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Meniscus suturing machine

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MENISCUS SUTURING MACHINE

ME 1501-1502

Technical Design Report

Meniscus Suturing Machine

Final Report

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Abstract

The meniscus Suturing Device is designed to apply quick, strong, reliable suture repair for transplanted or torn menisci. The new suturing device utilizes the chain stitch, a common, single-thread sewing stitch. The device is simple to use, has internal fault protection and safety mechanisms, and comes apart easily. The Meniscus Suturing Device operates on basic pneumatic and mechanical concepts. A pneumatic system powers the needle and grabber system and ties into the existing nitrogen supply already present in operating rooms. Mechanical systems maintain the appropriate tension in the suturing system. Both the receptor arm and needle assembly are disposable. A simple two-button system makes the device easy for any orthopedic surgeon to operate. The major benefits the suturing device provides include a tremendous reduction in operating time and decreased complexity of meniscus repair.

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INTRODUCTION

DESIGN PROBLEM

Meniscal Repairs

What is the Meniscus?

The meniscus is a crescent-shaped piece of flexible cartilage. Menisci are found in both the human wrist and knee. There are two menisci in each knee, the medial and lateral meniscus. The lateral meniscus rests atop the outer portion of the tibia, more commonly referred to as the shinbone. The medial meniscus rests atop the inner portion of the shinbone. Together, the two menisci act as a shock absorber between the tibia and femur, more commonly called the thighbone.

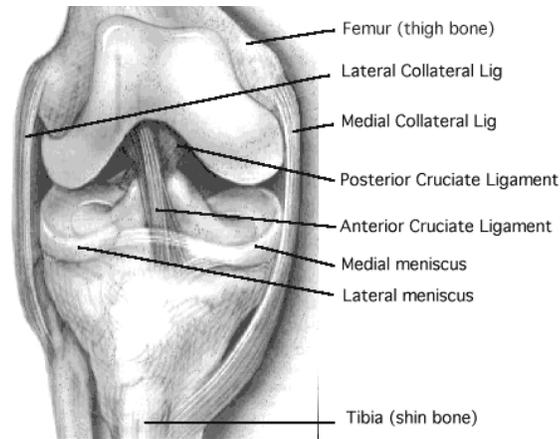


Figure 1.1: Anatomical view of the right knee

Meniscus Injuries.

Meniscus tears result from either degenerative joint disease or awkwardly landing on and twisting the knee. Over time, wear and tear damage and unnatural motions degenerate the menisci, causing the degenerative joint disease. More specifically, a concentration of force from the femur isolated on one portion of the meniscus drives degeneration. Eventually this causes either a catastrophic failure or small tear of the medial or lateral meniscus.

Symptoms of Meniscus Injuries.

Symptoms of meniscus tears include knee pain, swelling, locking, and sporadic failure of the knee. Meniscus tears are usually diagnosed by an orthopedist during a physical examination. Sometimes orthopedists and physicians use a magnetic resonance image (MRI) test to positively confirm the presence of meniscus tears. When doctors identify meniscus tears, they initially restrain from surgical procedures to allow the meniscus to heal on its own. If the tear does not heal on its own within about six weeks, it is unlikely that the meniscus injury will heal and arthroscopy is required. The arthroscopy allows doctors to locate the tear, its shape, and to determine the appropriate course of action to repair or remove the meniscus.

Types of Tears.

Meniscus tears vary in shape, size, alignment, and location, as menisci fail differently under the various encountered stresses. Meniscus tear types include the partial radial, complete radial, longitudinal, double longitudinal, flap, and horizontal cleavage tears. Refer to Appendix A for illustrations on the major meniscus tears. The most common type of tear that doctors repair is the bucket-handle tear.

The longitudinal meniscus tear, typically involving the posterior section of the meniscus, is the second most common meniscus tear. This tear occurs when a person runs or walks and abruptly changes direction with their knee bent, anchoring their foot to the ground, rotating the upper leg. The joint then traps the medial meniscus between the femur and tibia, pulling it towards the center and tearing it. The lateral meniscus is more mobile with less

peripheral attachment and commonly tears when the knee suddenly extends, placing a sudden distraction force on the meniscus. The tear then propagates along the circumference of the meniscus.

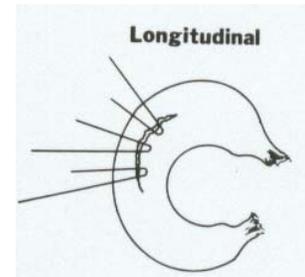


Figure 1.2: Longitudinal Meniscus Tear

Meniscus Repair or Removal.

Whether a meniscus tear is repairable or if meniscectomy (meniscus removal) is necessary depends on the blood supply to the area surrounding the tear. The outer one-third of the meniscus is vascular, with sufficient blood supply to induce meniscus regeneration. However, the inner two-thirds of the meniscus are not vascular and will not regenerate. If a smooth, straight tear occurs on the outer third of the meniscus, then a series of several small sutures are usually sufficient to repair the tear. However, if the meniscus tear is jagged or located in the inner two-thirds of the meniscus, then meniscectomy is required.

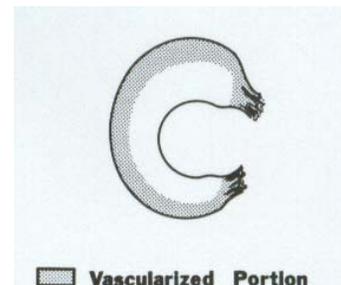


Figure 1.3: Shaded region is repairable portion of meniscus

Removed portions of the meniscus do not grow back. However, further joint degeneration often occurs if the damaged portion of the meniscus is not carefully removed. In the past, the entire meniscus was removed for all types of tears and patients had good knee function for many years. Currently, the precision of arthroscopy allows doctors to reduce the area of the meniscus that needs to be removed. Reducing the amount of meniscus removed increases the amount of time the patient will have normal knee function after meniscectomy (Rosse, Gaudum-Rosse, 1997).

Meniscus Repair Procedure Improvement Needs

Desired Design Solution.

Orthopedic surgeons desire to streamline meniscus repair operations. Currently, meniscus repairs take up to two hours and require two highly skilled orthopedic surgeons to apply seven to fifteen manual sutures to the meniscus. These procedures are expensive, requiring substantial doctor and operating room time to complete. A suturing device that provides the same strength and precision of manual hand sutures would reduce the total procedure time, meet the design specifications of surgeons and allow only one orthopedic surgeon to conduct the procedure.

RESEARCH ON CURRENT REPAIRS

MENISCUS REPAIR METHODS

Traditional Repair

Manual Suturing.

Manual suturing methods are the most common and widely used meniscus repairs and usually take up to two hours to complete. In this procedure, a surgeon inserts an arthroscope through a quarter inch incision made in the front of the knee. The knee itself is pumped full of surgical saline. The doctor uses the arthroscope to locate the tear on the meniscus. Next, two more incisions are made to facilitate the meniscus repair procedure. One small incision is made in the front of the knee, and another larger incision, around one-half inch, is made in the side of the knee.

A small metal tube called a cannula enters the knee through the second incision on the front of the knee to provide a path for suturing needles. Two flexible six-inch needles connected by suture material provide sutures for the torn meniscus. Each set of pre-threaded needles makes one suture and cost around \$50 per set.

A metal retractor is inserted in the larger incision on the side of the knee to protect the veins in the knee and help the second orthopedic surgeon find the needle after it passes through the meniscus.

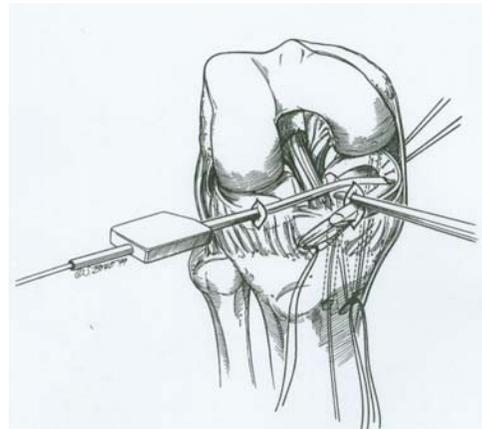


Figure 2.1: Meniscus Repair Instrument and Incision Locations on Knee

Once the equipment is in place, the suturing process begins. Initially, the needle is manually forced through the cannula and then through the meniscus until it hits the retractor. Next, the second surgeon pulls the needle through the meniscus from the retractor incision. The needle is advanced a quarter inch at a time using forceps to avoid buckling the flexible needle extended out the top of the cannula. After the needle is carefully pulled all the way through the knee, the cannula is placed diagonally across the tear in the meniscus, and then the second needle is pushed through the meniscus and retrieved in the same fashion as the first. The suture is made diagonally across the tear to ensure that the suture material, typically ethabon, will not damage the longitudinal thin fibers of the meniscus. The second surgeon, working through the retractor incision, cuts off the two needles, ties a knot in the thread, and then slides the knot tight against the backside of the meniscus. This procedure is repeated along the entire length of the meniscus tear.

Other Meniscus Repair Solutions

Regenbio SharpShooter System.

Regenbio developed their SharpShooter system to make manual suturing faster and easier. Cannulas are custom made to interface with a gun-type trigger mechanism. The sharpshooter advances the needles through the cannulas and subsequently the meniscus. In this device, longer needles are forced through the cannula by the trigger motion in the handheld portion of the system. The SharpShooter suturing system effectively eliminates buckling the thin needles above the cannula as they are being fed through the meniscus.



Figure 2.2: Regenbio SharpShooter

However, the SharpShooter does not address the arduous process of retrieving the needles once they have passed through the meniscus. It is also a cumbersome trigger to precisely manipulate.

As doctors need to exercise extreme precision to properly apply the sutures on the meniscus, the trigger compression force required to advance the needle makes the device unstable and therefore inaccurate. The cumbersome nature of the SharpShooter makes it an unattractive solution to suturing torn menisci. In fact, many doctors that have tried the SharpShooter subsequently discontinue its use and return to the tradition suturing method.

Mitek Meniscus Fastener.

The Mitek Meniscus Fastener is another tool some orthopedic surgeons use to repair torn menisci. The Mitek system eliminates the second incision required in the side of the knee. In this procedure, the doctor first measures the meniscus to determine the length of fastener necessary. Then, the properly adjusted fastener attaches to an applicator needle and incision device. The incision device has a hand trigger mechanism to deploy the fastener. The fastener is carefully pushed through the meniscus, and at the proper depth, the trigger is pulled, deploying the second end of the fastener.



Figure 2.3:
Mitek Meniscus
Fastener

Unfortunately, the Mitek fastener does not provide sufficient strength for the meniscus repair, as fastener repairs are not as strong as sutures. However, the fasteners are easy to implement and are useful in certain situations. When considering the application of a Mitek fastener, the doctor must decide between a complicated and lengthy yet strong repair and a quick, easy, yet weaker, repair.

Mitek Clearfix Meniscus Screw.

Mitek also manufactures the Mitek Clearfix Screw to repair longitudinally torn

menisci. Mitek's Clearfix meniscus screw secures the two sides of the meniscus together. This procedure requires only two incisions in the front of the knee, eliminating the third incision in the side of the knee. Specially designed cannulas

sheathe the screw while the doctor positions it. Once the cannula is properly positioned, the doctor forces the screw out with a specially designed screwdriver. Similar to conventional screws, the doctor turns the screwdriver clockwise to tighten the screw and counterclockwise to loosen or reposition the screw. The screws are designed to slowly bio-absorb after the meniscus is fully healed.



Figure 2.4: Mitek Meniscus Screw

Similar to the Mitek fastener, the Mitek Clearfix Screw does not provide sufficient strength for a meniscus repair. While the Mitek screw is a faster solution to repair a meniscus, it still does not provide the strength of suture repair.

EXISTING RELATED PATENTS

Thread Control

Thread Control Device For a Chain Stitch Sewing Machine.

United States Patent number 5,899,156 describes a device controlling the thread for a chain stitch sewing machine. Details on the patent are located in *Appendix B*. The thread management system described in the patent does not correlate with the proposed thread management system, but it does provide insight into the current design of chain stitch sewing machine thread management systems.

Knot Tying

Chain Stitch Sewing Machine With Knot Tying.

United States Patent number 5,887,533 describes a mechanical method of knot tying in the chain stitch process. The patent refers to a mechanical system of knot tying to secure the end of a chain stitch. Details on the patent and design are located in *Appendix B*. This mechanical system of knot tying is not applicable to the strict design criteria for the meniscus suturing machine. However, the design does describe one method of ending a chain stitch process.

Looper Systems

Looper Drive For a Chain Stitch Sewing Machine.

United States Patent number 5,540,162 describes a looper drive mechanism used for chain stitching. The design describes a complex mechanical looper drive system integrated into a chain stitch sewing machine. Details on the patent and design are located in *Appendix B*. While the looper drive mechanism does not immediately relate to the design, it provides insight into the looper drive mechanisms of other chain stitch sewing machines.

Double Pointed Looper Actuating Mechanism For Chain Stitch Sewing Machine.

United States Patent number 4,401,043 describes actuating system used in a chain stitch sewing machine. The design entails a double point looper and double tracked cam to control the movement of the actuator. Details on the patent and design are located in *Appendix B*. The actuating system does not relate directly to the suturing machine design, but it does describe one method of actuating a looper using cams. However, the design specifications do not provide space for such a mechanism.

Looper and Cam Assembly For Chain Stitch Sewing Machine.

United States Patent number 4,522,135 describes a looper and cam system used in a chain stitch sewing machine. In the design, the assembly controls the motion of the looper relative to that of the needle. Details on the patent and design are located in *Appendix B*. The patent provides useful insight into other methods of actuating loopers. However, the actuating method described significantly differs from the proposed design.

Looper For Sewing Machine.

United States Patent number 5,301,622 describes a looper used in some sewing machines. The looper described in the design actually is a system of an upper and lower looper. Details on the patent and design are located in *Appendix B*. The looper covered by the patent has a vastly different geometry and operating sequence than the proposed looper. While the patent does describe current loopers, it does not apply to the looper or system necessary to achieve the proposed design.

Hook Drive For Chain Stitch Sewing Machines.

United States Patent number 4,742,787 describes a mechanically operated hook drive for chain stitch sewing machines. The patent refers specifically to applications in hand-held sewing machines. Details on the patent and design are located in *Appendix B*. The intricate mechanical hook drive system is

different from all systems in the proposed design. Even though it does not relate directly to the proposed design, the patent does explain some mechanical drive systems in chain stitch sewing machines.

DESIGN CONCEPT

ABANDONED DESIGN IDEAS

Suturing Techniques

Bobbin System.

After understanding the general shape, size and geometry of the knee, various suturing styles were analyzed. Initially, it appeared best to model the suturing device as a typical sewing machine, utilizing a bobbin system on the back end to advance the thread. However, upon further investigation, this method of operation would have required the use of two threads and a relatively large, complicated bobbin apparatus. Those difficulties, in addition to extremely tight quarters, made the bobbin system unusable.

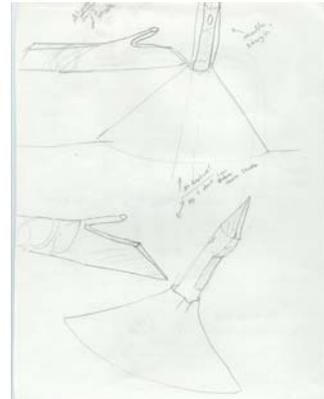


Figure 3.1: Initial Bobbin Design

Returning Needle.

Another initial solution that avoids the complicated bobbin mechanism was to somehow devise a flexible needle that returns to the cannula where the surgeon initiated the suture. At first, this option appeared appealing, as it did not require a third incision. However, after careful analysis, a returning needle system is all but impossible given the tight quarters and suture size.

Power Options

Hand-Powered Mechanical Device.

A hand-powered device was investigated to avoid the complexities associated with electrical and hydraulic devices. This system was initially thought to model the SharpShooter trigger system, where the trigger would activate a mechanical system of gears and pulleys to produce the proper needle and receptor motion. One particularly difficult part of this design involved the manufacturing of extremely small gears and other mechanical systems.

However, the most significant problem with this design was the compressive force required to activate the trigger. Any motions, however slight, affect the accuracy and precision of the suturing device, and a surgeon compressing a mechanical trigger would cause the system to become unstable and less accurate. The steadiness of the device is crucial for the success of the suture.

Electric Powered Device.

After it was determined an electrical, hydraulic, or pneumatic device was necessary, an electric motor was first analyzed. The electric motor system had many complications and was soon abandoned. For instance, the electric motor required had significant weight, and the final device must weigh less than 2 pounds. Another major problem was the manufacture and design of many miniscule complex mechanical systems to operate all the moving parts. Subsequently, the electric motor concept was dropped for a more effective hydraulic or pneumatic system.

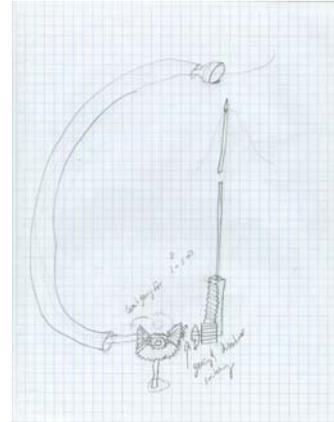


Figure 3.3: Gearing Sketch

Hydraulic Device.

Once it was determined that a hydraulic or pneumatic system was necessary to power the device, it was initially thought that a hydraulic system would yield the best results. However, hydraulics also had drawbacks. While most hydraulic fluids are incompressible, eliminating extensive calculations for air, which is a compressible fluid, the typical hydraulic fluids were too dangerous to use in the device for fear that a malfunction in the system would send hydraulic fluid spilling out of the device into the body. Sterile saline provided a suitable hydraulic fluid and solution to contamination fears. However, commercial vendors for hydraulic cylinders indicated that for the intricate parts required, a pneumatic system is more accurate and applicable. Therefore, the use of hydraulics for the suturing machine was subsequently abandoned.

Design Scope Consideration

Designing for Curved Cannulas.

An option to generalize the design to accommodate a larger variety of tears and knees included designing the receptor behind the knee to adjust for various shaped cannulas. In this design, the receptor arm is attached to the device with a pivot point, which allows it to rotate in different directions to compensate for the varying shape of the cannulas. With this system, curved cannulas could be fitted to the suturing device to easily reach more complex regions of the meniscus. This design option also generated other design considerations including: needle motion, needle rod shapes, and precision concerns. Integrating these concepts brings the project scope beyond what is reasonable in the allotted project time. Therefore, the initial design and prototype will address only straight cannulas. However, further advancements in the device to accommodate various cannula shapes and sizes are addressed in the *Future Considerations* section. Drawings are provided in *Appendix G*.

SUTURING DEVICE DESIGN CONCEPT

Overview

Design Description.

The meniscus suturing machine design will meet all specified design criteria for the project. Initial analysis and discussions with orthopedic surgeons and technicians indicate the innovative design concept should safely and effectively suture the meniscus.



A pneumatic system controlled through a pneumatic logic provides the suturing sequence for the device. A receptor arm attaches to the main housing unit. This receptor arm contours the geometry of the human knee. The end of the receptor arm holds the loopers that grab the thread from the needle. The main housing shall hold the pneumatic system, thread management system and some pneumatic controls. The ergonomically designed handle and housing shall attach to a standard cannula through which the needle will oscillate.

Figure 4.1: Design Rendering

Main Design Components

Main Housing.

The main housing provides a base structure for securing and positioning the components of the suturing machine. The components within the main housing dictate the size and shape of the outer casing. The overall shape of the main casing looks similar to a flask. Attached to the base of the casing is an ergonomically shaped handle with finger buttons providing control of the suturing functions. The receptor arm attaches to the main housing with a ski-binding type clip to easily secure the receptor to the housing before sewing begins. The needle, thread management, and cannula systems all attach to the main housing when the procedure begins.

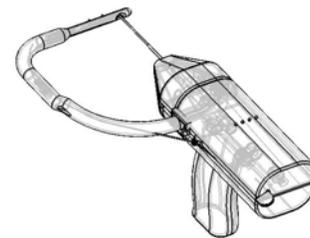


Figure 4.2: Wire-Frame Design Drawing

The main housing holds the pneumatic cylinders, signal lights and switches. The pneumatic controls are separate from the main housing, attached through hoses to the main housing. Keeping the controls out of the housing allows for a significant reduction in weight in the handheld portion of the device. Utilizing a

flask shape for the main housing, the overall size of the casing is minimized while still accommodating the shape of the two pneumatic cylinders

The main housing material is still under evaluation. The material will be a function of cost and effectiveness. Based on the final design specifications, a company manufacturing the device will choose a material to meet the product specifications and reduce cost as much as possible. The weight of the material used for the main housing is another important material consideration, as the weight of the device should be minimized for the comfort of surgeons. As long as the material meets the necessary design specifications, various materials can be used for the housing based on economics, availability, manufacturability, and comfort.

Pneumatics.

The Meniscus Suturing Device is pneumatically powered. After developing the pneumatic sequence, the actual device was purchased from Sprague Air Controls, Inc. Based on the developed sequence, any pneumatic vendor could produce an economically competitive hardware system. The specifications of the pneumatic system are a result of testing on human cadaver knees. The desired sequence was determined based on the cycle required to achieve the desired chain stitch.



The needles that power the needle and looper are the main features of the pneumatic system. The cylinders are controlled by a series of valves and switches that help them achieve the designed cycle sequence.

Figure 4.3 Pneumatic Cylinders

The minimum force that the needle must exert in order to penetrate the meniscus is 4g. Cadaver testing with manual meniscus suturing needles yielded this as the average magnitude of force necessary to completely penetrate the meniscus. Since the cadavers were preserved with chemicals, and were of slightly older persons, the menisci mechanical properties vary slightly from an average living adult. According to discussions with chemical preservation personnel, the toughness and force necessary to penetrate a chemically preserved meniscus exceeds that of a living person. Therefore, using the experimental data is a conservative design estimate. It was determined then that the force readings obtained will provide the limit for the minimum desired force necessary to penetrate the meniscus.

The thread tension also dictates the operation of the pneumatic cylinders. This tension is estimated at 1.5 kgf (14.71 N). Thus the necessary force for the needle to successfully penetrate the meniscus is the sum of the forces needed to penetrate the meniscus and that of the tension in the thread. The sum of these forces is 14.7492 N. Detailed calculations for the forces can be found in *Appendix D*.

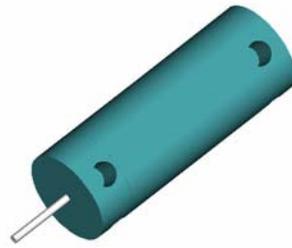


Figure 4.3: Pneumatic Cylinder

This force translates into a pressure of 46,948 Pa (2.168 psi). Detailed calculations are located in *Appendix D*. Most commercially available pneumatic cylinders are capable of operating at much greater pressures than this. Therefore, the force for operation of the needle cylinder is not a concern.

The needle cylinder operation occurs in the following sequence (sequence included in *Controls* section):

- 1.) Full extension stroke (44.5 mm)
- 2.) Retraction stroke of 5.5 to 6.5 mm to allow looper to catch suture loop
- 3.) Complete the retraction motion of the needle to its original position

A “3 position cylinder” will provide the appropriate cylinder motion.

A pneumatic cylinder also powers the looper. As this cylinder’s exact dimensions are not specified, it is assumed that it will be no larger than the other cylinder as it has a similar stroke with simpler operation specifications. The looper cylinder is also double acting and will function with a single complete stroke during both extension and retraction. The looper cylinder is attached to a flexi-cable that extends through the casing and receptor arm to the looper. Force transfers from the piston inside the housing to the looper device with a stiff steel wire, similar to those used in lawnmower throttles. The tube housing the stiff steel wire is composed of metal reinforced plastic. The end of the wire within the housing will attach to the piston through over a hole drilled perpendicular to its axis through the piston shaft. A crimped soft metal coupling the end of the wire and loopers will attach the loopers to the stiff steel wire.

Since operating pressures in existing hospital outlets typically fluctuate, and because the doctors do not want to use the existing cumbersome connection hoses, a pressure regulator and connection hose are included.

Thread Management System.

The thread management system controls feeding and tension in the thread during the suturing process. The thread is stored on a bobbin similar to those used in tradition sewing machines. The bobbin rotates on a bobbin post and is held in contact with a torsion disk by a compression spring. The torsion disk is attached to a torsion spring that rotates around the bobbin post. The compression spring applies pressure between the bobbin and torsion disk creating a friction clutch. These components presented in Figure 4.4 are simple in design to eliminate a potentially complex system. Keeping the thread management simple provides ease for operation and troubleshooting, while a more developed system adds for more potential problems with many components.

The friction clutch applies constant tension on the bobbin while it unwinds, but allows the bobbin to slip, as thread is required to feed out during the suturing process. The thread feeds out during the forward stroke of the needle and while the cannula is positioned for the next stitch. Adjustment of the clutch system delivers the desired consistent tension during these thread-feeding steps in the suturing process. If the surgeon needs to apply or release tension during the suturing, a manual thumb dial provides access for manual tension adjustments.



Figure 4.4: Thread Management System

The stitching process requires tension in the thread to be eliminated during the thread-looping step. To eliminate the thread tension a mechanical brake holds the thread. This brake is a simple cam and wedge. The cam is engaged by a wedge on the needle rod during its maximum forward stroke. The cam and wedge operate with from direct contact, as the wedge is driven forward it engages the cam to rotate on an offset axis. The cam pinches the thread on a solid backstop, holding the thread and preventing tension from being applied to the active stitch. The brake is released as the needle rod retracts the wedge disengages the cam and tension is returned throughout the stitch.

The thread management system created with simple concepts of a friction clutch, torsion spring and wedge/ cam brake reduces the chance for failure and allows for ease in initial test adjustments. These simple mechanical devices operate with few parts, reducing the potential for failure and providing direct output when adjusted. The prototype testing of the suturing device will bring refinements and provide data for finalizing the thread management system.

Needle.

The needles required for the suturing device need to withstand the compressive load during the forward stroke of the needle. The needle tip with the thread hole is subjected to the largest stress concentrations. The small diameter of the needle (.032 inches) and thread hole prevents application of

theoretical stress calculations and require experimental testing. The testing will be performed by applying a compressive force using the Instron Test Machine to a needle fixed at one end and free at the other end. Data will be collected to determine if the needles can withstand the desired load of 14.7 N before buckling, deformation of the tip and failure of the needle walls around the thread hole.

The needles for testing require slash points with a maximum diameter of .032 inches and various size thread holes. From the testing the appropriate thread, hole size will be determined, so the needle does not fail due to stress concentrations around the thread hole. At this time needles were machined to meet the U.S.P. (United States Pharmacopeia) limitations for 2-0 gauge diameter which requires a .0126 inch thread hole. Using the U.S.P. measurement classifications was an error and the needles machined do not meet the requirements needed for the needle testing. Correct needles for machining need to meet the Brown and Sharpe classification for 20 gauge which is the .032 inches. This error prevents the prototype from using the correct needles during initial testing because the machining time of 5-6 weeks required for more needles to be machined is beyond the time limit of the project.

Controls.

The cycle sequence was created to achieve the desired chain stitch. Safety features also were incorporated into the pneumatics design to ensure the safe operation of the Meniscus Suturing Device. To this end, a whisker valve was incorporated into the pneumatic circuit design. This way, if the machine fails to complete the partial retraction step of the needle cylinder, it will go back to the beginning of the cycle and start all over, avoiding this way the unwanted event of the stitches coming apart due to an incomplete cycle. The complete cycle sequence is as follows, where **A** is the needle cylinder and **B** is the looper cylinder:

1. Extension of **A** (at the push of a button)
2. Extension of **B**
3. Partial retraction of **A** (to intermediate position to create the loop in the thread)
4. Retraction of **B** (looper catches the loop of thread)
5. Complete retraction of **A** (to Reset position)
6. Reset

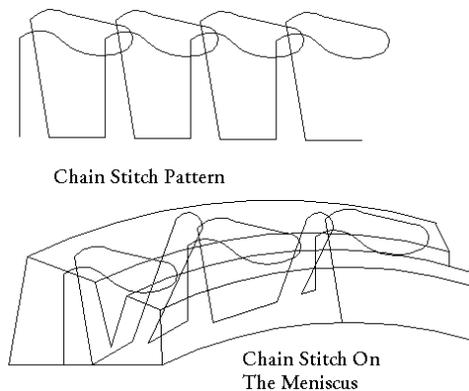


Figure 4.6: Chain Stitches

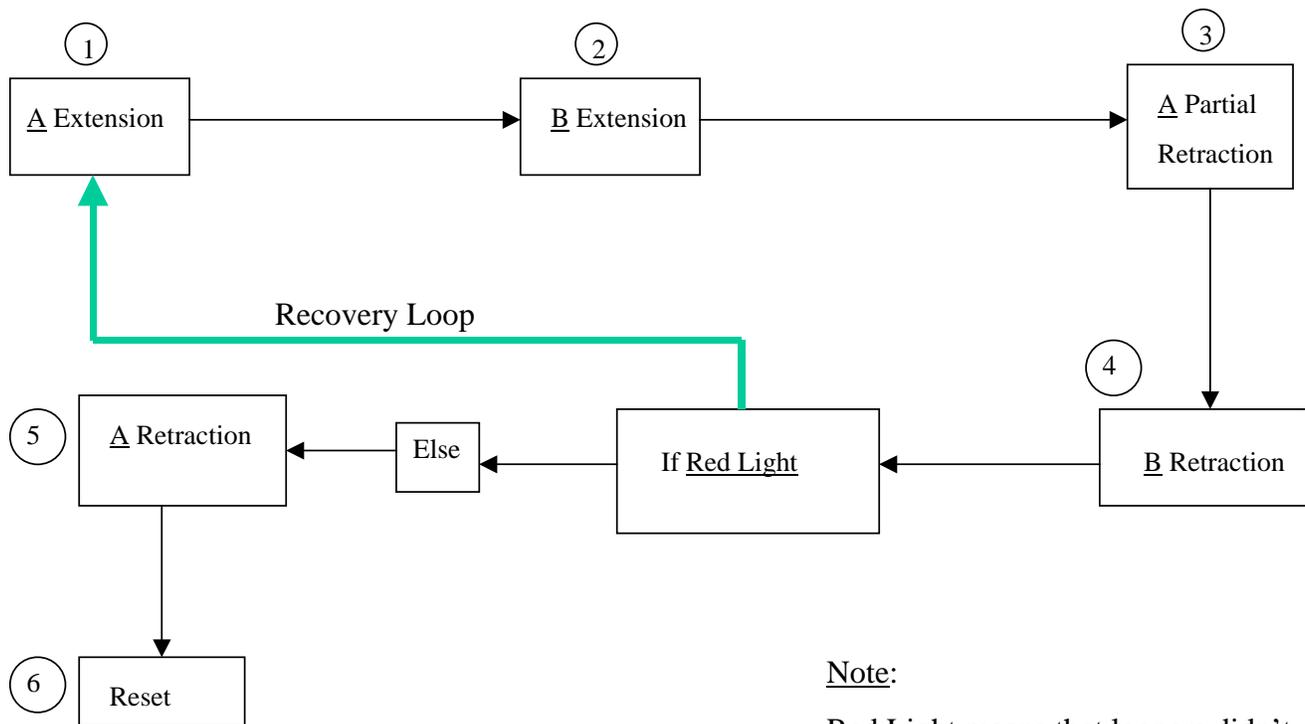


Figure 4.7 Pneumatic Cycle Sequence

There is no need for any special functions for the initial or final suture. In the final suture, the user simply depresses the “off” finger button, takes apart the device, and ties off the final stitch.

Receptor Arm Structure.

The receptor arm is the round curved structure containing the needle receptor at its end. The structure wraps around the knee so the needle receptor always remains directly opposite the needle. The arm must not bend to preserve the precise alignment necessary for the needle and receptor. The receptor arm is securely attached to the main housing with a ski-binding type clip to ensure the precise location of the needle receptor. The receptor arm structure was designed to accommodate the vast majority of knee shapes and sizes. Sample knees were measured to determine the necessary parameters for the receptor arm.

Receptor Arm Size.

The receptor arm is designed in a semi-circular shape to accommodate the largest number of knee geometries. Knees, like any other joint, are sometimes deformed because of injuries, arthritis, illness or accident. An elongated shape was originally chosen, but it was later disposed of for the more accommodating semi-circular shape.

Receptor Cross-Section.

The cross-section of the receptor arm is a round circular thin-walled tube. The outside diameter of the receptor arm is 12.7 mm. The inner diameter of the receptor arm is 11.7 mm. The receptor arm will be made of either surgical stainless steel or titanium, as these are the materials currently used inside the body during surgical procedures.

Receptor Arm Radius.

The external radius of the receptor arm is 141.3 mm. This dimension range was selected based on measurements taken from various knees, and accommodates larger than average knees. Another reason for enlarging the receptor arm radius is to account for the increased knee diameter during the procedure as a result of the swelling from the sterile saline solution.

Receptor.

The receptors purpose is to catch the suture off the tip of the needle and create a loop. The common name for a hook that catches the thread off a needle is a looper. To create a wide enough loop for the two loopers are used. The needle is located parallel to the plane of the loopers to eliminate the chance of the



looper grabbing the needle and jamming the machine or breaking the needle.

Figure 4.8 Receptor

The receptor was designed to fit into a .4-inch cylinder. This small size necessitated a very simple design. To eliminate the need for extra parts we use the receptor housing to guide the loopers. Small feet coming off the loopers sit into tracks in the receptor housing. To keep the loopers parallel to each other at all times each looper has two tracks. The back foot of each looper goes through a hole in a flat slide that links the two together. The loopers will be made of bent music wire and they will produce loop 75 thousandths thick.

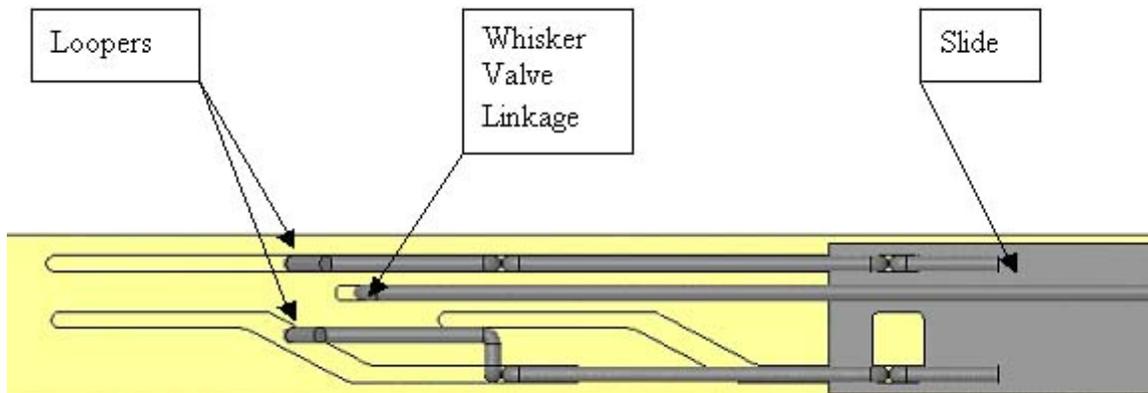


Figure 4.9a: Inside view of Receptor

If only one looper grabs the thread the loop will be off center and when the needle comes back into the receptor it won't go through the loop. Also, if neither looper grabs the thread and the needle is retracted out of the receptor the stitch will be lost and the doctor will have to start over. For these two reasons a feed back loop needs to be included in our design. A stiff wire will be situated in between the hooks on the loopers a bit before their retracted limits. This wire is linked to a whisker valve so that when the loop is pulled back the valve will be tripped.

The transfer of force between the cylinder in the housing and the loopers in the receptor will be achieved by a pull-pull. The pull-pull system will consist of a metal cable that will be pulled by the cylinder and then returned by a spring. The cable will be attached to the slide and the spring will act on the slide as well. The advantages of a pull-pull system over a push-pull system are increased flexibility, substantial weight decrease, and increased efficiency. The pull-pull system will also allow us to design our own system instead of being limited by the push-pull systems that are currently available.



Figure 4.9b: Pull-pull receptor system

Receptor Attachment to Main Housing.

The receptor arm easily attaches and detaches from the main housing with a ski-binding type clip. The clip design withstands fatigue stresses and is manufactured of plastic material. Some metals were investigated. However, a plastic part lasts a long time and is easily replaceable. The ease of attaching and detaching the receptor arm to the main housing is very important as the receptor is attached after the main housing is already secured to the cannula and needle.

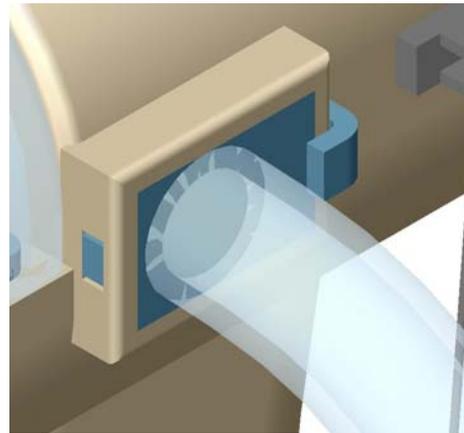


Figure 4.10: Receptor Arm Attachment

FUTURE DESIGN CONSIDERATIONS

ADDITIONAL DESIGN CONCEPTS BEYOND PROJECT SCOPE

Cannulas and Arms

Accommodating Curved Cannulas.

The next step in the design process after the prototype is built and fine-tuned is developing various receptor arms and needle rods for different cannula shapes. The different configurations allow the various cannulas to reach different portions of the meniscus. Changing the geometry of the cannula to match the geometries of current zone specific cannulas and then changing the receptor arm geometry to match the cannulas will achieve further specialization of the device. In this manner, a single machine with interchangeable arms, cannulas, and needle rods will reach any desired position on the meniscus.

Materials

Interchanging Materials.

Future designs will enhance the materials used in the design to further minimize weight and cost. The future designs will enhance strength and comfort. Most of the current design utilizes stainless steel and titanium, as they are the most common materials used in medical applications. Many materials opportunities exist with a project of this nature, from applying polymers, composites, and ceramics to advanced control, valve, and sensor materials. Future designs will enhance the material properties of the design.

Other Medical Applications

Widening the use of the suturing device.

Once the device works on the medial meniscus, its applications will be expanded beyond the medial meniscus. First, having a second attachment on the other side for the receptor will accommodate the lateral meniscus. After the device is modified to suture all the menisci in the knee, its applications will be expanded beyond the knee.

Research and consultations with doctors, physicians, and administrators will help determine other suturing applications within the human body where the suturing device could prove useful. There are many possible applications for a refined suturing machine.

CONCLUSIONS

Initial breadboard prototype testing successfully demonstrates the feasibility of the suturing process. Given the time restraints for the project, a breadboard prototype was used to test the suturing system. The breadboard prototype incorporates the actual pneumatic systems, dimensions, thread management system and loopers without the main housing. The testing results indicate that the designed suturing system is now ready to be integrated into a prototype main housing. While the actual housing and handle were not made, the design concept was proven feasible, and one of the various interested third-party medical device manufacturing corporations shall incorporate the designed suturing system into a main housing and bring the meniscus suturing device to the market.

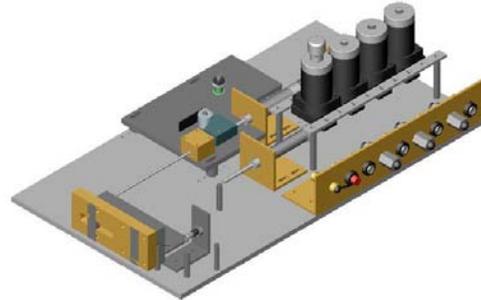


Figure 5.1: Breadboard Prototype

In conclusion, the Meniscus Suturing Device is, at this stage in testing, a successful design. Proving the feasibility of the design sparked the interest of many major medical device companies nationwide, and these companies as well as orthopedic surgeons accept the designed process. While it is unfortunate that time constraints restricted the project scope to only demonstrating the project feasible, the process is the most critical part of the meniscus-suturing device. The ergonomics and shape of the housing may evolve over time to accommodate the desires of various orthopedic surgeons, but the guts of the process will remain the same, as the developed suturing process is truly the heart and soul of the Meniscus Suturing Device. Having proved the theoretical suturing process successful on the breadboard, the project goals are satisfied, and the meniscus suturing device is now prepared for the next stage of prototype construction that shall include the actual housing and handle.

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APPENDIX A

APPENDIX B

APPENDIX C

APPENDIX D

APPENDIX E

APPENDIX F