Improvement of endoclip design using 3D CAD approach

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Abstract. Endoscopic clip (endoclip) is a metallic mechanical device used in gastrointestinal endoscopy practices with the intention of close mucosal surfaces deprived of the requirement for surgery and sew up. Nowadays, endoclip is accessible in the market predominantly in single firing mode, where the clip can only be used once in a period of process. Due to that, the clip is loaded to its applicator repeatedly during the operation which cause delay for the surgery that can lead to fatality. Therefore, this project aims to develop a multi-firing endoclip cartridge that can reduce the difficulty of reloading the endoclip system to its applicator by improving current design. Three design of multi-firing endoclip cartridges were produced by using different mechanism to apply the endoclip. The casing of the cartridge was designed in cylindrical shape with 40 mm diameter and 68 mm length with CATIA V5 software. These three designs formerly assessed by using decision matrix method for assortment of the best concept design. The result from the decision matrix table shows that design with revolve internal clip holder got the highest decision matrix selection amongst the three designs, advantaging in holding more clips and can reduce operation time compared to the other two designs.

1. Introduction
Metallic clipping such as endoclip were first introduced for the primary purpose of achieving haemostasis which is to stop the flow of blood of focal gastrointestinal bleeding. Endoscopic request of clips has been exposed to be effective in management of bleeding from peptic ulcer, Mallory-Weiss tear, Dieulafoy’s lesion, duodenum and colonic diverticula [1]. It is also playing an important role in non-haemostatic application such as markers to direct fluoroscopic stent placement and target surgical, binders to attach enteral tube and stent devices to the luminal wall and others.

Endoclip is used mainly alongside with the flexible gastrointestinal endoscope devices which are flexible instruments that combine fibre-optics and charged-coupled devices to facilitate illumination and visualization. The endoscope is made up of three basic parts: the tip, the insertion tube and the controller unit. The supplement tube is the part that enters the body of the endoscope and it contains a variable diameter working channel, which allows endoscopic accessories such as endoclip device to pass through [2].
There are several endoscopic clipping devices that are available on the market and others are being developed. Although they are different from each other but they share two similarities which are the metallic double or triple pronged clips and a delivery catheter-handle assembly. The most used types of endoclips are the Rotating Clip (Olympus Corporation), the QuickClip2 (Olympus Corporation), the Triclip (Wilson-Cook Medical Incorporated) and the Resolution Clip (Boston Scientific Corporation).

The endoclip applicator expedient contains of handle, slider, sheath and the clip. The procedural steps of endoclip are straightforward. The Teflon sheath functions as a cover for the clip and the catheter to prevent any damage and breakaway during the process of clip insertion inside the body. The orientation of the clip’s prongs can be accustomed by revolving the handle clockwise [3]. The clip must be press in contradiction of the lesions, put on suction and the slider necessity be rapidly dragged back to close the clip and then deploy it. A number of limitations had been identified by researchers when operating the endoclip devices and some improvement is essential to overcome the issue in the future. The development process is a essential stage in order to advance the device’s possible, efficiency and the usability in the gastrointestinal endoscopy practice. The limitations of the current endoclip device includes size of the lesion, access to the lesion, Fibrotic lesion and the single use submission.

This project aims to tackle the single use application of the existing endoclips. It is described that an average of 2.9 clips were required per patient to achieve haemostasis in a single procedure. Multi-firing clipping device such as the Clipmaster3 and the Multi-Clip are being developed and tested to overcome the same problem. Therefore, the need for design optimization of the endoclip device is a must to solve the issue at hand.

Using 3D computer aided design software (CATIA V5), a cartridge that covers multiple clip is planned to enable the endoclip to be multi-firing. The cartridge is designed to substitute the serious part of the endoclip, which is its catheter’s tip. Therefore, the scope of work of this project is to make an upgrading for the endoclip by designing a cartridge to replace the tip of its catheter and to create a prototype of the cartridge design by using 3D printing for the proof of concept of the design. The design of the cartridge is based on the Olympus endoclip (HX110-LR).

2. Concept generation
There are a few elements that necessity be measured when designing the improvement for the cartridge of the endoclip that lets the device to be multi-firing such as mechanism with attached endoclip, critical component identification and arrangement of clips inside cartridge.

The improvement idea for this project is to design a mechanism for the multi-firing endoclip cartridge is based on “Cartridge in Cartridge” design. The concept project has two cartridges attached together where the smaller cartridge which is for the settlement of the clips and the other bigger cartridge will house the smaller cartridge and it is design to replace the catheter of the clip application device.

The idea of the deployment mechanism is to hold the clip with a static part that is integrated with the larger cartridge and with the help of the spring to provide potential energy for the clips to move. Furthermore, other design must consider the difficulty of assembling the cartridges

3. Concept selection
Different cartridge deployment mechanism concepts are associated to control which concept is the best among the concept design. The selection of the concept design contains key components that must be considered and compared in order to accomplish the impartial of the project.

These components include design complexity, functionality, size of cartridge, ease of assembly and number of clips. So as to conduct the assortment process, all the conceptual design of endoclip cartridges were evaluated using the decision matrix method.
Table 1. Decision matrix for concept selection

| Criteria          | Design 1 | Design 2 | Design 3 |
|-------------------|----------|----------|----------|
| Design complexity | 4        | 6        | 2        |
| Functionality     | 4        | 4        | 4        |
| Size of cartridge | 2        | 4        | 2        |
| Ease of assembly  | 4        | 6        | 2        |
| Number of clips   | 4        | 4        | 2        |
| Total Average     | **18**   | **24**   | **12**   |

Qualitative Score Assignments

- Good: 6
- Fair: 4
- Poor: 2

4. Improvement design

Based on the evaluation from the decision matrix, the best designated was Design 2. Further details design regarding Design 2 was generated in the process, and all components of the design were
sketched using CATIA V5 software. Design 2 cartridge is composed with several important parts such as rotating cartridge, housing cartridge, spiral spring and clips.

![Figure 7. Isometric view of rotating clip](image1)

![Figure 8. Isometric view of housing cartridge](image2)

![Figure 9. Isometric view of the final design assembly](image3)

Each component was sketched based on the appropriate measurement and requirement, before being accumulated.

5. **Endoclip digital mock up**
The mechanism of the multi-firing cartridge was simulated by using Digital Mockup (DMU) Kinematics workbench in CATIA V5. The simulation shows the measure of the clips privileged the cartridge and the movement of the rotating clip which is the most critical part of this design. The spiral torsion spring stores the potential energy and can be converted as kinetic energy once the clip is deployed.
Fig. 10 shows that the first clip is being deployed to the affected area with a deflection of $\theta = 0^\circ$, this can be considered as the original orientation of the rotating cartridge. Fig. 11 shows that the first chamber is empty, and the rotating cartridge rotates anti-clockwise with a deflection of $\theta = 90^\circ$ to the next chamber that contains the second clip. The chamber is aligned with the hole at the housing cartridge because the static part at the rear of the housing cartridge holds the clip in place.

Fig. 12 shows that the third and final clip is being deployed to the affected area and rotates anti-clockwise with a deflection of $\theta = 180^\circ$, $270^\circ$ respectively. It uses the same mechanism concept in Fig. 16 where the spiral torsion spring rotates the rotating cartridge until the chamber and the hole at the housing cartridge is properly aligned.

6. Conclusions
In this project, the upgrading of endoclip design by designing a cartridge that covers numerous clips had met the objectives which is to design the mechanism for multi-firing endoclip cartridge and also to fabricate the optimize design using rapid prototyping. Three design concept of multi-firing endoclip cartridge were developed and each of the concept designs uses different deployment mechanism for the endoclip. The best design was selected by evaluating the critical component to achieve the objective by using decision matrix method.

The result of the decision matrix shows that design 2 got the highest mark in the table because it can hold more clip than the other two design and also it also can reduce operation time. The cartridge is designed to substitute the tip of the catheter of the endoclip so its design can be improved. Nonetheless, this project only gets the mechanism pattern of the multi-firing cartridge where it allows multiple clips to be deploy to the affected area without the need of reloading after single use.

For further research and design, the materials and properties for the endoclip cartridge and also the spring must be identified to continually improve the endoclip design. It is important also to develop on the attachment of the cartridge to the clip applicator so it can operate the endoclip.
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