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Novel endoscopic-multi-firing-clip applicator for endoscopic closure of large colonic perforations

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Abstract

Background Existing endoclip closure devices have difficulty in closing large colonic perforation. We developed a novel endoscopic-multi-firing-clip applicator (EMFCA) system to address these limitations, and report on its initial evaluation.

Methods The functionality and efficacy of the prototype EMFCA equipped with re-openable clamp and preloaded with 4 clips were assessed using standardized 1.5 cm incisions created in *ex-vivo* porcine colonic segments. Endoscopic closure of the lacerations with 2, 3 and 4 clips (n = 5 for each group), was followed by measurement of the leakage pressure of the three groups. Finite element analysis (FEA) was performed to validate the clip behavior and reliability during deployment.

Results All the 15 perforations were sealed without leakage until fully distended. The leakage pressures of colonic lacerations sealed with 2-, 3-, and 4-clips were 26.1±2.8 mmHg, 37.3±7.3 mmHg and 42.3±7.4 mmHg, respectively. The mean operation time to deploy one clip was 25.4±5.2 seconds. On FEA, the deformation of the shape of clip matched that of the intended design, with each clip sustaining a maximum stress of 648.5 MPa without any material failure during deployment.

Conclusions These initial results confirm the efficacy of the EMFCA prototype system for endoscopic closure of colonic perforations.

Keywords Gastrointestinal perforation, Endoscopic closure, Through-the-scope clips, Multi-firing

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Introduction

Colonic iatrogenic perforation is an occasional but major complication of colonoscopy, with the incidence rate being 0.07% and 0.1% for diagnostic and therapeutic colonoscopy respectively [1-4]. They are caused by blunt trauma inflicted on the colonic wall by the tip of the colonoscope [4, 5]. Endoscopic closure by application of endoclips, is preferable as it avoids surgical intervention and had has been shown to reduce/ prevent serious morbidity [6]. For this reason, it is preferred to surgical treatment in the first instance by most colonoscopists in view of its reliable outcome and convenience. Endoscopic closure is also the standard treatment for other gastrointestinal (GI) perforations [7, 8].

Over the past 40 years, significant progress has been made in the design and material composition of endoclips. Moreover, the clinical use of clips has been extended from GI hemostasis to the fixation of stents and catheters [9-11], and for other interventions [12-15]. Endoscopic clips include through-the-scope clips (TTSC) and Over-the-scope clip system (OTSC; Ovesco Endoscopy AG, Tübingen, Germany). Four common single-firing TTSC products are commercial available: QuickClip2 and QuickClip Pro (Olympus Optical Ltd., Tokyo, Japan), Resolution Clip (Boston Scientific, Natick, MA, USA) and Instinct Clip (Cook Medical, Bloomington, IN, USA). One report on the comparison of the mechanical properties of the TTSC products favors the Instinct Clip as it exhibits the greatest opening force and best overall performance [16]. Besides, multi-firing TTSC products include InScope Multi-Clip Applier (InScope, a division of Ethicon Endosurgery, Cincinnati, Ohio, USA) which is out of market and Clipmaster3 (Medwork, Höchststadt an der Aisch, Germany). Clipmaster3 can deploy three clips directly in one insertion [17], whereas it is not commonly used and lack clinical and experimental results.

However, most of TTSC products are single-firing and they have limitation in gathering both edge, hence they are not ideal for closing large GI perforation. In this respect, although OTSC is reported to result in good clinical outcome following its use in endoscopic closure of perforations [18], additional cumbersome procedure is needed for clip removal; whilst TTSC may drop off following application [19].

To address these issues, we have designed and developed an endoscopic-multi-firing-clip applicator (EMFCA), specifically for closure of large colonic perforations, and report on the initial ex-vivo evaluation of the initial prototype system.

Materials and methods

Design and fabrication

The EMFCA which is designed to deploy clips in single session, is equipped with a clamp that enables the operator improved orientation and approximation of the laceration before application of clips for closure of defect. The EMFCA includes a cartridge containing 4 clips, a tube outer sheath and handle (**Fig. 1a**). Each clip has a symmetrical “U” shape. The thin distal sections of the two arms are designed to interlock when applied to the tissue. The clamp which is located at the distal end of the cartridge, has a maximum opening angle of 110° enabling improved grasping/approximation of the laceration edges. The grooves on the opposing surfaces of the clamp serve as guide for the advancement of the clips after the clamp is closed for approximation of edges, when the opposed surfaces of the closed clamp form tunnels designed to bend the thin distal arms to engage the two approximated edges of the laceration. The handle opens and closes the clamp by a sliding slot, and a button is used to advance and deploy the clips. As the maximum outer diameter of the prototype of EMFCA is 5 mm, a special industrial boroscope with a large working channel was modified to enable its deployment through a large instrument channel (**Fig. 1b**). The modified boroscope incorporates 2 spacers, a camera for imaging, and contained PVC tubing internally, serving as the working channel for the EMFCA. The outer diameter of the modified boroscope is 15 mm. Clips, cartridge and clamp are made of stainless steel. The tube of both EMFCA and modified boroscope are made from PTFE tubing wrapped with waterproof tape as outer sheath.

Working mechanism

The clamp of EMFCA is opened for positioning on either side of the laceration edges with the cartridge containing the clips at 90° to the long axis of the laceration. It is essential that the laceration edges are in view and within clamp range (**Fig. 2a**). The clamp is then closed for approximation and grasping of the two edges which are squeezed on to the cartridge (**Fig. 2b**). As the row of clips is advanced, the most distal clip is pushed in the clamp, such that its two distal thin arms pierce the two edges of the clamped laceration. With the further advancement, the thin segments of the arms are bent by the inner curve of the closed clamp thereby clipping the two edges together (**Fig. 2c**). The deployed clip will retain the two edges on release as the clamp is opened (**Fig. 2d**).

System function

The EMFCA is inserted through the working channel of the modified boroscope in the closed position. Once the device appears in the field of view, the first step consists of opening the clamp by push sliding slot on handle (**Fig. 3a**). Next, the operator adjusts the orientation of the clamp and slot to ensure satisfactory position with respect to laceration. Thereafter, the edges of the perforation are approximated tightly by closure of the clamp. This is followed by clip advancement by pushing the button on the handle (**Fig. 3b**), after which the clamp is opened to release the clip holding the two approximated edges (**Fig. 3c**). Finally, succeeding clips are applied by repeating the same activating sequence to close the perforation up to a maximum of 4 depending on size of laceration (**Fig. 3d**).

Ex-vivo evaluation experiments

This was undertaken to assess the functionality of the prototype EMFCA in colonic closure using *ex-vivo* porcine colon segments. A total of 15 colonic 1.5 cm lacerations were closed with the EMFCA deploying 2, 3 and 4 clips (n = 5 for each group). Closure strength was assessed by measuring the leakage pressure. The whole process was performed in the academic center of university with the assistance of an experienced endoscopists (Bing HU, MD) and medical postgraduates.

The 15 experiments were undertaken on fresh *ex-vivo* 40 – 50 cm colonic segments obtained from local abattoir immediately after sacrifice, and cleaned of fecal matter with running water. A standardized 1.5 cm full-thickness incision was made by surgical scalpel at approximately 25 cm from one end of the specimens. The perforations were then expanded by inserting the tip of boroscope through incision repeatedly in order to make it circular. The prepared specimen was then mounted on the operating platform with plastic bars (**Fig. 4a**). The modified boroscope was inserted from the open ‘anal’ end of the segment with EMFCA inserted in the working channel. The clips were deployed with endoscopic guidance at intervals of 0.5 cm, 0.4 cm, and 0.3 cm depending on the number of clips (2, 3, 4) used for closure of laceration.

Following this, the segments were removed from platform. A PVC tube was inserted into one end of the segment for infusion, with the other end being cross-clamped (**Fig. 4b**). The leakage pressure was recorded when the closure site first began to leak. A one-way analysis of variance (ANOVA) was performed with SPSS 19.0 (SPSS Inc., Chicago, IL, USA) to determine whether the differences in leakage pressures were significant, statistical significance being set at 5%.

Finite Element Analysis

As closure is entirely dependent on the plastic deformation of the clips used to hold the edges to enable healing, accurate characterization of the suitability and reliability of the component material is crucial. For this reason, finite element analysis (FEA) was used to assess deformation and stress of the clip during deployment. The geometric models were designed in Solidworks 2010 (Dassault Systèmes SOLIDWORKS Corp., Waltham, MA, USA) and then were exported to Abaqus 6.10 (Dassault Systèmes Simulia Corp., Providence, RI, USA) for calculation. The same geometric model of the clip was created, but only half of the model was used in calculation due to its structural central symmetry. To reduce calculation time, a simplified model with a U-shaped-groove, the function of which was identical to that of the closed clamp during deployment was adopted (**Fig. 4c**). As the friction between tissue and clip was small, it was ignored in the analysis.

The nominal stress/strain data of material were acquired from the by using material testing machine (INSTRON 5965; INSTRON Corp., Norwood, MA, USA). The tensiometry data were then converted into true stress/strain. The elastic properties of the clip were Young's modulus (99.6 MPa) and Poisson's ratio (0.3) while the plastic properties were presented by yield stress (239 MPa), tensile strength (901.0 MPa) and fracture strain (0.262). The U-shaped-groove model was set as a discrete rigid body due to the great stiffness difference between two parts.

A hexahedral mesh model was generated onto the clip with the refinement in the thin arm (**Fig. 4d**) whereas a rough tetrahedral mesh model was generated onto the U-shaped-groove (not shown). A frictionless, general contact property was set to the entire system. The U-shaped-groove was fixed to reproduce the real working situation. The split plane of the clip was constrained except for axial movement to ensure the stability. An axial velocity load of 50.0 mm/s which accorded with the handle was applied on the top surface to advance the clip. The analysis ended when the axial displacement of clip has reached to 2 mm.

3 Results

Ex-vivo study

All the perforations were sealed without observable leakage from closed laceration when the specimens reached to their maximum distension during infusion. The infusion was continued beyond this point to determine the burst pressures of the three groups. As expected, the burst pressure of the closed 1.5 cm laceration depended on the number of clips, with the highest mean

pressure (42.3 ± 7.4 mmHg) observed in the 4 clip closure group. The average time to deploy one clip was 25.4 ± 5.2 seconds. On macroscopic examination of the 15 specimens closed by EMFCA, the clips were observed to have grasped the full thickness of the mucosa, reaching the submucosa.

The burst pressures shown in **Fig. 5** were statistically significant between the three groups. The 4-clip closure group was highly significantly stronger than the 2-clip group ($P < 0.01$); with the 3-clip closure being significantly greater than 2-clip group ($P < 0.05$) but lower than that of 4-clip group ($P = 0.281$).

Finite element analysis

Fig. 6 shows the centrosymmetric simulation result of clip after deployment. The deformed shape of the clip matched fully its original intended design. The thin arms of the clip bent inwards, toward each other, with the stress being concentrated in the center of thin arm. The maximum Von Mises equivalent stress of the clip was 648.5 MPa, which was less than the tensile strength (901.0 MPa). No material failure was encountered during all the 15 closures.

4 Discussion

Endoclips are widely used for the endoscopic control of gastrointestinal hemorrhage and closure of perforations, and it was proved to be technically feasible for closing large perforations [6]. However, TTSC products are not fully capable due to the two main problems. Firstly, the same drawback exists: TTSC products are created specifically for hemostasis rather than closure. Therefore, they are limited in the orientation and tissue gathering, lacking the ability of grabbing or approximating defects with large diastasis between edges. A combination technique by using clips and endoscopic loop has recently been suggested to tackle this issue, but it may require a double-channel endoscope that is not commonly used in hospital [20]. Secondly, a 1.5-cm perforation is too large to be closed with less than 5 clips clinically. Most of the existing TTSC devices can only deliver and apply one clip with each endoscopic insertions as they do not incorporate a multi-firing function. This means that several repeat insertion of the endoscope are needed to close a large defect endoscopically, resulting in increased operating time and overall costs of treatment [21, 22].

In this communication, we describe novel endoscopic-multi-firing-clip applicator (EMFCA) specifically designed to address this issue concerning endoscopic closure of large perforation, or any other endoscopic intervention, requiring precise multiple serial clip applications. To this effect,

the EMFCA system can deploy 4 clips during one insertion, with significant shortening of the intervention and improved precision of clip deployment and hence task quality. The clamp, an integral component of the EMFCA can be opened/closed without limitation to ensure the maximal accuracy in the approximation and make sure that even gaping edges of the defect can be easily captured when compared to other TTSC products. And teeth of clamp can be also useful both in grabbing edges and preventing the clamped tissue from slipping before the advancement of the clips.

The results of *ex-vivo* study indicate that EMFCA functions well and with its use, closure of 1.5 cm colonic perforations is feasible as all 15 perforations were sealed by EMFCA withstanding leakage at maximum distention of the colonic segments. Although our experiments showed all the closures created by EMFCA were not full-thickness, we do not consider this to be an issue, as this is the case with all available TTSC products, all of which produce partial-thickness apposition of mucosa and submucosa, which is compatible with *in-vivo* healing of large colonic perforations [6]. However, the leakage pressures of 3-clip and 4-clip closure groups were both significant higher than that closure of the 1.5 cm laceration by the 2-clip closure. This may represent better closure of large (1.5-cm) perforations and may possibly lead to improved clinical outcome; but this will require *in-vivo* studies for confirmation.

Nevertheless, the leakage pressure of EMFCA is relatively lower than that of standard clips according to the literature [23], which we think is closely related to the mechanism clips close the defect. In this respect, standard clips grab the defect from mucosa, squeezing the mucosal and/or seromuscular tissue, thus resulting in a relatively higher leakage pressure. However, there may be a slippage due to open-loop closure by standard clips, which is disadvantageous to long lasting anchoring. In contrast, the clamp of EMFCA is utilized to grasp and invert the margins of the defect, with the closure being formed beneath the submucosa of the clamped tissue by clips. In the case that a certain threshold (10 mmHg) is sufficient for maintaining the integrity of colon wall, closed-loop closure by EMFCA is beneficial to a long-term therapy.

In the present study, the average time required to deploy one clip by EMFCA (25.4 ± 5.2 seconds) was relatively long when compared to that by standard clipping devices since the deploying procedure of EMFCA has 4 steps while that of the standard clips only has 3 steps. However, regarding to the overall operation time, endoscopic closure of large perforations by the EMFCA

system is fast and certainly shorter, with 3 minutes being required to apply 1-4 clips to close a 1.5 cm laceration due to its multi-firing functionality. By comparison, approximately 10 min is needed to deploy 1 to 4 standard clips reported in the literature [1]. It is obvious that without the need for re-loading and repeat insertion of the endoscope, the operating time of the endoscopic intervention is shortened considerably.

The result of FEA study confirmed the reliability of the clip, the thick arms of which ensured the stability while the thin arms allowed the plastic deformation necessary for effective closure of the approximated edges. Relationship between closure strength and bending of the clip is unknown but we have demonstrated that the maximum stress of 648.5 MPa did not reach the maximal tensile strength of the hardened stainless steel material used in clip construction. Equally, it is difficult to remove the clip after deployment, ensuring secure closure resistant to clip dislodgement.

We acknowledge that the present study does have some limitations. First, the size of prototype was not small enough to be inserted into a standard colonoscope, and for this reason, we had to use a modified industrial boroscope, which is shorter and may not be able to reach all regions of the colon. A second-generation device of which the outer diameter is 3 mm is now in process to ensure its application in normal endoscope, with the length of the cartridge and clips being shortened in order to make it more flexible. Secondly, the flexibility of the boroscope was reduced because of its relatively rigid nature, such that the operator experienced difficulty in bending the endoscope beyond 30°. This problem is also going to be solved when using the normal endoscope.

5 Conclusions

EMFCA is preloaded with a cartridge containing 4 clips and equipped with re-openable clamp. These features enhance its capability for efficient endoscopic closure of colonic perforations. The multi-firing and reopening functions eliminates the need for reloading the endoscope if several clips are required. In addition, the clamp enables more precise approximation of the edges with improved accuracy of the clip deployment.

The feasibility and overall functionality of the EMFCA was confirmed by *ex-vivo* study experiments using porcine colonic segments; whereas the functional closure of the clips was evaluated by finite element analysis.

Developmental work is on-going to address the current limitations of the EMFCA. Once these are addressed, further assessment of the performance of EMFCA by in-vivo chronic large animal studies will be needed before commercialization and translation into a clinical device.

Acknowledgments

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Figure List:

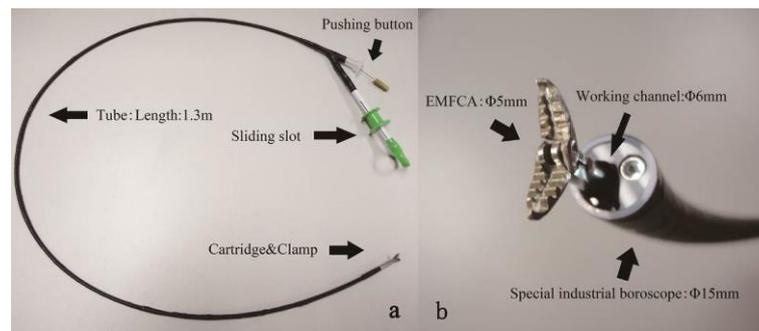


Fig. 1 Prototype of EMFCA and modified boroscope.

a Endoscopic-multi-firing-clip applicator system includes cartridge, clamp, tube and handle.

b Modified boroscope with large working channel was made to enable the deployment.

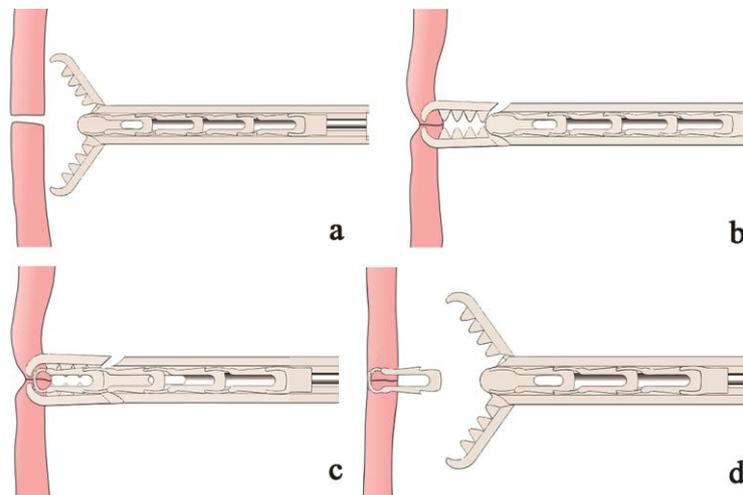


Fig. 2 Schematic diagram of EMFCA.

a Clamp is opened for positioning on either side of the perforation. **b** Clamp is closed to approximate and squeeze two edges of perforation. **c** The most distal clip is advanced for penetration of tissues and in the process the two pointed thin distal segments bend inwards clipping the edges. **d** Clamp is released to complete the deployment.

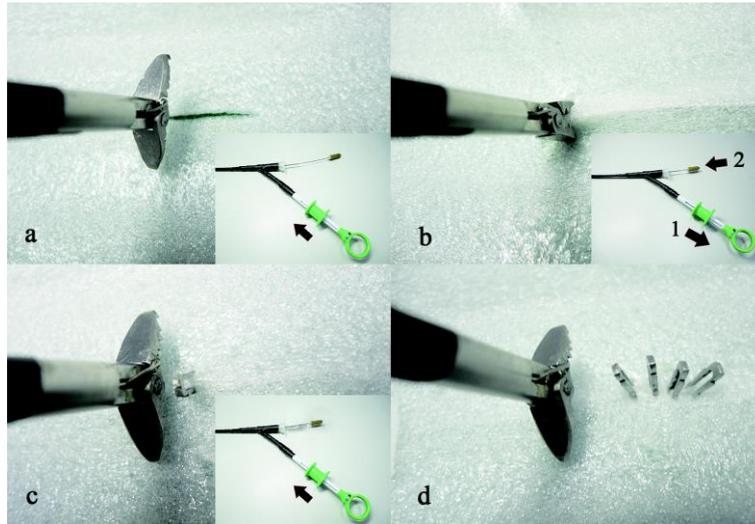


Fig. 3 Operation of EMFCA.

a Clamp opened by pushing sliding mechanism. **b** (1) Slide is kept open until the clamp jaws encompass the edges of the laceration, which are then opposed by closure of clamp, (2) advance clip by pushing the button, after which, **c** the slide is pushed further to deploy the clip on the edges. **d** Repeat sequence to achieve closure of perforation.

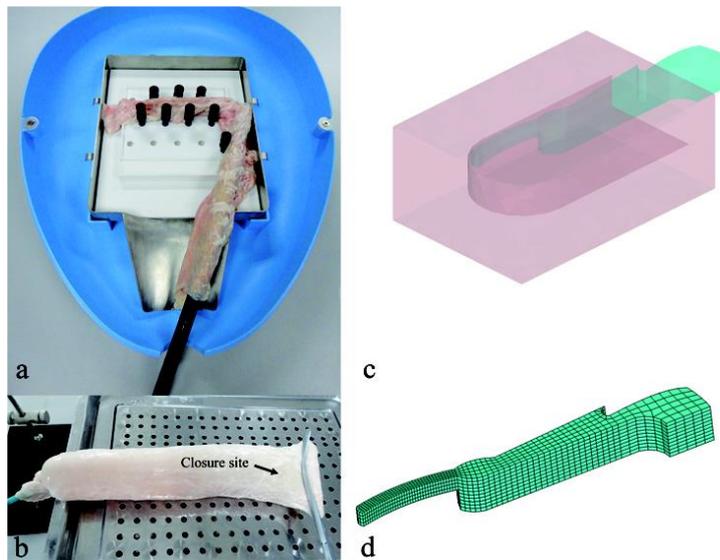


Fig. 4 a Operating platform - specimen was mounted with plastic bars. **b** Leakage pressure testing. The leakage pressure was recorded when the closed laceration first started to leak. **c** Geometry models of the clip and U-shaped-groove model. **d** Hexahedral mesh was generated to the clip.

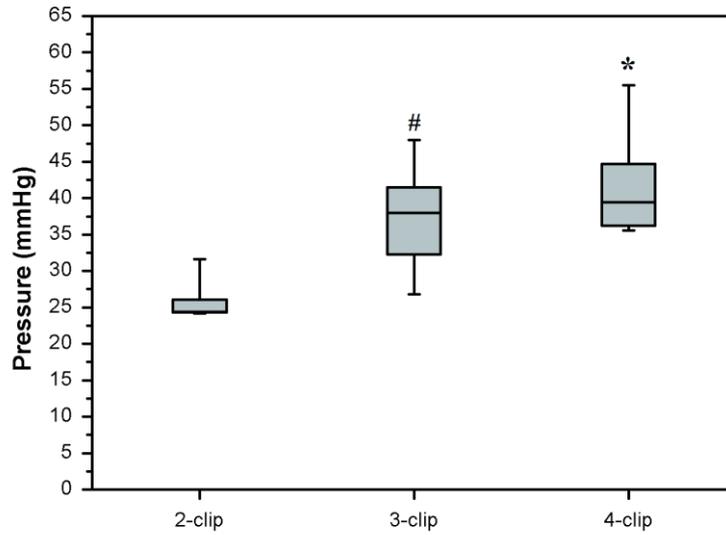


Fig. 5 Leakage pressures (median and range) for 2-clip, 3-clip, and 4-clip groups. *P < 0.01 for 4-clip versus 2-clip and #P < 0.05 for 3-clip versus 2-clip.

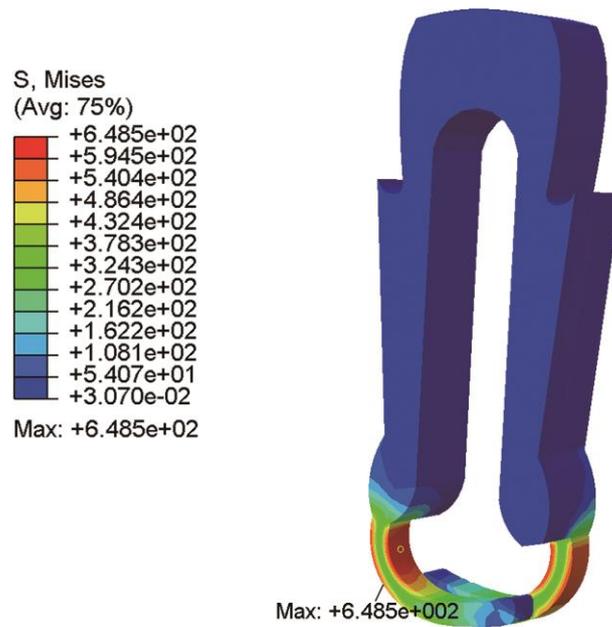


Fig. 6 Mises stress contour of the clip in a symmetrical view. The maximum stress was 648.5 MPa and was located in thin arms.