

# Computer aided modeling and analysis of a new biomedical and surgical instrument

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## ABSTRACT

**This paper describes the recent research and development of an endo surgical/biomedical instrument in surgical suture applications for minimally invasive therapy procedure. The newly developed instruments can not only protect the wound during the surgical procedure but also actively help the healing process. The new mechanism design of the surgical instrument aids in better ergonomic design, reliable functionality, and continuous cost reduction in product manufacturing. 3-D modeling technique, functionality analysis, kinematical simulation and computer aided solution have been applied to the instrument design, development and future improvement to meet the specific requirements of minimally invasive surgery procedure. The improved new endo surgical/biomedical instrument can prevent patient's vessels and tissues from being damaging because the distal move of clips are well controlled without clip drop-off incident. Plus the operational force to form the clip is lower than regular surgical/biomedical instruments due to this special new mechanism design. In addition to the above, the manufacturing and product cost can be decreased because the dimensional tolerance of components, such as clip channel and jaw guide track, can be loose due to this new instrument design. The prototypes of this new endo surgical/biomedical instrument design are analyzed through computer aided modeling and simulation, in order to prove its feasible functionality, reliable performance, and mechanical advantage. All these improved features have also been tested and verified through the prototypes.**

**Keywords:** Hemostasis; Endoscopic Device; Computational Simulation; 3-D Modeling; Mechanical Advantage

## 1. INTRODUCTION

The newly developed technologies have directed mini-

mally invasive surgeries [1]. The positive and feasible changes in surgical instruments have led to the new development of surgical techniques [2] and [3]. The biomedical and surgical instrument market is always adjusted and controlled for its functionality, performance, feasibility, quality, safety, and manufacturing cost. The surgical instrument market is very competitive, price sensitive and depicted by advanced technologies [4] and [5]. Biomedical and surgical instrument is technology based product and normally advanced techniques are especially required to develop special technology to compete the products in today's challenging market [6].

The applications include the closure of tissue defects, perforations, and anastomotic leakage in the esophagus and stomach. The endo surgical instrument has also been used to prevent post-polypectomy bleeding, placement of enteral feeding tubes. The recent studies show the versatility of endo surgical clips in therapeutic and endoscopic applications.

This endo surgical instrument is the innovative product that will allow for greater ease of use for surgeons and help to improve patient outcomes. Based on the field and clinical feedback, the new technology that simultaneously opens and aligns the jaws has been implemented, allowing well controlled surgical clip feeding and closure. This new surgical instrument design can provide more consistent and reliable mechanism to protect the clip from external and unanticipated disturbance while the surgical clip sits in the jaw track.

Endo surgical instrument has been widely used in hemostasis during endoscopy of the upper and lower gastrointestinal tract in which the bleeding lesions can be successfully clipped. The alternatives to endoscopic clipping of peptic ulcers are thermal therapy (such as electrocautery to burn the vessel causing the bleeding), or injection of epinephrine to constrict the blood vessel. Comparative studies between endo surgical clips and thermal therapy verify that endo surgical clips cause less trauma to the mucosa around the ulcer than electrocautery.

## 2. ANALYSIS OF ENDO SURGICAL INSTRUMENT

The operation procedure of endoclip instrument is described as follows. An endo surgical clip is loaded onto an endo surgical instrument and retracted into a protective sheath. The instrument is inserted through the open channel of an endoscope. Forcing the sheath backwards through the handle can drive the clip from the sheath. Pulling the clip back can open the prongs. When instrument jaw tips fully open, the distance between the clip prongs reaches the maximum. The orientation of the endo surgical clip prongs can be controlled by turning the instrument handle clockwise. The surgical clip can be closed by fully pull the clip proximally. In hemostasis application, the endo surgical clip is used to compress and clamp a bleeding vessel. If the vessel is clamped properly, the ligation should be permanent. Compared with the thermal and injection ligation, the endo surgical clip is the direct mechanical method that can reduce the injury to the near tissue. Endo surgical clips have been positively applied in the control of GI bleeding from multiple sources including peptic and stomal ulcers, lesions, gastric tumors, colonic diverticula, solitary rectal ulcers, and post-sphincterotomy bleeding.

The **Figure 1** shows new endo surgical instrument, **Figure 2** indicates the cross-section of new endo surgical instrument, and **Figure 3** displays the jaw mechanism section.



**Figure 1.** New endo surgical instrument.



**Figure 2.** Cross-section of new endo surgical instrument.



**Figure 3.** New endo surgical instrument jaw mechanism.

## 3. COMPUTER AIDED MODELING AND SIMULATION

$$N_{load} * V_{linear} = M * \omega \quad (1)$$

$$M * \omega = N_{pivot} * r * \omega = N_{pivot} * V_{angular} \quad (2)$$

$$N_{load} = (V_{angular} / V_{linear}) * N_{pivot} = (Vr) * N_{pivot} \quad (3)$$

The computer aided modeling and optimal simulation of S and r combination can help to reduce the operational force and determine the minimum instrumental handle force  $F_{finger}$  that surgeon needed to operate the surgical instrument. The computer aided solution indicated that S = 4.90 inch and r = 2.15 inch for best instrument performance.

Based on equation (3),

$$N_{finger} * 4.90 = N_{pivot} * 2.15$$

Referring equation (4),

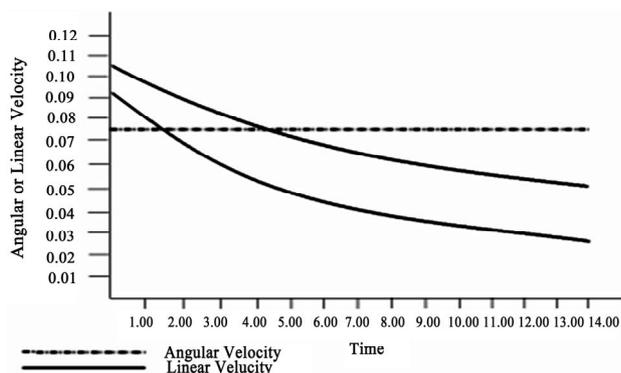
$$N_{load} = (Vr) * N_{pivot} = (Vr) * 2.28 * N_{finger} \quad (4)$$

The velocity ratio of  $(V_{angular} / V_{linear})$  can be found through computer aided modeling and simulation to determine the optimal instrument function. The computational solution is indicated in **Figure 5**.

Then the mechanical advantage of this new surgical instrument is as follows:

$$\begin{aligned} \text{Mechanical advantage} &= (VR) * 2.28 \\ &= (.04940 / .03548) * 2.28 = 3.175 \end{aligned} \quad (5)$$

This result indicated that the surgeons only need 3.149 lbf closure forces when 20 lbf forces are required to fully form the surgical clip. This is lower than normal spec of 4 lbf and it will benefit surgeons in their surgical operation and procedure. Furthermore, the computer aided modeling and simulation results are very close to the prototype testing results that verify the credibility and reliability of this new endo surgical and biomedical instrument. The prototype units have been sent to the sur-



**Figure 4.** Linear and angular velocity vs. time in instrument operation.

geons and clinic fields for more evaluations and feedbacks. Future modification will be anticipated to further improve instrumental function and reduce the unit cost.

#### 4. CONCLUSION

This paper introduces a new endo surgical instrument design using 3D computer modeling and simulation. 3D modeling and computer aided simulation can benefit geometrical, kinematical and dynamical analysis in conceptual and feasible design of biomedical and surgical instruments. The geometric, kinematical, dynamical and visual limitations of the surgical instruments are analyzed to assist the surgeon in surgical procedure. The kinematics of precision instrumental mechanism design can be simulated and modeled as either an open or closed-loop joint chain with some rigid bodies connected to each other in a series format, driven by actuated mechanism. The analysis of kinematical structure in

mechanism can provide a systematic and general approach to determine and calculate mechanism motion functionality. The kinematical and dynamic simulation of these multiple link system permits conceptual verification and feasible studies in the design and development stage. The computer aided simulation and prototype testing have shown the feasible and reliable function of this new endo biomedical and surgical instrument.

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#### Nomenclature

M: inch-lbf, torque on pivot point of trigger

$N_{load}$ : lbf, force required to close the jaws

S: inch, distance between trigger pivot center and surgeon's finger position

$N_{pivot}$ : lbf, normal force on linkage pivot

$\omega$ : degree per second, angular speed of trigger at pivot center

$N_{finger}$ : lbf, force on surgeon's finger

$V_{linear}$ : inch per second, distal linear moving speed of instrument drive bar

(Vr): velocity ratio

r: inch, center distance between trigger pivot and linkage pivot

$V_{angular}$ : inch per second, angular tangential speed at trigger pivot center