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Bioabsorbable poly-L/D-lactide (PLDLA) 96/4 triple-stranded bound suture in the modified Kessler repair: an ex vivo static and cyclic tensile testing study in a porcine extensor tendon model

**Anna-Kaarina Viinikainen · Harry Göransson ·
Katja Huovinen · Minna Kellomäki · Pertti Törmälä ·
Pentti Rokkanen**

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Abstract Previously the biomechanical properties of the bioabsorbable poly-L/D-lactide (PLDLA) 96/4 suture were found suitable for flexor tendon repair. In this study, three PLDLA suture strands were bound together parallel to each other side-by-side to form a triple-stranded bound suture and the modified Kessler tendon repair was performed. The biomechanical properties of the PLDLA repair in porcine extensor tendons ex vivo were investigated with static and cyclic tensile testing. In both biomechanical tests, the strength of the PLDLA repair achieved the estimated forces needed to withstand active mobilization.

1 Introduction

Early active motion rehabilitation programs have been developed to improve functional results after flexor tendon repair [1–8]. Active motion increases the forces subjected to the tendon compared to passive mobilization [9] placing additional biomechanical requirements on the strength of the flexor tendon repair [1, 7, 8, 10]. The forces subjected to the tendon repair during mobilization are not exactly known. According to Schuind et al. [9], the flexor tendon was subjected to mean force of 19 N but forces up to 35 N were measured during active unresisted flexion in intact tendons during carpal tunnel release. After tendon repair, the forces have been estimated to be 50% higher because of enhanced gliding resistance of the tendon due to swelling and repair bulking [11]. According to this, the tendon repair is subjected to mean force of 29 N and taking into account the individual variation to forces up to 53 N during unresisted active flexion.

To fulfil the biomechanical demands, stronger core suture techniques have been developed usually by increasing the number of strands across the repair site and often concomitantly the number of suture grips of tendon forming different types of multi-strand repairs [12–19]. However, multi-strand repairs are technically demanding increasing tendon handling and requiring more surgical time, which limits their clinical application especially in injuries within the tendon sheath.

To simplify the performance of multi-strand repair, the triple-stranded bound suture (three parallel 3-0 braided polyester suture strands side-by-side) was previously introduced in tendon repair [20]. The Pennington modified Kessler configuration [21] performed with the triple-stranded bound suture reached the yield force of 55 N fulfilling the estimated requirements for active mobilization [20].

Coated braided polyester sutures are commonly used in flexor tendon surgery. The disadvantage of this material is the large size of the knots, as five throws per knot are required to prevent slippage [22, 23]. The problem increases in multi-strand techniques with several separate knots between the tendon ends. Nonabsorbable braided polyester also remains in the tendon as foreign body.

For the use of bioabsorbable suture material in flexor tendon repair the first requirement is a half-life tensile strength long enough to ensure tendon healing. Previously in canine flexor tendon repair in vivo, monofilament polydioxanone reached significantly lower gap strength and breaking strength from 2 weeks onwards compared to coated braided polyester [24]. It was assumed that the

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A.-K. Viinikainen (✉) · H. Göransson · K. Huovinen ·
M. Kellomäki · P. Törmälä · P. Rokkanen
Helsinki University Central Hospital, Helsinki, Finland
e-mail: annaviinikainen@gmail.com

result was due to too early suture absorption, as the in vivo half-life tensile strength of 4-0 monofilament polydioxanone sutures was reported as 4 weeks [25]. In this way, the bioabsorbable PLDLA 96/4 3-0 suture material is more suitable for flexor tendon repair. The in vitro half-life tensile strength was reported as 10–13 weeks, and in the rabbit subcutaneous implantation the suture retained 75% of the initial tensile strength at 6 weeks [26], long enough considering flexor tendon repair. Furthermore, the strength and the stiffness of the suture were found suitable for flexor tendon repair [23]. Finally, the secure knot was achieved already with two or three throws, compared to braided polyester with five or six throws, decreasing the amount of suture material between the tendon ends [23]. Although the critical amount of suture material between the tendon ends to hinder the healing process is not exactly known [27], a smaller knot can be assumed to be advantageous.

The purpose of this study was to investigate a triple-stranded bound suture of the bioabsorbable PLDLA 96/4 with the Pennington modified Kessler configuration. The biomechanical properties of the repair were investigated both with static and cyclic tensile testing. In cyclic testing, the PLDLA repair was compared to the 6-strand Savage repair performed with 4-0 braided polyester which has earlier been investigated in static tensile testing [16, 28, 29] and has successfully been used clinically with active mobilization [5].

2 Materials and methods

The raw material used was a copolymer of L/D lactid acid (PLDLA) having an L/D monomer ratio of 96/4 and intrinsic viscosity of 4.98 dl/g (PURAC Biochem B.V., The Netherlands). The multifilament polylactide fibres for twisting were melt-spun using extruder (Gimac Castronno, Italy) having a die temperature of 270°C and oriented at elevated temperatures in a three-step process to final draw ratio of 4:26. The method has previously been described in more detail [30]. The final mean diameter of the filaments was 0.09 mm. After processing, the measured intrinsic viscosity of the polymer was 78% from initial. The suture was made by twisting six filaments which were then folded in the middle and twisted again to form a 12-filament twine. Three sutures were then tied parallel to each other side-by-side with two double filaments threaded over and beneath in turn (Fig. 1). The final width and thickness of the triple-stranded bound sutures were 1.630 and 0.580 mm, respectively. The end of the triple-stranded bound suture was pulled into the cut end of a 15-mm long injection needle with diameter of 21 gauge. The base of the needle was pressed tightly around the triple-stranded bound suture. The sutures were washed in ethanol, dried in vacuum for 16 h, packed individually, and sterilized by gamma irradiation with a minimum dose of 2.5 Mrad. The suture materials were tested as received from their individual sterile suture packages.

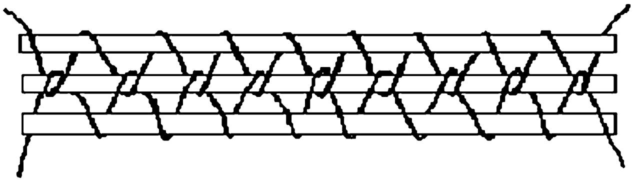

Fig. 1 Schematic picture of the PLDLA triple-stranded bound suture

Fresh pig hind-leg trotters were stored at −20°C and thawed to room temperature just before operation. The extensor digiti quarti proprius tendons were dissected out and kept moist by spraying with 0.9% saline during preparation and testing. Thirty tendons randomly divided into three groups of 10 specimens were used in the study. The tendons were transsected sharply and repaired under 2.5× loop magnification.

The Pennington modified Kessler repairs [21] (Fig. 2a) for static testing ($n = 10$) and cyclic testing ($n = 10$) were performed with the PLDLA triple-stranded bound suture. In the repair, the longitudinal components lay deep to the transverse component which was placed 10 mm from the cut tendon end. Each locking loop comprised approximately 15% of the cross-sectional area of the tendon [31]. For knotting, the three strands were separated in both ends and tied in pairs with three square throws [23] between the tendon ends.

The 6-strand Savage repairs [16] (Fig. 2b) for cyclic testing ($n = 10$) were performed with 4-0 coated braided polyester suture (Ticron®, Davies and Geck, San Isidro, Dominic Republic). The Savage repairs were performed in an interrupted pattern [16], thus three knots were formed between the tendon ends each knot consisting of one double throw and three single square throws [23].

Each repair was completed with an over-and-over running peripheral suture of 6-0 monofilament polypropylene (Prolene®, Ethicon, G.m.b.H., Hamburg, Germany). Suture grasps penetrated one-quarter of the tendon radius as confirmed by visual inspection, and each peripheral suture contained 12 loops when finished.

2.1 Static tensile testing of the PLDLA repair

Immediately after repair, the tendon specimen was aligned vertically in the tensile testing machine (LR Series Material Testing Machine LR30K, Lloyd Instruments Limited, Hampshire, UK) by securing the specimen ends in rough surface clamps to prevent tearing and gliding at the clamp-tendon junction. The distance between the tendon clamps

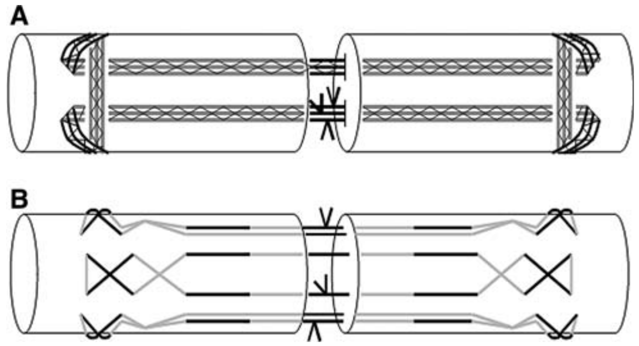

Fig. 2 The core repair techniques. **a** PLDLA repair. **b** Savage repair

was 35 mm, with the transsection line halfway between the clamps. The tendon was marked on both sides of the clamp with non-watersoluble ink to observe that no gliding occurred at the clamp-tendon junction during tensile testing. A graphpaper with 1 mm graduated markings was placed vertically behind the clamps, parallel with the tendon. A digital watch, placed beside the tendon specimen, was set on simultaneously with the tensile testing. The time point of each gap event was later used to define the corresponding extension and load values from the load–deformation data. The test was recorded with video monitoring (Sony Handycam CCD-TR425E, Sony, Japan) 25 frames/s. The specimen was distracted at a static rate of 20 mm/min. Load–deformation data were recorded with the computerised data acquisition system (R Control for Windows, Lloyd Instruments Ltd., Hampshire, UK), and a load–deformation curve was produced for each specimen (Fig. 3).

The load–deformation curve includes an initial non-linear toe region followed by a linearly increasing slope and finally the failure region. The first linear point represents the minimum point and the yield point the maximum point of the linear region of the curve. After the yield point during the failure region, the slope of the curve is reduced, but often the load continues to increase reaching the maximum at the ultimate point. An offset line was defined along the linear slope of each curve to define the stiffness (N/mm) of the repair. The first linear point and yield point were defined at the points of divergence of the offset line from the load–deformation curve. The first linear force, yield force, and ultimate force were defined. The repair site strain at the first linear point, strain at the yield point, and strain at the ultimate point were defined as repair site deformation (the change in the distance between the tendon clamps at each point) divided by the initial distance between the clamps. The appearance and development of gap formation at the repair site were analysed by frame-by-frame playback on the video recorder. Both partial and total gap values for 1, 2 and 3 mm gapping were defined. To eliminate the possibility of varying tightness of the specimens in the tensile testing machine, the load values below 1 N and the corresponding extension values were excluded from the load–deformation data before analysing the results.

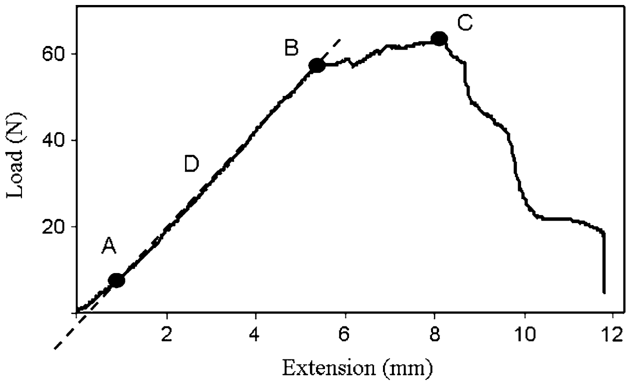

Fig. 3 Schematic presentation of the load–deformation curve. A = first linear point, B = yield point, C = ultimate point, D = linear region and offset line

2.2 Cyclic testing of the PLDLA and savage repairs

Cyclic tensile testing was performed with the servo hydraulic testing machine (Instron Fast Track 8801). The testing setup was identical to that of static tensile testing described above. During the test, force was applied and released by a computer-controlled pneumatic piston. The desired piston movement profile of FastTrack 2 program (Instron, High Wycombe, UK) controlling the pressure valves to obtain the desired load, frequency, and number of cycles, was made with the WaveMaker program (Instron, High Wycombe, UK). A 100 N dynamic load cell (Dynacell 100 N, type 2527-132, Instron, High Wycombe, UK) was used. No preload was applied; the initial load was manually adjusted to zero. All tendons were first subjected to 4000 cycles till 35 N. The applied force was increased in 10-N increments for an additional 4000 cycles at each new load level until the appearance of total 3 mm gap. The cycle rate was 1.5 mm/s at 35 N, 2.0 mm/s at 45 N, 2.25 mm/s at 55 N, and 2.25 mm/s at 65 N. The minimum and maximum extension data for every 100th cycles were recorded. The appearance of partial and total 1, 2, and 3 mm gaps with the corresponding number of cycles were recorded. Gap formation was measured with the cyclic force in its minimum.

A statistical comparison of Newton-cycles (product of the number of cycles and the applied load) between the examination groups at partial 1, 2 and 3 mm and total 1, 2, and 3 mm gap formation was performed using independent samples *T*-test with a level of significance set at $P < 0.05$.

3 Results

3.1 Static testing

The results of static tensile testing of the PLDLA repair are presented in Tables 1 and 2.

Failure of the peripheral suture initiated gap formation which started non-uniformly across the repair site as partial gap opening from one side of the repair. Partial 1 mm gap opening was seen after the yield point defined from the load–deformation curve (Fig. 4). Progressively increasing partial opening of the repair site preceded total gapping in all repairs. In 5 out of 10 repairs, the PLDLA triple-stranded bound suture pulled gradually out from one tendon end. Five specimens failed by rupture of the knot.

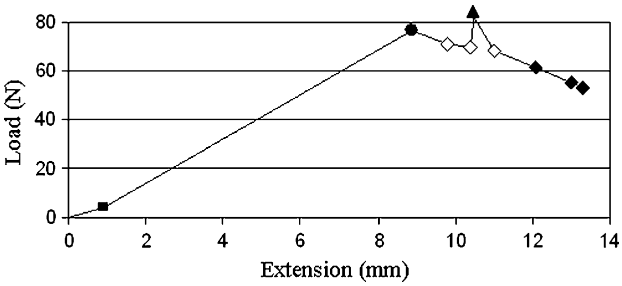

Fig. 4 The mean load–deformation curve of the PLDLA repair. ■ First linear point, ● yield point, ▲ ultimate point, ◇ partial 1, 2 and 3 mm gaps, ◆ total 1, 2 and 3 mm gaps

3.2 Cyclic testing

Rupture of the peripheral suture initiated gap formation in all repairs. In all 10 PLDLA repairs and 9 out of 10 Savage repairs gap formation started non-uniformly across the repair site by partial opening from one side of the repair and proceeded across the repair site to total opening. In 1 out of 10 Savage repairs opening started immediately as total gapping without preceding partial opening.

Nine PLDLA repairs out of 10 withstood 4000 cycles at 35 N without gap formation (Fig. 5). In one PLDLA repair gap formation initiated during loading at 35 N, in five repairs during loading at 45 N, and in four repairs during loading at 55 N. In two repairs the total 3 mm gap occurred during loading at 45 N, in seven repairs at 55 N, and in one repair at 65 N. In the average, partial 1, 2 and 3 mm gaps occurred during loading at 45 N, and total 1, 2 and 3 mm gaps during loading at 55 N (Fig. 6).

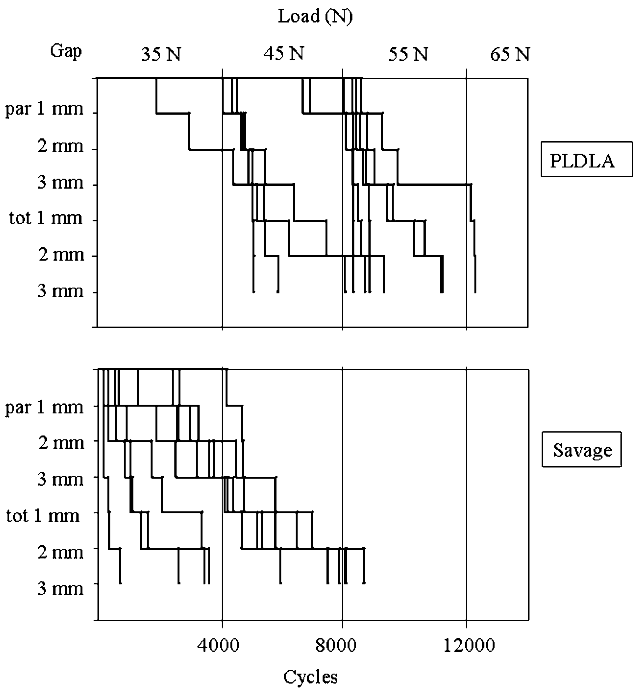

Fig. 5 The progressive failure of the PLDLA and Savage repairs during cyclic testing: Partial and total 1, 2, and 3 mm gap formation in relation to the load and the number of cycles

Table 1 Mean (95 % confidence interval) strain (mm/mm), force (N), and stiffness (N/mm) values of the PLDLA repair in static tensile testing

S_{FL}	S_Y	S_U	F_{FL}	F_Y	F_U	Stif
0.03 (0.02–0.03)	0.25 (0.23–0.28)	0.30 (0.27–0.33)	3.8 (3.8–4.8)	76.8 (66.7–86.9)	82.3 (73.4–91.3)	11.4 (10.6–12.1)

S_{FL} strain at first linear point, S_Y strain at yield point, S_U strain at ultimate point, F_{FL} first linear force, F_Y yield force, F_U ultimate force, *Stif* stiffness

Table 2 Mean (95% confidence interval) gap forces (N) of the PLDLA repair in static tensile testing

Par 1 mm	Par 2 mm	Par 3 mm	Tot 1 mm	Tot 2 mm	Tot 3 mm
71.0 (63.9–78.1)	69.9 (60.3–79.4)	68.0 (58.0–78.1)	61.5 (50.5–72.4)	55.2 (45.8–64.6)	53.1 (43.1–63.0)

Par partial, *Tot* total

In 9 out of 10 of the Savage repairs gap formation initiated during loading at 35 N (Fig. 5) and in one repair at 45 N. In four repairs gap formation proceeded to total 3 mm opening during loading at 35 N, in three repairs at

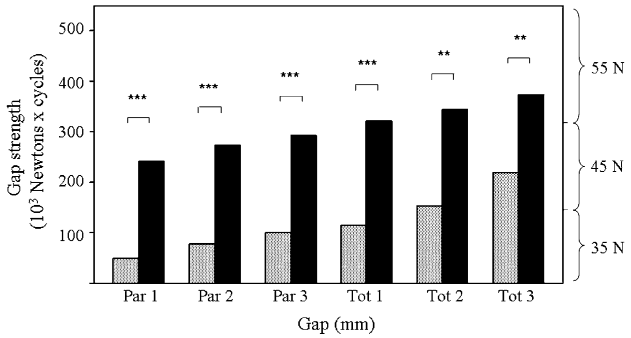

Fig. 6 The PLDLA repair (■) withstood a significantly more Newton-cycles compared to the Savage repair (▨) at every gap point. *Par* partial gap, *Tot* total gap. Statistical significance: ** $P < 0.01$, *** $P < 0.001$

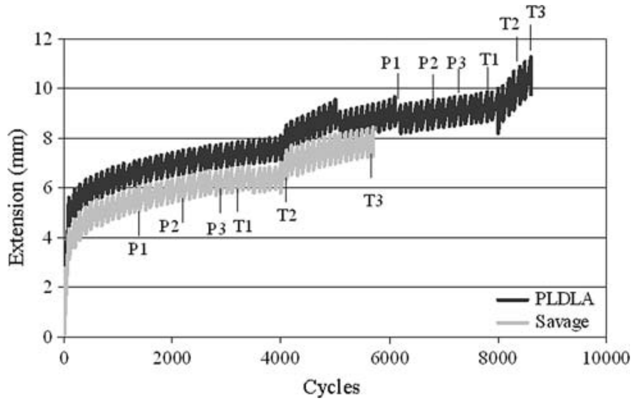

Fig. 7 The average extension curves of the PLDLA and Savage repairs during cyclic testing. *P* partial gap (mm), *T* total gap (mm)

45 N, and in three repairs at 55 N. In the average, partial 1, 2, and 3 mm and total 1 mm gaps occurred during loading at 35 N, and total 2 and 3 mm gaps were formed during loading at 45 N (Fig. 6).

The PLDLA repair withstood significantly more Newton-cycles compared to the Savage repair at every gap point (Table 3, Fig. 6).

In both groups, the relative extension was highest during the first 100 cycles (Fig. 7). In the PLDLA repair, the average minimum and maximum extension values at the 100th cycle were 4.4 and 5.6 mm, and for the Savage repair 3.1 and 4.3 mm, respectively. Thereafter, the average extension curves followed a similar profile (Fig. 7).

At partial 1 mm gap, the average extension was 8.2 mm for the PLDLA and 5.1 mm for the Savage repair. At total 3 mm gap, the average extension was 9.8 mm for the PLDLA and 7.3 mm for the Savage repair (Fig. 7).

4 Discussion

Previously a triple-stranded bound suture of braided polyester (Ticron®, Davies and Geck, San Isidro, Dominic Republic) was introduced in the modified Kessler tendon repair [20]. In static testing, the repair reached the estimated forces needed to withstand active mobilization. This repair concept offers several advantages considering flexor tendon repair. It is easy to suture and reduces the risk of violating the suture strands compared to traditional multi-strand techniques with several subsequent needle passes. When performing the repair the three strands tighten to the same tension. Hence, the subjected load is divided equally into each strand preventing overloading and rupture of single strands one by one. In the locking loops, the suture strands remain parallel, dividing the subjected load to a broader area on the tendon and thereby decreasing the tendency of the sutures to cut through the tendon tissue.

This study was performed ex vivo with porcine extensor digiti quarti proprius tendons because of their availability and similar size compared to the human flexor digitorum profundus tendon [32]. Although biomechanical and structural differences may exist between human and porcine tendons, the ultimate force values of the modified Kessler and Savage repairs in porcine extensor tendons [16, 28] and in human cadaver flexor tendons [29, 31, 33] correspond well to each other justifying the use of this model in this ex vivo study. It also allows comparison to previous results of static tensile testing of the modified Kessler repair performed with braided polyester triple-stranded bound suture [20] and the Savage repair [16, 28, 29], both of which fulfilled the estimated requirements for active mobilization.

In this study, the modified Kessler repair performed with PLDLA triple-stranded bound suture was first investigated with linear static tensile testing which is the most commonly used method to evaluate and to compare the biomechanical properties of different tendon repairs. When comparing the present results with those of the previous study of the modified Kessler repair performed with the braided polyester triple-stranded bound suture [20], both

Table 3 Mean (95% confidence interval) × 10^3 Newton-cycles of the PLDLA and Savage repairs at each gap point in cyclic tensile testing

Repair	Par 1 mm	Par 2 mm	Par 3 mm	Tot 1 mm	Tot 2 mm	Tot 3 mm
PLDLA	241.4 (169.2–313.7)	273.1 (198.4–347.8)	292.7 (225.4–360.1)	323.5 (240.4–406.5)	344.7 (259.9–429.5)	373.7 (289.7–457.8)
Savage	49.6 (12.6–86.5)	77.3 (38.4–11.6)	101.4 (61.7–141.0)	127.5 (78.7–176.2)	169.3 (107.8–230.7)	241.0 (162.1–319.8)

Par partial gap, *Tot* total gap

force and strain values increased and the stiffness remained virtually the same. We consider the present results are due to the higher material stiffness, rougher surface, and larger size of the PLDLA triple-stranded bound suture compared with silicone coated braided polyester triple-stranded bound suture. These factors may prolong the adjustment of the PLDLA repair to initial loading increasing the first linear force (PLDLA 3.8 N, polyester 2.0 N) and strain at the first linear point (PLDLA 0.03, polyester 0.01) compared with braided polyester repair [20]. The yield force (PLDLA 77 N, polyester 56 N) improved, but as the strain at yield point (PLDLA 0.25, polyester 0.18) increased concomitantly, the stiffness (PLDLA 11.4 N/mm, polyester 10.8 N/mm) showed only tendency to increase.

Dynamic testing offers a tool to evaluate the influence of repetitive loading on the strength of the tendon repair [34, 35] providing a more physiologic appraisal of the effects of postoperative active motion. The 35 N starting level of the staircase protocol was chosen to exceed the previously estimated mean load subjected to the repair during active unresisted flexion [9, 11].

In cyclic loading, the elongation of both PLDLA and Savage repair was relatively highest during the first 100 cycles. The PLDLA repair showed higher initial elongation compared to the 6-strand Savage. We consider this difference in elongation during cyclic 35 N loading reflects the lower stiffness of the PLDLA repair (11.4 N/mm) compared to the Savage repair (16.7 N/mm) [28] demonstrated in static tensile testing, as the strain at first linear point of the 6-strand Savage (0.04) and PLDLA (0.03) repairs are of the same magnitude. However, after the initial period the difference in stiffness showed no influence as elongation of both groups in cyclic testing proceeded at the same rate.

Gap formation initiated at significantly lower loads in cyclic compared to static testing both in the PLDLA repair and the 6-strand Savage repair [28]. This is in accordance with previous results of Pruitt et al. [35]. At each gap point, the elongation was similar in static and cyclic tensile testing in both groups [28]. In cyclic testing, the PLDLA repair withstood higher extension and significantly more Newton-cycles at every gap point compared to the Savage repair.

The results of this study show that the biomechanical properties of the modified Kessler repair performed with PLDLA triple-stranded bound suture exceed the properties of the braided polyester triple-stranded bound suture repair in static testing ex vivo and the Savage repair in cyclic testing ex vivo. However, further investigations are needed before clinical use can be considered. The degradation, biocompatibility, and influence of PLDLA material on the healing of flexor tendons enclosed within a tendon sheath are currently investigated in vivo. Furthermore, the influence of the PLDLA triple-stranded bound suture on the gliding resistance of the tendon repair needs to be investigated in human cadaver tendons in situ.

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