Multifiring endoclip conceptual design using cad approach

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Abstract. The endoclip design that will be done is by designing cartridge components that have several clips. In essence, endoclip is a mechanical device in the world of health, especially for endoscopic activities, which are also used for the process of hemostasis and also non-hemostatic applications. This study describes the relationship between end-time end-endoscopic problems during gastrointestinal standards. Currently, market-available endoclips only focus on single-firing, where the process is carried out one by one. The use of Endoclip at this time is very difficult because of the repetition of the clip loading process to the applicator. Therefore, the purpose of this research is to design cartridges which consist of several clips for endoclip and allow for mechanical movements. The method of selecting the appropriate and important part of the tip which is the most important way to solve the problem and the design and process of the simulation is done using CATIA V5 software. The aim of this study was achieved by increasing the critical part of the catheter by replacing it with a cartridge design that contained several clips that allowed the clipping process to be multi-firing, not one-shot and also by simulating the mechanism.

1. Introduction

Endoclip (Figure 1 and Figure 2) is a metal mechanical device used in the health world in the endoscopy process to carry out several conditions. An important point in applying for the hemostasis process is the presence of a process of stopping internal bleeding due to ulcers, Mallory-Weiss tears, gastric lesions and tumors, diverticular bleeding and bleeding that occurs or high risk polypectomy sites [1]. It is also used for non-hemostatic applications such as providing markers on safety stents, filling tubes and existing devices, endoscopic lesions for x-ray or magnetism, fistula closure and others [1, 2].

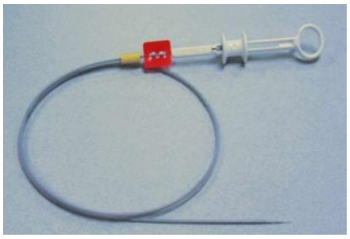

Figure 1. Common Endoclip by Olympus [5]

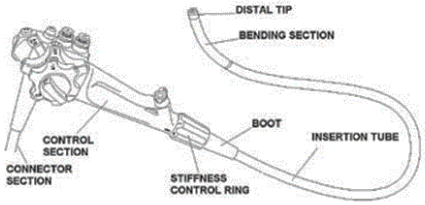

Figure 2. Flexible endoscope [3]

From the observations, it was found that there were 3 types of endoclips on the market. Each endoclips has its own specifications and is shown in table 6.

Table 1. Current specification for endoclips in market

Specification	Olympus Medical			Boston Scientific	Cook Medical Inc.	
Product name	Rotating Clip	QuickClip2	QuickClip2 (Long)	Resolution Clip	Triclip	Triclip
Clip size	>2.8 mm	>2.8 mm	>2.8 mm	>2.8 mm	>3.2 mm	>2.8 mm
Working lengt.	230 cm	240 cm	240 cm	235 c m	205 cm	207 cm
Max. initial lengt	17 mm	15 mm	17 mm	20 m m	18.5 mm	18.5 m m
Max. deployed length	13 mm	11 mm	13 mm	15. 5 mm	14.5 mm	14.5 m m
Max. opening width	11 mm	9.5 mm	11 mm	11 m m	12 mm	12 m m
Rotatability	Rotatable	Rotatable	Rotatable	Not rotatable	Not rotatable	Not rotatable
Re-opening	None	None	None	5 times	None	None
Clip material	Stainless steel	Stainless steel	Stain. steel	Stain. steel	Stain. steel	Stainless steel

The main issue for the current endoclip design is about its difficulty of loading the clips to the applicator. This is due to single firing operation of the clip standard gastrointestinal endoscopy practice. It has been explained that a patient requires an have an average of 3 clips that are in each process of clipping endoscopy, thus, the process of repetition of inserting and extracting the endoclip during the procedure need to be done [6]. The process will be time consuming and also could jeopardize the patient if involving emergency cases. Therefore, the solution of this problem is by designing a method of multi-firing of the clips during the endoscopic process which can reduce the process time and efficient in practice.

Thkalais paper mainly discuss about conceptual development of multi-firing clips in endoclip using Computer Aided Design (CAD), in order to visualize the mechanism of the multi-firing process. The approach taken for the conceptual design is aiming to put 3 clips inside a cartridge, then the cartridge will be put into a housing, it was designed to change the important part of the endoclip which is the tip of the catheter. The cartridge design prototype is carried out using 3D printing for a more tangible design of cartridge design and then making product samples. The type of endoclip that is chosen to be improved is Olympus endoclip (HX110-LR)

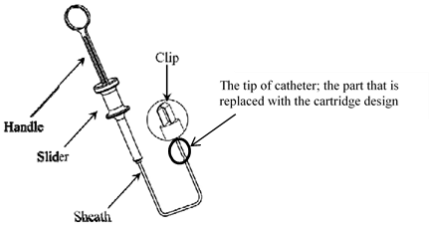

Figure 3. Components of endoclip [7]

The endoclip component consists of a slider, handle, sheath and clip at the end of the sheath as shown in Figure 3. The process for opening and closing processes can be arranged using the slider on the handle. The function of this sheath is to inhibit the damage that occurs and releases when the process is carried out from the clip during the insertion process of the clip inside the human body [7]. This envelope also functions to cover the catheter which is directly sticky to the clip component for clipping endoscopy so that insertion into the vein, for a narrow diameter, is slightly easier to implement. Clips that are located at the end of the casing can be opened and have the function of clipping and capturing the surgical area needed to do the clipping endoscope [7].

2. Conceptual generation for endoclip design improvement

Two elements have been considered in designing the arrangement of 3 clips inside a cartridge with respect to mechanism of multi-firing. The first one is about the arrangement of the clips inside the cartridge, then followed by arrangement of the designed cartridge in a housing which can be replace the tip of the catheter. All of the design is based on re-sketching of Olympus endoclip (HX110-LR) as in Figure 4.

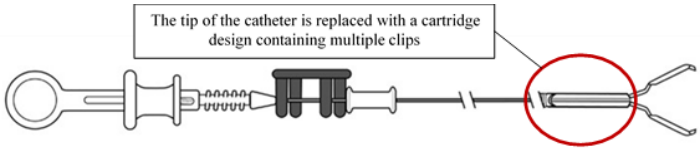

Figure 4. Sketch of endoclip device

For more detailed research, research using other concepts must be considered, this is said to be due to the difficulty of assembling cartridges. Therefore, other cartridges that are larger than the first cartridge must be complete, in other words having two pieces that can be combined and joined together, not just one part.

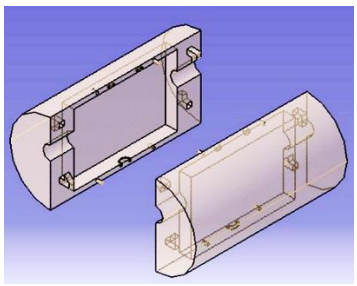

Figure 5. Two pieces parts of a housing design that can be clip together

3. Option of endoclip conceptual design

Three conceptual design have been develop to in consideration of few factors that highly influenced the mechanism of the multi-firing system. The considerations area placement of the clips, detailed complex designs, cartridge sizes on clips, clip mounting movements and overall system functionality. The computer aided design (CAD) models were develop using CATIA V5.

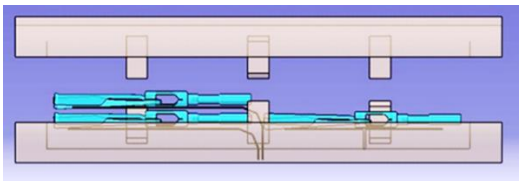

Figure 6. Model Concept 1 (side image)

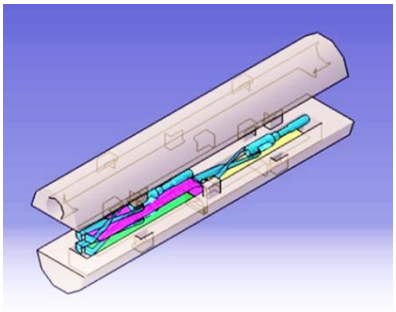

Figure 7. Model Concept 1 (isometric image)

Concept Design 1 (Figure 6 and Figure 7) shown the position of the clips that were arranged directly to the cartridge. Two standby clips are top of each other, standby to replace clip one after discharged.

Figure 8. Model Concept 2 (side image)

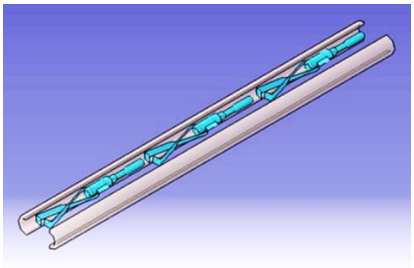

Figure 9. Model Concept 2 (isometric image)

Design for Model Design 2 (Figure 8 and Figure 9) arrange the clips back to back, which aims to replace the discharge clip in sequential mode. While for Concept Design 3 (Figure 10 and Figure 11) has stacking arrangement of clip inside a cartridge, and a housing will hold the cartridge during the operation.

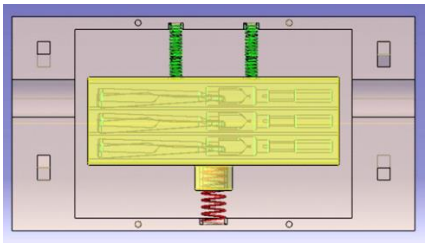

Figure 10. Design Concept 3 (side view)

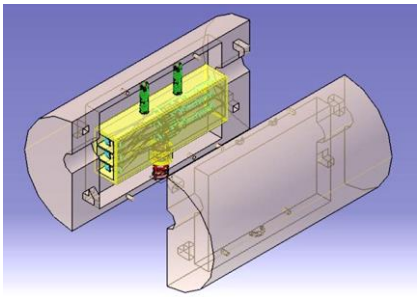

Figure 11. Design Concept 3 (isometric view)

For selection purposes, all of the concept designs were evaluated based on the concepts and component, and Decision Matrix tool was used to select the final design (Table 2 and Table 3)

Table 2. Decision Matrix

	Model 1	Model 2	Model 3
clip placement	4	2	6
Design Complex.	2	2	4
Dimension	4	6	2
Motion Clips	4	2	6
Functionality	4	2	6
Total Score	**18**	**14**	**24**

Table 3. Qualitative score assignment of the matrix

	Value
Good	6
Fair	4
Poor	2

4. CAD design and simulation of multifiring endoclip concept

Based on the weight of the overall score from the Matrix, Model Concept 3 was choosen. Therefore, further details design concerning Model 3 is complete for this procedure inclusive of mechanism simulation using CATIA V5 Digital Mock Up (DMU) unit. In details, Concept Design 3 composed of:

i) Clip cartridge : For the placement of multiple clips
ii) Housing cartridge : To hold the cartridge and replace the end catheter at endoclip

iii) Upper Spring : To align the position of cartridge with housing
iv) Lower Spring : To reposition the clips inside the cartridge which is under compression
v) Clips : Three clips for endoclip

The stacking arrangement of clips with spaces and movement to clips can be seen in Figure 12 and Figure 14. The housing design consists of pieces of RH and LF component. Assembly of both components is by using snap-lock joint (Figure 13). The movement of the clips is by lower spring which is in compressive mode.

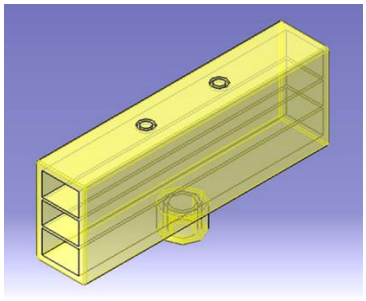

Figure 12. Conceptual design of clips cartridge

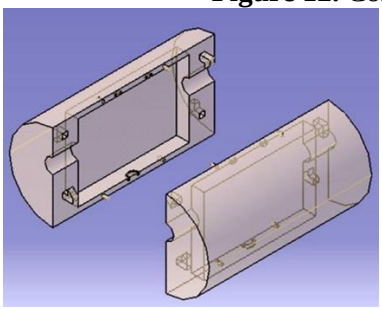

Figure 13. Two pieces snap-lock of cartridge housing holder

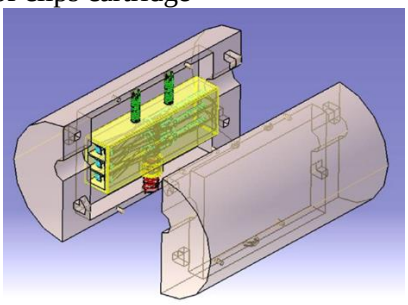

Figure 14. Complete position of the Concept Design 3, with position of clips, cartridge, upper spring and lower spring inside housing

The mechanism of discharging of clips from the cartridge has been made by using CATIA V5 DMU. However details design such as spring stiffness, stacking position and details attachment of the system to endoclip was not under consideration. However, the DMU was used to visualize the movement and mechanism of the system developed. It was shown in screen grab in Figure 15 – Figure 18.

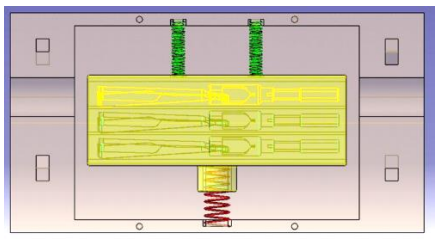

Figure 15. Discharge of first clip (top clip, highlighted with yellow colour)

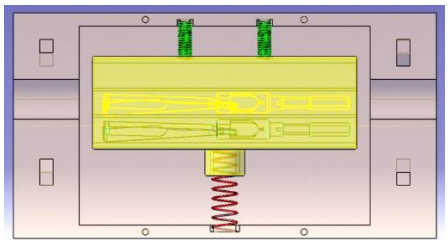

Figure 16. Alignment of cartridge by upper spring and reposition of clip by lower spring and ready for discharge number 2

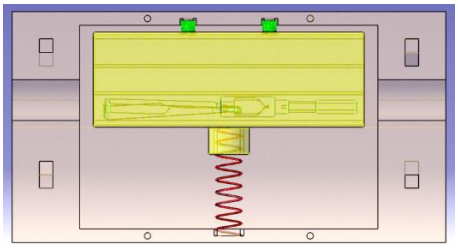

Figure 17. Repeating the mechanism of alignment of cartridge and reposition of clip

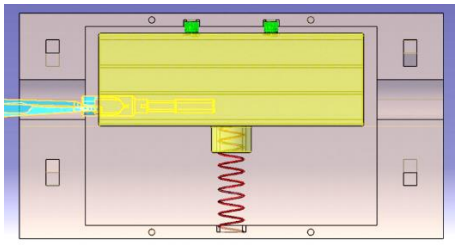

Figure 18. Discharging the final clip

5. Rapid prototyping model multifiring endoclip design

Prototype of this design was done by 3D printing process using Polyactic Acid (PLA) as the material. However, the size was upscale to 2.5 times due to small size of the design (Figure 19). The prototype was crucial in order to confirm the size, positon and arrangement of all parts from the Conceptual Design 3. It was found out that fitment of all component is acceptable and require to produce 1:1 scale of prototype for future works

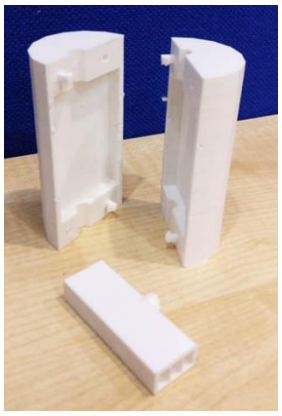

Figure 19. Prototype of cartridge design by using 3D printing process

6. Conclusion

From this project, the conceptual design of multi-firing clips for endoclip can used for further study. However, the detail design of the system is yet to be produced. Mechanical aspect of the design must be included for the next stage, focusing on the material selection for cartridge and housing, design and calculation for the spring system and replacement/ attachment of the system at the tip/ catheter of the endoclip.

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