

The "RoC" suture technique to allow early active rehabilitation in flexor tendon repair: a biomechanical study

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The «RoC» suture technique to allow early active rehabilitation in 1 flexor tendon repair: a biomechanical study 2 3 Marie CASTOLDI, MD, Federico Solla, MD, Olivier Camuzard, MD PhD Martine Pithioux, PhD, Virginie Rampal, MD PhD, Olivier Rosello, MD 4 5 **ABSTRACT** 6 7 Purpose. Current flexor tendon repair techniques do not provide sufficient tensile strength to 8 allow immediate active unprotected rehabilitation. The «RoC» repair, a new 4-strand 9 suture technique, is proposed to improve biomechanical properties, combining a high tensile 10 strength and a low gliding resistance without causing suture pullout by tendon laceration. 11 Our hypothesis is that the RoC technique can reach an ultimate tensile strength of 140N, and a 12 higher tensile strength than the Adelaide technique. 13 **Methods.** Four groups of 10 porcine flexor tendons were sutured with the RoC or 14 Adelaide technique, and with a 3-0 Polypropylene or Dyneema suture. An axial traction test 15 to failure (Instron machine) was administrated to each tendon to measure ultimate tensile 16 strength. **Results.** With the Dyneema suture, median ultimate tensile strength was 145N 17 for the RoC technique and 80N for Adelaide (p < 0.01). RoC tendons were 1.8 times more 18 resistant than Adelaide tendons with the Dyneema suture, and 1.2 times more resistant with 19 Polypropylene. Conclusion. Tendons repaired with the RoC technique and Dyneema suture 20 exceeded a tensile strength of 140N. The ultimate tensile strength was superior to that of 21 Adelaide technique regardless of the suture material. 22 23 24 **Key words**

Flexor tendon, hand injuries, suture techniques, tensile strength

25 INTRODUCTION

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Hand flexor tendon injuries are frequent and their treatment holds several challenges. Restoring satisfactory function after tendon repair requires a sufficient tensile strength and low gliding resistance to allow for early active mobilization ^{1,2}. Tensile strength of the repair is affected by the number of strands, the caliber of the core suture, the suture material (braided or not), surface treatments, size and shape of the needle, the knot configuration, the loop configuration and the number of anchor points 3-7 . Improvements in suture materials and repair techniques have led to stronger repairs. ^{3,8–10}. Despite these advances, conventional tendon repair techniques do not provide sufficient tensile strength to immediately allow unprotected mobilization 1,3,4,8,11,12 . Protected active rehabilitation implies permanently wearing a splint during the six weeks of tendon healing. Even then, adhesions, stiffness, and repair-site gapping remain a frequent outcome 8,12-14 There are three possible causes of tendon repair failure ²: suture breakage, knot failure, and suture pullout by tendon dilaceration. The axial tensile force applied to a repaired flexor tendon during full extension of the finger and active flexion is unknown from the literature; the active flexion of a healthy finger in vivo is up to 28N¹⁵; Savage ¹⁶ postulated that the strength of a flexor repair should be 5 times greater than the active flexion force (i.e. 140N). The most common techniques are a modified 4-strand Kessler technique, Becker, Adelaide or Strickland, with several variants; their biomechanical properties have been studied with in vitro tensile tests (on cadaver or porcine tendons) and, more rarely, in vivo ^{2,4,8,17–19}. An extensive literature review in 2000 defined the 6 characteristics of an ideal suture technique². Accordingly, the sutures have to be easily placed in the tendon with secure suture knots, allowing for a smooth juncture of the tendon ends, minimal gapping at the repair site, minimal interference with tendon vascularity, and a sufficient tensile strength throughout healing. Following these criteria, the Adelaide repair technique¹ (also known as locked Cruciate) can be considered a gold standard, because it provides the highest tensile strength in

- in vitro studies (up to 120N⁹). However, in a recent study, tendons repaired with a helical 6-
- strand Cruciate had a greater ultimate tensile strength (65N) than with the Adelaide technique
- 52 (46N)²⁰. Barbed sutures seem to provide a higher tensile strength, up to 64N, but largely below
- the 140N requested for active unprotected rehabilitation ^{21,22}.
- We propose a new 4-strand repair technique, the "RoC" technique, to combine a high tensile
- strength and a low gliding resistance without causing suture pullout by tendon laceration.
- The objective of this study is to compare, in vitro, the biomechanical properties of this new
- 57 technique with those of the Adelaide repair technique. We hypothesized that the RoC repair can
- reach an ultimate tensile strength of 140N, in order to withstand an immediate active
- 59 unprotected rehabilitation protocol.

2. MATERIALS AND METHODS

62 2.1. Study protocol

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- This study followed the design of published biomechanical evaluations of in vitro porcine
- 64 flexor tendon repair techniques ^{4,9,18,23}. The use of animal tissues complied with the guidelines
- of the authors' institution, the National Institutes of Health, and French law on the use of
- 66 laboratory animals.
- 67 Fresh porcine forelimbs were purchased and dissected. Both flexor tendons were harvested
- from each forelimb, with an average cross-sectional area of 20 mm² and a minimum length of
- 69 10cm, allowing them to be installed in the clamps of the traction machine. A clean cross-tendon
- cut with a scalpel simulated a traumatic section. To ensure consistency of the technique, section
- sites and points of entry of the core suture were pre-marked on the tendons, and all sutures were
- 72 performed by a single surgeon (MC).

Forty porcine flexor tendons were randomly allocated to 4 groups of 10 tendons (figure 1), cut transversally then repaired and tested in axial traction. The core suture (RoC or Adelaide) was performed with a 3-0 suture, either Prolene® (Ethicon® NJ 08876 USA) or Dyneema (KastKing®), and reinforced with a peripheral epitendinous running suture with a Prolene 6-0, 2mm from the section site. After the suture, the tendons were immediately stored in a freezer at -80°C ²².

2.2. Surgical technique: the "RoC" repair

The knots used for mountaineering inspired the loop configuration of this new repair technique, which owes its name to the initials of the creators and to a regional summit in the region of the authors. The basic pattern of the RoC repair is a 3-dimensional figure of eight with 4 anchors in the 3 planes of space. This pattern is repeated with two sliding sutures on both ends of the tendon, forming a 4-strand repair. The loop configuration is illustrated in figures 2 and 3. For optimal tensile strength, suture tensioning should result in approximately 10% shortening of the tendon length at the suture site ²⁴. The ends are tied suture by suture and then together in one knot.

The gold standard repair technique chosen for comparison in this study was the Adelaide ²³, or 4-strand locked cruciate repair (figure 4).

2.3. Suture materials

During preliminary testing, tendons repaired with the RoC technique and Prolene suture failed by suture breakage. Prolene is a non-absorbable polypropylene monofilament suture commonly used for flexor tendon repairs, pre-mounted with a curved taper needle. The observation of suture breakage prompted us to use a stronger suture. In existing studies, repairs with Dyneema suture had the highest tensile strength ^{9,10}. Dyneema is a non-

absorbable fiber made from ultra-high-molecular-weight polyethylene, a lightweight and high strength material used in arthroplasties since the 1980s and more recently in sutures. Therefore, we used a commercially purchased 100% Dyneema unmounted braid 0.25mm (diameter of a surgical 3-0 suture ²⁵) with a curved cutting-edge needle. Thus, both repair techniques were tested with a 3-0 Prolene (Ethicon®), and a 0.25mm Dyneema (KastKing®) suture.

2.4 Outcomes and mechanical testing

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The primary outcome was the ultimate tensile strength measured in Newtons (N). Secondary outcomes were the 2-mm gap formation force (N), failure mode of the repair (knot failure, suture breakage or suture pullout), stress (ultimate tensile strength divided by the tendon cross-section area, in N/mm2), and stiffness (in N/mm). Mechanical testing was conducted on an Instron 5566A® axial traction machine (Instron Corp, MA) (figure 5A). The tendons were thawed in saline-soaked gauze at 4°C for 24 hours. The dimensions of the tendon were recorded at the suture site and at a healthy site 30mm distal, to calculate the cross-section areas. Both ends of the repaired tendon were mounted into standard clamps. The initial distance between the clamps was set at 40mm for all tendons. Loading was applied to the repaired tendons to a single load-to-failure compression test. After application of a 1-N preload, the tendons were pulled at a constant speed of 10mm/min. Quasi-static loading with prescribed displacements at 1mm per min was applied up to failure. Data were recorded at a rate of 10 Hz. The software (Bluehill Universal, Instron Corp) created a load-displacement curve, from which the ultimate tensile strength was determined (peak of the curve). Stiffness was calculated as the slope of the initial linear section of the curve. A ruler was attached to the upper clamp next to the tendon, and the test was monitored by a high-definition camera in order to determine the 2-mm gap formation force (figure 5B and C).

Failure was considered to be the first local maximum before a load decrease was observed on

the load-displacement curve. Failure mode was determined by visual examination of the
 tendons, photographed after testing.

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2.5 Statistical Analysis

The Shapiro-Wilk test was used to ensure that the cross-section areas of the tendons were normally distributed. The non-parametric Mann-Whitney test was used to compare the numeric outcomes (mechanical testing results and cross-section areas) between each group. The exact Fisher test were used to compare the failure mode between each group. The alpha risk was set at 5% ($\alpha = 0.05$) 26 .

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3. RESULTS

- Gross mechanical testing results are presented in table 1 and compared group by group in tables
- 135 2 and 3.
- With the Dyneema suture, median ultimate tensile strength for the RoC technique was 145N.
- RoC tendons were 1.8 times more resistant than Adelaide tendons with the Dyneema suture,
- and 1.2 times more resistant with the Prolene suture (p < 0.01).

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4. DISCUSSION

- 4.1. Primary outcome Ultimate tensile strength
- 142 Tendons repaired with the RoC technique had a significantly higher ultimate tensile strength
- than tendons repaired with the Adelaide technique, regardless of the suture used (Prolene or
- 144 Dyneema). The median ultimate tensile strength with RoC and Dyneema exceeded 140N,

145 which was the targeted tensile strength to allow immediate unprotected active rehabilitation. 146 The lower value of the confidence interval was 130N, which is higher the previous data with a 4, 6, and 8-strand techniques ^{2,4,8,10,17,19–23,27}. 147 148 The tensile strength of 140N was not achieved with Prolene suture. RoC repairs with Prolene 149 exceeded the tensile strength of Adelaide by only 11N, and failed by suture breakage in all 150 cases, implying that the resistance of the suture material was the limiting factor. Indeed, RoC 151 tendons with Dyneema gain 82N in ultimate tensile strength compared with Prolene (p < 0.01). 152 In a previous study by Lawrence and Davis ⁴, repairs with the Adelaide technique reached a 153 mean ultimate tensile strength of 63N with a 4-0 Prolene suture; all their repairs reportedly 154 failed by suture rupture. On the contrary, in our study Adelaide tendons failed by suture pullout 155 in 9 out of 10 cases with Prolene and 8 out of 10 cases with Dyneema. Varying outcomes with 156 Adelaide and Prolene may be attributed to differences in tendon quality, suture caliber, and 157 loading speed during testing. 158 With Dyneema, Adelaide tendons in our study reached 79N, a similar tensile strength to Adelaide with 4-0 Fiberwire in the study by Lawrence and Davis ⁴, whereas the maximum 159 tensile strength reported for Adelaide was 119N with 3-0 Fiberwire in the study by Croog et 160 al. This difference may be explained by the cross-section area of the sutures²⁵: the area of 3-0 161 162 Fiberwire was 0.083mm² corresponding to a standard 2-0 size (USP), whereas the area of 4-0 Fiberwire wass 0.067mm² which is between standard 2-0 and 3-0 size, and that of a 3-0 Prolene 163 was 0.056mm², also between 2-0 and 3-0. By comparison, the cross-section area of 0.25mm 164 165 Dyneema suture we used would be 0.049mm². This difference in suture caliber between 3-0 166 Fiberwire and 0.25mm Dyneema may explain the higher tensile strength for Adelaide tendons in the study by Croog et al. compared to our study¹⁴. 167

4.2. Secondary outcomes: cross-section area and 2-mm gap

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There was no significant difference in cross-section area (suture site and healthy site) between

the groups. The stress outcome thus mirrored the ultimate tensile strength.

The 2-mm gap formation force of RoC repairs was significantly higher than that of Adelaide

repairs with Dyneema, but similar with Prolene. As with the ultimate tensile strength, lower

resistance of the Prolene suture may explain this outcome. Gap formation (1 to 3mm) has been

associated with adhesions and poorer clinical results ^{28,29}, but the exact limit for tendon healing

remains unknown ⁹.

4.3 Suture material and failure mode

Dyneema is the main component of the most resistant current braided sutures, but also fishing lines, climbing and boat ropes. We selected the most resistant available suture to test the repair technique itself and the knot without limitation related to the intrinsic resistance of the material. While using a Prolene suture for the RoC repair, failure occurred at 63N because of suture breakage. With the more resistant Dyneema suture, RoC tendons failed by suture pullout. In Adelaide tendons repaired with Prolene, suture pullout occurred in all but one case before reaching the maximum resistance of the suture or the knot. Suture pullout was also the main failure mode with Dyneema, but this result may be impacted by the use of a cutting needle. Indeed, the Dyneema suture was used with a separate cutting needle, whereas the Prolene suture has a pre-mounted taper needle. We hypothesize that the RoC repair with a surgical Dyneema suture and mounted taper needle such as Fiberwire would result in few suture pullouts, which may increase the ultimate tensile strength of the repair.

4.4. Limitations

The main limitation in this study is the use of a non-surgical Dyneema unmounted braid, instead of a surgical Dyneema suture, which was unavailable at the time of the study. The core resistance of the Dyneema suture we used should be identical to that of a surgical suture,

but surface treatments and threading techniques can alter the biomechanical properties. Moreover, the use of a separate cutting needle, different in shape and size from the premounted needle of a surgical suture, may have increased the tissue damage during the repair and favored suture pullout. Therefore, these outcomes require further confirmation with a surgical Dyneema suture. Other limitations are the classic limitations of in-vitro biomechanical studies for flexor tendon repair and their extrapolation to in-vivo conditions. The unique axial tensile test fails to account for different speeds and angles of elongation stress, for fatigue after multiple cycles, and for work of flexion, which will be the object of a following study. The use of porcine flexor tendons instead of human cadaver tendons can also constitute a limitation, although most studies about flexor repair have used porcine tendons due to their similarities to human tendons and the easy access to well-preserved tissue. Thus, the next step to evaluate the RoC repair will be a comparative work of flexion study on cadaver hands.

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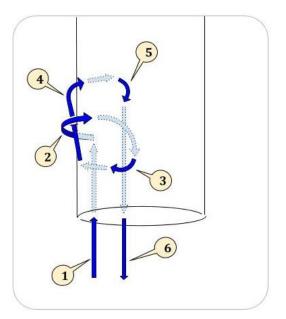
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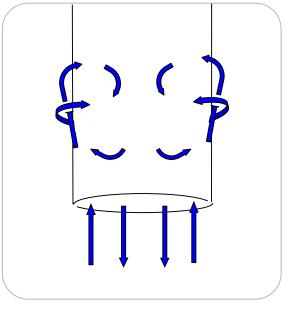
311 Legend 312 Figure 1. Study protocol. Allocation of each group of 10 tendons to a repair technique and a 313 suture type. 314 Figure 2. Illustration of the basic pattern of the RoC repair following passages of the suture in 315 the order of realization (A). Illustration of the completed RoC repair (B). Figure 3. Basic configuration of the RoC repair with Prolene 3-0 suture on the distal end of a 316 317 porcine flexor tendon. 318 Figure 4. A: Instron 3360 traction machine. B: HD camera and ruler for the 2-mm gap force. 319 C: Example of a tendon sutured with the RoC technique. Simultaneous display of the applied 320 load (236N) and the video image of the tendon and ruler measuring 2-mm gap. Table 1: Mechanical testing in axial traction. 321 322 Table 2: Statistical comparison of tendons sutured with Prolene suture: RoC versus Adelaide 323 technique (Group A versus C) 324 Table 3: Statistical analysis of tendons sutured with Dyneema suture. RoC versus Adelaide 325 technique (Group B versus D) 326 327

Figure 1: The groups

| | Group A | Group B | Group C | Group D |
|----------|---------|---------|----------|----------|
| Repair | RoC | Roc | Adelaide | Adelaide |
| Material | Prolene | Dyneema | Prolene | Dyneema |

Figure 2 RoC suture: drawing





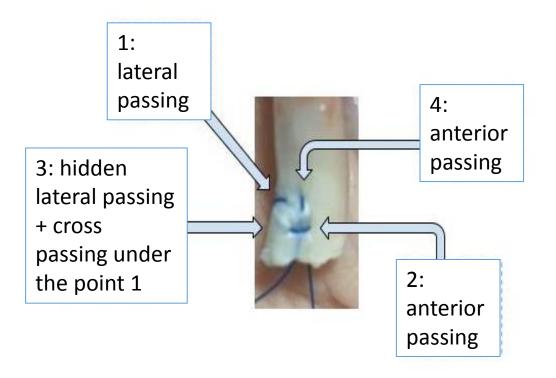


Figure 3
RoC suture: repaired tendon

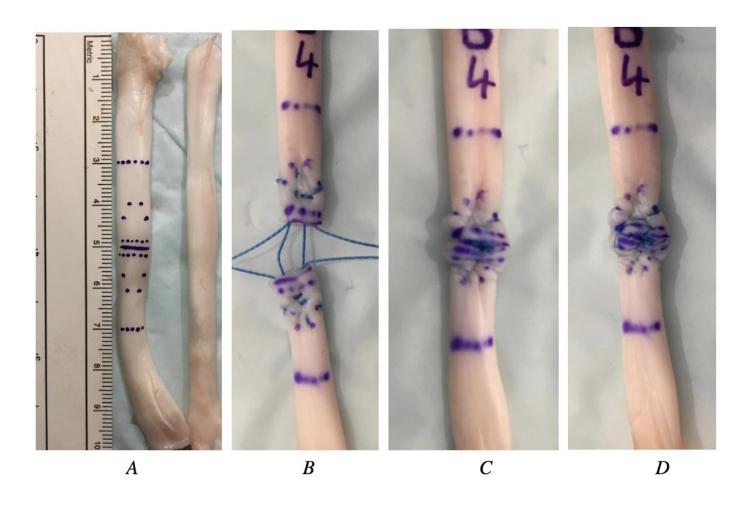
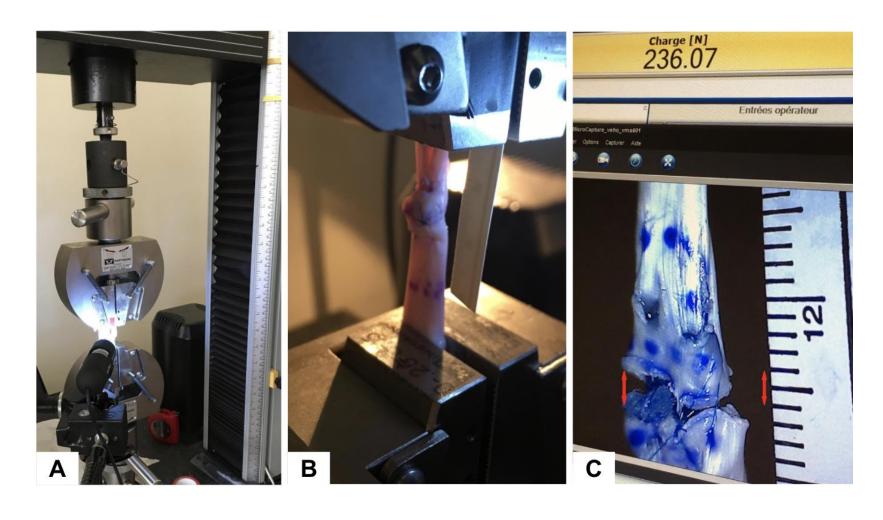


Figure 4: Instrom machine



<u>Table 1</u>. Mechanical testing in axial traction. Results are presented for each numeric outcome as Median value [95% Confidence Interval]. Failure mode is expressed as Number of tendons out of 10.

| | Group A | Group B | Group C | Group D |
|---|-----------------------------|--------------------------------|-----------------------------|--------------------------|
| | RoC + | RoC + | Adelaide + | Adelaide + |
| | Prolene | Dyneema | Prolene | Dyneema |
| Ultimate tensile strength (N) | 63.6 [59.56 - 69.49] | 145.54 [130.96 - 179.03] | 52.21 [46.80 - 58.79] | 79.76 [72.57 - 88.28] |
| 2-mm gap force (N) | 48.00 [43.91 - 54.28] | 136.50 [119.23 - 170.76] | 47.50 [40.65 - 53.34] | 79.00 [71.82 - 87.37] |
| Stiffness (N/mm) | 5.95 [5.30 - 6.73] | 14.92 [12.67 - 17.42] | 4.48 [4.01 - 4.77] | 10.12 [9.27 - 11.62] |
| Stress (N/mm ²) | 2.99 [2.58 - 3.82] | 8.70 [7.19 - 9.46] | 2.23 [2.06 - 2.66] | 4.76 [4.31 - 5.63] |
| Cross-section area at healthy site (mm ²) | 19.93 [17.40 - 25.05] | 18.97 [16.37 - 21.41] | 22.53 [20.51 - 24.55] | 15.56 [13.96 - 19.19] |
| Cross-section area at suture site (mm ²) | 30.29 [25.71 - 40.38] | 40.69 [38.89 - 48.65] | 37.22 [33.38 - 40.67] | 41.97 [37.20 - 49.57] |
| FAILURE MODE: | n = 10 | n = 10 | n = 10 | n = 10 |
| Suture breakage | 10/10 | 0 | 1/10 | 0 |
| Knot failure | 0 | 0 | 0 | 2/10 |
| Suture pullout | 0 | 10/10 | 9/10 | 8/10 |

Table 2. Statistical comparison of tendons sutured with Prolene suture: RoC versus Adelaide technique (Group A versus C)

| | Group A | Group C | Comparison group A |
|---------------------------------|-----------------|--------------------|--------------------|
| | RoC + Prolene | Adelaide + Prolene | versus C |
| Ultimate tensile strength | 63.6 | 52.21 | p < 0.01 |
| (N) | [59.56 - 69.49] | [46.80 - 58.79] | |
| 2-mm gap force (N) | 48.00 | 47.50 | p > 0.05 |
| | [43.91 - 54.28] | [40.65 - 53.34] | |
| Stiffness (N/mm) | 5.95 | 4.48 | p < 0.01 |
| | [5.30 - 6.73] | [4.01 - 4.77] | |
| Stress (N/mm ²) | 2.99 | 2.23 | p < 0.05 |
| | [2.58 - 3.82] | [2.06 - 2.66] | |
| Cross-section area at | 19.93 | 22.53 | p > 0.05 |
| healthy site (mm ²) | [17.40 - 25.05] | [20.51 - 24.55] | |
| Cross-section area at | 30.29 | 37.22 | p > 0.05 |
| suture site (mm ²) | [25.71 - 40.38] | [33.38 - 40.67] | |
| FAILURE MODE : | n = 10 | n = 10 | |
| Suture breakage | 10 (100%) | 1 (10%) | |
| Knot failure | 0 | 0 | p < 0.001 |
| Suture pullout | 0 | 9 (90%) | |

Table 3. Statistical analysis of tendons sutured with Dyneema suture. RoC versus Adelaide technique (Group B versus D)

| | Group B | Group D | Comparison |
|---|---|--|------------|
| | RoC + Dyneema | Adelaide + Dyneema | B vs D |
| Ultimate tensile | 145.54 | 79.76 | p < 0.01 |
| strength (N) | [130.96 - 179.03] | [72.57 - 88.28] | |
| 2-mm gap force (N) | 136.50 | 79.00 | p < 0.01 |
| Stiffness (N/mm) | [119.23 - 170.76] 14.92 [12.67 - 17.42] | [71.82 - 87.37] 10.12 [9.27 - 11.62] | p < 0.01 |
| Stress (N/mm ²) | 8.70 [7.19 - 9.46] | 4.76 [4.31 - 5.63] | p < 0.01 |
| Cross-section area at healthy site (mm ²) | 18.97 [16.37 - 21.41] | 15.56 [13.96 - 19.19] | p > 0.05 |
| Cross-section area at | 40.69 | 41.97 | p > 0.05 |
| suture site (mm ²) | [38.89 - 48.65] | [37.20 - 49.57] | |
| FAILURE MODE : | n = 10 | n = 10 | |
| Suture breakage | 0 | 0 | |
| Knot failure | 0 | 2 (20%) | p = 0.47 |
| Suture pullout | 10 (100%) | 8 (80%) | |