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A novel implant-free tibial pull-press-fixation for ACL reconstruction

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Abstract

Introduction Extracortical fixation techniques in anterior cruciate ligament reconstruction bear the risk of tunnel enlargement, while close-to-aperture fixations often show lower failure loads. The purpose for this study was to investigate the biomechanical benefits of a novel implant-free combination of an extra-cortical and close-to-aperture fixation.

Materials and methods Quadrupled human cadaveric semitendinosus tendons were fixed to 30 porcine tibiae with either a cannulated interference screw (I), an implant-free post-fixation (S), or a novel pull-press fixation (P). Specimens were cyclically loaded 20 times between 20 and 60 N followed by 500 cycles with 60–200 N, followed by a load-to-failure test with 1 mm/s.

Results The mean elongation of the tendons in the P-group during the 500 cycles between 60 and 200 N was significantly lower (5.69 ± 2.16 mm) compared to 9.20 ± 3.21 mm in S-group and 9.37 ± 3.1 mm in the I-group ($p < 0.05$). The mean maximum load-to-failure was significantly higher in the P-group (728.2 ± 76.4 N)

compared to 476.4 ± 68.8 N in the S-group and 625.9 ± 82.5 N in the I-group ($p < 0.05$). Stiffness of the constructs in the P-group was significantly higher (121.7 ± 44.9 N/mm) compared to 46.2 ± 17.7 N/mm in the S- and 72.8 ± 29.8 N/mm in the I-group ($p < 0.03$).

Conclusions This study indicates superior biomechanical properties of a novel implant-free tibial pull-press fixation to conventional implant-free and close-to-aperture interference screw fixations in terms of cyclic elongation and maximum load-to-failure.

Level of evidence Not applicable, basic science study.

Keywords ACL reconstruction · Hamstring tendons · Pull-press fixation · Implant-free reconstruction

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Introduction

The estimated incidence of anterior cruciate ligament injuries occurring in the United States each year is 80,000–200,000 [5]. In times of rising costs of implants used in modern surgery, we are bound to develop new implant-free methods that can provide similar results and are easy to perform so operating time is not prolonged.

Hardware fixation of tendon grafts in the bone tunnel is still most commonly used for anterior cruciate ligament reconstruction. Many different fixation techniques have been investigated [13, 14, 17]. For the fixation of the hamstring tendons implants outside (endobutton, suture, postscrew, staple) or inside (nonresorbable and resorbable interference screws, cross-pin) the drill holes are most frequently used [20]. The techniques are easy to perform, show reasonable result regarding maximum load-to-failure and stiffness [14] of the construct and allow a fast rehabilitation of the patient.

However, there are a number of drawbacks regarding these implants. Revision surgery may be complicated by the need of hardware extraction [18]. Some implants are known to cause graft lacerations [26]. Post-operative MRI diagnostic may be compromised by artifacts caused by the implants. Due to increased movement of the tendon graft, bone tunnel enlargement can occur with certain implants [3, 11]. Therefore, a lot of research has been conducted analyzing the biomechanical properties and outcome of implant-free methods. Tibial press-fit fixation using a bone cylinder has shown good clinical results regarding maximum load-to-failure, stiffness of the graft and bone tunnel enlargement [2, 6, 9, 25].

The pull-press fixation is a novel press-fit fixation without need for an additional bone cylinder that combines the mechanical benefits of a post-fixation and a close-to-aperture fixation. Like the press-fit procedures, the pull-press suture aims to add pressure to the bone tunnel, and therefore should foster tendon-to-bone healing [23]. The pressure should also reduce the tendon graft movement in the bone tunnel. This may decrease bone tunnel enlargement especially when hamstring transplants are used [8, 16].

The purpose of this study was to investigate the biomechanical properties of the novel pull-press fixation and by comparing cyclic elongation, ultimate failure load, and construct stiffness of this procedure to a conventional interference screw and implant-free suture fixation.

Materials and methods

This study was approved by the institutional review board. We used the knees of 15 human cadavers for the harvesting of 30 hamstring tendons, which showed no signs of degeneration or trauma. The average age of the deceased tendon donors was 60 ± 10.9 years. The explantation of the ligaments was performed on an average 1.5 ± 1.4 (0–3) days post-mortem. We used the tendons of 13 men and 2 women with an average height of 179.8 ± 8.6 (162–198) cm and an average weight of 84.3 ± 12.2 (65–105) kg for this study. The semitendinosus tendons we extracted were 32.5 ± 3.1 cm (29–40) long and were used as a four-stranded graft with an average length of 8.0 ± 0.7 cm (7–10) and an average diameter of 8.4 ± 0.4 mm. The tendons were frozen at $-27°$ C and thawed at 4 °C for 24 h prior to biomechanical testing. Tendons were kept moist using buffered physiological saline spray throughout the procedure.

We used the tibiae of 30 German landrace pigs for the tunnel preparation. The pigs were approximately 1 year old, fully grown, and weighed between 45 and 55 kg. All remaining soft tissue was dissected off the bone and the shaft was cemented into an aluminum holder using a polyurethane resin (RenCast FC 53; Huntsman Advanced Materials Ltd., Duxford, Cambridge, England).

10 graft constructs were used in each of the three groups. The tendons were randomly sorted to the three groups. The tibial bone tunnel was drilled using a 55°–65° tibial guide (Richard Wolf, Tuttlingen, Germany). After inserting and double-checking the guide-wire, the holes were reamed according to the diameter of the used graft. Before entering the graft into the tunnel, we removed any remnants of the drilling. For the S- and the P-group, a 10–15 mm wide bone bridge was created adjacent to the distal end of the tibial bone tunnel using a 4.5 mm drill-bit.

Before graft preparation, the intraarticular free part and the fixation in the clamp were determined and marked. At least 15 mm of the graft remained extracortical outside the tibial tunnel and at least 20 mm were used for the specially shaped proximal holding clamp. The remaining part of the graft was used for tibial fixation. For both the P- and S-group, a No. 2 FiberWire® (Arthrex Inc., Naples, Florida) was used for the tibial suture. After application of the pull-press suture, a No. 2 polyethylene suture (Ethibond, Ethicon US) was additionally inserted above in order to increase mechanical stability. The femoral part of the graft was armed with a No. 2 polyethylene suture for easier insertion into the clamp. Before pulling in the graft, the pull-press effect was tested by pulling on the FiberWire® suture. If the effect of the suture was satisfying and increased the graft diameter by at least 2 mm (Figs. 1, 2), the graft was inserted into the bone tunnel. One strand of the No. 2 tibial polyethylene suture and one strand of the FibreWire® were passed through the bone bridge. The pull-press fixation was now applied by firmly tightening the FiberWire® suture (Fig. 3). The tension causes a widening of the tibial part of the graft. The FiberWire® was locked with five knots. The No. 2 polyethylene suture (Ethibond, Ethicon US) was then locked with 5 opposing half hitches.

The S-fixation was performed using a No. 2 FiberWire® and baseball-stitching technique secured with 5 knots. In the I-group, a non-biodegradable soft-threaded cannulated titanium interference screw (Arthrex Inc., Naples, Florida) with a screw length of 20 mm and a diameter according to the diameter of the bone tunnel was inserted over a guide-wire using the instruments and guidelines provided by the manufacturer. The screw was advanced until the proximal outlet of the tunnel.

For mechanical testing and evaluation of the constructs, a servohydraulic mechanical testing system (Mini Bionix 858; MTS Systems Co., MN, USA) was used. The cemented tibiae were rigidly fixed in a base platform tilted at 30°, setting the bone tunnel-force direction angle to 0° (Figure Biomechanik). This position simulates a human ACL reconstruction with a knee flexion angle of 0°–30°
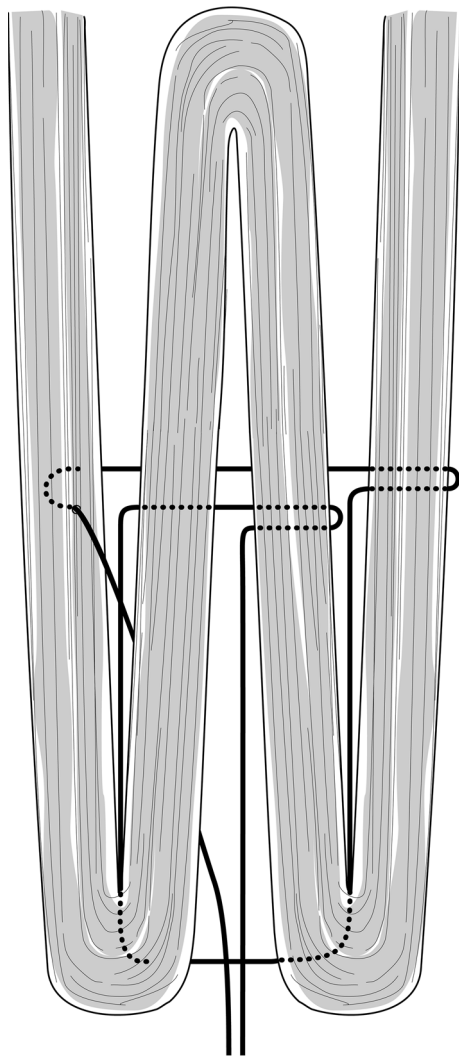
Fig. 1 Schematic drawing of the pull-press suture on a four-stranded graft (reprinted with permission [15])

(Lachman-position [21]). After graft preparation and fixation, the specimens were cyclically loaded 20 of times between 20 and 60 N followed by 500 cycles with 60–200 N. The increase in construct length was recorded during cyclic loading by a displacement sensor. After cyclic loading, loading of the specimens was ramped down to 10 N and held for 30 s. A load-to-failure test with an actuator speed of 1 mm/s was conducted. The maximum failure load, failure mode, and structural stiffness of the constructs were analyzed.

All mean values are described with standard deviations, and maximum to minimum ranges. The three groups were compared using a one-way ANOVA. If normality test was passed, an ANOVA model with a post hoc Tukey test was used. All operations were performed using SigmaStat 3.0 (SPSS-company, Chicago, IL 60606, USA). The significance level was set to 0.05.
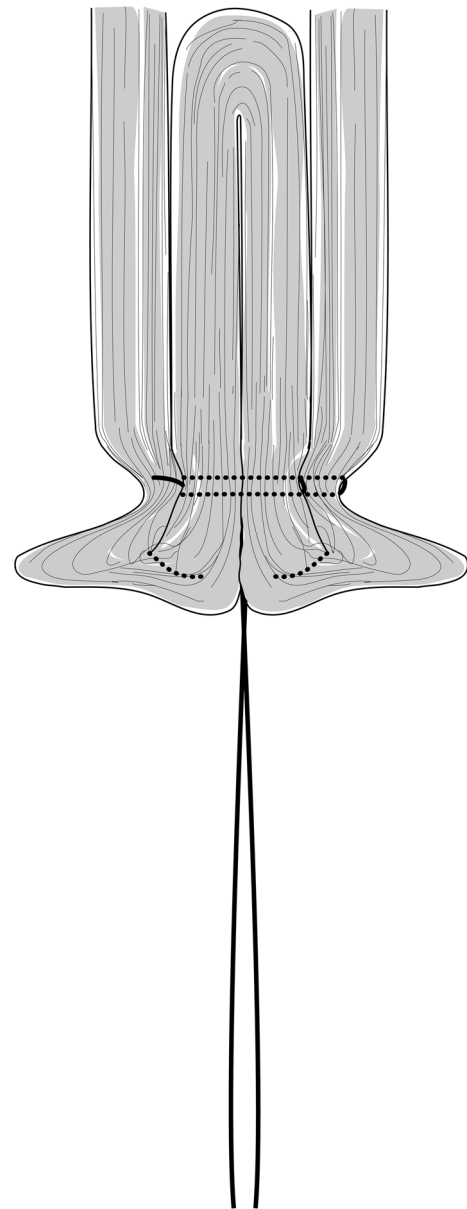

Fig. 2 Pull-press suture on a four-stranded graft after firmly tightening the suture (reprinted with permission [15])

Results

The age of our donors was 62.8 ± 12.8 years (range 40–71) in group S, 58.5 ± 10.2 years (range 43–68) in group P, and 64.3 ± 10.5 years (range 45–71) in group I, with no statistically significant difference ($p = 0.58$).

The diameter of the graft was 8.3 ± 0.4 mm (range 8.0–9.0) in group S, 8.3 ± 0.4 mm (range 8.0–9.0) in group P and 8.4 ± 0.4 mm (range 8.0–9.0) in group I with no significant differences being observed ($p = 0.87$). The length of the graft was 7.9 ± 0.1 mm (range 7.5–8.0) in group S, 7.7 ± 0.4 mm (range 7.5–10.0) in group P, and
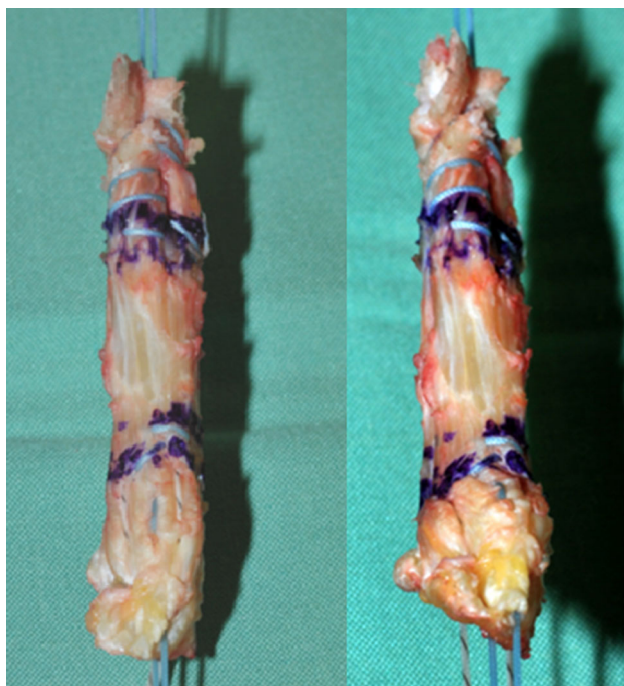
Fig. 3 Prepared graft using the pull-press suture before insertion. The pull-press effect is tested. The diameter of the graft should extend by at least 2 mm
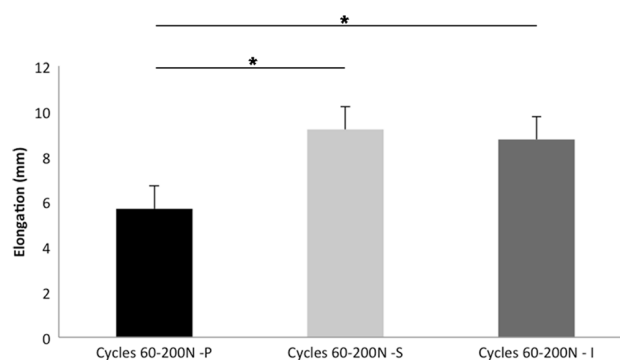

Fig. 4 Elongation in P between 60 and 200 N was significantly lower ($p < 0.05$) than in the S- and I-group. No significant difference between S- and I-fixation ($p = 0.76$)

8.2 ± 0.6 mm (range 7.5–9.0) with no significant differences either ($p = 0.35$).

Cyclic loading

After 20 cycles between 20 and 60 N, the elongation in the P-group was 1.16 ± 0.47 mm (range 0.4–1.69) compared to 2.23 ± 0.89 mm (range 0.7–3.38) in the S-group and 0.96 ± 0.33 mm (range 0.6–1.65) in the I-group. The elongation of the graft was significantly higher in S-group than in the P- and the I-group ($p < 0.01$). There was no significant difference in the P- and the I-group ($p = 0.3$).

The mean elongation of the tendons in the P-group during the 500 cycles between 60 and 200 N was significantly lower (5.69 ± 2.16 mm) compared to 9.20 ± 3.21 mm (range 4.29–13.69) in S-group and 8.75 ± 3.29 mm (range 4.25–14.95) in the I-group ($p < 0.05$). There was no significant difference in elongation between the S- and the I-group ($p = 0.76$). None of the fixations failed during cyclic loading (Fig. 4).

Ultimate load-to-failure, failure mode, and stiffness

The ultimate load-to-failure was 728.2 ± 76.4 N (range 614.1–819.4) for the P-group, 476.4 ± 68.8 N (range 358.7–545.8) for the S-group, and 625.9 ± 82.5 N (range

519.6–822.3) for the I-group. The maximum load-to-failure was significantly higher in the P-group than in the S- and the I-group ($p < 0.01$). The maximum load-to-failure in the I-group was significantly higher than in the S-group ($p < 0.01$).

Nine fixation failures (90 %) in the P-group were a result of ruptures of the suture fixation. In one case (10 %) the bone bridge broke. In the S-group, eight failures (80 %) were due to a rupture of the suture fixation. The tendon was pulled out of the suture in one case (10 %) and the bone bridge broke in one case (10 %). In the I-group, all ten tendons (100 %) were pulled out of the socket (Fig. 5).

Stiffness (Max. to failure (N)/elongation [4]) of constructs in the P-group was significantly higher (121.7 ± 44.9 N/mm) (range 60.9–180) compared to 46.2 ± 17.7 N/mm (range 29–76.6) in the S- and 72.8 ± 29.8 N/mm (range 50.1–130.9) in the I-group ($p < 0.03$) (Fig. 6).
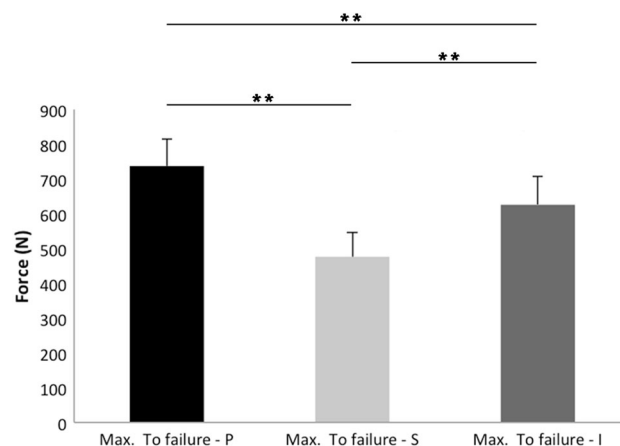

Fig. 5 Ultimate load-to-failure of the three techniques investigated in this study: there were significant differences between all techniques (ANOVA, Tukey test, $p < 0.01$)
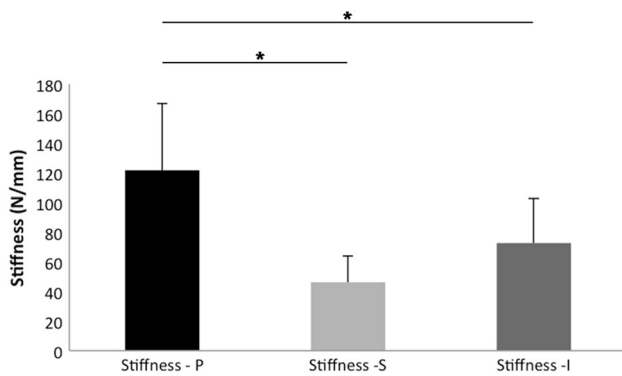
Fig. 6 Stiffness of the constructs of the three techniques investigated in this study; significant differences were observed (ANOVA, Tukey test, $p < 0.03$)

Discussion

The most important finding of this study was that a novel implant-free tibial pull-press fixation yielded superior biomechanical properties in terms of cyclic elongation and maximum load-to-failure compared to conventional implant-free and close-to-aperture interference screw fixations.

This study was conducted using human cadaveric hamstring tendons and young porcine tibae. Even though the mechanical properties of cadaveric tendons are different from in vivo human tendons in young patients, none of our fixations ruptured due to a failure of the graft. Either the sutures ruptured or the grafts were pulled out of the socket. The maximum load-to-failure results of the I-fixation should be not overestimated since the cancellous bone of the porcine tibae is known to be more rigid than human cancellous bone [19].

In our study, two out of three groups were affixed with a post-fixation using a cortical bone bridge. Since the cortical bone of the porcine tibae is similar to human cadavers [19], the results of the P- and the S-fixation are better comparable with the results obtained in human specimen. We chose our set-up to be able to compare our results with other similar studies [2, 10, 14, 17, 21] and because the bone structure of the porcine tibae is more homogenous than it is in human cadaveric tibae. In addition, we used a strain rate of 1 mm per according to previous research and the results of similar studies [2, 7, 9, 10, 13].

Our results for the interference screw fixation show maximum failure loads comparable to the results of other studies [10, 14, 24]. The load-to-failure of the pull-press suture showed a significantly higher result than a conventional baseball-stitched suture and the interference screw fixation. Stiffness of the interference screw showed results in the range of the standard deviation of the results found by Kousa et al. (91 ± 34 N/mm for BioScrew [14]).

Comparable studies using a 1 mm oversized interference screw [24] showed a higher stiffness than found in our set-up [10]. The stiffness of the pull-press group showed results that came close to the results of oversized interference screws (162 ± 27 N/mm Sysorb; Centerpulse Medical AG, Winterthur, Switzerland and 115 ± 34 N/mm for Smart Screw ACL [10, 14]).

We developed the pull-press fixation as a new implant-free approach that uses the advantages of the press-fit fixation without the need of an additional bone cylinder in order to minimize the risk of osteonecrosis and decrease postoperative pain. The extraction of bone cylinders is known to be associated with post-operative anterior knee pain [12].

In our opinion, this technique offers the possibility to reduce common side-effects of extracortical fixations such as the windshield-wiper effect that causes bone tunnel widening through increased antero-posterior translation of the graft [1, 22], by putting extra pressure close to the aperture. In addition, the pull-press effect should prevent synovial fluid to enter the bone tunnel. The idea is that the tendon-to-bone healing is fostered through the increased pressure of the graft close to the aperture and the decreased movement and synovial fluid.

Further clinical studies need to clarify the benefits of this novel fixation technique. These studies have to include a careful analysis of bone tunnel enlargement and long-term knee stability and graft failure.

Conclusion

This study indicates superior biomechanical properties of a novel implant-free tibial pull-press fixation to conventional implant-free and close-to-aperture interference screw fixations in terms of cyclic elongation and maximum load-to-failure.

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