Articulation: A New Innovation to Clip Appliers for Use in Minimally Invasive Surgery

K. N. Cloutier, F. Miletic, N. Milton, C. Vendetti
Department of Civil, Environmental and Biomedical Engineering, University of Hartford
200 Bloomfield Ave
West Hartford, CT 06117

Abstract—The purpose of this project is to design the distal end of Covidien’s minimally invasive surgery tool, the Articulating Clip Applier. The major constraints on this design are the angles of articulation and roticulation, the storage of clips in the device and the size of the device. Articulation should range from 0 to 60 degrees and roticulation will preferably be 360 degrees. The device should store at least 6 medium/large clips, although 10 clips is the preferred amount. The distal end of the applier is suggested to be 2.5 inches maximum, with a diameter of 10 millimeters maximum. The finished product must be able to fire clips, but designing the handle of the tool is neither required nor suggested. A team of four engineering students will conduct the project, with the guidance of Jason Iceman, a R&D Engineer at Covidien and Erik Carlson, a R&D intern at Covidien.

I. INTRODUCTION

Over the past several years surgeons have been adopting procedures which require fewer, smaller incisions and faster patient recovery times. In 2009 Covidien launched a product called the Single Incision Laparoscopic Surgery Port or (SILSTM) Port, which enables surgeons to access the abdomen through one incision in the navel, rather than three or four incisions [1]. Minimally invasive surgery has clear patient benefits but there is a tradeoff; the tools used by surgeons need to become more complicated. In single incision procedures, the surgeon’s access to the body’s organs is limited to one place, but the internal organs are distributed throughout the abdominal cavity. The interesting problem of how to gain access to these organs has become a focus of many surgical tool developers.

Current tools such as the SILSTM Stitch and surgical staplers have made it easier for surgeons to reach internal organs with the use of an articulating shaft. This shaft can bend up to 90˚ at the distal end. These tools have been used in the operating room for many years, but an articulating clip applier has never been designed, developed, or sold. The advantages of having an articulating distal end of a clip applier it to allow the surgeon to practically reach any location inside the abdominal site of interest during a given procedure.

The clip applier is benchmarked against the current Covidien Endo Clip III, which is a non-articulation device used to apply a ligating clip. Ligating clips are implantable medical devices, specifically titanium V-shaped clamps, used to seal ducts and arteries during a surgery. The design project goal is to develop a working model of an articulating clip applier, with clipping performance on par with the Endo Clip III [2].

II. DESIGN PROCESS

A. Design Constraints

Specific constraints need to be encompassed in the design in order for the tool to properly work in a minimally invasive, or laparoscopic procedure— using ports to access the abdominal cavity. Table I describes each constraint, as well as the methods of measurement, design targets and acceptable limits for design [3]. Also, Fig.1 displays a basic image of the distal end and identifies the locations of the articulation and roticulation angles.

B. Analyzing Current Design

Experimentation with existing devices, specifically the Endo Clip I, Endo Clip III, and the Endo Universal 65, allowed the team to familiarize themselves with the working components and mechanical processes. Each device was disassembled, documented and sketched to interpret the mechanical designs. Each team member was able to disassemble numerous devices to gain insight and firsthand experience with the devices.

<table>
<thead>
<tr>
<th>TABLE I</th>
<th>DESIGN CONSTRAINTS FOR ARTICULATION CLIP APPLIER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constraint</td>
<td>Method of Measurement</td>
</tr>
<tr>
<td>Articulation Angle</td>
<td>Measure the start and finish angles after articulation.</td>
</tr>
<tr>
<td>Roticulation Angle</td>
<td>Measure the start and finish angles after roticulation.</td>
</tr>
<tr>
<td>Length of Distal End</td>
<td>Measure using a ruler in inches from the point of articulation to the distal end.</td>
</tr>
<tr>
<td>Diameter of Shaft</td>
<td>Measured using a caliper around the shaft.</td>
</tr>
<tr>
<td>Storage of Clips</td>
<td>Depending on the length of the storage mechanism, the number of clips can change.</td>
</tr>
</tbody>
</table>
### C. Design Development and Evaluation

In order to maximize the number of prototype design ideas, each team member developed at least three design sketches. This allowed for a minimum of twelve design variations. Each sketch was rated using the Pugh Method, a method for concept selection using a scoring matrix called the Pugh Matrix. The Pugh Method was implemented by establishing an evaluation team, and setting up a matrix of evaluation criteria versus alternative embodiments. The evaluation criteria selected for the sketch evaluation included articulation angle, ease of articulation method, roticulation angle, storage of clips, complexity of clip closure method, complexity of advancement of clip, jam prevention method, and length of distal end. The initial comparative criteria were based on the current model of the Endo Clip III. The scoring matrix was a form of prioritization for the designs. The options were scored relative to criteria using a symbolic approach. Three symbols were used which include: better than (+), neutral (S), worse than the baseline (-). These were converted into scores using 1, 0, and -1 respectively and were finally combined in the matrix to yield scores for each design option.

Upon completion of the initial design evaluation, a final design was developed by each team member using the highest scoring components from the initial sketches. Another Pugh Method evaluation occurred to select the final design concept, which was presented to the project sponsor. Advice and constructive feedback about the concept was received and taken into consideration to improve the design.

### III. Prototype Development

All initial prototypes were designed first through trimetric hand drawings and then drawn in a 3D CAD program called SolidWorks. Each mechanical part was grown using a Stereo Lithography Apparatus (SLA) supplied by the New Haven branch of Covidien. After SLA models were received, the team assembled the prototype and discussed necessary changes. Adjustments were made to the SolidWorks files and then new files were submitted to be grown. Numerous iterations were created to ensure proper assembly and manufacturability of each individual part.

A mock handle was designed using a Thorlabs breadboard and a series of cables, levers and knobs to allow the articulation, roticulation and clip firing capabilities to be demonstrated. The final prototype will be developed using a stainless steel casting process. Stainless steel pins, wire, and rods, along with nitinol wire, were ordered separately from manufacturing companies.

### IV. Prototype Evaluation

A failure mode and effects analysis (FMEA) was conducted. The most severe modes of failure that were defined include: clip not advancing, clip not completely closing, clip falling out of the device, and clip jamming within storage mechanism. Recommended actions were developed for each failure mode. During the design process and the SLA prototyping, the FMEA was taken into consideration.

Upon final prototype assembly, testing of articulation and roticulation abilities will be measured through observation of movement. The firing capability will be tested by evaluating the clip application on silicon tubing, which simulates the consistency of a human vessel. In terms of clip advancement, the evaluation will address the ease of clip movement on the track and the ability for the clip pusher to maintain a consistent motion.

### ACKNOWLEDGMENT

We wish to acknowledge our University of Hartford senior project advisor, Dr. Mary Arico, for taking the time to charter the project with Covidien and for providing support to the team throughout all steps of the project. Also, we wish to acknowledge Covidien R&D Engineer, Jason Iceman, and R&D Intern, Erik Carlson, for giving us the opportunity to design the articulating clip applicer and for the continued support throughout the design and prototyping phases.

### REFERENCES

