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# Surgical Drill Bit Redesign

Final Design Report

MECH 4860

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# Contents

# List of Figures

# List of Tables

# Executive Summary

The Winnipeg Regional Health Authority (WRHA) is the entity responsible for the well-being of the residents of Winnipeg, East and West St. Paul, and Churchill. Optimization of the processes and devices used by the WRHA allows for more effective use of the operating budget allocated by the Canadian government. Surgical Innovations was tasked by the WRHA to redesign a flexible drill bit used in total hip replacement surgeries in an effort to reduce overhead costs of the procedure and ultimately optimize the process.

The flexible portion of this drill bit is composed of multiple counter-wound coils which allow for flexibility in the shaft while maintaining the ability to transfer torque. While in use, small debris and other contaminants enter deep within the coils. The deepest layers of coils are unable to be properly cleaned by the medical device reprocessing (MDR) staff at the WRHA.

The new design of the flexible drill bit has to maintain the functionality of the previous design and have the ability to be disinfected and sterilized by the MDR staff within the WRHA. Multiple concepts were generated and after a thorough screening process, it was decided that instead of a complete redesign of the flexible drill bit, a simple improvement would fulfill the design needs.

This simple improvement involves the application a sleeve over the flexible portion of the drill bit, preventing contaminants from entering into the coils of the drill bit shaft. It was determined that heat shrink tubing would be the most desirable material to use for the sleeve. This material creates a tight seal. The sleeve does not hinder the overall performance of the drill bit. The particular heat shrink tubing recommended by Surgical Innovations is TE Connectivity MT5000-1/2. Which is flexible medical grade heat shrink tubing.

In addition to the redesign of the surgical drill bit, procedures for the integration of this device into the current MDR processes have been developed. Along with this integration, new processes must be introduced to indicate whether the sleeve has been breached. After the drill bit has been used in a surgery, the sleeve will be removed during the disinfection of the instrument where luminol will be applied to the flexible portion of the drill bit. The luminol will react with any biological contaminants by glowing. This reaction will indicate if the protective sleeve has been

breached by contaminants. If the tubing is breached, the surgical drill bit must be disposed of. If no breach is indicated, new tubing will be applied during the kitting process at the MDR center. The new sleeve will then be shrunk onto the flexible drill bit using the heat applied by the steam sterilization process.

The sleeve was subjected to physical testing and analytical calculations were performed. These actions confirm that the design fulfills the criteria outlined by the client. Although this indicates the success of the design, it is recommended that further testing of the design be performed to verify the results found by Surgical Innovations. Processing simulations should be performed to validate Surgical Innovations proposal and minimize impact on the MDR staff.

Surgical Innovation performed a cost analysis that determined that the redesign, if implemented, will save the WRHA $393,698.88 per year. Moreover, the team has delivered a final design that satisfies the client’s needs and has accomplished its objective.

# 1.0 Introduction and Background

The Winnipeg Regional Health Authority (WRHA) cares for the largest health region in Manitoba [1]. The WRHA is responsible for the care of the residents of Winnipeg, East and West St. Paul, and Churchill. These locations account for more than 700,000 people. The WRHA's mission is "to co-ordinate and deliver safe and caring services that promote health and well-being". The WRHA accomplishes its mission with a 2.4 billion dollar budget, operating 200 facilities with 28,000 employees.

In order to reduce overhead costs within some of the facilities, the WRHA has tasked Surgical Innovations with redesigning a flexible drill bit used in total hip replacement surgeries. This new design must be easy to clean while maintaining the functionality of the previous device [2]. Currently, organic tissue and debris remains trapped in the inner layer of the flexible coils after use in surgery. The inner layer of the flexible coils is difficult to clean and nearly impossible to sterilize with current techniques used within the WRHA.

In a total hip replacement surgery, a cup must be inserted into the patient, into which the replacement ball joint will be inserted [2]. In order to fasten the cup into the hipbone, screws are used. These screws cannot simply be threaded into bare bone; instead, a pilot hole must be drilled through the bone first. The pilot hole is drilled using a flexible surgical drill bit, a standard drill bit cannot be used as the hole must be drilled at an angle which cannot be reached by a straight drill bit. The flexible surgical drill bit is a crucial component in hip replacement surgeries and affects the bottom line of the WRHA, as a total of 108 hip replacement surgeries are performed each month within the WRHA [3].

## 1.1 Project Objective

To reduce the overhead costs on total hip replacement surgeries, the objective is to redesign the current drill bit to be easy to clean while maintaining the functionality of the previous device. The new design will include technical specifications, general cleaning instructions, and handling methods of the new device.

## 1.2 The Current Device

The current device in use is seen in Figure 1.

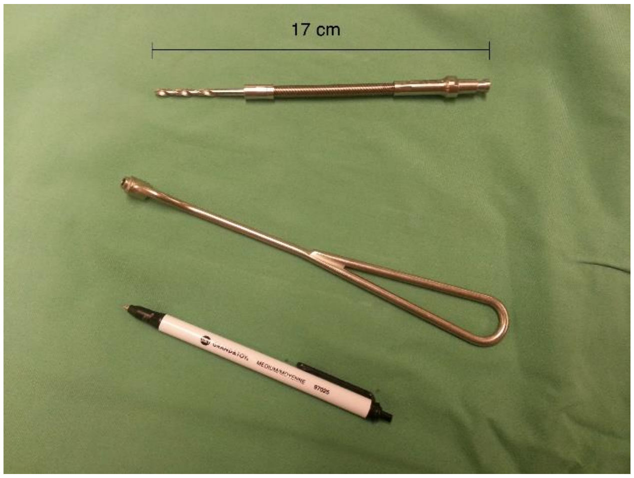

**Figure 1: Current device seen at the top of the picture, guide for the device in the center, and a pen for scaling purposes**

The drill bit located at the top of Figure 1 is a flexible drill bit which has the ability to transfer torque while flexed. This is accomplished through the use of multiple layers of springs wound in different directions, as seen in Figure 2.

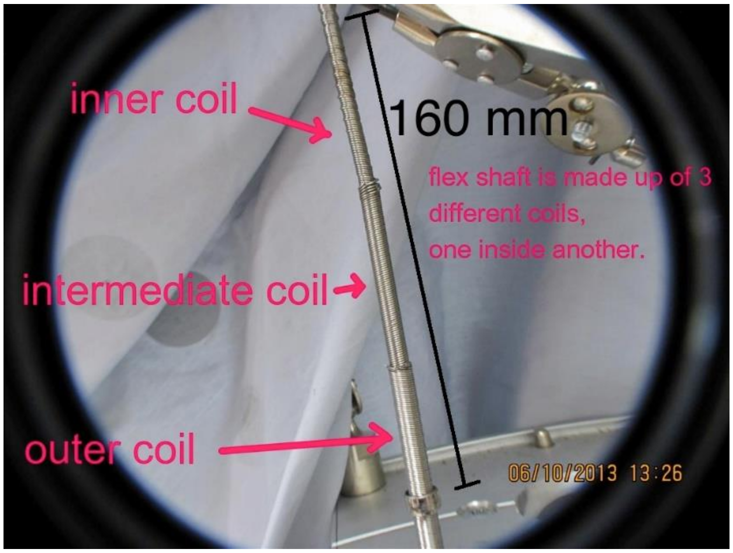

**Figure 2: Flexible drill bit dismantled to show the layers of springs [4] (Courtesy of Nhien Tu)**

When torque is applied to the shaft, the outer coil is wound so that it contracts while the intermediate coil is wound in the opposite direction such that it expands. These opposing motions cause the shaft to transfer the torque effectively without having the springs collapse due to the applied torque. Although the functionality of the device is achieved, these layers of springs present a major flaw: the intermediate and inner coils are extremely difficult to clean [4]. This flaw is illustrated in Figures 3 and 4. Figure 3 shows that there is particulate left on the intermediate coil after cleaning. This poses a problem, as the device is designed to be reusable and must be completely sterile before entering another human body. Any foreign contaminants brought into the body from non-sterile devices can cause serious bodily harm to the individual in which the device is used.

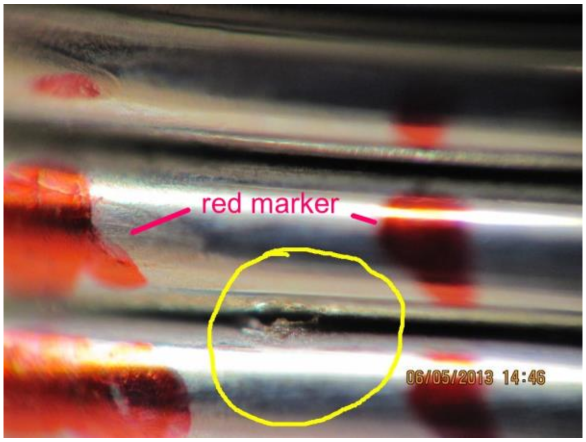

**Figure 3: Debris left on the intermediate coil after multiple cleanings [4] (Courtesy of Nhien Tu)**

Figure 4 shows that there are brown stains remaining after the device has been put through the cleaning process. This is evidence that the device is non-sterile after multiple cleanings. Figures 3 and 4 highlight the inability to penetrate the outer coil during the cleaning process. This is the main issue with the current device.

**Figure 4: Stains left on the inner coil after cleaning [4] (Courtesy of Nhien Tu)**

The price of a single unit is in the range of $350, and it is said to be “reusable”. Clearly, from the results observed, the device is not reusable in its current form and is considered a single use product by the WRHA [5]. Due to the inability to re-use the drill bit after only a single surgery, the cost per surgery of the drill bit is extremely high. This directly impacts the budget allotted to the WRHA.

### 1.3 Client Needs and Specifications

After multiple meetings with many stakeholders in the project, Surgical Innovations had an abundance of product information and user input. Surgical Innovations took the gathered information and generated a list of needs and target specifications. All of the criteria stem from the main objective of designing an easy to clean drill bit which is more cost effective than the current device.

Processing the data from the meetings held with machinists, the clinical engineering team, medical device reprocessing staff, and ER nurses, our team generated a list of 6 needs. These needs are:

- The design must be able to drill into bone
- The materials used in the design must not be harmful to the human body
- The design must be compatible with current drive equipment
- The design must be able to drill around a corner
- The design must be more cost effective than the currently used device
- The design must be reusable

Each of these main needs has sub-needs, which allow the applications of metrics. These metrics provide a baseline for the new device requiring the following specifications [5][6]:

- The ability to flex 20° and maintain the transfer of torque
- The ability to transfer 150 in-lbs of torque at 1200 RPM
- Cost per surgery below $350

The design Surgical Innovations will present will meet these specifications, if the design is to maintain the functionality of the previous device while reducing the cost.

# 2.0 Details of Design

The main goal of this project is to reduce the overhead costs of a total hip replacement surgery. The design proposed to solve this problem consists of a polymer sleeve covering the flexible portion of the drill bit used in the surgery. Polymers are versatile materials that can be seen in a wide range of applications. Desired properties for the polymer included the ability to be elastic and durable. The elasticity of the material benefits the design as it will allow the drill bit to maintain the ability to flex. The durability of the material ensures that the design will not likely fail at any time during the surgery. The elasticity of the polymer will allow the polymer to deform around the drill bit and create a tight friction fit of the sleeve on the drill bits crimped ends. This will ensure the stability of the sleeve while preventing contaminants from reaching the flexible coils contained there within.

Other concepts that were developed and subsequently ruled out by the selection process can be seen in Appendix A. The main reason a new design was not pursued is that there is no material that has the ability to transfer the amount of torque and have the flexibility required.

## 2.1 Final Concept Iterations

Surgical Innovations created two variations of the final polymer sleeve concept. One of the ideas is to put catheter tubing over the flexible portion of the drill bit. The second potential solution is to use flexible heat shrink tubing to cover the flexible portion of the drill bit.

The first idea involved pulling catheter tubing over the flexible portion of the drill bit. This was pursued because catheter tubing is extremely flexible and already approved for medical applications. When catheter tubing was applied the team noticed that the seal on the ends of the catheter tubing failed when the device was flexed. This level of performance was deemed unacceptable by both the team and the client. Another downfall of catheter tubing is that it is made of a material with poor adhesion properties; thus, improving the seals with some sort of adhesive will not be a possible.

The second solution involves the use of heat shrink tubing to cover the flexible portion of the drill bit. This solution is an improvement to the catheter tubing because it improves upon the flexibility of catheter tubing, and has the ability to be bonded to if needed. If the seal created by the shrinking of the tubing is deemed insufficient, application of an adhesive can be added to increase the quality of seal.

## 2.2 Design Specifications

The design proposed consists of heat shrink tubing acting as a protective covering over the flexible portion of the drill bit. This flexible coil portion is identified in Figure 5.

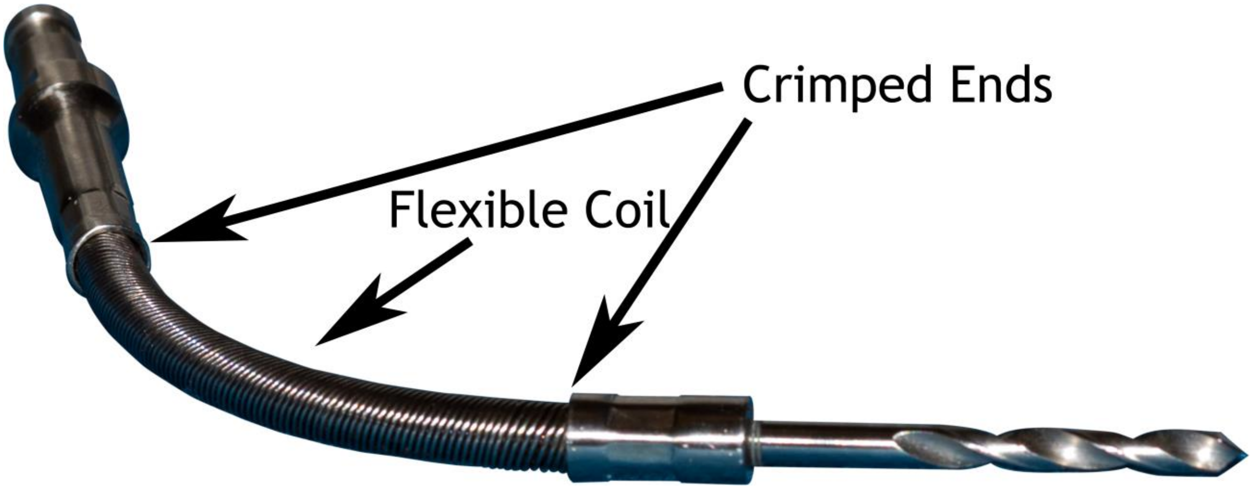

**Figure 5: Original flexible drill bit**

The heat shrink tubing recommended is MT5000-1/2 heat shrink tubing distributed by TE Connectivity. This tubing was selected for four main reasons. Firstly, this tubing is medical grade heat shrink tubing; secondly, this tubing is flexible; thirdly, the tubing's shrink ratio is high enough to create a good friction fit by; and finally, the initial diameter is large enough for easy application [7]. The friction fit is achieved when the heat shrinking tubing is shrunk on to an object that has a larger diameter than the minimum shrink diameter of the heat shrinking tubing itself. Heat shrinking the tubing around the drill bit crimps creates residual stresses that lock the tubing around the crimps it encases.

An added benefit of the material used to create the sleeve is that it is a polymer. If the sleeve fails during a surgery, the sleeve will exhibit a ductile behavior. This means that the tubing will stretch and separate but will not fragment into small and hard to see pieces. This is favourable as fragmented particles could be harmful to the patient.

Before heating, the tubing has an inner diameter of 25.8 mm and should be cut to a length which covers the drill bit from crimp to crimp. After heat application, the tubing will shrink to a diameter of 6.4 mm and have a wall thickness of .64 mm [7]. When the tubing has shrunk, it will form a friction fit with the crimped ends and cover the flexible portion of the drill bit, preventing contaminants from reaching the coils. The final product is illustrated in Figure 6.

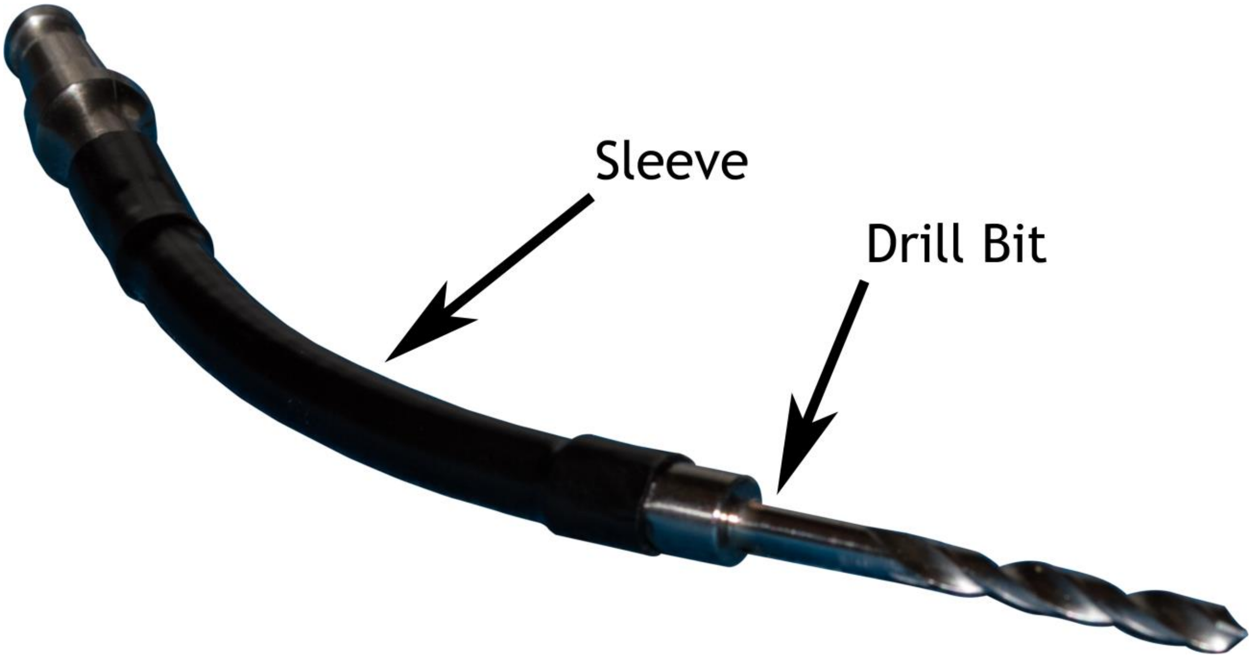

**Figure 6: Flexible drill bit with sleeve modification**

## 2.3 Process Integration

For the design to fulfill its objective, the design must be able to be integrated into the cleaning process already employed by the Winnipeg Regional Health Authority (WRHA). Integration of the design will be discussed, including how the design will fit neatly into the disinfection and sterilization process performed at the medical device reprocessing facility (MDR). There are three main stages of medical device reprocessing: disinfection, sorting, and sterilization.

### 2.3.1 Disinfection

After a surgical instrument is used in a surgery, it is sent for cleaning. The first stage of cleaning is the disinfection of the instruments. These instruments arrive via an elevator and are sorted immediately into easy to handle trays of equipment as show in Figure 7.

**Figure 7: Sorted surgical instrumentation to be disinfected**

At this phase, the flexible drill bit will have the sleeve removed. When the sleeve is removed from the drill bit, luminol will be sprayed onto the flexible portion of the drill. After this has been done, putting the device in a dark environment will reveal if any bodily fluids breached the seal. If the luminol glows, then the seal was broken and the flexible drill bit should be disposed of. If the luminol doesn't glow, the seal has not been broken and the flexible drill bit should be disinfected.

After all the devices have been sorted they are subjected to brushing. Every instrument is washed and scrubbed in a sink has shown in Figure 8.

**Figure 8: Disinfection cleaning area**

If the instrument demands a more vigorous cleaning, the staff place the instruments into a sonic bath. This bath vibrates the instrument in a cleaning bath, as the tool vibrates it causes cavitation bubbles to form and collapse on the surface of the tool. These bubbles enter tight spaces that cannot be reached by the human hand. The sonic cleaner is shown in Figure 9.

**Figure 9: Sonic bath**

Whether the instrument was subject to sonic cleaning or not, the next step in the process is to put the instrument through an advanced cleaning machine. This machine is essentially a high tech dishwasher which has rinsing, washing, and drying cycles just like a regular home dish washer but uses an enzymatic cleaning solution. This device is seen in Figure 10.

**Figure 10: Surgical instrumentation cleaning device**

### 2.3.2 Sorting

The instruments enter the machine shown in Figure 10 on one side, and exit on the other. Once this machine has ejected, the clean instruments they are disinfected and safe to touch. At this phase the instruments are checked and sorted into the appropriate surgical instrumentation kits.

During this phase, the heat shrink tubing will be applied to the flexible drill bit. The tubing will be supplied as rolls and will simply need to be cut to length and applied to the drill bit. The tubing should have a snug enough fit that if the kit is moved around, the tubing will not slide around on the flexible drill bit. The heat shrink tubing applied to the drill bits is shown in Figure 11.

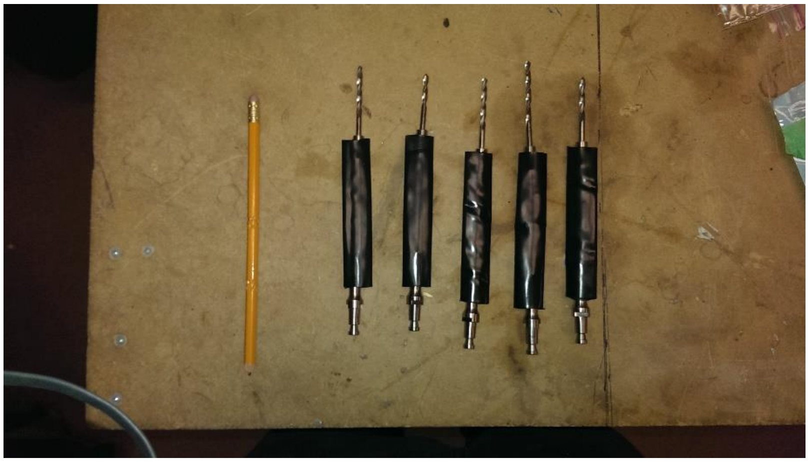

**Figure 11: Flexible drill bit with unshrunk heat shrink tubing**

Once the instruments are in their respective kits, they are wrapped and prepared for sterilization. A heat sensitive tape is wrapped around the kits to indicate that the sterilization process was executed properly and the instruments are safe to use for medical use. These packages are shown in Figure 12.

**Figure 12: Instrumentation packages**

### 2.3.3 Sterilization

Once the instruments are in packages as shown in Figure 12, they enter the sterilization machine. This machine subjects the instruments to a steam heating process. This process first draws a vacuum within the chamber of the sterilizer. Once a vacuum is obtained, the chamber is heated with steam to a temperature of 135° C. Once at a temperature of 135° C is obtained, the machine maintains this temperature for five minutes and then gradually decreases the temperature of the chamber back to room temperature. To finalize the process, the vacuum is released and the chamber is returned to the pressure of the surrounding areas.

During this sterilization process, the heat shrink tubing would shrink around the flexible drill bit and create a seal as shown in Figure 13.

**Figure 13: Flexible drill bit with heat shrink tubing shrunk onto the drill bit**

With the instruments sterilized and ready to use in surgery, they are sorted onto carts. These carts carry all the instruments a surgeon may need for any given surgery.

## 2.4 Supporting Analysis

To ensure that the sleeve performs as intended, analytical calculations and physical testing were performed to determine how the sleeve will behave while in use. Analysis was done to determine the operating life of the sleeve. The physical testing subjects the sleeve and drill bit to a simplified environment of operation that approximates regular use of the device.

Fatigue analysis calculations were performed to approximate the operation life of the sleeve in regards to bending. It was determined that the sleeve will not fail from fatigue due to bending. The analysis performed, used a finite element approach that allowed for the application of classical bean theory equations. Classical beam theory can be used to relate the stresses to deflections in object subjected to bending. Upon determination of the maximum stresses in the sleeve, the values were compared to a stress versus cycles graph (S-N curve) and showed that the sleeve would not fail during operation use. A more detailed explanation of the calculations performed can be seen in Appendix B.

During physical testing, the drill bit had a sleeve applied and was submerged in fluid. The drill bit shaft was bent at approximately a 20° angle and rotated at 1250 RPM using a drill press. The drill bit remained in operation at these conditions continuously for 20 minutes. Once the drill bit completed the 20 minute trial, it was removed from the test apparatus and its exterior was inspected for visible signs of wear or imminent failure. After inspecting the exterior, the sleeve was carefully opened, exposing the interior for inspection. The interior inspection revealed that no liquid breached the area between the sleeve and the flexible shaft. Furthermore, the fluid used in the test was filtered to show if any fragmented particles were present. The exterior and interior inspections returned positive results, as the sleeve did not show any indication of being breached, or imminent failure. The filtration of the fluid solution determined that no fragmented particles had broken off of the sleeve. B. The results of testing validate the functionality of the design. A more detailed explanation of the testing can be seen in Appendix B.

## 2.5 Marketability and Cost

To validate the use of heat shrink tubing as a successful solution from a business standpoint, a cost analysis will be performed. The process integration described in Section 2.3, will be used to perform a cost analysis in order to account for added processing and materials required for the proposed solution. Surgical Innovations’ solution reduces the total yearly cost to the WRHA by reducing the cost per use of the device. The solution presented does require additional costs in processing, labour and materials to enable the flexible drill bit to be suitable for multiple uses. However, the reusability of the drill bit will offset these addition costs. The associated material and labour cost will be discussed in the upcoming sections.

### 2.5.1 Material Costs

The largest cost in the process remains as the $350 required for the purchase of the drill bit [5]. Being able to spread this cost across multiple uses of the device, will lower the overall cost per use. The cost of the heat shrink tubing that the team has selected is quoted as 3.4 cents per foot [10]. The average length of tubing used on the flexible drill bits is assumed to be 6”, as this was observed to be a worst-case scenario. This leads to a material cost of 1.7 cents of heat shrink tubing per use. Therefore, the solution presented by Surgical Innovations shows that 1.7 cents of tubing is the lost cost rather than the $350 drill bit. This will significantly decrease the frequency the drill bits are disposed of and reduce the quantity of drill bits purchased by the WRHA.

A secondary material cost comes from the required testing to ensure that the drill bit is still safe to use in subsequent surgeries. A 16oz luminol testing kit costs $40 [11]. To be conservative, it is assumed that each test will consume 1 oz of luminol. This leads to a cost per test of $2.50.

### 2.5.2 Labor Costs

Another cost associated with the luminol test is the labour required to perform this test along with the tubing application, cleaning and removal. Labour rates were identified from a recent job posting from the Brandon regional health authority [12]. The posting advertises a salary ranging from $17.82-20.88/hr. This translates to $0.348/min for any labour performed in association with the addition of the heat shrink tubing to the process. Labour time was estimated to be 5 minutes individually for applying the tubing, removing the tubing and performing the luminol test. Cleaning the tubing before removal is a standardized method that requires 10 minutes of scrubbing. This is performed to prevent contamination prior to the removal of the sleeve [13].

### 2.5.3 Cost Analysis

TABLE I represents the costs savings associated with multiple uses. A range from 1 use to 10 uses shows the increasing savings related to the additional uses, with respect to the current device. A value of 10 uses was provided as a target number of uses. This is visualized as a plot in Figure 14.

**TABLE I: Cost Analysis**

| | | Number of Uses | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Material | Original Drill Bit cost | $ 350.00 | $ 350.00 | $ 350.00 | $ 350.00 | $ 350.00 | $ 350.00 | $ 350.00 | $ 350.00 | $ 350.00 | $ 350.00 |
| | Heat Shrink Tubing | $ 0.02 | $ 0.03 | $ 0.05 | $ 0.07 | $ 0.09 | $ 0.10 | $ 0.12 | $ 0.14 | $ 0.15 | $ 0.17 |
| | Luminol Test | $ 2.50 | $ 5.00 | $ 7.50 | $ 10.00 | $ 12.50 | $ 15.00 | $ 17.50 | $ 20.00 | $ 22.50 | $ 25.00 |
| Labour | Applying Tubing (5min) | $ 1.74 | $ 3.48 | $ 5.22 | $ 6.96 | $ 8.70 | $ 10.44 | $ 12.18 | $ 13.92 | $ 15.66 | $ 17.40 |
| | Cleaning (10min) | $ 3.48 | $ 6.96 | $ 10.44 | $ 13.92 | $ 17.40 | $ 20.88 | $ 24.36 | $ 27.84 | $ 31.32 | $ 34.80 |
| | Removing Tubing (5min) | $ 1.74 | $ 3.48 | $ 5.22 | $ 6.96 | $ 8.70 | $ 10.44 | $ 12.18 | $ 13.92 | $ 15.66 | $ 17.40 |
| | Luminol Test (5min) | $ 1.74 | $ 3.48 | $ 5.22 | $ 6.96 | $ 8.70 | $ 10.44 | $ 12.18 | $ 13.92 | $ 15.66 | $ 17.40 |
| | Total Costs | $ 361.22 | $ 372.43 | $ 383.65 | $ 394.87 | $ 406.09 | $ 417.30 | $ 428.52 | $ 439.74 | $ 450.95 | $ 462.17 |
| | Cost Per Use | $ 361.22 | $ 186.22 | $ 127.88 | $ 98.72 | $ 81.22 | $ 69.55 | $ 61.22 | $ 54.97 | $ 50.11 | $ 46.22 |
| | Cost Savings | -3% | 47% | 63% | 72% | 77% | 80% | 83% | 84% | 86% | 87% |

The added uses of the drill bit show a dramatic reduction in the cost per use, as seen in the second last row of Table I. The cost is reduced to just $46.22 per use when the drill bit is used 10 times. That is 87% lower than the cost of the current operating practice of disposing of the drill bit after a single use. Figure 14 shows an exponential decrease in costs based on the number of uses. This shows that even using the bit twice represents a significant improvement over current operating practices.

The WRHA performs 108 hip replacements per month, which equates to 1296 per year [3]. Since the flexible drill bits are currently disposed of after every use, the cost associated with yearly consumption of drill bits is $453,600.00. Assuming 10 uses per drill bit, Surgical Innovations' solution cuts the cost per use to $46.22, resulting in a yearly cost associated to drill bits of $59,901.12. This represents savings of $393,698.88 per year.

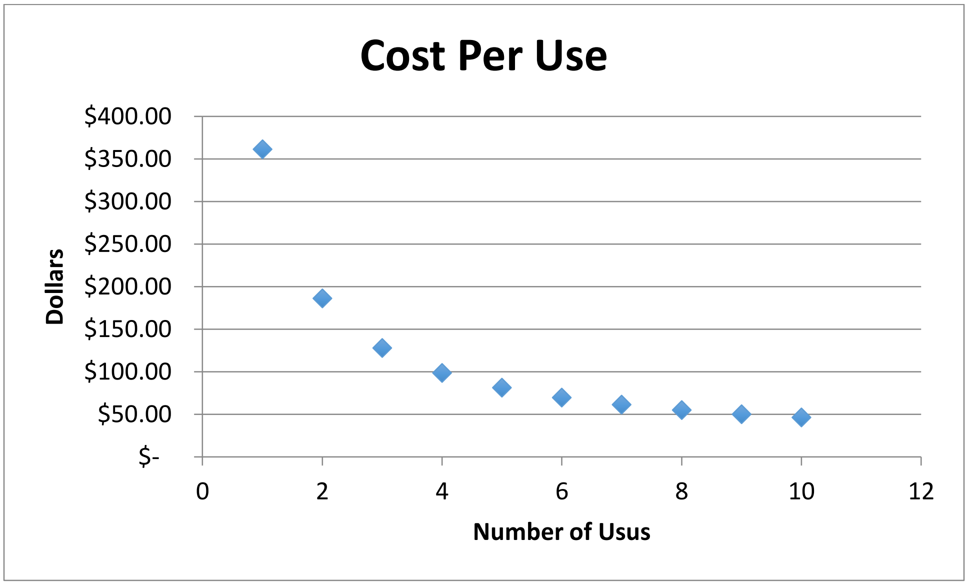

**Figure 14: Drill Bit cost per use**

### 2.5.4 Implementation Costs

When changes are implemented into an existing process, there is a cost associated with that implementation. These costs arise due to training of staff in the new process and the initial lost productivity as the staff familiarizes itself with the new process. Surgical Innovations' solution is a simple one, and as such, would only require on the job training as opposed to a formal training process that would raise the cost of implementation. However, should the WRHA feel a formal training process be implemented, the cost of such training would easily be offset by the savings generated by the proposed solution. The loss of productivity as the staff acclimates itself to the new process is accounted for in the cost analysis. The length of time used in the cost analysis for the removal and application of the heat shrink tubing provides ample time for the process to be completed. Surgical Innovations conservative time allocations allow for significant improvements and further savings as the staff progresses along the learning curve.

# 3.0 Recommendations

The final design was subjected to a rigorous validation process, but it is the recommendation of Surgical Innovations that the design be subjected to further physical testing. Also, the integration of the design into the MDR facilities should be subjected to a trial run to ensure minimal impact on the MDR staff.

Many unpredictable scenarios could occur during the surgery, including the puncturing of the sleeve by sharp instruments or the abrasion of the sleeve against rough surfaces. These scenarios could cause the sleeve to fail prematurely. Physical testing should be performed on the sleeve to determine the specific manner in which the sleeve will fail during the surgery when subjected to real surgical conditions. The resources available to Surgical Innovations did not allow for an accurately detailed simulation of these conditions. However, resources were used in efforts to model the scenarios as best as possible.

When modifying an established procedure, there is always an impact on the staff and on the procedures being executed. It is the recommendation of Surgical Innovations that the WRHA simulate the new processes being introduced into the MDR facilities to observe the impact on the system. These new processes included the removal and application of the sleeve, and the application of luminol. Surgical Innovations lacked the resources to produce a detailed simulation of the processes executed within the MDR facilities. Surgical Innovations is confident that the WRHA can easily simulate the processes prior implementation.

Finally, Surgical Innovations believes that the protective sleeve could be applied to other flexible surgical tools. It is recommended that the WRHA look into this possibility in order to further reduce their operational costs.

# 4.0 Conclusion

In conclusion, the WRHA was having issues with the reusability of the flexible drill bit used in total hip replacement surgeries. The inability to remove all the debris trapped deep within the flexible coils after multiple cleanings rendered the drill bit unsterile, and thus not safe to use for multiple surgeries. Surgical Innovations was tasked with redesigning the flexible drill bit such that the drill bit would be easy to clean, while maintaining the current functionality. The team succeeded in completing this task. By applying MT5000-1/2 heat shrink tubing manufactured by TE Connectivity to the flexible portion of the drill bit, contaminants are prevented from becoming lodged deep within the layers of the coils. The protection of the flexible coils is accomplished while maintaining current functionality of the drill bit. Physical testing validates that under normal operating conditions for the drill bit, the heat shrink tubing prevents contaminants from contacting the flexible portion of the drill bit. Furthermore, analysis shows that the tubing will not fail due to fatigue arising from bending stresses. The WRHA currently spends approximately $450,000 per year on flexible drill bits. By implementing the use of heat shrink tubing and assuming that each drill bit will be used 10 times, the yearly cost of flexible drill bits is reduced to $59,901.12. The cost analysis indicated this to be a $393,698.88 in savings per year for the Winnipeg Regional Health Authority. Even if ten uses are not achieved, merely using the drill bit twice indicates a yearly savings of $212,258.88.

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# APPENDIX A: Original Concepts and Concept Selection

# Contents

# List of Figures

## List of Tables

# 1.0 Introduction

To design a drill bit which has the ability to be cleaned by the Medical Device Reprocessing (MDR) Center at the Winnipeg Regional Health Authority (WRHA), Surgical Innovations generated a multitude of concepts which could potentially fulfill the needs of the design. Once the concepts are generated, they are subjected to a rigorous selection process in which the concepts are compared against the existing device, qualitatively ranked against the needs of the design, and finally compared quantitatively against each other to see which concept is the optimal solution.

# 2.0 Original Concepts

Surgical Innovations internal research consisted largely of brainstorming with the primary emphasis of being the quantity of ideas. Producing a high quantity of ideas without criticism the ideas can lead to new and innovative solutions to a problem. The brainstorming started with each team member clearly understanding the problem definition. Once the problem definition was clearly established, each team member was tasked to individually sketch as many ideas as possible along with brief descriptions. The brainstorming was done individually to emphasize the creation of unique solutions to the problem statement. A number of ideas were produced out of the individual brainstorming sessions. These ideas are briefly outlined below along with rough brainstorming sketches.

These brainstorming concepts focus on specific problem areas of the drill bit rather than being complete designs for the entire object. Some ideas can potentially be joined together to become a more complete solution to the problem statement. The main problem area is the cleaning of the shaft

## 2.1 Flex Shaft

Within this section of brainstorming, we present Surgical Innovations ideas to create a flexible shaft.

## S1: Machined Helical Shaft

The machined helical shaft is illustrated in Figure 1.

**Figure 1: S1, Machined helix shaft**

A machined helical shaft allows for some flexibility while maintaining torque transfer. A helix is easy to machine into a solid shaft on a lathe .

## S2: Two Extended Universal Joints

An extended universal joint shaft is shown in Figure 2.

**Figure 2: S2, Extended u-joint**

Universal joints are used to transfer torque in a multitude of applications and accomplish this quite effectively. The extended linkage allows for minimal universal joints and more effective torque transfer.

## S3: Disposable Polymer Seal

This disposable polymer seal would keep the flexible drill bit free from contaminants and is melted away during the high temperature sanitization and cleaning process. The main idea being embraced with this concept is keeping the current device and slightly modifying the shaft to be cleanable.

### S4: Hollow Polymer Shaft with Pressurized Water

A hollow polymer shaft with pressurized water inside is observed in Figure 3.

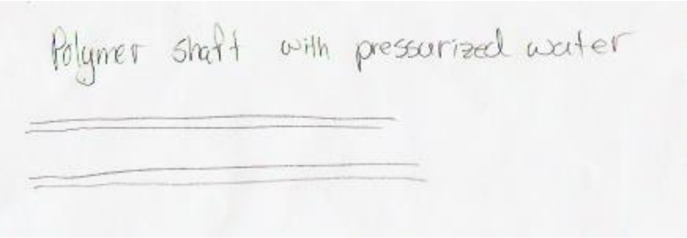

**Figure 3: S4, Hollow shaft with pressurized water**

In this hollow polymer shaft the water pressure could be adjusted to maintain various degrees of flexibility while preventing collapse of the hollow polymer shaft.

### S5: Carbon Fiber Tube

A carbon fibre tube shaft is shown in Figure 4.

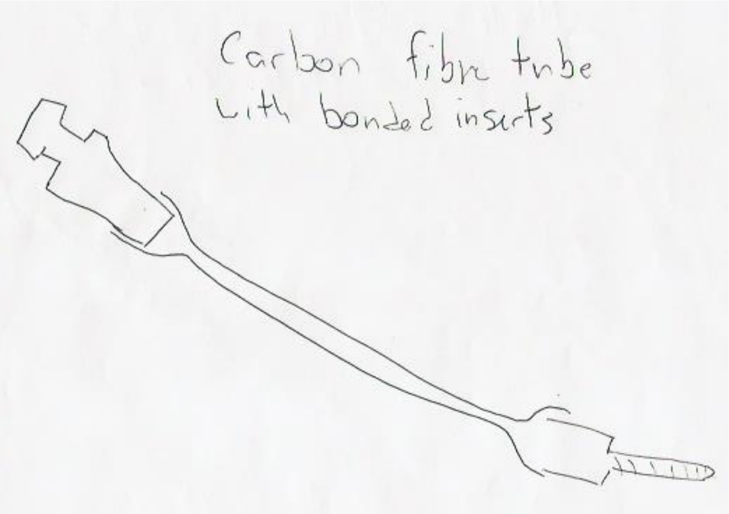

**Figure 4: S5, Carbon fibre tube**

A directional carbon fiber tube with bonded inserts could provide flex while hopefully allowing for effective torque transfer in one specific direction.

### S6: Steel Rods Embedded in Polymer Shaft

Steel rods embedded in a polymer shaft is illustrated in Figure 5.

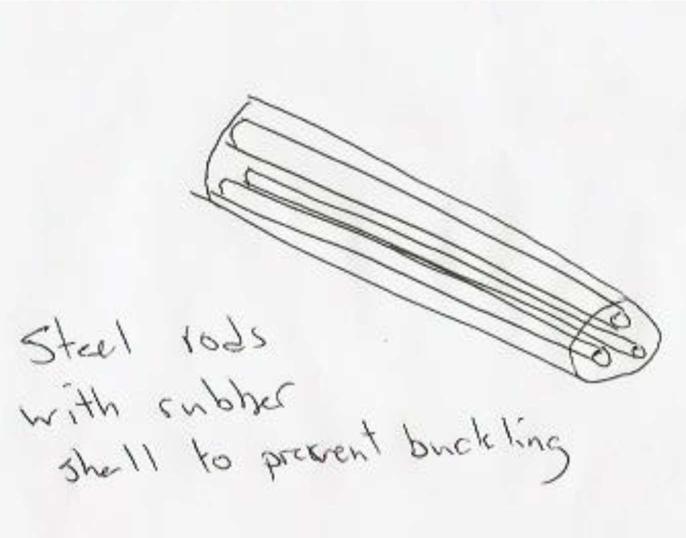

**Figure 5: S6, Steel rods embedded in a polymer shaft**

In this idea thin steel rods run axially, allowing for flexibility and torque transfer. The polymer encasing prevents excessive deformation of the rods.

### S7: Hollow Rubber Shaft with Embedded Steel Mesh

A hollow rubber shaft with embedded steel mesh is observed in Figure 6.

**Figure 6: S7, Hollow rubber shaft with embedded steel mesh**

A hollow rubber shaft would allow for flexibility and effective use of material while the embedded steel mesh would maintain effective torque transfer.

## S8: Plastic or Rubber Coating around Flexible Shaft

A plastic or rubber coating around a flexible shaft is seen in Figure 7.

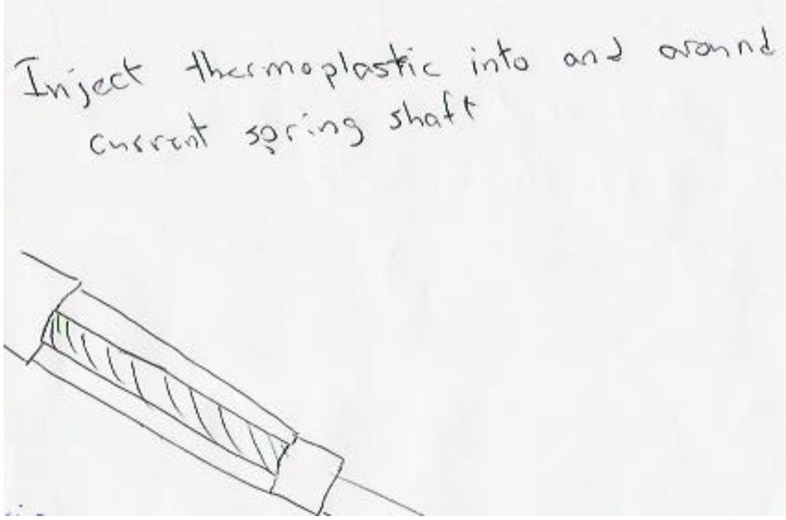

**Figure 7: S8, Plastic or rubber coating around the existing flexible shaft**

An injected plastic or rubber would infuse the device’s flexible shaft to prevent contaminants from entering the spring-like structure. This idea would maintain the original functionality of the current device and make the current device easier to clean.

## S9: Modular Flexible Shaft

A modular flexible shaft is illustrated in Figure 8.

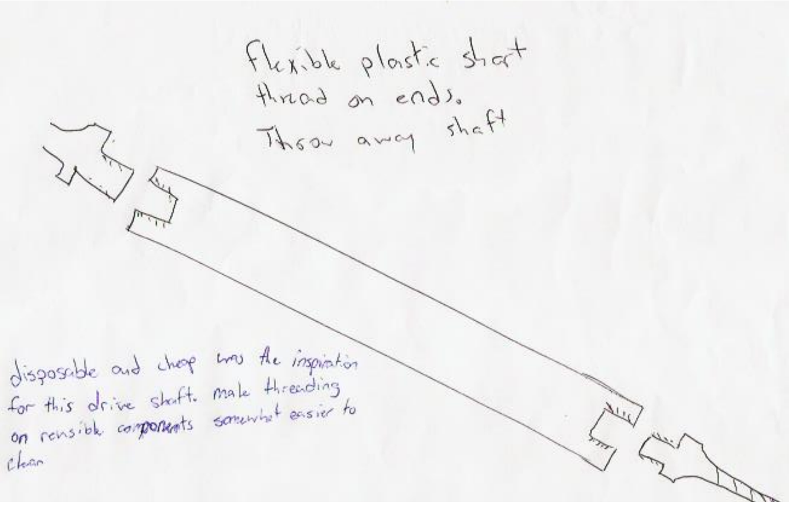

**Figure 8: S9, Modular flexible shaft with female threaded ends**

A modular shaft can be more easily cleaned or disposed of and replaced. With the shaft being disposable it could be comprised of cheaper materials as reliability would not be an issue. Modularity would allow for the shaft to become universal.

### S10: Threaded Steel Shaft

A threaded steel shaft is seen in Figure 9.

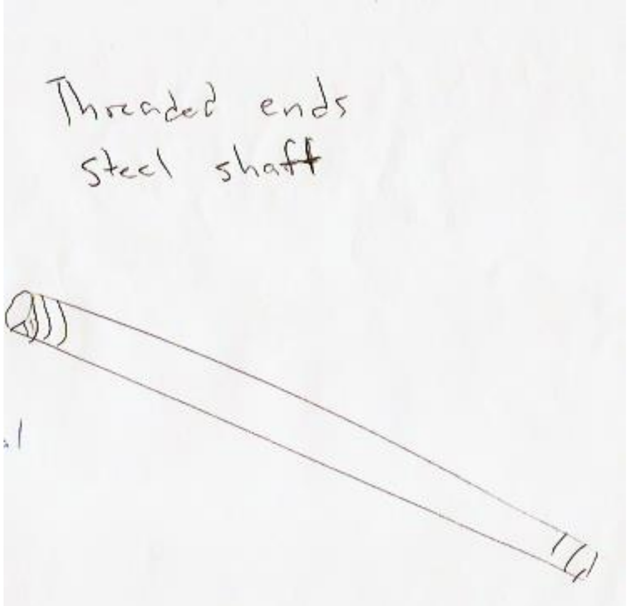

Figure 9: S10, Modular steel shaft with male threaded ends

A modular steel shaft that threads onto the coupling and tip would allow for interchangeable tips and make the shaft a universal part.

### S11: Rope with Threaded Ends

A rope with threaded ends is seen in Figure 10.

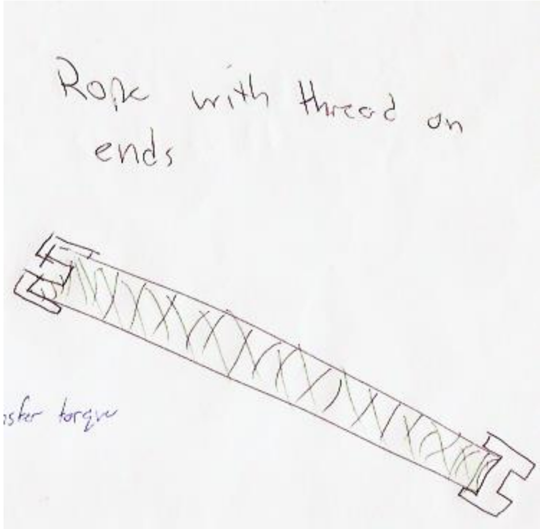

**Figure 10: S11, Rope with threaded ends**

A pre-twisted and modular rope for torque transfer and flexibility would accomplish the goals of a flexible shaft.

**S12: Flexible Plastic Shaft with Slots**

A flexible plastic shaft with slots is observed in Figure 11.

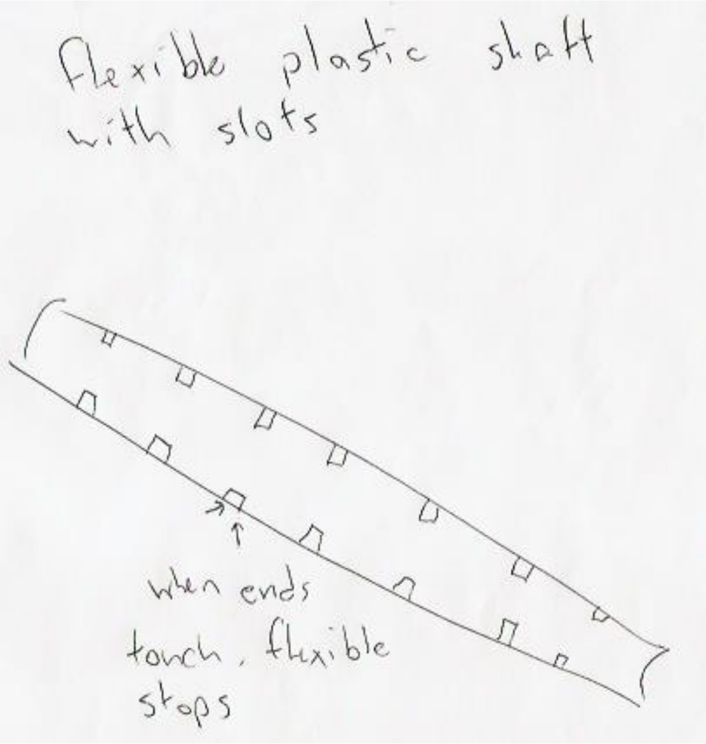

**Figure 11: S12, Flexible plastic shaft with slots**

A slotted plastic shaft would allow for a high degree of flexibility while having a solid core to transfer torque.

## S13: Helix Surrounding Nitinol Core

A helix surrounding a nitinol core is illustrated in Figure 12.

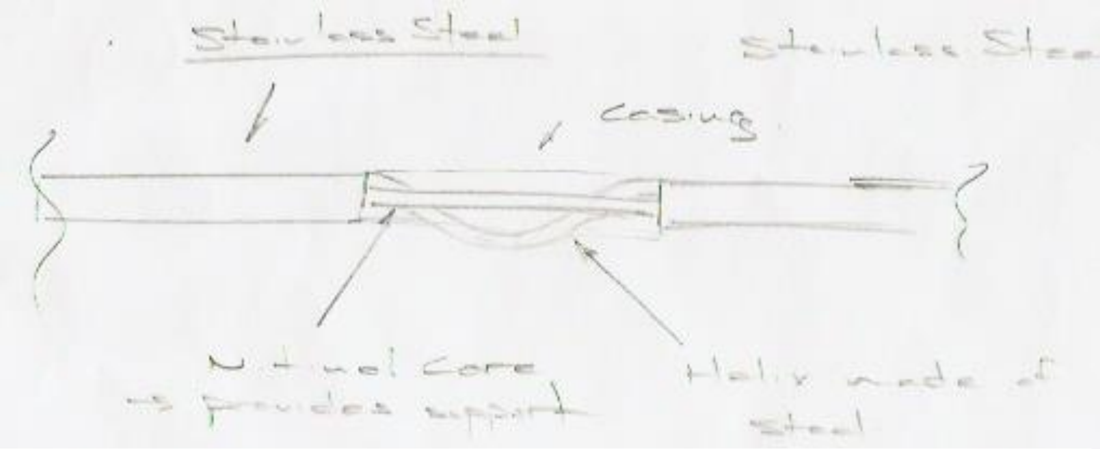

Figure 12: S13, Metal helix surrounding a nitinol core

A steel helix surrounding the nitinol coil would transfer the torque while the nitinol core would provide support and ensures the helix does not collapse due to some applied torque.

## S14: Interlinked Chains

Interlinked chains are shown in Figure 13.

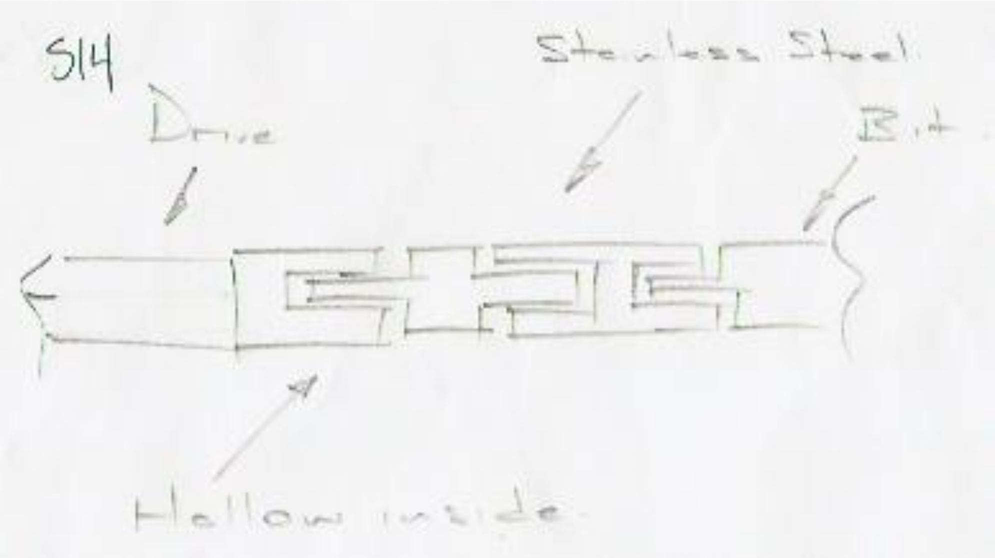

Figure 13: S14, Interlinked chains

Interlinked chain-like pieces would allow for flexibility and effective torque transfer.

## S15: Stronger Single Layer Spring

A stronger single layer spring is seen in Figure 14.

Figure 14: S15, Stronger single layer spring

A reduction of the triple layer spring-like shaft in the original drill bit to a single spring of greater strength makes for cleaning of the device much easier.

### S16: Rounded Interlinking Shaft

A rounded interlinking shaft is shown in Figure 15.

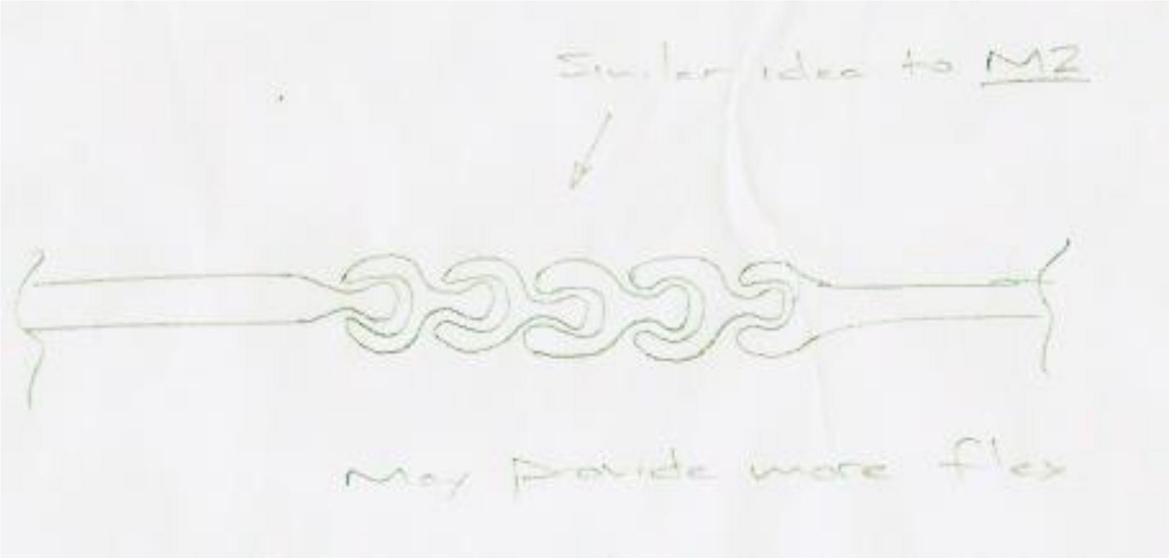

**Figure 15: S16, Rounded chain interlinking shaft**

Interlinking components make up the hollow flexible shaft, similar to S14.

## S17: Ball and Socket Links

A ball and socket linked shaft is shown in Figure 16.

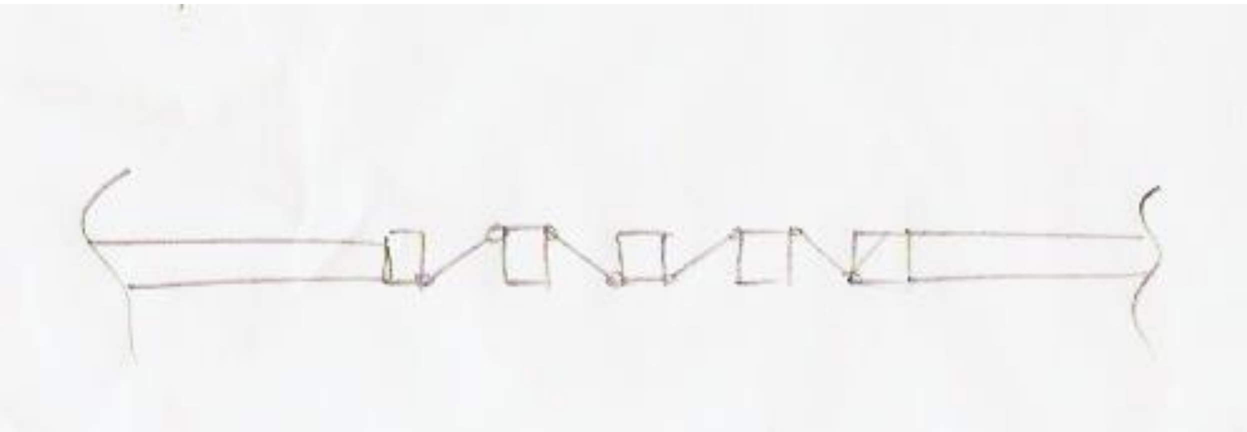

**Figure 16: S17, Ball and socket links in a camshaft arrangement**

Links would be connected with a ball and socket joints in a camshaft arrangement. This concept would allow for flexibility and torque transfer.

## S18: Grooved Steel Shaft

A grooved steel shaft is illustrated in Figure 17.

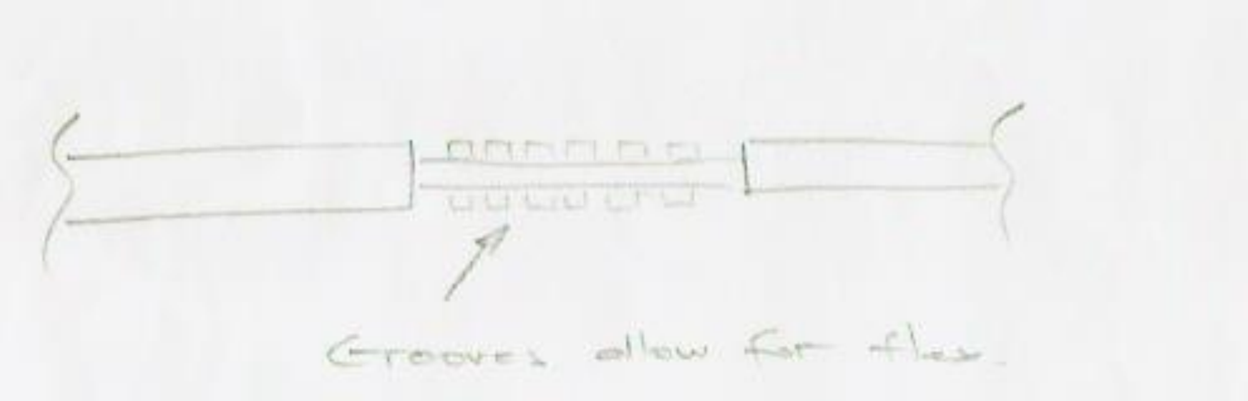

**Figure 17: S18, Grooved steel shaft**

A grooved steel shaft would allow for flexibility due to the grooves and the solid metal core would allow for efficient torque transfer.

## S19: Sleeve or Covering around Flexible Shaft

A sleeve or covering around the flexible shaft is seen in Figure 18.

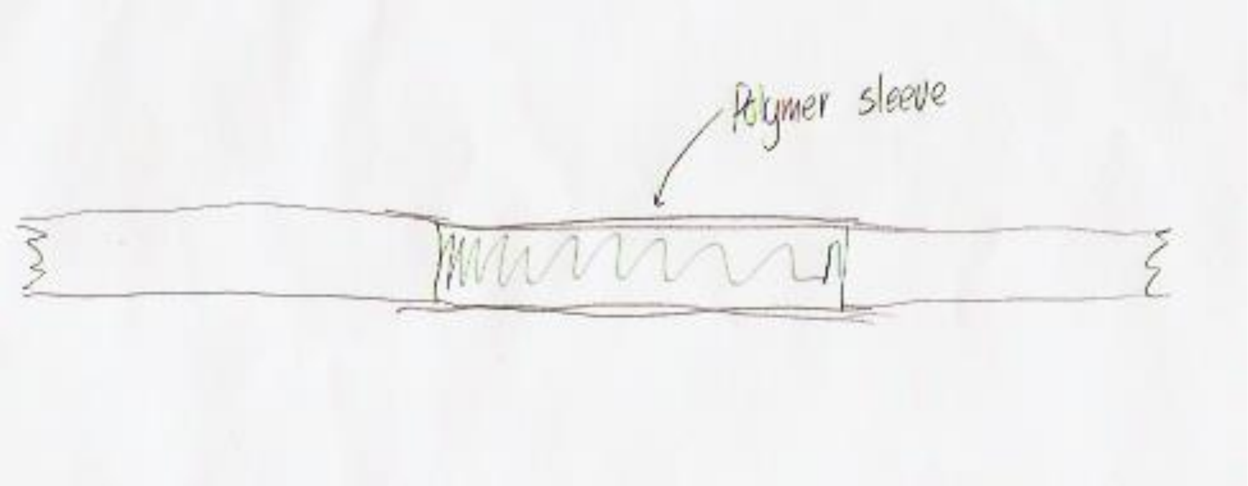

**Figure 18: S19, Sleeve or covering around existing flexible shaft**

A reusable or disposable sleeve would cover the flexible portion of the current device. This prevents contaminants from getting into the spring-like structure of the bit. Also, this allows the current device to stay in use which assures that the functional requirements of the bit are maintained.

### S20: Solid Plastic Shaft

A solid plastic shaft is illustrated in Figure 19.

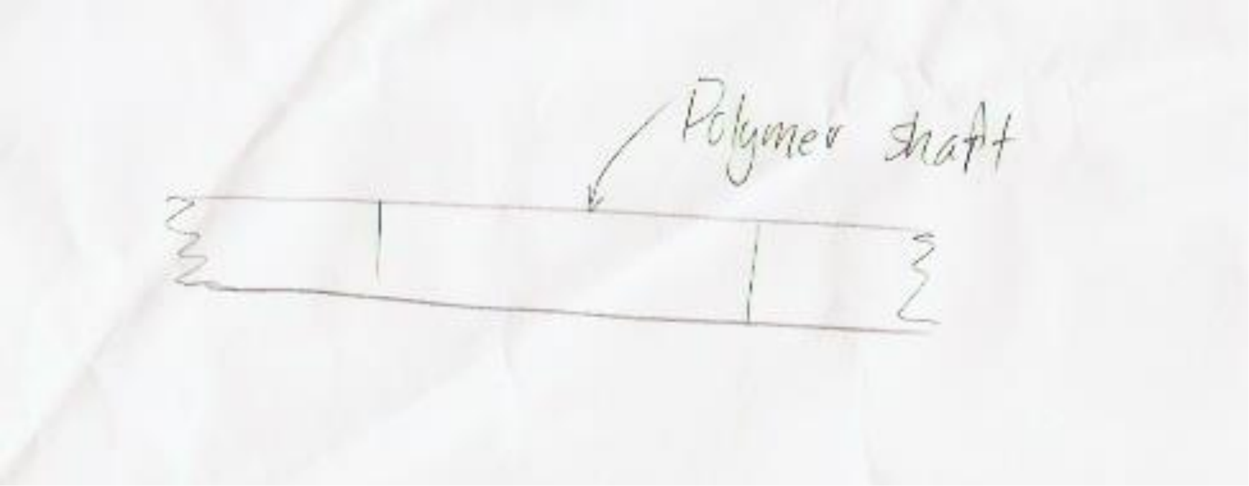

**Figure 19: S20, Solid polymer shaft**

A solid plastic shaft makes the cleaning process simple while allowing for flexibility.

### S21: Ball and Socket Joints

A ball and socket joint shaft is shown in Figure 20.

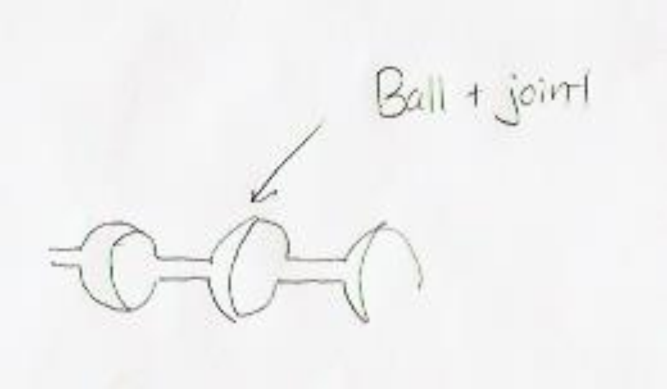

**Figure 20: S21, Ball and socket joints**

A series of ball and socket links would allow flexibility in the shaft of the drill bit.

## S22: Thin Steel Shaft

A thin steel shaft is seen in Figure 21.

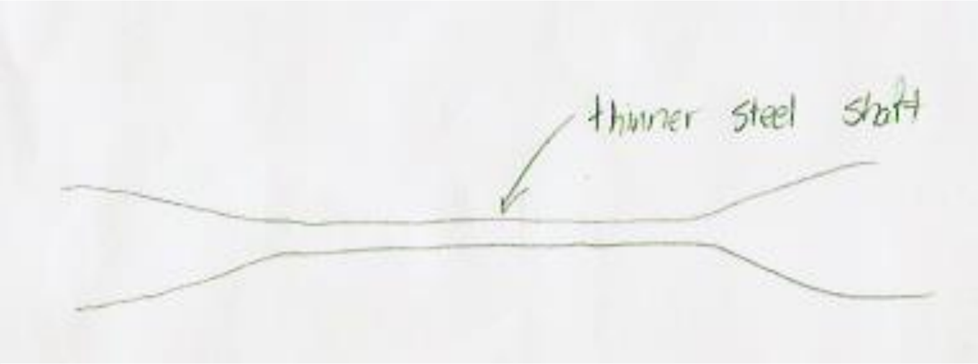

**Figure 21: S22, Thin steel shaft**

This idea takes its inspiration from currently used flexible wood drill bits. Flexible wood drill bits utilize a long and thin steel shaft to bend around corners and drill into hard to reach areas, while maintaining torque transfer through the shaft.

### S23: Gears Instead of Flexibility

A rigid gearbox shaft is observed in Figure 22.

**Figure 22: S23, Rigid gearbox**

Gears rotating on planes 90° apart provide a rigid method for torque transfer around a corner.

# 3.0 Concept Selection

After a multitude of concepts have been generated, they will be narrowed down using a screening process. The goal of the screening process is to evenly compare each of the conceptual designs against each other using various design requirements. The initial screening of concepts can be a daunting task considering the large number of designs presented by Surgical Innovations.

## 3.1 Design Criteria

The criteria used for the primary screening process were initially developed with Surgical Innovations determined needs in mind. This lead to the following 6 criteria:

- Able to drill through bone
- Not harmful to human (biocompatible)
- Compatible with current drive equipment
- Drill around a corner (flexibility)
- Cost effective
- Reusable

The team built a weighting matrix for these criteria and sent it to the clinical engineering team for concurrence. Clinical engineering's response to our weighting scale was not what the team had expected. Clinical engineering sent back a response stating that the previously listed weighting criteria was too broadly spread across the whole device and not focused enough on the flexible shaft portion of the drill bit, which is the area Clinical engineering felt the team should concentrate on. They tasked the team with developing a new list of criteria that would allow the screening of concepts. The new criteria should concentrate on the main design features that would make a new flexible shaft design successful in the desired application. The team agreed with this while initially trying to screen the concepts using the previous criteria. The previous criteria were not optimally created to reflect success of a design.  This was because they were all required for a design to be successful and not features that the team would like to make trade-off between, particularly the biocompatibility. The team realized that the criteria should reflect design challenges and features that could be trade-offs between each other.

The following criteria were then created concentrating on the flexible shaft and not on the overall drill bit product:

- Flexibility
- Cleanability
- Durability
- Torque transfer capability
- Cost effectiveness
- Manufacturability

## 3.2 Benchmark Comparison

With the revised criteria in place the team can effectively screen the concepts for further development. By being provided with a current design, the team is given a slight advantage in the screening process by offering a benchmark design to compare all other conceptual designs against. This leads the team to use a “+/-/0” screening process to initially screen all the concepts. This method is chosen over a weighted screening process because the team feels it will be much more simple for initial screening. The weighted screening requires each design to be assigned a numerical value. This may lead to much discussion and debate when assigning agreeable values.  Having many concepts to evaluate, the team feels it will take far too long to score every concept in this manner. The “+/-/0” process allowed the team to directly compare the concepts, with the baseline design being the current drill bit, while reducing the time taken to perform the initial screening.

TABLE I shows the results of the teams initial screening process following the “+/-/0” method. The “+” indicates the concept performs better than the current design, the “-“ indicates the concept performs worse than the current design, and the “0” indicates the concept performs equal to the current drill bit design.

**TABLE I: BASELINE COMPARISON METHOD**

| Idea Labels | Flexibility | Cleanability | Durability | Torque transfer Ability | Cost Effectiveness | Manufacturability | Totals |
|---|---|---|---|---|---|---|---|
| S9 | 0 | + | + | - | + | + | 3 |
| S2 | - | + | + | 0 | + | - | 2 |
| S6 | 0 | + | 0 | 0 | + | 0 | 2 |
| S12 | + | + | - | - | + | + | 2 |
| S15 | 0 | + | + | 0 | - | + | 2 |
| S18 | - | + | + | 0 | + | 0 | 2 |
| S20 | + | + | - | - | + | + | 2 |
| S22 | + | + | - | - | + | + | 2 |
| S1 | 0 | + | 0 | 0 | + | - | 1 |
| S5 | 0 | + | + | + | - | - | 1 |
| S7 | 0 | + | - | - | + | + | 1 |
| S10 | 0 | - | 0 | 0 | + | + | 1 |
| S16 | 0 | 0 | + | + | - | - | 0 |
| S3 | 0 | + | 0 | 0 | - | - | -1 |
| S4 | 0 | + | - | - | + | - | -1 |
| S8 | - | + | + | 0 | - | - | -1 |
| S13 | 0 | + | 0 | 0 | - | - | -1 |
| S14 | - | 0 | + | + | - | - | -1 |
| S19 | 0 | + | - | 0 | - | 0 | -1 |
| S11 | + | - | - | - | + | - | -2 |
| S23 | - | - | + | + | - | - | -2 |
| S21 | + | - | 0 | - | - | - | -3 |
| S17 | + | - | - | - | - | - | -4 |
| Baseline | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

The results of this initial screening showed that there was a clear leader in this simplified screening process; however, where to place to cut-off for further analysis proves less simple. The team wants to use this process to narrow down to four or five design that could be further developed. The team decides a further round of screening is necessary to reduce the list of concepts further to keep the project moving forward. The team concludes that using the concepts that scored highest, a total rating of 2 and 3, will be best suited for the final design. A meeting with the team's faculty advisor leads to also include concept S19, which involves adding a sleeve to the current design. This design is added to the list of concepts as it is simple and easy to implement.

## 3.3 Qualitative Selection

To further screen the designs, a weighted system is used. To create the weighting, the team uses matched pairs to pit one criterion against another to decide which criterion would have the most importance for the final design. Table II shows the results of the matched pairs analysis.

**TABLE II: NEEDS WEIGHTING**

| | | Flexibility | Cleanability | Durability | Torque Transfer Ability | Cost Effectiveness | Manufacturability |
|---|---|---|---|---|---|---|---|
| 1 | Flexibility | x | 1 | 1 | 4 | 1 | 1 |
| 2 | Cleanability | | x | 2 | 4 | 5 | 2 |
| 3 | Durability | | | x | 4 | 5 | 3 |
| 4 | Torque Transfer Ability | | | | x | 4 | 4 |
| 5 | Cost Effectiveness | | | | | x | 6 |
| 6 | Manufacturability | | | | | | x |
| | | | | | | | |
| | **Weight** | 0.27 | 0.133 | 0.066 | 0.333 | 0.133 | 0.067 |

The weighting matrix indicates that the major design criteria include the ability to transfer torque as well as be flexible, scoring 33% and 27% respectively. The flexible shaft on the current drill bit performs these two aspects very well according to our client and industry specialists. This is consistent with what one would expect from a flexible drill bit. The next highest ranked criteria are cleanability and cost effectiveness, which is where the current flexible shaft fails to meet the client’s needs. This weighting informs the team that any successful design must perform as well as the current flexible shaft and secondarily must be cost effective and easy to clean. This matches well with what a customer would expect from a product in this category.

The team then moves to applying the weighted criteria as shown in Table III.

**TABLE III: MATCHED PAIRS**

| Needs | Weight | S19 | S15 | S18 | S20 | S22 | S6 | S12 | S9 | S2 |
|---|---|---|---|---|---|---|---|---|---|---|
| Flexibility | 0.267 | 5 | 4 | 2 | 4 | 4 | 4 | 5 | 4 | 4 |
| Cleanability | 0.13 | 4 | 4 | 4 | 5 | 5 | 5 | 4 | 5 | 2 |
| Durability | 0.067 | 3 | 4 | 3 | 2 | 3 | 4 | 2 | 5 | 5 |
| Torque Transfer Ability | 0.33 | 5 | 3 | 3 | 2 | 3 | 4 | 2 | 3 | 5 |
| Cost Effectiveness | 0.13 | 5 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 2 |
| Manufacturability | 0.067 | 4 | 3 | 4 | 5 | 5 | 2 | 4 | 4 | 1 |
|  | **TOTAL** | 4.67 | 3.6 | 3.2 | 3.53 | 3.93 | 4.13 | 3.6 | 4 | 3.67 |

The team rates each of the top design from the primary "+/-/0" screening. Each design is given a rating from 1-5, 5 being the best, of how the team feels the concept will achieve the desired need. The results of these ratings show the team three possible design concepts to pursue with further detailed engineering design. The concepts being a polymer sleeve over the current design, multiple steel rods encased in rubber, and a disposable polymer shaft.

## 3.4 Quantitative Selection

Analytical calculations are utilized to further narrow down the concepts selected in order to choose one final concept to pursue.

### 3.4.1 Background Equations

The maximum shear force in a shaft, $\tau_{max}$:

$$\tau_{max} = \frac{Tc}{J} \tag{1}$$

where $T$ is the torque in the shaft, $c$ is the maximum distance from the axis of rotation, and $J$ is the polar moment of inertia.

The maximum axial stress in a shaft undergoing bending, $\sigma_{max}$, is:

$$\sigma_{max} = \frac{M_{max}c}{I} \tag{2}$$

where $M_{max}$ is the maximum moment in the shaft, $c$ is the maximum distance from the neutral axis, and $I$ is the moment of inertia.

The von Mises stress can be used to compare the yield stress of a material to the general state of stress. The general form of the von Mises stress is as shown

$$\sigma_v = \sqrt{\frac{(\sigma_{11} - \sigma_{22})^2 + (\sigma_{22} - \sigma_{33})^2 + (\sigma_{11} - \sigma_{33})^2 + 6(\sigma_{12}^2 + \sigma_{23}^2 + \sigma_{31}^2)}{2}} \tag{3}$$

where $\sigma_{11}$, $\sigma_{22}$, and $\sigma_{33}$ are the normal stresses at the location of interest, and $\sigma_{12}$, $\sigma_{23}$, and $\sigma_{31}$ are the shear stresses at the location of interest.

The angle of bend in a shaft with a large degree of bending can be approximated by breaking a shaft of length, $L$, into $n$ small elements of length, $\Delta L$, and assuming each small element has a small degree of bending.

The shaft is assumed to be fixed at one end with a transverse force, $P$, applied at the opposite end. The shaft has a modulus of elasticity, $E$. The fixed end of the shaft is set at the origin in which $x_0 = 0$ and $y_0 = 0$. The $x$ and $y$ position of the end of the first element is given by Equations 4 and 5 [1].

$$y_1 = \frac{P(\Delta L)^3}{3EI} \tag{4}$$

$$x_1 = \sqrt{(\Delta L)^2 - y_1^2} \tag{5}$$

The $x$ and $y$ positions of the end of the $i$th element is given by Equations 6 and 7 [1].

$$y_i = y_{i-1} + (y_{i-1} - y_{i-2}) + \frac{P(x_{i-1} - x_{i-2})^3}{3EI} \tag{6}$$

$$x_i = x_{i-1} + \sqrt{(\Delta L)^2 - (y_i - y_{i-1})^2} \tag{7}$$

A diagram of the first three elements is shown for clarity in Figure 24.

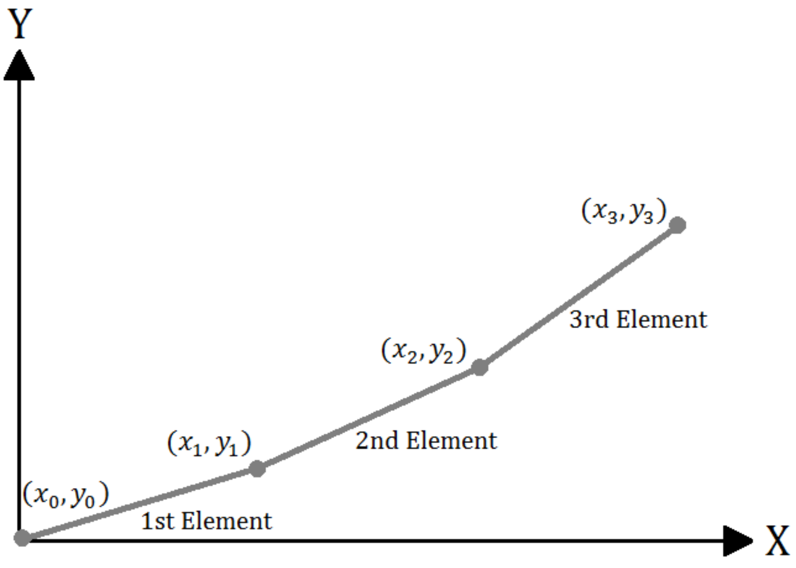

**Figure 23: The first three elements in the bending of a shaft**

This allows the bend angle of a beam of $n$ elements to be calculated as:

$$\theta = \tan^{-1}\left(\frac{y_n - y_{n-1}}{x_n - x_{n-1}}\right) \tag{8}$$

### 3.4.2 Solid Polymer Shaft

Based upon the approximate spatial limitations of the device it will be assumed that the length of the shaft will be between 5 and 10 cm and the diameter of the shaft will be between 4 and 12 mm. Based upon these dimensions, the required strength and modulus of elasticity can be determined.

The polar moment of inertia of a solid circular shaft is

$$J = \frac{\pi}{2} R^4 \tag{9}$$

Combining Equations 1 and 9, the equation for the maximum shear stress simplifies to:

$$\tau_{max} = \frac{2T}{\pi R^3} \tag{10}$$

The moment of inertia of a solid circular shaft is:

$$I = \frac{\pi}{4} R^4 \tag{11}$$

The shaft of length, $L$, will be assumed to be fixed at one end with a force, $P$, applied transversely at the opposite end. This gives a maximum moment of:

$$M_{max} = PL \tag{12}$$

Combining Equations 2, 11, and 12, the equation for the maximum axial stress is simplified to:

$$\sigma_{max} = \frac{4PL}{\pi R^3} \tag{13}$$

The von Mises stress (Equation 3) for the shaft can be simplified based on the loading conditions to:

$$\sigma_v = \sqrt{\frac{2\sigma_{max}^2 + 6\tau_{max}^2}{2}} \tag{14}$$

The yield stress, $\sigma_{yield}$ must be greater than the von Mises stress to ensure failure does not occur. Therefore:

$$\sigma_{yield} > \sqrt{\frac{2\sigma_{max}^2 + 6\tau_{max}^2}{2}} \tag{15}$$

By substituting Equations 10 and 13 into equation 15, the inequality is simplified to:

$$\sigma_{yield} > \frac{2}{\pi R^3}\sqrt{4P^2L^2 + 3T^2} \tag{16}$$

It is assumed that the force exerted to bend the shaft is no more than 50 N, as this is a reasonable force exerted by a surgeon to bend the shaft, and the maximum torque exerted by the drill will be 150 in-lb (16.95 N).

In TABLE IV, the calculated minimum yield strength required for various dimensions are shown.

**TABLE IV: CALCULATED MINIMUM YIELD STRENGTH FOR VARIOUS LENGTHS AND DIAMETERS OF A SOLID SHAFT**

| Length (cm) | Diameter (mm) | Yield Strength (MPa) |
|---|---|---|
| 5 | 4 | 2369.9 |
| 5 | 12 | 87.8 |
| 10 | 4 | 2375.2 |
| 10 | 12 | 88.0 |

An Excel spreadsheet along with the “Goal Seek” function was used to calculate the maximum modulus of elasticity required to achieve a bend angle of 20°. The Excel calculations were based upon Equations 4 through 8. The maximum allowable moduli of elasticity are tabulated in TABLE V.

**TABLE V: CALCULATED MODULUS OF ELASTICITY FOR VARIOUS LENGTHS AND DIAMETERS OF A SOLID SHAFT**

| Length (cm) | Diameter (mm) | Modulus of Elasticity (GPa) |
|---|---|---|
| 5 | 4 | 0.009111 |
| 5 | 12 | 0.000112 |
| 10 | 4 | 0.036428 |
| 10 | 12 | 0.000450 |

Based upon the calculated data, MatWeb, an online material property database, is utilized to find materials that meet the required properties. Additionally, a material selection chart of modulus of elasticity versus strength (see Figure 25) is examined to determine if any material fit within the limits of the required properties.

**Figure 24: Material selection chart of modulus elasticity versus strength (PERMISSION PENDING) [2]**

However, both methods utilized show that no materials have the required strength and modulus of elasticity. Therefore, a solid shaft is not an option for this application.

### 3.4.3 Wires Embedded in a Polymer Shaft

For the shaft of embedded wires, it will be assumed that the wires take up the entire load and are much stiffer than the polymer. The wires will be embedded in a cylindrical polymer shaft. The wires will run along the axis of the shaft and the wires will be positioned at an equal distance from the center of the shaft in a circular fashion. Figure 26 depicts a cross-section of the shaft, where the grey circles represent wires and the larger circle outlined in black represents the polymer shaft. Based upon the approximate spatial limitations of the device it will be assumed that the length of the shaft will be between 5 and 10 cm and the wires will be positioned between 3 and 5 mm from the center of the shaft. It will also be assumed that there will be between 6 and

50 wires within the shaft. Based upon these assumptions, the required strength and modulus of elasticity can be determined.

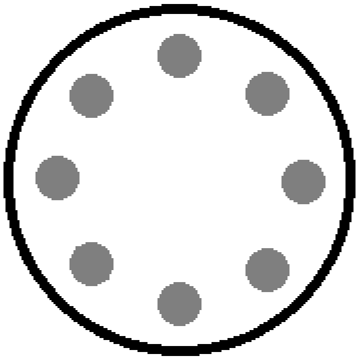

**Figure 25: Cross-section of polymer shaft with embedded wires**

The polar moment of inertia of a shaft containing $N$ wires of radius $r$ with centers located a distance $R$ from the center of the shaft is given by

$$J = N\left(\frac{\pi}{2}r^4 + \pi r^2 R^2\right) \tag{17}$$

By combining equations 1 and 17, the maximum shear stress is found as shown:

$$\tau_{max} = \frac{T(R+r)}{N\left(\frac{\pi}{2}r^4 + \pi r^2 R^2\right)} \tag{18}$$

The moment of inertia depends on the configuration and number of wires in the shaft and a general equation for the moment of inertia is not trivial. However, if the number of wires is constrained to be an even number and we take the moment of inertia about an axis passing through the centers of two wires and the center of the shaft, a simple equation for the moment of inertia can be found.

Therefore, the moment of inertia for these configurations of wires is:

$$I = N\left(\frac{\pi}{4}r^4 + \frac{\pi}{2}r^2R^2\right) \tag{19}$$

The shaft of length, $L$, will be assumed to be fixed at one end with a force, $P$, applied transversely at the opposite end. The maximum moment force can then be calculated using equation 12.

By combining Equations 12 and 19 into Equation 2, along with the knowledge that $c = R + r$, an equation for the maximum axial stress is found:

$$\sigma_{max} = \frac{PL(R + r)}{N\left(\frac{\pi}{4}r^4 + \frac{\pi}{2}r^2R^2\right)} \tag{20}$$

The yield stress of the shaft must be greater than the von Mises stress for the shaft, as shown in Equation 15.

The force exerted to bend the shaft is no more than 50 N and the maximum torque exerted by the drill is 150 in-lb (16.95 N m). Also, a 20° bend angle is required for the device. Table VI lists the minimum yield strength and maximum modulus of elasticity required for the given shaft configurations. The results were found using Excel's "Goal Seek" function, and are based upon Equations 4 through 8. It should be noted that some of the configurations are not physically possible due to conflicting parameters.

**TABLE VI: CALCULATED STRENGTH AND MODULUS OF ELASTICITY FOR VARIOUS CONFIGURATIONS OF WIRES EMBEDDED IN A POLYMER SHAFT**

| Length (cm) | Distance from Center (mm) | Wire Diameter (mm) | Number of Wires | Minimum Yield Strength (MPa) | Maximum Modulus Of Elasticity (GPa) |
|---|---|---|---|---|---|
| 10 | 3 | 0.5 | 6 | 8967.8 | 0.086085 |
| 10 | 3 | 0.5 | 50 | 1076.1 | 0.010033 |
| 10 | 3 | 2 | 6 | 655.8 | 0.005115 |
| 10 | 3 | 2 | 50 | 78.7 | 0.000614 |
| 10 | 5 | 0.5 | 6 | 5226.7 | 0.031059 |
| 10 | 5 | 0.5 | 50 | 627.2 | 0.003727 |
| 10 | 5 | 2 | 6 | 366.5 | 0.001906 |
| 10 | 5 | 2 | 50 | 44.0 | 0.000229 |
| 6 | 3 | 0.5 | 6 | 8967.8 | 0.030990 |
| 6 | 3 | 0.5 | 50 | 1076.1 | 0.003719 |
| 6 | 3 | 2 | 6 | 655.8 | 0.001841 |
| 6 | 3 | 2 | 50 | 78.7 | 0.000221 |
| 6 | 5 | 0.5 | 6 | 5226.7 | 0.011181 |
| 6 | 5 | 0.5 | 50 | 627.2 | 0.001342 |
| 6 | 5 | 2 | 6 | 366.5 | 0.000686 |
| 6 | 5 | 2 | 50 | 44.0 | 0.000082 |

Based upon the calculated data, MatWeb is utilized to determine suitable material for the calculated properties. Furthermore, a material selection chart of modulus of elasticity versus strength is looked at to determine if any material fit within the required properties (see Figure 25 on page 53). No such material exists that satisfies the required properties; therefore, a polymer shaft with embedded wires is not a viable option for this application.

### 3.4.4 Polymer Sleeve

Seeing as the drill bit takes up the majority of the torsional stresses, the sleeve is simply subjected to bending stresses. Looking at the analyses performed in sections 3.4.3 and 3.4.2 it can be seen that these designs failed because they needed to bend to a certain degree and be able to withstand the torque transfer. Since the sleeve only has to bend to a certain degree, this concept is completely viable. Due to this fact, this concept is the final concept to be pursued.

# 4.0 Conclusion

Surgical Innovations started with a multitude of concepts. A selection process including both qualitative and quantitative analyses were employed which narrowed down the concepts generated to a single final concept. The final concept selected by this process is a sleeve which will cover the flexible portion of the existing device to prevent foreign contaminants from entering the difficult to clean flexible portion of the shaft. This concept will also maintain the functionality of the drill bit.

# References

[1] Paul Labossier. MECH 4750, Topic: “Assignment 3 Solutions.” EITC E2-125, University of Manitoba, Winnipeg, MB, 2013, Oct.

[2] M. F. Ashby. *Materials Selection in Mechanical Design*. Burlington MA: Elsevier, 2011, pp. 69.

# APPENDIX B: Technical Analysis and Testing of the Final Design

# Contents

# List of Figures

# 1.0 Introduction

The final design requires verification of its ability to satisfy the client's needs. This is performed through theoretical calculations accompanied by physical testing. The goal of the design is to ensure that the flexible surgical drill bit is easy to clean and maintains the current functionality of the existing design. As the proposed solution consists of adding a sleeve to the flexible shaft of the existing design, Surgical Innovations is not altering the original functionality of the drill bit. That is, the drill bit will operate the same as it would without the sleeve, thus, it can be concluded that the functionality of the drill bit is maintained. Establishing that the sleeve does not hinder the functionality of the drill bit, the sleeve acts as an impermeable boundary between the flexible coils and the contaminants. A technical analysis will give a theoretical justification supporting the design while physical testing will further verify the technical analysis and provide empirical evidence validating the design.

# 2.0 Technical Analysis

It will be assumed that the tubing is fixed at one end and has a load, $P$, applied transversely at the opposite end. The length, $L$, of the tube is assumed to be 6 cm, the outer radius, $r_o$, of the tube is assumed to be 3.32 mm, and the inner radius, $r_i$, of the tube is assumed to be 3.00 mm. The properties of the polyolefin, the material used in heat shrink tubing, have a range of possible values. In a worst case scenario, the modulus of elasticity is high and the ultimate strength is low. The maximum modulus of elasticity, $E$, is 0.00980 GPa and the minimum ultimate strength, $S_u$, is 6.50 MPa [1].

The angle of bend in a shaft with a large degree of bending can be approximated by breaking a shaft of length, $L$, into $n$ small elements of length, $\Delta L$, and assuming each small element has a small degree of bending.

The fixed end of the shaft is set at the origin in which $x_0 = 0$ and $y_0 = 0$. The $x$ and $y$ position of the end of the first element is given by the Equations 1 and 2 [2].

$$y_1 = \frac{P(\Delta L)^3}{3EI} \tag{1}$$

$$x_1 = \sqrt{(\Delta L)^2 - y_1^2} \tag{2}$$

The $x$ and $y$ positions of the end of the $i$th element is given by Equations 3 and 4 [2].

$$y_i = y_{i-1} + (y_{i-1} - y_{i-2}) + \frac{P(x_{i-1} - x_{i-2})^3}{3EI} \tag{3}$$

$$x_i = x_{i-1} + \sqrt{(\Delta L)^2 - (y_i - y_{i-1})^2} \tag{4}$$

A diagram of the first three elements is shown for clarity in Figure 1.

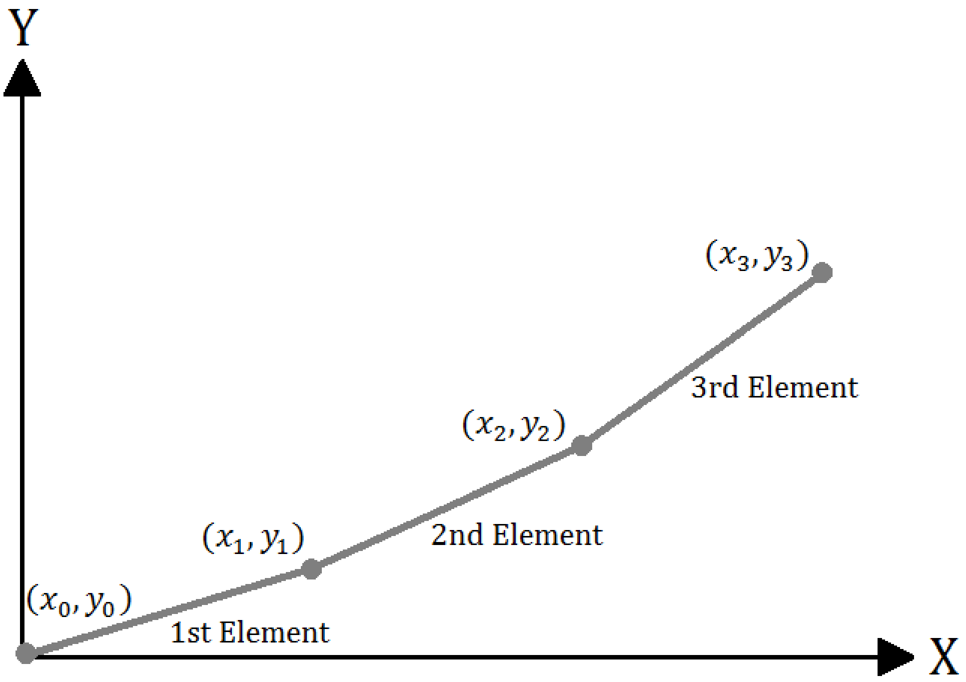

**Figure 1: The first three elements in the bending of the shaft**

This allows the bend angle of a beam of $n$ elements to be calculated shown:

$$\theta = \tan^{-1}\left(\frac{y_n - y_{n-1}}{x_n - x_{n-1}}\right) \tag{5}$$

Excel was utilized to solve for the bending. Based upon a bend angle of 20° the “Goal Seek” function from Excel shows that a force of $P = 0.024477\ N$ is applied at the end of the tubing.

The maximum moment in the tubing occurs at the fixed end and is given by:

$$M_{max} = PL \tag{6}$$

$$M_{max} = (0.024477\ N)(6\ cm) = 0.0014686\ Nm$$

The maximum axial stress in the tubing can be calculated as shown:

$$S_{max} = \frac{M_{max} r_o}{\frac{\pi}{4}(r_o^4 - r_i^4)} \tag{7}$$

$$S_{max} = \frac{(0.0014686\ Nm)(3.32\ mm)}{\frac{\pi}{4}((3.32\ mm)^4 - (3.00\ mm)^4)} = 153{,}311.0762\ P = 153.3\ kPa$$

After the drill bit rotates 180° the minimum stress will occur at the point in which the maximum stress had occurred previously. The minimum stress must be:

$$S_{min} = -S_{max} \tag{8}$$

$$S_{min} = -153.3\ kPa$$

The stress amplitude is equal to:

$$S_a = S_{max} - S_{min} \tag{9}$$

$$S_a = 153.3\ kPa + 153.3\ kPa = 156.6\ kPa$$

The mean stress is equal to

$$S_m = \frac{S_{max} + S_{min}}{2} \tag{10}$$

$$S_m = \frac{153.3\ kPa - 153.3\ kPa}{2} = 0\ kPa$$

For polymers the endurance limit $S_e$ is typically equal to 20% to 30% of the ultimate strength of the material [3]. Therefore, the endurance limit is equal to at least:

$$S_e = 0.2S_u \tag{11}$$

$$S_e = 0.2(6.50\ MPa) = 1.3\ MPa = 1300\ kPa$$

Based upon the Goodman relation a safety factor, $SF$, can be found for the assumed loading condition. The Goodman relation states:

$$\frac{S_a}{S_e} + \frac{S_m}{S_u} = \frac{1}{SF} \tag{12}$$

Therefore, the safety factor is:

$$SF = \frac{1}{\frac{S_a}{S_e} + \frac{S_m}{S_u}} = \frac{1}{\frac{306.6\ kPa}{1300\ kPa} + \frac{0\ kPa}{6500\ kPa}} = 4.2$$

With a safety factor of 4.2 under the given loading condition, the tubing will not fail due to fatigue.

# 3.0 Physical Testing

The physical testing to be performed will simulate as best a situation that the final design will encounter when in use. This is a requirement of the validation of the design, and shall provide empirical evidence that this design is well suited for its intended application.

## 3.1 Background

A flexible surgical drill bit is expected to be used for a maximum of 20 minutes in a hip surgery. Currently, organic material gets trapped deep within the flexible coils after a single surgery. Due to this, the drill bit is very difficult to properly disinfect and nearly impossible to sterilize. Due to these factors the drill bit has been deemed a single use device.

The purpose of the heat shrink tubing is to act as a protective sleeve over the flexible portion of the drill bit. The heat shrink tubing will protect the flexible coils from unsanitary and unsterile organic material that currently renders the multiple use drill bit a single use device. The sleeve must not hinder any mechanical abilities of the drill bit and must maintain an impenetrable seal around the flexible portion of the drill bit.

The protective sleeve is designed to increase the lifetime of the device without losing any functionality of the current device. The protective sleeve has a lifetime of a single surgery. In practice, the protective sleeve is applied before sterilization and removed during disinfection and sterilization after a surgery.

## 3.2 Apparatus

The simplicity of the design and availability of the material allows for physical testing of the final design. The objective of testing is to ensure that the structural integrity of the design remains after being subjected to loading. When in use, the surgical drill bit is exposed to a harsh environment and dynamic loading. The primary function of the drill bit is to allow a surgeon to drill a hole into the hipbone while at an angle. This function will be the basis of the testing. The test apparatus consists of:

- Drill Press (1)

- Heat Gun (1)
- A Tank (1)
- Wooden Block Retainer for the Drill Bit (1)
- Food Coloring (50mL)
- Water (3L)
- MT5000-1/2 Heat Shrink Tubing (5x3.5”)
- Flexible Surgical Drill Bits (5)
- Sample Containers (12)
- Filters (12)

**Figure 2: Test apparatus set up**

In this experiment a heat gun is used to apply the MT5000-1/2 heat shrink tubing to the surgical drill bits. First the heat shrink tubing will be placed on the surgical drill bit such that both crimped ends are covered as shown Figure 3.

**Figure 3: Flexible surgical drill bits with heat shrink tubing prior to heat addition**

The heat gun will apply the correct temperature for the tubing to shrink. To ensure that the tubing is heated uniformly, the heat gun will be moved in a back and forth motion along the entirety of the tubing. The application of the heat to the tubing should last between 7-9 minutes. The surgical drill bit with the MT5000-1/2 heat shrink tubing is ready for testing as shown in Figure 4.

**Figure 4: Flexible surgical drill bit with heat shrink tubing after heat addition**

Next, the tank and retainer need to be assembled together. The retainer will be inserted into the tank and will ensure that the drill bit is on an angle when the drill bit is in operation as shown in Figure 5.

Figure 5: Wooden block retained keeping drill bit at an angle

The surgical drill bit with MT5000-½ heat shrink tubing will be loaded in the drill press, followed by placing the drill bit within the tank and the drill bit inserted into the retainer. Once the drill bit is secured in place and the whole apparatus secured, a food coloring and water solution will fill the tank. The food coloring and water solution will aid in detecting if the design succeeds or fails. The final configuration of the test apparatus with test specimen will look like Figure 6.

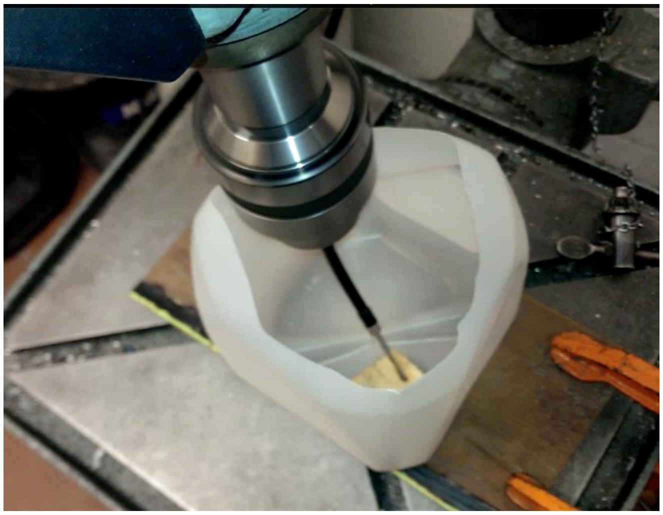

Figure 6: Flexible surgical drill bit in test apparatus prior to food colouring

## 3.3 Method

In this test the drill press will operate at 1250 RPM for 20 minutes. This will simulate both the operating load and operating time the flexible surgical drill bit is used in a surgery. After the 20 minute trial, the exterior of the sleeve be visually inspected. If no food coloring and water solution is present on the inside of the sleeve or on the coiled portion of the surgical drill bit, the design has succeeded. If the exterior of the sleeve is heavily damaged to the point where the coils can be seen, the design has failed. Four samples of the food coloring and water solution will be taken and allowed to rest for four hours. This will allow any wear particles from the sleeve to settle. After the resting period, the samples will be poured out through filters. This will allow for the observation of wear particles if they to arise under normal operating conditions.

## 3.4 Results

Results of the physical tested yielded favourable results. While observing the drill bit in use, no visible signs of imminent failure or wear could be seen. After the trial was completed, closer inspection of the sleeve, again, did not show any signs of failure or wear. This is seen in Figure 7.

**Figure 7: Sleeve on the drill bit after testing**

The next step in verifying the results requires carefully removing the sleeve by making a single incision along the length of the sleeve, to reveal the interior of the sleeve and the flexible coils. One of the main objectives of the sleeve is to prevent any sort of liquid from reaching the flexible coils. As shown in Figure 8, the interior of the sleeve remained completely dry through out the trial.

**Figure 8: Interior of the sleeve after removal**

Further to the interior of the sleeve remaining dry, a dry paper towel is run along the flexible coils to detect any moisture that it may have contained. The paper towel remains completely dry. From these results, it is determined that the seal provided by the heat shrink tubing and the tubing itself, are sufficient in protecting the flexible portion of the drill from any liquids or debris.

Another crucial component of the design required the determination of wear particles. In samples of the water and food colouring solution collected, no wear particles were seen to have settled either on the bottom, or on the top of the solution. In addition, when the samples were filtered through paper towels, no wear particles were observed, as shown in Figure 9. This indicates that the sleeve does not wear when subjected to normal loading conditions.

**Figure 9: Filter after water from testing was poured through it**

# 4.0 Conclusion

A fatigue analysis and physical testing was required to confirm the abilities of the new design and ensure it that it meets the design criteria. In the fatigue analysis the sleeve was analyzed by setting a bending angle of 20° and using a finite element analysis approach to find the maximum stress in the tubing. The calculations showed that the material, while subjected to normal loading conditions, is far below its failure threshold for fatigue. From this analysis, it was determined that the new design will not fail due to fatigue under normal operating conditions.

For physical testing, Surgical Innovations created a test apparatus that would allow for simulation of the normal loading conditions seen by the drill bit. The test was performed to mimic a single use. After the trial was completed, a close inspection was performed to determine if the sleeve had signs of imminent failure, whether or not the seal had been broken and finally if any wear particles resulted from the use. The results yielded a favorable outcome, as the sleeve remained in excellent condition with no signs of imminent failure, the seal remaining intact and no wear particles were observed. The overall results of the analysis and testing confirm that the design performs as intended.

# References

[1] MatWeb. (n.d). *Overview of Materials for Engineered Polyolefin* [Online]. Available: http://www.matweb.com/search/DataSheet.aspx?MatGUID=2df57261a319439b8c746ef4675b846c&ckck=1 [Nov 15, 2013]

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