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Pull-off characteristics of double-shanked compared to single-shanked ligation clips: an animal study

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Abstract

Background: The use of surgical ligation clips is considered as the gold standard for the closure of vessels, particularly in laparoscopic surgery. The safety of clips is mainly achieved by the deep indentation of the metal bar with a high retention force. A novel double-shanked (DS) titanium clip was compared to two single-shanked clips with respect to axial and radial pull-off forces.
Methods: In a porcine model (8 animals, 51±1 kg), arteries were prepared immediately after euthanisation, assigned to either a medium (2–4 mm; n=120) or a medium-large (3.5–7 mm; n=120) clip size group, and clipped with the appropriate clip size. After dissection, axial and radial pull-off forces were measured.
Results: The axial pull-off force of the DS-Clip was higher than one single-shanked clip and comparable to the other single-shanked clip, and overall was linearly correlated to the cross-sectional area of the clip. The radial pull-off force of the DS-Clip was significantly higher than both single-shanked clips and, for the single-shanked clips, was correlated to the total clip thickness. The variation of radial pull-off force was lower for the DS-Clip due to a defined catch in the clip applier.
Conclusions: The radial pull-off force was lower than the axial pull-off force in total and therefore appears to be the critical point of dislocation. Due to the higher total holding mass, the DS-Clip provided a clear advantage in this regard and might therefore decrease the dislocation rate. The catch in the applier increases the reproducibility in clip placement.

Keywords: double-shanked; pull-off force; surgical ligation clips; titanium.

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Introduction

Despite current developments in bipolar or ultrasonic devices, surgical clips still remain the gold standard for the ligation of vessels and hollow organs, especially in the field of minimally invasive surgery. This is mainly due to safety, availability, speed and, not least, cost. However, this technique has one major drawback that should be addressed carefully: clips might dislocate intraoperatively either through handling (e.g. linked with further surgical steps) or through physiological movement-induced shearing forces. Their application should be monitored carefully, as an early intraoperative dislocation or late dislocation and migration may cause major complications [1–7]. Nevertheless, ligation clips are used very frequently. This results in numerous clipped vessels and contributes to the accumulation of the risk.

The shearing forces that result in the dislocation of the clip may be either in the axial direction of the vessel or radial to the vessel or a combination of both. Theoretically, the axial pull-off force may be mainly influenced by the geometry, the material and the diameter of the clip shanks, resulting in different tissue-clip adhesion forces at the interface. Radial pull-off forces may be additionally influenced by the retention force of the hinge. The occurrence of clips bursting away from the vessels due to blood pressure appears to be a minor effect [8]. To address this safety issue, it is not uncommon for surgeons to place a sequence of two clips on the remaining vessel stump.

This has led to the development of double-shanked (DS) clips, which allow the placement of a clip with two parallel shanks in one procedure, a technique that is already applied successfully in appendectomy [9, 10]. The question arises whether these clips provide increased shear forces for removal and thereby increase the resistance of the clip to accidental or physiological displacement.

Materials and methods

Animals

The research related to animals use has been complied with all the relevant national regulations and institutional policies for the care and use of animals. After approval by the institutional review board for animal experiments, eight female German Landrace pigs weighing 51±1 kg received a two-step intramuscular premedication consisting of atropine (0.05 mg/kg) and azaperone (4.0 mg/kg) followed by midazolam (1.0 mg/kg) and ketamine (14 mg/kg). After transfer to the operating theatre and placement of a peripheral venous catheter, the animals received heparin (200 IU/kg i.v.) and were euthanised by T61 (150 µL/kg i.v.).

Preparation and clipping of vessels

Arteria saphena, arteria carotis, arteria axillaris and arteria femoralis were prepared for the application of the clips. Twenty DS-Clips (DS: DS-Clips, Aesculap AG, Tuttlingen, Germany) of each size [medium (M) and medium-large (ML)] and each pull-off direction (radial and axial) were compared to an equal number of two state-of-the-art single-shanked clip systems (S1: Ligaclip, Ethicon, Cincinnati, OH, USA; S2: Horizon Titanium Ligating Clips, Teleflex Medical, Athlone, Ireland) by a single experienced surgeon (G.M.), resulting in a total number of 240 applied clips (Figure 1). Clip dimensions were measured using a micrometre gauge (precision ±2 µm; Table 1). The vessel diameter was determined using a ruler. Clips of size M were applied

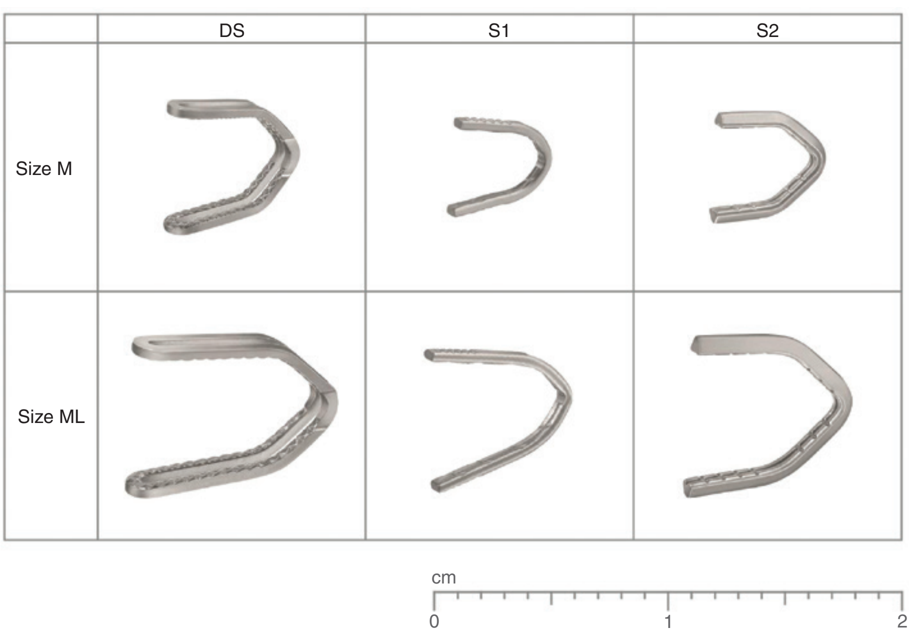

Figure 1: Ligation clips analyzed in the study (DS: DS-Clip, Aesculap AG; S1: Ligaclip, Ethicon; S2: Horizon, Teleflex Medical).

Table 1: Shank dimensions from 12 measurements (mean±SEM).

Clip size	DS		S1		S2	
	M	ML	M	ML	M	ML
Material thickness (µm)	482±2	579±1	503±1	603±1	678±2	834±1
Shank width (µm)[a]	538±3	648±2	759±2	1043±2	802±1	966±2
Cross-sectional area (mm^2)[a]	0.259	0.375	0.382	0.628	0.543	0.806

[a]DS-Clip measurements refer to one clip shank.

to vessels of 2–4 mm and clips of size ML were applied to vessels of 3.5–7 mm. The sequence was predefined by a block randomisation protocol (DS, S1, and S2 in all six permutations). The vessels were dissected leaving 15 mm on the proximal side and 2 mm on the distal side of the clip for axial pull-off and 12 mm on both sides for radial pull-off.

Evaluation of pull-off forces

The pull-off forces were measured as described previously [11, 12]. In brief (Figure 2), for the evaluation of radial pull-off forces, a ligature was placed inside the hinge of the clip, the vessel was fixed on both ends and the ligature was connected to a tension testing machine (testControl II, Zwick, Ulm, Germany). Subsequently, the clip was removed from the vessel. For the evaluation of axial pull-off forces, the proximal stump of the vessel was fixed and the clip was fixed on both sides and removed by the tension testing machine.

The tension testing machine was calibrated according to the manufacturer's instructions. The rate of feed was set to a constant 5 mm/min. The maximum removal force was determined from the load-displacement diagram.

Statistics

All results were given in mean±SEM. The groups were compared using the Tukey-Kramer test for unpaired samples, with $p<0.05$ considered significant. Due to the clip design (Figure 1), the cross-sectional area was counted twice for the DS-Clips. A rectangular approximation was used for the cross-sectional area (Table 1).

Results

All possible confounding parameters were distributed homogeneously amongst the groups (Table 2). The axial pull-off force for the M-sized DS-Clip (4.6±0.2 N) was significantly higher than the single-shanked control S1 (3.3±0.2 N; $p<0.05$; Figure 3, left) and slightly higher than the single-shanked control S2 (4.1±0.2 N, n.s.). The pull-off force of the ML-sized DS-Clip (7.8±0.5 N) was higher than the control clip S1 (6.1±0.5 N; $p<0.05$) and the pull-off force of the control clip S2 (8.7±0.5) was higher than the control clip S1 ($p<0.05$; Figure 3, right).

The radial pull-off force of the DS-Clip in both sizes (2.1±0.1 N for the M size and 3.0±0.2 N for the ML size) was significantly elevated compared to the single-shanked clips ($p<0.05$ for all comparisons; Figure 4).

Irrespective of the anatomical vessel, clip size and manufacturer, there was a linear correlation (R=0.982) between the radial pull-off forces of single-shanked

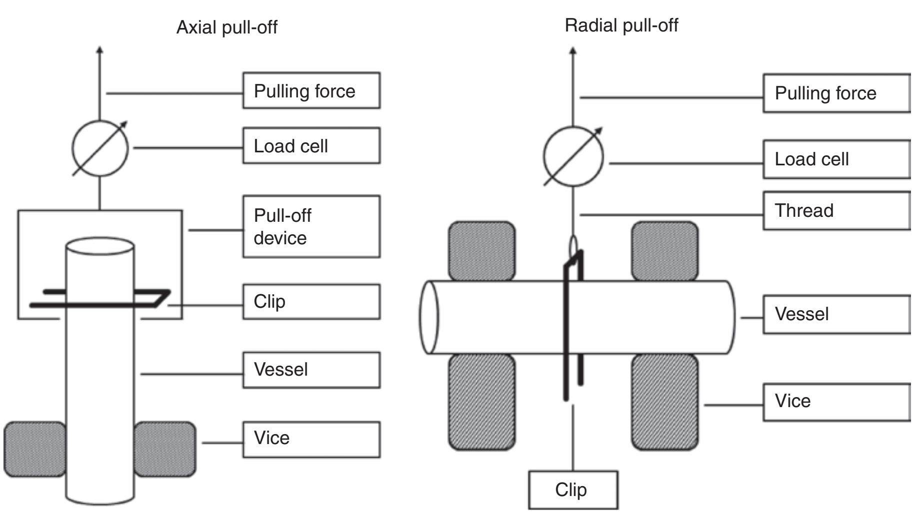

Figure 2: Schematic drawing of measurement set-up.

Table 2: Possible confounding parameters (mean±SEM).

	DS	S1	S2	p-Value
Vessel diameter size M (mm; n=40 per group)	2.8±0.1	2.9±0.1	2.7±0.1	n.s.
Vessel diameter size ML (mm; n=40 per group)	5.4±0.1	5.6±0.1	5.4±0.1	n.s.
Time from death to clip application (min; n=80 per group)	71±5	68±5	68±5	n.s.
Time from clip application to dissection (min; n=80 per group)	2.7±0.2	2.6±0.1	2.7±0.2	n.s.

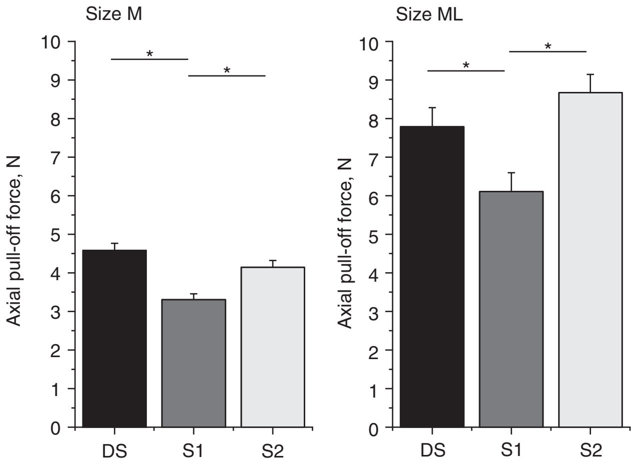

Figure 3: Comparison of axial pull-off forces in the three experimental groups with M-sized clips (left; n=20 per group) and ML-sized clips (right; n=20 per group; *p<0.05).

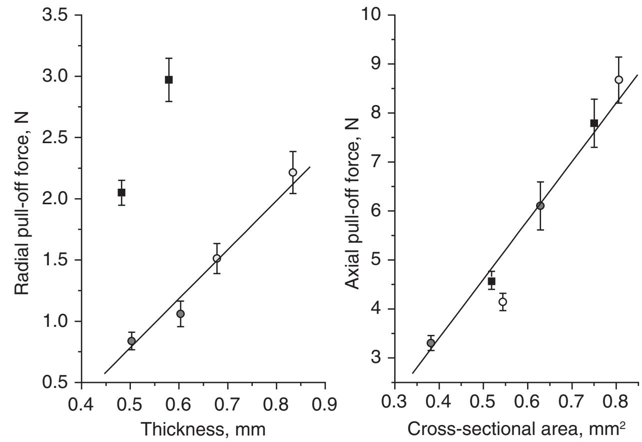

Figure 5: Correlation between clip material thickness and radial pull-off force (left; ■ for the DS-Clips and ● for the single-shanked clips; p<0.001) as well as cross-sectional area and axial pull-off force (right; ■ for the DS-Clips and ● for the single-shanked clips; p<0.001, one point ○ excluded).

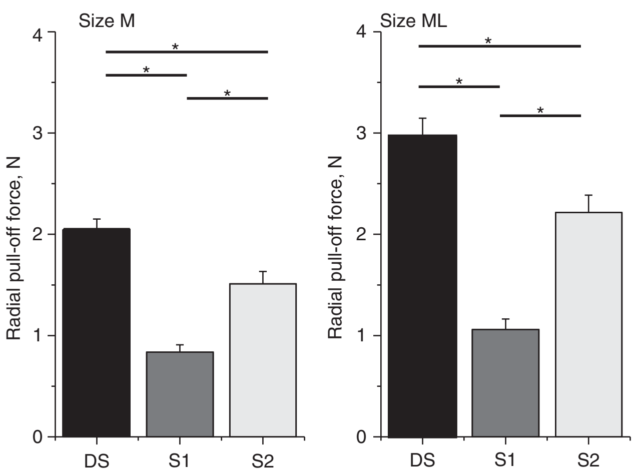

Figure 4: Comparison of radial pull-off forces in the three experimental groups with M-sized clips (left; n=20 per group) and ML-sized clips (right; n=20 per group; *p<0.05).

clips and material thickness. With the DS-Clip, higher pull-off forces were obtained even with a lower material thickness (Figure 5, left). This was in good correlation to the observations of significant differences between S1 and S2 groups (Figure 4). A comparably linear correlation (R=0.992) was observed between the cross-sectional area of the clip and the axial pull-off force (Figure 5, right).

The variation coefficient of pull-off forces of the DS-Clip applier of the M size in the radial pull-off setting was 22% compared to 38% in the S1 group and 36% in the S2 group (Figure 6, right). For the ML-sized clip applier in the same setting, the variation coefficient of the DS-Clips was 27% compared to 44% in the S1 group and 35% in the S2 group. The variation in axial pull-off forces was comparable in all clip types for the M size (Figure 6, left).

Discussion

Addressing the removal safety issue, it became obvious that the radial pull-off force is less than half the force needed for axial pull-off. In accordance with in vitro results, it can be concluded that the radial type of shear stress can be expected to be crucial in clip dislocation [13, 14]. The Nelson et al. study using silicon tubes resulted in a 1.8-fold axial removal force compared to radial removal force and was comparable to the results of the present study in the animal model (2.2-fold). With respect to the radial pull-off force, the DS-Clip provides a clear advantage over single-shanked clips.

The axial pull-off force obtained in this study was comparable to that obtained by an axial pull-off study on cystic duct stumps [15]. The axial pull-off force of the DS-Clip is higher than one single-shanked clip (S1) and comparable to the other single-shanked clip (S2).

The usage of non-perfused vessels of dead animals as a limitation of the model may be regarded of only limited importance for two reasons. First, in all laparoscopic and open-surgical interventions, the second and potential further clips are placed on non-perfused vessels as well. Second, it is not likely that the stop of the blood flow will change the biological and physical properties of the vessel.

In general, it was observed that the crucial radial retention force has a linear correlation to the horizontal

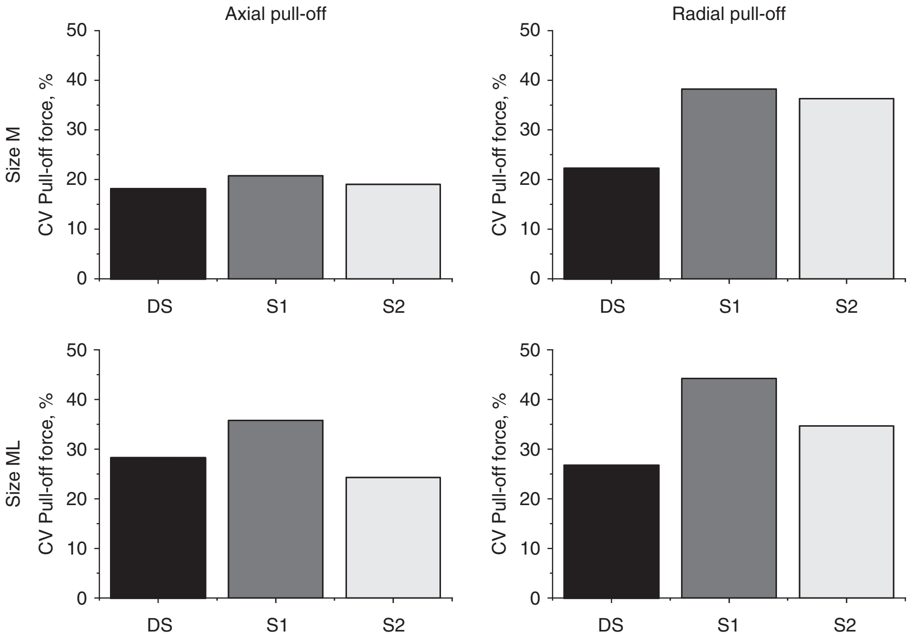

Figure 6: Comparison of the coefficient of variation (CV) of pull-off forces with respect to clip size and pull-off direction.

thickness of the tested clips, explaining the differences between S1 and S2 groups. During the bending process, the tapering of the material on the outside and compression on the inside in the hinge region influences the retention force. One might consider surgical clips with an asymmetric material distribution resulting in a higher material thickness in that crucial region. The axial retention force is correlated to the combination of horizontal and vertical thicknesses. Taking into account the fact that materials, surface structures and jaw parts were comparable amongst the tested clips, it could be considered that an increase in safety might be achieved only by increasing material thickness. This may, however, be limited by the force needed to close the applier.

A lower variation coefficient for radial pull-off forces of the DS-Clips was observed. These results were obtained despite all the clippings being performed by a highly experienced surgeon. This may be due to the defined catch in the applier of the DS-Clips. These findings have to be confirmed by a cross-sectional study involving a larger cohort of surgeons with different professional experience, hand size and force. One might expect that the catch significantly contributes to the reproducibility of clip application.

The old saying "more is better" is an obvious truth in surgical clip application. The DS-Clip expanded the linear correlation of material thickness and cross-sectional area and led to higher safety. Although a safe vascular closure can be obtained with thinner and single-shanked clips, the wider DS-Clip is more resistant against removal. The defined catch in the applier may help to standardise application forces and may help surgeons to gain reassurance regarding closing forces.

Author Statement

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Author Contributions

Data retrieval: Gottfried Mueller, Tim Oliver Greiner, Christine Fahrner; *Revision of the manuscript*: Gottfried Mueller, Alfred Koenigsrainer, Christian Thiel; *Approval of the manuscript*: Alfred Koenigsrainer.

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Supplemental Material: The article (DOI: 10.1515/iss-2016-0003) offers reviewer assessments as supplementary material.