Delivery System for Hernia Mesh Fixation

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Abstract
The objective of this project is to design a hernia mesh fixation delivery system for High Road Medical’s (HRM) provided surgical fastener design. By surgeon request, the group will also implement a system that amplifies the insertion force providing feedback that signifies a successful delivery. The delivery system consists of a distal portion that interfaces with the fasteners and a proximal portion that the surgeon holds. The system must rotate and advance the fastener 180° and 0.225” plus some overdrive for successful fixation. Several distal portion concepts were designed and modeled and two final concepts were chosen. The first design, referred to as the “Threaded Rotator”, utilizes threaded fasteners on a rotating lead screw to advance the fasteners forward to ramp features that force the fasteners to spin into tissue. The second design, referred to as the “Tip Drive”, uses a rotating and advancing inner tube with engaging tip features to drive each fastener. After analysis of deflection, yielding, and manufacturability, the two designs mentioned were prototyped at a 3 times scale. Proximal portion design was driven by the necessary actuation of the distal portion. A purely rotational actuator was designed to spin the rotating lead screw, while a more complex actuator was designed for the rotating, translating, and helixing Tip Drive design. The group will build two final prototypes, each of which incorporate an easy way to connect and disconnect the proximal portion to the distal portion, which is designed to be a disposable cartridge in order to meet High Road Medical’s cost goals. A feedback system that amplifies the force seen at the distal portion using a spinning frictional disk and a lever arm has been designed and will be implemented into the proximal portion of the Threaded Rotator. Manufacturing processes and material selection will be considered to ensure biocompatibility and reduced costs.

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The Need for Project

With High Road Medical’s superior fastener design requiring an applicator and the opportunity for significant cost reductions, this new applicator has the potential to provide better patient care and increased profit margins in a large and growing market. Over a million hernia surgeries are performed annually in the US, with an increasing percentage of these surgeries conducted laparoscopically. A key aspect of the surgery is the insertion and fixation of a mesh to cover the hernia. There are several existing applicators currently used to fix this mesh. All current applicators are fully disposable and contain about 30 fasteners. With a cost between $600 and $800 (Rep. 6.2), this results in expensive surgeries and waste. The demand for a new applicator comes from two main improvements: High Road Medical has designed a superior bioabsorbable fastener that will maintain retention strength and a low profile after insertion; and the associated applicator will consist of a reusable proximal portion with disposable distal cartridges, housing various quantities of fasteners. The low quantity cartridges will allow for the use of fasteners and minimal waste in hernia surgeries that may only require a few fasteners. Improvements on the fastener, combined with a unique applicator, will lead to superior patient care and a portal into a large and growing market. These main improvements will allow for significant cost reductions, resulting in the potential for less expensive surgeries yet higher margins.

The Design Project Objectives and Requirements

The objective is to design a novel delivery device for High Road Medical’s fastener that will be the most cost effective per fastener delivery on the market for hernia repair. The device must be designed for laparoscopic surgery, and appeal to surgeons. Design Objectives

The objectives of this Capstone Project are to design a hernia mesh fixation device superior to those currently on the market. The two features that separate this design from current devices are the fastener design and the per tack delivery cost reduction. High Road Medical’s fastener combines geometric advantages of a strap, which holds the mesh to tissue better, and the helix, which has a stronger retention force in the tissue. High Road Medical gave the group a production cost goal of $2.71 per tack delivery. This can be achieved by creating a reusable, sterilizable proximal portion and a disposable distal cartridge. The cartridge would come in quantities ranging from 5 to 30 fasteners.

Design Requirements

The applicator must fit with a standard 5 mm laparoscopic trocar and have a distal length of 14 inches. The fastener itself is 0.265 inches in length and 0.173 inches in diameter. From testing a current market...
fastener in chicken, the insertion force was calculated. The maximum force required to insert HRM’s fastener into flesh was 0.74 lbs and the maximum torque was 0.023 in\textordmasculine*lb. By surgeon request, the proximal portion will include a mechanical system that amplifies the reaction forces from the tissue that act on the fastener. (Rep. 7.1-3)

**The Design Concepts Considered**

**Focusing on the distal cartridge actuation, four initial concepts were narrowed to two after analysis. Both designs were justified to prototype.**

Four concepts were developed to deliver HRM’s fastener. One design was discarded early on because of manufacturability concerns. (Rep. 8.4) Another concept involves actuating guide rails with snap features on the tips and a custom outer tube. The outer tube has features that cleave off one fastener at a time, and then the guide rails grasp and actuate it appropriately. After a stress and deflection analysis, the guide rails were determined to be too small to design using readily available materials. Also, the snap features would not work as needed, eliminating this design. (Rep. 9.3, 10.3) The third concept consists of a threaded rotator and inner tube with ramp features. The fasteners have molded-in threads and are spaced appropriately on the lead screw rotator. As the rotator spins, the fasteners are held rotationally by interfacing channels, resulting in forward advancement. When the fasteners reach the end of the distal portion, they hit ramps that appropriately eject them with a 180° rotation. (Rep. 9.1) The fourth concept focuses on a tip drive that actuates only the ejecting fastener. The main components are an inner tube with tip features interface and actuate fasteners; guide rails for storage; a fastener advancing system; and an outer tube. The outer tube and guide rails are fixed with respect to the proximal portion and the inner tube actuates. Both the Threaded Rotator and the Tip Drive concepts were chosen for prototyping. (Rep. 9.2)
**Recommended Design Concept**

Currently both the Tip Drive and Threaded Rotator designs remain as the recommended concepts. Both designs successfully deliver the fasteners with different advantages. Until one or the other prototypes proves more favorable or cost effective, both will be considered.

The two design concepts selected for prototyping are both recommended as complete designs. Since each design meets all requirements and offers unique advantages, they are both viable solutions.

The Tip Drive concept is recommended for its ability to easily transfer all necessary motions as well as its unique, patentable design. The tip features on the inner tube include a rectangular helical cutout and pin-like extrusions. The rectangular cutout allows a tack to be loaded by essentially threading the fastener through this cutout. The fastener is ejected in the necessary helical motion with some overdrive, and the process can be repeated as needed. Analytical calculations and FEA analysis of the inner tube verify that there will be no significant stress or deflection. The prototype for this design is made up largely of parts constructed on an Objet™ printer. Functionality tests act as a proof of concept. Further testing will address concerns with binding and repeatability. An actuator has been designed and is being constructed. The actuator will transfer the required motions to the inner tube so that a fastener can be ejected via a simple trigger depression. The actuator is intricate and raises concerns with regards to complexity and cost of the proximal portion. Since only the ejecting fastener is driven, a key advantage of this design is its consistency ejecting fasteners. The ability to add overdrive and fully control the ejecting fastener’s motion is highly desirable. (Rep. 9.2)

The Threaded Rotator concept converts rotational motion into linear motion to simultaneously advance the plurality of fasteners. This is accomplished by having a threaded through-bore within the fasteners, which are threaded onto a multi-start lead screw. Loading the fasteners onto the lead screw rotator allows for controlled spacing between each fastener and permits the actuating motion to systematically delivery 1 fastener at a time. As the lead screw rotates it attempts to rotate the fasteners as well, but they are held rotationally from the interface between fastener barbs and the inner tube channels, causing the fasteners to advance toward the delivery tip. After testing it
was discovered that the added friction between the fastener barbs and the inner tube channels doesn’t affect the fastener delivery. The exit ramps of the inner tube supply the necessary 180° rotation per fastener delivery with a repeatable fastener prong exit position. The Threaded Rotator distal portion design requires a simple actuator to provide rotational energy to the lead screw. A simple gearing system was designed to convert the depression of the applicator trigger into rotation of the lead screw. The 3X scale prototype lead screw requires nine rotations to advance the fasteners one full fastener length. This was done through two consecutive gear ratios; a 1:2.25 ratio between the molded-in gear teeth of the trigger and a spur gear, and finally a 1:4 between two bevel gears. By limiting the throw of the applicator trigger and incorporating a ratcheting mechanism, the user must fully depress the trigger for each fastener delivery, and therefore engage the actuator system for the 9 rotations needed. (Rep. 9.1)

The simplicity of the Threaded Rotator actuator allows for the addition of a force feedback system. By incorporating this feature the fastener insertion force can be amplified to the applicator trigger. The feedback system amplifies the insertion force by transmitting rotation from the proximal portion to the distal portion through a spinning frictional disk and a lever arm. As the torque to deliver a fastener increases, the normal force between the lever arm and frictional wheel increases, intensifying the required depression force to the applicator trigger. This system supplies feedback that signifies a successful delivery to the user, which appeals to surgeons. (Rep. 9.5)

**Financial Issues**

The overall cost of building both prototypes and a force amplification system was $1,383. Rapid prototyping of complex parts accounted for a large portion of the project expenditure. These parts all have the potential to be injection molded in bulk, which would dramatically reduce the price. Another concern with a 1X scale distal portion for the Threaded Rotator design is the cost increase of a custom miniature lead screw. However production quantities should drive this cost down a considerably.

**The cost of procuring both final prototypes and a force amplification system, including initial prototyping was $1,383. This cost will be significantly reduced using large-scale manufacturing processes.**
Although the production cost goal of $2.71 per tack delivery cannot be proven, the current designs consist of independent proximal and distal portions that allow for a disposable cartridge and a reusable body. Reusing the proximal portion drives down the production cost and sales price, increasing the marketability of the device.

**Recommended Improvements**

- The actuation of the Tip Drive design can be simplified to reduce cost, while the
  - The Tip Drive design can be improved by either simplifying the required actuation or simplifying the actuator used. This would reduce production and assembly costs for the proximal portion of this design.
- Threaded Rotator design needs a means to produce overdrive.
  - The Threaded Rotator design needs a means to produce overdrive. Currently, the system can achieve the necessary rotation and translation to deliver a fastener, but does not have a method to overdrive after delivery. Overdrive is desired to ensure complete delivery.
  - Potential issues could arise with particles being emitted due to wear in the force amplification system and migrating through the distal portion into the patient. This can be fixed by placing some kind of enclosure around the system.