



Research Article

A Review and Comparison of Vessel Ligation with Ligaclips

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Abstract

Background: For almost half a century, ligation using clips has been a standard method of obtaining hemostasis and duct closure quickly and inexpensively. During this period, Ligaclip has become the most widely used clip applier based on its performance in providing reliable hemostasis. This study reviews the application of Ligaclip and Ligamax in various surgical procedures and compares them to other devices in performance features that are critical in ensuring hemostasis and vessel sealing.

Methods: Ligaclip Multiple Clip Applier and Ligamax 5 Endoscopic Clip Applier were compared to conventional clip appliers for axial and transverse clip retention, and in the case of Ligaclip, for proximal gap.

Results: Ligaclip had 43% higher axial and 46% higher transverse retention force, and 36% smaller proximal gap than a conventional product. Ligamax had 122% higher axial and 22% lower transverse retention force than a conventional device.

Conclusion: Ligating clips, while simple in concept, are a versatile tool for hemostasis that are frequently used when other standard methods, such as staplers or energy devices, cannot be readily used. Additionally, the cost per procedure is typically lower than other approaches. Ligaclip and Ligamax have been shown to provide higher retention forces than other clip appliers, making them a popular choice for vessel sealing in a variety of surgical procedures.

Keywords: Blood vessel hemostasis; Clip retention; Ligation; Ligaclip

Introduction

A common risk during surgery is the possibility of incompletely secured blood or lymphatic vessels. Inadequate closure of vessels can lead to clinically, even life-threatening, bleeding or fluid accumulation. During surgery, the ligation of blood or lymph vessels with ligating loops or stitched ligature can be time consuming and sometimes challenging [1,2]. There are several surgical options for achieving adequate ligation of tubular structures such as hemostatic agents, electrocautery, surgical intervention with sutures or ligation clips. Advantages and disadvantages are associated with each approach and the choice depends upon the anatomic area of use and surgery indications and contraindications. Compared to the above therapies, there are no

patient characteristics that limit or define the use of clips. Studies have shown that the use of endoscopic clips decrease operative time, and they do not have the potential to cause thermal injury since clips do not heat tissue,[3] or lead to smoke exposure [4,5] Adverse effects of using hemostatic agents include incomplete product absorption, inflammation, and granuloma formation. In addition, neurologic manifestations may result from either direct neurotoxicity or unintended compression of adjacent neural structures [6].

Ethicon's Ligaclips are made of a biocompatible titanium alloy and are available in a variety of sizes. The clips work by closing opposing clip arms thereby clamping the vessel and/or producing vascular compression. Ethicon's clip appliers and clips are designed to deliver superior retention, efficient ligation and minimal vessel damage. Ligaclip Single-Clip Appliers (SCA's) are reloaded after each application, and may be re-sterilized for

multiple uses. SCA's are available in Open and Endoscopic (for 12 mm trocars) versions. Ligaclip Multi-Clip Applicators (MCA's) can be loaded with up to 30 clips that automatically advanced after each application. MCA's are available in Open and Endoscopic (for 12 mm trocars) versions. Ligamax 5 can also deliver multiple clips, but is designed to fit 5 mm trocars. The Endoscopic versions of Ligaclip MCA and Ligamax 5 have heads that can fully rotate by 360° for improved access. Both Ligaclip MCA's and Ligamax 5 are single-use devices, and cannot be re-sterilized.

When clips are properly applied and secured, leakage of fluid, such as blood or bile is prevented.[7] Ultimately, the tissue or vessel occluded by the clip is permanently stenosed and following inflammatory reactions, sealed by normal healing processes. Clips have been known to come off the ducts or vessels to which they have been applied, especially if they have not been fully closed. Clips have been observed being dislodged as they were being placed and immediately after they had been placed. These clips can also become dislodged from the severed end of the duct or vessel. If the vessel lumen is not effectively occluded, bile or blood is free to leak into patients postoperatively. The formation of fluid collections or hematomas may occur, potentially necessitating surgical re-exploration, blood transfusions, or other interventions. It is essential that clips have a high retention force and low rate of clip scissoring to reduce the risk of slippage or leakage after application. This study aimed to provide benchtop data to evaluate the retention force and closure for both Ligaclip MCA and Ligamax 5 Endoscopic MCA (Figure 1) compared to other conventional clip applicators.

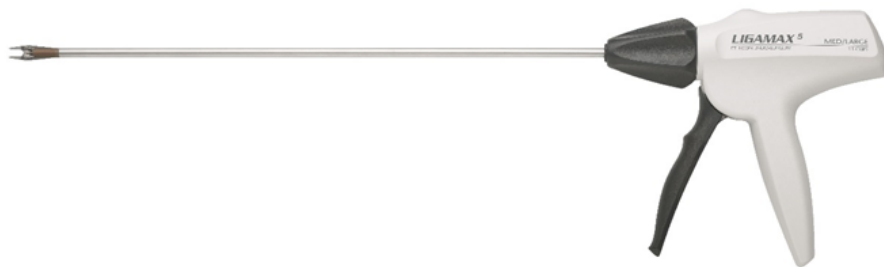


Figure 1: Ligamax 5 Clip Applicator.

Methods

Comparisons of functionality and physical characteristics were performed between Ligaclip MCA (MCS20, Ethicon, Cincinnati OH) and Premium Surgiclip S-9.0 (134046, Medtronic, Minneapolis MN). Clip gap was measured at the proximal end for fully formed clips fired in air (Figure 2). Axial and transverse clip retention (Figure 3) were measured on micro-polyurethane tubing (BB520-50, 1.0 mm I.D, 1.4 mm O.D, Scientific Commodities, Inc, Lake Havasu City, AZ). Pull-off force was measured using an Instron Test System with a 9 Newton load cell (Instron Corp, Norwood MA). Axial and transverse clip retentions were compared between Ligamax 5 Endoscopic Multiple Clip Applicator (EL5ML, Ethicon, Cincinnati OH) and Epix Universal Clip Applicator (CA500, Applied Medical, Rancho Santa Margarita, CA). Two clips from each device were tested for axial clip retention and two for transverse clip retention. For axial retention, the clip applicator was used on micro-polyurethane tubing (BB520-50, 1.0 mm I.D, 1.4 mm O.D, Scientific Commodities, Inc, Lake Havasu City, AZ). For transverse retention, the clip applicator was used on Silastic tubing (508-011, 3.4 mm I.D, 4.6 mm O.D, Dow Silicones, Midland, MI). Pull-off force was measured using pneumatic grips attached to a 44 Newton load cell with a pull rate of 5 cm/min. Statistical comparisons were performed via Student's t-test or Mann-Whitney if the data were non-normal, with an alpha of 0.05.



Figure 2: Proximal gap of a formed clip.

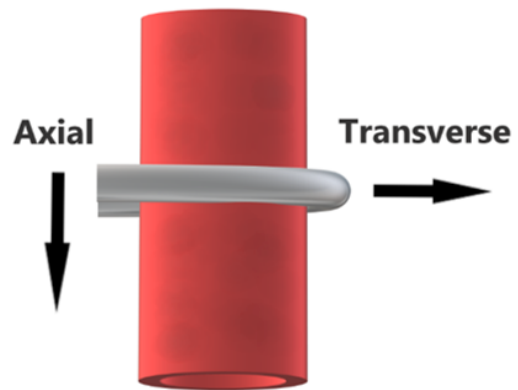


Figure 3: Direction of axial and transverse pull-off of clip relative to the blood vessel.

Results

Ligacclip MCA had a 36% smaller proximal gap than Surgiclip. Ligacclip MCA had a 43% higher axial retention force and a 46% higher transverse retention force than Surgiclip (Table 1, Figure 4). Axial retention force Ligamax 5 was 122% greater than the axial retention force for Epix, while Epix had a 28% higher transverse retention force (Table 2, Figure 5).

Measure	Ligacclip MCA	Surgiclip	p-value
Proximal Gap			
n	60	60	
Mean ± St Dev	40.1 ± 13.4 µm	62.4 ± 17.5 µm	<0.001
Axial Retention Force			
n	30	30	
Mean ± St Dev	5.50 ± 0.45 N	3.85 ± .0.30 N	<0.001
Transverse Retention Force			
n	30	30	
Mean ± St Dev	2.27 ± 0.21 N	1.56 ± 0.04 N	<0.001

Table 1: Summary of comparisons of Ligacclip MCA and Premium Surgiclip.

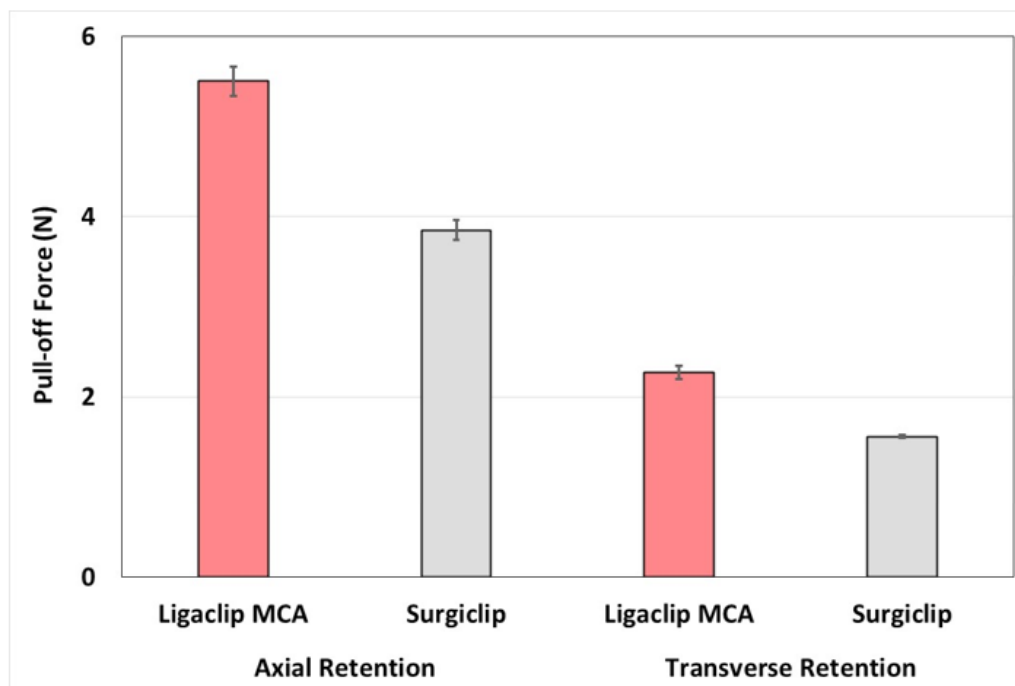


Figure 4: Axial and transverse retention forces for Ligacclip MCA and Premium Surgiclip. Error bars represent 95% confidence interval of the mean.

Measure	Ligamax 5	Epix	p-value
Axial Retention Force			
n	31	31	
Mean ± St Dev	7.45 ± 1.18 N	3.36 ± 1.33 N	<0.001
Transverse Retention Force			
n	32	32	
Mean ± St Dev	4.02 ± 0.19 N	5.14 ± 0.24 N	<0.001

Table 2: Summary of comparisons of Ligamax 5 and Epix.

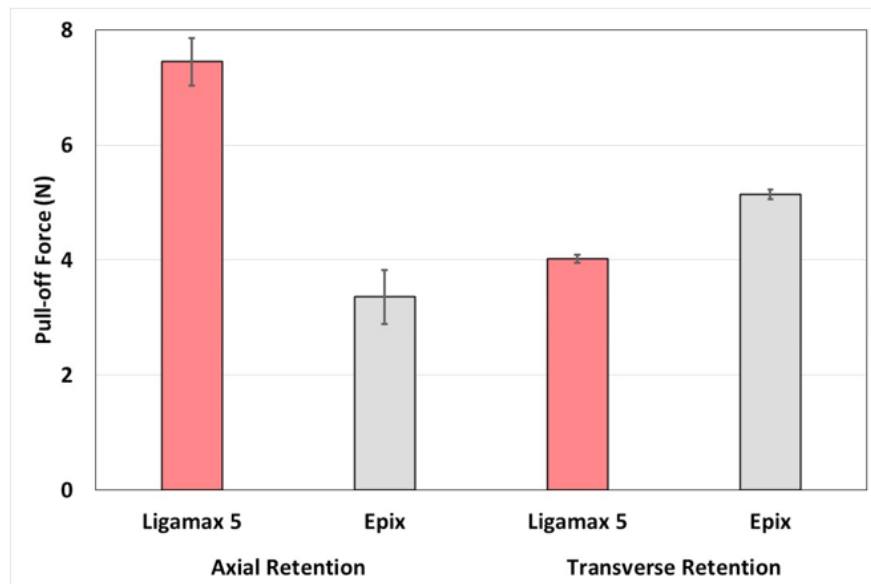


Figure 5: Axial and transverse retention forces for Ligamax 5 and Epix. Error bars represent 95% confidence interval of the mean.

intracorporeal knot tying and are less costly than endostaplers. The titanium endoclip can also be safely applied to an inflamed appendix base, and studies show that it has been safely applied to appendiceal diameters of up to 20 mm.[10] Moreover, complication rates are similar between endoclips and the other methods of stump closure, making it a suitable choice for use in laparoscopic appendectomy [10].

Controlling the renal hilar vessels during laparoscopic nephrectomy is typically performed by laparoscopic staplers, however, several cases of stapler malfunction were reported necessitating the search for better alternative methods for controlling the renal pedicle. Chibber, et al, demonstrated that the 10mm Ligaclip can be used for adequate renal hilar control without any incidence of slippage or dislodgment of clips for the vast majority of patients. In addition, they are approximately 6-fold cheaper than plastic clips and 12-fold cheaper than the staplers, making the Ligaclip a much more cost effective method for renal hilar control.[11] Titanium clips for vascular control have been shown to be cost effective in laparoscopic nephrectomy. [7] With regards to the cost effectiveness of clip closure, Albeniz, et al, found that clipping after resection of large colon lesions can provide a cost saving,[12] and Usmani, et al, noted that in appendectomy, clips were a cost-effective alternative compared to endoloops and surgical ties.[13] In contrast to surgical procedures where there are

numerous ways in which to achieve ligation of critical structures, endoclips are considered the gold standard for cystic artery and cystic duct ligation during laparoscopic cholecystectomy. One of the drawbacks of the metal endoclip is the possibility of surgical clip migration, but this is a very rare and oftentimes a late onset complication with less than 100 cases reported in the last 30 years. [14] Even though some studies have shown that using absorbable clips may be as safe and effective as metal endoclips, it appears that metal endoclips may be more beneficial for shorter cystic duct ligations due to the decreased likelihood of dislodgement [15].

Some metallic clips are known to slough off at 18-26 days after their application during gastrointestinal endoscopic procedures, whereas others will remain at their original site for up to a year.[16] Sloughing of metallic clips off vessels or ducts in the context of tissue healing has not been widely discussed in the surgical literature, but after endoscopy, it is reported that metallic clips can safely fall off and pass through the gastrointestinal tract within 3 weeks.[17] Tissue healing occurs in approximately 2-3 weeks in healthy individuals, allowing any vessels or mucosal defects that were clipped to heal effectively. Of note, tissue healing is likely to be prolonged for patients with several comorbidities or those undergoing additional treatments such as chemotherapy or radiation.



Figure 6: Scissoring of a formed clip.

Ligaclip Ligating Clips feature lateral and transverse grooves designed for secure fixation on the structure and increased resistance to dislodgement of a formed clip. Both Ligaclip MCA and LigaMax have a higher axial retention compared to other commercially-marketed products. The results observed in this study are in agreement with previous comparisons of clip retention. [18] If a clip is dislodged transversely prior to transection of the vessel, it can be replaced prior to substantial blood loss. However, if after transection a clip were to fall off axially, there is a potential for blood loss. Hence, the high axial retention force of Ligaclip applicators provides increased assurance that vessels will remain sealed perioperatively and thereafter. Scissoring is a non-alignment of the legs of a closed clip (Figure 6) and an excessive amount of scissoring may affect the integrity of the vessel sealing. Clips should have scissoring of less than half the width of a leg, typically about a half millimeter. Ligaclips have exhibited mean scissoring of only 0.05 mm, a wide safety margin providing confidence in sealing.

There are several devices that can be used for ligation of vessels, lymphatics, ducts, and tissue sealing, and both Ligaclip and Ligamax are tools that can help effectively achieve these goals during laparoscopic or open surgery. The cost per procedure for surgical clips is typically lower than other approaches. Ligating clips, while simple in concept, are a versatile tool for hemostasis that are frequently used when other standard methods, such as staplers or energy devices, cannot be readily used.

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