorks 2013 and the property being tested for is the flexibility of the distal end of the tube. The relevant materials were selected for the components, and then flexed using the flex property. The flex property does not work for assemblies hence flexing components individually. The cumulative flex force is noted.

3.2.1.2 Position lock mechanism

The role of the position lock mechanism was to hold the tip of the insertion tube in a particular position. This was of high clinical value, as the clinician may want to focus on a specific area of anatomy to carry out diagnosis or a procedure. To hold the tip of the insertion tube in a specific position, force transmission had to be stopped. The position lock mechanism was introduced to curb any force transmission that may occur due to accidental moving of the angulation knob or the counter-torque generated by the bending sleeve as it tries to return to its undeformed form.

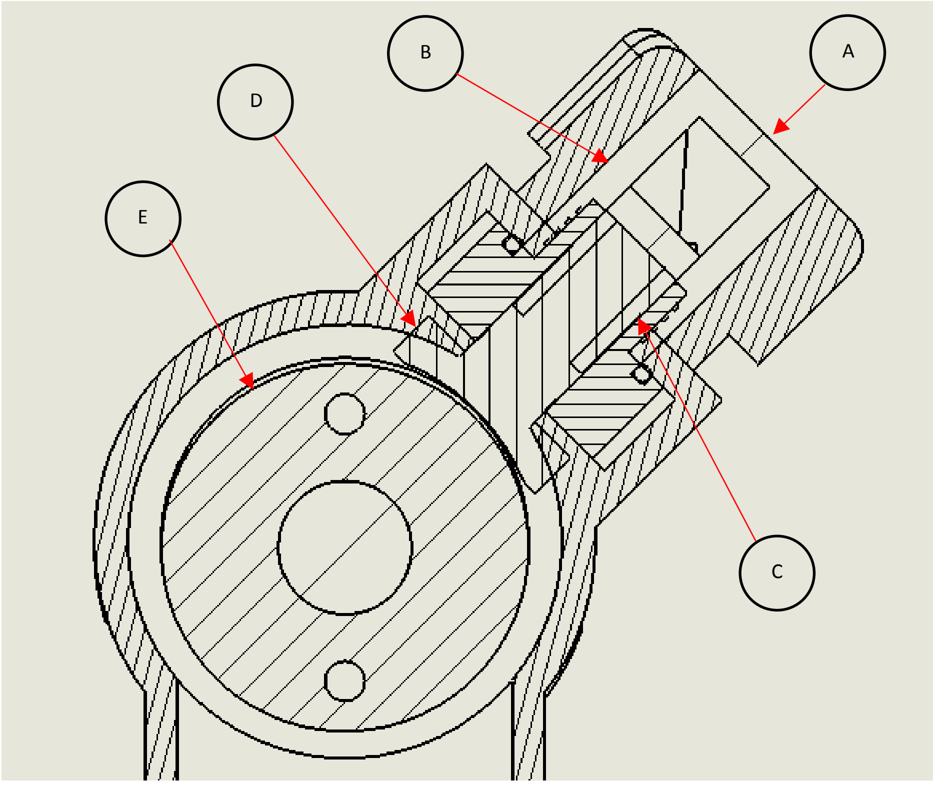


Figure 20: The cross-sectional view showing the components of the position lock mechanism

The position lock mechanism is shown in Figure 20 above through a cross-sectional view of the proximal parts of the control section. When the lock knob (A) is turned, it causes the shoe mover (B) to move linearly within the lock shaft housing (C) and moving the short shoe (D) in turn. When the short shoe encounters the cable wheel (E), rotational motion is stopped and inhibits any potential of it moving. This causes the cable wheel to be locked in a particular position and the steel cables attached to the cable wheel are the ones that control the bending of the bending sleeve, hence the tip is kept at a particular position. The components and the design calculations of the position lock system are detailed in Appendix C.2.

The mechanism works in that a rotational motion of the lock knob, converted into linear motion by the mechanism moves the shoe into contact with the cable wheel that is fixed on to the shaft. The shaft is attached to the steel cables that actuate the bending. Any motion arrest to the cable wheel causes motion arrest to the shaft, hence locking the distal end of the ureteropyeloscope in that particular position. Figure 21 a) shows the assembled position-lock mechanism without the lock-knob it mates with or the cable wheel, which the short-shoe interacts with to arrest the motion. Figure 21 b) shows the exploded of the lock-position mechanism.

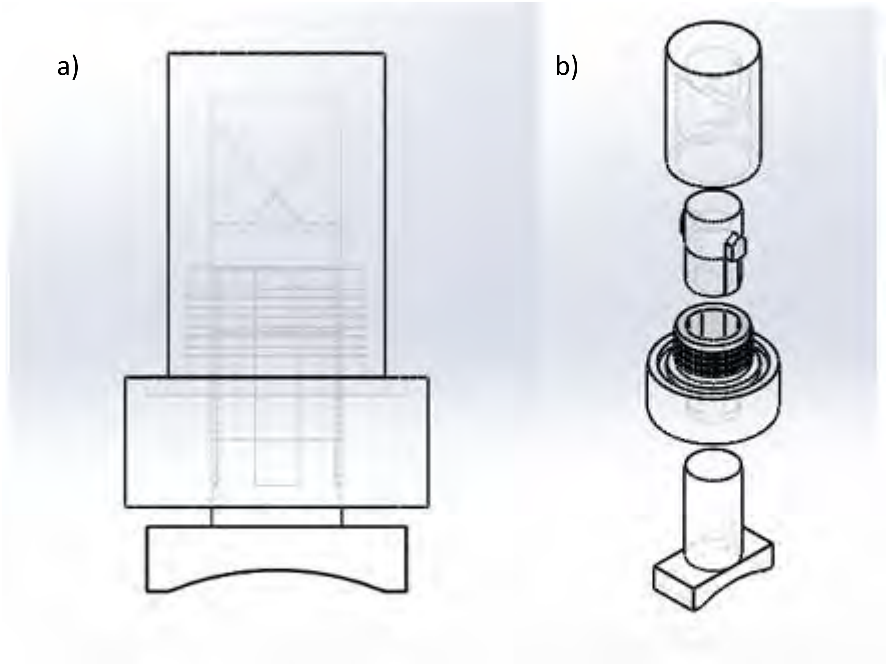


Figure 21: The position-lock mechanism components. a) shows the assembly whilst b) shows the exploded view

A simulation of the position-lock mechanism to illustrate the movement of the components involved in motion arrest of the shaft was developed. The simulation test carried out was to verify the desired rotational movement to linear movement correlation. This was done to make sure that the position lock system is assembled in the properly place and that it does not interfere with other components.

3.2.2 Irrigation and instrument subsystem

The two main responsibilities of this subsystem were 1) provide a navigable passage for the accessory instruments from point of entry, in the control handle, to the distal end of the insertion tube and 2) provide a duct in which the irrigant can flow through the ureteroscope from the point of entry to point of exit. For a clinician, the size of the channel was critical in its use as it must be able to support currently existing accessory devices such as lithotripters. Such accessory instruments come in specific sizes and these sizes were accounted for in the design of the channel.

The subsystem is comprised of a tube whose path starts at the control handle all the way to the distal end of insertion tube. Material used for the channel must be durable and flexible. Flexibility is required for the manoeuvring the insertion tube in to the patient anatomy in which the tube in enclosed. Durability is a desired characteristic due to the need to increase the ureteroscope durability and the instrument channel was described as one of the major components that cause failure in ureteroscope due to damage caused by improper use of the holium laser (Landman & Clayman, 2003). Additionally, durability is necessary for lowered repair costs. The chosen material for the channel is nylon because is it known to be durable and flexible.

The ureteropyeloscope was equipped with a camera on the distal end for video capture and had an instrument-irrigation channel. The irrigant flow was supposed to occur designated path; any leak would pose potential harm to the patient if the leak happened during use as it may damage the video capture system. The leakage of the irrigant from instrument-irrigation channel was tested *in-silico*. The irrigant, introduced through the irrigation-instrument channel opening in the control handle, flowed from the control section through the adaptor module and all the way to the distal end of the insertion tube where the irrigant exits the ureteropyeloscope.

Figure 22 below illustrates the path taken by the irrigant as it flows through the ureteropyeloscope with the red line. This is the same path taken by the accessory instrument, such as a lithotripter, through the ureteropyeloscope to reach the distal end. This implies that not only should be the instrument-irrigation channel be waterproof but also strong as it was found out that in previous studies that damage to the instrument-irrigation channel was also one of the causes of need for early repair. However, this characteristic of durability is hard to simulate, as the simulation of the introduction of the accessory instruments was not possible (Shaun, MECAD 2013).

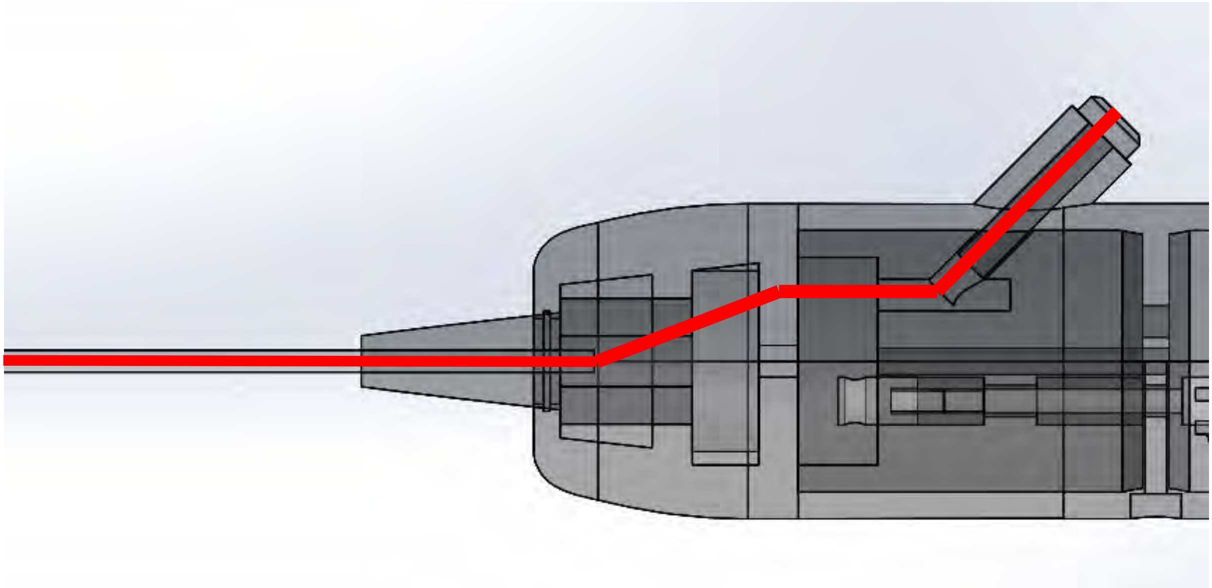


Figure 22: Illustration of the path of flow of the irrigant in the irrigation/instrument channel

Not only do the electronics needed protection from leakage of the irrigant from the instrument-irrigation channel but also from entry of sterilising fluids as well as other cleaning fluids during the process of cleaning and sterilisation. The entry of the fluids into the inner parts of the ureteropyeloscope was tested, checking the integrity of the joints and their tightness. An example of a major joint tested is joining of the two halves of the control handle casing, which make up the handle. Should this joint not have been waterproof, water leaking into the inner parts of the handle will cause damage to the wireless transmitter thus rendering the ureteropyeloscope not usable. All such critical places were tested and results noted.

3.3 Durability

Forty percent of the failures of the ureteroscopes is due to failure of the bending section (Afane et al., 2000). The actual mode of failure was not discussed and the author assumed that it was the actual component responsible for bending, failing by either static loading, fatigue loading or poor component design. The bending sleeve used for the design has no joints hence the possible modes of failure were high static forces applied to the bending sleeve during the position-lock or fatigue failure due to cyclic loading. Even though the cyclic loading undergone by the bending sleeve was not of high frequency, it was taken as a potential way of failure of the bending sleeve. *In-silico* fatigue tests were carried out in SolidWorks 2013.

3.3.1 Static loading

The bending sleeve was equipped with cuts which were rounded at the base to account for stress concentrations which may occur due bending. On bending, one side was compressed and the cuts account for the compression, whilst the other side was under tension. The side under tension had a tension relief mechanism which was accounted for by the cuts and the rounded off base of the cuts to prevent any crack initiation and propagation as the bending sleeve is bent. The static loading test was carried out to find out where the region of highest stress occurs and if the stress is above the yield stress.

Different set ups were used to approximate the loading of the bending sleeve. The static loading four different loading set ups, were (1) an offset axial loading force, (2) a perpendicular force, (3) a combination of the offset axial force and perpendicular force, and (4) a bending moment. The configuration of the loading is shown in Table 10 below. The arrows show where the forces are applied. The application of the forces is done via the steel cables for all configurations.

Table 5: Table for different types of loading

Offset axial loading	Perpendicular loading	Combination of offset axial and perpendicular	Torque loading
			

3.3.2 Fatigue loading test

Fatigue loading tests are carried out to determine the number of cycles of loading from unloaded to maximum attainable position that the bending sleeve can endure before failing. The tests were ran in-silico using SolidWorks 2013. Two different tests were ran, the first one had a desired number of cycles and the loading force defined, and the strain was the parameter sought after. The second test had the loading force and maximum strain defined and the number of cycles endured before failure were the desired outcome.

3.4 Wireless video transmission subsystem

3.4.1 Video capture

Capturing high-resolution images was a requirement for accurate diagnosis of the region of anatomy being viewed. Bright, clear and precise images enable the clinician to provide an accurate and reliable diagnosis. The size of the video capture was also as critical as the properties that it should embody. The video capture device must be able to be fitted in the distal end of an insertion tube, which from studies by Grasso & Bagley, (1998) and Afane et al., (2002), with the outer diameter ranging from 7.2 to 9Fr (2.4 to 3mm).

The Medigus camera was found to be the camera that was the best for the application. At 1.2mm diameter and 5mm length it was noted that it could fit in the distal end of the insertion tube. The depth of field was 5-50mm or 2-6mm due to 2 focus settings available for the camera and a field of view of 100°/130°. The camera has an added advantage of being waterproof. The camera was to be tested for the image quality. This was done through taking images of a TV test screen using the camera and currently used ureteropyeloscope and comparing the two images. Figure 23 shows the TV test screen.

Figure 23: An image of the TV test screen used to test the video capture resolution

3.4.2 Data transmission

The captured video had to be transmitted from the camera to the monitor wirelessly to meet desired requirements. The transmission of the captured video wirelessly facilitated the reduction of the number of cables around the workspace. This was made possible using a camera and wireless video transmitter powered by a battery. These components were housed within the insertion tube and the control handle. The specifications of the wireless transmitter are shown in Table 6 below.

Table 6: Different types of transmitters for the captured videos

	Frequency	**Data transmission rate**	**Chosen**
Minimum requirements	800MHz	78mbps	
FireLink	60Ghz	156mbps	
DX-8	900MHz	Video transmission	X
AWV365TX/AWV366RX	2.4GHz	Video transmission	
Intel 5100	2.4Ghz	130mbps	

FireLink transmitters are said to be suitable for remote network applications, backbone network, wireless transmission of videos due to the transmission speed of 60GHz, which is unnecessary for purposes at hand ("NRD wireless transmitter sends data at 156Mbps," 2002). However, the transmission device signal sending is powerful enough to withstand obstacles such as rain, fog and haze, and therefore it can withstand any conditions within the operating room of the clinician. The Intel chipset, Intel 5100, is a 1x2:2 meaning that it has only one transmit radio but two receive radio chains. The same signal can be sent to two different destination but only one spatial stream can be used whilst transmitting, this results in the device having a receive data rate of 130Mbps alongside 2.4GHz transmission frequency ("Is the 802.11 PHY link rate always determined by the transmitter, never receiver?," 2013).

Figure 24: DX-8 transmitter size shown relative to one cent of USA ("WORLD'S SMALLEST FM VIDEO TRANSMITTER 900 MHZ FOR MEDICAL RESEARCH," 2012)

The chosen DX-8 transmitter is the smallest transmitter form the list, with the dimension of 7.62mm x 7.62mm x 6.35mm. Figure 24 shows the size of the transmitter relative to a one-cent USA coin. The data transmission rate is sufficient to transmit videos as it is described as a small FM video transmitter. The supply voltage of the transmitter is 3.6V, which means the transmitter can be powered by small batteries, the 4SR44 battery (see Appendix E for battery details). A prototype was developed to test for the plausibility of making the wireless video transmission system. The prototype did not use the actual materials prescribed for the design but cheaper materials of which some approximated the prescribed materials whilst others did not. The video capture system was tested for in the prototype. The images captured by the wireless transmission and wired transmission were compared for suitability of use of wireless transmission.

3.5 Manufacturability Assessment

The ureteropyeloscope must be manufacturable and this is tested in two ways, (1) by assessing whether the components can be assigned a processed in which they were fabricated by, and (2) assessing the assembleability of the manufactured components *in-silico* to give a fully functional system. For the component to pass the manufacturability test it had to have a clearly defined manufacturing process in which materials underwent to give a product component. Examples of such processes are milling and drilling, or injection moulding.

3.5.1 Component design for manufacture

The manufacturability of the ureteropyeloscope components was assessed through simulation (*in-silico*) of the manufacturing processes that the components would undergo to be produced. Assessment of manufacturability of components was done through

SolidWorks 2013 ‘DFMXpress Module’. The module evaluated the design of the component with respect to manufacturing process assigned to the component to verify if the component could be made via that chosen process. Standard components did not need be tested for manufacturability as they underwent this process before the manufacturing process; even if they did not undergo this process, their continued use implies reliability. All the custom components of the ureteropyeloscope were tested for manufacturability using the ‘SolidWorks 2013 DFMXpress module’ and the results are given in the relevant section.

3.5.2 Design for Assembly (DFA)

Design for Assembly (DFA) principles were used on the design of the ureteropyeloscope and the product was tested for proper application of DFA principles. The overlaying of components over each other on assembly was tested for by using an interference test in SolidWorks 2013 via the ‘Check Geometry Tool Module’. The components of major concern about interference were the lock position mechanism, angulation control mechanism and the adaptor subsystem. The collision of moving components such as the position lock mechanism and angulation control was tested for. The test was done to detect if the components in given mechanisms collided with other objects, moving or stationary.

Chapter 4: DESIGN OUTCOMES

The *in-silico* testing of the ureteropyeloscope design meeting requirements yielded results which were analysed for streamlining the design for implementation for future developments. This chapter presents the results of the design and *in-silico* simulations undertaken during the validation process. The results were analysed, interpreted and discussed in the Discussions chapter that follows.

4.1 Design of the Ureteropyeloscope

4.1.1 Angulation control subsystem

4.1.1.1 Bending tip test

The bending test carried out using the flex property in SolidWorks 2013 was to find the best-suited parameters for bending. The angulation of the bending sleeve had to meet two parameters, the bending radius and the bending angle. The flex property allowed the setting of one of the two parameters, took material used into consideration and then was used to find what the value of the other parameter was. Table 7 shows the results of the tests. In Test 1, the bending angle of the bending sleeve was the set parameter and in Test 2, the bending radius was set. NiTinol was the used material for the calculations.

Table 7: Results from flex property of the bending of the bending sleeve

	Test 1	**Test 2**
Bending angle	170 deg	222.51 deg
Bending radius	19.63mm	15 mm

Figures 25 and 26 are the illustrations from the tests of the flexing. The bending tube is assumed to be over the length of the tube governed by the trim planes as shown in the figures. The trim planes, which are the edges that determine where the bending starts and ends, are placed where the actual model is constrained. Trim plane 1 was placed in the lowered end of the insertion tube where the bending sleeve is constrained by the two helical tubes. Trim plane 2 was placed in such a way that the line of action of the steel cables lied on the trim plane.

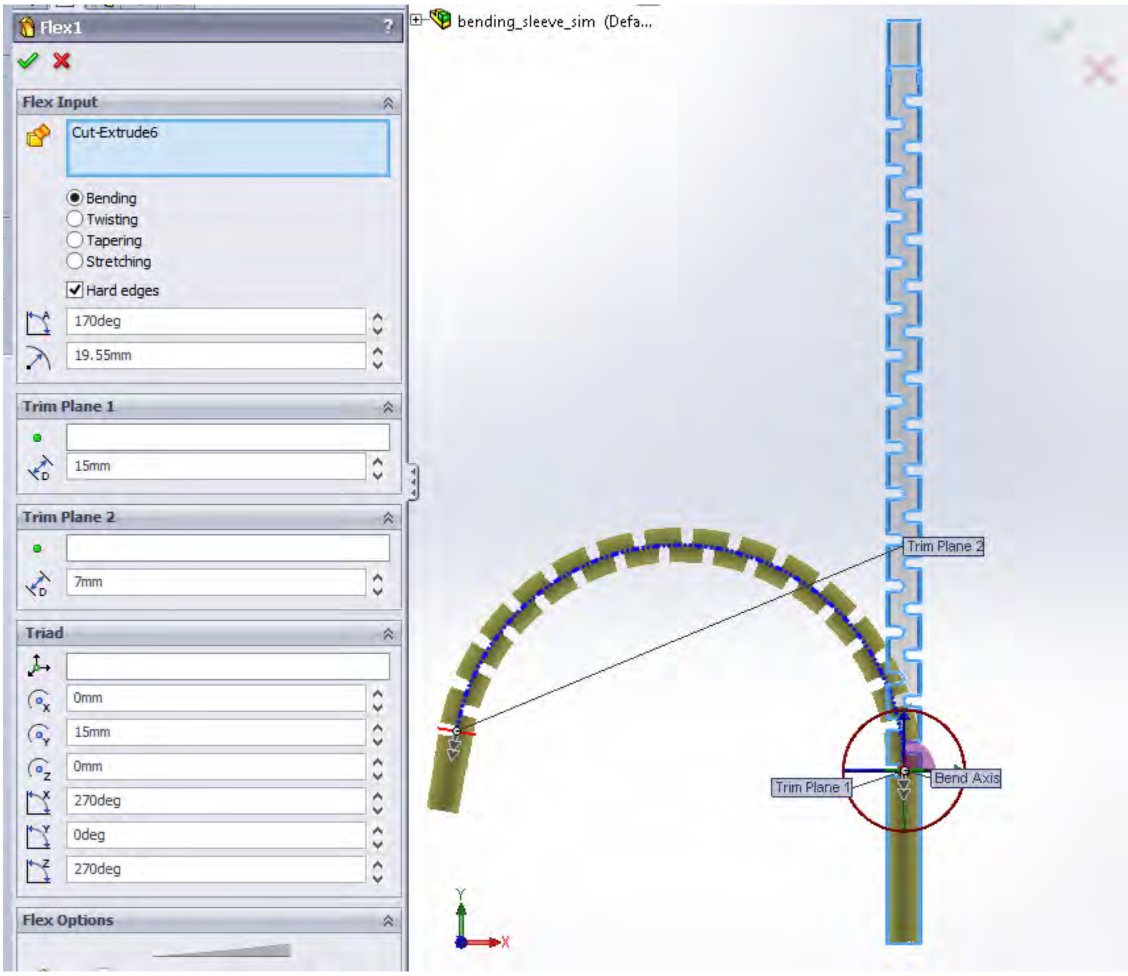


Figure 25: Test 1 with the bending angle being the fixed parameter.

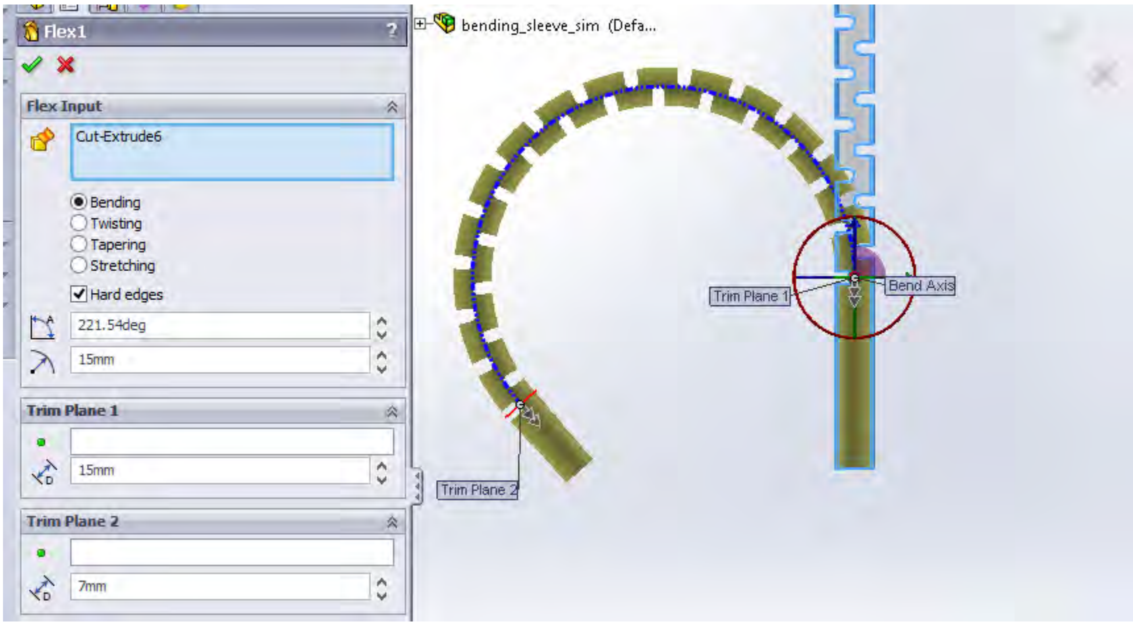


Figure 26: Test 2 with the bending radius being the set parameter.

The same test was carried out on the outer tube because the bending sleeve is enclosed in it. The results are shown in Table 8. Figures 27 and 28 show the screenshots from the tests of the flexing of the outer tube. Comparing the tests between the two components, the difference between the bending radius when the bending angle is the set parameter, the bending radius of the bending sleeve is 19.63mm whilst that of the outer tube is 19.55mm. With the bend radius set, the bending angle of the 221.54 degrees was attained.

Table 8: Flex property results for the outer tube

	Test 1	**Test 2**
Bending angle	170 deg	221.54 deg
Bending radius	19.55 mm	15 mm

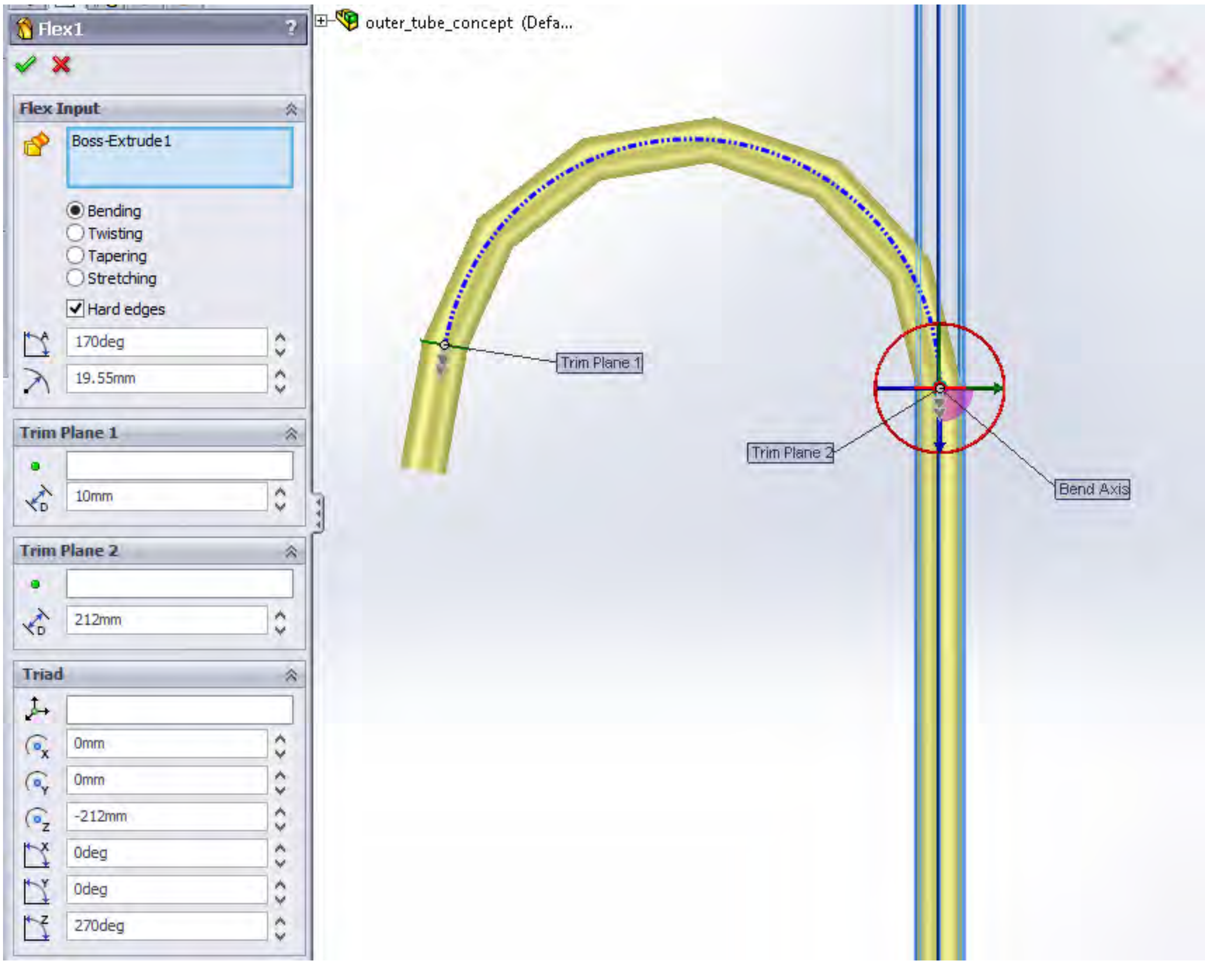


Figure 27: Test 1 with the bending angle set and the bending radius being the parameter sought after

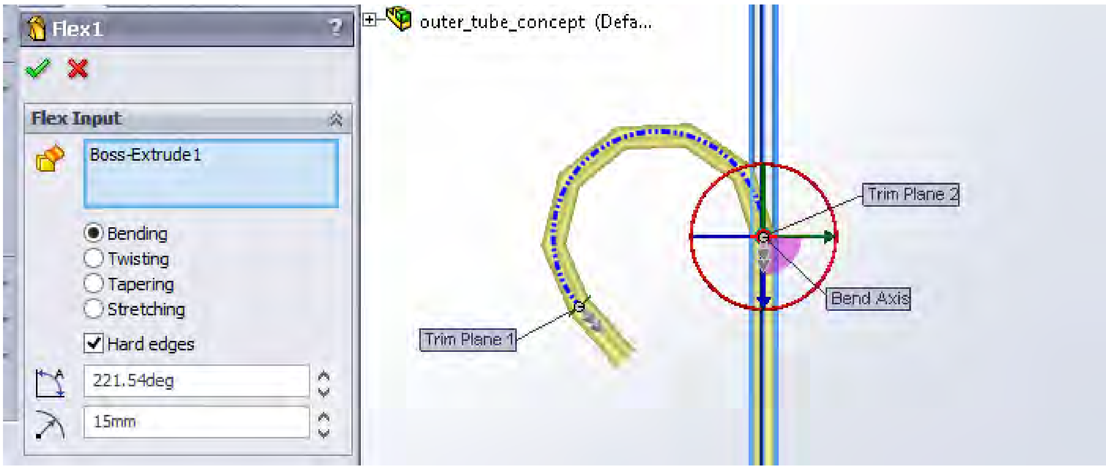


Figure 28: Test 2 with the bending radius set and seeking out the bending angle

4.1.1.2 Position lock test

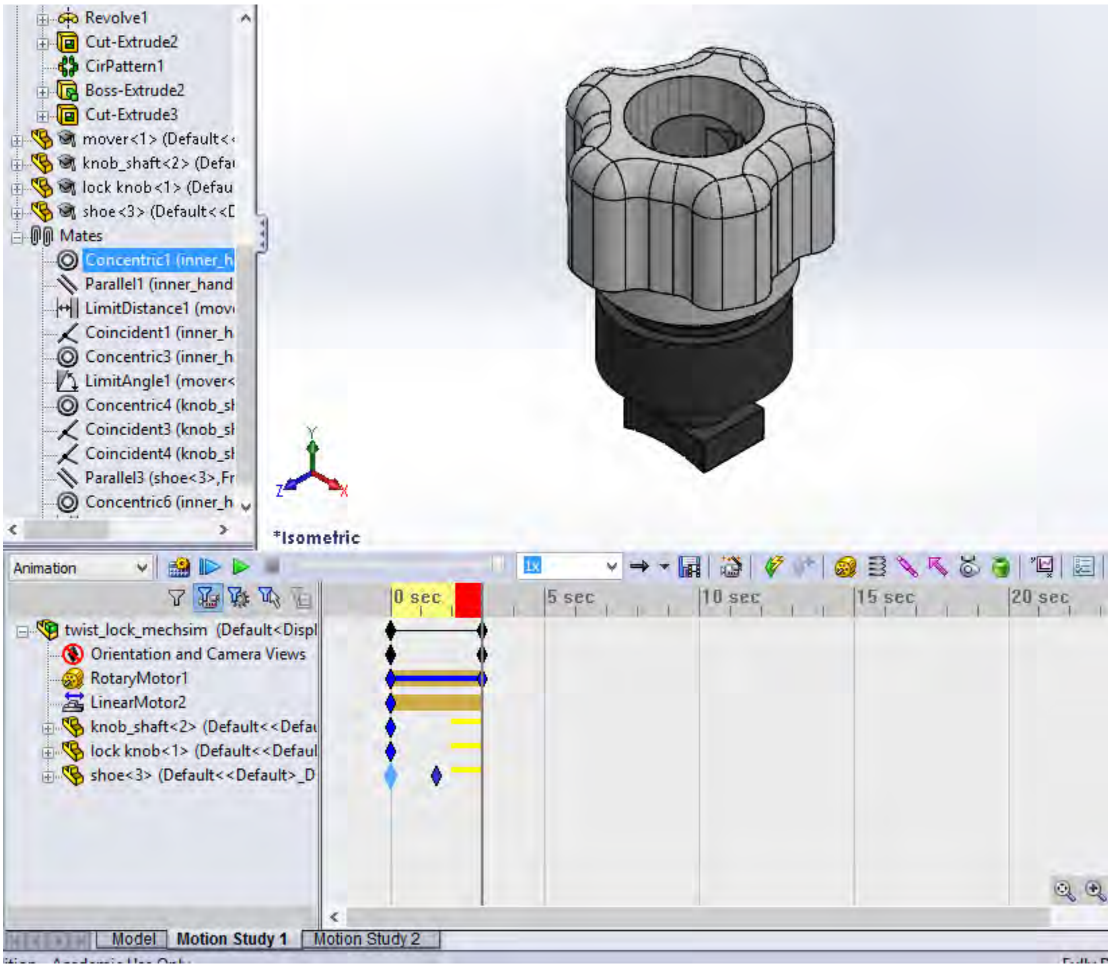


Figure 29: Motion study of the position lock mechanism

The position lock test was done through the Motion Study simulation in SolidWorks 2013. Figure 30 shows the use of the constraints and motion used during the motion study. The rotary motion of the knob caused the shoe to translate linearly towards the cable wheel to stop any movement. The output of the simulation was a video that could not be shown on the report. However, a series of images were generated to illustrate what the video showed. Figure 31 is a series of the images captured to illustrate the movement of the knob and the subsequent shoe movement. The red lines and red circles were placed to highlight the movement and the correlation between the angular movement of the knob and the linear movement of the shoe.

Figure 30: Series of images illustrating the animation of the position lock mechanism.

4.1.2 Irrigation and instrument subsystem

The leakage test was done in SolidWorks 2013. Firstly, for the verification of the flow of the fluid in the irrigation-instrument channel and secondly for the influx of fluids during sterilisation. For the first part of the leakage test, only the components involved in the irrigation-instrument channel are considered for clear results visualisation. A geometry conducted for the leakages, as shown in Figure 31, calculated the volume of fluid from entry point to exit point in the ureteropyeloscope is 0.47ml.

The flow simulation results showed how the pressure dropped as the irrigant flowed in the irrigation-instrument channel. Table 9 displays the inlet velocity, inlet flow rate, outlet velocity and outlet flow rate. Since the inlet velocity was defined in the study, this meant that also the inlet flow rate did not fluctuate with the number of iterations. However, the outlet velocity and the outlet volume flow-rate fluctuated as the tests were carried out. The relationship between velocity or the volume flow rate with the number of iterations is illustrated in Figure 32 and Figure 33 respectively.

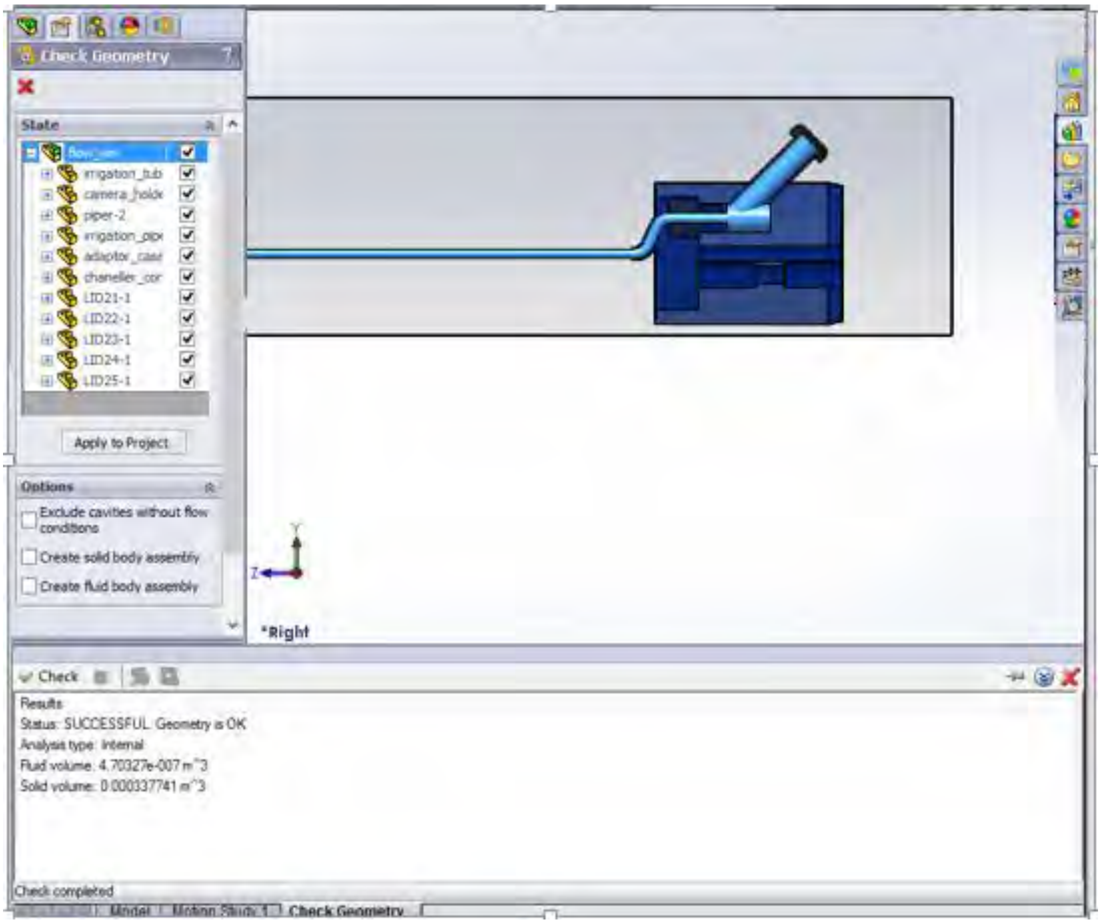


Figure 31: Running of the check geometry for any leaks before running the flow simulation

Table 9: Entry and exit flow velocity

	Steady state flow velocity	Steady state volume flow rate
Entry	0.1m/s	6.93e-7 m^3/s
Exit	0.86m/s	-7.52e-7 m^3/s

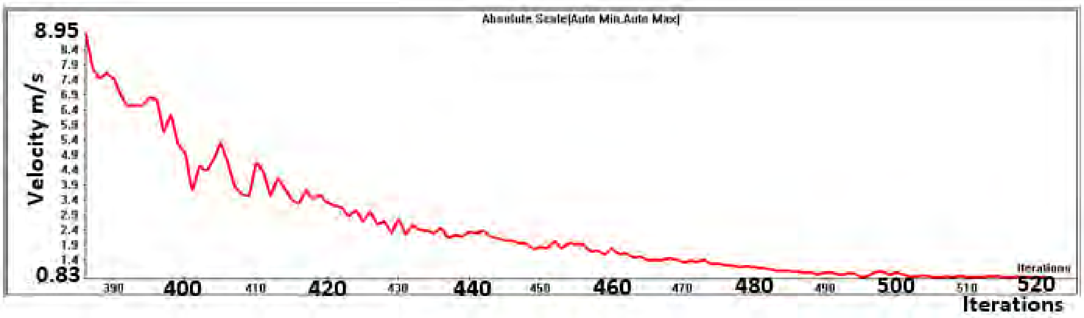


Figure 32: Graph of outlet velocity against the iterations performed

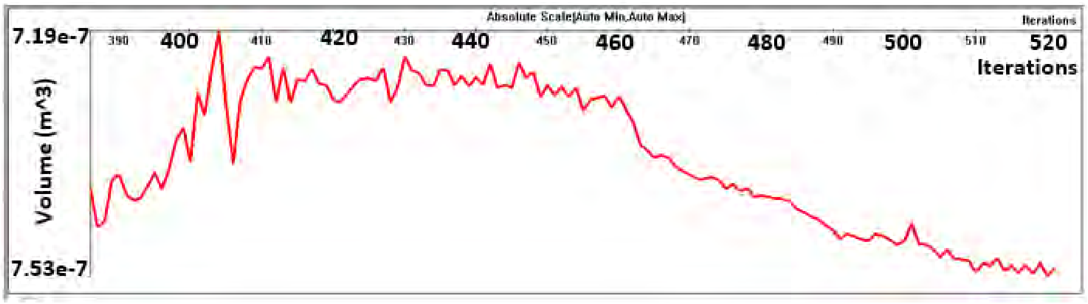


Figure 33: Graph of outlet volume-flow rate against iterations performed

For the influx of fluids during sterilisation, the test that was carried out was the Check Geometry via SolidWorks 2013 Flow Simulations. The design was found out to be watertight by the analysis, even though 97 invalid contacts were. Problems were detected and automatically fixed by the 'SolidWorks 2013 Check Geometry Module'. The invalid contacts found did not affect or influence the outcome of the tests; the errors were due to lines zero radius curves having zero-thickness and were resolved. Figure 35 illustrates the running of the test.

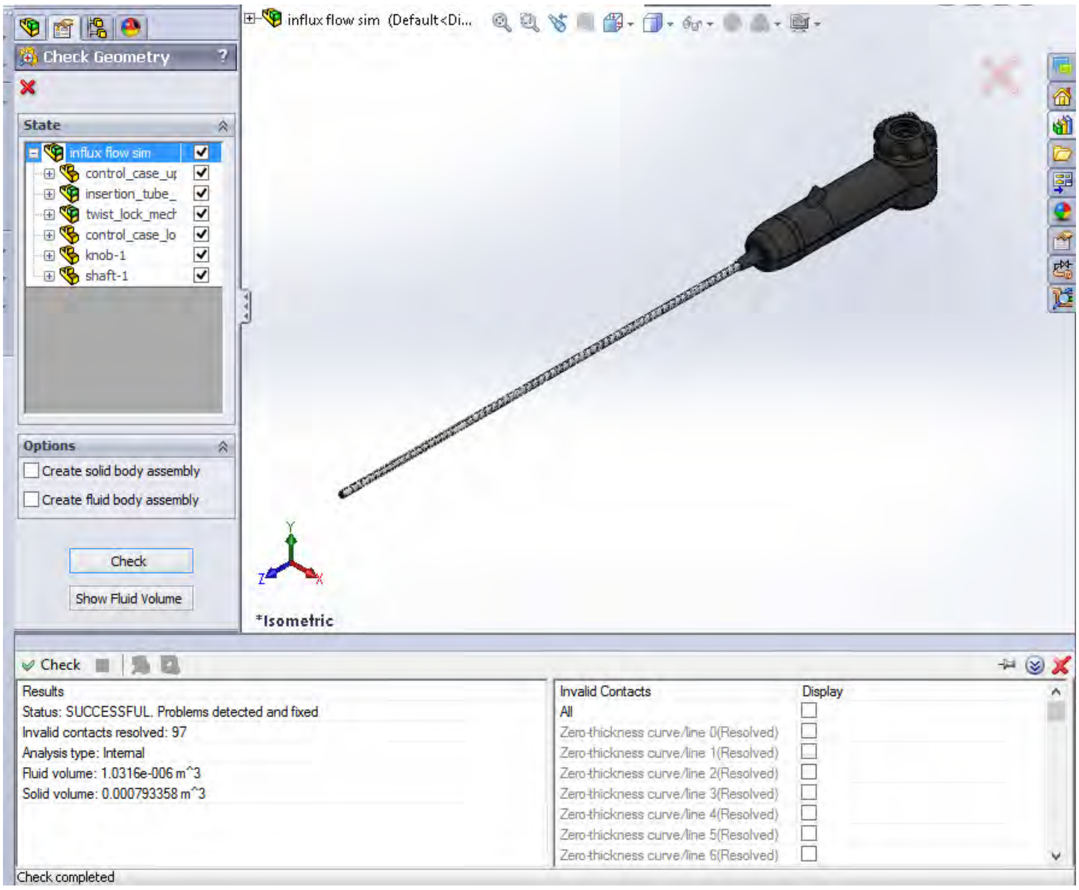


Figure 34: The Check Geometry results for the ureteropyeloscope to test for water tightness.

4.2 Durability

4.2.1 Static loading

The results of the four different types of the static loading are given in Table 11 below and the loading parameters and the resultant stresses and strains of the bending sleeve are shown. For all the loading configurations, the bending sleeve was constrained in a similar manner. Figure 35 below shows the method of constraining the bending sleeve. The blue arrow shows the constrained region of the bending sleeve and the constraining is done in such a manner to make the rest of the bending sleeve is bent relative to the region which lies between the two constrained sections.

Table 10: Results summary for the loading of the bending sleeve.

Type of loading	Loading Force (N)	Moment (Nm)	Max stress (GPa)	Max strain
Offset axial	3	-	2.68	1.61 e-2
Perpendicular	3	-	3.82	2.22 e-2
Combination	1.5	-	3.43	2.03 e-2
Torque	-	0.1	2.26	1.32 e-2

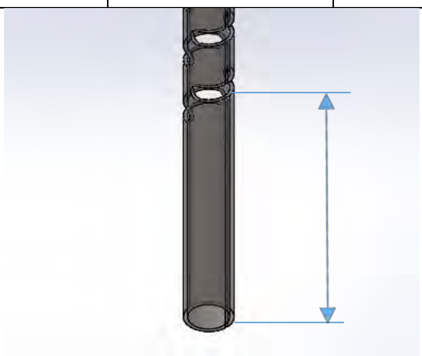


Figure 35: Illustration of where the bending sleeve is assumed constrained for the loading simulations.

Figure 36 shows the deformed bending sleeve under the axial loading. The regions of highest and lowest loading were highlighted. Figure 37 shows a zoomed in section of the region of the highest stress. Figures 38, 39 and 40 show the deformed bending sleeve caused by perpendicular, combination of axial and perpendicular and torque loading respectively. These also show the regions of highest and lowest stresses. Table 11 shows the regions of stress concentrations with the type of loading the bending sleeve underwent.

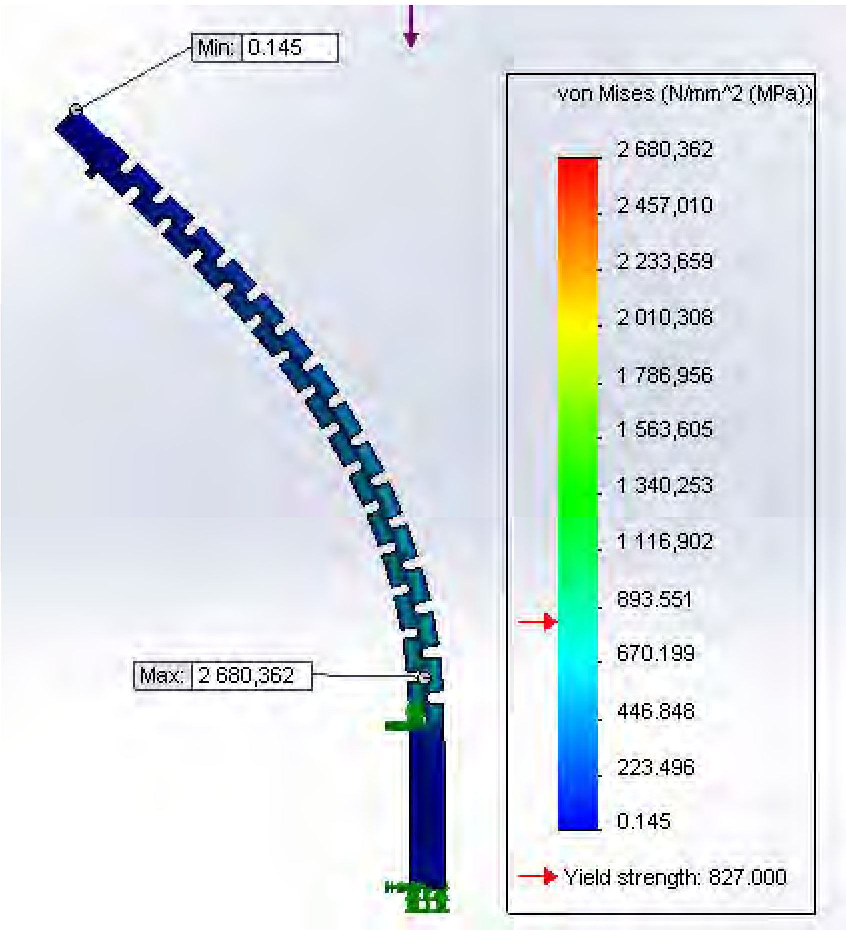


Figure 36: Deformation of the bending sleeve and stress patterns of axial loading

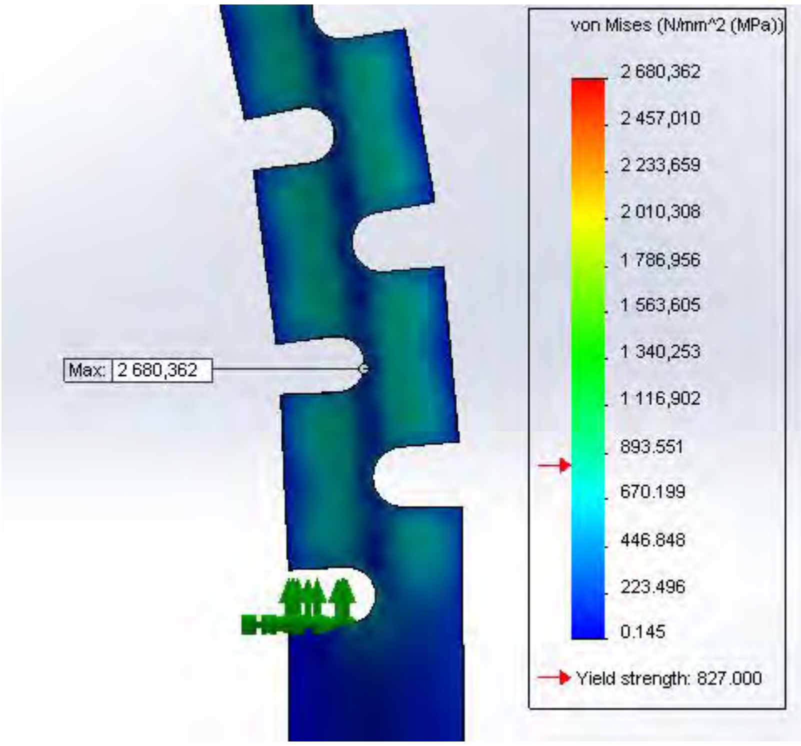


Figure 37: Zoomed in section of highest stress

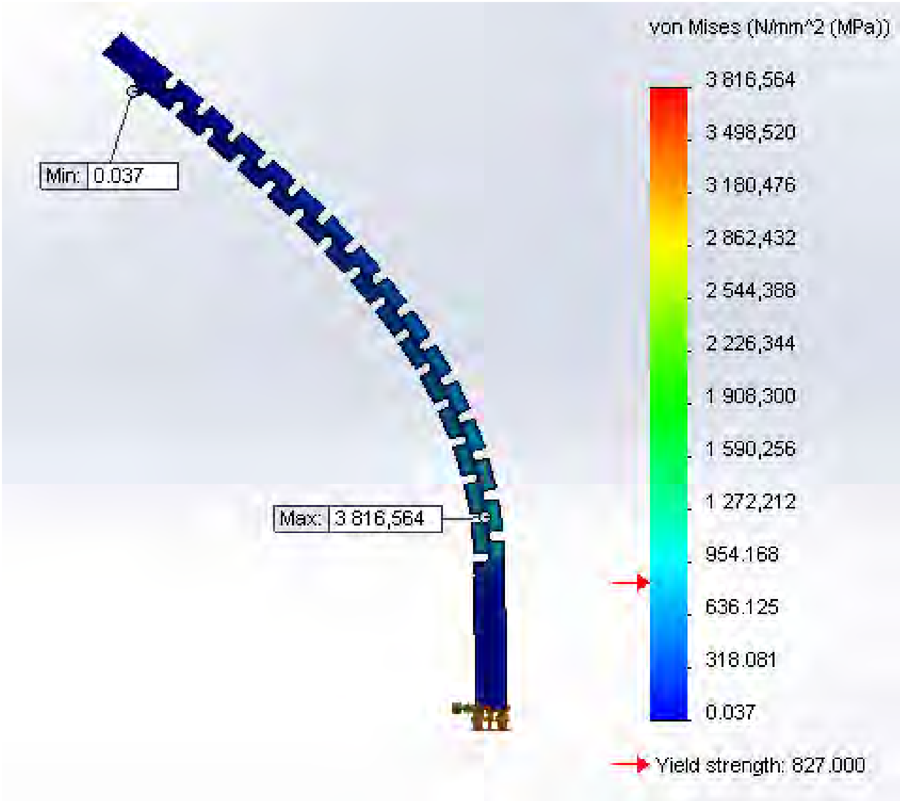


Figure 38: Deformation of the bending sleeve and stress patterns of perpendicular loading

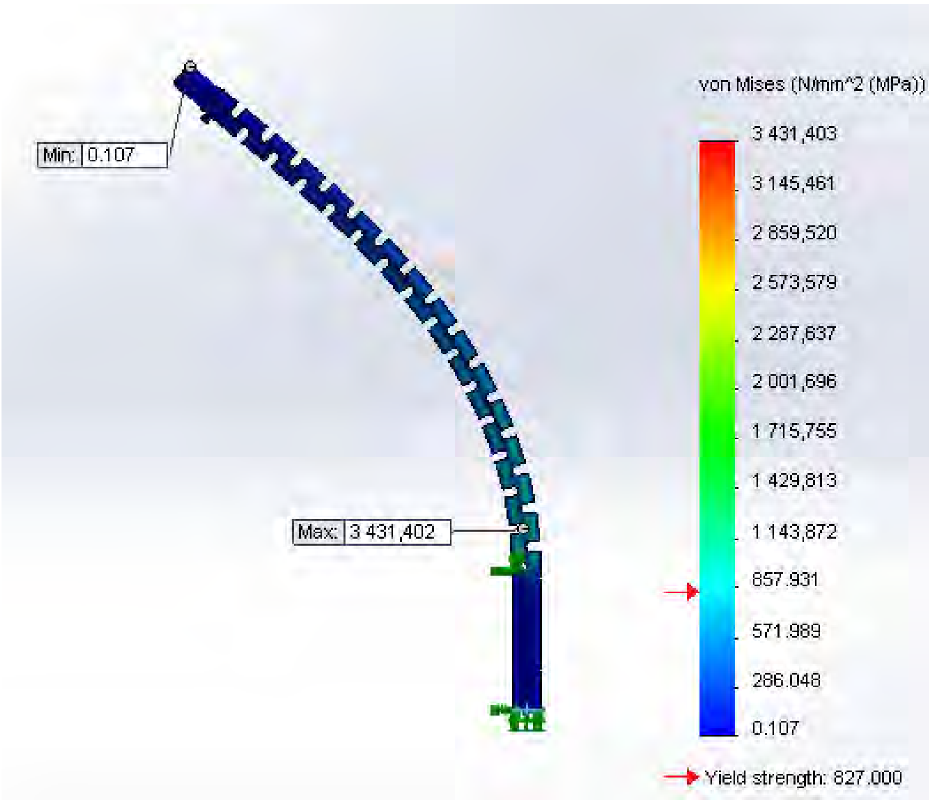


Figure 39: Deformation of the bending sleeve and stress patterns of combinational loading

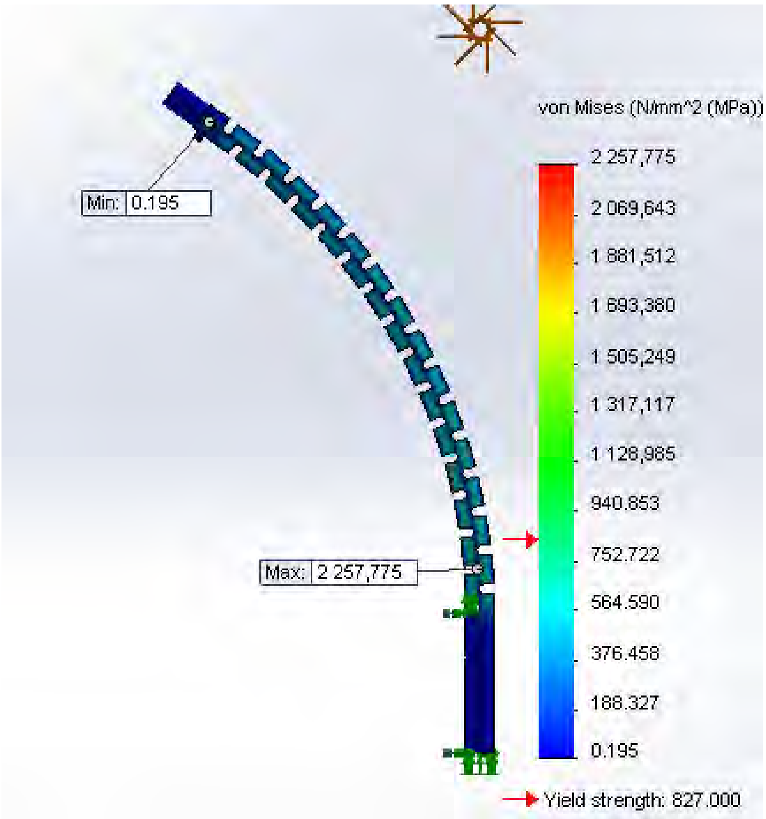
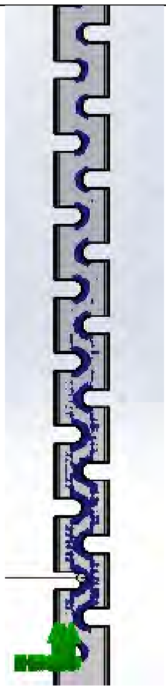
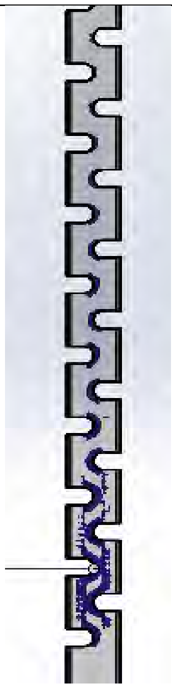
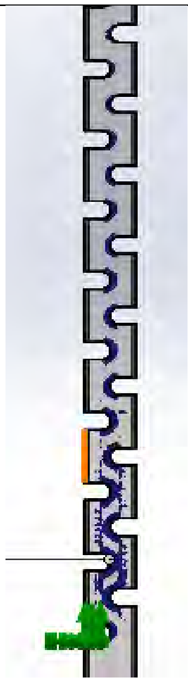
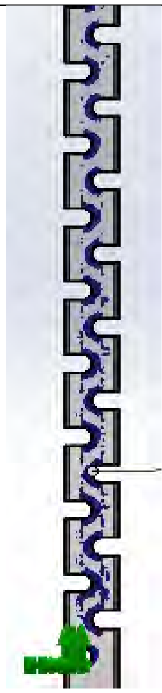


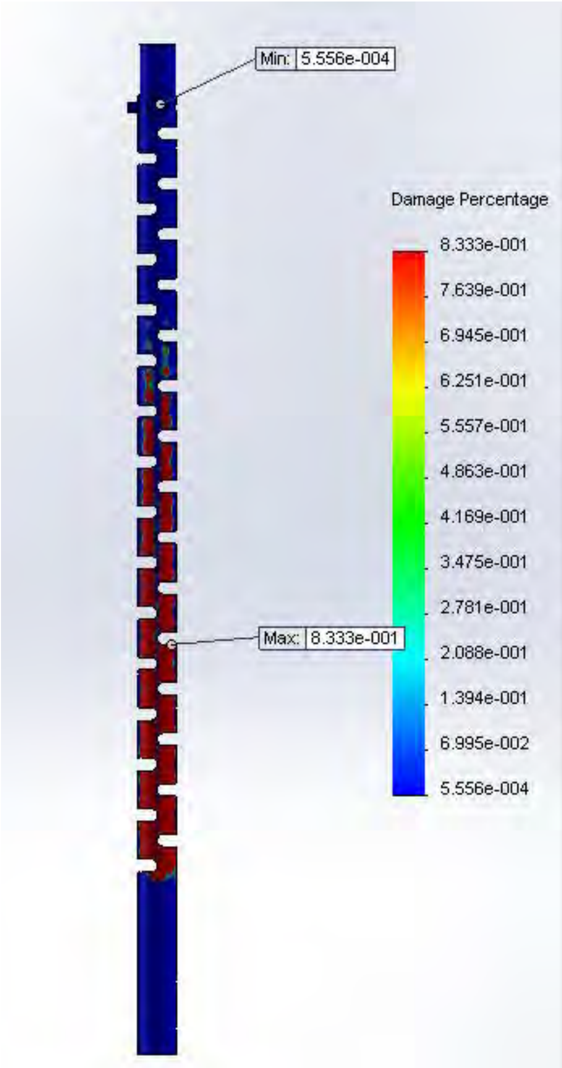
Figure 40: Deformation of the bending sleeve and stress patterns of torque loading

Table 11: Regions of highest stress with different types of loading

Offset axial	Perpendicular	Combination	Torque
			

4.2.2 Fatigue loading

The bending sleeve was tested for the number of cycles undergone before failure and damage per use. Figure 41 shows the regions that underwent the most damage when the tube was cyclically loaded for 1000 cycles, which was assumed as the number of cycles per use. The region that underwent the most damage is show by red and the particular place pointed out in the diagram, and the damage done at that particular point is 0.83% for 1000 cycles. It was noted that the cyclic loading affects the region closer to the area of constraint more than the region where the steel cables are attached.



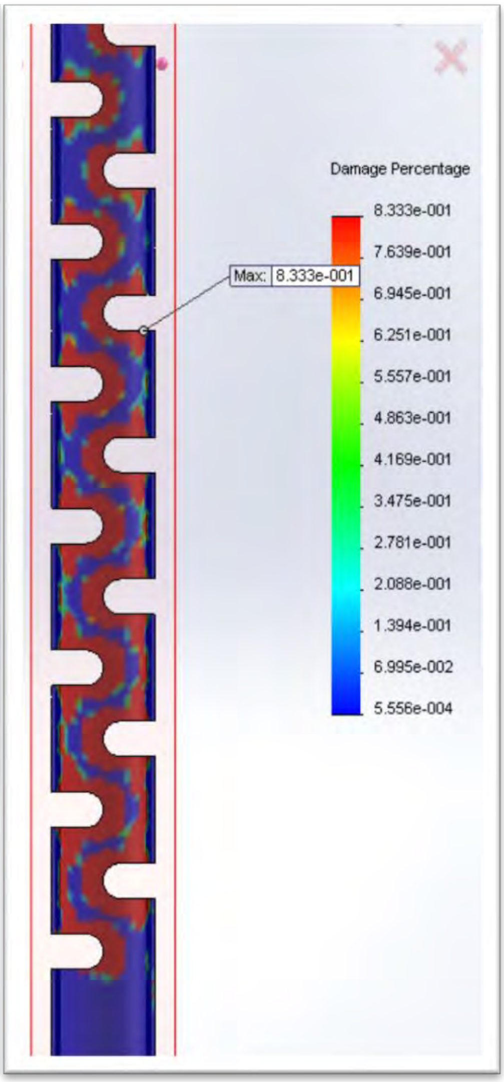


Figure 41: Damage to the bending sleeve after 1000 cycles

The bending sleeve was also tested for infinite cycles to determine the cycles undergone by the bending sleeve prior to failing. The region that was noted to fail first is the same region as that with the most damage after a 1000 cycles. This region failed after 12000 cycles and is shown in Figure 43, which illustrates the failed regions by the brick red areas. The region with the least damage was found out to be able to go up 18000000 cycles before failure.

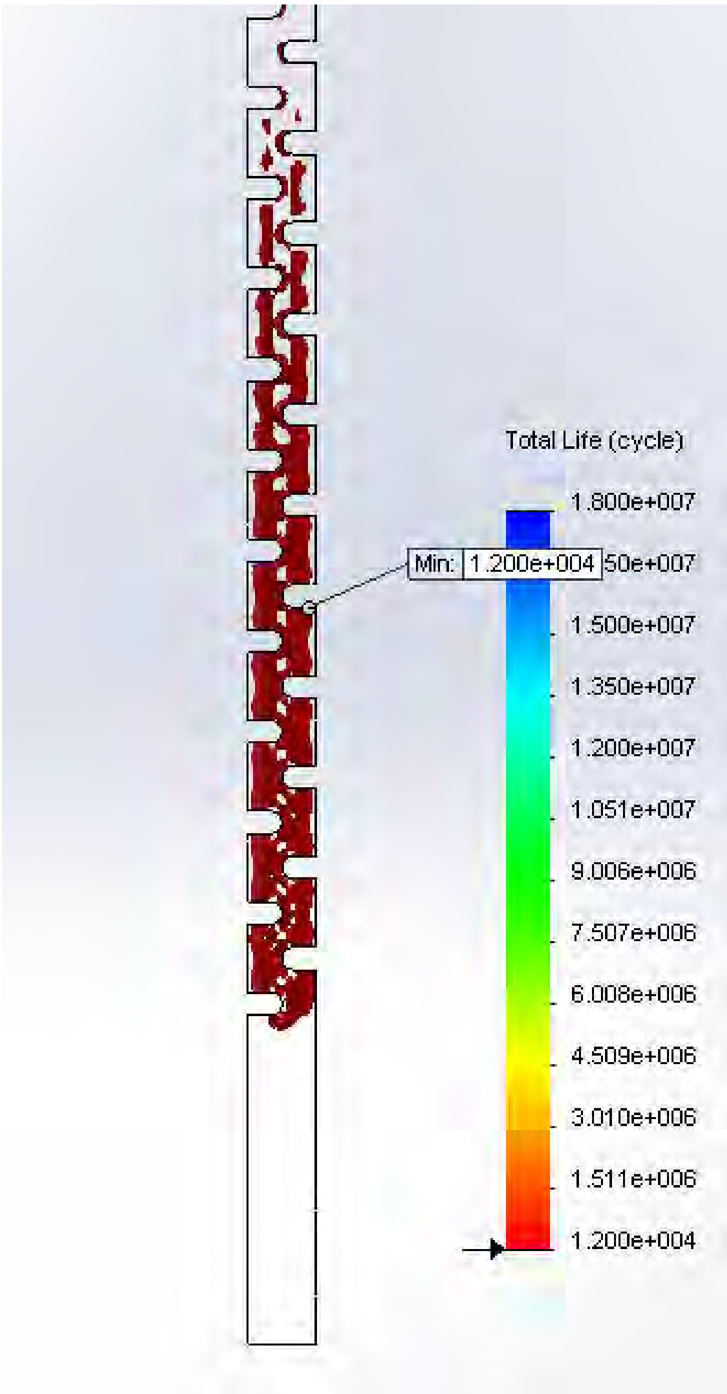


Figure 42: An image of ISO clipping for regions that fail at 12000 cycles of loading

A comparison between the results of the tests and currently existing ureteropyeloscope was tabulated in Table 12 next page. Table was drawn up to show the similarities or contrasts between the designed system and already existing ureteropyeloscopes. Some properties for the current designs were based on assumptions of the ureteropyeloscope operations and were not found in literature and these are cycles undergone before failure and percentage damage per 1000 cycles.

Table 12: Comparison of the designed system and current ones

	Design ureteropyeloscope	Current designs
Angles	170 degrees	270 (Abdelshehid et al., 2005; Rajamahanty & Grasso, 2008) 180 (Grabover et al., 2004)
Active bending sites	1	1 (Abdelshehid et al., 2005; Rajamahanty & Grasso, 2008) (Grabover et al., 2004) 2 (Bach et al., 2008) (Rajamahanty & Grasso, 2008).
Damage per use (1000 cycles)	0.83%	2% (Afane et al. (2000))
Minimum cycles undergone before failure	12000	6000 (Lei & Du, (2010)) 3000 (Afane et al. (2000))

4.3 Wireless transmission

4.3.1 Video capture

The image captured by the video capture system is shown below in Figure 43 juxtaposed to image of the same TV test screen captured by a currently used ureteroscope. Figure 43a) is the image of the TV test screen and is used as a means to compare and evaluate the quality of the video capture device. Figure 43b) shows that the video capture device.

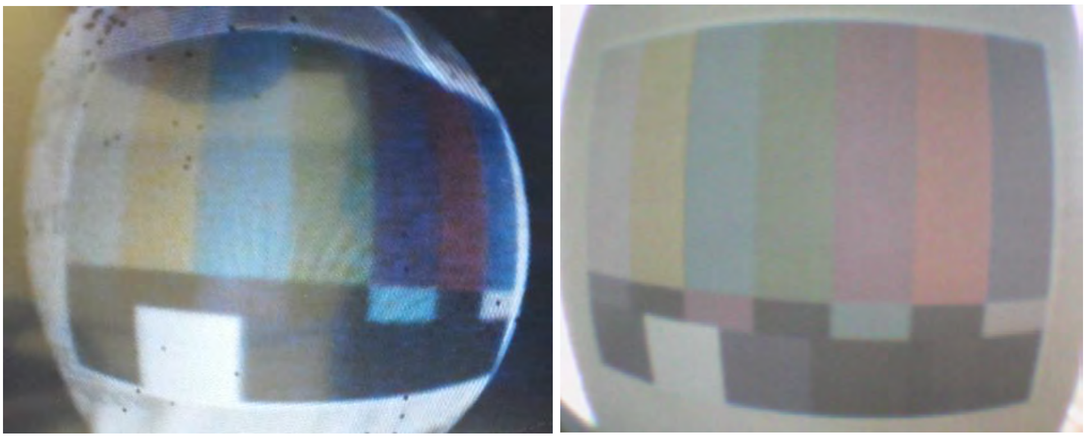


Figure 43: a) TV test screen images from currently used ureteroscopeb) image from designed ureteropyeloscope

The colours of the image of the TV test screen captured by currently used ureteroscope are brighter than those of designed ureteropyeloscope. However, the red in the acquired image appears more orange and blue appears darker than it actually is. The lower colours of the TV test screen can barely be recognised; purple and the dark blue on extreme left were not easily told apart.

4.3.2 Data transmission

For video transmission, the wireless video sender shown below in Figure 44 was used in the prototype. The frequency of transmission of the data was 2.4GHz and the bit rate was not given but was sufficient for video transmission as the name of the device states. The use of the video capture whilst observing the monitor was used to determine if there was any delay in the use of the wireless transmission system.

Figure 44: The video sender transmitter and receiver

Images captured with the use of the wireless video transmission system were compared to the images captured without the use of the wireless video transmission system. Figure 45a below shows the image of a TV test screen acquired with the use of the wireless video transmission system whilst Figure 45b shows the images captured without the use of the wireless video transmission system. From the two images, it can be seen that there is no significant visible differences between the captured images.

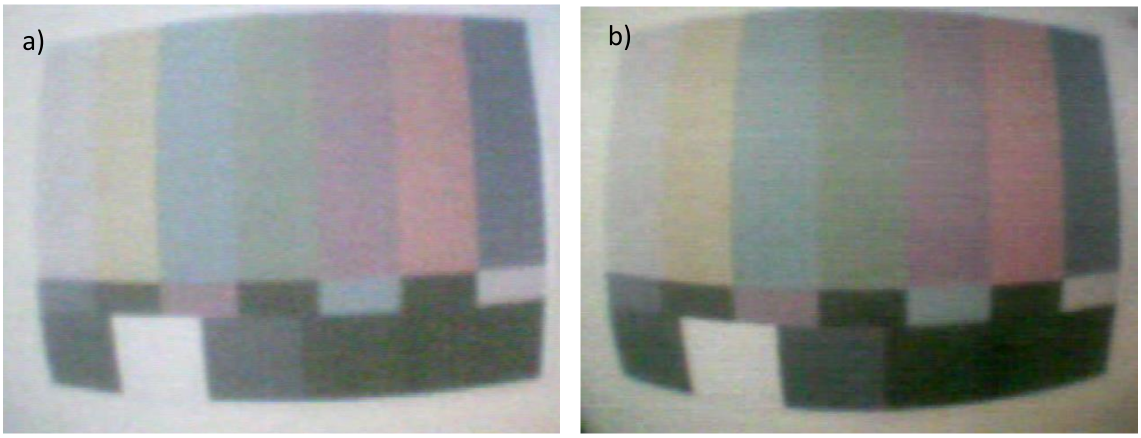


Figure 45: The image captured via a) wired transmission and b) wireless transmission

4.4 Manufacturing

4.4.1 Component design

Laser precision 3D printing can print any shape desired hence the components 3D printed are taken as standards, hence it was prescribed for some components of the ureteropyeloscope. The components, which were assumed manufactured through milling and drilling, were tested for production process through SolidWorks 2013 DFMXpress Module. Components assumed to be manufactured by milling and drilling included bending sleeve and the insertion tube attacher amongst other components. Other components that were not assumed manufactured through milling and drilling but through pressing could not be tested for manufacturability using SolidWorks 2013 modules. These included the metal end cover, found at the distal end of the insertion tube, and the helical tubes. Components that were assumed to be made through Injection moulding were also tested using the 'DFMXpress module'.

Table 13 below shows the manufactured components that were assumed to be manufactured by milling and drilling, pressing or by injection mould. Components not specified in the table below but critical to the ureteropyeloscope were deemed standard components or off the shelf components.

Table 13: DFMXpress of the components assumed to be manufactured

Component	**Material**	**Manufacturing process**	**Result**
Camera holder	PTFE	Injection Mould	Passed
Bending sleeve	Nitinol	Milling and drilling	Passed
Metal end cover	Stainless steel	Sheet metal	Passed
Helical tubes	Stainless steel	Sheet metal	Passed
Torque tube	Stainless steel	Turn with Mill Drill	Passed
Control attacher	Stainless steel	Turn with Mill Drill	Passed
Adaptor case	PTFE	Injection Mould	Passed
Control cases	PTFE	Injection Mould	Passed
Battery case + batteries	PTFE and standard components	Injection Mould	Passed
Angulation knob	PTFE	Injection Mould	Passed
Shaft	PTFE	Injection Mould	Passed
Cable wheel	PTFE	Injection Mould	Passed
Shaft friction plates	Nylon	Injection Mould	Passed
Case friction plates	Nylon	Injection Mould	Passed
Lock short-shoe	Nylon	Injection Mould	Passed
Lock shoe mover	PTFE	Injection Mould	Passed
Lock shaft housing	PTFE	Injection Mould	Passed
Lock knob shaft	PTFE	Injection Mould	Passed
Lock knob	PTFE	Injection Mould	Passed
Channeller tube	PTFE	Injection Mould	Passed

The bending sleeve was assumed to be manufactured by mill and drill processes only. The material used for the bending sleeve is nitinol, which is a superelastic material. The milling and drilling simulation was carried out in-silico through ‘SolidWorks 2013 DFMXpress’ and Figure 46 illustrates the simulation for the bending sleeve manufacturability test. There are rules which can be set in terms the manufacturing requirement such as the hole depth/diameter ratio. Hole to depth ratios of more than three should be avoided according to drilling principles, however, due to the geometry of the bending sleeve manufacturing requires breaking of this principle.

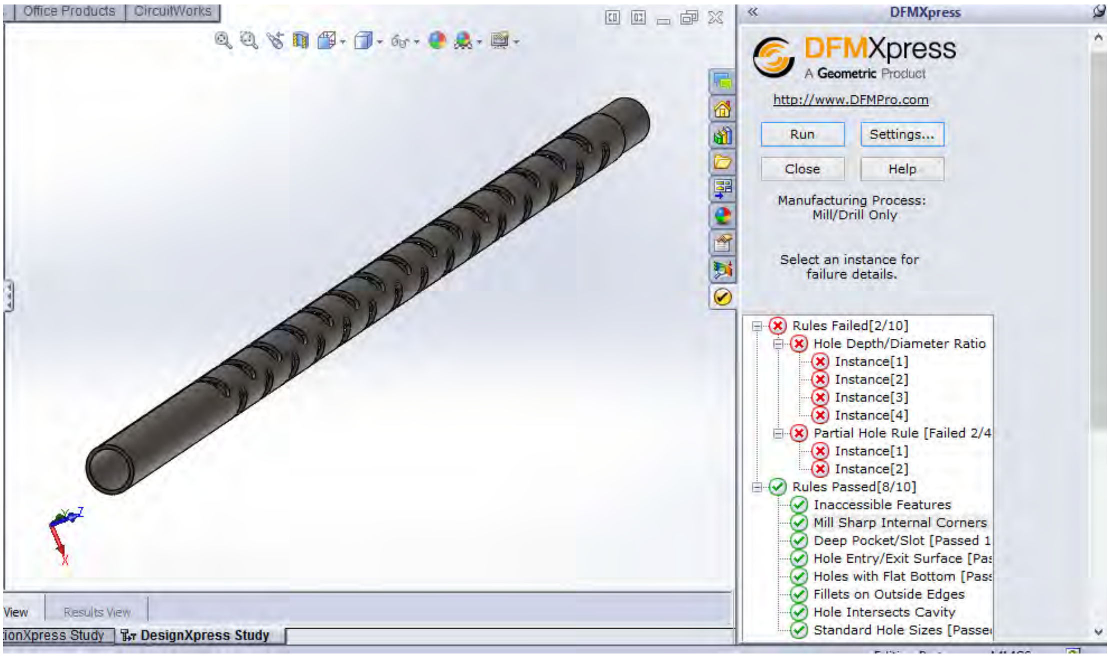


Figure 46: An illustration of manufacturability test for bending sleeve.

It was evident from the geometrical analysis of the bending sleeve that the hole depth to diameter ratio must not adhere to general design requirements. Micro-scale manufacturing is capable of producing the bending sleeve with its given parameters. Whether the turn with mill or drill process was used or a mill/drill process was used the results are similar. For the injection mould, Figure 47 illustrates the test ran. All the set conditions were met

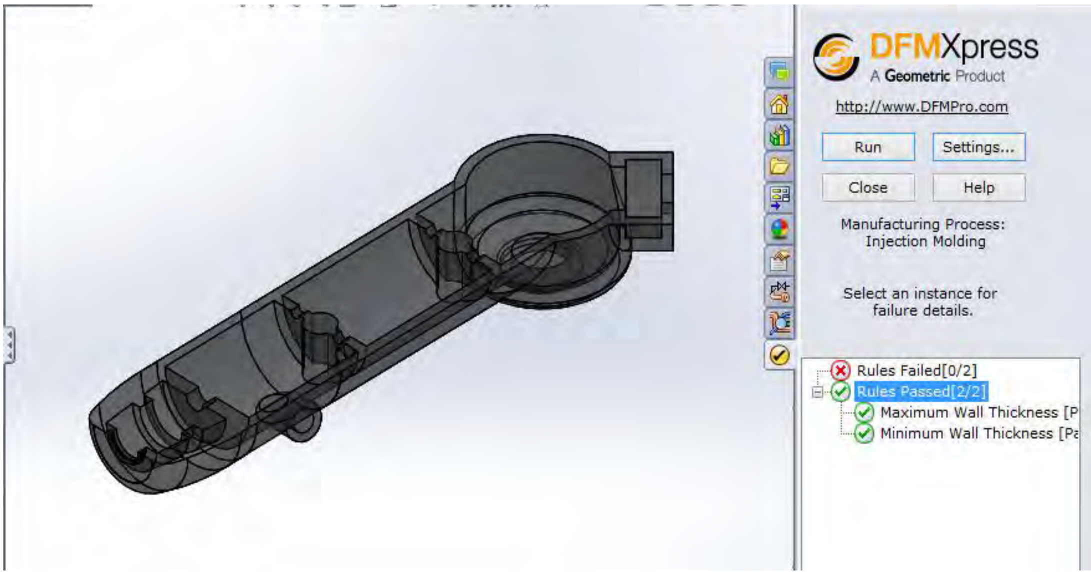


Figure 47: An illustration of results of an injection mould component simulation test

4.4.2 Design for Assembly

The design for assembly was tested through the prototype. The prototype made was assembled by the author and ease of assembly was noted to be a function of component sizes and the joining method. The developed prototype is shown in Figure 48 below. Table 14 shows the components considered for the design for assembly aspect of the ureteropyeloscope.

Figure 48: The prototype for assessing if the ureteropyeloscope adheres to design for assembly principles

Table 14: Analysis for ease of assembly

Subsystem	Components	Joining method	Component sizes	Comments
Insertion tube	Metal end cover & Outer tube	Glued	Small	Provides a strong joint and sealing
Interchangeability subsystem	Steel cables & Rods	Tying a knot	Very small	The steel cables have to be tied into a knot and the knot made is
Control Section	Cable wheel & steel cables	Tying a knot	Very small	Tying a knot interferes with the surfaces
Control section	Position lock mechanism & casing	Glued	Medium	Only one side is glued and the other is not
Control section	Shaft & angulation knob	Glued	Medium	Gluing components means the ability to disassemble is lost
Control section	Upper case & lower case	Screwed together	Large	Waterproofing should be tested for

Chapter 5: DISCUSSION OF DESIGN OUTCOMES

5.1 Design of the Ureteropyeloscope

The design of the ureteropyeloscope was successful and all the requirements met. The design was viewed from two vantage points (1) the CAD design and (2) the prototype of the ureteropyeloscope. The CAD design was successful in that all the tests that were carried out on the prototype which are bending sleeve tests, position lock test and irrigation and water influx flow test were passed by the design. Micro-scale manufacture and assemble of the ureteropyeloscope was prescribed.

The interchangeability aspect of the ureteropyeloscope could not be tested for the design due to constraints of tools available. SolidWorks 2013 did not have the module for the analysis of the actual joint design even though it was very helpful for modelling the parts and illustrating how they all fit in together.

Assembly of the prototype was preceded by the sandpapering of the components due to mating components not mating properly because of the 3D printing tolerance. All parts came out bigger than the prescribed design size. However, holes and all other internal structures were found to be smaller than prescribed design sizes. Ceramic-based 3D printing maybe cost efficient but it proved not to be time efficient due to the time spent sandpapering the components down and on sanding the components the cylindrical structures were not perfect cylinders anymore. Small components could not be sanded down due to their size and fragility and hence the components could not be used. The rods and ends rods are such components.

5.1.1 Angulation control subsystem

5.1.1.1 Bending tip test

The required angle of angulation of 170 degrees has a radius of 19.55mm for both the bending sleeve and the outer tube overlaying the bending sleeve. This implies that there would be no disparity in bending rate between the two. However, from mechanics of materials this cannot be true because the bending sleeve and outer cover have different modulus of elasticity. Noting that the bending sleeve has slots along its body and has a different thickness to the outer tube, it raises question to the credibility of the simulation of the bending of both the bending sleeve and the outer tube.

When bent to a radius of 15mm, the bending sleeve and the outer tube both attain a minimum angulation angle of 220 degrees. The reaching of this angle in the simulation could be attribute to the fact that the simulation may not take into account the fact that the outer tube material bulges up when bent. In addition, the modelling of the bending test does not account for accessory instruments.

There was a notable difference between the *in-silico* loading bending profile to the flex property one. This was due to the fact that the flex property does not take into account some parameters that the loading simulation takes into account. These include but are not only limited to finite element analysis and different constraints.

5.1.1.2 Position lock test

The simulation of the position lock mechanism was instrumental in deciding where the position lock design should be attached to. The extension of the shoe was required to press into the cable wheel and lock its position, and this was achieved is the relative twist between the lock shaft housing and the knob was fully realised. However, if not positioned properly, the extension of the shoe through the relative twisting of lock shaft housing and the knob, the cable wheel will fail to be locked and this could be detrimental to the patient during use. This simulation helped position the position lock system in the rightful position.

5.1.2 Irrigation and instrument subsystem

The flow of the irrigant through the instrument/irrigation channel did not have any leaks. This meant that the design of joints was tight and the waterproof as water was used as the flowing fluid. From Figure 32 it is evident that the interchangeability of the insertion tube is possible when considering the flow of the fluid. The proximal end of the irrigation/instrument channel on the insertion tube can be slid in and hold tight on to the adaptor.

For the test of the influx of fluid from the external into the ureteropyeloscope, done through the Check Geometry, detected 97 invalid contacts in the design. These were resolved and did not affect the fluid flowing from outside to the inside of the ureteropyeloscope. The invalid contacts were due to edges, which did not exactly lie up fully with another edge. This was of no major design consequences and was autocorrected by the Check Geometry module. The leakage test done *in-silico* was taken as the first step of leakage tests in the product development. However, it should be noted that the *in-silico* leakage test merely shows path taken by the irrigant, the pressure drops and joints traversed. The actual joint integrity can only be tested on an actual prototype at a later stage of the ureteropyeloscope development.

5.1.3 Prototyping of model

5.1.3.1 Bending tip test

The prototype failed the bending test due to the components used for the design and the materials the components are made of. The bending of the distal end of the insertion tube did not happen as expected due to components used for the prototype. In the CAD design, the bending sleeve was taken as the main component responsible for the bending of the angulation. However, the prototype does not have the bending sleeve due to the manufacturing constraints and the cost of getting a component that would approximate it.

5.1.3.2 Position lock test

The position lock test of the prototype, shown in Figure 31, carried out the desired function. The shoe was not incorporated in the prototype due to space constraints; however, the position lock mechanism was able to arrest the motion of the angulation shaft. The adaptation of the position lock from a twist pen was more beneficial in terms of manufacturing and the functioning more accurate than the prototyped one due to the prototyped having mating problem. The CAD position lock system had a shoe with rough contact surface, which the prototype model did not have. The shoe was assumed to give the prototype a longer life as it was design for enduring more friction upon contact.

5.2 Durability

5.2.1 Static loading

The angulation of the bending sleeve simulated through SolidWorks 2013 was to test the design calculations made and the angulation they effected. Nitinol properties, inputted by the author on SolidWorks 2013, did not have the superelasticity behaviour because nitinol did not come as a standard material nor does superelastic behaviour in the SolidWorks 2013 Materials Library. This meant that the simulations were not fully accurate and the degree of accuracy could not be determined.

Forces applied on the bending sleeve for angulation, shown in Table 17, all show that even with different types of loading applied, the region of highest stress is the same. Moreover, these regions are seen to have stresses beyond yield stresses. The loading simulated on SolidWorks 2013 assumes constant force loading throughout the process of force application. This is known not to be true as phase transformation undergone by nitinol makes it easier to deform, hence after phase transformation lower forces are required angulating the bending sleeve.

From the analysis of Figures 37, 39, 40 and 41, it is evident that there are regions of the bending sleeve that experience stresses beyond the material yield strength. This means those regions have undergone phase transformation and the nitinol is weaker in those regions. In this phase, the nitinol is easily deformable and needs lower forces to deform. This region is similar in all types of loading. The rounded edges at the bottom of the slots face the highest stresses as depicted on Table 19 and the rounding helps curb crack propagation.

Table 11 shows the regions of the bending sleeve which experience the most stresses, and for three of the configurations of loading the region is the same (except for the torque loading). The regions of highest stress were found to be more proximal (closer to the handle) than distal (further from the handle). This may be due to the loading of the bending sleeve having a sort of buckling effect type of loading when loaded. In buckling loading scenarios, stress is higher closer to the fixed point or the base of the column.

5.2.2 Fatigue loading

For fatigue loading for a single procedure, the regions that underwent most damage is shown in Figure 42, the bending sleeve underwent a 0.83% damage. This test does not take into account the phase transformation undergone during bending. In addition, when phase transformation is accounted for the 0.83% damage made on the bending sleeve could be reversed. For full on fatigue failure the first point to fail would do so after 12 000 cycles. This means that the likelihood of the bending sleeve to fail through fatigue is very small.

Table 12 showing the comparison between the designed ureteropyeloscope and some of those being currently used highlighted the fact that there is an increase in durability for the designed ureteropyeloscope. Single use deterioration for the was 0.83% compared to 2% for currently used ones. This means that the designed ureteropyeloscope was 2.4 times more durable than previous designs in terms of single use durability. Failure for the designed ureteropyeloscope occurred at 12000 cycles compared to 3000 (Afane et al. (2000)) and 6000 (Lei and Du, (2010)) cycles. This means that the design life was increased by 200% and 100% respectively.

5.3 Wireless transmission

5.3.1 Video capture

The camera used determined the quality of images acquired. The images, as it can be seen in Figure 44, acquired by the image capture device was sufficient to distinguish between the colours of the TV test screen. However, the resolution of the image acquired did not match up to the resolution of the images captured by currently used ureteroscopes. This was due to the quality of camera used. The camera resolution used for the prototype is different for the camera specified for the final product, hence the resolution of images captured by the final product will be clearer than the ones captured and shown by current prototype.

The ureteropyeloscope is used for intervention procedure in the urinary system and therefore whether blue appears darker or not does not really affect the function that it is intended for, as there are no blue regions within the urinary system. Furthermore, the size of the camera used for the prototype was bigger than that specified for the final product.

5.3.2 Data transmission

There were no detectable image quality differences between the wired transmission and wireless transmission, the clarity of the captured images was similar. The noise associated with wireless transmission was keep to a minimal and the result was that it could not be detected. Lack of any detectable differences between the two modes of transmission implies that the use of wireless transmission of the images was as effective as the transmission of the images using a wired transmission. However, the wireless transmission is better than wired transmission due to reduction of cables in the working space of the clinician.

Size of the image-transmission device matters as it must fit inside the handle of the control section. The prototype of the ureteropyeloscope used a large image transmission system due to cost implications. The wireless transmitter used had two audio channels that are not necessary and elimination of these channels would be instrumental in size reduction of the wireless transmitter.

5.4 Manufacturing

5.4.1 Component design

The components shown in Table 15 are theoretically producible according to the SolidWorks 2013 DFMXpress module. However, it must be noted that because the DFMXpress module says that a component is manufacturable it does not necessarily mean it is. The DFMXpress module when deciding the manufacturability of a component did not consider the machine tolerances and actual manufacture processes. This meant that 3D printing the components and assuming they would be manufacturable through milling and drilling could be misleading and components, which were suspected to be difficult to mill and drill, were crosschecked with a fitter and turner. This validated the SolidWorks 2013 result.

The cost of manufacturing small parts that mate with other small parts requires micro-scale manufacturing. Production of these parts is most likely to be expensive due to the size, strength and reliability required of them. The assembly of the small parts with the small parts in the given environment would require specialised machines or highly skilled people, which in turn affect the cost of manufacturing. Component design is a critical means to lower the cost of manufacture for the ureteropyeloscope

Deep, narrow holes with length to diameter ratios of larger than three should be avoided. Deeper holes are possible but the drill will tend to wander and possibly break. One way to avoid a deep, narrow hole is to use a stepped entrance. Blind holes should be drilled to a depth 25% deeper than the actual hole in order to provide space for chips. However, in some cases the above conditions could not be avoided for example the bending sleeve. The bending sleeve was prescribed to be made of nitinol, which is a superelastic material. On Milling and drilling nitinol to make the slots to compensate for bending burring may occur which affects the functioning of the metal.

The parts that were made for the prototype were either 3D printed or standard parts. This meant that the running costs of manufacturing were kept low. The 3D printing used was ceramic-based 3D printing and as mentioned before the components were made bigger than required and had to be sandpapered down for mating components to fit in together as desired. The desired strength of components varied and the ceramic-based components managed to achieve the strength required for most components. The only components that needed higher strength or a plastic deformation plateau before failure was the control cases. This was due to the forces that were applied to it in assembly and its likelihood to be dropped during use, which would shatter the cases.

5.4.2 Design for Assembly

The sequence of assembling the components was important for the optimising of the time spent assembling. The components that were left out of the prototype due to manufacturing constraints had negative impact on the assemble of the prototype as discussed in the Design Outcomes. The sequence of assembling for prototype needed three pairs of hands, one holding the angulation knob and position lock mechanism in place, second pair of hands handling the cables at the distal end for attaching the cables to the camera holder and third pair to screw the control cases together. The assembling of the components had to be done this way due to failure of manufacturing of some components. For example, had the rods and ends rods manufactured, the pair of hands holding the cables at the distal end of the insertion tube would not be necessary.

The prototype at hand was fully assembleable and disassembleable with the exception of the angulation knob. The joining of the angulation knob to the angulation shaft was done through gluing because the shaft could not be threaded. The attachment mechanism of the angulation knob to the angulation shaft was a screw on for the CAD model and this made the ureteropyeloscope easily disassembleable. Using glue to join the angulation knob and angulation shaft made the joint permanent, meaning that the ability of the ureteropyeloscope prototype to be disassembled and assembled at will was lost.

Chapter 6: CONCLUSIONS AND RECOMMENDATIONS

The main objectives of the study are 1) increasing the durability of the ureteropyeloscope, 2) decrease the number of cables around the workspace of the clinician and, 3) assessing the manufacturability of the designed ureteropyeloscope. Further, this study provides groundwork for future work of the development of endoscopes in a South African context. This chapter gives the conclusions and recommendations for future work from the study

6.1 Evaluation of the Attainment of Objectives

The design of the ureteropyeloscope documented in the study at hand and components used for the design are specified. The designing and modelling of the ureteropyeloscope was successful in meeting requirements stipulated by a clinician. Durability of the deflection unit was tested through static and fatigue tests on the CAD model via SolidWorks. The CAD design was also used in assessment of the manufacturability of the ureteropyeloscope through analysis of component manufacture and assemble.

The assessment of the durability of the bending sleeve suggested that the bending sleeve was as twice to four times as durable as previous designs. However, it is worth noting that increase in durability of the ureteropyeloscope was assumed to be directly linked with bending sleeve whereas the failing mechanism in previously used ureteropyeloscope may have been in the assembly of the bending system not merely the bending sleeve. The lack of in-*silico* testing of the insertion tube leaves the current results needing more tests to validate the increase in durability.

The prototype built was a first of prototypes in the development of the ureteropyeloscope. The prototype was modelled on the actual design size, was not scaled up, and this highlighted the need for micro-scale precision manufacturing of some of the components, such as the rods and the ends rods. The prototype showed that the ureteropyeloscope design needs a highly skilled individual or machinery for the assembly of components. The prototype did not include all required components due to high expenses involved in making those components, and this showed that manufacturing such medical instrument is expensive.

The prototype was successful in showing the functioning of the wireless video transmission system. The wireless video transmission system used in the prototype is sufficient for transmission of the captured images to be viewed in real-time, therefore the design of the wireless video transmission system is successful.

6.2 Suggestions for future designs

6.2.1 Design suggestions

For the next design iteration, the design and manufacture of the ureteropyeloscope must be done with strict adherence to the ISO 13485:2003. This document provides comprehensive quality management system for the design and manufacture of medical devices.

It is imperative to draw up a Life Cycle Cost Analysis (LCCA) for the ureteropyeloscope in the next design iteration. The LCCA would aid in assessing the return-on-investment on the design of the ureteropyeloscope including full costs to manufacture including labour, periodic maintenances and unforeseen repairs. This document would help inform the viability of further development of the ureteropyeloscope.

6.2.2 Testing and prototype suggestions

The prototype documented in this study is an initial prototype and the second prototype for the subsequent design iteration must test the flow of fluid within the ureteropyeloscope. The flow of fluid must be tested for cavitations and bubble formation, which may occur during the flow as the irrigant traverses from the control section to the distal end of the insertion tube. Bubble formation may cause air embolisms, which may lead to death in the patient. Flow characteristics of the second prototype must be detailed to determine regions where cavitations may occur. Furthermore, the irrigant flow must be tested in the presence of an accessory instrument in the channel.

For the next prototype developed, the bending mechanism must be built to the exact specifications of the design and tested accordingly. This must be done to test for the actual forces required for the angulation, further assessment of the components involved and the assemble thereof, and how the design can be improved in terms of space minimising and strength of components.

The wireless video transmission system used in the current prototype was an off-the-shell component. The size of the component was too big to be fitted into the handle of the ureteropyeloscope. Custom-made wireless video transmission system must be developed and fitted in the control case of the next prototype. The custom-made wireless video transmission would rid the circuitry of the unnecessary components, which exist in the currently used wireless video transmission system. Making the system fit in the control case would also aid in the testing of the waterproof aspect of the ureteropyeloscope to ascertain that the scope is sterilisable.

Component manufacture for the subsequent prototype must be plastic-based 3D printed components. This would ensure that the components would be closer to the desired design specifications compared to ceramic-based 3D printed components, which upon being printed were slightly larger than the design specifications.

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Appendices

Appendix A: Design Process Documentation

A1: Product Requirements Specification

Functions and features

1. The main function of the device is to provide an image of internal organs during an intervention procedure of the urinary system.
2. The device must be capable of providing real-time images of the internal organs.
3. Batteries must power the device for the duration of the procedure.
4. The device shall be easy to handle and shall be aesthetically attractive.
5. The device shall weigh as little as is engineering possible.
6. The device shall be robust and strong to withstand falls from heights of 2 metres.

Functional performance

The device shall be capable of:

1. Illuminating the area of interest from its own insertion tube.
2. Providing the clinician with high quality images.
3. Being handled easily by the clinician.
4. Being operated for the duration of an endoscopic intervention procedure, however long it takes, without running out or low on power.
5. Being operated in water medium, device must be waterproof to protect the wireless video transmission system.

Ergonomics

1. The device must be able to be operated by a clinician, using only one hand (left hand).
2. The handle design must be comfortable enough to be operated for as long as six hours.
3. The handle must be light enough to be held comfortable for long hours.

Safety

1. The device must not pose any danger of harming the user in case of control failure. It must have a failsafe mechanism.
2. The device must comply with regulations of invasive devices

3. Shock of the patient must never occur even during failure of the device.
4. There must be stable wireless transmission during use.

Maintenance

1. The mean time between maintenance (MTBM) must exceed 6 months.
2. The Life Expectancy of the device must be 5 years.
3. The device must be cleanable by a damp soapy clothe as well as disinfection liquids for endoscopes.

Environment

1. The device must have as few cables as possible.
2. The usage of the device in the consultation room must not hinder other activities in the in the room or interfere with other devices and machines.
3. 60% of the parts should be reusable (Wish).

70% of the material used should be recyclable (Wish).

A2: Design Specification Form

FORM		
What will it look like?	It will look like currently used flexible ureteroscopes	
What materials will be used	Made up of different materials depending on the function of the component	
	Bending sleeve	Nitinol
	Control casing	PTFE
	Insertion tube covering	PTFE
	Adaptor case	ABS
What is its size?	Insertion tube diameter	4mm
	Insertion tube length	450mm
	Control case diameter	24mm
What are its special features?	A 1.2mm camera at the distal end of the insertion tube connected to a wireless transmitter for image transmission	
FUNCTION		
What is the type and purpose of the product?	The product is a biomedical invasive device called an endoscope. It is used for diagnostic and therapeutic kidney stones procedures.	
What will it do?	The product will provide clinicians with images of the urinary system as well as provide means to carry out therapeutic procedures as well as provide means to access diseased regions.	
How will it do this?	The product will be introduced into the human bladder and then navigated up the urinary system where it will aid the clinician with images of the internal structures for diagnosis and therapy.	
USER		
What is this product used for?	Product is used for accessing the urinary system for therapeutic procedures carried out by a clinician	
What does the user want to	The product helps access the urinary system for	

do with the product?	diagnosis and therapeutic procedures for urological disease diagnosis and therapy.	
Where and why will the product be used?	It will be used in an operating theatre to aid in diagnosis and therapeutic procedures for kidney stone removal.	
What do users want the product to look like?	The product must look like currently existing ureteroscopes.	

A3: Functional Analysis

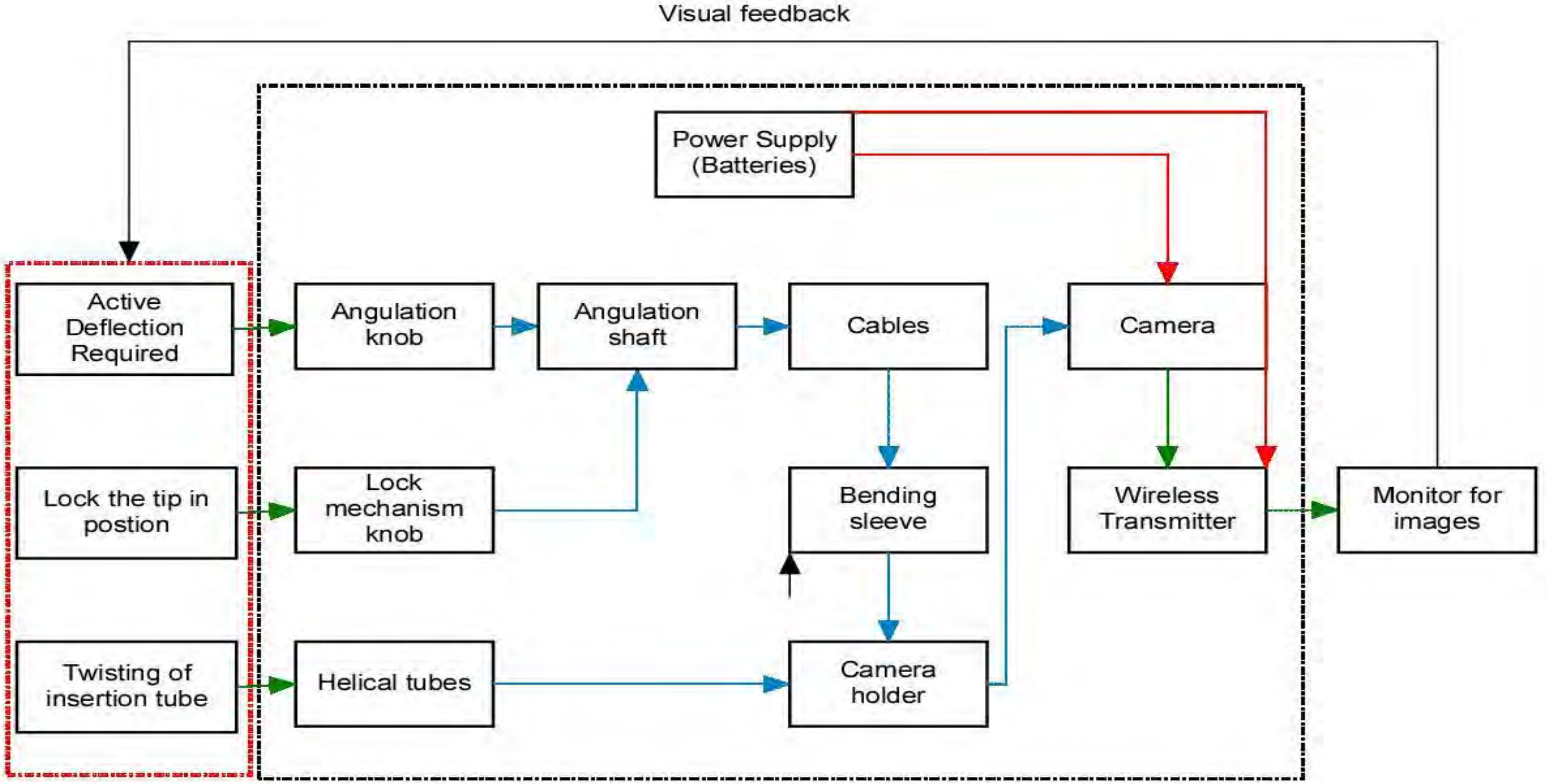

Figure 49: The functional analysis of the ureteropyeloscope showing how information, forces and masses flow

A4: Benchmarking

Direction of improvement											
		Engineering Property	Max deflection angle	Radius of deflection	Logical deflection	Image capture frame rate	Resolution	Data rate	Instrument channel	Irrigation channel	Maintainance Cost (MTBM)
Need	**Priority**										
Safety	0.3		3	3	1				3	3	
Reliability	0.3		3			3	2	3	3	3	
Power consumption	0.2					2		3			
Cost	0.2		2			2	3	2	1	1	2
Total			2.2	0.9	0.3	1.7	1.2	1.9	2.0	2.0	0.4
Ranking			1	7	9	5	6	4	2	2	8
Units			deg	mm		fps	pixels	MBps	Fr	Fr	USD deflection /optics
Target Values			170/170	15	+	2	512x512	4	3.6	3.6	500/4,000
Storz 11274AA			170/120	0	+				3.6	3.6	500/3,995
Olympus ACMI AUR 7			160/120	0	+				3.6	3.6	5,965/5,965
Wolf 7325.171			160/130	0	+				3.6	3.6	4,195/4,195
Mitsubishi 971101			134/170	0	+				3.6	3.6	
Olympus URF-P2Y			100/180	0	-				3.6	3.6	5,965/5,965

Appendix B: Ureteropyeloscope Component Drawings

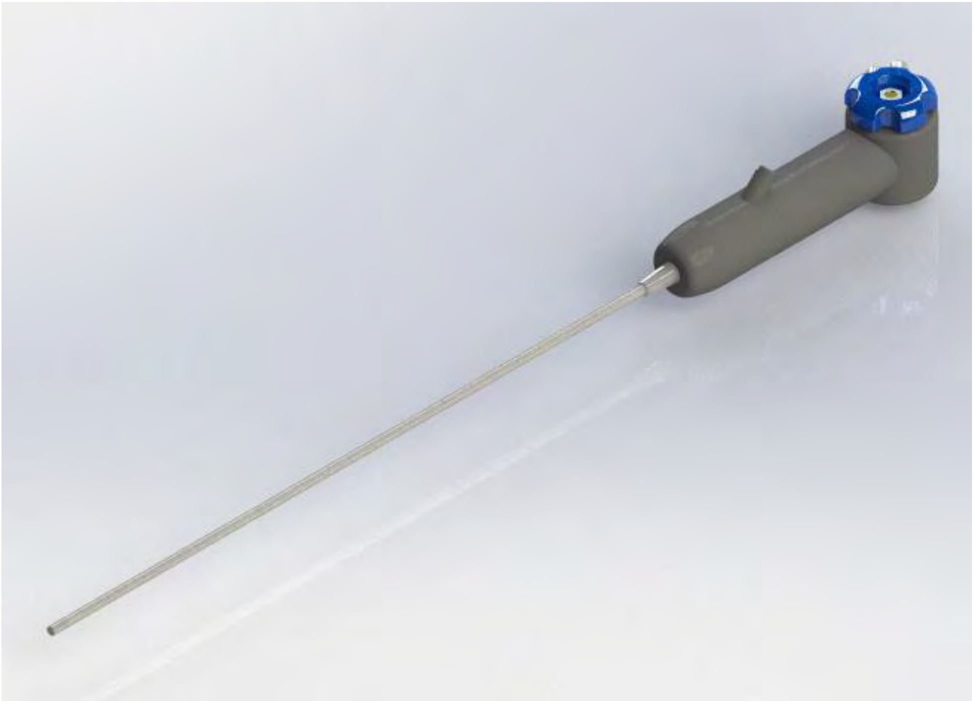

Figure 50: Illustration of the ureteropyeloscope model

B1: Angulation Control Subsystem

The angulation system

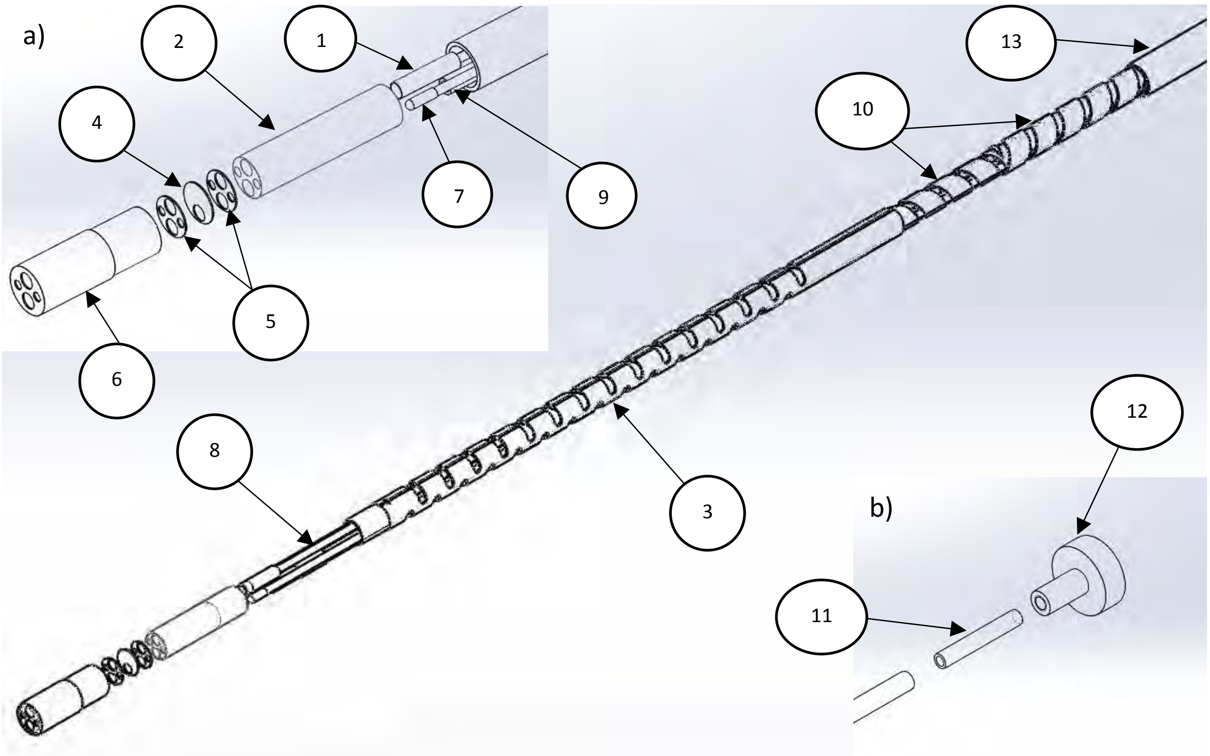

Figure 51: The exploded view of the insertion tube. Insert a) shows the distal end of the tube while insert b) shows the proximal end components

Table 15: Components of the insertion tube and their function

	Component	Function
1	Camera	To provide visuals for the navigation and procedure of the insertion tube
2	Camera holder	To hold the camera in position at the distal end of the tube
3	Bending sleeve	Provides a means to actively bend the distal end of the insertion to aid in the navigation of the urinary system
4	Glass cover	Provides a way for the camera contained within the insertion tube to view the anatomy which is outside the insertion tube
5	Cushioning rubber seals	They have a dual function of 1) sandwiching the glass cover between hard components (metal end cover and camera holder) providing cushioning hence avoiding glass breakage and 2) acts as seals to prevent fluid entry to the camera holder
6	Metal end cover	Provides a rigid tip for the insertion tube
7	LEDs	Illuminate the areas of interest for navigation and examination
8	Electrical cables	For powering the LEDs and transmission of the captured image to the wireless transmitter
9	Irrigation/instrument tube	Has two purposes 1) for channelling the irrigant to the distal end of the tube and 2) providing a channel for an accessory instrument for a procedure
10	Clockwise and Anticlockwise helical tubes	Both of these provide the insertion tube with torqueability characteristics which allow 1:1 torque transmission between proximal and distal ends of the insertion tube
11	Torque tube	Helps the attachment of the helical tubes to the control attacher

	Component	Function
12	Control attacher	Provides a means to attach the insertion tube to the control section
13	Outer tube cover	To keep what is inside the insertion tube inside and acts also as an waterproofing case for the tube contents

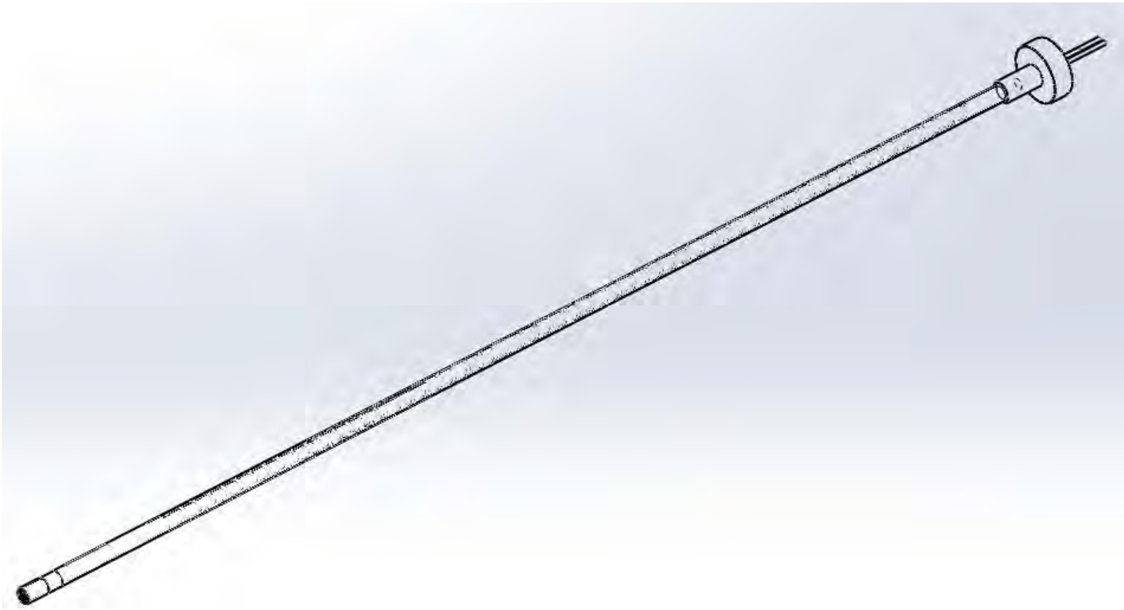

Figure 52: An illustration of the insertion tube

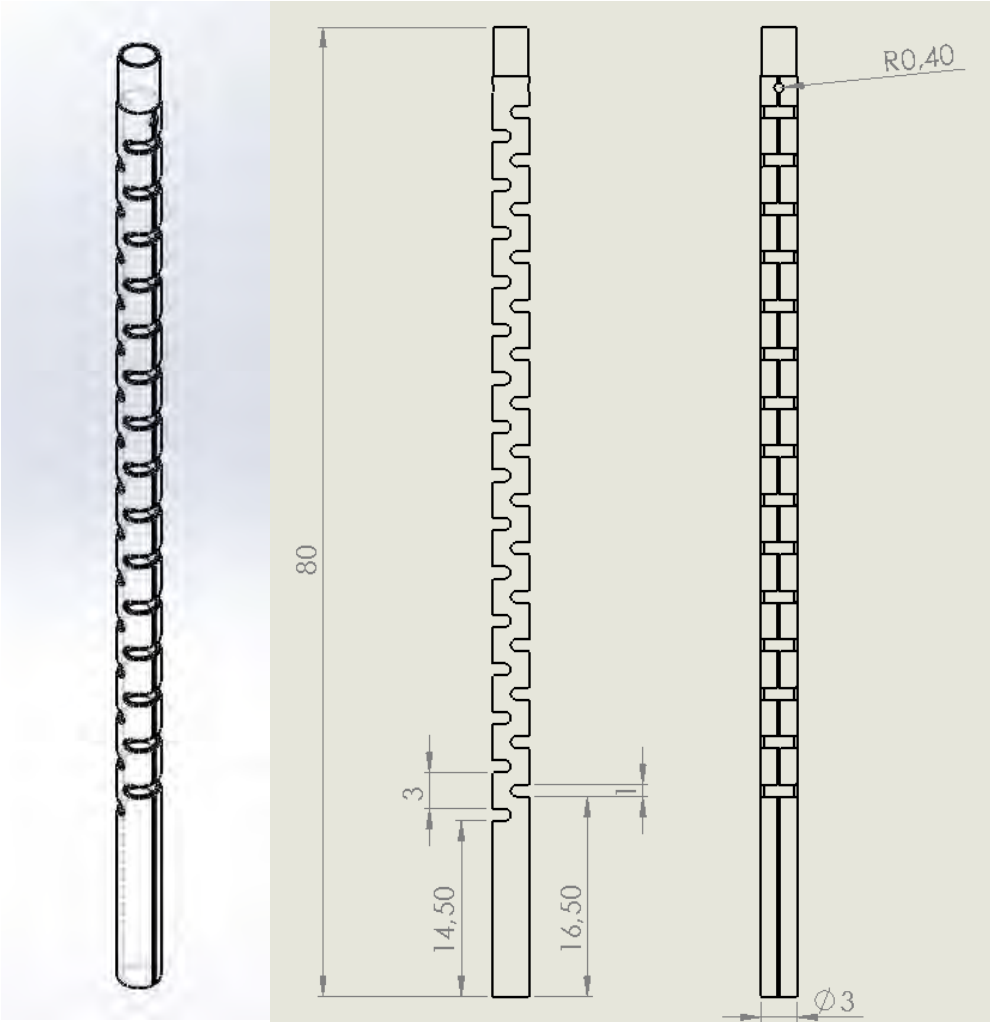

Figure 53: The bending tube size

The bending sleeve is the most important component of the design of the ureteropyeloscope. The main function of the bending sleeve is to provide a means of active bending to the ureteropyeloscope or provide a region of the insertion tube that can be manipulated by the clinician at will. This is achieved primarily through the design of the tube and use of appropriate materials to compliment the design. The design mechanics of the tube are discussed in Appendix A. Material used to make the bending sleeve is Nitinol because of the qualities of combining high strength for hoop stress support whilst being superelastic. Nitinol has a higher strain rate than all metals (in general, metals have a 4% strain rate whilst Nitinol has 8%). Furthermore, nitinol has been used in the design of ureteroscopes meaning that it has been rigorously tested for functionality in this role and deemed appropriate.

The insertion tube was required to have a minimum active bending angle of 170 degrees either direction from unloaded position in a single plane, this was done using a Nitinol tube having cuts along its length. The cuts mean the bending of the sleeve require less force, therefore easier to bend. Figure 53 shows the design of the bending sleeve as well as its dimensions.

The bending sleeve is joined to the camera holder on the distal end and on the proximal end it is joined to the one of the two helical tubes, the inner clockwise helical tube in particular. The outer anti-clockwise tube was in contact with the bending sleeve but not joined to it. A transition tolerance fit is used to join the bending sleeve and the camera holder. This is because the camera holder is made from a plastic material and the bending sleeve is made of nitinol which is a metal and the best method for joining, considering ease of disassemble, is a transition fit. The same transition fit is used to join the inner clockwise helical tube to the bending sleeve for the same reasons as previously mentioned.

End metal cover

The end metal cover is the part of the insertion tube which first encounters the human body. It contains the most distal face, which can be taken as the viewing face of the ureteroscope. It is understood that the metal end cover must be biocompatible, easily cleaned and sterilisable. Figure 54 showed how the metal cover and the glass cover are related in the assembly. It should be noted that the glass cover has only one hole, which allows passage of the irrigant and accessory instruments. The glass allows passage of light in and out while restricting translational movement of components.

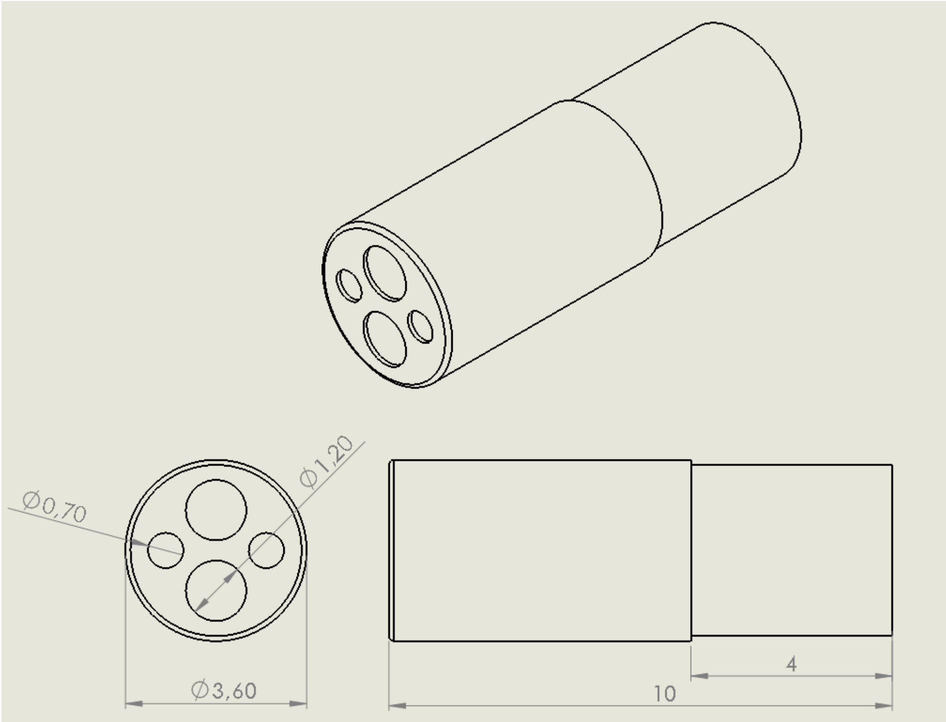

Figure 54: The model of the end metal cover and the illustration of its size

The end metal cover shown in Figure 54 has four holes on the front face, two for LED lighting, one for the camera to pick up visuals and the last for irrigation and/or instrument channel. The irrigation channel poses a leakage threat to the camera. The introduction of rubber seals and the glass cover, illustrated in Figure 55, deal with this threat. The glass cover is pushed against the end metal cover with a rubber seal between the two surfaces. The squashed rubber then prevents water entry into the inner parts of the end metal cover whilst simultaneously protecting the glass. The end metal cover joins the outer cover tube at its proximal end. The end metal cover is prepared for the joining by introduction of a slightly small diameter end. A biocompatible high strength glue or an applicable technology also joins the two components together.

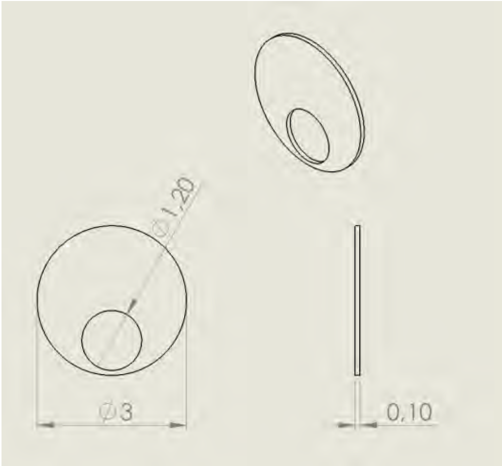

Figure 55: The glass cover which allow light transmission while restricting components movement

Clockwise and anti-clockwise helical tubes

The clockwise and anti-clockwise helical tubes are used to ensure a torque transmission ratio of 1:1 between the proximal and distal end of the insertion tube. These tubes are illustrated in Figure 56 next page, and it is evident that they are not of the same size. It is also important that the tubes are capable of bending to follow the urinary system anatomy.

Using one tube instead of two, which are coiled in opposite directions, has its advantages and disadvantages. The major advantage is that the torque transmission mechanism would take up less space. This is important, as the size of the device is critical. However, the major disadvantage is that the torque transmission would be different in the two directions of twist. If a clockwise helical tube is used, twisting it clockwise would transfer a 1:1 torque between distal and proximal parts but however when twisted anti-clockwise the tube would have a tendency to shrink in diameter before torque transmission and this implies two different torque ratios depending on the twisting direction.

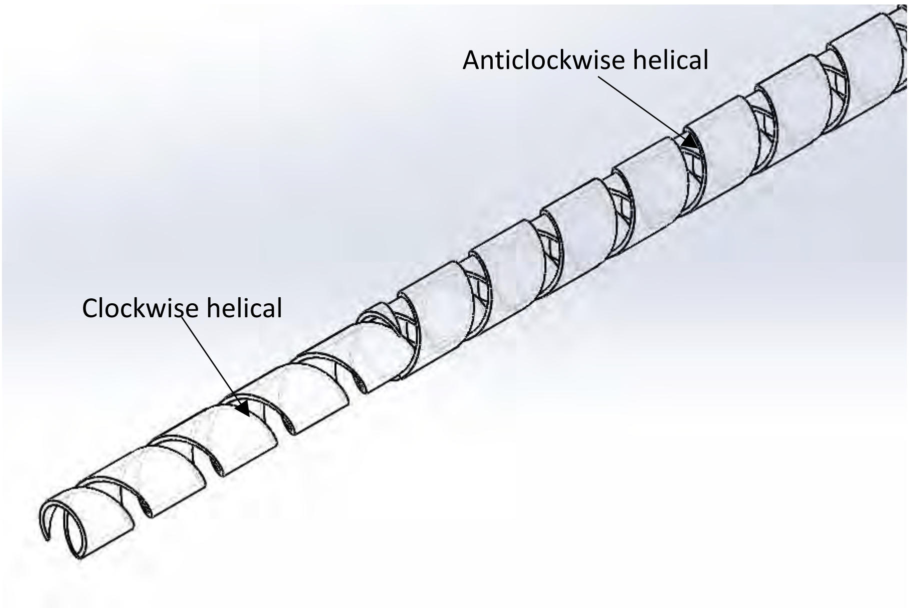

Figure 56: Illustration of the clockwise and anticlockwise helical tubes

The two opposite coiling helical tubes were chosen over braiding due to the braiding complexity. The braiding which was considered is that which is found in the Fibertech report ("How It Works: The Angulation System," 2012). In some endoscope design, like the one illustrated by Ginsberg et al., 2005 both the opposite coiling helical tubes and the braiding is used. This may be due to the size of the endoscope and its length because the endoscope is for gastroscopy. Using both in this design in impractical due to space constraints and it would increase the cost.

Control Section

The control section subsystem is mainly responsible for the control of the navigation of the insertion tube and the housing of components that facilitate the access and control of the insertion tube and the wireless circuitry. Some of the major components of the control section subsystem are the knob (for insertion tube tip manoeuvring), instrument channel and irrigation channel inlet port, wireless transmitter and its power supply and the case (which encloses all the other components). Table 8 shown below gives the list of the components that make up control section and states their function.

Current ureteroscopes sizes were used in the development of the handle. Literature detailing the actual handle sizes, and different types of handles was used for input, however, the simplest handle type was chosen by the author to avoid unnecessary costs due to intricate design. Literature did not state the dimensions of the sizes of handles, as it was not the focus. Nonetheless, a few brochures with dimensions were found and their main concern was highlighting improvements in making the handles smaller. Figure 57 and 58 show the control section subsystem, the exploded view of the control section shown in Figure 58 illustrates major components of the subsystem. Upper casing, waterproof lipping and battery case are not shown in Figure 58.

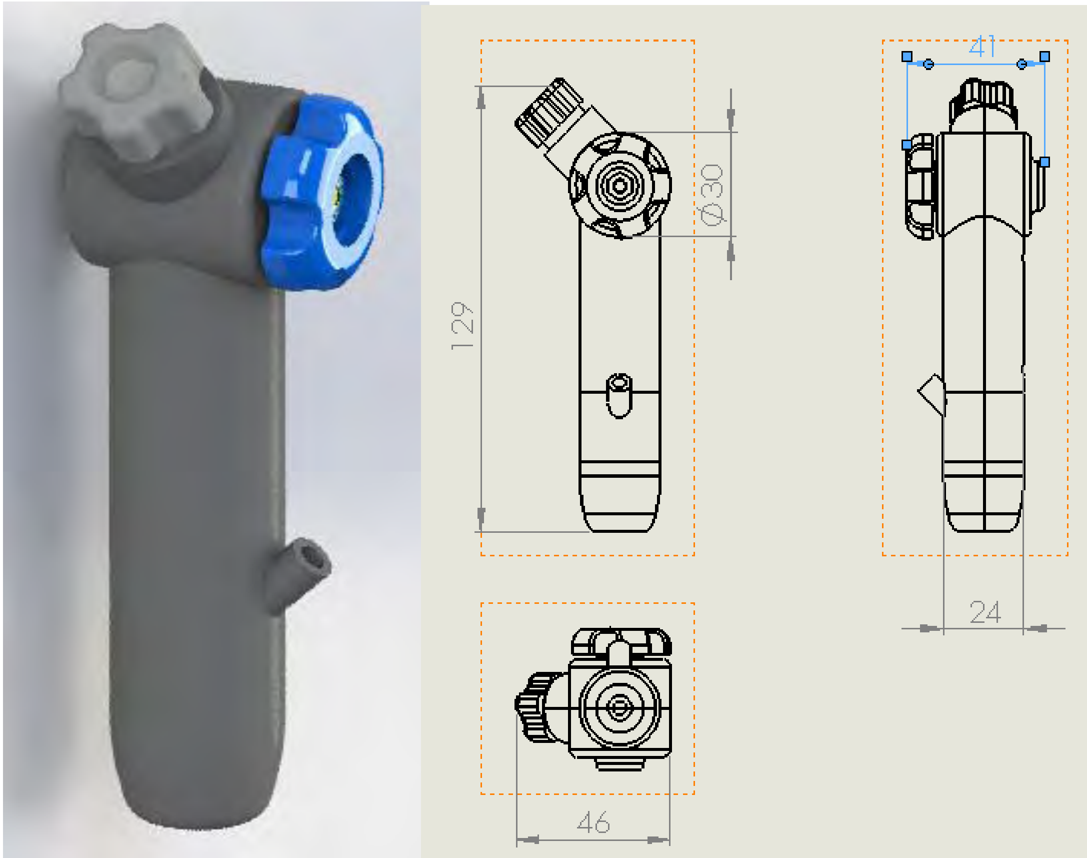

Figure 57: The illustration of the control section subsystem a) depicts its 3D representation whilst b) shows the dimensions when assembled

Table 16: The table of control section subsystem components

	Component	Function
1	Control cases	To provide a housing for the components which need to be separated from the outside environment such as wireless circuitry
2	Wireless transmitter	To wirelessly transmit the captured images to the viewing monitor
3	Electrical cables	To connect the wireless transmitter to camera for image acquisition

4	Battery case + batteries	For electrical circuitry power supply
5	Angulation knob	For bending the distal end of the insertion tube
6	Shaft	Connects the knob to the cable that is attached to the steel cables for bending the bending sleeve
7	Cable wheel	Translates the knob movement into the bending of the bending sleeve
8	Shaft friction plates	Act as motion dampers for bending of the bending sleeve
9	Case friction plates	Act as motion dampers for bending of the bending sleeve
10	Lock short-shoe	When in contact with the cable wheel it hinders rotation of the cable wheel hence stopping bending.
11	Lock shoe mover	Translates the rotary motion of the lock knob into linear movement of the lock short shoe
12	Lock shaft housing	Holds the lock shaft, lock shoe mover in place
13	Lock knob shaft	Arrests the active bending of the distal part of the insertion tube
14	Lock knob	Actuates the shoe to lock the position of the lock short-shoe
15	Flat and O-ring seals	Helps in keeping the fluids outside during sterilisation
16	Screw	To hold the control cases together

The control cases house components such as the bending mechanism, lock mechanism, wireless transmitter and the adaptor module. When fully assembled, the two outer cases are in full contact, and the control section subsystem must be waterproof for the protection of the wireless circuitry housed within. Screws are used to hold the two cases tightly together. The edges of the outer bodies are lipped with a rubber for waterproofing and to ensure that the tightening of the screws does not damage the outer bodies.

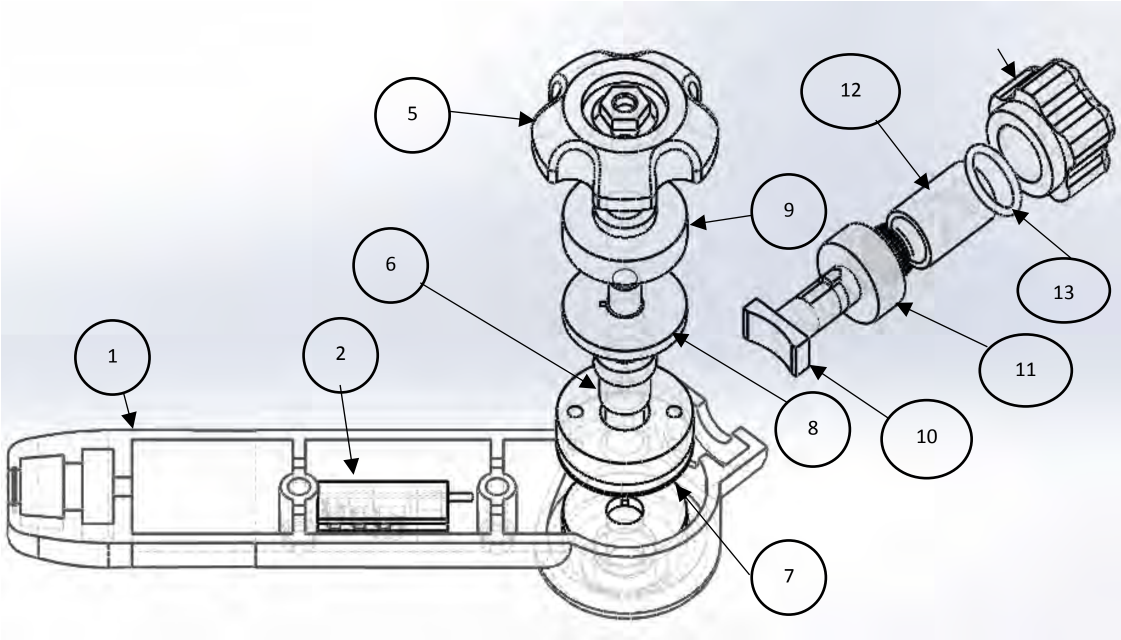

Figure 58: Illustration of the exploded view of the control section with the upper casing of the control section and battery case not shown (parts from Table 8 not shown 3, 4, 15 and 16).

Appendix C: Design Calculations

C1: Angulation of Bending Sleeve Calculations

The bending of the sleeve governs how much the tip of the ureteropyeloscope deflects. Since a superelastic material is used for the design of the bending sleeve is very critical to note that it has different elastic region behaviour as compared to the elastic regions of steel and other metals. Figure 59 shows the configuration of the bending sleeve before loading and as well as when fully loaded. To achieve the required bending the geometry of the sleeve has to be precise and the loading must the within limits.

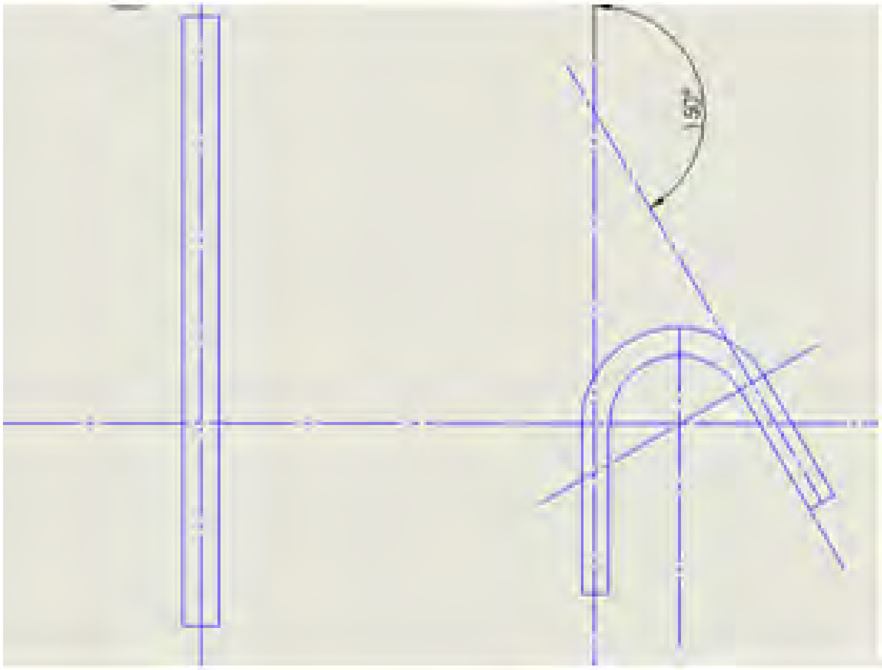

Figure 59: A depiction of bending sleeve before loading and at full loading

Geometry of the sleeve

The angle of bending was specified 170 degrees and the radius of curvature was required 15mm. The radius of curvature is measured for the edge closest to the centre of curvature. Figure 60 next page shows the deflecting section of the bending sleeve. The cuts on the sides of the deflection sleeve account for the bending, and the base of the cut is rounded for withholding stress concentrations and to curb crack propagation.

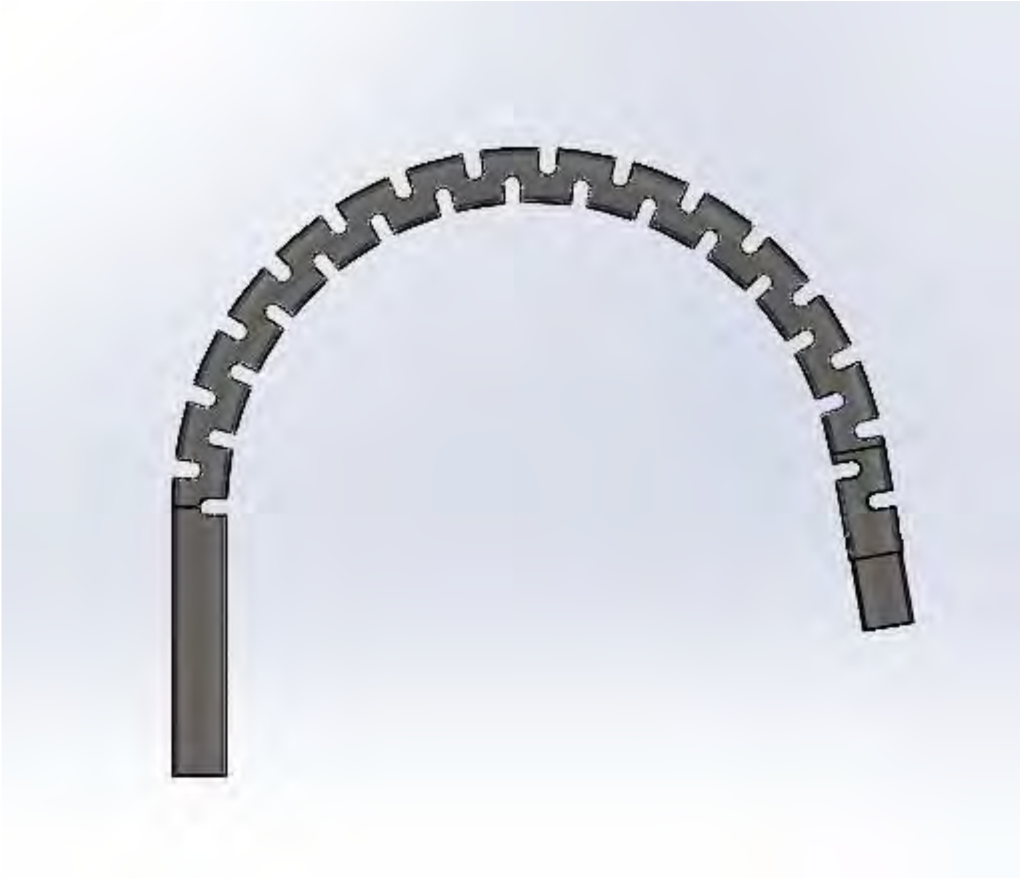

Figure 60: Sleeve design before loading and at full loading for 160 degree deflection

Table 17: Bending sleeve parameters for calculations

Bending angle	170 degrees
Bending radius of edge closest to bending centre	15mm
Bending radius of neutral axis	16.5mm

Loading forces

The force needed to make the sleeve bend as much as required are also to be calculated to ensure that enough force is supplied by the user via the knob. Knowing the force required to deflect the tip is also pivotal in the design of the deflection system because a braking or locking system may be required to keep the tip deflected in a specific position. To find the range of forces required for deflection the bending sleeve is approximated by two types of loading. Firstly, the sleeve is assumed to be a tube of solid material and then secondly as a beam. These are independent calculated and their range taken as an approximate force for tip deflection range.

When the bending sleeve is assumed to be a hollow tube the calculations for the force needed to bend the tube as much as is required is assumed to be governed by equations of elastic region loading of steel. This is a very bold assumption considering that the material used is a superelastic material. The assumed loading setup is as shown below as adapted from Shigley et al., (2008) Table A-9, and page 969.

C2: Bending sleeve mechanics

The bending sleeve was found to be the most important aspect of the design of the ureteroscope. The main aim of the bending sleeve was to provide a means of active bending to the ureteropyeloscope and this was achieved primarily through the design of the tube itself as well as the material used to make the tube. The design mechanics of the tube are discussed in the next section. Material used to make the bending sleeve is Nitinol. Nitinol was used due to the qualities of combining high strength for hoop stress support whilst being superelastic. Nitinol has a higher strain rate than all metals (in general metals have a 4% strain rate whilst Nitinol has 8%).

The required minimum active bending angle was 170 degrees in either direction. This was implemented by using a Nitinol tube having cuts along its length. The cuts were made to make the bending of the sleeve easier and hence require less force. Figure 61 next page shows the design of the bending sleeve. Figure 61c helps further to illustrate how the bending angle of 170 degrees is achieved cumulatively by small bends at each slot. A single cut is shown in greater detail and it is these cuts which define the required bending angle.

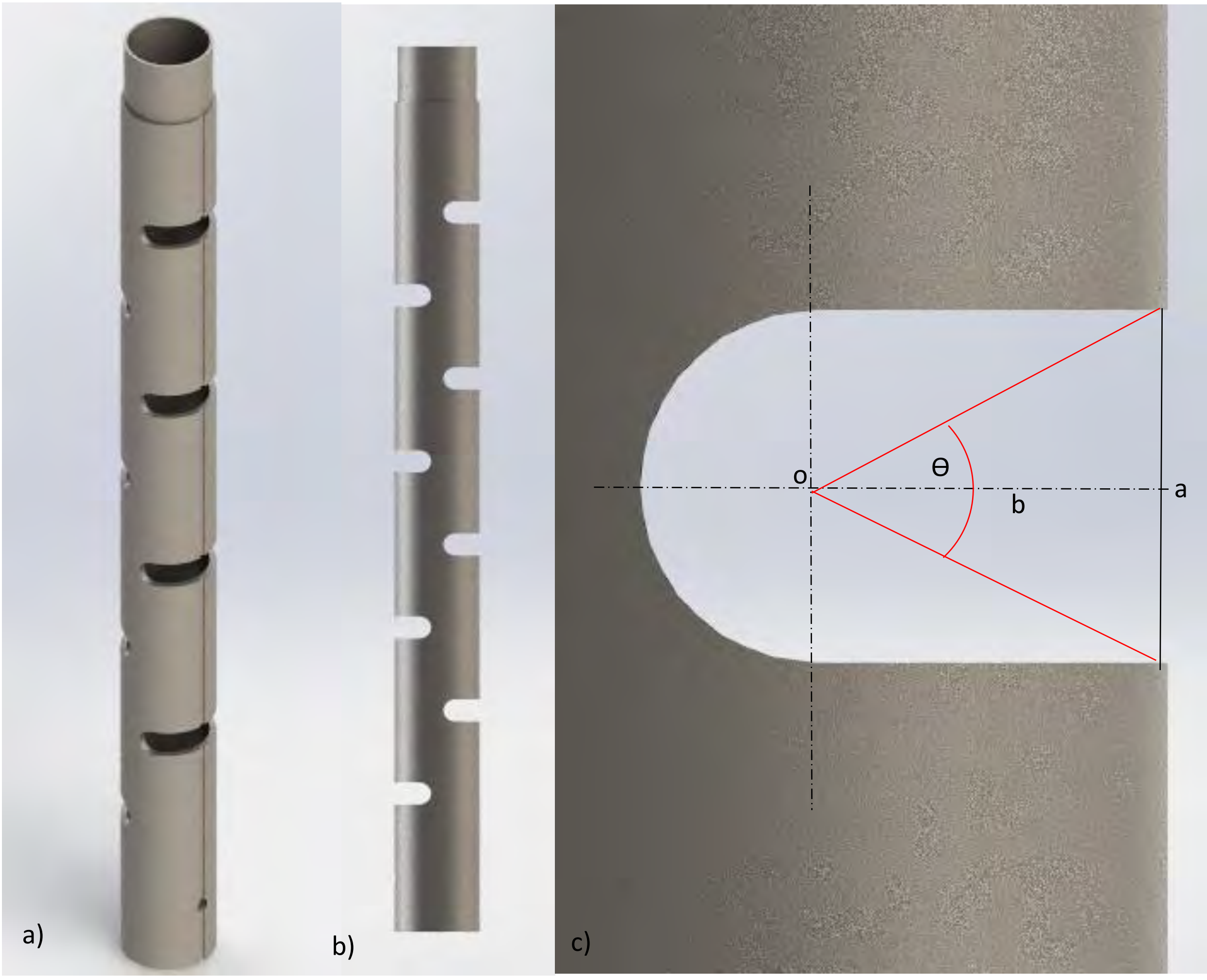

Figure 61: Illustration of the bending sleeve

A force is applied to bend the bending sleeve, and it is assumed that the bending occurs in one plane. The bending plane cuts through the two grooves where the angulation cables run. Bending happens in this plane and the cuts are assumed to be the places where the bending happens. On bending point O was assumed to be the point of rotation between two adjacent "sections". On bending point P approaches point Q and at maximum bending point P and Q are coincident. Using trigonometry for the design of the cut the chosen values of a and b were a = 2mm and b = 2mm. This makes Ɵ = 53.2 degrees. The bending sleeve has four cuts on each side which means a angle of 206.8 degrees is achievable on bending.

Material properties play a major role in governing how much bending is possible. According to Reedlunn et al. (2013) the initial bending response of shape metal alloys is nearly linear and the strain profile is also linear. The experiments carried out on a tube proved that the neutral axis of the tube starts near the origin and shifts upwards towards the compression side as bending progresses. This shift is assumed to be due to the R-phase non-linearity on the tension side. The bending at the cut is assumed to be linear and is approximated by linear strain bending. The overall bending of the bending sleeve is the summation of the bending at the cut hence can also be approximated as linear bending. However, due to the presence of the cuts the bending sleeve cannot be calculated for bending properties as a whole hence localised cut calculations were made.

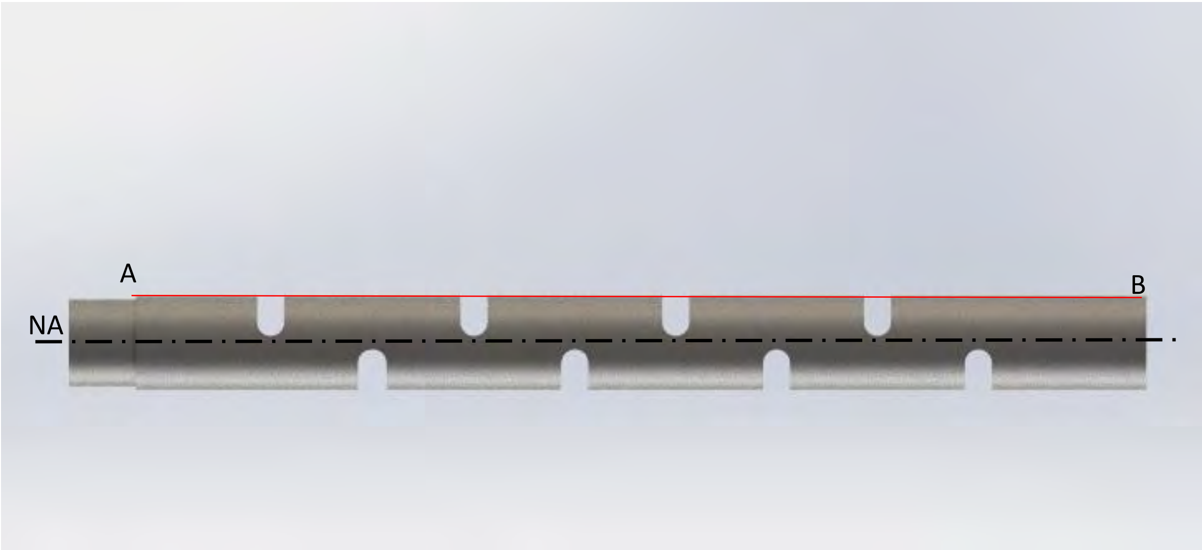

Figure 62: Loading of the bending sleeve.

The loading of the bending sleeve is shown in Figure 62 above. The loading is done by a draw wire and is attached to the distal end of the bending sleeve. Pulling the wire exerted a moment at the distal part of the bending sleeve. This moment was the one responsible for bending the sleeve. A force was applied along A-B and the moment was applied at A because that is where the point of attachment of the draw wire is. The moment applied at A was found to be;

$$M_A = F \times d$$

Where F is the force applied at A and d is the distance between A and neutral axis.

Due to the form of the bending sleeve the force needed to bend the sleeve to required angle was approximated by using a lower and upper bound which were found by approximating loading of the sleeve by different means. The loading for both upper bound and lower bound was identical. The difference was the cross section of the loaded part and the dimensions. Figure 63 shows the loading configuration of the parts.

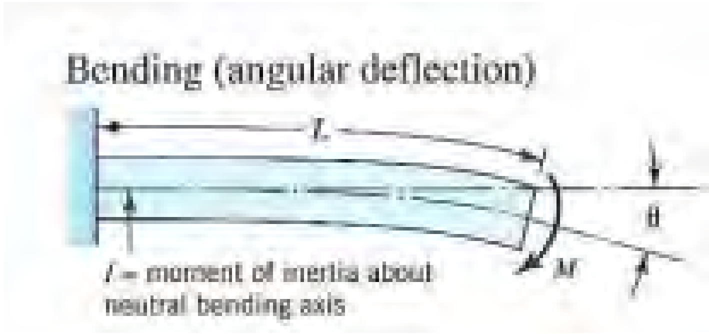

Figure 63: The general loading configuration of the bending sleeve.

Lower bound force

For the lower bound force the bending sleeve is assumed to have a cross section similar to that of the cut through its whole length. This is based on the assumption that the cut sections are the ones mainly responsible for the bending. The cross section of the bending sleeve where there are cuts is shown in Figure 64 below. It is assumed that the loaded part is the sectioned part. The loading of the bending sleeve therefore becomes approximated as shown in Figure 64 b and with the annotated dimensions.

b)

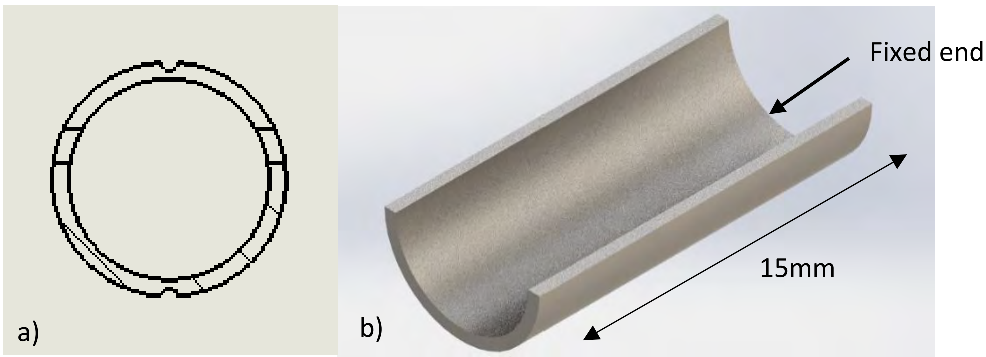

Figure 64: Cross section of the cut showing its half pipe form.

Upper bound force

For upper bound force, the bending sleeve was assumed to be a tubular structure with no cuts. Assuming that there are no cuts makes the bending of the sleeve require more force than necessary. The approximate loading for the upper bound was as shown in Figure 65. The Young's Modulus of a material describes the material's ability to endure strain (changes in the length). Shape memory alloys have greatly varying Young's Modulus which is dependent on alloy composition, elongation and temperature. For Nitinol in austenite phase Young's Modulus is 75GPa whilst for martensite it is 28GPa (Gilbertson, 2000). Both values are used to see the influence on the force for both the lower and upper bound forces.

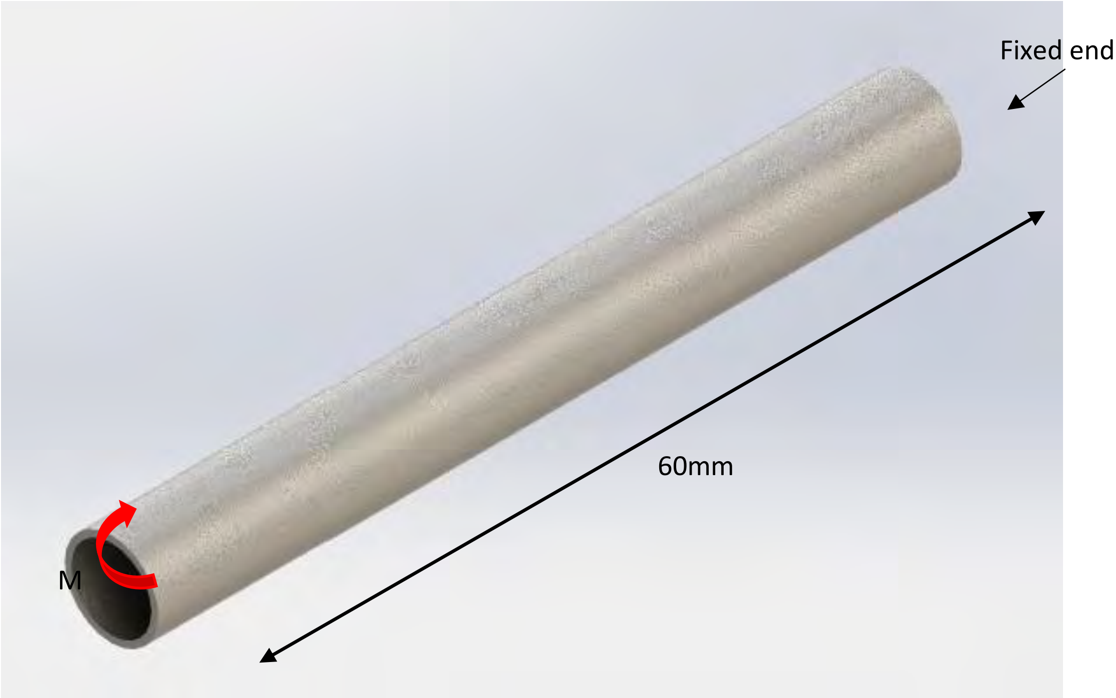

Figure 65: Approximate loading for calculation for the upper bound force.

Buckling of the bending sleeve is also tested for *in-silico*. The columnar strength of the bending sleeve is very important with regards to the failure of the bending sleeve. The force applied on the wires to cause the bending also has a potential to cause the bending sleeve to buckle. This is because the force is applied off-centre and is most likely to be a large force. This coupled with the sleeve dimensions, buckling was taken as a highly likely to occur.

Appendix D: Manufacture of Components

D1: Assembly Drawing of Ureteropyeloscope

Table 18: Table of components of the ureteropyeloscope

	Part name	Materials	Joining to?	Joining method	Standard component	Manufacturability of custom component
1	Camera	Off-the-shelf component with a metal case	Housed within camera holder	Glue is used to hold it in position within the camera holder	Yes	Not Applicable
2	Camera holder	PTFE	Metal end cover, glass and bending sleeve	Transition fits	No	Manufacturable
3	Bending sleeve	Nitinol	Camera holder and helical tubes, electrical wires	Transition fits	No	Its manufacturable and it is expensive to do so due to material used and process undertaken
4	Glass cover	Glass	In contact with metal end cover and camera holder	In contact with other components no joining method needed	No	Simple manufacturing technique required which is cutting of required holes in glass

	Part name	Materials	Joining to?	Joining method	Standard component	Manufacturability of custom component
5	Cushioning rubber seals	Rubber	In contact with metal end cover, glass cover and camera holder	It is in contact with the other components no joining method required	Yes	Not applicable
6	Metal end cover	Stainless steel	Outer tuber cover and camera holder	Glued to outer tube cover, a transition fit with camera holder	No	Made from a punched sheet of metal
7	LEDs	Standard component	Housed with camera holder	Transition fit to camera holder and electrical cables soldered to LEDs	Yes	Not applicable
8	Electrical cables & molex connectors	Standard component	Electrical components such as LEDs, wireless transmitter	Soldering to electrical components	Yes	Not applicable
	Part name	**Materials**	**Joining to?**	**Joining method**	**Standard**	**Manufacturability of**

					component	**custom component**
9	Irrigation/instrument tube	PTFE	Camera holder adaptor case	Press fit for camera holder and screwed to the adaptor case	No	Made via the plastic tube manufacture technology
10	Clockwise and anticlockwise helical tubes	Stainless steel	Bending sleeve, torque tube	Transition and press fit respectively	No	
11	Torque tube	Stainless steel	Control attacher, helical tubes	Press fit to helical tubes and screwing to the attacher	No	Made by turning and threading
12	Control attacher	Stainless steel	Torque tube, control case	Screwing to the torque and transition fit to the control cases	No	Made by turning and threading
13	Outer tube cover	PTFE	Metal end cover and control attacher	Glued to the metal end cover and control attacher	Yes	Not Applicable
	Part name	**Materials**	**Joining to?**	**Joining method**	**Standard**	**Manufacturability of**

					component	**custom component**
14	Adaptor case	PTFE	Housed by the control case	Transition fits	No	Injection mould or medical grade 3D printing
15	Control cases	PTFE	Channeller,	Press fit to channeller. The two halves are screwed together	No	Injection mould or medical grade 3D printing
16	Wireless transmitter	Standard component	Not applicable	Not applicable	Not applicable	Not applicable
17	Electrical cables	Standard component				
18	Battery case + batteries	PTFE and standard components	Control cases	Glued to the case	Batteries are standard components while the casing is not	Injection mould process can be used to make the casing
	Part name	**Materials**	**Joining to?**	**Joining method**	**Standard**	**Manufacturability of**

					component	**custom component**
19	Angulation knob	PTFE	Shaft	Transition fit and screwed to the shaft	No	Injection mould process can be used to make the casing
20	Shaft	PTFE	Angulation knob, cable wheel, shaft friction plates	Transition fit and screw to angulation knob, interference fits, keys and glue to cable wheel and shaft plates	No	Turning with milling and drilling
21	Cable wheel	PTFE	Shaft and angulation cables	Interference fit, key and glue	No	Injection moulded
22	Shaft friction plates	Nylon	Shaft	Interference fit with key and glue	No	Injection moulded or 3D printed
23	Case friction plates	Nylon	Casing	Interference fit with key and glue	No	Injection moulded or 3D printed
	Part name	**Materials**	**Joining to?**	**Joining method**	**Standard component**	**Manufacturability of custom component**

24	Lock short-shoe	Nylon	Lock shaft housing, lock shoe-mover	Interference fit	No	Injection mould process can be used to make the casing
25	Lock shoe mover	PTFE	Lock shaft housing, lock short-shoe	Interference fits	No	Injection moulded or 3D printed
26	Lock shaft housing	PTFE	Lock short-shoe, lock shoe mover	Interference fits	No	Injection moulded or 3D printed
27	Lock knob shaft	PTFE	Lock knob	Press fit	No	Injection moulded or 3D printed
28	Lock knob	PTFE	Knob shaft	Press fit	No	Injection moulded or 3D printed
29	Flat and O-ring seals	Rubber	Lock mechanism	Surface contact	Yes	Not applicable
30	Screw	Stainless steel	Casing	screw	Yes	Not applicable
31	Channeller tube	PTFE	Casing	Transition fit	No	Injection moulded or 3D printed
	Part name	**Materials**	**Joining to?**	**Joining method**	**Standard component**	**Manufacturability of custom component**

32	Cable rod	Stainless steel	Cables	Tied up to the cables	No	Not applicable
33	Cable nut	Stainless steel	Cable rod	Screwed on	Yes	Not applicable
34	Spring	Stainless steel	Does not join anything but in contact with adaptor casing		Yes	Not applicable

D2: Angulation Control Subsystem

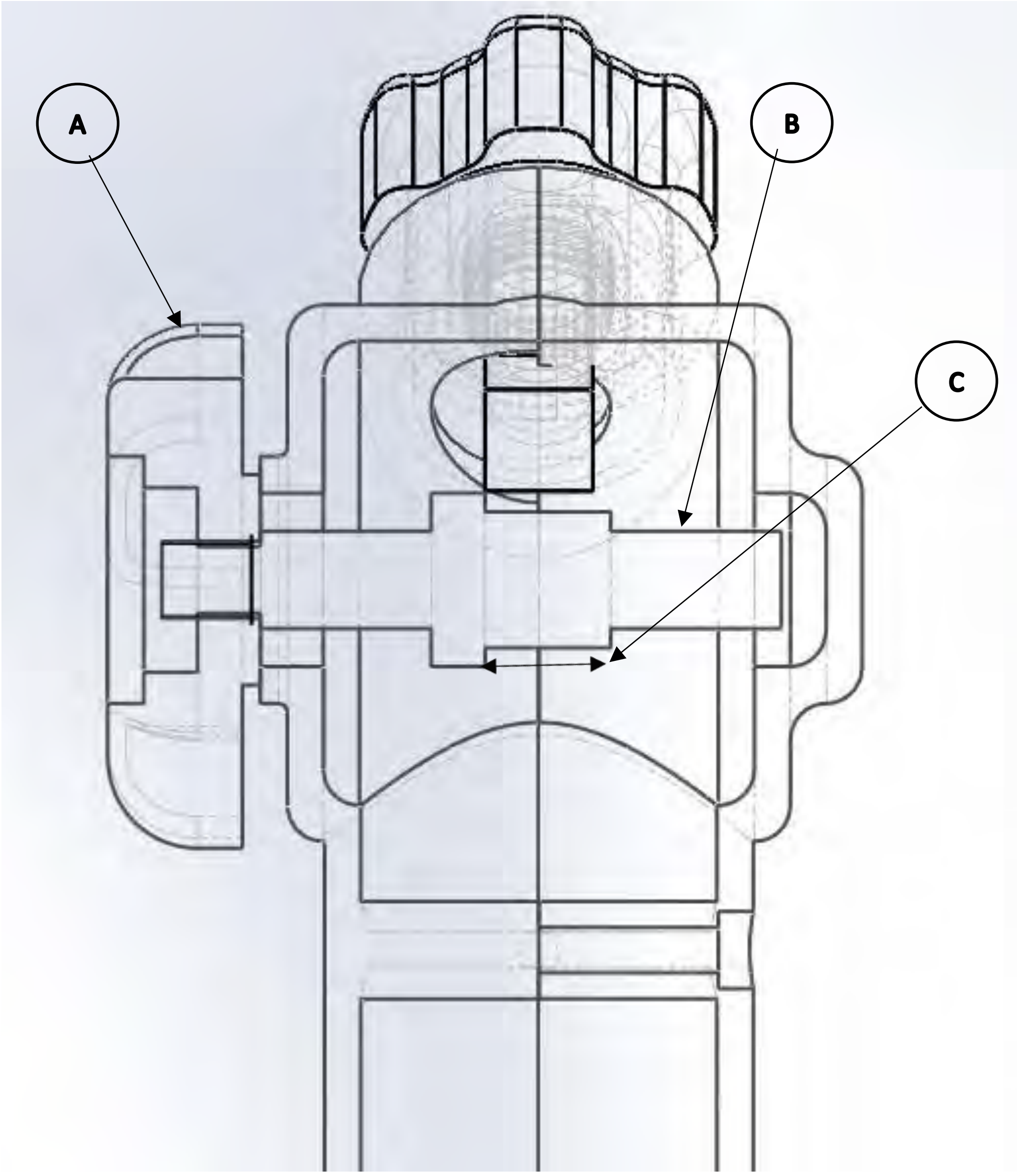

Figure 66:Cross-section of the assembly of angulation control.

Figure 66 shows a cross-section of the handle to show the interaction of the knob, the shaft and the cable wheel. A shows the knob which is attached to the shaft B via a screw. The cable wheel which is not shown in the Figure 66 above is inserted in the region marked C. on turning the knob the shaft coupled to it also turns and causes angulation as previously described.

D3: Irrigation and Instrument Subsystem

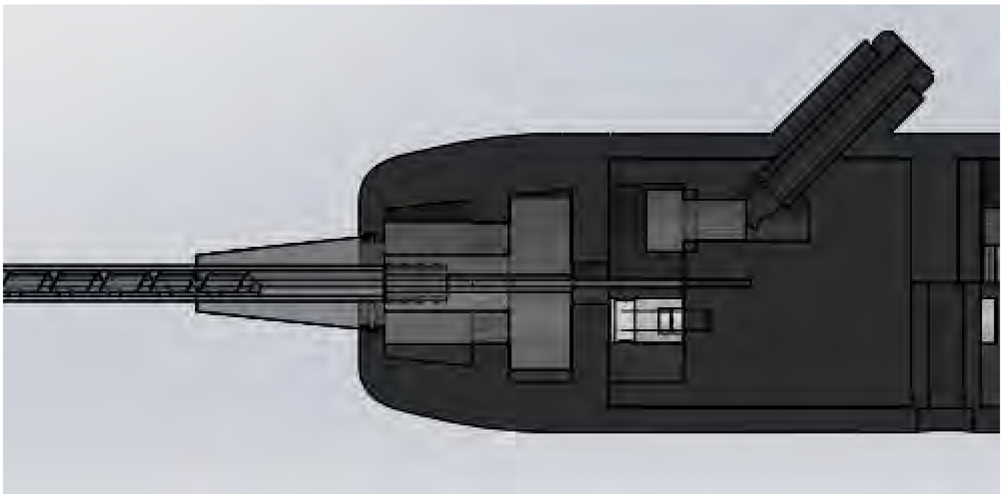

Figure 67: The irrigation system of the ureteropyeloscope

The irrigation and instrument subsystem is the simplest system of all in terms of functioning as well as the number of components involved. The Figure 67 above shows the components of the irrigation and instrument subsystem that the pipe for fluid transporting shown as it goes into the insertion tube. The joining method between the pipe and the adaptor is a transition fit to make the assemble and disassemble easy. The tubing is not shown in the figure above. The irrigation pipe runs all the way to the distal end of the insertion tube.

D4: Wireless Video Transmission Subsystem

The speed of image transmission is very critical for real-time viewing of the video captured. The recommended speed for transmission is 2.4GHz as many real time endoscopes use this frequency for its transmission speed. Moreover, they use radio frequency as a mode is transmission. Examples of such video transmission system are the TVBTECH, the Given Image System and . The Given Image System uses Ultra High Frequency (UHF) band telemetry transmitter for the image transmission However, it should be noted that the TVBTECH endoscope is not used in a clinical setting but it is used in an industrial setting.

Colour video images of quality 256 x 256 are transmitted at a rate of 431.1MHz successfully according to the Given Image System. The system does not send video but images only as the procedure the system is used for only requires images not a video for real-time viewing. The Given Image System endoscope is a capsule endoscope and is used to take images, not videos, of the gastro intestinal tract. A data rate of approximately 1Mbps for a 256 x 256 resolution camera is required to consider the transmitted video for real-time viewing.

The size of the antenna for the transmission is very important due to space limitations of the design. The wireless transmitter will be housed in the handle of the ureteropyeloscope and this means that the antenna cannot be too long such that it would not fit into the handle. The length of the antenna affects the resonance frequency; however, the antenna can be coiled to take up less space. The antenna bandwidth has to be set at correct frequency because at low frequency will not be wide enough for data transmission. Furthermore, the antenna was located in the control handle due to availability of space but more so the fact that the transmitter is not wanted in the insertion tube because of the radiation on transmission.

The radiation direction is uncontrolled for the transmitter therefore the antenna is designed to propagate the transmitted signal independent of the transmitter position and the receiver pick up the signal whatever the transmitter position is. This is isotropic radiation. The transmitter prescribed was required to meet this condition. In addition, the transmitter frequency must not interfere with other devices that may be in the environment such as pacemakers and such defibrillators. Interference with these maybe detrimental to the patient.

Table 19: Transmission properties of the VBTech endoscope

Data rate	4Mbps
Transmission speed	2.4GHz
Sensitivity	-86bBm

D5: Manufacturing of the bending sleeve comparison

The sleeve manufacturing depends on the material chosen. Given in this section is a comparison of two different sleeves made from different materials. One is made from Nitinol and the other from stainless steel. The sleeves are compared to ascertain which method of production is more conducive for lowering costs. The Nitinol tube is considered first and then the stainless steel tube discussed.

Nitinol sleeve

Nitinol is an alloy of nickel and titanium and the two elements are of approximately same quantities. The two characteristics of Nitinol which make it an important alloy are shape memory and superelasticity. For the bending sleeve shape memory is not the reason for the use of the alloy but rather the superelasticity. The bending mechanism needs to be bent to angles of 170 degrees without failure and still be able to retain its original shape (not undergo plastic deformation) when the load is taken off.

The shape of the tube is governed by use and it should be void of any corners for ease of assemble with other components as well as manufacturing. The making of the bending sleeve using nitinol is shown via a process flow diagram in Figure 68 next page.

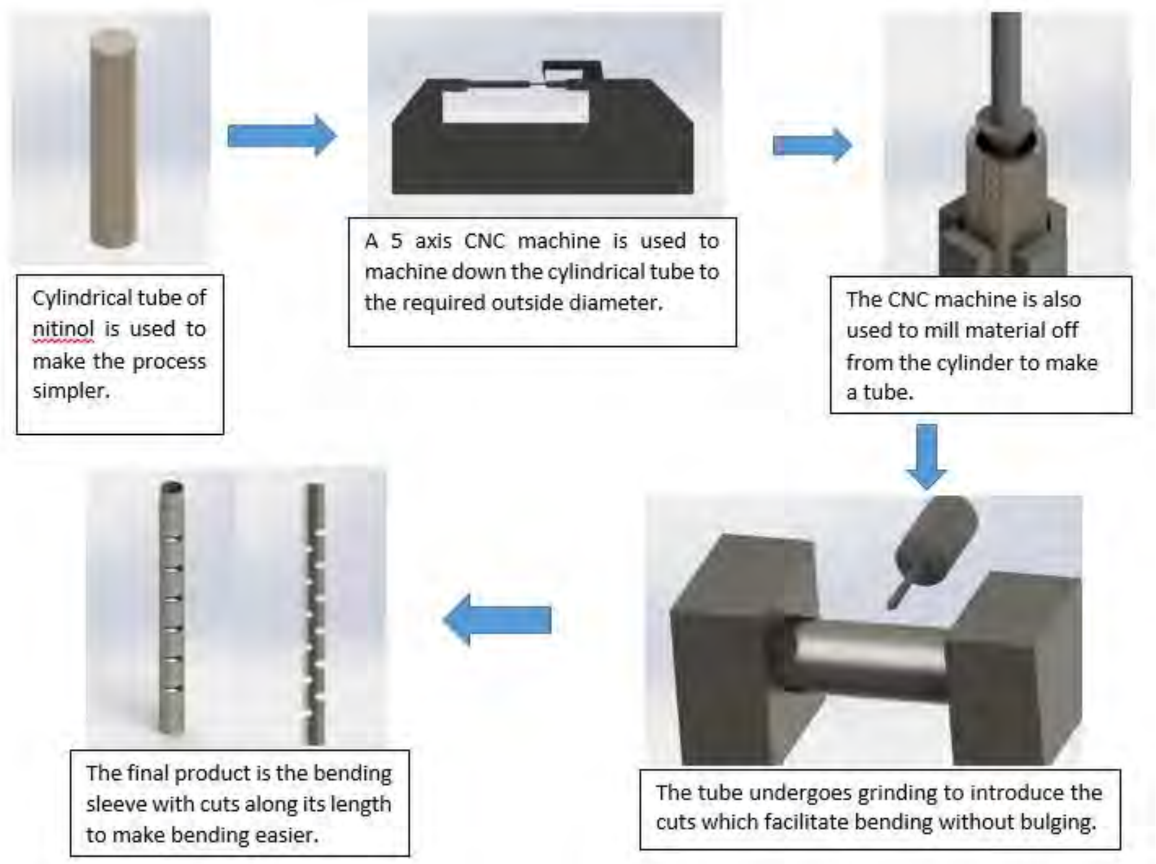

Figure 68: the manufacturing process of nitinol bending sleeve.

Cutting conditions used to machine the nitinol are very important as they would govern the characteristics of the product. Nitinol is difficult to make and is also expensive compared to stainless steel. Nitinol, like all shape memory alloys, has two phases' martensite and austenite and undergoes the phase transformationin their crystalline structure when cooled from austenite (stronger, higher temperature form) to martensite (weaker, low temperature form) and it's this phase transformation which gives the shape memory alloys the unique properties of shape memory and superelasticity. Nitinol exhibits superelastic behaviour if it is deformed at a temperature that is slightly higher than its transformation temperatures. In its austenite state when stresses are applied localised stressed-induced martensite regions are formed which makes it more deformable. Upon stress removal the martensite reverts to undeformed austenite.

Stainless steel sleeve

The stainless steel sleeve is made out of sheet metal folded and welded along the edge to give a tubular structure. Due to the properties of stainless steel the bending of the tube does not rely majorly on the properties of the material but rather on the design of the pattern on the tube. The process undertaken to make the stainless steel tube is shown below.

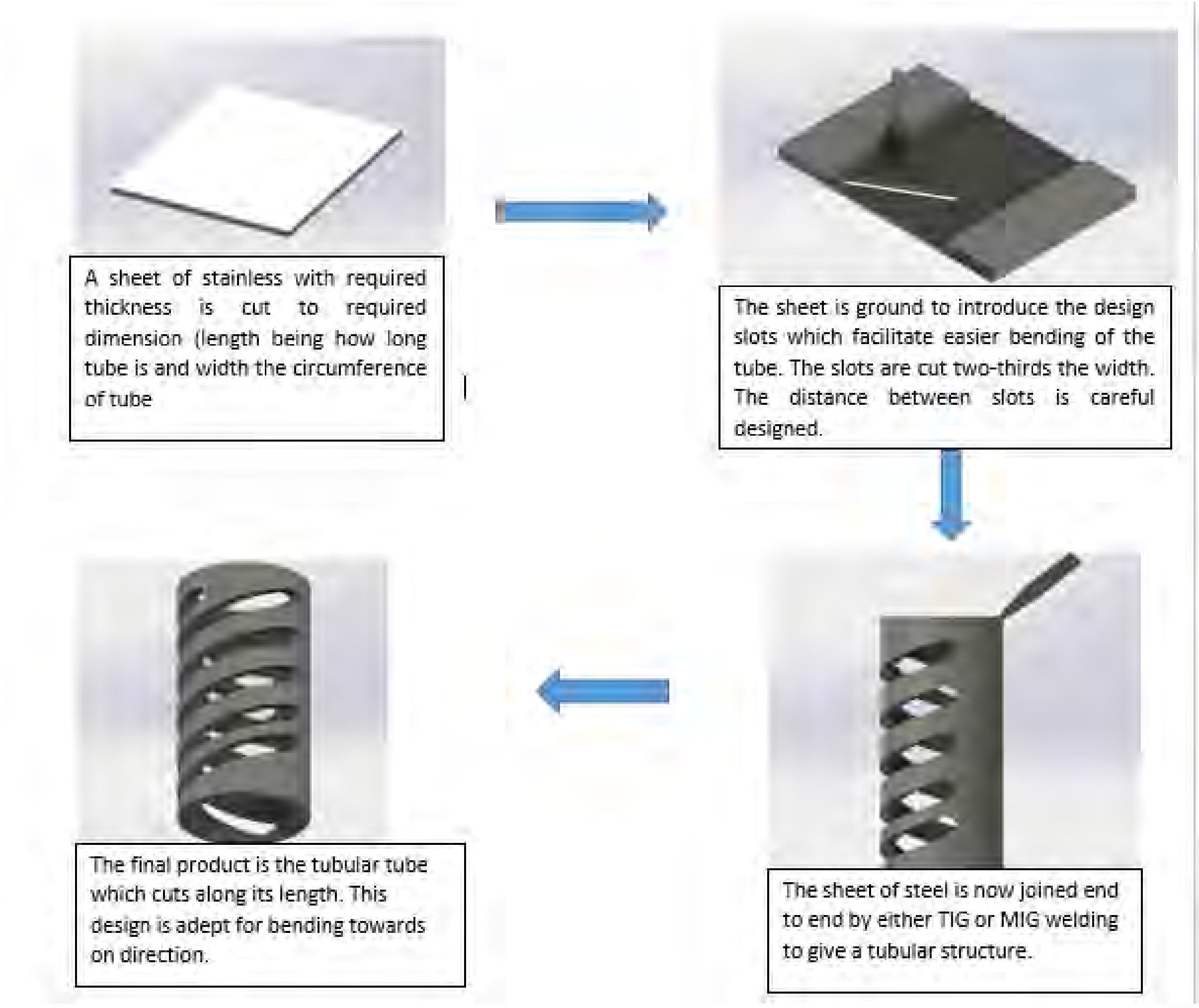

Figure 69: Making of the stainless steel bending sleeve

Appendix E: Electrical Components

E1: Power Supply to Ureteropyeloscope

The ureteropyeloscope has circuitry that needs to be powered via battery. The camera used for the design and the circuitry used would be different to the one described in the next section of Prototype of Circuitry due to different components used. The method of connection the circuitry is illustrated in Figure 70 below. The battery prescribed for the ureteropyeloscope's specifications are shown alongside the battery in Figure 71. The Medigus camera requires 5V whilst the wireless transmitter requires 5V to be powered, which the battery can supply.

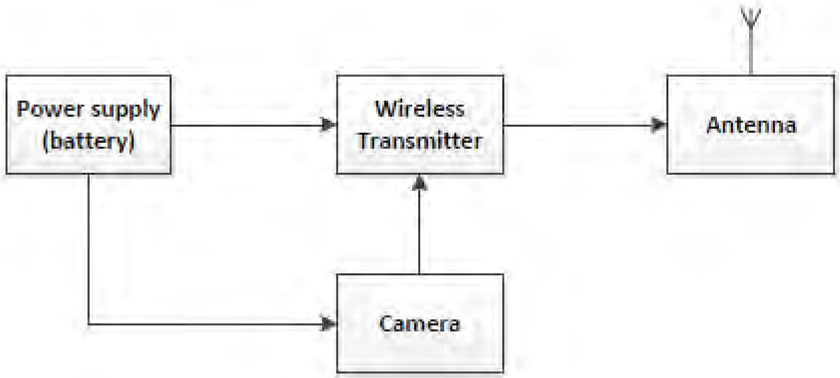

Figure 70: The method of connecting the electrical components

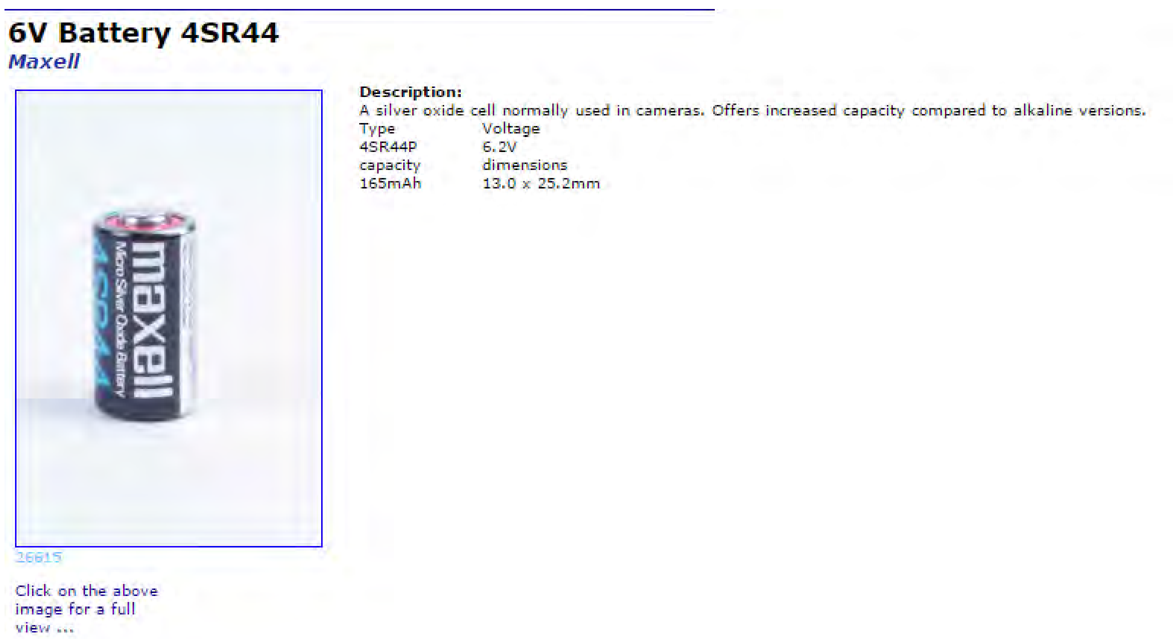

Figure 71: Product battery specification (Maxell: 6V Battery 4SR44, 2014)

E2: Prototype of Circuitry

The circuitry connection used for the prototype is show in block diagram form in Figure 72 below. A 6.5V battery powers the wireless transmitter and the camera and each component had its own voltage regulator due to different voltages for each component. Figure 73 shows a block diagram connection for power supply to the wireless transmitter and camera via voltage regulators. Figure 74 and Figure 75 show the circuits for the wireless transmitter voltage regulator and camera voltage regulator respectively.

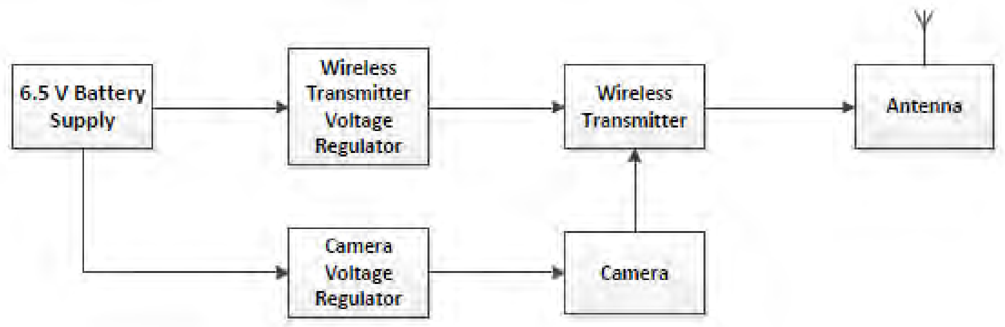

Figure 72: Block diagram of the electrical connection of the prototype circuitry

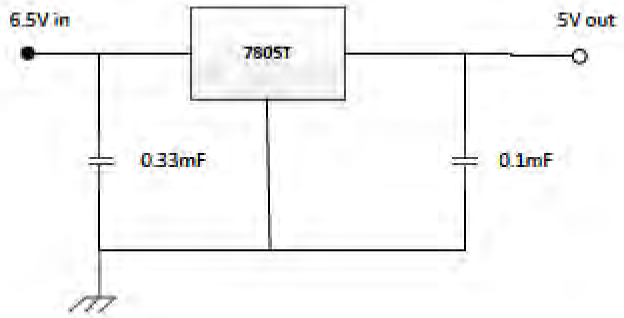

Figure 73: The voltage regulator of the wireless transmitter

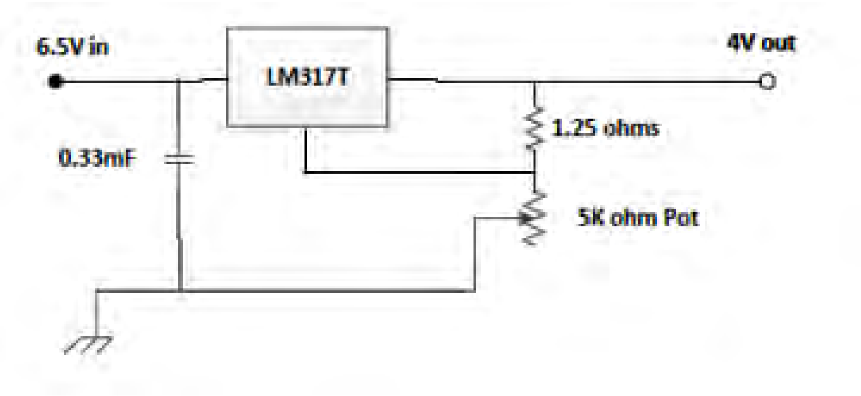

Figure 74: The voltage regulator of the image capture device

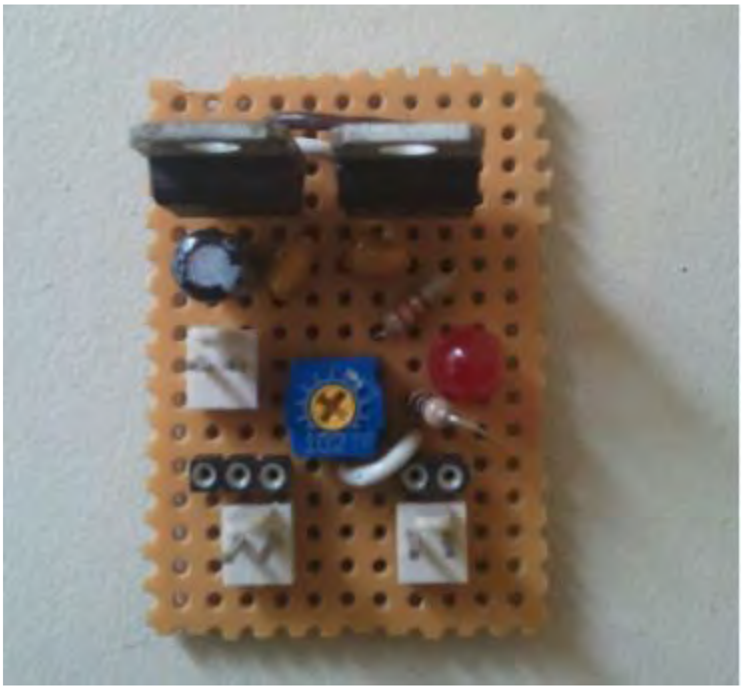

Figure 75: The circuitry for the prototype

Appendix F: The prototype

Figure 76: Currently used ureteropyeloscope in which the prototype is modelled after

Figure 77: the position lock mechanism

Figure 78: The ureteropyeloscope with electrical wires for image transmission and power lines

Figure 79: The handling of the ureteropyeloscope prototype