Project Proposal

Improved Sphincterotome Tip

Project 39 for Dr. John W. Birk M.D.

Team 20

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Client Contact:

Dr. John W. Birk M.D.

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Executive Summary

Endoscopic procedures are growing rapidly in popularity and correspondingly evolving in their effectiveness. Certain issues with their implementation, however, have yet to be addressed. One procedure in particular, endoscopic retrograde cholangiopancreatography (ERCP), based on its success rate, has become the preferred method for bile duct cannulation despite its high degree of difficulty. In order to increase the effectiveness of this procedure even further, the sphincterotome tip will be redesigned to more easily breach the papilla of Vater. In all, the cost of designing and producing a prototype for an improved sphincterotome tip will be approximately $85.95.

1. Introduction

1.1 Background

Endoscopy directly translates to “look inside”. However, over the last 200 years the term has evolved to include a long list of high level procedures. These are preferred over other surgeries because of their low risk and minimally invasive nature. In an endoscopic procedure, a long, lighted, maneuverable camera is inserted into the body and used to examine or perform procedures on internal organs.
Endoscopic retrograde cholangiopancreatography (ERCP), enables physicians to access the bile and pancreatic ducts, which are separated from the duodenum by the papilla of Vater, as portrayed in Figure 2. First, contrast dye is injected into the ducts and fluoroscopy is used to detect any abnormalities. If necessary, a tube-shaped device called a sphincterotome is fed through the working channel of the endoscope and the papilla may be widened via electric current (sphincterotomy) to remove gallstones or the ducts may be cannulated to restore their proper function.

1.2 Purpose

Even with a steady hand and ample experience, maneuvering the sphincterotome through the duodenum and into the pancreatic or bile ducts is a complex task and is not always successful. Dr. Birk is seeking an improved sphincterotome tip design to increase the efficiency of the ERCP procedure and hopefully increase the likelihood of its success.

1.3.1 Previous Work

The general design of a sphincterotome includes a metal guidewire enclosed by flexible, plastic tubing that is tapered and molded into a hook at one end. The guidewire is inserted into the device through a trigger-like handle that is equipped with an input for applying electric current to a cutting wire also housed within the device. If necessary, this cutting wire is retracted by the trigger device away from the plastic housing and incised through local tissue. Colored bands on the tip of the device delineate known distances, enabling the physician to more
easily interpret how far the tip has moved. Boston Scientific is the leading manufacturer and
distributor of sphincterotomes in the U.S. They offer three different models. The Hydratome,
portrayed in Figure 2, is their standard model and consists of a metal alloy core surrounded by
PTFE. Their Autotome offers a guidewire locking mechanism for added stability, and their
Dreamtome boasts “merging lumen technology” that allows for contrast injection and guidewire
manipulation to be carried out simultaneously.

1.3.2 Patent Search Results

David M. Hardin Jr. and John A. Karpel filed a patent on August 8, 2007 for a
sphincterotome with a structural element that is used to block a specific passageway that is not to
be cannulated. This element serves to redirect the guidewire in the desired direction and thus
reduces the potential for error. The application number is 11/835,837.

John A. Girego and Hem Chin were issued a patent on May 24, 2011 for a steerable
sphincterotome with threaded stabilizing elements and pivot elements in addition to a guidewire
for enhanced control of the sphincterotome. The patent number is 7947056.

2. Product Description

2.1 Objective

Upon request by Dr. Birk that
priority be given to improving the
endoscopy bite block (an additional
project), modification of the
sphincterotome tip will be slight. The
standard sphincterotome tip, displayed

Figure 3. Standard sphincterotome tip.
in Figure 3, possesses a rounded tip that Dr. Birk feels is not ideal for breaching the papilla of Vater. He suggests an arrowhead shape for easier access into the papilla as well as a stronger hold once the papilla has been breached.

Because the redesigned sphincterotome will not be permitted for human trials, there is a potential need for a testing mechanism that will prove whether or not maneuverability of the sphincterotome has indeed been improved. This setup will consist of a simulated duodenum with papilla of Vater followed by a mock bile duct. Contact sensors will be placed within the duct to determine when the sphincterotome has successfully reached a given point within the bile duct.

2.2 Methods

The initial step in designing Dr. Birk’s improved sphincterotome tip will require a rough form of modeling to provide a general overview of how the new tip will be shaped. This will be accomplished with modeling clay, which will provide an inexpensive means of illustrating the exact tip shape that Dr. Birk has in mind.

After the tip shape has been selected, the design will be modeled using SolidWorks, at which time precise measurements will be applied so that the final product will fit through the working channel of the endoscope as well as be physically capable of breaching the papilla of Vater.

A 3D printer will then be used to mill the SolidWorks model out of polyetheretherketone (PEEK), a durable, biocompatible polymer. For the prototype, to ensure that the tip is a suitable alternative to the original tip design, the original tip will be removed from an existing sphincterotome and replaced with the new design.
In terms of validation of the device, the simulated papilla of Vater will consist of a small opening surrounded by a synthetic, tissue-like substance such as silicone. After the opening, a plastic tube 4mm in diameter (the mean diameter of a normal bile duct) will be attached with sensors lining the inside of the tube. These sensors will be integrated with a multiple-diode circuit such that each successive diode will light as the sphincterotome is maneuvered further and further up the simulated duct.

3. **Budget**

The budget shown in Table 1 is a rough estimate of what it will cost for the parts, many will be determined as we go forward with this project. Due to the fact some of the detailed work on the model is being researched, there is a rough guess what the parts will be. Until further research is done, we have come up with the following parts in order to manage the budget.

<table>
<thead>
<tr>
<th>Sphincterotome</th>
<th><strong>Zeus PTFE Light Wall</strong></th>
<th>End tip of Sphincterotome</th>
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<tbody>
<tr>
<td></td>
<td>Tubing 28</td>
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<tr>
<td></td>
<td>Gauge 100’ Length Coil</td>
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<td></td>
<td>or Spool</td>
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<td></td>
<td><strong>Crayola Crayola Model</strong></td>
<td>May need more for additional designs</td>
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<td></td>
<td><strong>Microtivity 5mm</strong></td>
<td>Simulation Connection Training</td>
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<td></td>
<td>w/ Resistors (5 Colors,</td>
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<td></td>
<td>Pack of 25)</td>
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<tr>
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<td>750-point Experiment</td>
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<td></td>
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<tr>
<td>Item</td>
<td>Description</td>
<td>Cost</td>
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<td>-------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
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<tr>
<td>Breadboard w/ Jumper Wires</td>
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<tr>
<td>750-point Experiment</td>
<td>with possibility of using additional software for circuit analysis</td>
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<td>Breadboard w/ Jumper Wires</td>
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<tr>
<td>Duracell Coppertop Batteries (12)</td>
<td>Possible Voltage Supply for simulation</td>
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<td>Magnet Wire</td>
<td>Magnetic wire to receive the flux which lights up the LED</td>
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<tr>
<td>1.0 Lbs</td>
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<td>TOTAL</td>
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Estimated Budget for Sphincterotome Tip

4. Conclusion

The newly designed Sphincterotome tip would replace the original tip in order to facilitate cannulation and improve the outcomes of the procedure of Endoscopic Retrograde Cholangiopancreatography. The intermediate design of the cost-efficient tip would easily breach the papilla of Vater. This will possibly be validated by using a mock biological design that simulates and provides feedback by integrating sensors and circuits near the mock duct. This
design could also provide training for operators in order to decrease the procedure time as well as increasing the procedure success outcome.

5. References

Figure 1: http://medgadget.com/2007/05/spyglass-direct-visualization-system-makes-ercps.html

Figure 2: Boston Scientific

Figure 3: http://www.cookmedical.com/esc/content/lg_thumbnail/esc_dash21.jpg