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Recent Research and Development of Open and Endo Biomedical Instrument in Surgical Applications

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1. Introduction

The biomedical surgical instruments are mainly designed to perform specific functions during the surgical procedures including modifying biological tissue, open and close the organs and tissues, and providing access to view it. The surgical instruments are designed for general or specific procedures in surgery, and specialized professionals and engineers can provide assistance to surgeon with proper handling of surgical instruments in surgical operation. The important difference in surgical instruments is the amount of bodily disruption and tissue trauma that instruments might cause the patients. The development of minimally invasive surgical instruments is in the positive and future directions for surgical product industry. Surgical instruments were designed and developed since ancient times. The following real breakthrough in surgical instrument development comes with advanced biomedical technologies, better materials, and improved manufacturing techniques (Lin et al., 2007). Later more new surgical instruments were again invented and designed with the new biomedical engineering technologies to allow surgeon performing more complicated surgical procedures to patients. Some precision medical instruments were developed for microsurgery and endoscopic surgery in the late 20th century (Cheng et al., 2004). In order to prevent the instruments from corrosion due to blood contamination and sterilization, the nontoxic, durable and anti-corrosion materials were developed for surgical instruments. The modern manufacturing techniques help to produce the cost effective biomedical surgical instruments. The advanced biomedical researches over the past centuries significantly improve human's life quality. Biomedical instrument design and development is to apply engineering principles and techniques to the biomedical fields to reduce the gap between engineering and surgery and combine the engineering design knowledge and problem solving with biomedical and surgery science to improve surgical procedures, diagnosis and treatment. Biomedical surgical instrument design and development is an interdisciplinary field that affected by other technological and biomedical fields including mechanical, electrical and chemical engineering. The surgical instrument design should be collaborated regarding prospective design improvements based on clinical experiences. The development progression of the state-of-the-art instruments must be traced to reconstruct procurement patterns and influence the trajectory of surgical instrument innovation accordingly. Biomedical Surgical instruments are developed to facilitate many different

procedures and operations. The good understanding of fundamental engineering knowledge, different engineering disciplines, human anatomy and physiology is required in surgical instrument design and development.

The surgical instruments include the devices performing clamping, occluding, probing, suturing, and ligating. Improper use of surgical instruments will lead alignment problems (Piatt et al., 2006). While using surgical instruments, the institutional and professional protocols must be strictly followed, and necessary medical trainings will be required. In surgical procedure, the previously sterilized instruments must be maintained clean to keep blood and tissues from hardening, otherwise the blood and hardened tissues will be trapped between organ surface and surgical instruments. The minimally invasive surgery, aided by improved surgical instruments, can minimize the trauma to patients, reduce health care costs, and shorten the recovery time after surgery. Similar to ligatures, suture might cause the suppuration surround the wound edges (Evans et al., 2006). The process is slow and patients feel pain when remove the sutures. Our new surgical instruments including open and endo clip instruments can speed up the suture process and improve surgical procedure. This chapter introduces the new surgical open and endo clip instruments with improved mechanism to apply the metal clips to patient's vessel / tissues in the surgical operations. The new surgical instrument design aids in better ergonomic design, reliable functionality, continuous cost reduction, and minimally invasive therapy procedure. The improved clip delivery systems have been designed and developed in these two types of surgical instruments to improve the clip distal move from clip channel into jaw guide track and resolve the problems of clip accidental shooting out when surgical clips are being loaded into jaw pair by compression spring that has been normally used in some current surgical clip instruments. With this improvement, the new surgical open and endo clip instruments 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 forces to form the open or endo surgical clips are lower than regular surgical instruments due to new mechanism design. Moreover, the manufacturing and product costs of these two surgical instruments can be decreased because the dimensional tolerance of components, such as clip channel and jaw guide track, can be wider due to the new instrument design. The prototype of these new open and endo surgical instruments are analyzed and optimized through computer aided modeling and simulation to prove its feasible function, reliable performance, and mechanical advantage. All these improved features have also been tested and verified through the prototype.

2. Open surgical instrument:

In the surgical operations, surgeons and doctors need to apply the hemostasis instrument to the severed organs or tissues to stop the bleeding. The instrument jaw pair is placed at the organ or vessel structures. When instrument handles are being brought together, the clip can close and secure the tissue or vessel to prevent them from bleeding. The next surgical clip is automatically loaded into the instrument jaw when instrument handles are released. Surgical procedures need ligation of blood vessels, severed tissues and organs to stop bleeding. Surgical clip instruments for quickly applying a surgical clip onto tissue or vessel include single clip and multiple clip applications (Sun et al., 2005). A new clip is loaded into the apparatus after applying each clip in single clip applications and the multiple clip applications include a series of clips that can be sequentially applied to tissue during the

course of a surgical procedure. Open surgical clip instruments normally have a trigger handle mechanism, a major body portion, a clip crimping assembly and some other functioning components including a pair of jaws. Although the current surgical instruments for continuously advancing individual clip have been proposed, the continuing improvements for better surgical clip delivery with cost-effective apparatus is required to provide efficient occlusion of a blood vessel.

Currently some feedbacks from clinic fields indicated the incidents of clip dropping off from clip channel while being delivered to the jaw pair in the existing open surgical clip instruments. In these cases, the closed jaw pair will sever or damage the tissue if there is no surgical clip in the jaw pair. The clip drop-off problem is mainly caused by improper dimensional tolerance control in clip channel, clip guide track in jaw pair, and transition area between these components during production process. In order to smoothly load the clips through compression spring, the high cost manufacturing process is required to precisely maintain the high surface quality and accurate dimension controls on these components, otherwise the clips will be dropping off if the dimensional tolerance is too wider or clips will not be moving by spring force if the dimensional tolerance is too tight. The clip delivery mechanism of new surgical clip instrument is different from current clip instrument. In this new design, clips are advanced to jaw pair through distal movement of clip pusher which is driven by instrument handles. When surgeons and doctors bring the instrument handles together, the clip will be fully formed after clip pusher distally delivers clip into the jaw guide track. When surgeons release instrument handles, the clip pusher returns proximally to original home position and then picks up next clip. Because the clip advancing process can be easily and well controlled in this new design, the high dimensional tolerance control is not required to these components in manufacturing process. This can ease the machining process, increase the productivity, and save the production cost.

The prototype tests have been carried out on dogs including vascular occlusion, ligating for tubular ducts, and applying the surgical clip to the tissue. The preliminary testing results indicated no clip drop-off incident in this new surgical instrument design and the closure force to fully form the clip is between 3.38 lbf that is lower than 4 lbf in current surgical clip instrument.

2.1 Analysis on new open surgical instrument

The surgical clip instrument, shown in Figures 1, 2 and 3, is first placed around patient's body tissue or vessel, and then clip is distally moving to jaw pair through clip pusher and secured onto the tissue or vessel when surgeons close the trigger handles. When surgeons release the trigger handles, jaw pair is open, clip pusher and driving bar return to their original positions. Compared with the current clip delivery apparatus in which the clip is advancing to jaw pair through compression spring that sometime causes accidental clip shooting out from instrument, the clip delivered into jaw pair in this new instrument design is well guided and controlled. The driving bar that linked to the pivot pin in handles moves distally to advancing clip into jaw pair when surgeons gradually close the instrument handles. Such clip linear motion can be easily and well controlled by surgeons to prevent the clip from accidentally shooting out from instrument. The preliminary prototype testing of this new design has proved its proper and reliable performances since there is no clip shoot out and operational force is lower than usual.

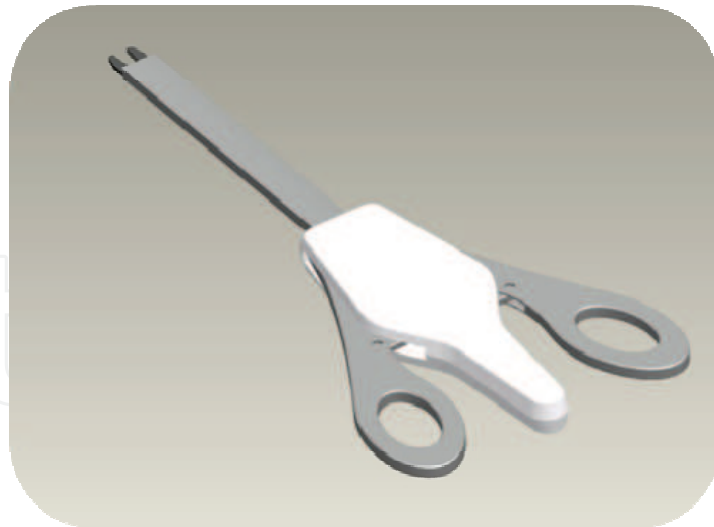


Fig. 1. Prototype of new open surgical instrument

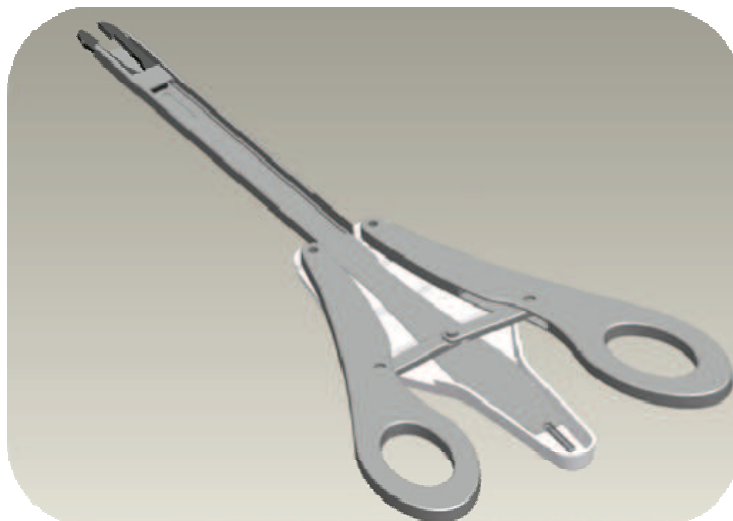


Fig. 2. New mechanisms including handle, linkages, driving bar and clip pusher

2.2 Computer aided modeling and analysis on new design

The velocity ratio of ($V_{\text{angular}} / V_{\text{linear}}$) can be determined through computational simulation targeting the optimized instrument performance, and simulation results are indicated in Figures 4 and 5.

The mechanical advantage of this new instrument can be determined when surgical clip has been fully formed:

$$\begin{aligned} \text{Mechanical advantage} &= (\text{VR}) * 2.148 \\ &= (.04866 / .03533) * 2.148 = 2.958 \end{aligned} \quad (1)$$

The above result shows that if 20 lbf forces are required to fully form or close the surgical clip, the force loaded on surgeon's finger will be 3.380 lbf which are lower than the normal spec of 4 lbf in surgical operation procedure and this meets the surgeons' requirement. Also, the results of this computational simulation and prototype testing are very close to each other which verify the credibility of this new instrument design and research methodology.

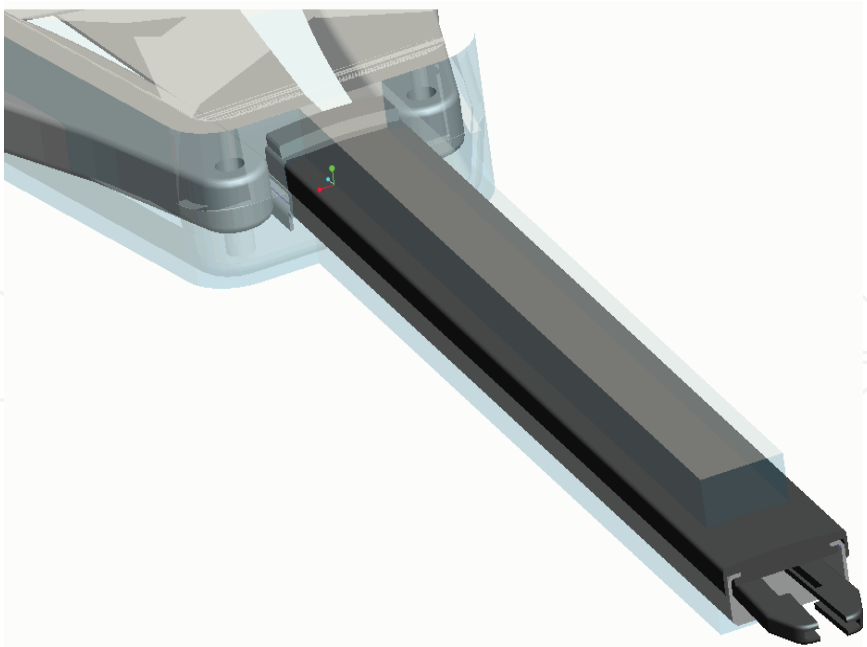


Fig. 3. Front view of new open surgical instrument

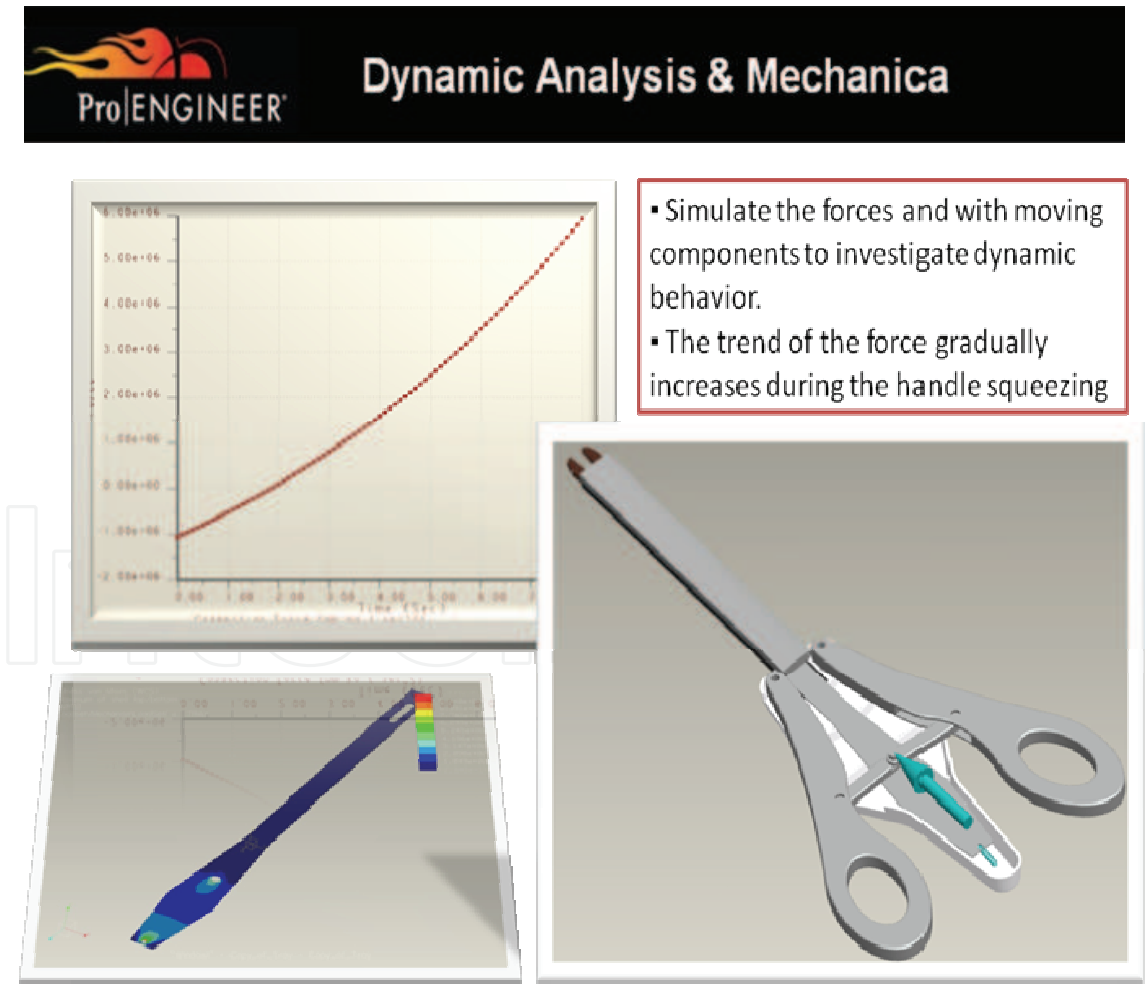


Fig. 4. FEA and dynamic analysis of mechanism in this surgical instrument

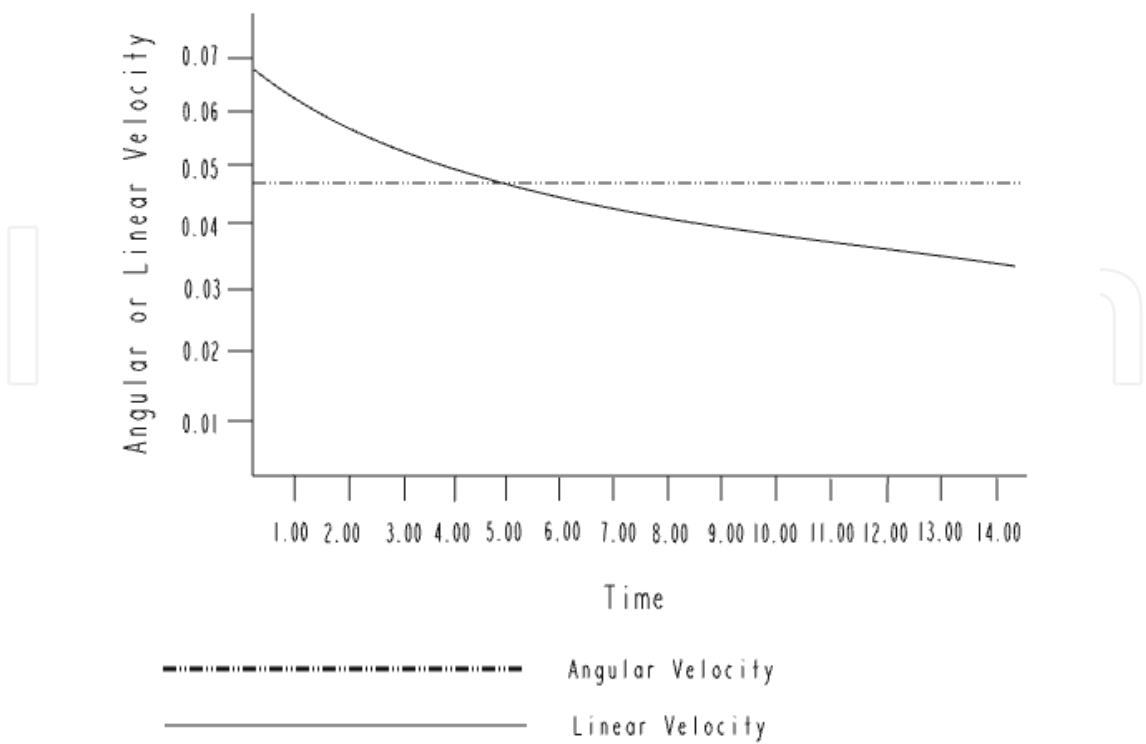


Fig. 5. Linear and angular velocity vs. time phase in operating the instrument

2.3 Discussion

The feasible functioning and reliable performance of this new open surgical instrument has been preliminarily proved based on the instrumental functional study, computerized simulation and prototype testing. The major advantages of this new surgical instrument include that the clip distal advancing can be well guided and controlled to prevent patient’s vessel and tissue from damage due to accidental clip shooting out during surgical procedure, operational force to fully form clip is lower than usual, manufacturing and product cost will be decreased because of this new instrument design. The prototype of this new surgical instrument has been tested and the preliminary results show the potential improvement. While this new instrument is being sent to fields for clinical evaluation, the further improvement will be considered including enhancing the structure of jaw pair to prevent jaw pair from twisting in case the instrument is not being used properly in the field, adding supporting feature to prevent jaw pair from accidental close when unanticipated side load exerted to the jaw pair, and simplifying the instrument design to further reduce the product cost.

3. Endo surgical instrument.

The biomedical/surgical instrument market is very competitive and has been measured and controlled for its performance, feasibility, safety, and production cost (Chu et al., 2005). This market is price sensitive and dominated by different advanced technologies. Biomedical/surgical instrument is technology based product which requires the special techniques to compete today’s challenging market. The endo surgical instruments can be

applied to close tissue defects, perforations, and anastomotic leakage in the esophagus and stomach (Starly et al., 2005). The recent studies indicate the versatility of endo surgical clips in therapeutic and endoscopic applications (Laufer et al., 2007). Endo surgical instruments have been normally applied in hemostasis using endoscopy to the upper and lower gastrointestinal tract in which the bleeding lesions can be effectively clipped. The methods other than endoscopic clipping of peptic ulcers are thermal therapy or injection of epinephrine to constrict the blood vessel (Kassam et al., 2007). Comparative studies between endo surgical clips and thermal therapy verify that endo surgical clips cause fewer traumas to the mucosa around the ulcer than electrocautery.

3.1 Analysis of endo surgical instrument

The operation of this endoclip instrument is illustrated as follows. An endo surgical clip is loaded and retracted into a protective sheath in this endo surgical instrument. The instrument is inserted through the open channel of an endoscope and the sheath is forced backwards by the instrument handle which can drive the clip from the sheath. The clip can be pulled back to open its prongs. The distance between the clip prongs reaches the maximum when instrument jaw tips fully open. Turning the instrument handle clockwise can adjust and control the orientation of endo surgical clip prongs and pulling the clip proximally can fully close the surgical clip.

The figure 6 shows this new endo surgical instrument, figure 7 indicates the cross-section view of endo surgical instrument.

3.2 Computer modeling and simulation

Referring figure 8, the energy balance and force equations in this new endo surgical instrument design can be derived as follows.

AB represents the pushing bar and EF is the trigger handle. Considering the ergonomic factor, the length of EF should properly fit most surgeons' hand size. When calculating the geometry factor of this mechanism, the length of BC, CD, DE and angle should be first determined. Assume the squeeze force is F , angle EDC is θ , angle ABC is α .

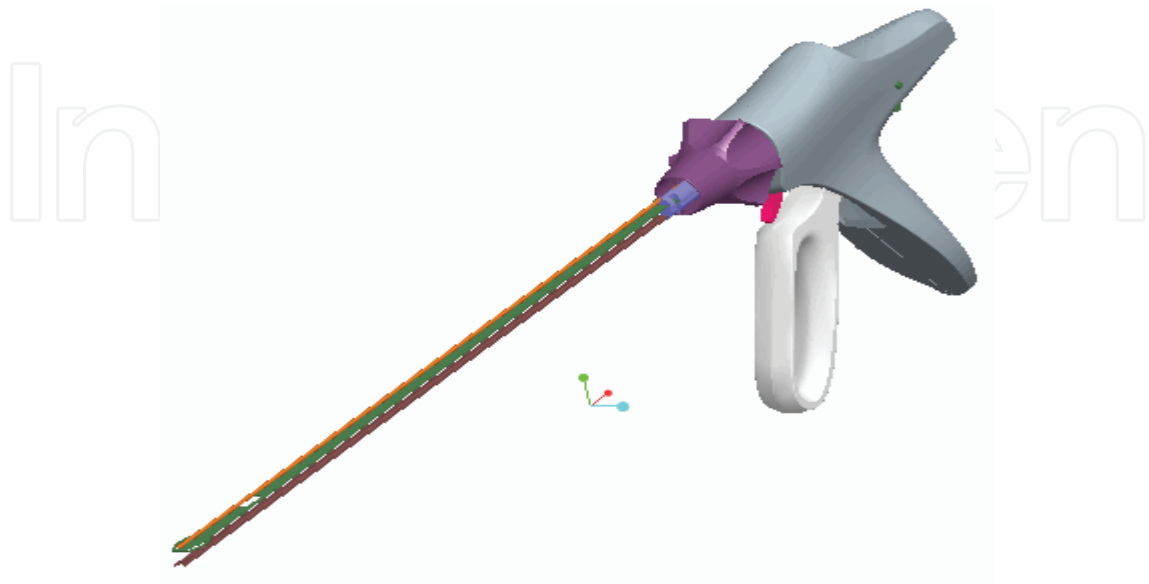


Fig. 6. Endo surgical instrument

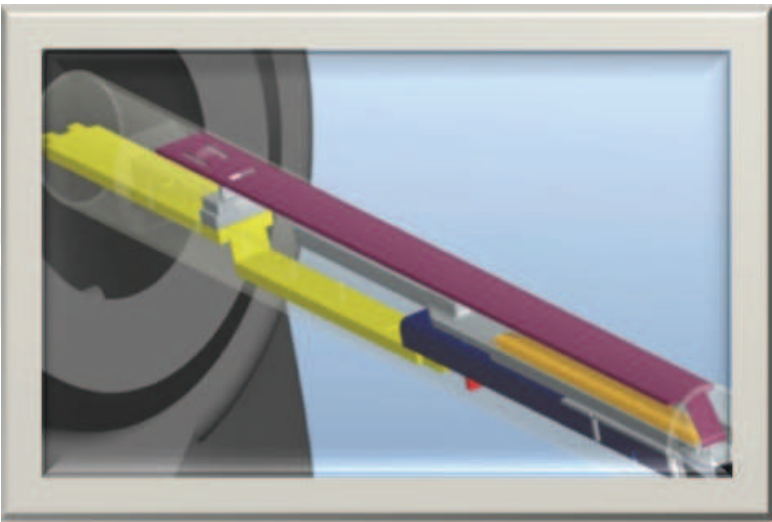


Fig. 7. Cross section view of endo surgical instrument

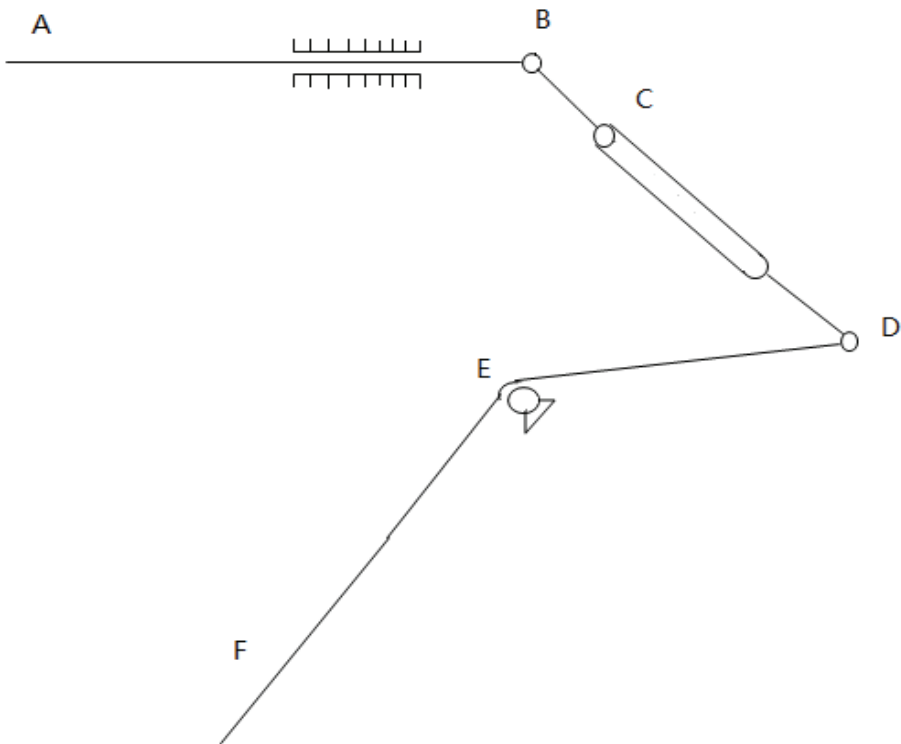


Fig. 8. Mechanism diagram

$$F \cdot 0.5 EF = F_1 \cdot DE \tag{2}$$

$$F_1 \cdot \cos(\theta) = N \cdot \cos(180-\alpha) \tag{3}$$

N is the force exerted onto pushing bar.
The velocity ratio of ($V_{\text{angular}} / V_{\text{linear}}$) can be determined by computer aided simulation targeting optimized instrument performance, and simulation results are shown in Figure 9.

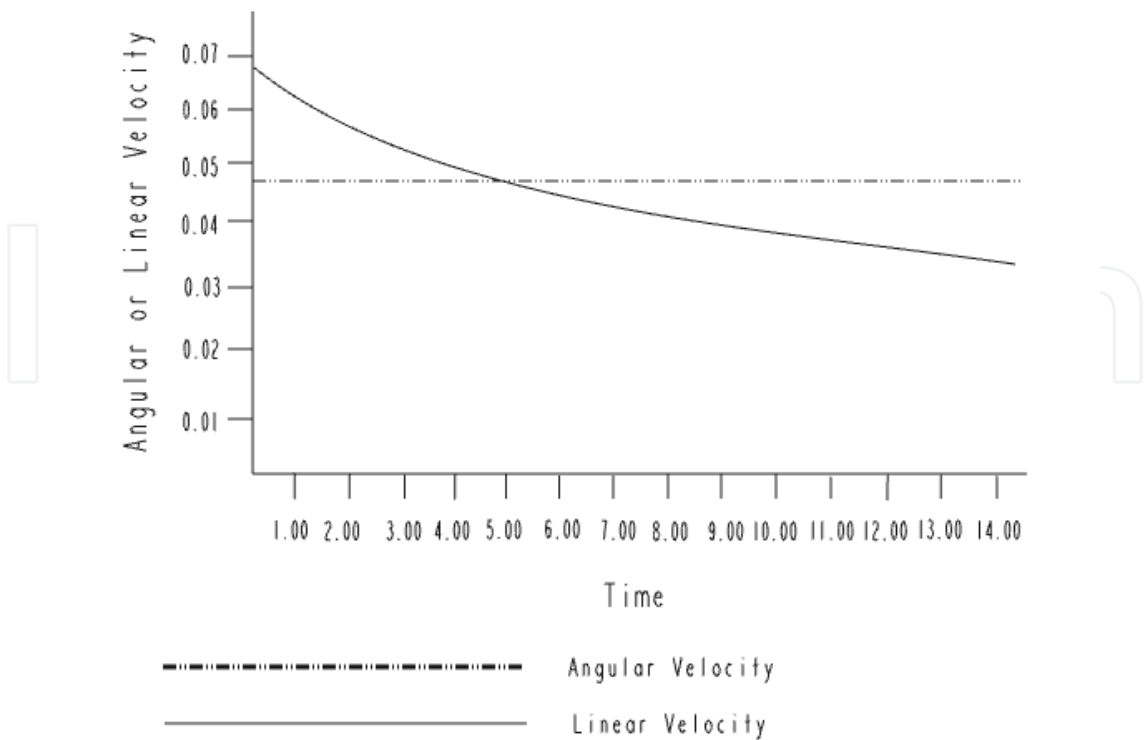


Fig. 9. Linear and angular velocity vs. time phase of instrument operation

The mechanical advantage of this new instrument can be found when surgical clip is fully formed:

$$\begin{aligned} \text{Mechanical advantage} &= (VR) * (3.75 / 1.70) \\ &= (.04840 / .03125) * (3.75 / 1.70) = 3.415 \end{aligned} \tag{4}$$

This result shows that, if 20 lbf forces are required to fully form the surgical clip, the operational force that surgeon needed is 2.928 lbf that is lower than normal spec of 4 lbf and this will benefit surgeons in their surgical procedure. Also, both computational simulation and prototype testing results are very close which verify and prove the credibility of this new instrument design and research methodology.

3.3 Discussion

This section presents the results of a new endo surgical/biomedical instrument design using 3D modeling simulations with CAD modeling software and structure/stress analysis by FEA simulation software. 3D modeling and computer aided simulation can benefit geometrical and dynamical analysis in conceptual and feasible design of biomedical surgical instruments. The geometric, dynamical and visual limitations of the surgical instruments are analyzed to assist the surgeon in surgical procedures. 3-D CAD modeling simulation is applied to the endo surgical equipment based on its feasible geometry and weeping boundary. The kinematics of precision 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. This new endo surgical instrument shows its feasible and reliable functionality, better mechanical advantage, cost effective in manufacturing process, and safe in use. This new biomedical/surgical instrument design has been analyzed and verified through the computational simulation and prototype testing. In addition to the preliminary lab testing, this new instrument has been sent for further hospital and field evaluations to continuously improve this instrument including enhancement of jaw section to keep instrument jaw tip portion from extra deformation when instrument is not being operated correctly in surgical processes, adding wedge plate between jaw area to keep jaw from unanticipated closure while additional side load exerted to the jaw tips, and modifying the instrument mechanism to further reduce the manufacturing cost.

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