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**Comparison of the use of two barbed sutures for pelvic flexure enterotomy in the horse**

**Title:**

**Ex vivo comparison of barbed sutures for pelvic flexure enterotomy in horses**

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**Abstract**

**Objective:** To compare closure of pelvic flexure enterotomy sites in normal equine cadavers between two different knotless barbed sutures, a single-layer closure and a double-layer conventional suture closure with absorbable suture by evaluating construction time, luminal reduction percentage, bursting pressure, leakage, exposed suture and cost.

**Study design:** Ex-vivo study.

**Sample population:** 24freshcadaver adult equine large colons.

**Methods:** A 10cm long pelvic flexure enterotomy was created in each specimen and was randomly assigned to one of four closures (n=6): single-layer absorbable suture, double-layer absorbable suture, single-layer unidirectional barbed suture or single-layer bidirectional barbed suture. Construction time, radiographic evidence of luminal reduction (percentage), bursting pressure and method of failure were measured for each construct. Cost, leakage, exposed suture and general appearance of each construct were recorded. Comparisons between groups were performed with a one-way ANOVA and post hoc Bonferonni test with significance at P<0.05.

**Results:** Double-layer closure had the highest bursting pressure (mean=178.50 mmHg, SD= 9.79, P< 0.001) but took more time to place (P= 0.001) than all other groups. Construction time of both barbed suture closures did not differ from the single-layer closure (P=0.27 and P=0.06). Bursting strengths of both uni- (mean= 91.67mmHg, SD= 5.57) and bi-directional (87.50mmHg, SD= 8.69) barbed sutures were lower than both single- (mean= 117.67 mmHg, SD= 11.69, P<0.001) and double-layer (mean= 178.50 mmHg, SD= 9.79, P<0.001) closures. No exposed suture was visible with either barbed suture but knots were exposed on both single- and double layer closures.

**Conclusion**: Uni- and bi-directional barbed sutures may shorten surgical time and reduce exposed suture material and knots in pelvic flexure enterotomy closures but had lower bursting strengths compared to conventional single- and double- layer closures.

**Clinical significance:** Further evaluation of the use of barbed sutures for pelvic flexure enterotomy closure is warranted to determine if they can withstand normal physiological pressures that may be encountered in the equine large colon.

**Introduction**

Enterotomy of the pelvic flexure (PFE) is commonly performed during exploratory laparotomy to facilitate treatment of impaction of the large colon by removal of foreign bodies, facilitate re-positioning of the large colon and to evacuate large colon contents to assist management of more distally positioned lesions.1,2 Traditionally, double-layer closure with hand sewn techniques using 2-0 absorbable suture material with either a simple continuous pattern in the seromuscular layer followed by a Lembert or a Cushing pattern has been recommended.1 PFE increases surgical time, results in additional handling of bowel, can result in contamination of the surgical site and may leave suture material exposed on the serosal surface of bowel. 2 Resultant local inflammation can decrease intestinal motility and promote adhesion formation. 2 A number of recent studies have evaluated hand-sewn single-layer, hand-sewn double-layer and stapled closures ex vivo to determine the effectiveness of different techniques for closure.2–4 The latter studies reported conflicting outcomes regarding the bursting strength of single- versus double-layer closure. A partial thickness inverting suture pattern resulted in less contamination of the surgical site than a full thickness appositional pattern. 5 In a study by Gandini et al 3, stapled and one layer suture closures of PFE were faster to construct but resulted in lower bursting pressures than traditional double- layer closure. Aldrich et al2 concluded that double-layer closure with line reversal (using a single suture tied off after the first layer and then reversed back along the incision) resulted in similar bursting pressures to traditional double-layer closure and had no difference in construction time.

Barbed sutures have recently become commercially available and can be either unidirectional or bidirectional. This type of suture is self-anchoring such that it can be advanced through tissue but cannot be reversed due to the presence of barbs on the surface. The proposed benefits of barbed suture includes; even distribution of tension; decreased construction time; increased holding ability and decreased total suture material within tissues. These factors have potential to reduce tissue inflammation and knot-associated complications 6–9 and suggest exciting potential for use in equine surgery. Systematic reviews and meta-analyses have concluded that use of barbed sutures during human gynaecological procedures had equivalent results compared to conventional absorbable suture material 10 and in some cases decreased complication rates. 11

Recently barbed sutures have been examined ex vivo in the equine bladder, 13 in vitro in equine jejunum, 6 and linea alba14 and laparoscopically for inguinal ring closure, 15 ablation of the nephrosplenic space 16 and uteropexy. 17 To the best of the authors’ knowledge, there is no information regarding the use of barbed suture in equine large colon where the effect of reduced surgical time, decreased volume and exposure of suture could offer significant benefit during PFE closure.

The objective of the study presented here was to compare closure of cadaver PFE using one of the following; two different knotless barbed sutures; single- layer closure with conventional absorbable suture; and double- layer conventional suture closure. Total construction time, luminal diameter, bursting pressures, leakage, visual appearance/exposed suture and cost were evaluated for each technique. The first hypothesis was that total construction time for the barbed sutures would be less than that required for conventional double-layer closure. Secondly, we hypothesised closure of the PFE with barbed suture would have comparable bursting pressure and reduction in luminal diameter when compared to a single-layer conventional suture closure.

**Materials and Methods**

Large intestinal segments, including the pelvic flexure, were harvested from 24 horses at a licenced abattoir. The Animals (Scientific Procedures) Act 1986, Schedule 2, does not define collection from these sources as scientific procedures and ethical approval was therefore not required. All of the colons in the study were harvested immediately following slaughter, emptied of ingesta, rinsed in a water bath and placed in saline filled bags for transport at room temperature as previously described by Gandini et al.3 Testing was performed within six hours of collection. Collection of samples and testing adhered to the research guidelines of the University of Liverpool’s Institutional Ethics Committee.

Large colon segments were each 60 cm long and were centered at the pelvic flexure. The enterotomy site was marked with a permanent marker using a 10 cm template, centred over the pelvic flexure on the anti-mesenteric border. A metal cannula was inserted into the lumen at both ends of each specimen and was secured with two cable ties. The cannula in the left dorsal colon was attached to an insufflation pump (Storz electronic laproflator, Karl Storz endoscopy, Tuttlingen, Germany). The cannula in the left ventral colon was then attached to a manometer. The construct was inflated with CO2 to a pressure of 10mm Hg as previously described3. Radiographic examination was performed as per the protocol described by Gandini et al: the generator was vertically orientated with the colon placed on the radiographic plate below and the beam was centred over a second mark-up line, made with permanent marker, perpendicular to the line on the anti-mesenteric border indicating the location of the enterotomy. Two radio-opaque markers (skin staples) were placed on the second line at approximately 1/3 and 2/3 of the distance between the mesenteric and anti-mesenteric surfaces. A digital radiograph was then obtained (Figure 1). The enterotomy was then performed with a #10 scalpel blade over the marked incision in the inflated specimen.

Following the creation of the incision, the specimens were assigned to one of four equal groups of six specimens for closure by random allocation (number drawn from an envelope). A single operator (MS) performed closures immediately. Stay sutures were applied at either end of the enterotomy and were clamped to the table with U-clamps at set points to ensure that standard tension was applied to each construct. All techniques had previously been practiced in both foam models and ex vivo equine pelvic flexures including suturing with both types of barbed suture.

The groups were as follows:

1. Single layer (S-L) – the enterotomy was closed with a single layer continuous Cushing pattern with 2-0 USP /3 Metric braided glycolide/lactide copolymer (Polysorb, Lactomer 9-1, Synature, Covidean, Mansfield, MA) with a 1/2 taper point 30 mm needle. A surgeon’s throw was performed followed by four overthrows for a total of five throws. Suture passes were placed 4mm from the cut edge and were spaced to ensure even inversion of the suture line and the suture line was extended 5mm beyond the cut edge before the knot was tied with a surgeon’s knot followed by two further throws.
2. Double layer (D-L) – the enterotomy was closed using braided 2-0 USP /3 Metric braided glycolide/lactide copolymer (Polysorb, Lactomer 9-1, Synature, Covidean, Mansfield, MA) in a simple continuous suture pattern in the seromuscular layer with bites placed 5mm from the cut edge. The first line was tied off, cut and then was over-sewn with a Cushing suture pattern with suture passes placed to cause even inversion of the suture line. The suture line was extended 5mm beyond the cut edge before the knot was tied.
3. Unidirectional barbed suture (V-Loc 90, Absorbable Wound Closure Device, Synature, Covidean, Mansfield, MA) (V-Loc) – the enterotomy was closed in a single continuous Cushing pattern with 2-0 USP /3 Metric 1/2 taper point 30 mm needle V-Loc suture with a technique as previously described by Major et al. 13 To start the suture line, the needle was passed through the seromuscular layer on the upper right side of the incision. The needle was then fed through the tail loop and tightened. The needle was passed through the seromuscular layer on the opposite (lower) side of the incision and a traditional Cushing pattern was performed (Figure 2). The tension was adjusted by gentle traction on the suture after each bite was placed along the suture line during construction. The suture line was extended for a further 5mm beyond the enterotomy incision before being reversed by taking two retrograde passes which overlapped the already closed incision. This acted as the knot and prevented suture pull through.
4. Bidirectional barbed (Quill Monoderm, Surgical Specialities Corporation, Wyomissing, Pennsylvania) (Quill) – the enterotomy was closed in a single continuous Cushing pattern with the 0 USP/ 3.5 Metric Quill with ½ circle 18 diamond point needle equivalent to 2-0 USP conventional suture as previously described by Major et al. 13 To start the suture line, the suture was passed through both sides of the incision at the midpoint, through the seromuscular layer and was pulled until the barbs on the second half of the suture engaged. The suture line was then closed in a Cushing pattern first from the center to the right and then from the center to the left. The suture line was extended for a further 5mm beyond the enterotomy incision before being reversed by taking two retrograde passes that overlapped the already closed incision. This acted as the knot and prevented suture pull through. (Figure 3).

Construction time was obtained from video recordings of the procedure and was considered the time in minutes from the placement of the stay sutures to the point at which the suture was cut at the end of the construct. After construction each specimen was subjectively visually assessed (MS) for inversion of the suture line (Yes/No), exposed suture material (Yes/No), and distortion of the intestinal contour (Yes/No). The cost of each construct was also recorded (USD).

Visual tests for leakage at anastomosis sites using methelyne blue have previously been validated 3,18 . Two litres of tap water coloured with 10 ml Methylene blue were instilled through the port of one metal cannula and the cannula portals in the ventral and dorsal colons were closed. The dye containing fluid was massaged past the enterotomy site to determine if there was any leakage and was then removed via the cannula in the left dorsal colon. The constructs were then re-inflated to 10 mmHg and a repeat radiograph was taken with the same positioning to compare pre- and post-enterotomy luminal diameters (Figure 1). Digital radiographic images were viewed on the image-processing software Visbion Image Viewer 64 (Visbion Ltd, Version 4.1.0.6, Surrey UK) and measurements were made to determine the percentage luminal reduction. The two radio-opaque markers were used to center a line drawn from each inner edge of the lumen to the opposite side. This measurement was taken three times for each sample before and after closure of the enterotomy. A median value was obtained and the percentage reduction was calculated as previously described 3 using the formula:

$\frac{First distance-second distance}{First distance}$ X 100

All measurements were performed by a single operator (MS).

Finally, bursting strength was measured using a modified gas inflation water tank test 3,19 where each construct was inflated by direct connection to a compressed CO₂ tank followed by inflation at 1L/min until construct failure. Results were recorded on digital video and failure pressure was determined by the presence of bubbles from the construct; decreased luminal pressure; rupture/bursting of the enterotomy; or rupture of intestine adjacent to the suture line.

**Statistical analysis**

Output variables of construction time (minutes), percentage decrease in luminal diameter and bursting pressure (mmHg) were compared between PFE closure groups. A Shapiro-Wilks test for normality was performed. Mean and standard deviation (SD) were calculated for the output variables of construction time, percentage decrease in luminal diameter and bursting pressure. Comparisons between groups were made using 1-way ANOVA. Post hoc Tukey multiple comparisons of means were then performed for a pairwise comparison between groups. The effect of suturing order on construction time was assessed for each group by Spearman’s rank correlation. Homogeneity of variance was assessed with Levene's Test. Statistical analysis was performed in the R statistical environment (R core team, 2018). Significance was set at P< 0.05. Cost of suture material (USD), leakage at the enterotomy site (yes/no), inversion of the suture line (yes/no), suture visible (yes/no) and distortion of the suture line (yes/no) were recorded and summarised.

**Results**

Pelvic flexures were harvested from 24 horses (age 2-14 years, mean weight 510 kg).

Construction time did not differ between S-L, Quill and V-Loc groups (Figure 4). D-L closures (mean=8.94 mins, SD=0.47) took longer than the other groups by an average of 4 minutes (p<0.001 for all three comparisons) (Table 3). No association between construction time and suturing order was observed (p=0.051). Within the Quill group, suturing time decreased by 1.4 minutes between the first and last construct resulting in a negative correlation (p=0.03). No difference was seen within other groups.

There was no difference in percentage reduction in mean luminal diameter between the groups S-L, D-L and Quill (Figure 5). The V-Loc group (mean= 11.64% ± 4.16; Table 2) had greater reduction in mean luminal diameter compared to the other groups (P= 0.004, 0.02, 0.004 for the S-L, D-L and Quill, respectively; Table 3).

Bursting pressure was highest for the D-L group (mean= 178.50 mmHg, SD= 9.79) and was higher than the S-L (P<0.001), V-Loc (P<0.001), and Quill (P<0.001) (Table 3). The S-L, while lower than the D-L with a mean bursting pressure of 117.67 mmHg (Table 2), was also higher than the V-loc and Quill (P<0.001 for both). (Figure 6) There was no difference in bursting pressure between the V-Loc and Quill groups.

No leakage was observed in any of the groups. Exposed suture (knot) was visible in all constructs in the D-L and S-L group (Table 1). The physical appearance of each enterotomy following closure was similar, with good inversion of the suture line in all cases. Distortion (puckering) of the suture line was seen in the V-Loc group. The cost and physical characteristics of the suture lines are summarised in Table 1. Construct failure occurred adjacent to the suture line in four of the six cases for the V-Loc; five of the six cases for the Quill and S-L groups, and in all cases for the D-L group (figure 8).

A summary of the mean and standard deviations for all outcomes is given in Table 2.

**Discussion**

This study is the first to assess the use of barbed suture for closure of pelvic flexure enterotomies in equine cadaver colons. Uni- and bi-directional barbed sutures had similar bursting pressures, although this was lower than those of traditional single- and double-layer closure. The use of barbed suture resulted in a reduction in overall time for enterotomy closure than traditional double-layer closure and provided appropriate inversion with a watertight closure and no exposed suture material.

The D-L group had a significantly greater construction time than the other groups as hypothesised; however, this was only by a mean of four minutes and was therefore considered to be of limited clinical significance. Time could be saved by line reversal in double- layer closures, but this has been shown to be no different from a standard double layer closure 2 and is not routinely used in the authors’ hospital. Single layer closure with barbed sutures was chosen as this is the most common application of the material.20 Single versus double layer barbed suture has previously been shown to have no advantage in other viscera such as the bladder. 13

Previous work has shown a reduction in lumen diameter at PFE between 4.7% to 16 % depending on the location and measurement technique used. 2–4 The V-Loc suture did result in puckering of the PFE (Figure 7), and this may have contributed to the greater reduction in luminal diameter in this group. To prevent puckering of the suture, the technique could have been modified with locking passes made intermittently to secure the suture along the line. This was not performed in the current study but could be considered in future studies. A significant reduction in luminal diameter at the pelvic flexure may cause complications in the immediate post-operative period, when motility at the site may also be reduced due to inflammation. Reduction in luminal diameter could also delay passage of ingesta if the reduction persisted once normal levels of feed had been introduced. 3 The V-Loc suture had a mean reduction percentage of 11%, which is below the values described in previous studies. 2-4

The D-L group had the highest mean bursting strength of all groups and was significantly greater than the other groups. This was in agreement with Gandini et al, 3 but contrary to the findings of Aldrich et al. 2 In comparison to a single- layer closure, the bursting strengths of both unidirectional and bidirectional barbed sutures were lower. No published data currently exists on the physiological pressures of normal equine large colon. However, extrapolation from other reports suggests that in vivo intraluminal pressure would never attain the high pressures assessed in this and previous studies. Maximal intraluminal pressures of 48.5 mmHg were measured in horses with strangulating large colon volvulus. 21 The failure pressures tested here are well above that report and are comparable to single layer closures seen in other studies. 2–4

A further proposed advantage of barbed suture is the fact that there are no knots, which eliminates the complications associated with knot failure. A reduction in the volume of suture material also reduces the risk of tissue reaction, suture sinus and adhesion formation. Almost no suture was visible at the enterotomy site in the V-Loc and Quill groups (Figure 7). The S-L group had the most material visible where knots or parts thereof where visible at both ends. Suture knots and foreign material in the abdominal cavity have been shown to increase the risk of granuloma and adhesion formation in humans 2,23 and this may be mitigated with both unidirectional and bidirectional barbed suture enterotomy closures in equines.

The cost of the unidirectional barbed suture was nearly ten times (9.68) the cost of the braided lactomer per construct, and the cost of the bidirectional suture was 7.1 times that of the braided lactomer per construct. While cost should not be the guiding factor in clinical decision-making, the current recommended standard in this case was significantly less expensive than the barbed sutures tested.

Consistent with findings of Aldrich et al 2 and Rosser et al, 4 failure of the constructs occurred adjacent to, and not at, the suture line (Figure 8). In the majority of cases (barbed and non-barbed suture), it was the serosal layer that failed initially, and complete failure occurred shortly thereafter. This may be due to intrinsic tissue characteristics in cadaver material and further research is needed to determine the relevance of this finding.

A number of limitations exist in the current study. The numbers in each group were small and characteristics of cadaver material may differ from the clinical scenario. Large colon from healthy adult horse was used, and the handling and physiological characteristics may be different to those in diseased animals. The wall thickness was not measured, but subjectively varied between specimens and this could play a role in the differences seen in bursting strengths. A further limitation is that the observer measuring the reduction in luminal diameter was not blinded and was the same person performing the constructs. It has been argued that bursting pressure is not the most valid method to assess the clinical relevance of suture constructs. 2,3 Bursting pressure was reported because the authors believe it to be a more physiologically appropriate measure of testing the strength of repair in a tubular organ then a bloc tissue tensile strength force test to failure. 13

The authors acknowledge the limitations of comparing multifilament and monofilament suture materials in this study. However, in order to make this study comparable to existing literature and clinically relevant, the materials and techniques chosen were consistent with previous studies3,4 and surgical texts. 1

In conclusion, both unidirectional and bidirectional barbed suture produced comparable closures to each other but had lower bursting strengths than single- and double-layer closure. They had reduced construction times compared to a double- layer closure and carry the possible advantage of having no exposed suture material. Further research is needed to determine if the bursting pressures exceed those likely to be encountered in vivo in equine large colon before barbed sutures can be assessed for closure of pelvic flexure enterotomies in clinical cases.

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**Conflicts of interest**

The authors have no conflicts of interest, financial or other to declare.

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**Figure legends**

Figure 1: Radiographs showing placement of staples as markers before (left) and after (right) enterotomy construction to determine the percentage change in luminal diameter. The red line shows how the markers were used to determine the same line for measurement before and after testing. The suture shown here is the V-Loc closure.

Figure 2: Schematic diagram of a pelvic flexure construct demonstrating how the V-loc was placed and the suture reversed to ensure locking. **A**- The first pass is performed through the tissue at the start of the incision (left in the picture) and the needle is passed through the loop. **B**- A second pass is then made through the opposite side and tightened to start the pattern. **C**- A retrogradegrade pass is then made to the left of the incision. **D**- The Cushing pattern is then performed. To finish two passes are made in a Cushing pattern in a retrograde direction, each in a more reverse direction before the end of the suture is cut.

Figure 3: Schematic diagram of a pelvic flexure construct demonstrating the use of the bidirectional Quill suture. **A**- The first pass is made through the centre of the incision and perpendicular to it (Red line indicates tissue bites and green line indicates suture crossing incision), the suture is pulled through until the barbs change direction. **B-** The first half of the incision is then closed in a Cushing pattern. To finish two passes are made in a Cushing pattern in a retrograde direction each in a more reverse direction before the end of the suture is cut. The second half of the incision is closed in the same fashion.

Figure 4: Boxplot of construction time in minutes per group on X-axis. (S-L: Single layer continuous Cushing; D-L: Single layer simple continous and continuous Cushing oversewn; V-Loc: Single layer unidirectional barbed suture; Quill: Single layer bidirectional barbed suture). Boxes represent 25th and 75th percentile and whiskers are 1.5\*IQR. The star represents significant results.

Figure 5: Boxplot comparing the percentage reduction in luminal diameter for each pattern tested on X-axis. (S-L: Single layer continuous Cushing; D-L: Single layer simple continuous and continuous Cushing oversewn; V-Loc: Single layer unidirectional barbed suture; Quill: Single layer bidirectional barbed suture). Boxes represent 25th and 75th percentile and whiskers are 1.5\*IQR. The star represents significant results.

Figure 6: Boxplot comparing the bursting pressure for each suture pattern tested in mmHg on X-axis. (S-L: Single layer continuous Cushing; D-L: Single layer simple continuous and continuous Cushing oversewn; V-Loc: Single layer unidirectional barbed suture; Quill: Single layer bidirectional barbed suture). Boxes represent 25th and 75th percentile and whiskers are 1.5\*IQR. The star represents significant results.

Figure 7: Digital image showing puckering of the suture line with the V-loc suture. No knots are externally visible.

Figure 8: Digital images illustrating failure (red arrows) of the enterotomy adjacent to the suture line. Pictured here is the V-Loc suture on the left image and D-L on the right.

Table 1: Summary of direct comparison variables of cost, gross appearance and enterotomy leakage. (S-L: Single layer continuous Cushing; D-L: Single layer simple interrupted and continuous Cushing over sewn; V-Loc: Single layer unidirectional barbed suture; Quill: Single layer bidirectional barbed suture).

|  |  |  |  |
| --- | --- | --- | --- |
|  | Cost (USD per packet) | Gross appearance | Leakage |
| S-L | 4.48 | Smooth inverted surface, exposed suture material at knot sites, normal intestinal curvature. | No leakage |
| D-L | 4.48 | Smooth inverted surface, exposed suture material at knot end, normal intestinal curvature. | No leakage |
| V-Loc | 43.58 | Smooth inverted surface, no exposed suture, no knot visible, some puckering of suture line and distortion of intestinal contour.  | No leakage |
| Quill | 32.09 | Smooth inverted surface, no exposed suture, no knot, normal intestinal curvature. | No leakage |

Table 2: Summary of mean and SD for mean bursting pressure, percentage reduction in luminal diameter, and construction time.

|  |  |  |  |
| --- | --- | --- | --- |
| Suture type | Construction time (minutes) | Luminal reduction percentage (%) | Bursting Pressure (mmHg) |
| Mean | (SD) | Mean | (SD) | Mean | (SD) |
| S-L | 5.02 | (0.18) | 3.90 | (2.93) | 117.67 | (11.69) |
| D-L | 8.96 | (0.47) | 5.40 | (3.33) | 178.50 | (9.79) |
| V-Loc | 4.56 | (0.55) | 11.64 | (4.16) | 91.67 | (5.57) |
| Quill | 4.34 | (0.40) | 3.24 | (3.06) | 87.50 | (8.69) |

Table 3: Tukey multiple comparisons of means outcomes, showing difference between pairs, 95% confidence intervals and p-values.

|  |  |  |  |
| --- | --- | --- | --- |
| Suture type pairs | Construction time (minutes) | Luminal reduction percentage (%) | Bursting Pressure (mmHg) |
| Difference(95% CI)  | p-value | Difference(95% CI)  | p-value | Difference(95% CI) | p-value |
| D-L:S-L | 3.9(3.3; 4.6) | <0.001 | 1.5(-4.0; 7.0) | 0.87 | 60.8 (46.0; 75.7) | <0.001 |
| Quill:S-L | -0.5(-1.1; 0.2) | 0.27 | -0.7(-6.1; 4.8) | 0.99 | -30.2(-45.0; -15.3) | <0.001 |
| V-Loc:S-L | -0.7(-1.4; 0.02)  | 0.06 | 7.7(2.2; 13.2) | 0.004 | -26.0(-40.9; -11.1) | <0.001 |
| Quill: D-L | -4.4(-5.1; -3.7) | <0.001 | -2.1(-7.7; 3.3) | 0.70 | -91.0(-105.9; -76.1) | <0.001 |
| V-Loc: D-L | -4.6(-5.3; -3.9) | <0.001 | 6.2(0.7; 11.7) | 0.02 | -86.8(-101.7; -72.0) | <0.001 |
| V-Loc: Quill | -0.2(-0.9; 0.5) | 0.83 | 8.4(2.9; 13.9) | 0.002 | 4.2(-10.7; 19.0) | 0.86 |