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Pseudo-Fluid Control Extension System

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Abstract

An interventional cardiologist (IC) performs procedures using a transesophageal echocardiogram transducer (TEE). The TEE is positioned by an echo cardiologist who is present for the entirety of the procedures. The purpose of this project was to redesign the user interface of the TEE in order to minimize the role of the echo cardiologist and give more control to the IC. This was accomplished by creating an extension of the TEE control system that can remotely control the TEE from a distance of five feet. Preliminary designs were created using cable and fluid hydraulic systems; however, both types of systems were problematic. A pseudo-fluid system consisting of tubes filled with steel balls was developed to capture the positive aspects of the cable and fluid systems. The user interface of the new system consisted of two rotatable knobs that actuate rack and pinion gear sets, which push the pseudo-fluid balls through tubes. At the distal ends of the tubes, the balls move the racks of rack and pinion gear sets that in turn rotate shafts in the current TEE. The resulting user interface has similar ergonomic and mechanical properties as the original TEE.

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Chapter 1 Introduction

According to the National Vital Statistics Reports, heart disease is the leading cause of death in America [1]. In fact, an American dies nearly every minute due to a heart-related incident [1]. The most common procedure for diagnosing heart disease is echocardiography. While traditional echocardiograms have been standard in the medical industry for quite some time, transesophageal echocardiogram transducer (TEE), a system of creating three-dimensional, real-time video images of the heart, is becoming increasingly popular and has the potential to revolutionize the field of cardiac diagnostics.

TEE is a three-dimensional form of a basic two-dimensional echocardiogram. According to Abdulla, a noted cardiologist, a typical two-dimensional echocardiogram procedure involves placing an imaging probe on the front surface of the chest cavity over the heart and directing ultrasound beams through the patient's chest and toward the heart [2]. Two-dimensional images of the heart are produced from the ultrasound beams and displayed on a nearby screen in the procedure room. During a TEE procedure, a TEE imaging probe is inserted down the patient's esophagus and positioned behind the heart. With closer positioning of the TEE probe, the ultrasound beams do not need to travel through the chest cavity to get images of the heart [2]. The most important aspect of TEE is that it provides real-time, three-dimensional images of the heart. TEE is used for the same purposes as a standard echocardiogram, but it provides clearer, three-dimensional pictures of the heart.

The procedure for TEE is fairly straightforward. After the patient is given sedatives to relax his or her muscles, an anesthetic is typically sprayed down the patient's throat in order to numb it. Other measures may be taken that are necessary to keep the patient from gagging or biting the probe. Then, the probe of the TEE is pushed down the esophagus of the patient and the tip of the TEE probe is positioned directly behind the heart by the echo cardiologist. Once positioned, images of the heart are seen on a video monitor. Next, the interventional cardiologist, the leading doctor of the procedure, checks the images to make sure the screen is displaying what he or she needs to see for the procedure. If adjustments need to be made, the interventional cardiologist tells the echo cardiologist how the probe needs to be adjusted, and the echo cardiologist adjusts the position of the probe TEE using two rotational knobs, which control the two degrees of freedom of the probe. After the probe is positioned correctly, the interventional cardiologist performs the desired procedure. When the TEE images are no longer needed, the echo cardiologist slowly removes the probe from the patient's body.

While this new technology is advantageous for a number of reasons, there are concerns with the current procedure. The problem that was focused on is that the echo cardiologist is required to be in the operating room for the duration of the procedure. Thus, the purpose of this project was to redesign the user interface of the TEE to minimize the role of the echo cardiologist and give more control to the interventional cardiologist or another physician in the medical room.

Chapter 2 Background

This section provides information that is relevant to TEE and mechanisms that the TEE uses and is common in the medical device industry. Information about TEE in general, the role of an echo cardiologist, and an overview of the procedure will be presented. Patents associated with the TEE are also explained. These patents include the patent for the TEE system, the patent for the control mechanism of the TEE, and the guidance system for the TEE. FDA regulations are also discussed, considering their strong influence on the design of medical devices. Mechanisms such as rack and pinion gears, cam locking systems, and foot pedals used in medical applications are examined. Lastly, backlash in theory and actual backlash in the TEE probe are discussed.

2.1 What does an echo cardiologist do?

According to Fogoros, a cardiologist is a physician who is trained to treat problems of the cardiovascular system [3]. An echo cardiologist typically is trained to use ultrasound. Echocardiography is a test that uses sound waves to create pictures of the heart and is used to detect heart problems. It tells a doctor the size and shape of a heart and how well the heart's chambers and valves are working. Echocardiography identifies areas of heart muscle that are not contracting normally because of poor blood flow or injury from a heart attack. An echocardiogram can also detect blood clots, fluid buildup in the pericardium, and problems with the aorta. This test is very useful for studying the heart's anatomy, which is shown in Figure 1. An echocardiogram is a non-invasive, safe procedure. When well-trained cardiologists interpret echocardiograms, the results are very accurate [3].

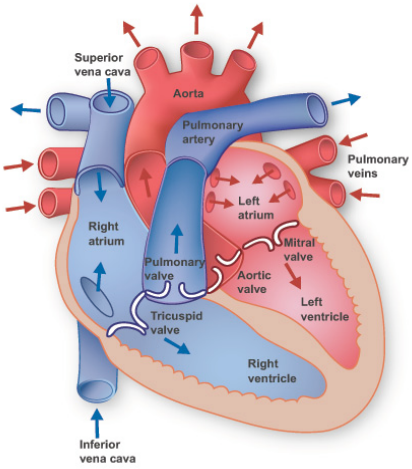


Figure 1 - Anatomy of the Heart. TEE can produce three-dimensional images similar to this on a video monitor in real time [4].

2.2 What is TEE?

TEE stands for transesophageal echocardiogram. According to Abdula, TEE is very useful in detecting blood clots, masses and tumors that could be inside the heart [2]. TEE can also be used to monitor the severity of certain valve problems, detect infections of heart valves and locate certain congenital heart diseases. One example of a problem that TEE can detect is a hole between the upper chambers of the heart known as an atrial septal defect. Tears of the aorta are also detected with TEE. Yet another issue TEE evaluates is patients that have had mini or major strokes as a result of blood clots. TEE has the ability to detect the clot that caused the problem inside the left atrium [2].

Physicians choose to use TEE or a standard echocardiogram based on the situation. A standard echocardiogram is obtained by applying an echocardiogram transducer to the front of a patient's chest and delivers a conical set of ultrasound beams through the chest cavity and toward the heart (Figure 2). Sometimes, obesity and emphysema cause technical difficulties for standard echocardiograms by limiting the transmission of the ultrasound beams to and from the heart. In a situation like this, a physician may choose TEE over standard echocardiogram. TEE is positioned down the esophagus of a patient and positioned behind the heart where the transducer sends a conical form of ultrasound beams directly at the heart (Figure 3). This option provides clearer images of the heart, especially the left atrium, because the echo beam does not have to travel through the front of the chest [2].

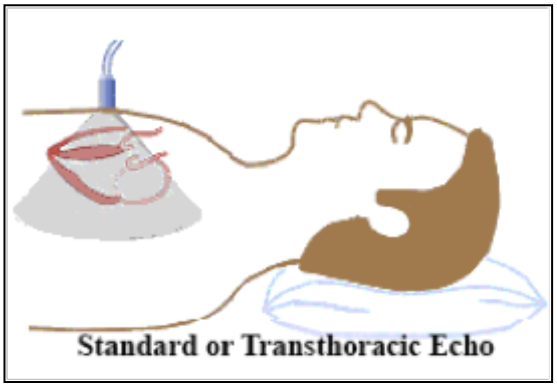


Figure 2 - Transducer positioning of a standard echocardiogram. The transducer is placed over the top of the chest and a set of ultrasound beams is delivered in a conical shape through the chest cavity and towards the heart in order to capture a two-dimensional image of the heart [2].

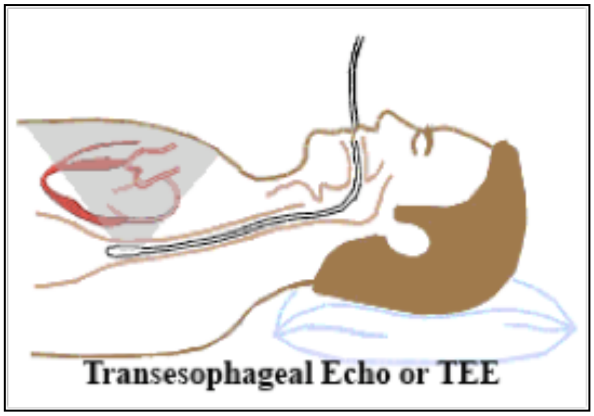


Figure 3 - Transducer positioning for TEE. The transducer is positioned down the esophagus and behind the heart. A conical form of ultrasound beams is sent at the heart, producing a three-dimensional image [2].

2.3 The Procedure

The flow chart in Figure 4 shows the basic parts of the procedure. First, the nurse sprays a numbing medication onto the patient's throat. The patient also has the option to gargle the medication. The numbing medication lasts approximately thirty minutes. Some patients require anesthesia, but this route is unfavorable, so it is ignored in this discussion. After medication is applied, the nurse positions the patient onto the operating bed on his or her left side with his or her left arm behind his or her back. The nurse then inserts a mouthpiece. This mouthpiece keeps the patient's mouth open and prevents the patient from biting the TEE probe when it goes down the esophagus and also from biting the physician's fingers. The patient then puts his or her chin downward and the doctor slowly inserts the shaft of the TEE probe while the patient takes slow deep breaths, which opens the patient's pathway of the esophagus. If the patient gags, more numbing medication is used. As the doctor inserts the shaft of the TEE probe, the patient swallows to help reduce gag reflexes. The doctor inserts the tube approximately fourteen to eighteen inches down the esophagus. Images of the heart are then projected on a video monitor. The interventional cardiologist then carries out the necessary procedure. These procedures vary based on the patient's needs. As the interventional cardiologist carries out the procedure, he or she might ask the echo cardiologist to adjust the position of the TEE. Once the procedure is completed, the echo cardiologist slowly pulls the shaft of the TEE probe out from the patient's mouth. Figure 4 shows the order of the operations in the procedure and who is performing them.

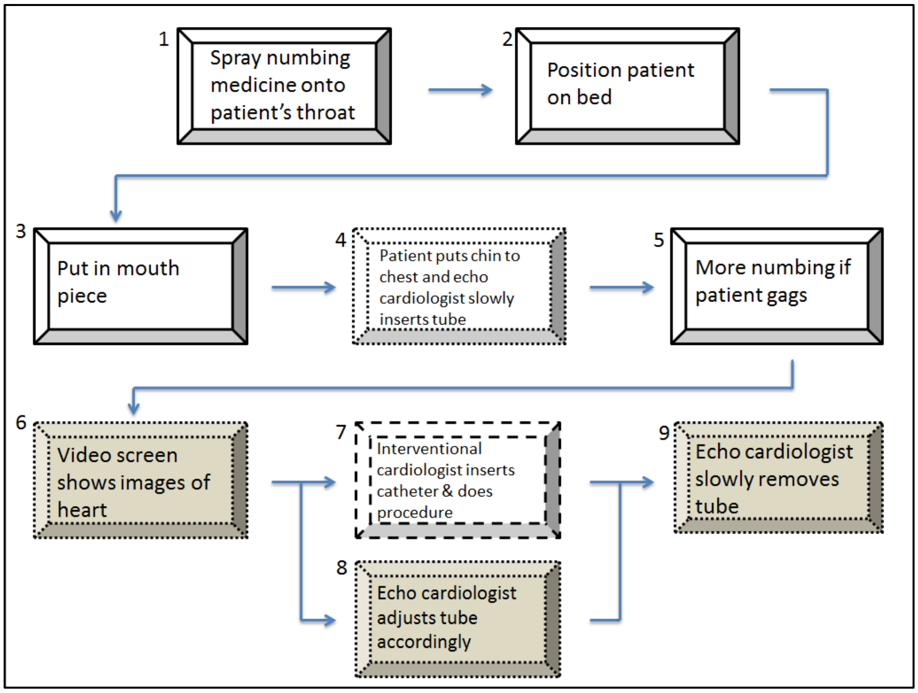


Figure 4 - Flow chart showing general process of procedures that use TEE. Steps 1,2,3, and 5, which are white boxes with a solid black line are steps performed by a nurse. Step 4 which is a white box surrounded by a dotted line, is performed by an echo cardiologist. The interventional cardiologist performs step 7, which is in a white box surrounded by a dashed line. Steps 6, 8, and 9, which are colored gray boxes and surrounded by a dotted line, are performed by an echo cardiologist but can potentially be performed by another physician.

Figure 4 also shows where there is potential to replace the echo cardiologist with another physician. The boxes filled in with grey show where this can be done. It is more desirable in this case to have another physician perform these parts of the procedures because the echo cardiologist may be needed for other procedures or different types of procedures. The echo cardiologist would be in the operating room to set up the TEE and its necessary components and make sure that the tube goes down smoothly without any complications, and then someone else would carry out the rest of the procedure.

2.4 Procedures that Utilize TEE

TEE is used to assess the overall function of the valves and chambers of one's heart. Doctors use TEE in order to determine if a patient has a healthy heart or if the patient needs more medical attention. TEE is also used to determine the presence of many types of heart disease such as valve disease, myocardial disease, pericardial disease, infective endocarditis, cardiac masses, and congenital heart disease which will all be further discussed throughout this section [5].

TEE is used in various procedures. For example, if something defect is detected in a valve and must be repaired, a ring may be sewn around the opening of the valve to tighten it. An incision is made in the heart or aorta in order to do so. If the valve needs to be replaced, parts or all of the damaged valve and its structures may be removed. The correctly sized replacement valve is selected, positioned in the valve opening and sewn firmly into place. Other parts of the valve may be cut, shortened, separated, or made stronger to help the valve open and close right. If the valve cannot be repaired, it may be replaced with a prosthetic valve [6].

Another disease TEE can be used to help treat is myocardial disease. A myocardial disease, or heart attack, is caused by a blockage in one of the coronary arteries that supply blood to the heart muscle. Most blockages are caused clots that form in a coronary artery, which has been narrowed by atherosclerosis. Atherosclerosis affects the walls of the arteries (University of Southern California, 2010). TEE is also used in the diagnosis of pericarditis. Treatment for pericardial disease sometimes includes medication for pain and inflammation. A medication that may be used could be non-steroidal anti-inflammatory drugs, including ibuprofen in large doses. Depending on the cause of the pericarditis, antibiotics or antifungal medication may be taken [5].

TEE is also used in the treatment of infective endocarditis treatment involves intravenous (IV) antibiotic therapy. IV antibiotics can be given for as long as six weeks to control the infection. Symptoms are monitored throughout this process with therapy and blood tests. This also ensures that the treatment is working. This could lead to the possibility of heart valve damage and could require surgery as mentioned earlier [5].

2.5 TEE Imaging System Patent

The Transesophageal Ultrasound Imaging Systems patent, which is US Patent 0028107 by Miller et al., describes an invention that is a semi-invasive imaging system used for imaging biological tissue.   It includes a transesophageal probe that is connected to a two-dimensional ultrasound transducer array, a transmit beamformer, a receive beamformer, and an image generator [7].

This system consists of a probe that has an elongated body with a distal end, shown in Figure 5 as part number 12, which is made up of a two-dimensional ultrasound transducer array, a transmit beamformer, and a receive beamformer that acquires ultrasound data from echoes. The probe on the image system is a transesophageal probe. This semi-invasive ultrasound imaging method involves inserting the probe down the esophagus and positioning the transducer behind the heart that results in the desired picture. The invention can generate at least two orthographic projection views of a selected tissue volume [7].

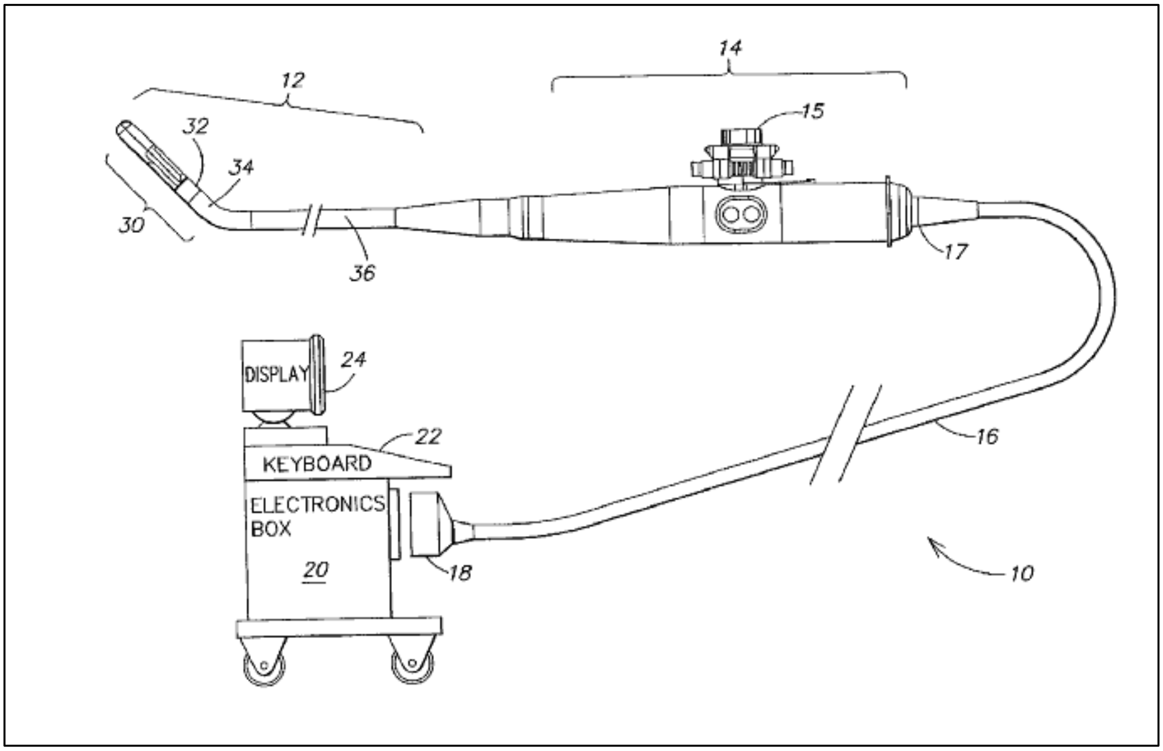


Figure 5 - TEE Imaging System. 12 and 14 show the TEE, which is connected to a computer system that produces the echocardiogram images [7].

2.6 Control Mechanism Patent for TEE

US Patent 7588536 by Michael Peszynski, describes the mechanism that controls the output motion of the probe for the Philips Healthcare TEE probe. This patent describes a mechanism that controls the output the motion of the probe by the input of two rotational knobs on the handle of the TEE, which has a handle and a flexible shaft. The mechanism includes two rotatable knobs, which are independent of each other; inner and outer pinion shafts, which are coaxial and rigidly connected to the first and second knobs, respectively; and an intermediate shaft that is positioned partly inside the outer pinion shaft and partly around the inner pinion shaft. There are also O-rings positioned between the pinions shafts and the intermediate shaft that seal the inside of the TEE and also transfer torque from the pinion shafts to the intermediate shaft. The intermediate shaft is grounded, thus it does not transfer any torque. An imaging sensor is located at the distal end of the shaft. In clinical use, the flexible shaft is maneuvered within the body through a body cavity, typically the mouth [8].

Figure 6 and Figure 7 show the main components of this rack and pinion mechanism (10) include two rotational knobs (18 and 20), an inner rotatable pinion shaft (22), an outer rotatable pinion shaft (28), an intermediate shaft (34), four racks (linear gears, 12 and 14), ball bearings (50, 52, 54, and 56), O-rings (42 and 46), and a frame (16). The first pinion is mounted on the frame and rigidly connected to the first rotatable knob, so as the user rotates the knob, the pinion shaft also rotates causing movement of a pair of linear gears placed 180 degrees apart on either side of the pinion shaft. In a similar way, the second pinion shaft, which is coaxial with the first pinion shaft, is rigidly connected to the second rotatable knob and when turned, causes actuation of two linear gears, one forward and one backward. The intermediate shaft is positioned between the two pinion shafts, at least partially around the inner shaft and inside the outer pinion shaft. The intermediate shaft, which is pinned to the frame and does not rotate, reduces the transmission of torque between the two pinions shafts, so that one's respective rotation does not affect the other's rotation. The intermediate shaft can also move axially. There are also ball bearings between the intermediate shaft and both first and second pinion shafts that allow rotation of the two pinion shafts relative to the intermediate shaft. Lastly, there is at least one O-ring in a groove of the first pinion shaft and also touching the intermediate shaft, which transmits torque between the two. The O-ring also provides a seal between the first pinion shaft and the intermediate shaft. There is also an O-ring in contact with both the intermediate shaft and the second pinion shaft. Its position and purpose are the same as the O-ring between the intermediate shaft and the first pinion shaft [8]. Figure 6 and Figure 7 shows cross-sectional and top view of the mechanism respectively.

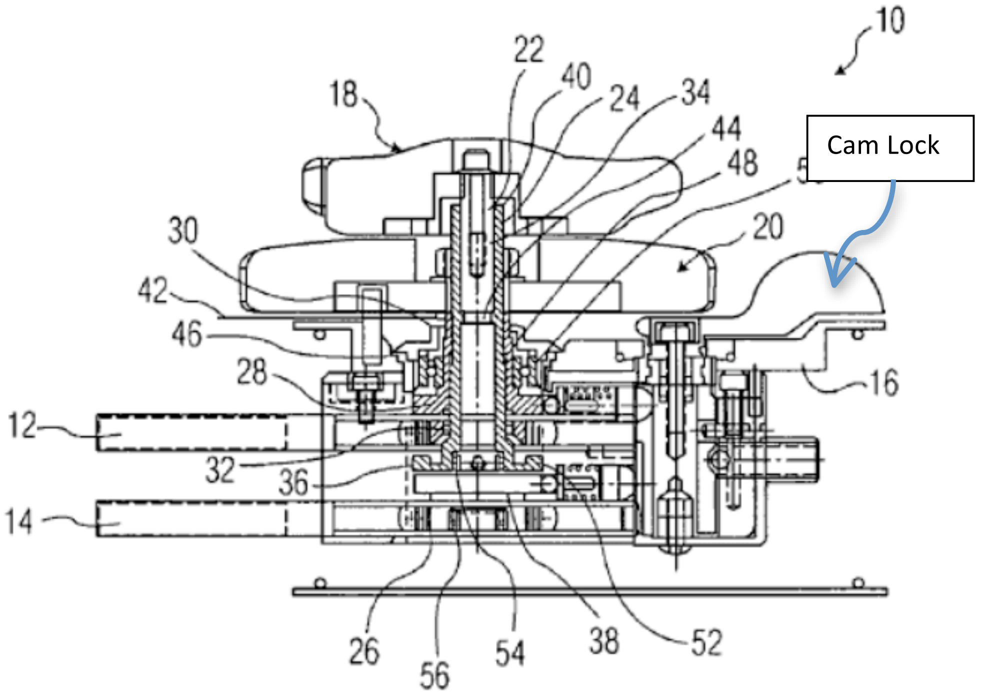


Figure 6 - Cross-sectional View of the knob control mechanism and cam locking system. Refer to section 2.6 for more details [8].

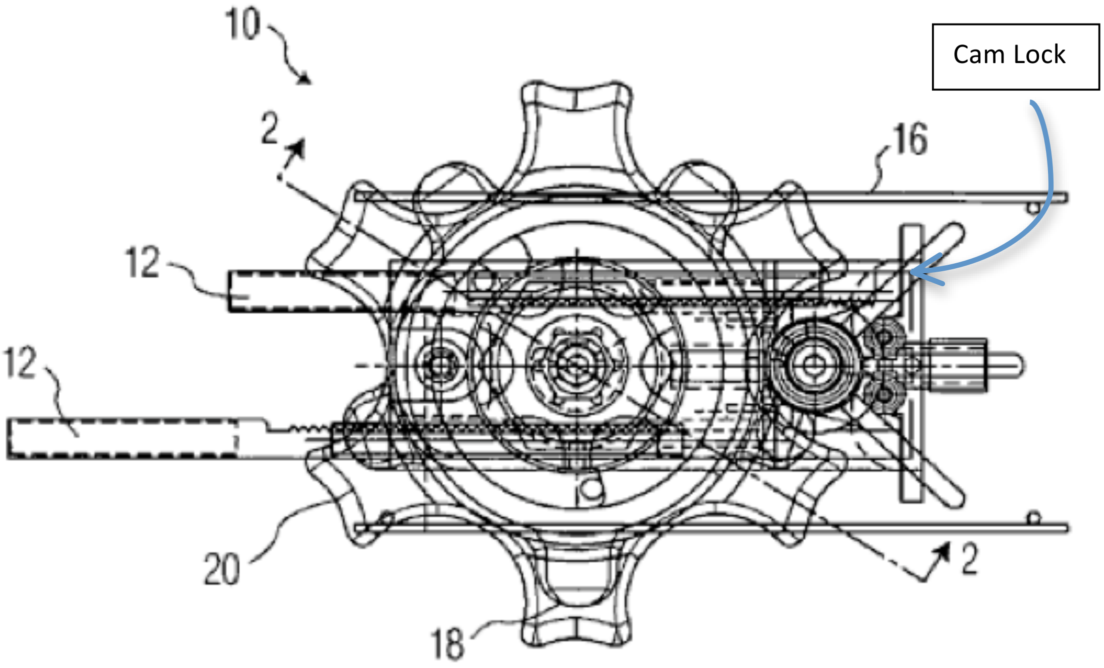


Figure 7 - Top View of the knobs and cam locking system. Refer to section 2.6 for more details [8].

2.7 Guidance System Patent

US Patent 7529393 B2, titled Guidance of Invasive Medical Devices by Wide View Three Dimensional Ultrasonic Imaging, describes an invention of a three dimensional ultrasonic diagnostic imaging system that helps guide the ongoing operation of a medical device. This patent works in conjunction with the TEE patent because the guidance system helps the echo cardiologist and interventional cardiologist navigate the probe of the TEE through the body. The system shows different views as the probe moves down the esophagus and near the heart. This invention ultrasonically displays a medical device and the volumetric region of the body in which it is located [9]. Figure 8 illustrates a block diagram showing how the three-dimensional ultrasonic imaging system guides a medical device.

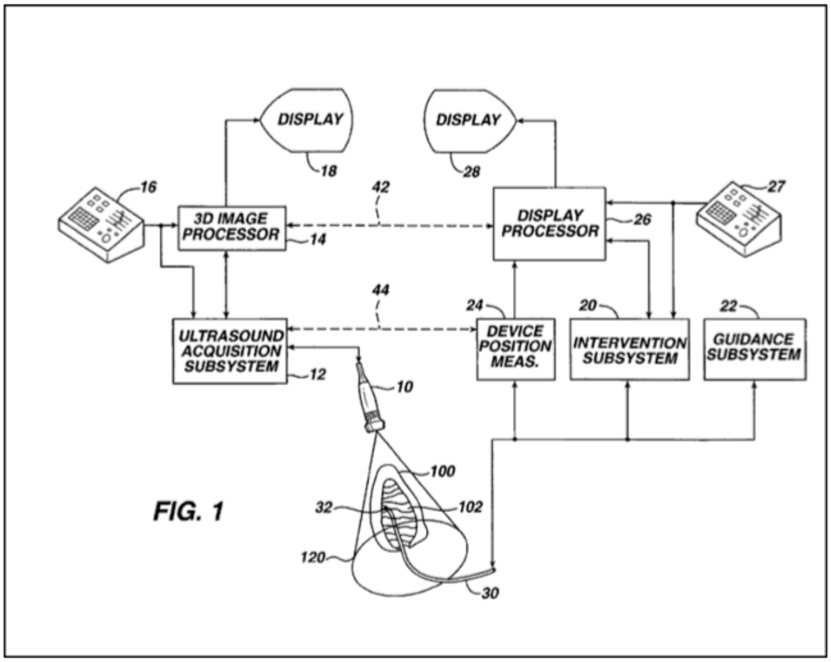


Figure 8 - Block Diagram for Patent 7529393 B2, showing how a three-dimensional imaging system guides a medical device [9].

2.8 Actual TEE Probe

The TEE probe consists of a black probe shaft that is about one meter in length, an ultrasound transducer at the distal end of the probe, a handle with two rotatable knobs that control the movement of the probe, and an electrical connection that connects to a computer, all of which is shown in Figure 9. Additional pictures of the TEE are located in Appendix A.

Figure 9 - Transesophageal echocardiogram probe. The TEE consists of a black probe that is inserted into a patients esophagus, a ultrasound transducer located at the distal end of the probe, a silver handle with two rotatable knobs that control the motion of the probe, and an electrical connection that connects to a computer.

The handle portion of the TEE consists of a hollow metal cylindrical shell of varying diameter that houses a rack and pinion gear set that controls the movement of the TEE probe. There are two rack and pinion gears sets, which control the two degrees of freedom that the probe maintains. The knobs on the TEE are connected to the coaxial pinion shafts of the two different rack and pinion gear sets. The diameter of the top knob is about 2.15 inches while the diameter of the bottom knob is about 2.53 inches. The length of the aluminum handle is about 10.75 inches. There is also a cam lock, shown in Figure 10, which allows the knobs to lock into position.

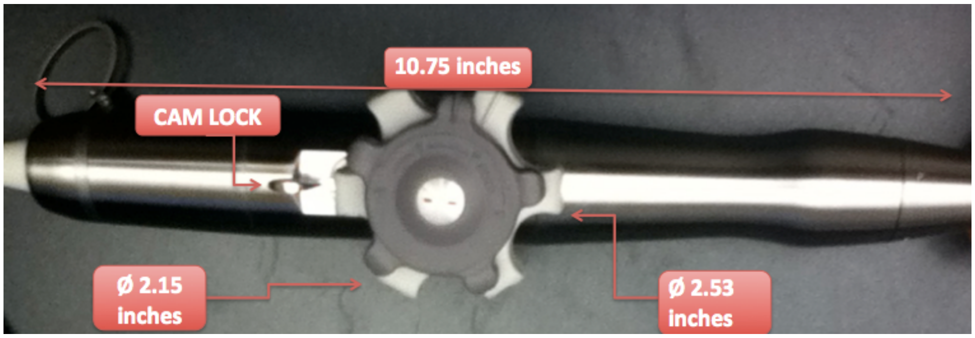


Figure 10 - Handle portion of the TEE showing the that length of the handle is about 10.75 inches while the top and bottom knobs are 2.15 and 2.53 inches in diameter, respectively.

Figure 11 shows the probe shaft of the TEE, which is inserted down a patient's throat. When completely straight, the length of this section is about one meter from the proximal point to the very tip of the distal end.

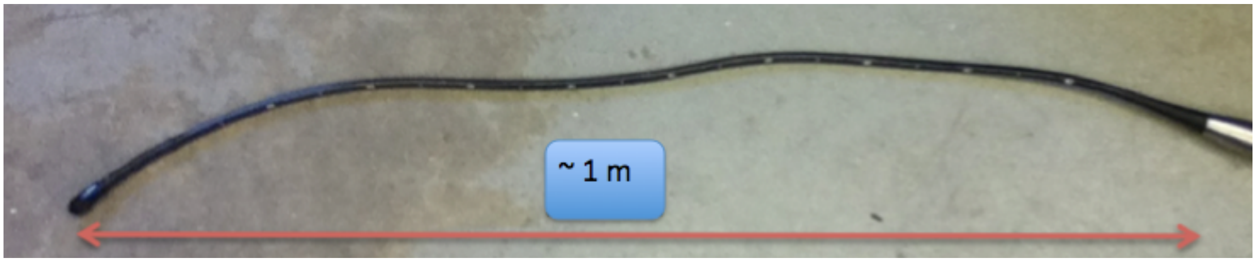


Figure 11 - Probe shaft of the TEE, which is about one meter from the proximal end to the tip at the distal end.

Figure 12 displays all of the different components of the TEE. These components include the knobs, handle, probe shaft, probe tip, cables, electronics, cam lock, and racks of the rack and pinion gear set.

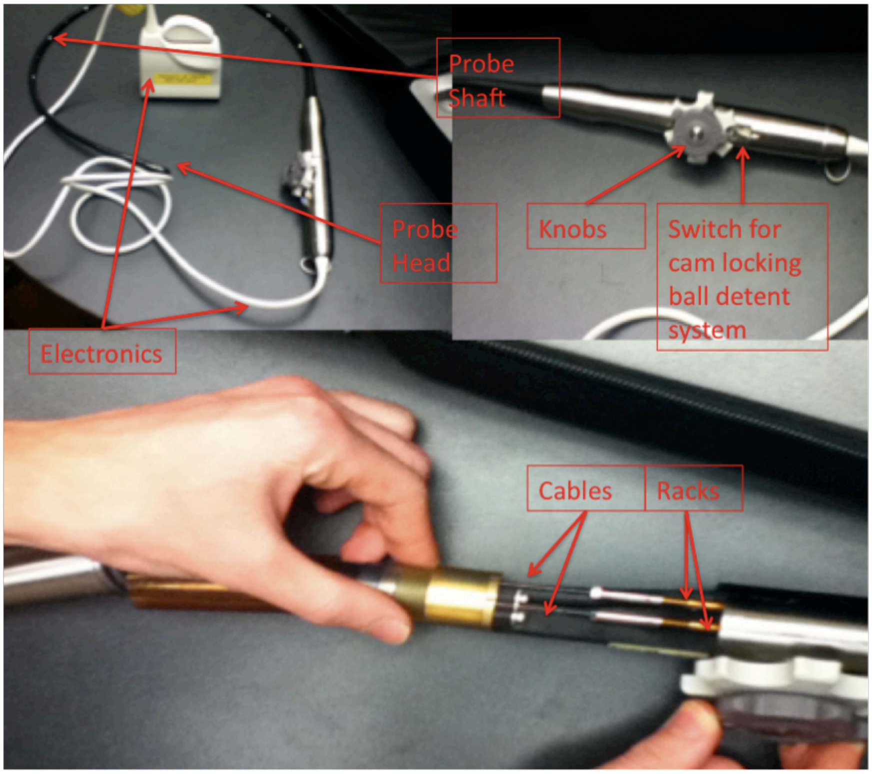


Figure 12 – Different components of the TEE including the probe shaft, probe head, cam lock for ball detent system, racks of the rack and pinion gear set, cables, knobs, and electronics.

2.9 FDA Regulations

The FDA regulates medical devices according to the level of control required to ensure that they are safe and effective. There are three classes, or panels of devices, Class I, Class II and Class III. The higher the classification number of a device, the more heavily regulated it is. It is a multi-step process to determine what class a device is. Firstly, it is necessary to determine whether or not the product is truly a medical device. According to the FDA, "A device is: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes [10].""

Secondly, if the product emits radiation, it is a class III device. Radiation emitting devices are regulated more heavily to ensure that people are not exposed to radiation unnecessarily. A Class III device must undergo a premarket approval before the FDA will allow it to be marketed. Class III devices are sometimes exempt from Premarket Approvals (PMA's). Class II devices are often exempt from PMA's, but in most cases must still undergo a premarket notification, also called a 510(k), to ensure that it is safe for the market. Class I devices are often exempt from both PMA's and 510(k)'s. Class I devices are also often exempt from Good Manufacturing Processes (GMP's). The purpose of exemption is to provide as much freedom as possible to researchers, while still maintaining a safe product [10].

PMA shows the FDA that a device is ready and safe for the market. They include full statements about the components and principals of operation. They include the results of investigations of the devices safety and effectiveness. PMA's are thorough and are used to prove that a new product is safe enough to be sold on the market. They are used primarily for class III devices. 510(k)'s serve to show the FDA that a device is ready and safe for the market, without being as time consuming as the PMA. They do this by citing similar devices that have already been approved through a PMA. Class II devices typically need 510(k), but are sometimes exempt. Class III devices which are exempt from PMA still require 510(k) [10].

Class I devices are devices which are not used to support human life, do not pose serious health hazards and do not have the potential to cause serious injury. Class I devices are regulated by general controls (Sections 501, 502, 510, 516, 518, 519, or 520). Class II devices are those that cannot be safely regulated by general controls, and have sufficient data to facilitate the creation of special controls that will provide the safety and effectiveness of the device. Class III devices are those that cannot be safely regulated by general controls, and for which not enough information is known to safely regulate it under special controls. Class III devices are also those that are used in supporting human life, or those that have the potential to cause serious injury. Devices classes may be changed after more data has been collected to provide that they could be safely regulated by a lower set of controls. Special controls and reclassification are carried out by the Secretary of the Department of Health and Human Services. The Secretary can also prescribe regulations (GMP' (Sec. 520 Part f)) regarding the manufacture of a device, if it is deemed necessary to ensure the safety and effectiveness of the device [11].

The TEE is a Class II device. The TEE requires only a 510(k) provided that it is substantially equivalent to an existing TEE, which has already been granted PMA. Any TEE, which is substantially equivalent to one that has already been approved, can be approved through a 510(k). A device is substantially equivalent to a previously approved device if: the intended use of the device is the same, the intended use of the two is the same, and any differences in the new device do not raise questions of safety. In terms of this project, this means that any changes that do not significantly alter the device will not require a change in class or a premarket approval [10].

2.10 Mechanisms

The following sections describe various mechanisms that are found in the TEE or that are common in the medical device industry.

2.10.1 Cam Locking Systems

This section will describe cam locking systems. First, general cam locking systems will be discussed and then the cam locking system that is used in the TEE will be described.

2.10.1.1 General Cam Locking System

Cam locks are one of the most common and simplest locks available. The lock is comprised of a metal plate, in which the cam is attached to the core of the locking device and rotates as the key is inserted and turned. The cam, which locks and unlocks the system, rotates between 90 and 180 degrees. There are two basic types of cam locks. Figure 13 shows one type called a flat key cam lock. This lock is opened using a flat key. The key is designed similar to that of a house or car key. Figure 14 depicts the second type of lock called a tubular cam lock. The tubular cam lock operates the same way as the flat key cam lock. It is opened with a key that is round and that pushes into the cam lock. As opposed to having a flat opening for the key, the tubular cam lock has a circular opening for the key [12].

Figure 13 – Example of a Flat Key Cam Lock [12].

Figure 14 – Example of a Round Key Cam Lock [12].

2.10.1.2 TEE Cam Locking System

The locking system used in the TEE to prevent movement of the probe head once it is positioned correctly is a cam actuated ball detent lock (Figure 6 and Figure 7, cam lock). The ball detent mechanism uses a spring-loaded plunger that engages into dents or holes in the part to be stopped. The cam is used to engage and disengage the ball detent mechanism. As the lock handle is turned into the locked position the displacement of the cam causes the spring in the ball detent mechanism to become loaded with force. In this device, the dents that the plunger of the ball detent mechanism locks into are located on the shafts of the control knobs. The ball detent mechanism in this device prevents major unwanted movements, but it is not a fixed lock. It will allow movement with enough force, to prevent the probe head from injuring a patient while the TEE is removed in the event that the operator forgets to unlock it. If the control knobs are turned while the lever is in the locked position, the effects of the ball detent mechanism can be felt; the knob seems to click through positions, which is the plunger in the dents.

2.10.2 Rack and Pinion

Figure 15 pictures a rack and pinion gear system, which is used in the current control mechanism for the TEE. Rack and pinions convert angular input motion into linear output motion or vice versa. The mechanism consists of a prismatic joint, pinion, and a handle. This type of gear system does not provide a strong mechanical advantage, but produces little backlash. Rack and pinion gears are commonly used for steering in automobiles [13].

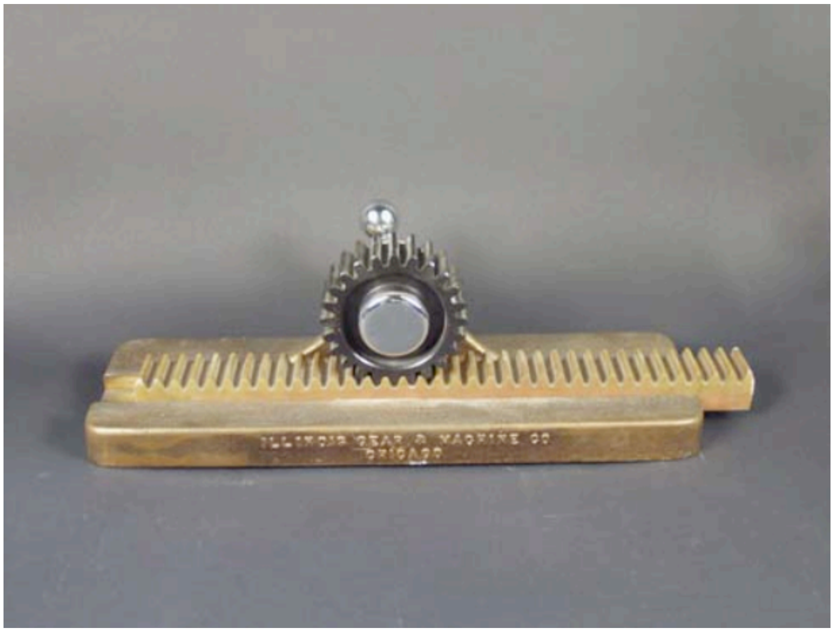


Figure 15 - Rack and Pinion Gear System [14].

2.10.3 Foot Pedals Used in Medical Applications

Foot pedals are often the user interfaces for medical devices. For the most part, foot switches or pedals used in an industrial application are installed once and are usually never moved. Because of this permanent installation, the mechanical wear expected in an industrial environment, foot pedals are designed to withstand a lot of wear and tear. However, foot pedals used in medical applications are often moved during the procedure or moved between procedures. The foot pedals are also moved between rooms. Because the foot pedals are moved frequently, foot switches are required to be light. The goal when making a design for a foot switch is to not be too light or too heavy. Optimal weight assures stability, ease of movement and a tolerable weight for routine relocation, cleaning and/or storage [15].

Foot switches are subject to biohazards, disinfectants, and/or routine cosmetic cleaning. In order for cleaning to be effective and easy, the design must consider many different aspects. These aspects include, shape and contours of the unit, clearance spacing between actuators and between the actuators and their host console, drainage of the surfaces, level of sealing integrity, surface texture of the various elements of the unit, availability of special surface coatings, use of powder-coating and molded-in colors instead of painted surfaces that can crack, peel, or flake, and the use of stainless steel hardware. The foot switch also needs to be ergonomic, easy to use, and reasonably priced [15].

The presence of liquids is very common in medical applications (either during the procedure or for cleaning). Drainage considerations and sealing integrity are important design factors that affect reliability and serviceability [15]. Figure 16 shows different types of foot pedals used in medical applications.

Figure 16 – Examples of foot pedals used in medical applications [15].

2.11 Backlash

The following sections describe backlash of different systems.

2.11.1 Backlash Found in Gears

Backlash is the rotational arc clearance formed between a pair of mounted gears. It can also be described as play or lost motion between loosely fitting machine parts. Backlash is crucial to any gear set for checking the damages caused by the gear tooth interference. Lack of backlash can cause noise, overloading, overheating of gears and bearings, seizing and, failure. Backlash is measured by limiting the rotation of one member, which generally is the pinion, while measuring the other component's rotational movement at a reference radius. Backlash is measured in units of angular degrees and its subdivisions (minutes or seconds). It can also be measured as an arc value to the angle in radians. Because backlash is usually a small angle it is measured in angular minutes. A true precision low backlash servo gear head has a backlash of two to eight angular minutes, measured at the output. The arc movement measurement thus obtained is converted to degrees by the equation shown below.

$$\text{Backlash (degrees)} = \frac{\text{Arc Movement (inches)} \times 57.296}{\text{Radius (inches)}}$$

In order to measure the backlash of a gearbox, a proper testing rig and instruments are required. The fixture holding the gearbox and its output shaft should be as rigid as possible. The usually very small rotational angle of the output shaft can be measured directly by a precision encoder or by indirect methods. The indirect method utilizes mainly a long rigid arm at the shaft allowing measuring the displacement at a defined distance with a dial indicator and calculating the corresponding rotational angle.

The biggest challenge is the precision required for the gears to work. If any of the gear teeth are cut imperfectly such as too large or with the wrong angle, the two gears will wear badly or at worst will actually jam when the over-large section tries to pass by. It is possible to machine gears so they mesh absolutely precisely, but doing so can be expensive. However, if the gear teeth are made slightly smaller or are spaced slightly farther apart than they need to be then the air space around the teeth provide relief so that minor imperfections do not jam the gears. This deliberate under-sizing does not affect accuracy as long as the motor is always being driven in a consistent direction.

Some mounts allow adjusting of the alignment and spacing of the internal gears, which gives some ability to reduce backlash. Usually, this is possible on higher-end mounts where the gearing is built into the mount, but not on lower end mounts where the gearing is an external after-market accessory. Adjusting gears to reduce backlash requires some disassembly of the mount.

2.11.2 Backlash Found in Hydraulics

Backlash is found in hydraulics due to air bubbles found in the tubing. If the fluid used in the tubing is not properly put inside of the tubing, it will create air bubbles. If there are air bubbles in the tubing and force is applied to one of the pistons (assuming a closed hydraulic system with pistons on either end), the force applied will not result in immediate motion on the opposite end of the tube. This is referred to as backlash.

2.11.3 Backlash Found in Cable Systems

Backlash is found in cable systems for various reasons. One reason is that sometimes the cables can become stretched out, which allows for play in the cables. In addition, if the cables are not tightly connected to two fixed points, there will be play in the cables. Also, un-tensioned cables experience backlash or play.

2.11.4 Backlash Found in TEE

The backlash of the TEE was also studied. It seemed to have a lot of backlash stemming from several sources. The cables inside the mechanism can move approximately a millimeter without moving either of the racks from the gear system or the probe head. The probe head can also move approximately 10 degrees in either plane without seeing any movement in the knobs. The knobs can move approximately 5 degrees without seeing any movement in the probe head (if it is restrained). If restrained, the racks in the gear system can rotate the shaft of the TEE the manipulates the top knob of the original TEE approximately 5 degrees and the bottom knob can feel a very slight wiggle, but not enough to be significant. If the ball detent mechanism is engaged, there are several locations throughout the range of motion where the knobs move a full click with no movement of the probe head. Figure 17 shows the different components of the TEE where backlash occurs. Overall, there is a fair amount of backlash that already exists in the system.

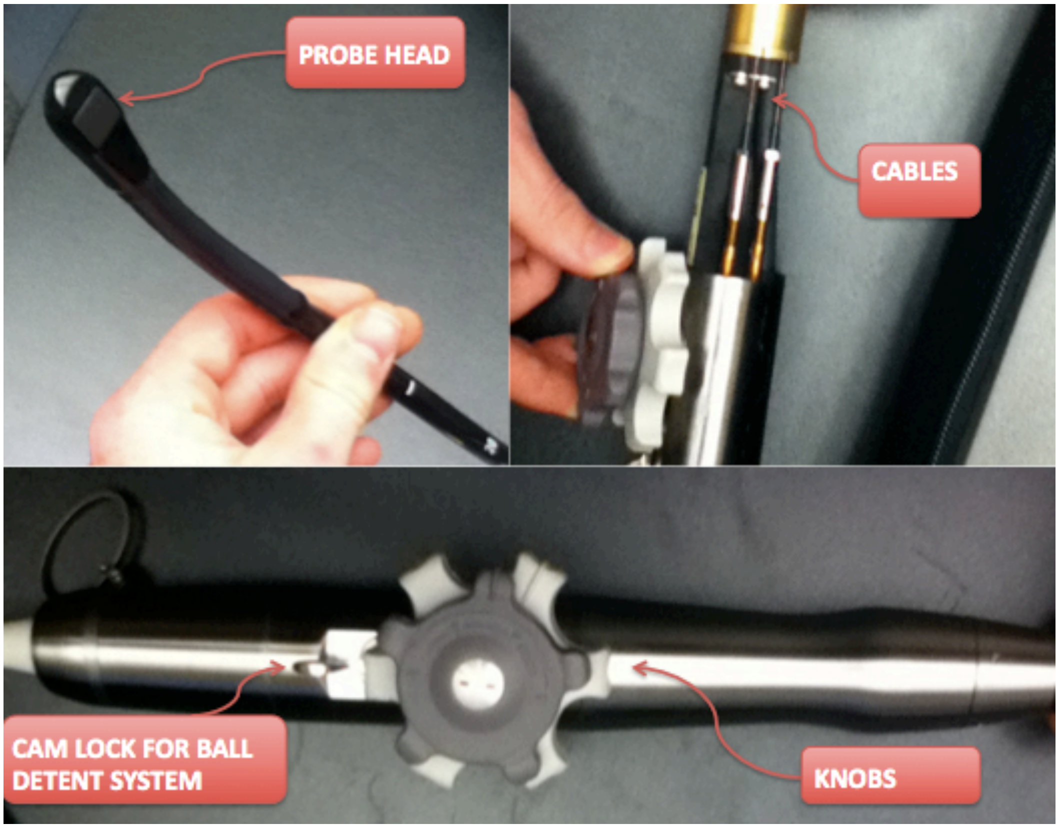


Figure 17 - Different components of the TEE where backlash occurs including the probe head, cables, knobs, and the ball detent system.

Chapter 3 Project Objective

The main problem with procedures that utilize TEE is that the echo cardiologist is required to be in the operating room for the duration of the procedure. Therefore, the purpose of this project was to redesign the user interface of the TEE to minimize the role of the echo cardiologist and give more control to the interventional cardiologist or some physician in the medical room.

3.1 Problem Statement

The primary focus was to determine a way to reduce the amount of time that the echo cardiologist is required to be in the procedure room. Although this issue may seem trivial, it causes a number of other issues. Figure 18 pictures a WHY-WHY diagram that functionally decomposed the main problem.

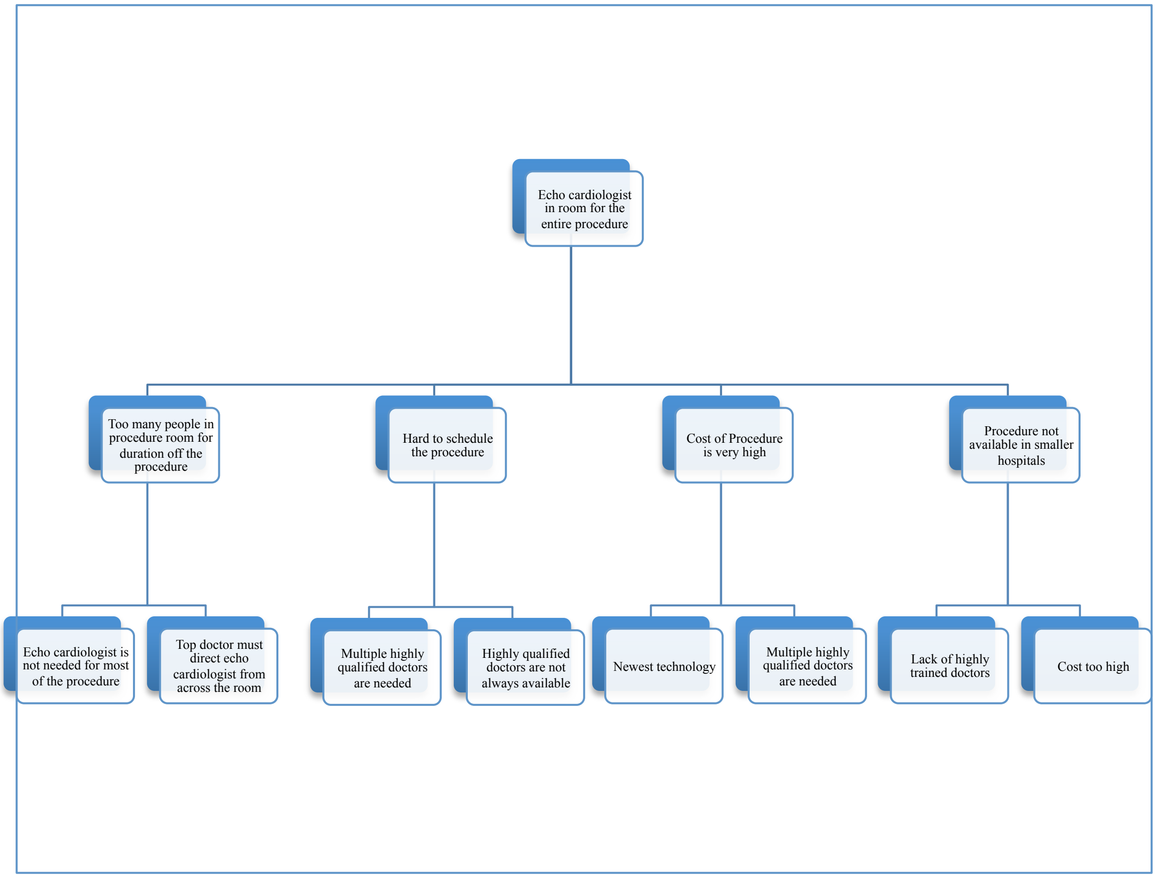


Figure 18 - WHY-WHY diagram for TEE procedure that functionally decomposes the main problem.

Many problems occur due to the echo cardiologist being in the medical room for the entirety of procedures. These include the abundance of people in the operating room during the procedure causing a lack of space, difficulty of scheduling the procedure, high costs of the procedure, and low general availability of the procedure. These problems lead to other problems such as multiple highly qualified doctors are needed to schedule a procedure, the echo cardiologist seems to have minimal participation in the procedure, and a lack of qualified doctors in certain geographical areas. Obviously, not all of these problems are independent of each other.

One problem stemming from the main problem is that there are too many people in the room during the procedure. While the echo cardiologist performs the very important function of deploying the TEE down the patient's throat and adjusting its position per the verbal request of the interventional cardiologist, he or she has minimal participation for much of the procedure. Also, the interventional cardiologist may have difficulty at times explaining to the echo cardiologist exactly how he or she wants the probe end adjusted.

Another problem that stems from the echo cardiologist being in the room the entire procedure is that procedures using TEE are difficult to schedule. The procedure requires two highly specialized doctors for the entire procedure. Thus, a procedure has to be scheduled around both of their schedules, and the required physicians are not always available. While the doctors needed are usually found at large hospitals, smaller hospitals may not have the necessary doctors or equipment (due to high costs), so the procedure may not be available at those institutions.

The procedure itself is also very expensive. While the high costs are in part due to the fact that TEE is a new and revolutionary technology, there are also other reasons as to why the procedure is so costly. The main reason is that highly qualified doctors are required to do tasks that could be done by lesser-qualified physicians.

3.2 Design Goals

After understanding the procedure and associated problems, the goal of this project was to redesign the user interface in order to minimize the role of the echo cardiologist and give more control to the interventional cardiologist or another physician in the medical room. Keeping the purpose of the project in mind, a list of objectives was set and is explained in the following paragraphs.

The primary goal was to increase the interventional cardiologist's control of the system. Similarly, the system needed to be simple as not to increase the cognitive load of the person controlling the inputs of the system. Likewise, the system needed to eliminate or minimize the role of the echo cardiologist during the procedure. As the developers of this system, it was important to make the system compliant with regulatory standards. Lastly, the system needed to produce the two degrees of freedom that control the two degrees of freedom of the TEE probe.

Another goal for this project was to create a system that controls the movement of the probe of the TEE and could be controlled by the interventional cardiologist from his or her general location in the procedure room. The goal of minimizing the role of the echo cardiologist during the procedure hinged on the interventional cardiologist being able to control the system from wherever he or she was located in the procedure room. A typical distance from the where the TEE was positioned inside the patient to where the interventional cardiologist usually stands was about five feet.   Figure 19 shows a typical procedure room and where the interventional cardiologist usually stands with respect to where the TEE was stationed.

Figure 19 - Typical Procedure room showing where interventional cardiologist usually stands and where TEE probe is usually located.

Another goal was to make the manipulation of the TEE easy and reliable, and remotely operated, so that someone other than the echo cardiologist could manipulate the TEE probe. While an echo cardiologist is needed to position the TEE probe down the patient's throat, some other physician could potentially manipulate the controls of the TEE once positioned. If someone other than the echo cardiologist could handle this part of the procedure, the procedure could be easier to schedule, cost less, and provide more space in the procedure room for at least part of the procedure. This goal would also make the procedure available to more institutions (specifically smaller institutions) because one reason this procedure is not already available is that the institution may not have enough qualified doctors on call all the time and the cost is too high.

Next, the system needed to be "simple." That is, the human input for the system needed to be minimal. Ideally, the system would have two inputs that control the two output motions of the probe. The idea was that the interventional cardiologist would be controlling the system, but he or she is involved with many activities during the procedure. Anything that increases the doctor's cognitive load more than necessary takes away from his or her focus in the main aspects of the procedure, and this was undesirable.

Next, the system needed comply with regulatory standards, including FDA standards. Any devices used inside the procedure room are constrained by a long list of regulations. Device developers are responsible to make sure that the device complies with all standards

Lastly, the desired output for the probe end of the TEE was two degrees of freedom. The required input of the existing pull-pull cable system has two degrees of freedom, which are controlled by two knobs, so the desired output of our device needed to translate the existing cables or rotate the existing knobs.

The desired input was a simple control system. Overall, there were many design goals for this new system. A numbered list of the original design specifications before the system was designed is listed below (also found in Appendix B):

1. Output must provide the probe two degrees of freedom (DoF)
    a. The current output of the distal end of the TEE probe has two translational degrees of freedom. This should remain unchanged if a control mechanism is added to this existing device.
2. Input should be two DoF
    a. The current input of the device consists of two rotational knobs that provide two rotational degrees of freedom. This 2 DoF input should remain unchanged if a control mechanism is added to the existing device.
3. Must comply with FDA regulations
    a. Any device that enters an operating room must comply with FDA regulations. If it does not, the institution performing the procedure cannot legally use the device. The engineering team is responsible for making sure that the device abides by all FDA regulations.
4. Existing probe must not be changed
    a. The inside mechanism of the probe shaft and mechanism that controls the probe shaft should remain unchanged.
5. Backlash of the additional controls must be minimal.
    a. The existing TEE has a lot of backlash already, so any additional controls added need to have as little backlash as possible.
6. Mechanism that controls the motion of the probe shaft must be able to translate the same amount that it already translates.
    a. The distal end of the probe shaft should have the same range of movement that already exists in the current mechanism.
7. The distal end of the probe shaft should be able to be stopped at any point in its rotation without significant backlash.
    a. This system must have a system to provide resistance against movement of the probe once the probe is positioned but able to be overridden.
8. Maximize the number of standard size parts
    a. This design goal goes along with the one previously mentioned. If more standard sized parts are used, the cost will be decreased. Also, standard sized parts are easier to obtain.
9. Input moment required to manipulate system should be minimal, but high enough so that the control will not move if it is tapped or bumped into.
10. Total Weight of System should be minimized
    a. The system should be easily stored and moved. Also, any mechanism that is created should not be cumbersome, so the weight should be minimized. A 50% increase in weight is acceptable.
11. Connection between TEE and new system should be enclosed

    a. The current connection between the inputs (rotational knobs) and the parts that cause the output motion (racks connected to pull wires) is enclosed in a metal shell. Any connection that is to be made should remain in a sealed case. This lends to easier cleaning of the device.

12. User interface should require the same cognitive load that the present device requires to operate
    a. There is an objective to have the interventional cardiologist to be able control the control system. The act of controlling an additional mechanism must not detract from his or her primary focus. Someone other than a cardiologist could possibly control the system.
13. Controls of mechanism must be accessible to the interventional cardiologist
    a. There is an objective that the any control system should be able to be manipulated by the interventional cardiologist. The user interface should be situated so he or she can use it, wherever they may be.
14. User interface must not exceed the dimensions of a normal sized adult hand
    a. The user interface should not be excessively large because we do not want the system to take up a large amount of additional space in the procedure room.
15. The controls of the system must be ergonomically designed
    a. There should be no slip when the controls of the system are manipulated. The gripping location of the user interface should be easily controlled. User controls need to be easily manipulated.
16. Adjusting the end of the probe via the control mechanism should not disturb the insertion depth of the probe in the patient's throat
    a. The positioning of the probe shaft down the patient's throat should not be moved because that could cause damage to the inside of the body and also could change the position of the probe once it was already positioned correctly.
17. TEE handle should be positioned in space such that the probe cord is not moved unintentionally
18. Time from human input motion to probe output motion must be within 1 second
    a. There should be less than 1 second delay in time from human input to probe output. If time is greater than one second, the doctor could become confused and increase the difficulty of correctly positioning the probe.
19. Connection between TEE and control mechanism should be incorporated directly onto TEE or attached and detached easily.
    a. If it is desired that the system should be detached or attached from the existing mechanism at any time, the degree of difficulty to dismantle or assemble the system should be fairly simple.
20. Reliability: minimal structural maintenance should be needed for this system for 10 years
    a. The structural components of the control system should not need to be replaced or fixed for at least 10 years.
21. System should be easily cleaned
22. Materials must be FDA approved

Chapter 4 Preliminary Design Ideas and Zeroth Order Prototyping

Many preliminary designs were created and sketched. A morphological chart was used to brainstorm ideas to reach the design goals and certain components of the new system. Then, those components were pieced together to make full system designs. Once full system designs were created, zeroth order prototypes were made to test for feasibility.

4.1 Morphological Chart

A morphological chart was used to find different ways to achieve the design goals for the system. The results are shown in Table 1.

Table 1 - Morphological chart used to combine ideas for achieving desired goals.

Alternative Control System for TEE

Desired functions or goals	**Partial concepts or means to achieve each of the desired goals**					
Manipulation of user interface	Cam actuated, foot-control	Lever actuated, foot-control	Plunger actuated, foot-control	Lever actuated, hand-control	Joystick actuated, hand-control	Knob actuated, hand-control
Transfer of movement from control interface to user interface	Cables	Hydraulics	Pseudo-fluid balls	X	X	X
Manipulation of control interface	Rack & Pinion	X	X	X	X	X

4.2 Preliminary Component Designs

Preliminary designs were made and sketched for different parts of the system. All of the designs were analyzed in order to select components for full system designs.

4.2.1 Foot-controlled Designs

All of the designs in section 4.2.1 are for systems that would have used foot pedals as the user interface of the system.

4.2.1.1 Design 1: Foot-Controlled, Cam Actuated Cable System

Design 1 uses a foot pedal control. It would feature a stiff pivoting joint at the heel end of the foot pedal, and a cam at the toe end of the pedal. The cam would actuate a follower, which would pivot a link. Pull-pull cables would be attached to the pivoting link at equal distances from the pivot point. This design would require two foot pedals, one for each degree of freedom. It would attach to the existing cable control system. One of the advantages of this design is that it would offer fine control of the probe head. This design is currently force closed, which does not work well with the TEE but the cam could be made form closed instead. This system could be used with a hydraulic fluid by turning the follower into a piston. Figure 20 shows the foot-controlled, cam actuated cable system.

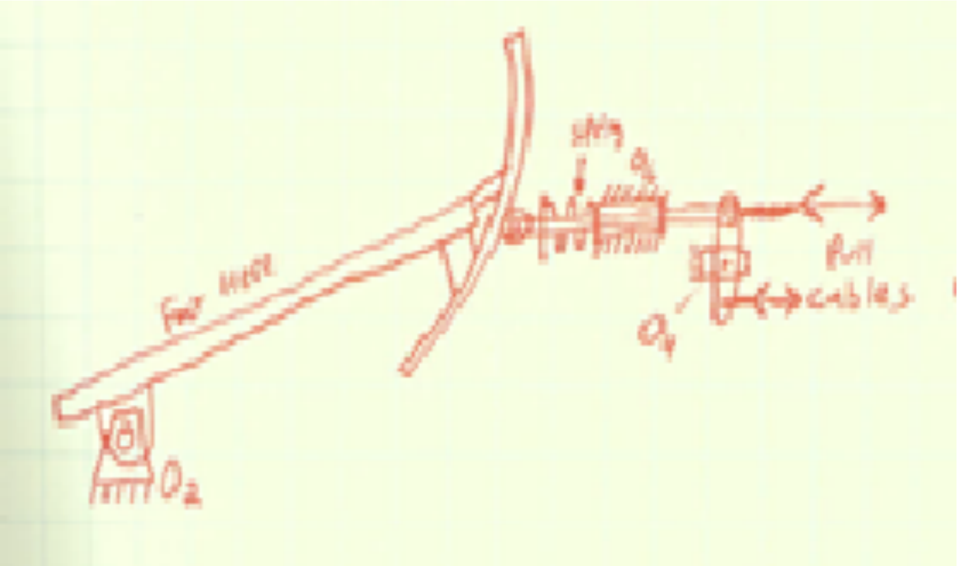


Figure 20 – Foot-controlled, cam actuated cable system. This design uses a foot pedal to control a cam that actuates the cables for a cable system.

4.2.1.2 Design 2: Foot-Controlled, Lever Actuated Cable System

Design 2 uses a foot pedal that pivots in the middle of the pedal. This design would require two foot pedals for full control of the device. Cables would attach directly to the pedal, at equal distances from the pivot point. They would then be redirected to the existing cables inside the TEE. This design could be made to offer different levels of accuracy by changing the distance from the pivot that the cables are located. An alternative single pedal design could be made which stacks two of these pedals, one pivoting front and back and the other side to side. This system could be used with hydraulic fluid by attaching pistons to points A and B instead of cables. Figure 21 shows the foot-controlled, lever actuated cable system.

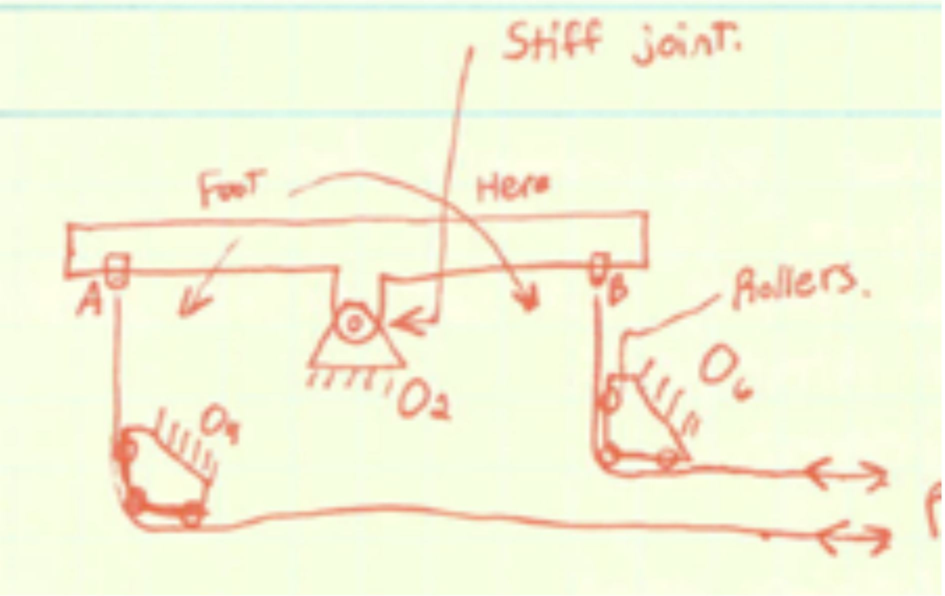


Figure 21 – Foot-controlled, lever actuated cable system. This design uses a hand-controlled lever to control a set of cables.

4.2.1.3 Design 3: Foot-Controlled, Plunger Actuated Cable System

Design 3 requires four foot pedals to fully control the system. It utilizes a foot pedal that pivots at the heel end. At the toe end, the pedal actuates a push, and the rod then pulls on the cable through a pulley system. A disadvantage of having four pedals is that as one pedal moves, it must force its counterpart to move, adding more stresses to the cables. This design could be modified to use only two pedals by having the push rod make a link pivot, the same way that design 1 works. This design could also work as a modification of design 2, but having a push rod spaced equally on either side of the pivot. Figure 22 shows the foot-controlled, plunger actuated cable system.

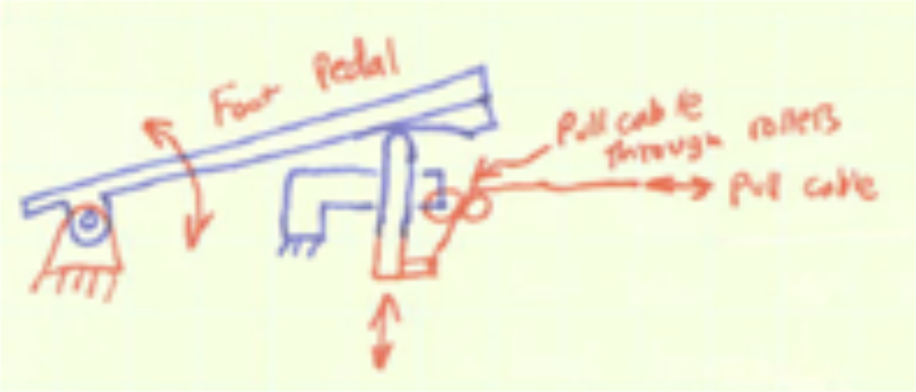


Figure 22 – Foot-controlled, plunger actuated cable system. This design uses a foot pedal to control a plunger, which actuates a set of cables.

4.2.2 Hand-controlled Designs

The designs in section 4.2.2 are for systems that would have used a handle-controlled user interface. Foot-controlled systems are inferior to hand-controlled systems for several reasons. With a foot-controlled system, the doctor may have to balance on one foot. Similarly, humans have much finer motor control with their hands than their feet, so fine adjustments would be more easily made with a hand control. Another point that should be noted is that foot-controlled user interfaces used in medical settings are typically used as "on-off" switches whereas hand-controlled user interfaces are usually utilized for controls for devices that need fine adjustments.

4.2.2.1 Design 4: Hand-Controlled, Lever Actuated System

Design 4 is the same as design 2, except the design uses a handle instead of a foot pedal. This would allow for finer control. This design would have been good if the interventional cardiologist had time to use his hands during procedures. Figure 23 shows a sketch of design of the hand-controlled, lever actuated system.

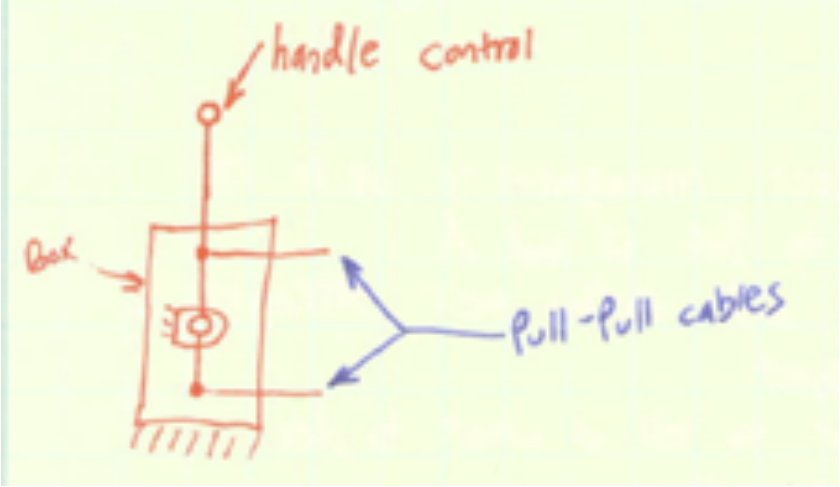


Figure 23 – Hand-controlled, lever actuated cable system. This design uses a hand-controlled lever to actuate a set of levers.

4.2.2.2 Design 5: Hand-Controlled, Joystick Actuated Cable System

Design 5 uses a mechanical joystick that would control the directly control both degrees of freedom of the current TEE. A sphere would guide the joystick with four equally spaced pins in it located perpendicular to the joystick handle. The sphere would be closely fitting (close enough that it does not move freely, but will move with a small amount of applied force) in a matching spherical cutout in the base, with slots for the guide pins to fit into. This would allow the joystick to be guided in the right directions, operate all directions simultaneously but without allowing the joystick to flop around on its own. Figure 24 shows a sketch of the hand-controlled, joystick actuated cable system.

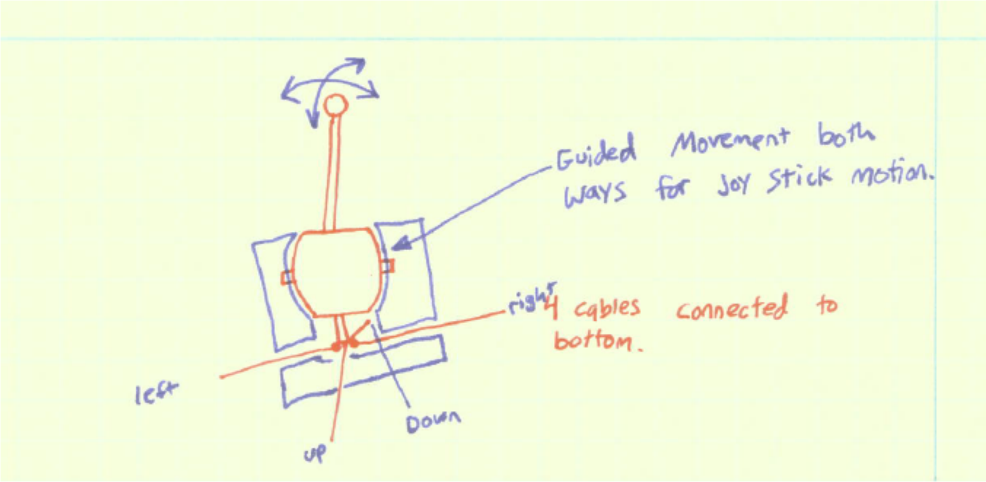


Figure 24 - Hand-controlled, joystick actuated cable system. This design uses a mechanical joystick to actuate a set of levers.

4.2.2.3 Design 6: Hand-Controlled, Rack and Pinion Actuated Hydraulic System

Figure 25 shows a sketch of a system that uses a lever that can be maneuvered by hand in order to apply pressure to fluid in the tube. A lever would be connected to a pinion of rack and pinion system. Then, a piston would be attached to the racks. Additionally, another tube and rack would be added to the other side of the pinion, which could allow control of forward and backward motion.

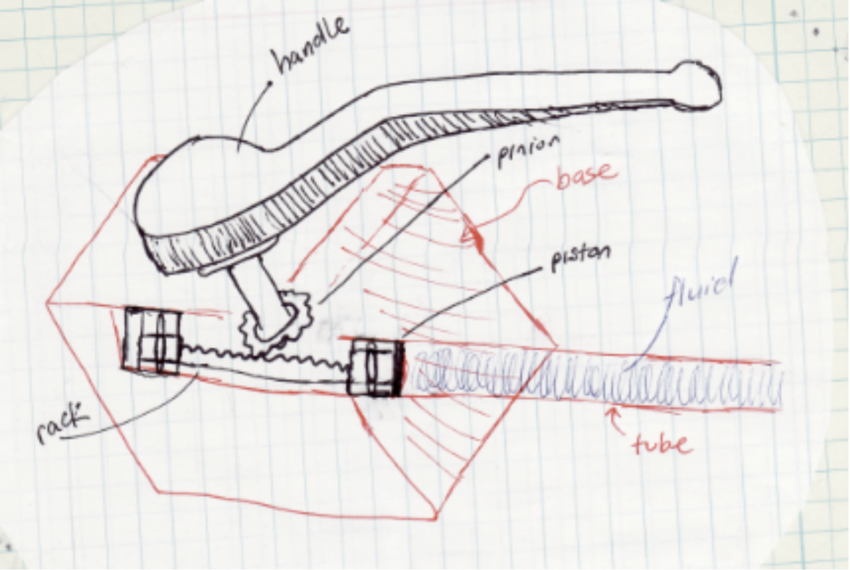


Figure 25 - Hand-controlled, rack and pinion actuated hydraulic system. This system is manipulated by a handle that is rigidly connected to a pinion shaft of a rack and pinion system. The rack and pinion would push a hydraulic fluid back and forth.

4.2.2.4 Design 7: Hand-Controlled, Rack and Pinion Actuated Cable System

Design 7 is focused on a drag switch control, shown in red in Figure 26. This switch would be rigidly connected to a rack of a rack and pinion gear set. This idea for a control would allow someone to “drag” the switch up and down in order to control forward and backward motion.

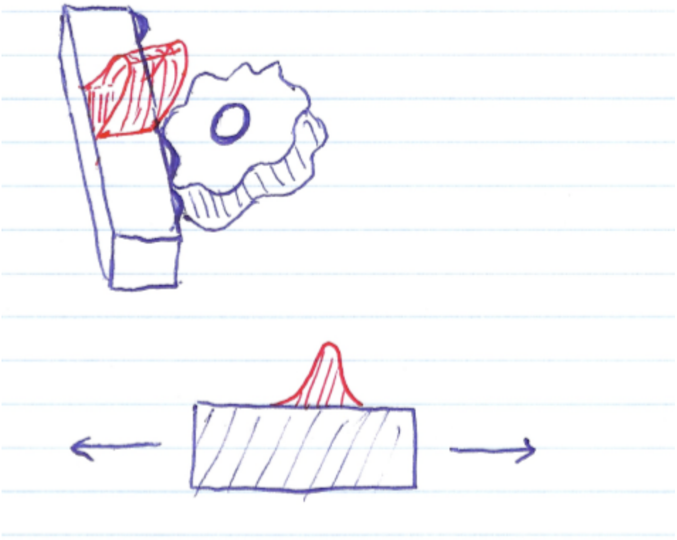


Figure 26 - Hand-controlled, rack and pinion actuated cable system. This design shows that a switch could be used to manipulate a rack and pinion gear set.

4.2.2.5 Design 8: Hand-Controlled, Lever Actuated Cable System

Design 8 uses a double lever cable system. Figure 27 shows the main lever, link sets, and cables used in the system. This lever has two sets of links, two on the top and two on the bottom. The bottom two links are connected by a rigid connection on the top left side of Figure 27 shown in red. The links are shown in blue. The main lever is shown in black. A large pin would fit in the large hole in the main lever and the lever would rotate about the large pin. A smaller pin would fit in the small hole where the two sets of links meet and the link sets would be connected to the smaller pin. The top right side in the figure shows a rear view of one of the levers. Spacers are included to reduce deflection of the top links. The bottom half of the figure shows a rear view of the double lever cable system with a basic frame. In this picture, the larger pin is shown.

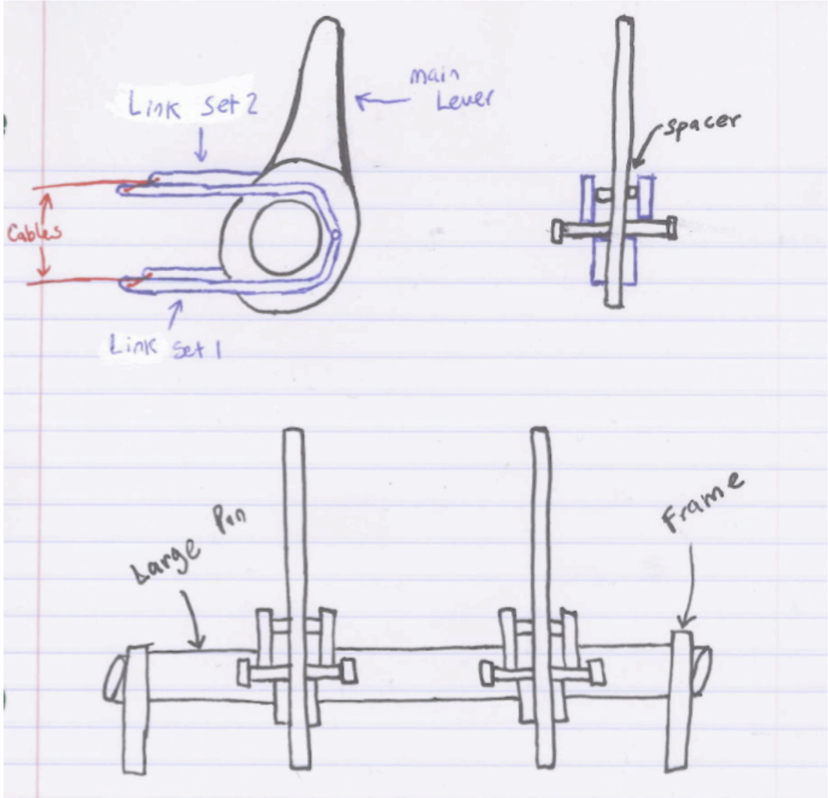


Figure 27 - Hand-controlled, lever actuated cable system. This design uses a lever to control a set of links that actuate a set of cables.

4.2.2.6 Design 9: Rearranged Knob System

This design keeps all the same mechanics as the original TEE but the knobs would be placed on the outer edge of the TEE handle. As opposed to having one knob on top of each other, one knob would be put on each side of the TEE handle. The knobs would act similar to the controls of a standard microscope. Each knob would control a degree of freedom. Figure 28 shows a sketch of the rearranged knob system.

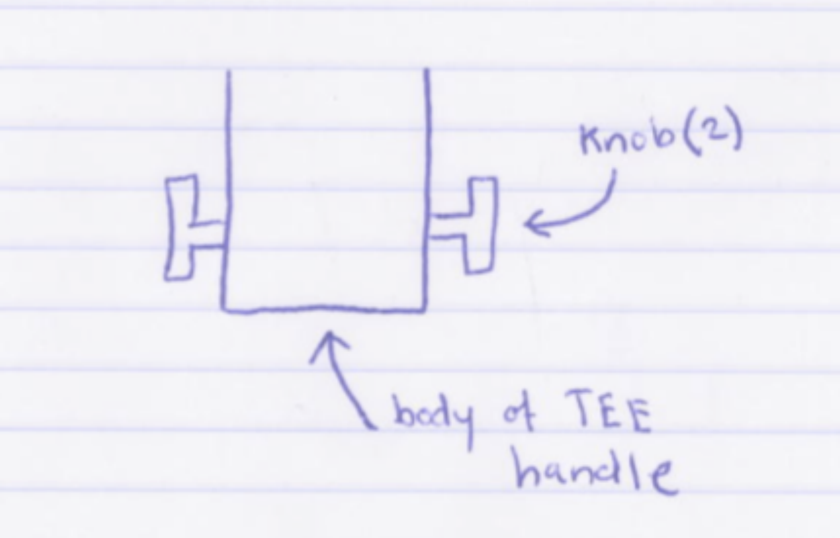


Figure 28 - Rearranged knob system. This idea shows a user interface that would rotate the location of the knobs on the TEE handle by 90 degrees and opposite sides opposed to the knobs being concentric.

4.2.3 Interior Mechanical Systems

The following designs describe how the mechanics of the inside of the system would potentially be controlled. These mechanical systems would be connected to a set of controls.

4.2.3.1 Design 10: Hand-Controlled, Chain and Sprocket Actuated Cable System

Design 10 uses a knob to control the system. The knob would be connected to a sprocket, which has a chain going around a portion of it. This is very similar to the existing mechanism inside the TEE. The sprocket would act as a pinion in a rack and pinion gear set and the rack would be flexible and wrapped around the pinion. For this system, a lever could be used to control the sprocket by pivoting the lever back and forth. Figure 29 shows a sketch of the hand-controlled, chain and sprocket actuated cable system.

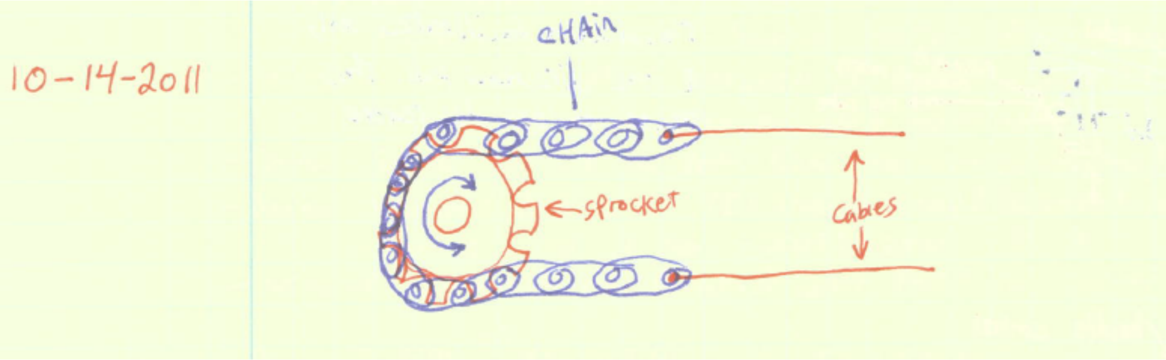


Figure 29 - Hand-controlled, chain and sprocket actuated cable system. This design involves using a chain and sprocket in place of a rack and pinion in order to actuate a set of cables.

4.2.3.2 Design 11: Hand-Controlled, Counter Wound Shaft Actuated Cable System

Design 11 is a system that would have two vertical shafts with spiraled cuts going up each shaft. The bottom half of each shaft will be wound by wire, and the wire will be hooked to the shaft about midway up. The top half of each shaft will be wound by a different wire in the opposite direction, and again this wire will be hooked to the shaft about midway down. This system provides a mechanism that causes both counter-clockwise and clockwise motion using one handle or knob that would be attached to either shaft, utilizing a pull-pull system. Figure 30 shows a sketch of the hand-controlled, counter wound shaft actuated cable system.

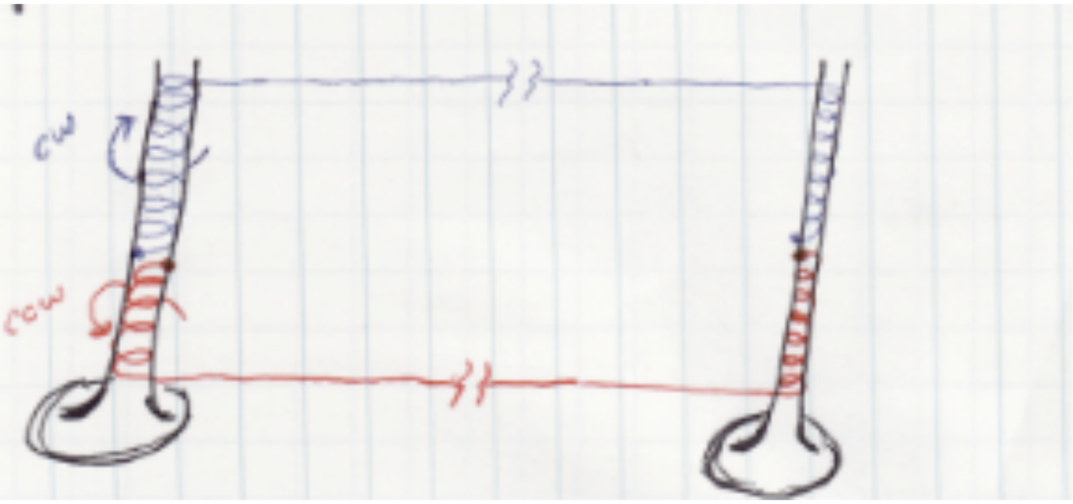
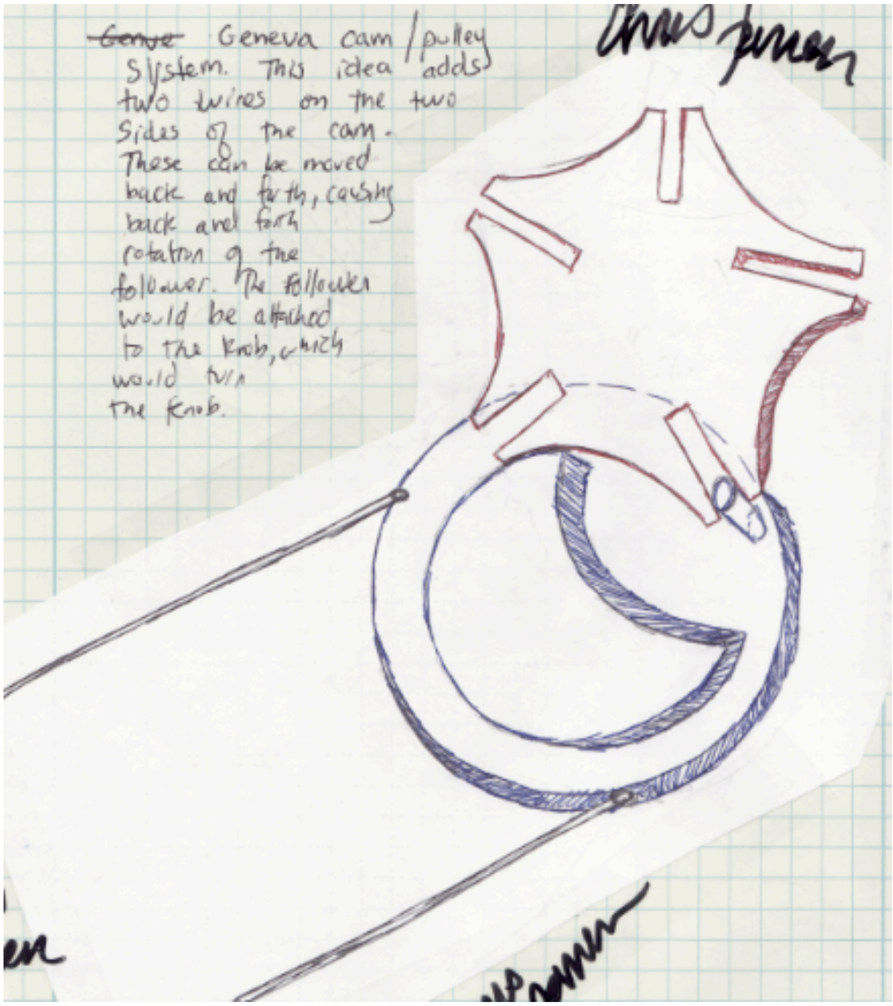


Figure 30 - Hand-controlled, counter wound shaft actuated cable system. This system would consist of two vertical shafts that would be wound be two different wires opposite directions. The rotation of one shaft would actuate a pull-pull mechanism.

4.2.3.3 Design 12: Hand-Controlled, Geneva Cam System

Design 12 involves the use of a Geneva cam system in which two wires are attached to the sides of the cam. The wires would be moved back and forth, causing rotation of the follower. Figure 31 shows a sketch of the hand-controlled, Geneva Cam system.



~~Genve~~ Geneva cam / pulley system. This idea adds two wires on the two sides of the cam. These can be moved back and forth, causing back and forth rotation of the follower. The follower would be attached to the knob, which would turn the knob.

Figure 31 - Hand-controlled, Geneva cam system. This idea uses a Geneva cam that is pulled back and forth by cables in order to actuate a follower.

4.2.3.4 Design 13: Hand-Controlled Modified Rack and Pinion System

This design positions a worm gear between the pinion and rack of a rack and pinion gear set. This would help reduce backlash and also to allow for finer adjustment of the control system. Figure 32 shows a sketch of the hand-controlled modified rack and pinion system.

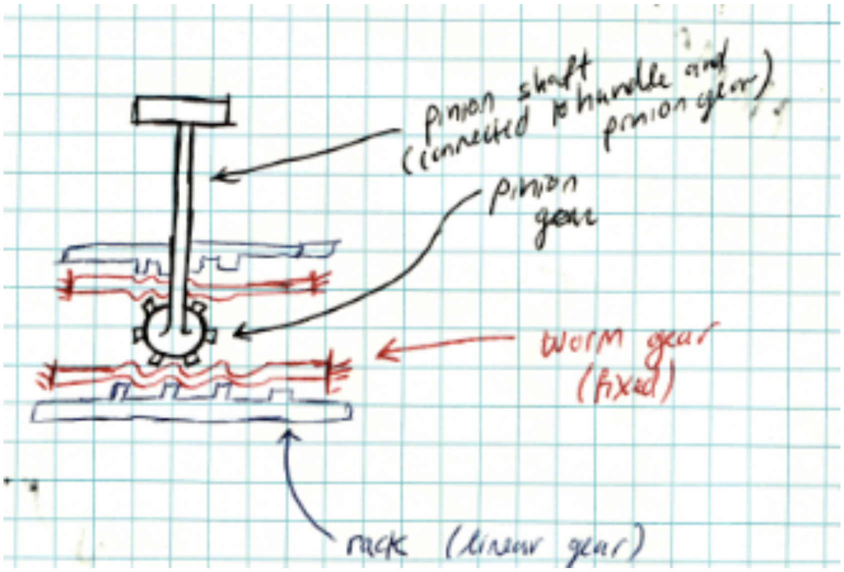


Figure 32 - Hand-controlled modified rack and pinion system. This design positions a worm gear in between the pinion and racks of rack and pinion system.

4.2.3.5 Design 14: Gear with Attached Ratchet

Design 14 is a gear with a ratchet attached. The ratchet would be a leaf spring, which provides resistance against one way of rotation. The second part of this design would use a modified ratchet that is easier to override. Figure 33 and Figure 34 shows the gear with attached ratchet idea.

Figure 33 - Ratchet idea. This design would have ratchet connected to a gear.

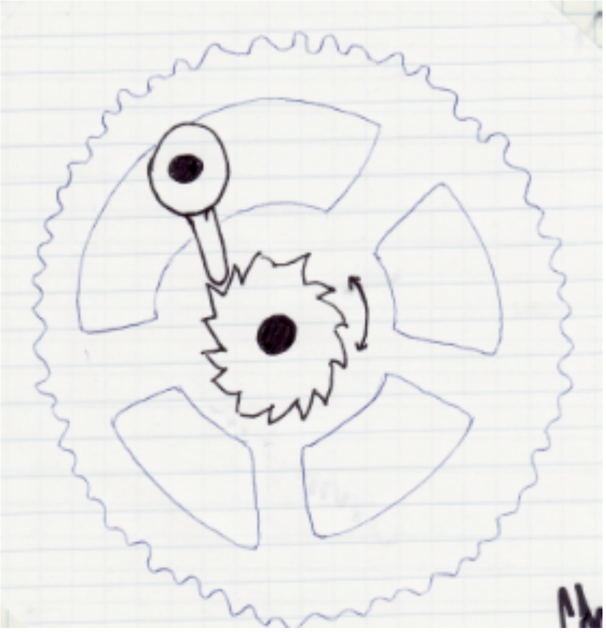


Figure 34 - Override- ratchet idea. This part of the design would have a ratchet attached to a gear that is easier to override than the ratchet in Figure 33.

4.2.3.6 Design 15: Locking Pin

This design consists of a pin that drives in and out. The pin would be perpendicular to a rotating gear. As the gear rotates, the pin depresses so the gear can freely rotate. Once the gear stop rotating, the pin would spring up and lock the gear in place. This idea helps minimize backlash. Figure 35 shows a sketch of the locking pin design.

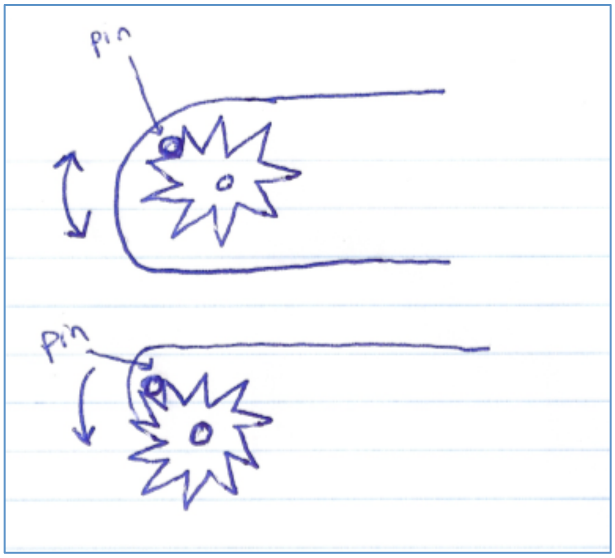


Figure 35 - Locking Pin Idea. This design consists of a spring-loaded pin that can hold the gear in place but can be overridden with enough force.

4.2.3.7 Design 16: Pseudo-fluid movement-transfer system

This design involves the movement of chrome steel balls inside a plastic tube to be used as push-push system. At either end of the tube, ”pistons” would be place tangent to the last ball in the tube (on both sides) and the axis of the “piston” would be collinear with the horizontal axis of the balls. As you push one of the pistons, the movement will be transferred to the other end of the tube and the other piston will move the same amount. This design is similar to a closed hydraulic system. Figure 36 shows a sketch of the pseudo-fluid movement-transfer system.

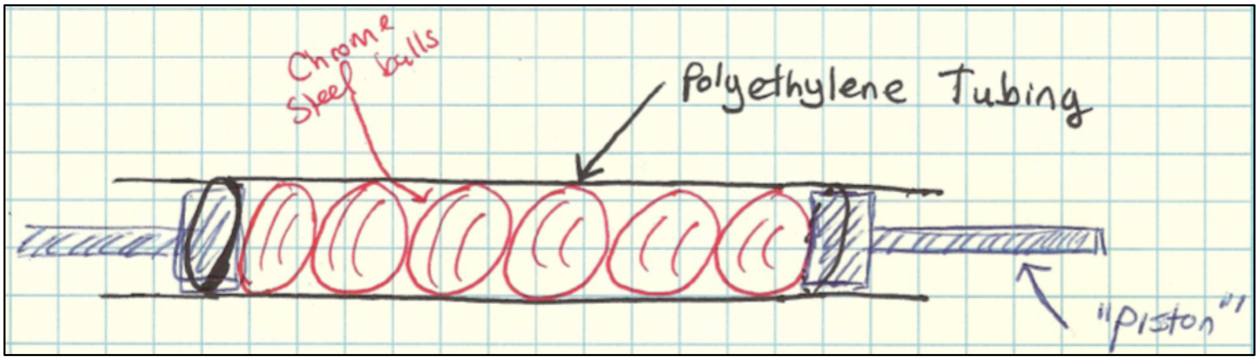


Figure 36 - Pseudo-fluid movement-transfer system. This design creates a push-push movement system using small metal balls inside a plastic tube. This idea is similar to a closed hydraulic system.

4.2.4 Attachments

Designs in section 4.2.4 describe ideas that can be used as attachments or accessories to the TEE.

4.2.4.1 Design 17: Wall Mount

This design is a wall mount for the TEE. The TEE would slide into a mold on the mount. The TEE could be manipulated using the same controls that are already on the current model. Figure 37 shows the wall mount idea.

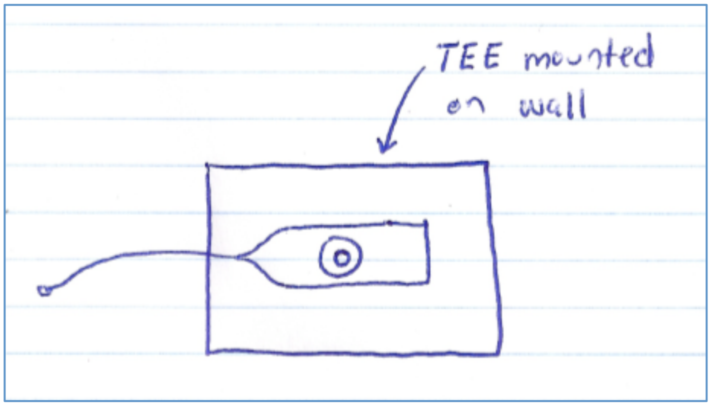


Figure 37 - Wall Mount Idea.

4.2.4.2 Design 18: Mobile Stand

This idea is a simple holder for the TEE. The stand would have wheels on the bottom of it so it could be easily move around. Figure 38 shows a sketch the mobile stand idea.

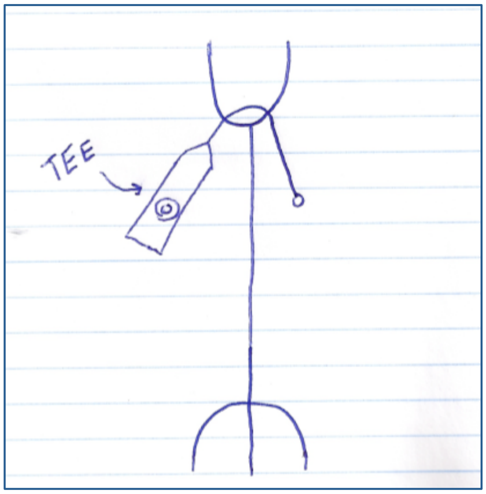


Figure 38 - Mobile Stand Idea. This idea is basically a holder for the TEE.

4.3 Preliminary Full System Designs

After brainstorming ideas for the different components of the system, full system ideas were developed.

4.3.1 Hydraulic Joystick Push System

Figure 39 shows a hydraulic system that uses a mechanical joystick as the user interface. The movement of the joystick causes the flow of a fluid (closed hydraulic system). The fluid would push on the racks of a rack and pinion system that would control the shafts on the TEE handle, which control the movement of the TEE probe. In this manner, the movement of the joystick controls the movement of the TEE.

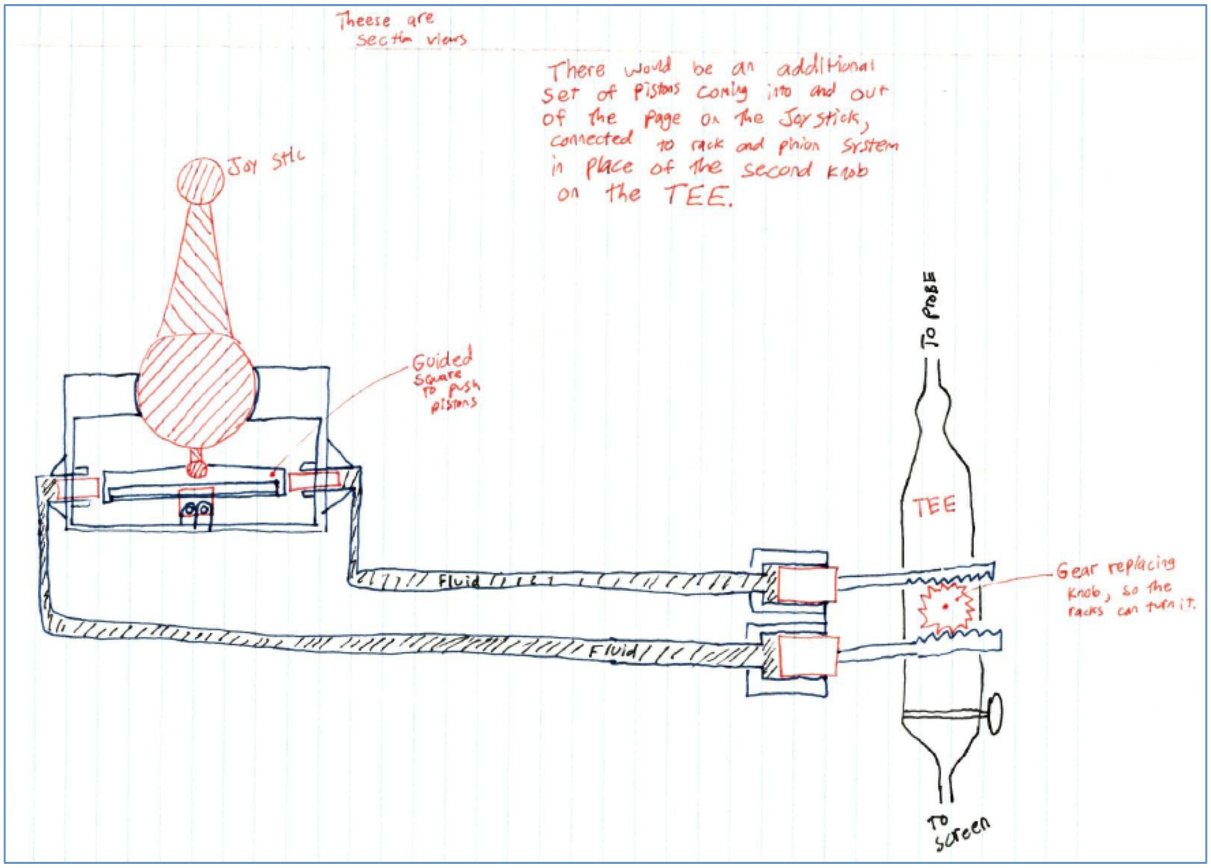


Figure 39 - Hydraulic joystick push system. The user interface of the system would be a mechanical joystick that would actuate fluid flow of a closed hydraulic system, which would control racks of a rack and pinion system at the TEE interface. The rack and pinion at the TEE interface would control the shafts of the TEE handle that control the movement of the TEE probe.

4.3.2 Rocker Handle Hydraulic System

Figure 40 shows a lever controlled hydraulic system. The movement of the lever causes two pistons to push a fluid. The fluid then pushes pistons at the TEE interface, and those pistons push on a rack and pinion system. The pinion of the rack and pinion system is mounted on the shafts of the TEE, so as the lever is moved, the shaft is spun. This system would use two levers, one for each of the shafts on the TEE. Each of the levers would be linked to a rack and pinion system in the same manor described in section 4.3.1.

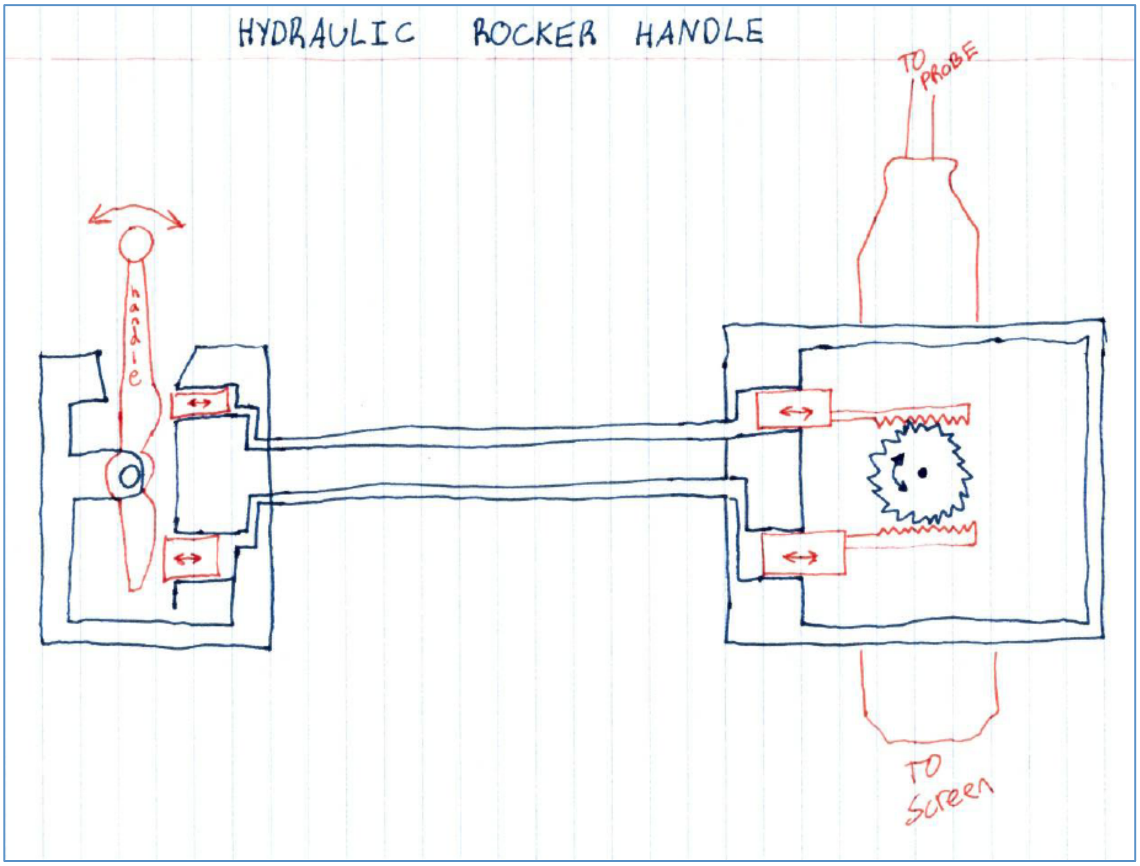


Figure 40 - Rocker handle hydraulic system. The user interface of the system would be a handle that can rock back and forth. The handle would actuate fluid flow of a closed hydraulic system, which would control racks of a rack and pinion system at the TEE interface. The rack and pinion at the TEE interface would control the shafts of the TEE handle that control the movement of the TEE probe.

4.3.3 Rocker Handle Cable System

Figure 41 shows a lever controlled cable system. The movement of the lever would cause the cables to be pulled. The cables would be mounted at equal distances from the pivot point on the lever so that they would both move the same amount. The cables would wrap around a pulley at the TEE. They would be fixed to a point on the back of the pulley where the cable would be required to be in contact with it throughout the range of motion. As the lever pulls the cables, the cables would cause the pulley mounted on the shaft of the TEE to rotate, making the probe head move. There would be two levers in this system, one for each of the shafts on the TEE.

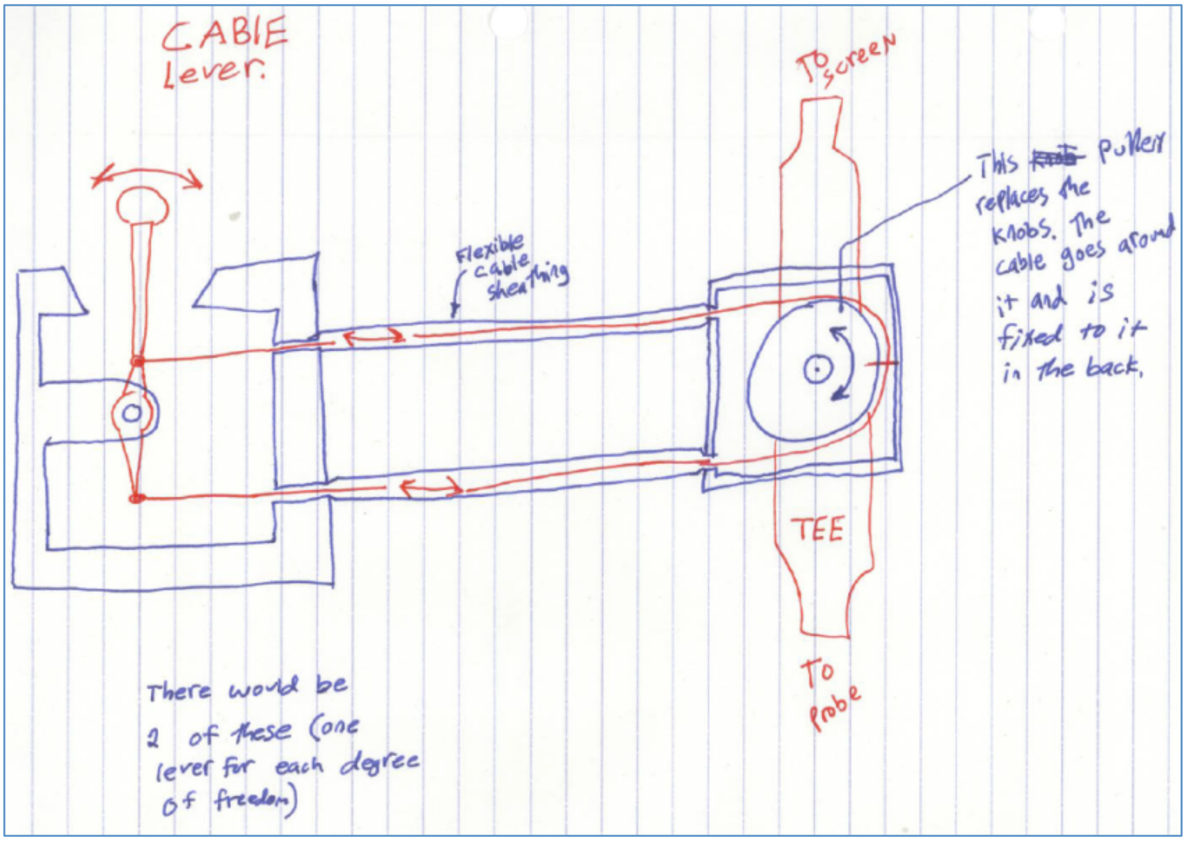


Figure 41 - Rocker handle cable system. The user interface of this system would be a lever that can rotate back and forth. The lever would actuate the movement of cables, which cause a pulley rigidly attached to the shafts of the TEE to rotate. This rotation would actuate the movement of the TEE probe.

4.3.4 Double Rack and Pinion Hydraulic System with Knobs

This design would involve minimal alterations to the current TEE. The system would have a rack and pinion at the TEE interface and the user interface. Knobs would be connected to the pinion shafts of the rack and pinion system at the user interface. Rotation of the knobs would actuate the fluid of closed hydraulic system and cause the movement of racks of a rack and pinion gear set at the TEE interface. The rack and pinion gear set at the TEE interface would control the movement the shafts inside the TEE handle, which would control the movement of the TEE probe. Figure 42 shows a sketch of the double rack and pinion hydraulic system.

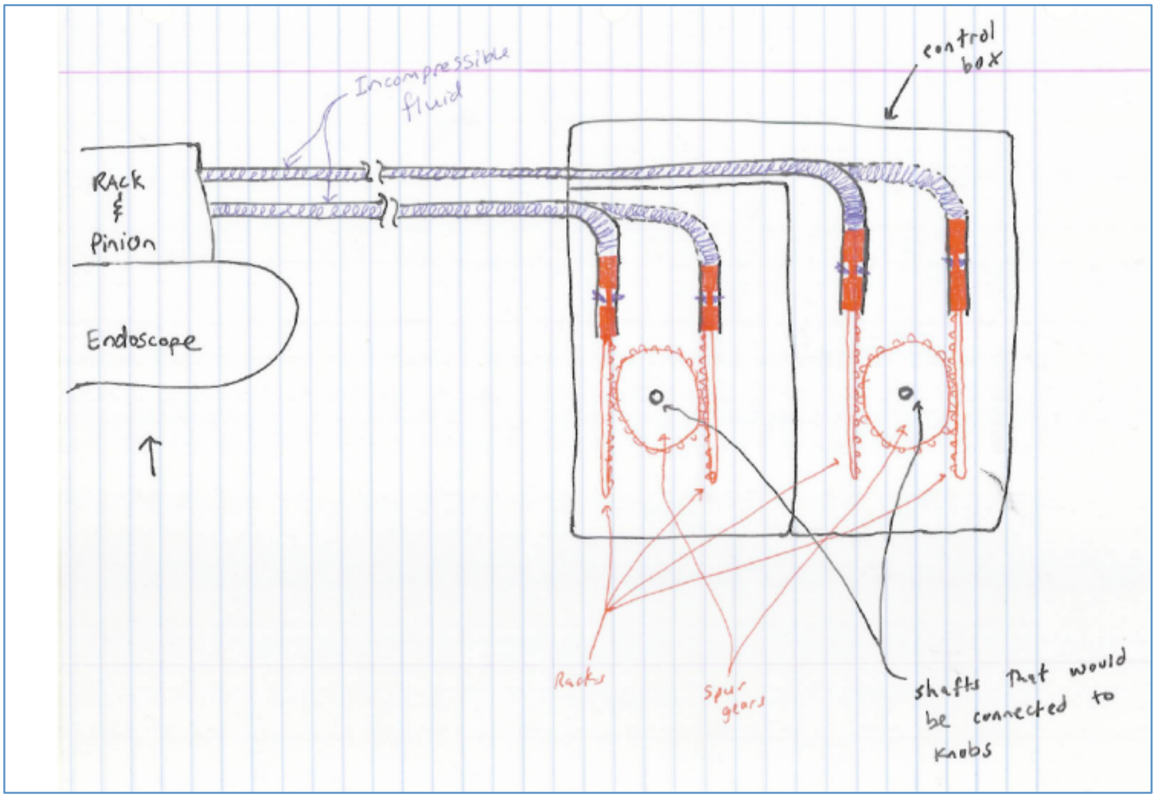


Figure 42 - Double rack and pinion hydraulic system. The system would have a knob controlled rack and pinion system at the user interface. That rack and pinion gear set would manipulate the movement of a controlled hydraulic system that would cause the movement of racks of a rack and pinion gear set at the TEE interface. The rack and pinion at the TEE interface would control the movement of the TEE probe.

4.3.5 Synchromesh Pull Hydraulic System

This design uses a knob-controlled rack and pinion at the user interface. Rotation of the knob would actuate fluid flow of a closed hydraulic system that would cause rotation a synchromesh pulley system that would control the shafts in the TEE handle. Synchromesh cable would be wrapped around a “sprocket” at the TEE interface. Only the maximum amount of needed synchromesh as determined by the amount of rotation needed would be used. As you rotate the knobs that would connect to the pinion shafts of the control box, one piston is pulled causing the other one to push forward. As the piston pushes forward, it will push the piston forward at the TEE interface. Figure 43 shows a sketch of the synchromesh pull hydraulic system.

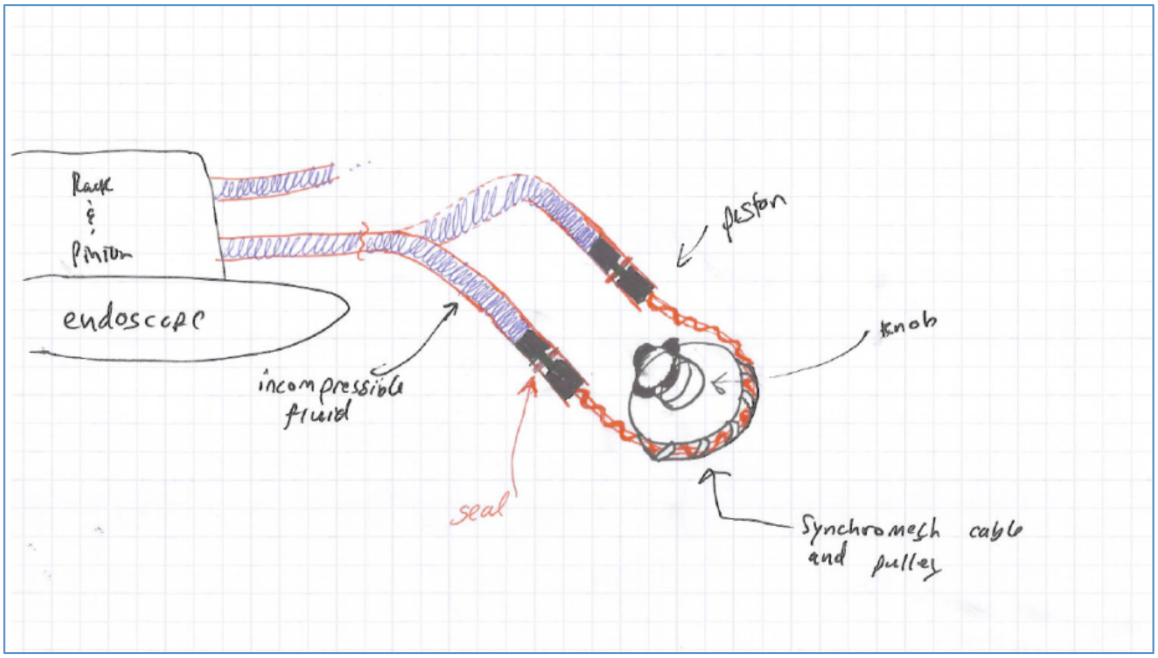


Figure 43 – Synchromesh pull hydraulic system. This design uses a rack and pinion at the user interface, which actuates fluid flow in a closed hydraulic system, which controls the movement of a synchromesh pulley system that controls the movement of the shafts in the TEE handle. The shafts in the TEE handle control the movement of the TEE probe.

4.3.6 Double Lever Hydraulic System

This design is a double lever hydraulic system. Figure 44 shows side view of one of the lever controls. This lever has two sets of joints, two on the top and two on the bottom, both of which are flexible so that they can rotate around a central pin. The bottom two joints are connected to a stiff joint that connects to a piston. The large hole is where a large pin would go and the lever would pivot about the large pin. The small hole is where a smaller pin would go and the two sets of joints (top and bottom) would be connected to the smaller pin. Spacers are included to reduce deflection of the top joints. This system would use a rack and pinion gear set at the TEE interface. Movement between the levers at the user interface and the rack and pinion at the TEE interface would be transferred through a closed hydraulic system. Figure 45 shows a rear view of one of the levers at the user interface. Figure 46 shows how two levers would be connected to a small frame.

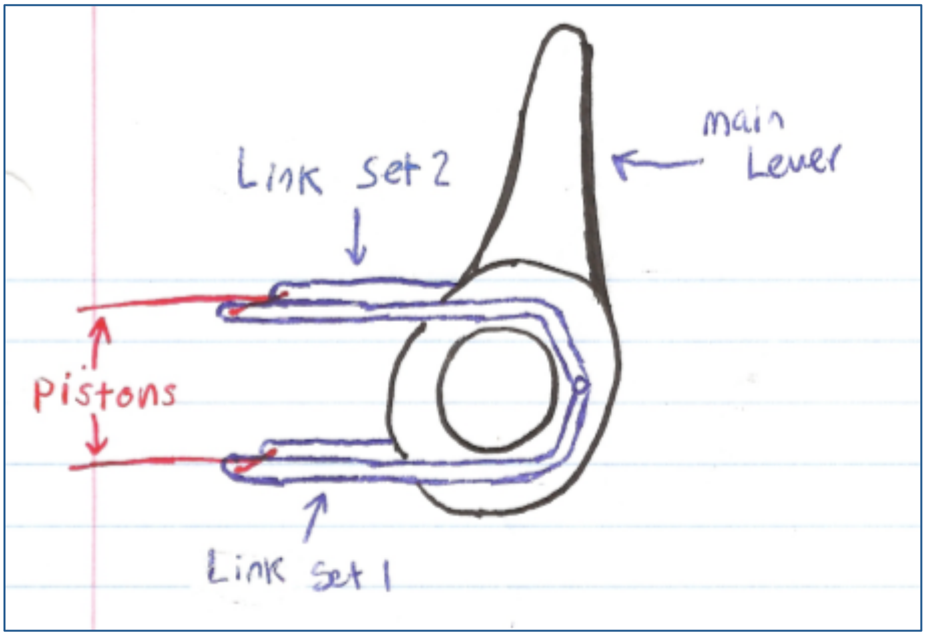


Figure 44 - Side view of one of the levers of the double lever hydraulic system. The main lever would cause motion of the two flexible link sets. A stiff joint would be connected at the end of the link sets (shown in red) and the connected to a piston.

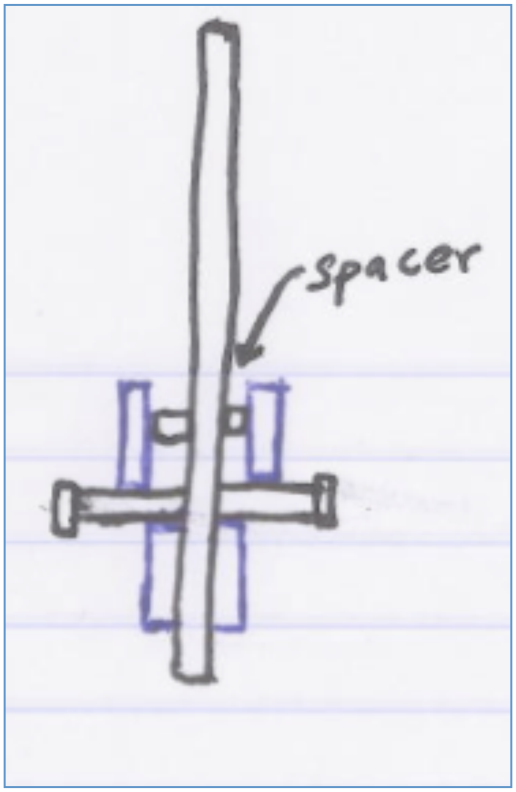


Figure 45 - Rear view of one of the levers at the user interface of the double lever hydraulic system.

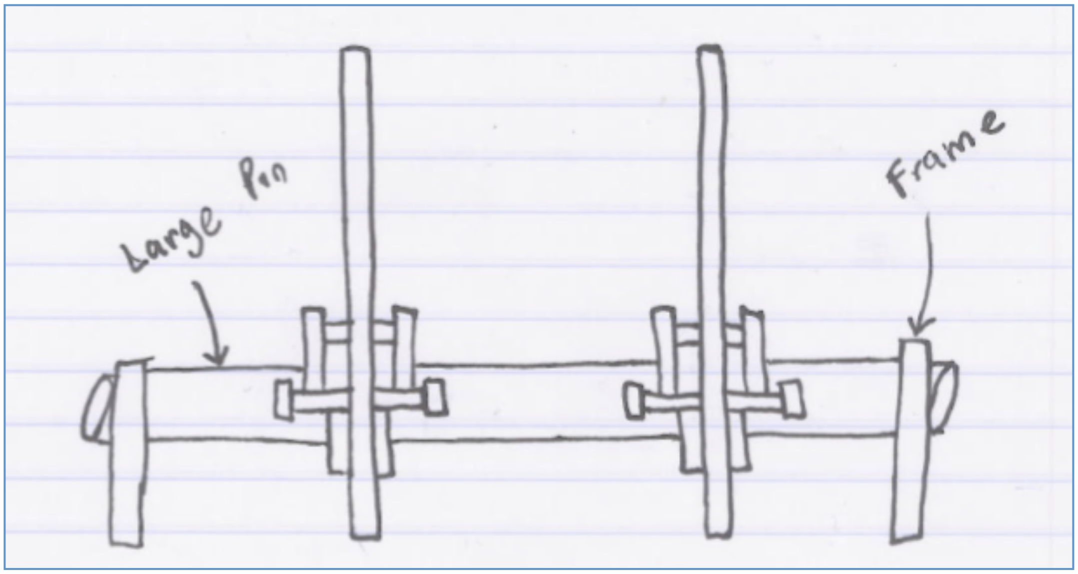


Figure 46 - Rear view of two of the levers for the double lever hydraulic system. Two levers would be connected to a small frame at the user interface and rotate about a large pin.

4.3.7 Pseudo-Fluid Rocker Handle

Figure 47 shows a lever controlled pseudo-fluid system. This system is very similar to the hydraulic rocker handle design, except small chrome steel balls are used in place of the fluid. The movement of the lever causes two pistons to push a series of small metal balls. The balls then push racks of a rack and pinion system at the TEE interface. The pinion of the rack and pinion system is mounted on the shafts of the TEE, so as the lever is moved, the TEE probe is manipulated. This system would use two levers, one for each of the shafts on the TEE.

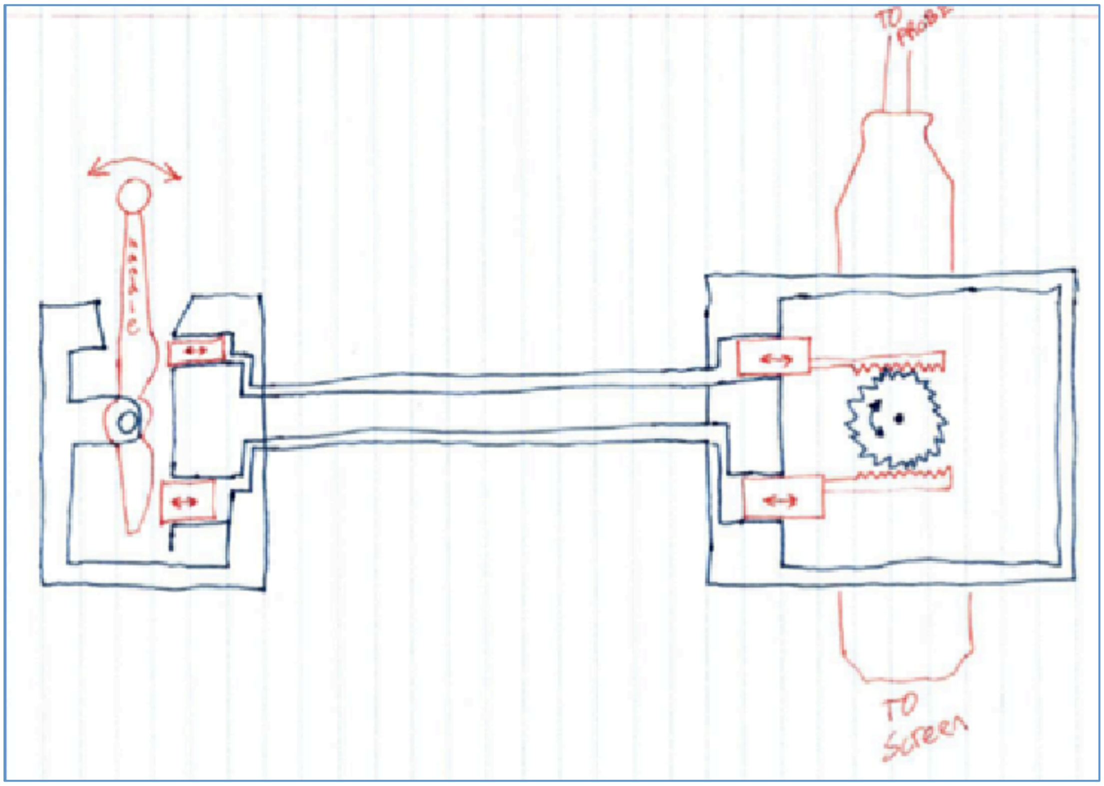


Figure 47 - Pseudo-Fluid Rocker Handle System. The system uses a handle that rock back and forth at the user interface. The handle actuates a series of small metal balls through plastic tube that push back and forth and control the movement of racks of a rack and pinion gear set at the TEE interface. The rack and pinion gear set at the TEE interface controls the shafts of the TEE, which control the movement of the TEE probe.

4.3.8 Pseudo-Fluid Double Rack & Pinion

This system is very similar to the hydraulic rocker handle design, except small chrome steel balls are used in place of the fluid. The system would have a rack and pinion at the TEE interface and the user interface. Knobs would be connected to the pinion shafts of the rack and pinion system at the user interface. Rotation of the knobs would actuate the movement of small metals ball through plastic tubes and cause the movement of racks of a rack and pinion gear set at the TEE interface. The rack and pinion gear set at the TEE interface would control the movement the shafts inside the TEE handle, which would control the movement of the TEE probe. Figure 48 shows a sketch of the pseudo-fluid double rack and pinion system. The tubes in Figure 48, labeled, incompressible fluid, would be filled with pseudo-fluid balls, not a hydraulic fluid.

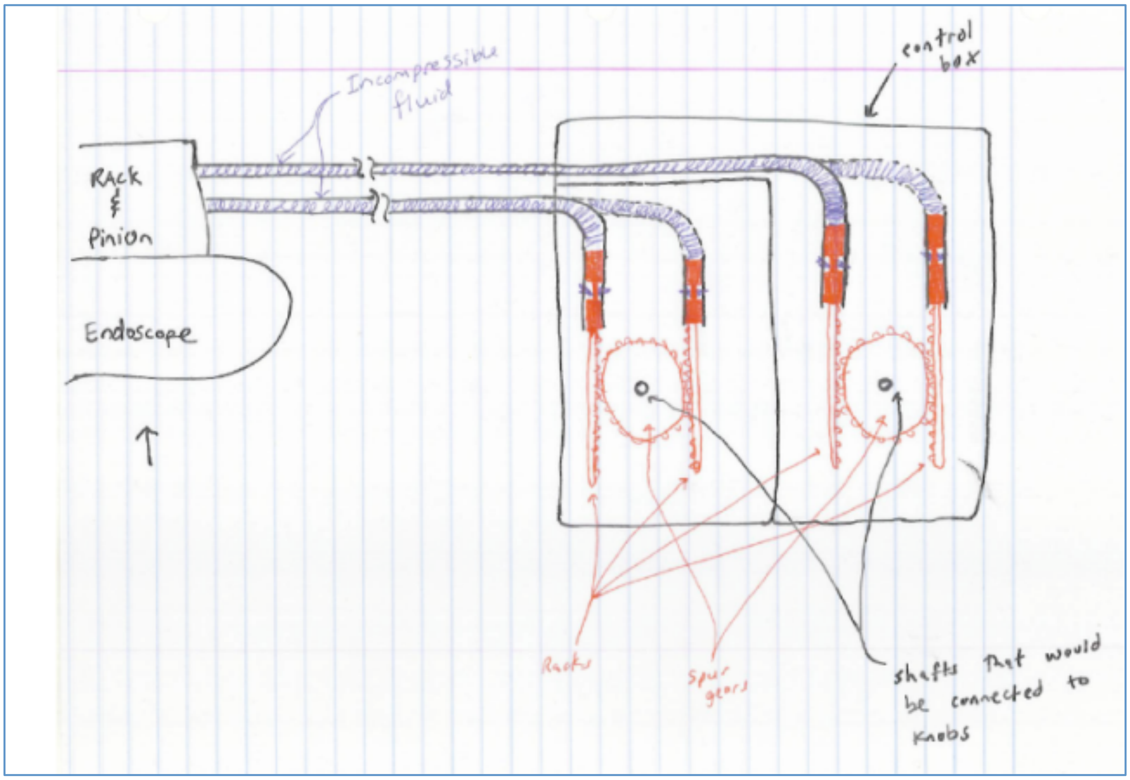


Figure 48 - Pseudo-fluid double rack and pinion. This system uses a rack and pinion gear set at the user interface and the TEE interface. Movement is transferred between the two gear sets by a series of small metal balls through plastic tubes. The rack and pinion at the TEE interface controls the shafts in the TEE, which control the movement of the TEE probe. The tubes labeled as incompressible flow are actually filled with pseudo-fluid balls not hydraulic fluid.

4.4 Zeroth Order Prototypes

Zeroth order prototypes for hydraulic, cable, and pseudo-fluid systems were created to test for feasibility of the different movement-transfer systems.

4.4.1 Basic Hydraulic System

A zeroth order prototype was built for a basic hydraulic system since many of the designs were based on a hydraulic system. It was a concern that it may not be possible to make a closed hydraulic system that will work repeatedly without problems. A zeroth order prototype of a simple closed hydraulic system to test for feasibility was created. The prototype was based on the Rocker Handle hydraulic system because that system was easiest and quickest to make. The basic sketch of this is shown in Figure 40.

First, four small plastic pistons, one of which is shown in Figure 49, were rapid prototyped with O-rings acting as seals to fit into a short section of clear vinyl tubing with an 1/2 inch outer diameter and a 3/8 inch inner diameter. One side of the tube was plugged with the plastic piston and the remaining space inside the tube was filled with water. Then the top of the tube was plugged with another plastic piston. The results were very poor. The water was not viscous enough and leaked past the O-rings. Vegetable was used in place of water to provide a fluid with more viscosity. This attempt was unsuccessful since the fluid continued to leak. The clear vinyl tubing did not keep its shape very well either, which was considered a major contributing factor to the poor results of the closed hydraulic system. Figure 50 shows the set up using the clear vinyl tubing. A piece of stock alloy tubing that also had a 3/8-inch inner diameter was also used to try and make the system work. After repeating the procedure, the results were much better, but there was still some leakage and air bubbles, which was believed to be from the poor seals (O-rings), the small coupling area between the piston and the tube (which caused the piston to move around and not be completely parallel to the rigid tubing the entire time), and the porous pistons created in the rapid prototype machine. There was also a fair amount of static friction that needed to be overcome due to the O-ring sticking to the inside wall of the cylinder.

Figure 49 - Rapid Prototyped Piston for Zeroth Order Prototype of Basic Hydraulic System. This was used for a feasibility test. Refer to text for more details regarding the experiment.

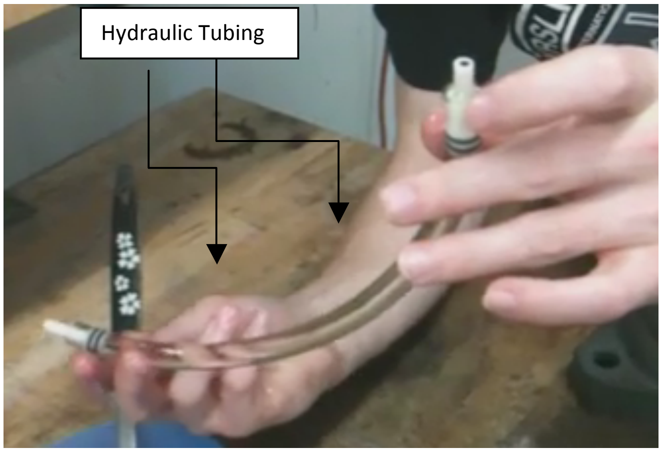


Figure 50 - Clear Vinyl Tubing for Hydraulic System including tubing, pistons and fluid. The system did not work very well because when one piston was pushed, fluid leaked out the other side.

Brass pistons, which were turned down in a lathe, were also used in attempt to increase the contact area between the piston and tube. Figure 51 shows an example of one of the brass pistons. Using these brass pistons instead of the plastic pistons produced better results, but leakage and static friction were still issues. Hydraulic systems proved not to be feasible for this project.

Figure 51 - Brass Piston Used for Zeroth Order Prototype of Basic Hydraulic System.

4.4.2 Rocker Handle - Cable System

A zeroth order prototype of a cable-based system was constructed. This prototype was based upon the rocker handle cable system show in Figure 41. The rack and pinion part of the system, which would be used at the TEE interface, is shown in Figure 52. Two, five foot long bicycle cables were connected to the end of the racks in the rack and pinion prototype. L-shaped aluminum brackets were screwed onto a plastic board in order to hold up the wire along with four hex nuts and two screws with through holes in them. This was done in order to keep the cables straight so it could better control the rack and pinion. This attachment was also used as tensioning device for the cables (Figure 53).

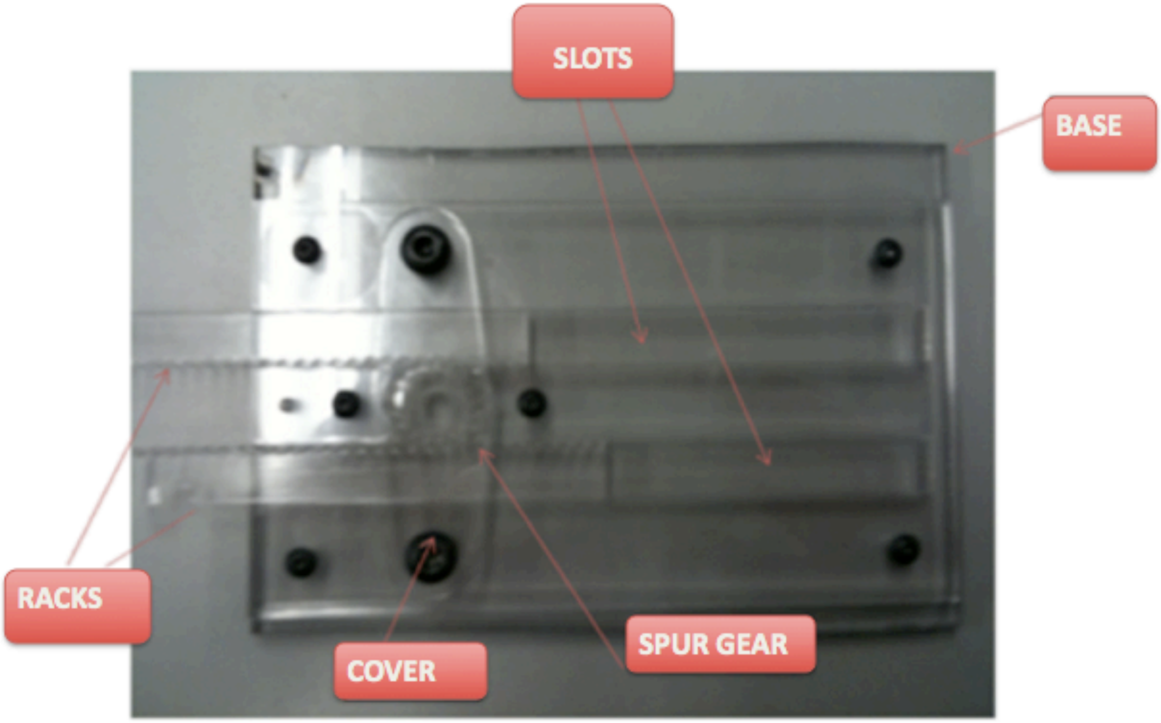


Figure 52 - Rack and Pinion Assembly for the TEE interface used for the zeroth order prototype for the zeroth order prototype of the rocker handle cable system.

Figure 53 - Rack and Pinion connected to bicycle cable attached to an L-bracket, which is used for support and tensioning. This was used in the creation of the zeroth order prototype of the rocker handle cable system.

The handle is located on the other end of the system at user interface. This end of the system also has an L-bracket system similar to the one used at the TEE interface. The heads of the cables are small cylinders and are connected to the handle. The handle, along with the bracket, was bolted down to a plastic board in order to better control the system. Figure 54 shows the user interface of the system. The entire cable system is shown below in Figure 55. The cable resulted in a system that worked but the cables seemed to stretch. The cable driven system proved to be feasible but maybe not the best solution.

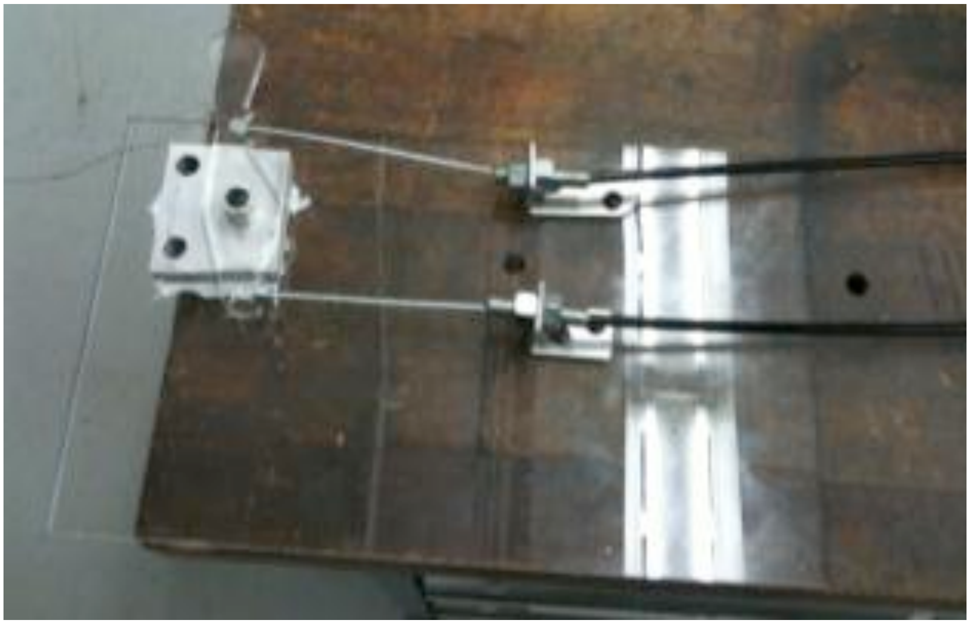


Figure 54 - Rocker Handle- User Interface of the Rocker Handle System zeroth order prototype, showing handle, cables, and tensioning system.

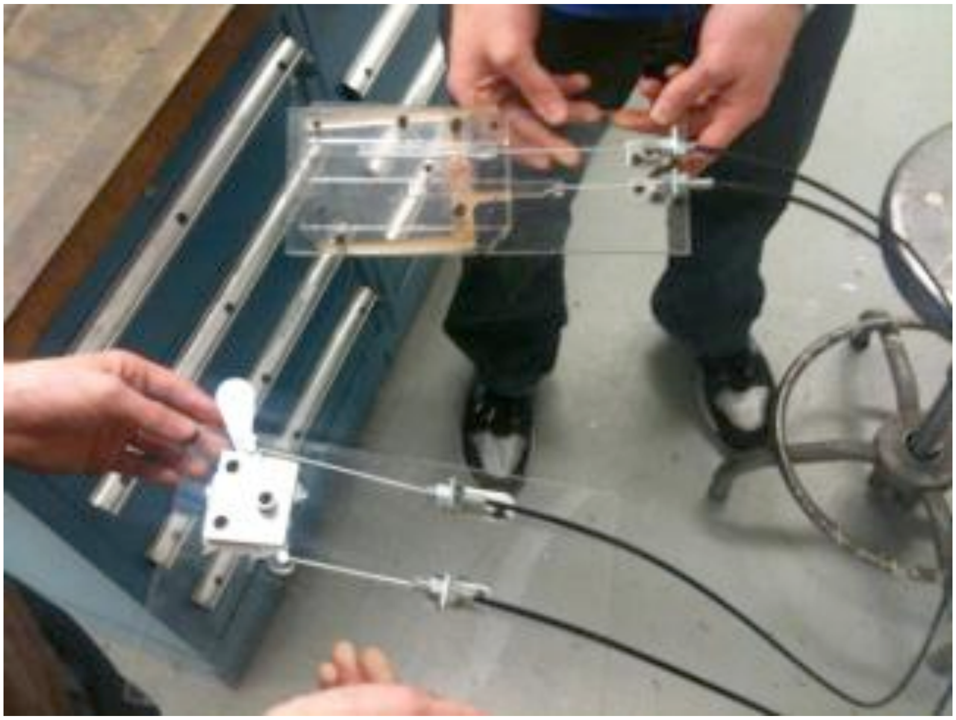


Figure 55 - Entire Rocker Handle Cable System zeroth order prototype. The rack and pinion shown in the top of the photo simulates the rack and pinion that would be used at the TEE interface. The black wires are bicycle cables that were used to transfer movement from the TEE interface to the user interface. The user interface located in the bottom of the photo and is manipulated by a rocking handle that creates a pull-pull system.

4.4.3 Pseudo-Fluid Ball System

The pseudo-fluid ball system combines the advantages of backlash control of the hydraulic systems, but does not leak and does not need to overcome a large amount of static friction to operate. The construction of the pseudo-fluid ball system required approximately four hundred chrome steel balls (3mm in diameter). The balls were inserted into a five-foot section of high-density polyethylene tube that had an I.D. of 0.125 inches and an O.D. of 0.250 inches. Stainless steel pistons (0.125 inches in diameter) on either end of the tube acted as pushers to push the balls back and forth, acting as a push-push system. Figure 56 shows the pseudo-fluid ball system. The results of this system were very positive. The amount of force to push the balls through the tube was very minimal, and there was no backlash. This system provided advantages of both the cable and hydraulic systems.

Figure 56 - Pseudo-fluid ball system. The system consists of a plastic tube filled with small ball bearings that can be pushed back and forth by pistons. This system is advantageous because provides advantages of cable and hydraulic systems and does not include disadvantages such as leaking (hydraulic) and stretch (cables).

4.4.4 Zeroth Order Prototype Summary

The three different movement-transfer systems were tested for feasibility. The hydraulic system did not prove to be feasible. The cable system was feasible and did not yield very much backlash. The pseudo-fluid system resulted in the best performance, as it yielded no backlash and no leakage. Cable and pseudo-fluid systems were analyzed further in order to choose a final design.

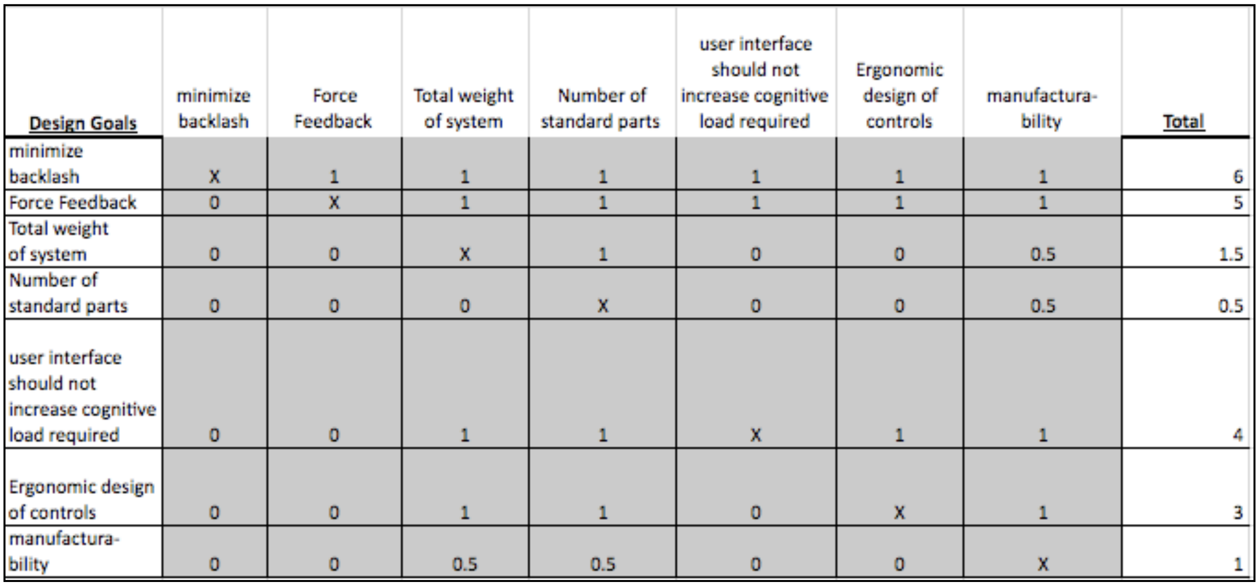
Chapter 5 Design Selection

Chapter 5 discusses the process of selecting a final design. Many factors were considered. First, the design goals were evaluated and put into a pair-wise chart to determine which were the most important. Then, the design goals were put into a decision matrix with the full system designs to see which designs were the best. After analyzing these charts as well as the results of the zeroth order prototypes, a second decision matrix was constructed in order to select the final design.

5.1 Preliminary Design Selection

After developing preliminary designs, the design specifications were reevaluated, and the specifications that were thought to potentially have variability amongst the different designs were put into a pair-wise table. This gave a better indication of which specifications weighed more in a design matrix. Table 2 shows the pair-wise chart comparing various design specifications against each other. A score of a 1 meant was given to the goal that was more important. A score of 0.5 was given of the goals were of equal importance, and a score of 0 was given if the goal was less important goal. Minimizing backlash resulted in being the most important goal. Having the correct amount of force feedback turned out to be the second most important design goal.

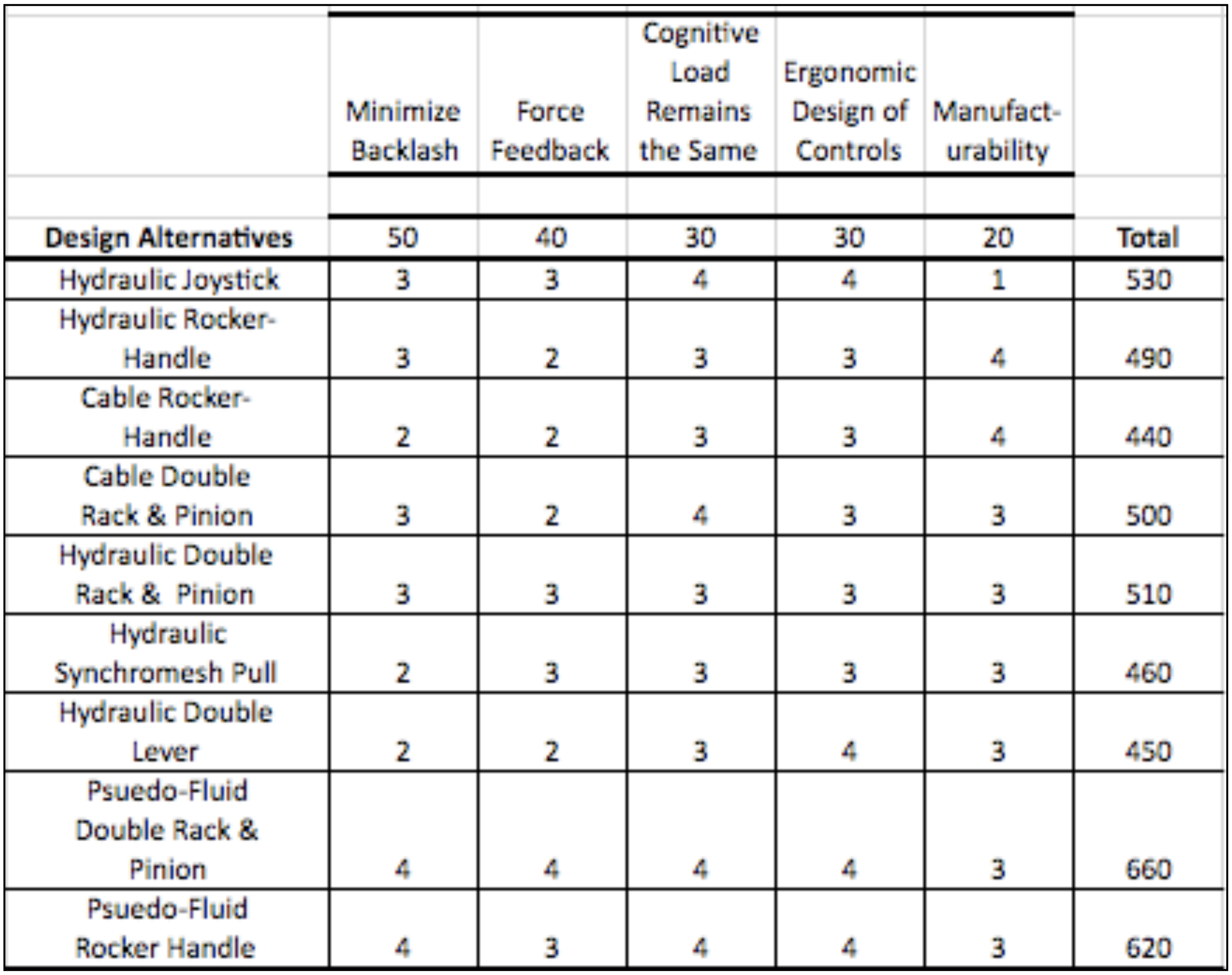
Table 2 - Pair-wise chart of design goals that may have variability amongst the different designs. This chart was used to find relative importance of the design goals.



Design Goals	minimize backlash	Force Feedback	Total weight of system	Number of standard parts	user interface should not increase cognitive load required	Ergonomic design of controls	manufactura-bility	Total
minimize backlash	X	1	1	1	1	1	1	6
Force Feedback	0	X	1	1	1	1	1	5
Total weight of system	0	0	X	1	0	0	0.5	1.5
Number of standard parts	0	0	0	X	0	0	0.5	0.5
user interface should not increase cognitive load required	0	0	1	1	X	1	1	4
Ergonomic design of controls	0	0	1	1	0	X	1	3
manufactura-bility	0	0	0.5	0.5	0	0	X	1

The results of the pair-wise chart showed that backlash, good force feedback, simplicity of user interface, and ergonomic design of controls were the most important design goals. After analyzing the results of the pair-wise chart, a decision matrix (Table 3) was made using the results of the pair-wise chart to give relative weighting factors for each of the design goals included. Some of the design goals were omitted from the decision matrix because some of the designs would receive the same score for that specific design goal, therefore skewing the results. The pseudo-fluid designs received the highest scores. Each goal in the decision matrix was given a value based on what the projected outcome was expected to be. Table 4 shows what each value for every goal in the decision matrix represents.

Table 3 - Decision Matrix for the different full system design alternatives. This chart was used to show which designs were the best.



	Minimize Backlash	Force Feedback	Cognitive Load Remains the Same	Ergonomic Design of Controls	Manufact-urability	
Design Alternatives	50	40	30	30	20	**Total**
Hydraulic Joystick	3	3	4	4	1	530
Hydraulic Rocker-Handle	3	2	3	3	4	490
Cable Rocker-Handle	2	2	3	3	4	440
Cable Double Rack & Pinion	3	2	4	3	3	500
Hydraulic Double Rack & Pinion	3	3	3	3	3	510
Hydraulic Synchromesh Pull	2	3	3	3	3	460
Hydraulic Double Lever	2	2	3	4	3	450
Psuedo-Fluid Double Rack & Pinion	4	4	4	4	3	660
Psuedo-Fluid Rocker Handle	4	3	4	4	3	620

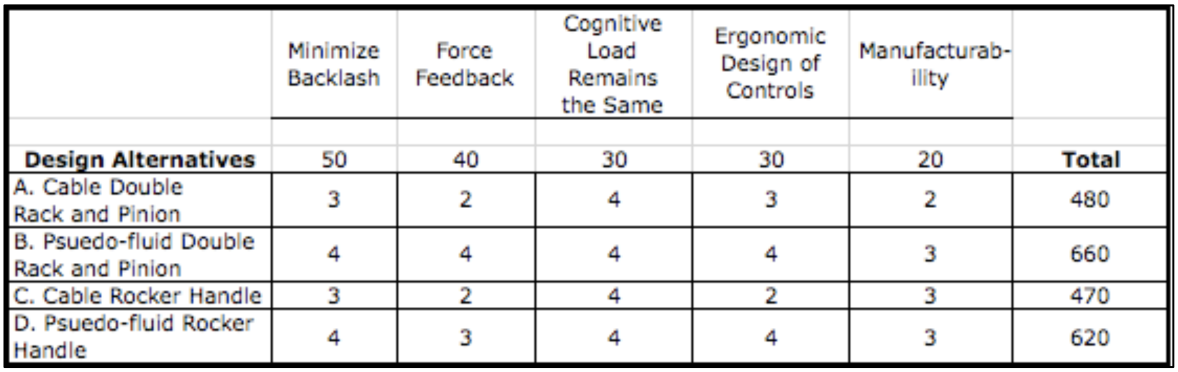
Table 4 - Score descriptions for decision matrix in Table 3

	Backlash	**Force Feedback**	**Cognitive Load Remains the Same**	**Ergonomic Design of Controls**	**Manufacturability**
1	>20% increase in backlash	> 25% decrease in force feedback compared to current TEE	Very hard to use	Unacceptable amount of awkward positioning, unacceptable amount of force. One feels tired and strained after use, may affect other activities during procedure	Very difficult to manufacture/assemble, advanced procedures/techniques required, many processes required
2	10-20% increase in backlash	>10-25% decrease in force feedback compared to current TEE	More complicated than current design	Small amount of awkward position required, not a large amount of force required, one may feel a little tired or strained, but use does not affect other activities during procedure	Somewhat difficult to manufacture/assemble, advanced procedure/techniques required for some of the processes, increases processes required
3	Same as current backlash within 10%	Force feedback is equal to current force feedback of TEE	Same cognitive load currently required	No awkward positioning of hands or feet, increased effort required to manipulate controls, small amount of increased strain during use, does not affect other activities during procedure	Fairly easy to manufacture/assemble, for the most part-minimal amount of procedures required, some additional processes may be required
4	Less than 10% better	Force feedback is slightly greater than current force feedback of TEE	Less complicated than current design	No awkward positioning of hands or feet, little effort required to manipulate controls, no additional strain to person manipulating, does not affect other activities in procedure	Very easy to manufacture and assemble, minimal amount of procedures required to manufacture/assemble

5.2 Final Design Selection

Hydraulic designs were ruled out after analyzing the zeroth order prototypes and the first decision matrix. Four remaining designs were evaluated using a final decision matrix, Table 5.

Table 5 - Final Decision Matrix used to determine the final design.



	Minimize Backlash	Force Feedback	Cognitive Load Remains the Same	Ergonomic Design of Controls	Manufacturability	
Design Alternatives	50	40	30	30	20	**Total**
A. Cable Double Rack and Pinion	3	2	4	3	2	480
B. Psuedo-fluid Double Rack and Pinion	4	4	4	4	3	660
C. Cable Rocker Handle	3	2	4	2	3	470
D. Psuedo-fluid Rocker Handle	4	3	4	4	3	620

The pseudo-fluid systems received the highest scores. The pseudo fluid double rack and pinion system received the highest score, so that design was chosen as the final design. This system was chosen because it yields no backlash, has good force feedback control, requires the same amount of cognitive load that it already required in the current TEE to operate, the controls are ergonomic, and the system would be easy to manufacture and assemble.

Chapter 6 Prototype Development

Chapter 6 describes the design, development, and construction of the pseudo-fluid control extension system.

6.1 Prototype Design

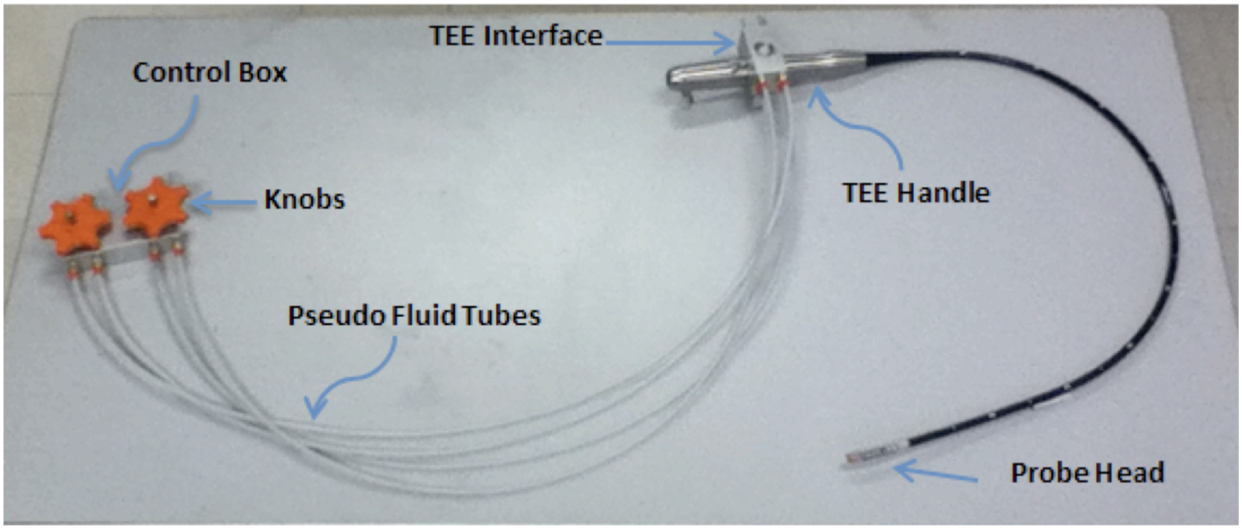


Figure 57 - Final Prototype Assembly.

The prototype (Figure 57), works through a system of rack and pinions. The rack and pinions on the TEE side of the system are linked to the rack and pinions on the control side of the system through a pseudo-fluid system. The concept of the pseudo fluid system uses a tube filled with steel balls to transfer loads. The tube, which is connected to the control box and TEE interface block using a standard air fitting (Figure 58) is high-density polyethylene with an outer diameter of .250 inches and an inner diameter of .125 inches. The tube is filled with .118 inch diameter steel balls. This gives .007 inches of clearance for each ball in the tube, allowing them to slide and roll easily and also allowing the tube to bend without binding on the balls. If too much clearance is given to the balls in the tube, a larger portion of the applied load is transferred into a force component directed radially into the walls from each ball rather than from one ball to the next (Figure 59).

Figure 58 - Standard Air Fitting used in final design to attach plastic tubing to aluminum blocks

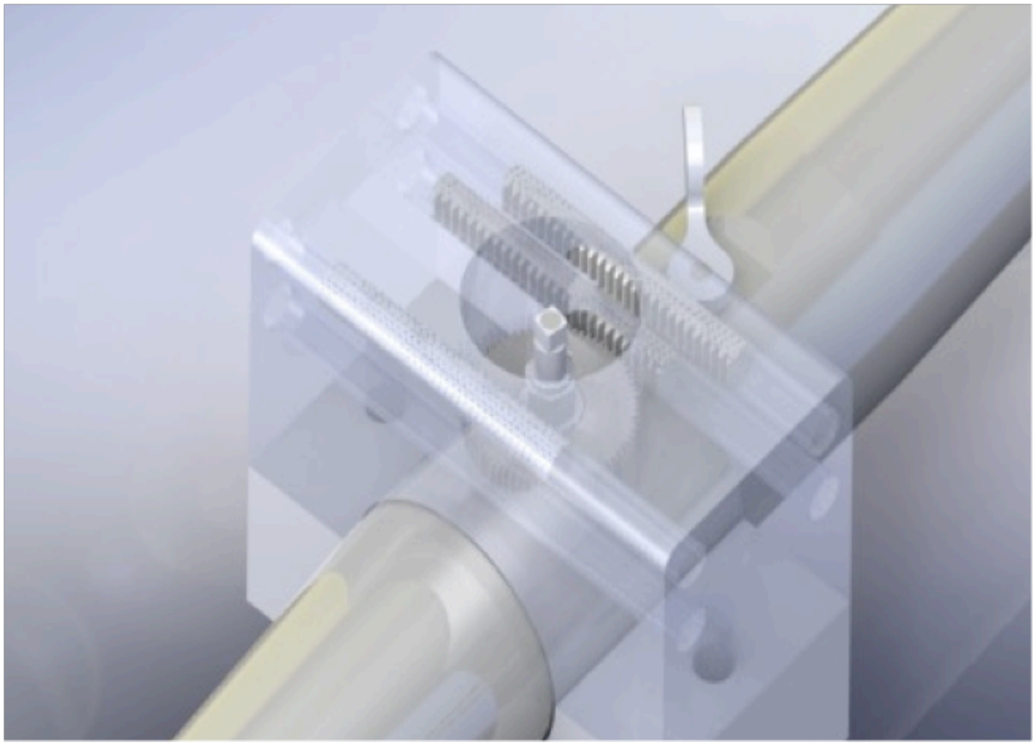


Figure 59 - TEE interface for pseudo-fluid system, shown transparent with top gear and bottom racks removed to show detail.

The bodies of both the TEE interface and the control box are made of aluminum. Aluminum is an ideal material for these parts in the prototype because it is easy to machine, strong, and lightweight. Aluminum can also be polished for aesthetic purposes. One downside of aluminum in this application is that it is not a good bearing surface, it will wear away over time and it can also cause galling issues. High density polyethylene was chosen for the pseudo-fluid tubing because it has a good flexibility while not being so soft as to interfere with the ball movement and it was readily available in a large quantity. The balls are made out of chrome steel so that they will not wear out from rubbing and sliding against each other. The shafts for the control knobs and gears are low carbon steel; it is inexpensive and exceeds all requirements for this task. The knobs and the gear adapters were made on the rapid prototype machine because plastic is suitable for these parts in a prototype application, and they would have been difficult to make otherwise. The pushers that transmit force from the racks to the balls are made from plastic, this allows them to flex slightly with the tubing if it is required.

6.2 Prototype manufacture and assembly

Parts for the prototype were manufactured in the Washburn shops. The original knobs of the TEE were removed, and in each ones place is a gear. The gears are adapted to the shaft with small adapter pieces made in the rapid prototype machine (Figure 60).

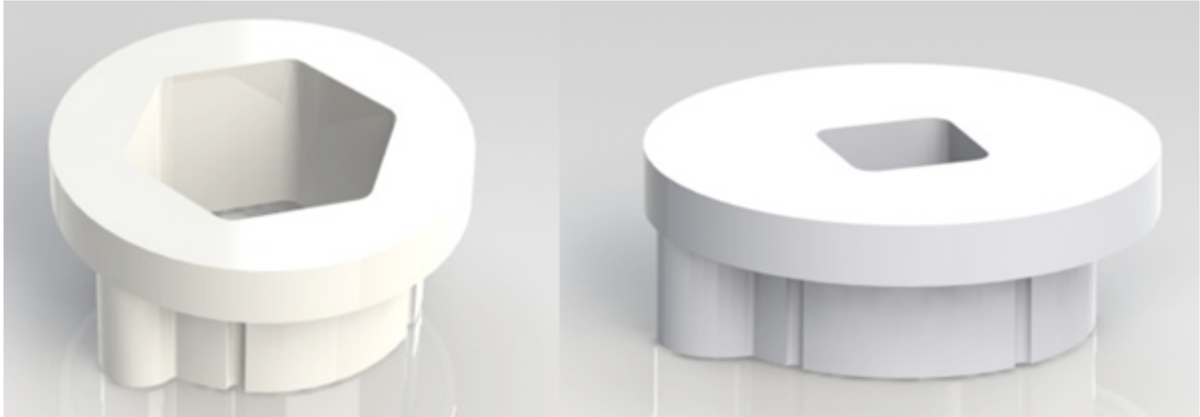


Figure 60 - Small adapters pieces that attach gears to the shafts in the TEE handle.

The TEE interface clamps around the body of the TEE, with a thin rubber spacer to prevent marring and help ease any misalignment issues induced during assembly. Each gear on the TEE shafts mate with two pinions, which slide within brass bushings in the TEE interface block. The controls of the prototype are located at the control box. This is an aluminum block with several holes in it to accommodate racks, gears and bearings. The control knobs and corresponding gears are rigidly attached to each other; when the knob is turned, it turns the gear. These shafts run in bearings within the control block. Each gear mates with two racks, which slide within the control block. Each of the 8 racks used in the assembly pushes on a plastic push rod, which is the interface between the racks and the pseudo-fluid balls. These pusher rods are required because the tubes have an inner diameter of .125 inches, and the racks have an outer diameter of .250 inches. The push rods have an outer diameter of .120 inches, allowing them to slide within the tubing. The final knobs, Figure 61, are designed with radii on the corners and smooth curves to maximize comfort during use. Pockets were added for aesthetics and to reduce weight.

Figure 61 – Ergonomically designed knob used in prototype.

6.3 Mechanical Advantage and Gear Size Calculations

The purposes of the following calculations were to find the appropriate gear size, knob size, and mechanical advantage for the top and bottom parts of the system. The first step was to find how much force it took to push about 500 stainless steel (or chrome steel) balls, 3mm in diameter, through 5 feet of High Density Polyethylene (HDPE) tubing that has inner diameter of 0.125 inches. This was done experimentally and was found to average 0.35 lbf. This experiment is described in section 7.1.2. Next, the torque to rotate the current TEE was determined experimentally to be 1.20 and 1.79 in-lbf for the top and bottom knob, respectively.

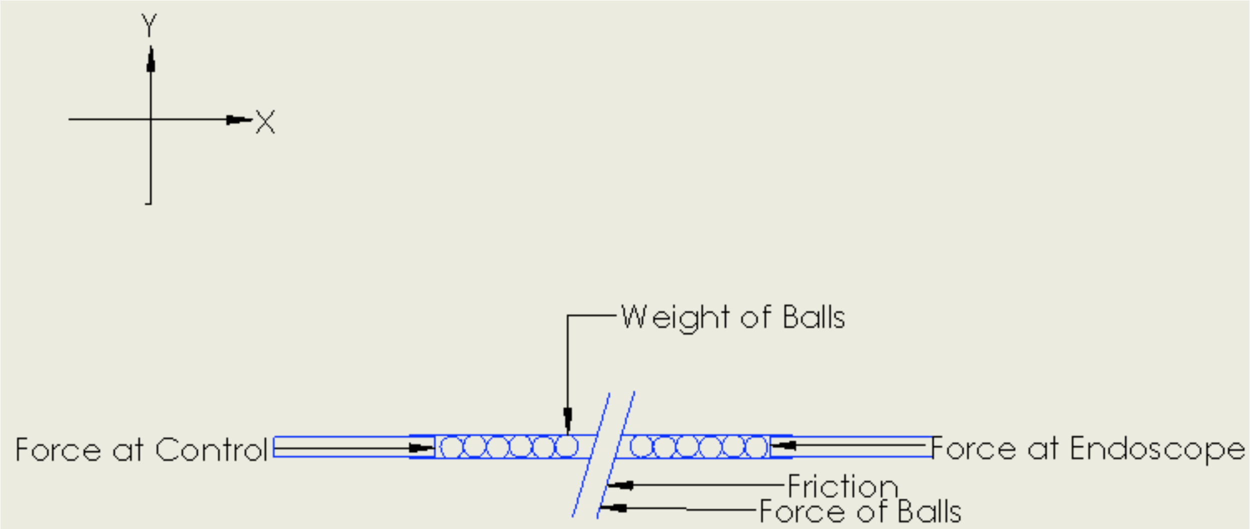


Figure 62 - Free Body Diagram of Pseudo-Fluid System.

The average torque found to rotate the knobs was used to in order to find how much force would be transmitted by a 1.0 diametral pitch spur gear at the TEE interface in place of the larger diameter knobs by using the equation [T = F*R] where T is the torque, F is the force transmitted, and R is the radius. In order to get a similar "feel" at the control interface, it was determined that the force should equal the summation of the force to push the balls through the tube and force transmitted at the TEE interface. Figure 62 shows a free body diagram of the pseudo-fluid system. Knowing the force at the control interface, the torque needed to rotate a pinion gear for different diametral pitches was calculated using the equation [T = F*R). The same amount of torque would be needed to rotate larger diameter knobs that would be required to rotate the gears in the control box. So, the force transmitted by the knobs was calculated using the previous torque calculations and the specific diameter of the knob. Lastly, the mechanical advantage was calculated using the initial force transmitted at the spur gear at the TEE interface and the force transmitted at the knob at the control interface by using the equation:

$$MA = F_{initial} / F_{control}$$

The mechanical advantage was calculated for a 1.0-inch diametral pitch spur gear at the TEE interface, three different pinion gears at the control interface (0.6042, 0.75, and 1.0 inches), and several different control knob sizes. The gear sizes were chosen based what was commercially available and on the significant figures listed in the catalogue. The size knob that would provide the most ergonomic design determined the diameter of the knobs. The results shown in Figure 63 and Figure 64 reveal that knob diameters between 2 and 4 inches produce a mechanical advantage between 1 and 3 for the top and bottom knobs. The full calculations that were used to find these results are in Appendix E.

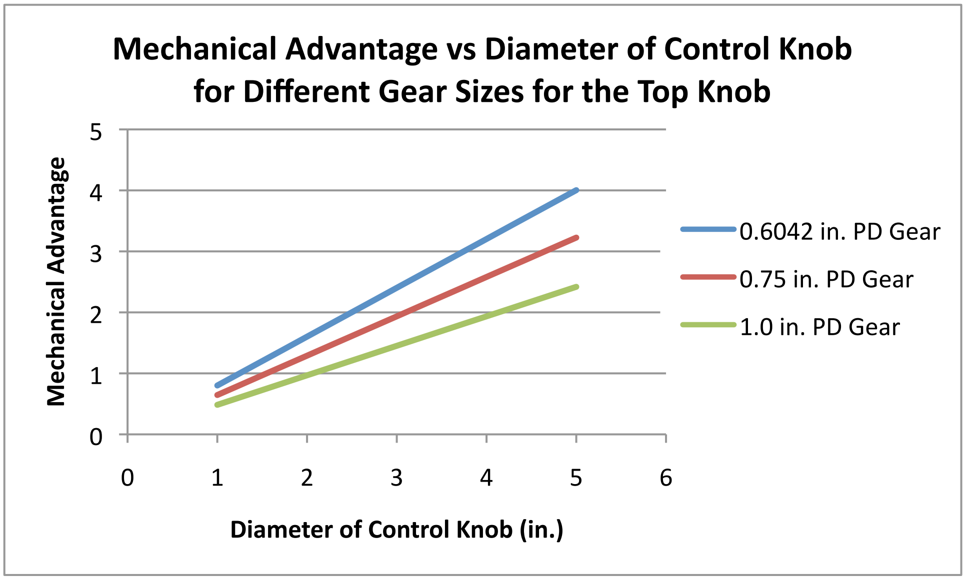


Figure 63 - Mechanical advantage vs. control knob diameter for different pinion gear diametral pitches for the top knob.

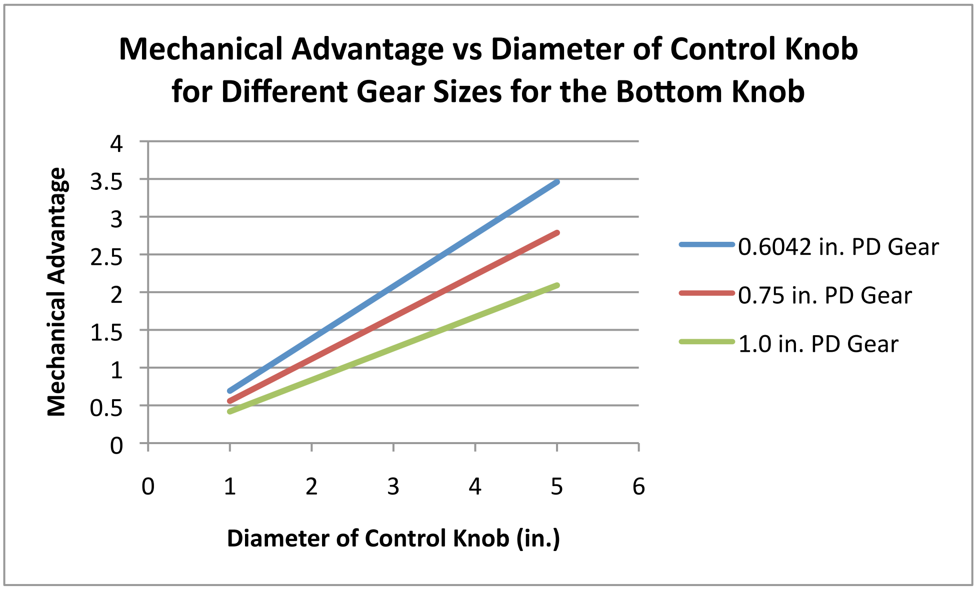


Figure 64 - Mechanical advantage vs. control knob diameters for different pinion gear diametral pitches for the bottom knob.

Chapter 7 Testing and Results

7.1 Testing

This section describes different tests that were conducted in order to analyze the development of the pseudo-fluid control extension system.

7.1.1 Torque required to rotate knobs of existing TEE

The purpose of this test was to determine how much torque was required to rotate the knobs of the existing TEE. This test was completed by knotting one end of a string to a portable force gauge and attaching the other end to the tip of one of the knobs on the TEE handle, and then the knobs were pulled tangentially by the force gauge on the horizontal plane. The results of this test showed that the average tangential force to pull the top and bottom knob was 1.50 and 1.79 pounds, respectively. The torque to rotate the knobs was calculated using the following equation:

$$T = F*R$$

Where T is the torque required to twist the knobs, F is the tangential force required to pull the knobs, and R is the radius of the knobs.

Figure 65 shows the radii of the knobs. The radius of the top knob is about 0.8 inches (from where string attached to the knob) and the bottom knob is about 1.0 inches (from where the string attached to the knob). The average torque required to rotate the knobs was 1.2 and 1.79 in-lbf for the top and bottom knobs, respectively. Table 6 shows the results. Appendix C shows a detailed report of the experiment.

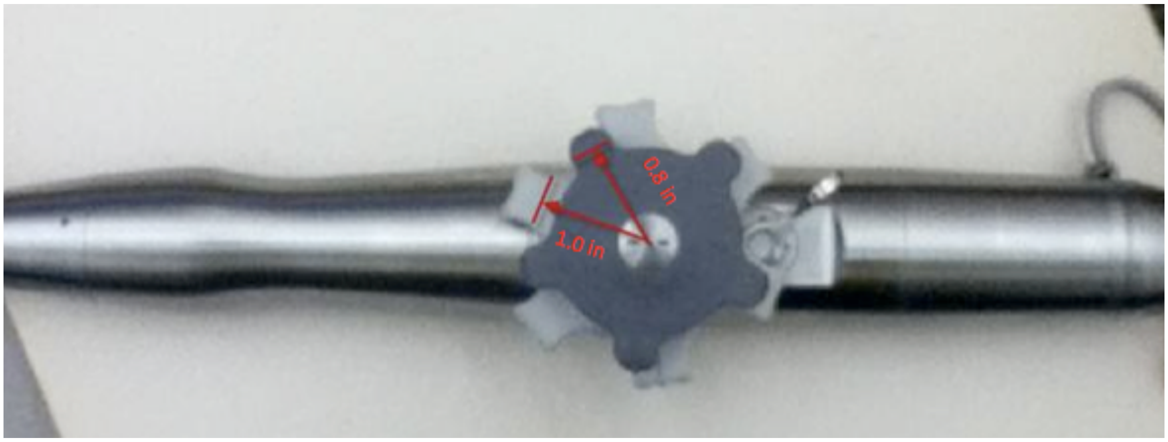


Figure 65 - Knobs of the TEE probe, showing the radii of the two knobs from where they were pulled in the determination of how much torque was required to rotate the knobs.

Table 6 – Torque required to rotate the knobs of the TEE handle. First, the tangential force required to pull the knobs using a piece of string was measured using a portable force gauge. Then, the torque was calculated using the known radius values of the knobs.

	Top Knob Force (lbs)	Bottom Knob Force (lbs)	Torque (in-lb) Top Knob	Torque (in-lb) Bottom Knob
1	1.14	1.41	0.91	1.41
2	1.62	1.80	1.30	1.80
3	0.97	2.14	0.78	2.14
4	1.97	0.91	1.58	0.91
5	1.58	1.52	1.26	1.52
6	1.43	2.14	1.14	2.14
7	1.80	2.50	1.44	2.50
8	1.18	1.14	0.94	1.14
9	1.59	1.99	1.27	1.99
10	1.67	2.36	1.34	2.36
Average	1.50	1.79	1.20	1.79
S.D.	0.31	0.53	0.25	0.53

7.1.2 Force required to push pseudo-fluid balls through plastic tubing

The purpose of this experiment was to determine the force required to push approximately 400 ball bearings through five feet of plastic tubing. This was determined by pushing the balls through the section of tubing with a metal “plunger” that acted as the connection between a portable force gauge and the pseudo-fluid balls. The test was conducted with the tube straight and with the tube wrapped around different objects with varying diameter. The average force to push the balls through a straight section of high-density polyethylene (HDPE) tubing was 0.35 pounds. The average force to push the pseudo-fluid balls through the plastic tubing at various radii was 0.35 lbf (Table 7).

Table 7 - Force required to push stainless steel balls through HDPE Tube of varying radii.

Force Data - All values in lbf					
Trial	Straight	Radius of Curvature, R = 2.34375"	Radius of Curvature, R= 3.75"	Radius of Curvature, R= 6.875"	Radius of Curvature, R= 10.703"
1	0.24	0.4	0.48	0.21	0.27
2	0.4	0.33	0.53	0.26	0.27
3	0.25	0.36	0.53	0.23	0.48
4	0.34	0.42	0.46	0.24	0.39
5	0.35	0.41	0.61	0.23	0.32
6	0.31	0.46	0.58	0.24	0.48
7	0.29	0.65	0.62	0.26	0.29
8	0.34	0.58	0.60	0.25	0.25
9	0.25	0.49	0.52	0.25	0.26
10	0.28	0.49	0.69	0.23	0.23
Average	0.31	0.46	0.56	0.24	0.32
S.D.	0.05	0.10	0.07	0.02	0.09

7.1.3 Determination of whether pseudo-fluid balls roll or slide inside plastic tubing

The main purpose of this test was to determine whether the pseudo-fluid balls rolled, slid, or some combination of the two inside the plastic tube when loads were transferred. Various types of balls, including ping pong balls and billiards balls, were placed in a line inside a track on a smooth surface with a constant clearance between the outside of the balls and the inside of the tracks. Various surfaces and various amounts of clearance were tested. In most cases, the balls exhibited a combination of rolling and sliding. As the amount of clearance was increased, the balls seemed to roll more until the amount of clearance approached the amount where two balls could fit across between the tracks, at which point the balls started to transmit more force into the inside walls than longitudinally from ball to ball. Table 8 shows a table explaining some of the results.

Table 8 - Results of test determining whether pseudo-fluid balls rolled or slid inside plastic tubing. Balls seemed to roll more often with a larger clearance between the balls and the inside walls of a track. Surface did not seem to have a major effect on whether the balls rolled or slid.

	Billiard Balls	**Ping Pong Balls**
Billiard Table	With a very tight clearance, the balls both roll and slide. But as tolerance increases the balls roll	When there was little to no clearance, the balls slid. When clearance was increased, they rolled.
Smooth Counter Surface	With a very tight clearance, the balls both roll and slide. But as tolerance increases the balls roll	When there was little to no clearance, the balls slid. When clearance was increased, they rolled without any sliding.

7.1.4 Torque required to rotate knobs of pseudo-fluid system

The purpose of this test was to determine how much torque was required to rotate the knobs of the pseudo-fluid system. This test was completed by knotting one end of a string to a portable force gauge and attaching the other end to the tip of one of the knobs at the control box of the pseudo-fluid system, and then the knobs were pulled tangentially by the force gauge on the horizontal plane. The results of this test showed that the average tangential force to pull the top and bottom knob was 1.68 and 4.65 pounds, respectively. The torque to rotate the knobs was calculated using the following equation:

$$T = F*R$$

Where T is the torque required to twist the knobs, F is the tangential force required to pull the knobs, and R is the radius of the knobs

Figure 66 shows the radii of the knobs. The radius of both knobs is about 1.75 inches (from where string attached to the knob). The average torque required to rotate the knobs was 2.93 and 8.14 in-lbf for the top and bottom knobs, respectively. Table 9 shows the results.

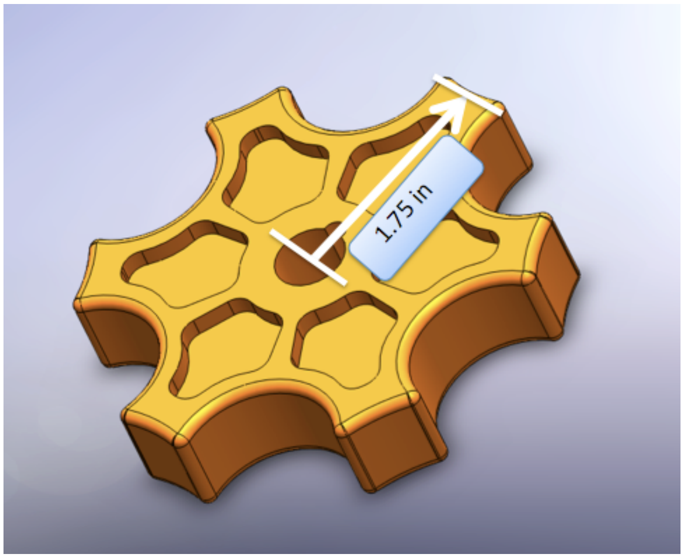


Figure 66 - Knobs of the pseudo-fluid control extension system, showing the radii of the two knobs from where they were pulled in the determination of how much torque was required to rotate the knobs.

Table 9 – Torque required to rotate the knobs of the pseudo-fluid control extension system. First, the tangential force required to pull the knobs using a piece of string was measured using a portable force gauge. Then, the torque was calculated using the known radius values of the knobs.

	Top Knob Force (lbs)	Bottom Knob Force (lbs)	Torque (in-lb) Top Knob	Torque (in-lb) Bottom Knob
1	1.47	4.50	2.57	7.88
2	1.72	4.52	3.01	7.91
3	1.91	4.92	3.34	8.61
4	1.50	4.37	2.63	7.65
5	1.61	4.63	2.82	8.10
6	1.74	4.96	3.05	8.68
7	1.88	4.59	3.29	8.03
8	1.56	4.39	2.73	7.68
9	1.78	4.83	3.12	8.45
10	1.59	4.82	2.78	8.44
Average	1.68	4.65	2.93	8.14
S.D.	0.15	0.22	0.27	0.38

7.2 Results

The resulting system showed that manipulating the TEE from a five-foot distance is feasible. All of the major design specifications were achieved. The system maintained two degrees of freedom. The existing probe was not changed. The user interface was ergonomically designed and did not increase the cognitive load required. The range of motion of the new system mimics the range of motion of the original TEE; however, it does not completely duplicate the range of motion because the racks are not positioned exactly right. The range of the probe due to the top knob was originally a 90 degree range, with 45 degrees in either direction. The range of the probe due to the top knob in the extension system is about 60 degrees, 30 in either direction. The range of the probe due to the bottom knob was originally about 180 degrees, 45 degrees one way and 135 degrees the other way. The range of the probe head due to the bottom knob of the extension system is about 110 degrees, 35 degrees one way and about 75 degrees the other way. If the racks were positioned correctly during assembly and there was no backlash present within the pseudo fluid system, the full range of motion would have been achieved. If longer racks were used, assembly would have been easier and the full range of motion of the TEE probe would have been achieved. The probe head can be stopped at any point during its rotation with minimal backlash, although there is backlash at the user interface. The main source of backlash is due to the fact that the positioning of the end of the tube can shift back and forth because they are attached to the TEE interface and control box using air fittings (Figure 58) that move slightly (because the “push-to-connect” feature is not very strong). This causes there to be small gaps (about 2-3 ball lengths, which is about 6-9mm) between the balls and the push rods and/or racks. This problem causes the knobs at the control box to rotate about 10 degrees without any movement of the TEE probe. If the small gaps were eliminated, the range of motion would be improved. The torque required to rotate the knobs was a little higher than expected, but the design specification for “the torque to be high enough so that if the controls were accidently bumped into, the position of the probe would not be changed” was achieved. It was expected that there the new knobs would require twice as much torque to rotate. A comparative plot showing the torque to rotate the top and bottom knobs for the original TEE and the pseudo-fluid system is seen in Figure 67. The “top” knob for the pseudo-fluid system refers to the knob at the control box that controls the degree of freedom of the TEE probe originally manipulated by the top knob in the TEE while the “bottom” knob refers to the knob at the control box that controls the degree of freedom of the TEE probe originally manipulated by the bottom knob in the TEE. The amount of torque to rotate the knob in the pseudo-fluid system that controls the “top knob” of the original TEE was about two times more than the original value. The torque to rotate the knob at the control box that manipulates the “bottom knob” is about 4 times greater than the original. This problem stems from the rack slots in the control box for the knobs being slightly misaligned.

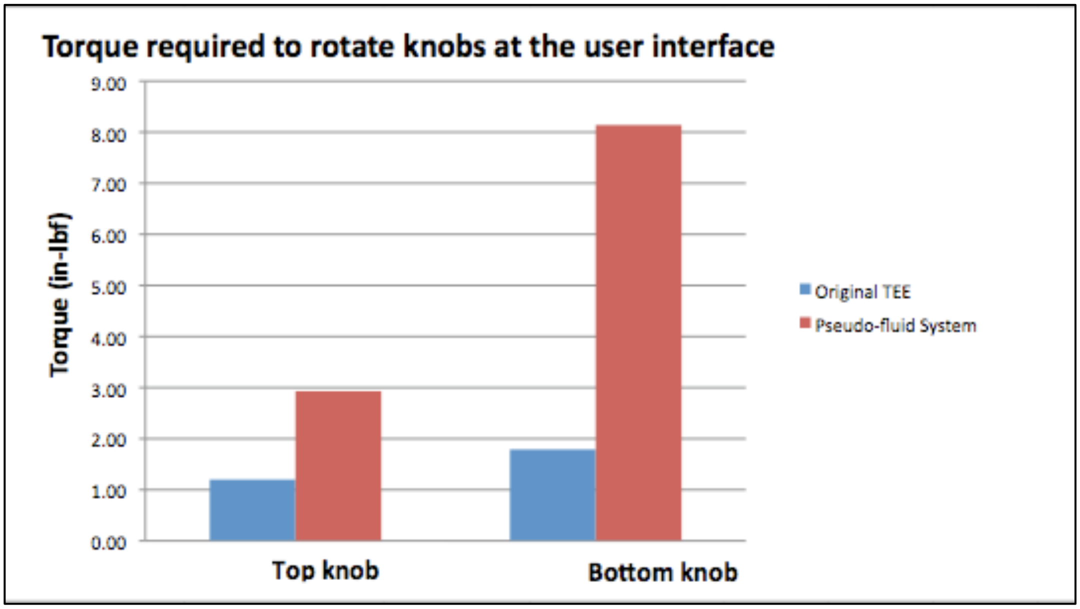


Figure 67 - Comparison of how much torque is required to rotate the top and bottom knobs for the original TEE and the pseudo-fluid system. How much torque required to rotate the “top knob” for the pseudo-fluid system refers to how much torque is required to rotate the knob at the control box that manipulates the degree of freedom of the probe that the top on the original TEE manipulated, while the “bottom knob” for the pseudo-fluid system refers to how much torque is required to

rotate the knob at the control box that manipulates the degree of freedom of the probe that the bottom knob of the original TEE manipulated.

The pseudo-fluid system also maximized the number of standard parts. Standards parts of the system include the steel balls, HDPE tubes, air fittings, gears (these had to be modified with a key way), racks, and bearings. The control box, TEE interface block, knobs, and gear inserts were custom made. The total weight of the system was minimized by using aluminum and plastic. The TEE interface was enclosed in a plastic case. Similarly, the TEE interface was incorporated directly onto the TEE handle. The time for human input motion to probe output motion is immediate. Lastly, the system is easily cleaned and all materials are FDA approved.

If the system were manipulated in a normal procedure room, the control mechanism would be accessible to the interventional cardiologist. Likewise, adjustment of the probe laterally would not affect the insertion depth of the probe. To demonstrate the feasibility of the system, the location of the TEE handle was not important. If used in real procedures, the TEE interface would be positioned in space such that if the TEE was bumped into accidentally the position of the probe head would not move.

The only design specifications that were not met were the reliability specification and the FDA compliance specification. However, neither of these specifications would be met when showing feasibility. Reliability testing takes more time than was available for this project. Finally, the FDA only considers products that are ready to go on the market for compliance. Research and development of devices is not regulated. Therefore, this specification did not need to be met to show feasibility.

Chapter 8 Discussion and Conclusion

8.1 Discussion

The pseudo-fluid control extension system achieved all major design specifications. The resulting device was a knob driven system that utilized racks and pinions at both the user interface and the TEE interface where loads were transferred back and forth via small steel balls contained within high-density polyethylene tubing. The interfaces between the racks and the steel balls were plastic cylinders (push rods) with a slightly smaller diameter than the inner diameter of the plastic tube. The resulting system mimicked the original TEE very well. The range of motion of the new system was about 60-70% of the original range of motion of the TEE. The decreased range of motion was a result of various losses in the system and assembly. The main problem with the assembly was that the racks were too short. The racks were designed and manufactured for a system with no losses and perfect assembly. Assembling the device exactly as originally designed was extremely difficult and was not done perfectly. Doubling the length of the racks would have accounted for losses in the system and provide greater assembly tolerance. Backlash was also a contributing factor to a loss in the range of motion.

Backlash existed in the system at the control interface. This was due to various reasons. Firstly, the plastic tubing was attached the control box by air fittings. The problem was that the air fittings allowed the tubing to move back and forth slightly and did not allow for the pseudo-fluid balls to mate exactly with the plastic push rods, causing the knobs to be able to rotate back and forth a small amount correlating to the "empty" ball space. Small compression springs were added at the end of the tubes between the last few balls near the plastic push rod/pseudo-fluid ball interface to act as a "tensioner," but the springs compressed completely when loads were applied to the system and the balls squished though the inside of the spring and caused the system to completely jam. Springs with a stronger spring constant and smaller diameter could have potentially been successfully used as a tensioner. Alternatively, different air fittings could have be used that maintained the tubing in a constant position to allow the push rods to constantly mate to the pseudo-fluid balls. The plastic rods also jammed a small amount inside the plastic tubing. The plastic tube was not held perfectly straight directly outside of the air fitting, and the racks drove the plastic push rods into the walls of the plastic tubing. Similarly, the balls did not always transfer loads along one axis for all of the balls. The balls were pushed into the walls of the tube. This was partly due to the fact that the inner diameter of the plastic tubing varied greatly. The ends of each tubes measured a .010 inch difference in inner diameter and there was no way of knowing how much the inside of the tube varied. Tubing with better dimensional control of the inner diameter would result in better performance of the system. WD-40 was added between the balls and tube to help solve this problem, but it was not completely solved. Stiffer tubing would help the jamming from the balls and push rods but the tubing still needs to maintain enough flexibility to curve around a hospital bed. Clearance between the gears also caused a small amount of backlash but was insignificant compared to the other factors.

The system required an increased amount of torque to rotate the knobs at the user interface than at the original TEE. The knob of the pseudo-fluid system that manipulated the shaft on the TEE that was originally connected to the top knob required about 2.4 times more torque than the original top knob of the TEE, while the bottom knob of the new system required about 4.5 times as much torque as the original bottom knob. The jamming of the push rods and pseudo-fluid balls was the major cause of the increase in torque. Frictional losses between the racks and associated slots at each interface also increased the amount of torque required to manipulate the system. This was due to slots for the racks being slightly misaligned, the bearing below the spur gears in the rack and pinion sets not working correctly (because they were press fitted into the block too tightly), and the spur gears were not held down so they tended to rise up. Obviously, machining to tighter tolerances would have helped these problems. However, replacing the aluminum blocks with plastic blocks (such as Teflon or high-density polyethylene) would have had a greater effect on these problems. The plastic would reduce frictional losses and allow the bearings to work properly because the plastic would not apply as much pressure on the bearing surfaces and the coefficient of friction would be lower.

Aside from the disadvantages, the system proved to be effective in showing the feasibility of the project. The pseudo-fluid system did this by capturing the advantages of classic cable and hydraulic systems. The pseudo-fluid system was more advantageous than those types of systems because it eliminated the risk of leakage and did not require slack in the system when used around tight bends. Leakage is a pitfall of the hydraulic system while cable systems cannot leak. The cable system requires slack around tight bends, which is a pitfall of the cable system, whereas hydraulic systems do not require slack around tight bends. The pseudo-fluid system is basically a hydraulic system that cannot leak. In summary, the goal of the project was to show the feasibility that the TEE could be manipulated from a distance of five feet and that was accomplished.

8.2 Conclusion

The pseudo-fluid system is a new means of transferring loads over a distance. Existing means include cables, hydraulics, and rigid shafts. Cables can only transfer loads in tension, by pulling. Cable systems require slack to operate in a flexible manner. The cable of a cable system must rub on whatever is guiding it any time that the cable moves. Thus, cables can wear out. Cables can also stretch over time. Hydraulics can be used for both push and pull applications, but hydraulics can leak. It is hard to get hydraulic seals to seal properly without also causing high static friction. A rigid shaft will transfer a large load, but it is not easily moved and it is inherently inflexible. The pseudo-fluid system operates on a push. It is flexible and it does not leak. The balls of the pseudo-fluid system minimize contact and are very hard, so the wear associated with movement is nearly eliminated. The pseudo-fluid system can also see use in systems where loads must be transferred though odd pathways, and if it is from two points which do not move then rigid tubing can be used. Rigid tubing would increase the performance of the pseudo-fluid system. The pseudo-fluid system can also be used in situations where a load must be transferred through a pathway with a very sharp curve in it. The pseudo-fluid system adapts to curved paths better than cable systems do because it does not require slack to operate fully. Lastly, the pseudo-fluid system is ideal for small load transfer situations.

Chapter 9 Recommendations

There are several recommendations and changes that could be made to improve the system. Depending on the location of the interventional cardiologist, longer tubes may be required. This would require purchasing a significant number of additional stainless steel balls. It could also be possible to create a tube with an adjustable length based on what the interventional cardiologist prefers or what is necessary for the procedure being done. This would require a method or taking up the space in the pseudo fluid system as the tube was lengthened. A large improvement that could be made is the addition of an anti-backlash system of some type. A spring type anti backlash system was considered and experimented with. This system utilized springs in each of the tubes filled with balls. The spring would take up any backlash in the system, and be pushed along with the balls. This idea requires springs that will not compress significantly due to the force applied to the balls. This system did not work in the existing tubes, because springs with 1/8 outside diameters were not strong enough to hold up under the force exerted by the balls. One disadvantage of this system is that each rack and pinion system would constantly be under more stress due to the force of the springs pushing on them. Other anti-backlash systems could be developed that may have more success. To make this system more compact and portable servo motors could be used. The motors would be best implemented right into the handle of the TEE. A servo could be mounted on either side of the handle controlling a rack with a lead screw or controlling the shaft directly with a belt or chain system. This would eliminate the tubes filed with balls, making the system more maneuverable. Servos could also be controlled remotely from longer distances, which would allow a physician to manipulate the TEE from any location in the procedure room. Aluminum could also be replaced with a plastic at the control box and the TEE interface. This would make the system lighter. Also, the design of the push rods could be optimized. Rods that are somewhat flexible would be ideal but should also have the strength to push the balls. Longer racks would also provide to a wider range of motion.

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Appendix A – Pictures of TEE

This section shows different views of the TEE probe.

Figure 68 - TEE handle and knobs.

Figure 69 - Inside components of the TEE.

Figure 70 - Racks of the rack and pinion system in the TEE handle.

Figure 71 - The probe head of the TEE shaft.

Appendix B – Design Specifications

The following is the complete list of design specifications.

1. Output must provide the probe two degrees of freedom (DoF)
    a. The current output of the distal end of the TEE probe has two translational degrees of freedom. This should remain unchanged if a control mechanism is added to this existing device.
2. Input should be two DoF
    a. The current input of the device consists of two rotational knobs that provide two rotational degrees of freedom. This 2 DoF input should remain unchanged if a control mechanism is added to the existing device.
3. Must comply with FDA regulations
    a. Any device that enters an operating room must comply with FDA regulations. If it does not, the institution performing the procedure cannot legally use the device. The engineering team is responsible for making sure that the device abides by all FDA regulations.
4. Existing probe must not be changed
    a. The inside mechanism of the probe shaft and mechanism that controls the probe shaft should remain unchanged.
5. Backlash of the additional controls must be minimal.
    a. The existing TEE has a lot of backlash already, so any additional controls added need to have as little backlash as possible.
6. Mechanism that controls the motion of the probe shaft must be able to translate the same amount that it already translates.
    a. The distal end of the probe shaft should have the same range of movement that already exists in the current mechanism.
7. The distal end of the probe shaft should be able to be stopped at any point in its rotation without significant backlash.
    a. This system must have a system to provide resistance against movement of the probe once the probe is positioned but able to be overridden.
8. Maximize the number of standard size parts
    a. This design goal goes along with the one previously mentioned. If more standard sized parts are used, the cost will be decreased. Also, standard sized parts are easier to obtain.
9. Input moment required to manipulate system should be minimal, but high enough so that the control will not move if it is tapped or bumped into.
10. Total Weight of System should be minimized
    a. The system should be easily stored and moved. Also, any mechanism that is created should not be cumbersome, so the weight should be minimized. A 50% increase in weight is acceptable.
11. Connection between TEE and new system should be enclosed

    a. The current connection between the inputs (rotational knobs) and the parts that cause the output motion (racks connected to pull wires) is enclosed in a metal shell. Any connection that is to be made should remain in a sealed case. This lends to easier cleaning of the device.

12. User interface should require the same cognitive load that the present device requires to operate
    a. There is an objective to have the interventional cardiologist to be able control the control system. The act of controlling an additional mechanism must not detract from his or her primary focus. Someone other than a cardiologist could possibly control the system.
13. Controls of mechanism must be accessible to the interventional cardiologist
    a. There is an objective that the any control system should be able to be manipulated by the interventional cardiologist. The user interface should be situated so he or she can use it, wherever they may be.
14. User interface must not exceed the dimensions of a normal sized adult hand
    a. The user interface should not be excessively large because we do not want the system to take up a large amount of additional space in the procedure room.
15. The controls of the system must be ergonomically designed
    a. There should be no slip when the controls of the system are manipulated. The gripping location of the user interface should be easily controlled. User controls need to be easily manipulated.
16. Adjusting the end of the probe via the control mechanism should not disturb the insertion depth of the probe in the patient's throat
    a. The positioning of the probe shaft down the patient's throat should not be moved because that could cause damage to the inside of the body and also could change the position of the probe once it was already positioned correctly.
17. TEE handle should be positioned in space such that the probe cord is not moved unintentionally
18. Time from human input motion to probe output motion must be within 1 second
    a. There should be less than 1 second delay in time from human input to probe output. If time is greater than one second, the doctor could become confused and increase the difficulty of correctly positioning the probe.
19. Connection between TEE and control mechanism should be incorporated directly onto TEE or attached and detached easily.
    a. If it is desired that the system should be detached or attached from the existing mechanism at any time, the degree of difficulty to dismantle or assemble the system should be fairly simple.
20. Reliability: minimal structural maintenance should be needed for this system for 10 years
    a. The structural components of the control system should not need to be replaced or fixed for at least 10 years.
21. System should be easily cleaned
22. Materials must be FDA approved

Appendix C – Force and Torque Experiment

Names:	John Dunbar, Chris Farren, Mari Freitas
Date:	01/18/2012
Project Name:	Philips TEE MQP
Reason for Test:	Preliminary Data

Method

I. Purpose:

One purpose of this experiment is to find the average force needed to push the stainless steel balls through the HDPE tubing for the pseudo-fluid system. The other purpose is to find the amount of torque needed to rotate both the top and bottom knobs on the TEE.

II. Background

We are currently determining the proper sizing of the parts involved in the system, specifically the gears. We need to know how much force is required to push the balls in the tubing and also how much torque is required to rotate the knobs on the current TEE.

III. Procedure and Equipment

Equipment:

- TEE probe
- Vice/clamps
- String
- 250 3mm diameter stainless steel balls
- 60" HDPE Tubing (.125 I.D.)
- Steel rod (.125 O.D)
- Force Gauge

Procedure:

1. Test how much torque is required to rotates the knobs first
    a. Position TEE into the vice and clamp as seen below. Make sure the knobs are in the unlocked position. Figure 72 shows the set up.
    b. Attach knotted string to notch on top knob and hook attachment to force gauge.
    c. Pull the force gauge gently away and record maximum force. Figure 73 shows the procedure in action
    d. Repeat 9 additional times.
    e. Repeat steps a-d for bottom knob.
    f. Repeat steps a-d for top and bottom knobs in locked positions.
    g. Determine the torque of each trial using the radius of the knobs.
2. Test how much force is required to push stainless steel balls through HDPE tubing
    a. Polish steel rods so there are no visible burrs. Slightly chamfer the ends.
    b. Put balls in tube and steel rods on either end and lay tube flat on table.
    c. Compress the force gauge into the steel push rod with the flat attachment at consistent rate.
    d. Record the maximum force.
    e. Repeat 9 additional times.
    f. Repeat steps a-e for the other end of the tube.
    g. Repeat steps a-f for four (4) different radii of curvature. Figure 74, Figure 75, Figure 76, and Figure 77 show the set up.

Figure 72 - Set up for the test to determine how much torque was required to rotate the knobs of the TEE.

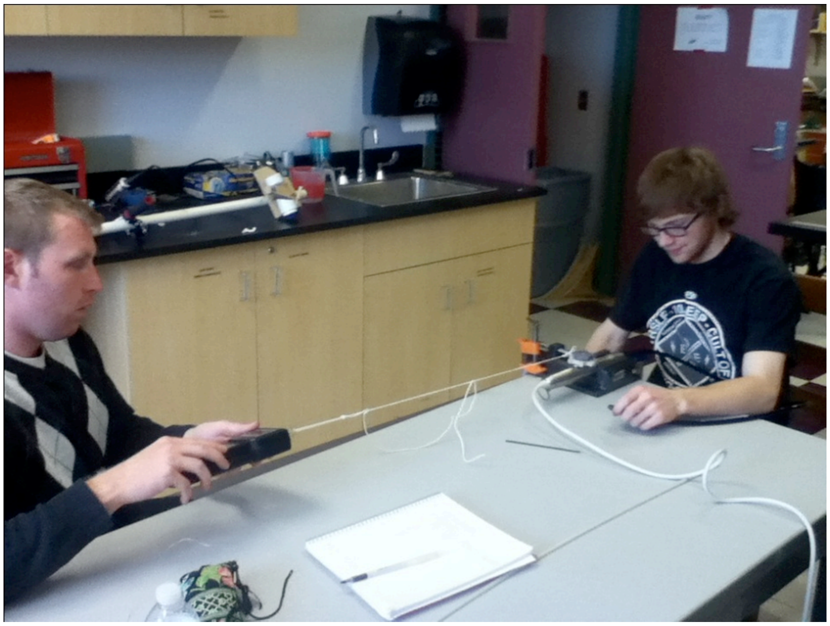


Figure 73 – Procedure to determine how much torque was required to rotate the knobs of the TEE.

Figure 74 - Set up for test to determine how much force is required to push pseudo-fluid balls around a bend with a 10.703” Radius.

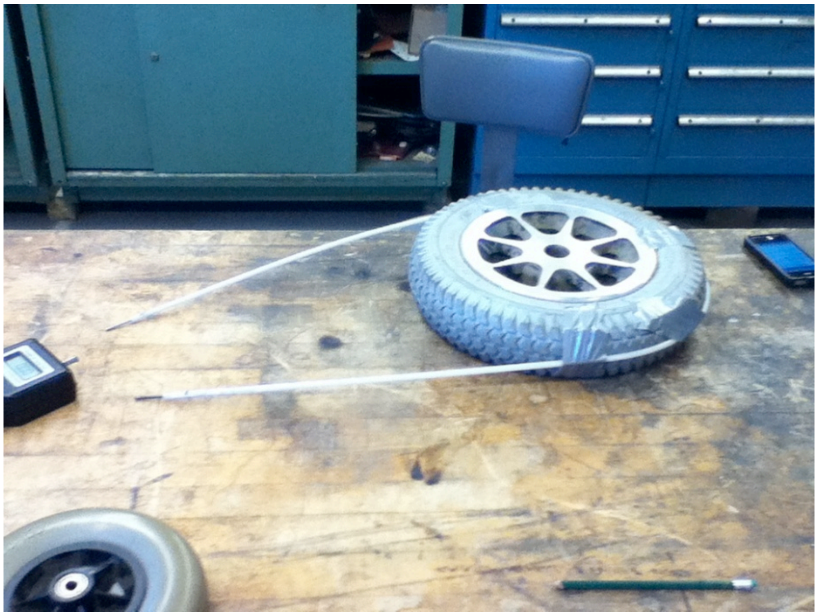


Figure 75 - Set up for test to determine how much force is required to push pseudo-fluid balls around a bend with a 6.875" Radius.

Figure 76 - Set up for test to determine how much force is required to push pseudo-fluid balls around a bend with a 3.75" Radius.

Figure 77 - Set up for test to determine how much force is required to push pseudo-fluid balls around a bend with a 2.34375" radius.

Results

I. Test 1:

The results from this test (Table 10 and Table 11) showed that average force for to pull the bottom knob unlocked was 1.79 pounds. The average force to pull the top knob unlocked was 1.50 pounds. The average force to pull the top knob locked was 2.00 pounds. The average force to pull the bottom knob locked was 3.44 pounds. The radius of the top knob where the perpendicular force was applied was 0.8 inches while the radius of the bottom knob where the perpendicular force was applied was 1.0 inches. Figure 78 shows the radii of the knobs. The average torque required to rotate the knobs is 1.2 and 1.79 in-lbs for the top and bottom knobs, respectively.

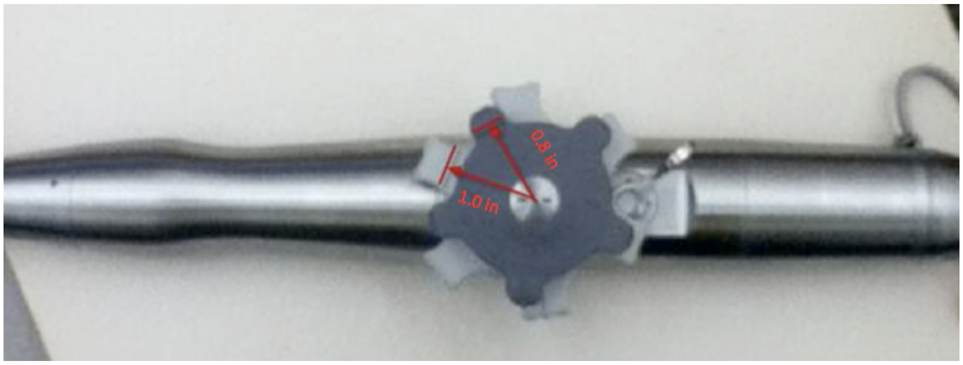


Figure 78 - Knobs of TEE showing the radius used to determine how much torque is required to rotate the knobs.

Table 10 – Torque data showing how much torque is required to rotate the knobs of the TEE when the knobs are in the locked position. The torque was calculated using the tangential force applied and the known radius.

Unlocked	Top Knob Force (lbs)	Bottom Knob Force (lbs)	Torque (in-lb) Top Knob	Torque (in-lb) Bottom Knob
1	1.14	1.41	0.91	1.41
2	1.62	1.80	1.30	1.80
3	0.97	2.14	0.78	2.14
4	1.97	0.91	1.58	0.91
5	1.58	1.52	1.26	1.52
6	1.43	2.14	1.14	2.14
7	1.80	2.50	1.44	2.50
8	1.18	1.14	0.94	1.14
9	1.59	1.99	1.27	1.99
10	1.67	2.36	1.34	2.36
Average	1.50	1.79	1.20	1.79
S.D.	0.31	0.53	0.25	0.53

Table 11 – Torque data showing how much torque is required to rotate the knobs of the TEE when the knobs are in the unlocked position. The torque was calculated using the tangential force applied and the known radius.

Locked	Top Knob Force (lbs)	Bottom Knob Force (lbs)	Torque (in-lb) Top Knob	Torque (in-lb) Bottom Knob
1	1.48	3.03	1.18	3.03
2	2.41	3.87	1.93	3.87
3	1.55	4.75	1.24	4.75
4	2.16	3.02	1.73	3.02
5	1.81	3.15	1.45	3.15
6	2.26	4.00	1.81	4.00
7	1.45	4.02	1.16	4.02
8	2.08	2.91	1.66	2.91
9	2.36	3.28	1.89	3.28
10	2.46	2.39	1.97	2.39
Average	2.00	3.44	1.60	3.44
S.D.	0.40	0.70	0.32	0.70

II. Test 2:

The results from the 2nd procedure (Table 12) showed that the average force to push from one end of the tube was 0.38 pounds. The average to push from the other end of the tube was 0.32 pounds. The average force of all cases was 0.35 pounds. Values for the force to push the balls in a straight line for side 2 were not recorded because the balls were jamming. Some of the balls fell out during the experiment and we had to put them back in the tube. We think there were some burrs at the end of the tube (where it is threaded so it can be screwed shut) and when we put the balls back in the tube some burrs got stuck in between some of the balls and caused the system to jam.

Table 12 - Force required to push stainless steel balls through HDPE Tube.

Force Data - All values in lbs					
Side 1					
Trial	Straight	Radius of Curvature, R = 2.34375"	Radius of Curvature, R= 3.75"	Radius of Curvature, R= 6.875"	Radius of Curvature, R= 10.703"
1	0.24	0.4	0.48	0.21	0.27
2	0.4	0.33	0.53	0.26	0.27
3	0.25	0.36	0.53	0.23	0.48
4	0.34	0.42	0.46	0.24	0.39
5	0.35	0.41	0.61	0.23	0.32
6	0.31	0.46	0.58	0.24	0.48
7	0.29	0.65	0.62	0.26	0.29
8	0.34	0.58	0.60	0.25	0.25
9	0.25	0.49	0.52	0.25	0.26
10	0.28	0.49	0.69	0.23	0.23
Average	0.31	0.46	0.56	0.24	0.32
STDEV	0.05	0.10	0.07	0.02	0.09
Side 2					
Trial	Straight	Radius of Curvature, R = 2.34375"	Radius of Curvature, R= 3.75"	Radius of Curvature, R= 6.875"	Radius of Curvature, R= 10.703"
1	x	0.27	0.45	0.28	0.24
2	x	0.26	0.32	0.26	0.22
3	x	0.47	0.31	0.24	0.28
4	x	0.45	0.34	0.36	0.27

5	x	0.36	0.30	0.28	0.25
6	x	0.32	0.31	0.29	0.31
7	x	0.33	0.32	0.27	0.22
8	x	0.41	0.41	0.25	0.25
9	x	0.38	0.47	0.29	0.21
10	x	0.50	0.56	0.31	0.24
Average	x	0.38	0.38	0.28	0.25
STDEV	x	0.08	0.09	0.03	0.03

Conclusion

Valuable data was obtained. The results of determining how much torque is required to rotate the knobs of the TEE will be compared to how much torque is required to rotate the knobs of the pseudo-fluid system. The results of determining how much force is required to push the pseudo-fluid balls through the tubes will be taken into account upon final design.

Appendix D – Puck and Ball Experiment

Names:	John Dunbar, Chris Farren, Mari Freitas
Date:	01/18/2012
Project Name:	Philips TEE MQP
Reason for Test:	Preliminary Data

Method

I. Purpose:

Determine the effect of weight and/or materials against each other to see if the pucks/balls slide and/or roll against each other. Determine how much clearance can be allowed for maximum rolling and minimum sliding.

II. Background

The team is trying to understand how the balls move inside of the HDPE tubing. In this experiment, the team tries to create situations where the movement of the balls is mimicked in different situations.

III. Procedure and Equipment

Equipment:

- Plastic 3 inch diameter hockey pucks
- Rubber 3 inch diameter hockey pucks
- Standard billiard balls
- Ping pong balls
- Tracks to guide balls/pucks
- Air hockey table
- Billiard table
- Smooth counter surface

Procedure:

Step 1: Secure tracks to air hockey table with no clearance/extremely little clearance between the track and the puck. Draw a mark on the outer edge of both the rubber and plastic pucks. Align plastic 3-inch diameter hockey pucks in tracks. Push pucks through the tracks and observe movement of the pucks. Keep increasing the clearance and see whether or not the pucks will slide against the tracks or roll along each other. Do the same with the rubber hockey pucks. Repeat with both the plastic and rubber pucks on a smooth surface. Compare the movement of the two against both surfaces.

Step 2: Secure tracks on a billiard table with no clearance/ extremely little clearance. Draw a mark on both the billiard and ping pong balls. Align billiard balls inside of the tracks. Push balls through the tracks and observe movement of the balls. Keep increasing the clearance and see whether or not the pucks will slide against the tracks or roll against each other. Do the same with the ping pong balls. Repeat with both the billiard balls and ping pong balls on a smooth surface. Compare the movement of the two against both surfaces.

Results

Table 13 - Results Part 1 of the Puck and Ball Experiment, showing how various objects move when aligned inside a track on a given surface.

	Rubber Pucks	Plastic Pucks
Air Table	All of the pucks were sliding regardless of the clearance	With a very tight clearance, the pucks both slide and roll. As the clearance increase the pucks roll more with no/minimal sliding
Smooth Counter Surface	All of the pucks were sliding regardless of the clearance	With very little to no clearance, the pucks both roll and slide at what seems to be an equal ratio. As clearance is increased, the pucks slide with very little rolling.

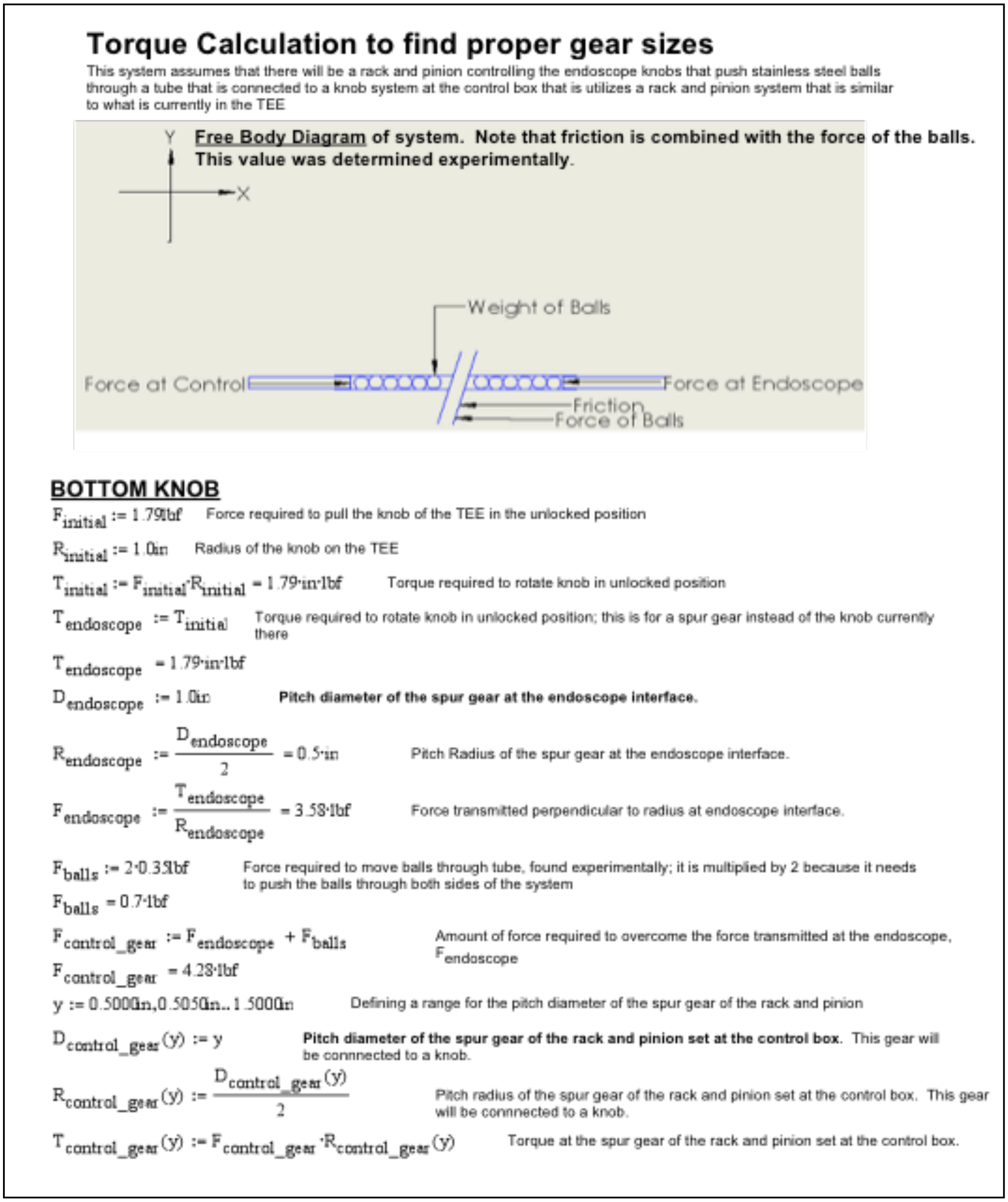
Table 14 - Results Part 2 of the Puck and Ball Experiment, showing how different ball types move when aligned inside a track on a given surface.

	Billiard Balls	Ping Pong Balls
Billiard Table	With a very tight clearance, the balls both roll and slide. But as tolerance increases the balls roll	When there was little to no clearance, the balls slid. When clearance was increased, they rolled.
Smooth Counter Surface	With a very tight clearance, the balls both roll and slide. But as tolerance increases the balls roll	When there was little to no clearance, the balls slid. When clearance was increased, they rolled without any sliding.

The balls inside of the HDPE tubing seemed to roll. This was witnessed by marking some of the stainless steel balls and pushing on one plunger while leaving the other open ended and looking inside and observing the blacks mark on the ball rotate. The balls seemed to be rolling with no sliding. The billiard balls and ping pong balls both slid and rolled with no clearance. When the clearance increased, they rolled. This relates to how the balls inside of the tube act.

Appendix E – Mechanical Advantage Calculations

Bottom Knob Calculations



Torque Calculation to find proper gear sizes

This system assumes that there will be a rack and pinion controlling the endoscope knobs that push stainless steel balls through a tube that is connected to a knob system at the control box that is utilizes a rack and pinion system that is similar to what is currently in the TEE

Free Body Diagram of system. Note that friction is combined with the force of the balls. This value was determined experimentally.

BOTTOM KNOB

$F_{initial} := 1.79\,lbf$ Force required to pull the knob of the TEE in the unlocked position

$R_{initial} := 1.0\,in$ Radius of the knob on the TEE

$T_{initial} := F_{initial} \cdot R_{initial} = 1.79 \cdot in \cdot lbf$ Torque required to rotate knob in unlocked position

$T_{endoscope} := T_{initial}$ Torque required to rotate knob in unlocked position; this is for a spur gear instead of the knob currently there

$T_{endoscope} = 1.79 \cdot in \cdot lbf$

$D_{endoscope} := 1.0\,in$ **Pitch diameter of the spur gear at the endoscope interface.**

$R_{endoscope} := \frac{D_{endoscope}}{2} = 0.5 \cdot in$ Pitch Radius of the spur gear at the endoscope interface.

$F_{endoscope} := \frac{T_{endoscope}}{R_{endoscope}} = 3.58 \cdot lbf$ Force transmitted perpendicular to radius at endoscope interface.

$F_{balls} := 2 \cdot 0.35\,lbf$ Force required to move balls through tube, found experimentally; it is multiplied by 2 because it needs to push the balls through both sides of the system

$F_{balls} = 0.7 \cdot lbf$

$F_{control\_gear} := F_{endoscope} + F_{balls}$ Amount of force required to overcome the force transmitted at the endoscope, $F_{endoscope}$

$F_{control\_gear} = 4.28 \cdot lbf$

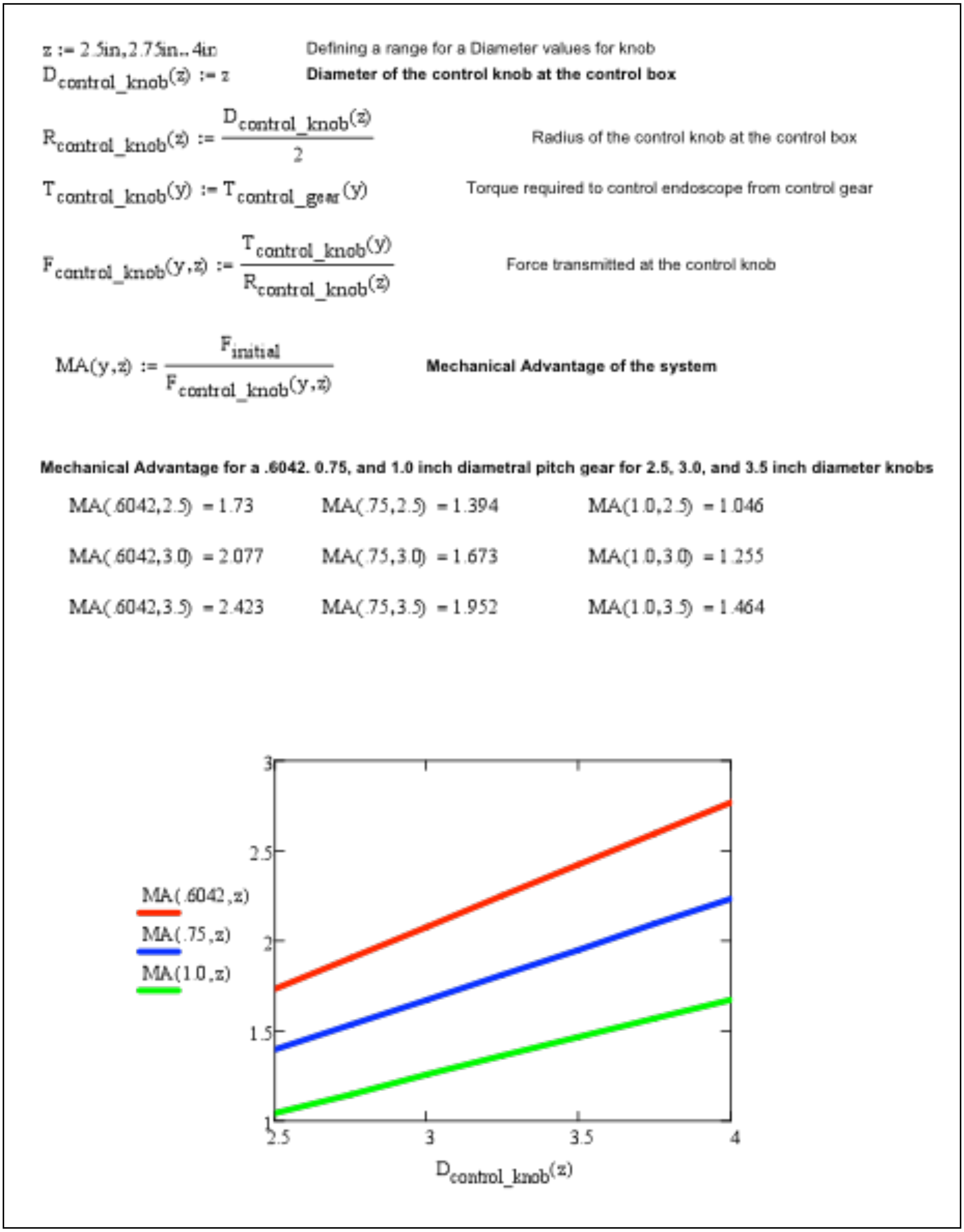
$y := 0.5000in, 0.5050in .. 1.5000in$ Defining a range for the pitch diameter of the spur gear of the rack and pinion

$D_{control\_gear}(y) := y$ **Pitch diameter of the spur gear of the rack and pinion set at the control box.** This gear will be connnected to a knob.

$R_{control\_gear}(y) := \frac{D_{control\_gear}(y)}{2}$ Pitch radius of the spur gear of the rack and pinion set at the control box. This gear will be connnected to a knob.

$T_{control\_gear}(y) := F_{control\_gear} \cdot R_{control\_gear}(y)$ Torque at the spur gear of the rack and pinion set at the control box.

Figure 79 - Mechanical Advantage Calculations for the bottom knob of the TEE, Part 1, performed in Mathcad.



$z := 2.5\mathrm{in}, 2.75\mathrm{in} .. 4\mathrm{in}$ Defining a range for a Diameter values for knob

$D_{control\_knob}(z) := z$ **Diameter of the control knob at the control box**

$$R_{control\_knob}(z) := \frac{D_{control\_knob}(z)}{2}$$ Radius of the control knob at the control box

$T_{control\_knob}(y) := T_{control\_gear}(y)$ Torque required to control endoscope from control gear

$$F_{control\_knob}(y,z) := \frac{T_{control\_knob}(y)}{R_{control\_knob}(z)}$$ Force transmitted at the control knob

$$MA(y,z) := \frac{F_{initial}}{F_{control\_knob}(y,z)}$$ **Mechanical Advantage of the system**

Mechanical Advantage for a .6042. 0.75, and 1.0 inch diametral pitch gear for 2.5, 3.0, and 3.5 inch diameter knobs

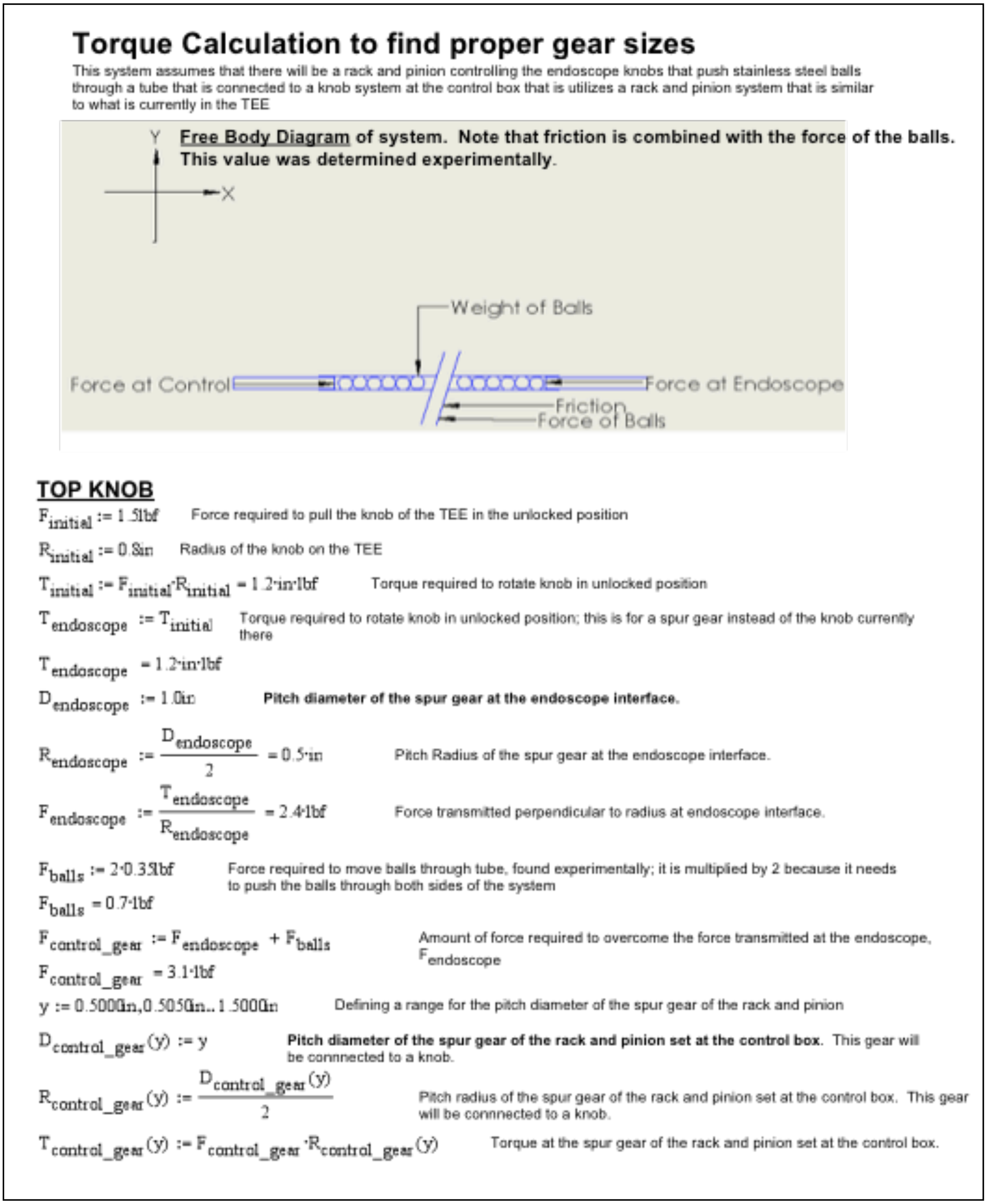
$MA(.6042,2.5) = 1.73$ $MA(.75,2.5) = 1.394$ $MA(1.0,2.5) = 1.046$

$MA(.6042,3.0) = 2.077$ $MA(.75,3.0) = 1.673$ $MA(1.0,3.0) = 1.255$

$MA(.6042,3.5) = 2.423$ $MA(.75,3.5) = 1.952$ $MA(1.0,3.5) = 1.464$

Figure 80 - Mechanical Advantage Calculations for the bottom knob of the TEE, part 2, performed in Mathcad.

Top Knob Calculations



Torque Calculation to find proper gear sizes

This system assumes that there will be a rack and pinion controlling the endoscope knobs that push stainless steel balls through a tube that is connected to a knob system at the control box that is utilizes a rack and pinion system that is similar to what is currently in the TEE

Free Body Diagram of system. Note that friction is combined with the force of the balls. This value was determined experimentally.

TOP KNOB

$F_{initial} := 1.5lbf$ Force required to pull the knob of the TEE in the unlocked position

$R_{initial} := 0.8in$ Radius of the knob on the TEE

$T_{initial} := F_{initial} \cdot R_{initial} = 1.2 \cdot in \cdot lbf$ Torque required to rotate knob in unlocked position

$T_{endoscope} := T_{initial}$ Torque required to rotate knob in unlocked position; this is for a spur gear instead of the knob currently there

$T_{endoscope} = 1.2 \cdot in \cdot lbf$

$D_{endoscope} := 1.0in$ **Pitch diameter of the spur gear at the endoscope interface.**

$R_{endoscope} := \frac{D_{endoscope}}{2} = 0.5 \cdot in$ Pitch Radius of the spur gear at the endoscope interface.

$F_{endoscope} := \frac{T_{endoscope}}{R_{endoscope}} = 2.4 \cdot lbf$ Force transmitted perpendicular to radius at endoscope interface.

$F_{balls} := 2 \cdot 0.35lbf$ Force required to move balls through tube, found experimentally; it is multiplied by 2 because it needs to push the balls through both sides of the system

$F_{balls} = 0.7 \cdot lbf$

$F_{control\_gear} := F_{endoscope} + F_{balls}$ Amount of force required to overcome the force transmitted at the endoscope, $F_{endoscope}$

$F_{control\_gear} = 3.1 \cdot lbf$

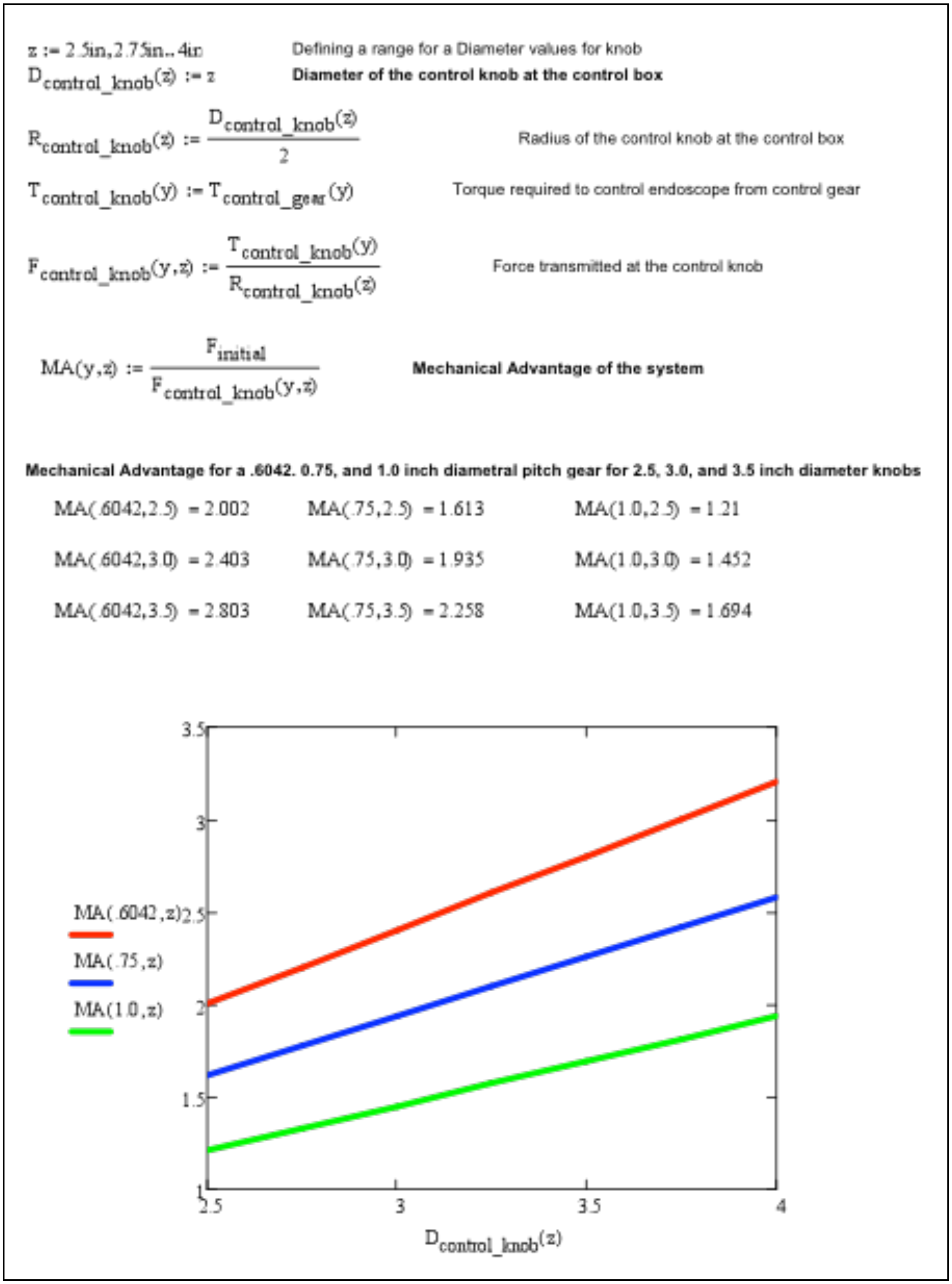
$y := 0.5000in, 0.5050in .. 1.5000in$ Defining a range for the pitch diameter of the spur gear of the rack and pinion

$D_{control\_gear}(y) := y$ **Pitch diameter of the spur gear of the rack and pinion set at the control box.** This gear will be connnected to a knob.

$R_{control\_gear}(y) := \frac{D_{control\_gear}(y)}{2}$ Pitch radius of the spur gear of the rack and pinion set at the control box. This gear will be connnected to a knob.

$T_{control\_gear}(y) := F_{control\_gear} \cdot R_{control\_gear}(y)$ Torque at the spur gear of the rack and pinion set at the control box.

Figure 81 - Mechanical Advantage Calculations for the top knob of the TEE, part 1, performed in Mathcad.



$z := 2.5\text{in}, 2.75\text{in} .. 4\text{in}$ Defining a range for a Diameter values for knob

$D_{control\_knob}(z) := z$ **Diameter of the control knob at the control box**

$$R_{control\_knob}(z) := \frac{D_{control\_knob}(z)}{2}$$

Radius of the control knob at the control box

$T_{control\_knob}(y) := T_{control\_gear}(y)$ Torque required to control endoscope from control gear

$$F_{control\_knob}(y,z) := \frac{T_{control\_knob}(y)}{R_{control\_knob}(z)}$$

Force transmitted at the control knob

$$MA(y,z) := \frac{F_{initial}}{F_{control\_knob}(y,z)}$$

Mechanical Advantage of the system

Mechanical Advantage for a .6042. 0.75, and 1.0 inch diametral pitch gear for 2.5, 3.0, and 3.5 inch diameter knobs

$MA(.6042, 2.5) = 2.002$ $MA(.75, 2.5) = 1.613$ $MA(1.0, 2.5) = 1.21$

$MA(.6042, 3.0) = 2.403$ $MA(.75, 3.0) = 1.935$ $MA(1.0, 3.0) = 1.452$

$MA(.6042, 3.5) = 2.803$ $MA(.75, 3.5) = 2.258$ $MA(1.0, 3.5) = 1.694$

Figure 82 - Mechanical Advantage Calculations for the top knob of the TEE, part 2, performed in Mathcad.