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Biomechanical characterization of double-bundle femoral press-fit fixation techniques

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Abstract
Purpose Press-fit fixation of patellar tendon bone anterior cruciate ligament autografts is an interesting technique because no hardware is necessary. To date, no biomechanical data exist describing an implant-free double-bundle press-fit procedure. The purpose of this study was to characterize the biomechanical properties of three double-bundle press-fit fixations.
Methods In a controlled laboratory study, the patellar-, quadriceps- and hamstring tendons of 10 human cadavers (age: 49.2 ± 18.5 years) were used. An inside out press-fit fixation with a knot in the semitendinosus and gracilis tendons (SG) combined with an additional bone block, with two quadriceps tendon bone block grafts (QU) was compared with press-fit fixation of two bone patellar tendon bone block (PT) grafts in 30 porcine femora. Constructs were cyclically stretched and then loaded until failure. Maximum load to failure, stiffness and elongation during failure testing and cyclical loading were investigated.
Results The maximum load to failure was 703 ± 136 N for SG fixation, 632 ± 130 N for QU and 656 ± 127 N for PT fixation. Stiffness of the constructs averaged 138 ± 26 N/mm for SG, 159 ± 74 N/mm for QU, and 154 ± 50 N/mm for PT fixation. Elongation during initial cyclical loading was 1.2 ± 1.4 mm for SG, 2.0 ± 1.4 mm for QU, and 1.0 ± 0.6 mm for PT (significantly larger for PT and QU between the first 5 cycles compared with cycles 15–20th, $P < 0.01$).
Conclusion All investigated double-bundle fixation techniques were equal in terms of maximum load to failure, stiffness, and elongation. Unlike with single-bundle press-fit fixation techniques that have been published, no difference was observed between pure tendon combined with an additional bone block and tendon bone grafts. All techniques exhibited larger elongation during initial cyclical loading. All three press-fit fixation techniques that were investigated exhibit comparable biomechanical properties. Preconditioning of the constructs is critical.

Keywords ACL · Double bundle · Knee · Press-fit

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Introduction

Most surgeons today use hardware for fixation of the graft in the drill holes [21, 23, 26]. This approach is compromised by artifacts during postoperative magnetic resonance imaging and the necessity of implant removal in case of ACL revision surgery [6, 29]. Hardware-free press-fit fixation is a potential solution to these drawbacks [33].

The use of hamstring tendons is being applied more and more frequently. The technique is associated with less donor-site morbidity [7, 19, 39], and 5-year results appear

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to be equally good compared with patellar tendon reconstructions [5, 34, 36].

Although Mott [27] reported about two separated bundles in 1983, only more recently has attention been paid to the thorough biomechanical analysis of the behavior of the two bundles [35, 42]. The reconstruction of the ACL using two separate bundles has been claimed to improve the rotational stability after ACL replacement [42]. There is supposed to be more room for impingement-free transplant positioning if an additional femoral tunnel is created [43]. Although the hamstring tendons have been most commonly suggested, the procedure can be performed with any autograft [33], allograft [38], or synthetic material [15].

A various number of fixation techniques have been recommended. Endobutton fixation has been associated with migration of the graft in the bone tunnels [14]. Both titanium and bioresorbable screws have shown adequate fixation strength [40]. This close to the joint space, fixation is critical in order to achieve graft healing with the formation of Sharpey-like fibers [41]. Despite proper fixation, bone tunnel widening has been observed following reconstruction of the ACL, especially when using tendon grafts without bone blocks [39]. Although there is disagreement about whether biological or mechanical factors predominantly cause this problem [39], it is evident that bone plugs heal faster and show less tunnel enlargement postoperatively [9, 17, 18]. It has moreover been observed that interference screw fixation widens the bone tunnels significantly [4].

Based on these reports, press-fit fixation of the hamstring tendons would be a desirable technique, especially if the press-fit procedure would include a bone block that induces more rapid tendon bone consolidation.

The objective of this study was to evaluate if a femoral double-bundle press-fit fixation with hamstring tendons, combined with an additional bone block, is mechanically equivalent to patellar tendon bone or quadriceps tendon bone fixation.

Materials and methods

The knees of 10 human cadavers (20 knees) were used for acquisition of the hamstring tendons, quadriceps tendon with bone blocks, and the patellar tendon with bone blocks. The age of the cadavers from which the tissue was obtained was 49.2 ± 18.5 years (range: 23–75). The harvesting of the tendons was performed an average 1.7 ± 0.76 (range: 1–3) days postmortem. We used tendons from 8 men and 2 women with a mean body size of 175.7 ± 10.3 (range: 154–183) cm for this investigation. There were no signs of ligament degeneration or tibial tuberosity disorders. A bone block of 30 mm length was harvested with the patellar tendon from the tibial tuberosity. It was trimmed into two grafts, each with a bone block, in order to fit into a 6- to 7-mm drill hole each. The patellar tendon grafts were 5–6 mm wide and detached at the insertion of the patella. The quadriceps tendons were harvested with a patellar bone block with the length of 30 mm. It was trimmed into two grafts in order to fit in a 7-mm drill hole. Additional bone blocks measuring 6–7 mm were harvested from the tibia medial to the tibial tuberosity in a region where positioning of the tibial tunnel for ACL reconstruction has been recommended [3, 30]. Parts of the block were cortical bone. The knot of the hamstring tendons had an average diameter of 4.5 ± 0.6 mm for the gracilis and 7.6 ± 1.6 mm for the semitendinosus graft. For the femoral drill holes, we used the femurs of 30 German Landrace pigs. The pigs were 1 year old, fully grown, and had a weight between 100 and 120 lbs. The femoral neck was cut off and the shaft of the femur cemented into an aluminum holder using cold-curing methylmethacrylate resin (Technovit 4071, Heraeus Kulzer, GmbH, Wehrheim, Germany).

Graft preparation and fixation

There were 10 constructs used in each group. Grafts and bone blocks were kept moist using saline spray during preparation and testing and refrigerated at −20°C before and after preparation.

All bone tunnels were drilled with an external axial rotation of 30° and a femoral shaft flexion of 60° and 45° in the 10 o'clock or 2 o'clock position, simulating tunnels that are drilled with the knee flexed 120° and 90° [32]. The anteromedial tunnel was positioned in the posterior quarter of the intercondylar roof [11], and the posterolateral tunnel adjacent to the cartilage of the lateral femoral condyle, leaving a 2-mm separating bridge (Fig. 1b).

Quadriceps tendon graft (QU)

The bone blocks of the quadriceps tendon grafts were trimmed to fit into a 6- to 7-mm drill hole and to create a cone. A central 2-mm drill hole was placed within each bone block, and a nonresorbable suture (Ethibond 3, Ethicon GmbH, Norderstedt, Germany) was advanced through the hole in order to insert the graft inside the femoral tunnel.

Hamstring tendon knot graft (SG)

Similar to the hamstring technique described by Paessler [31, 33], a knot was tied with the semitendinosus/gracilis tendons leaving 10-mm tendon behind the knot (Fig. 1a); knots were secured by 4 sutures (Vicryl No. 0, Ethicon Inc., Somerville, New Jersey). The knots were tightened

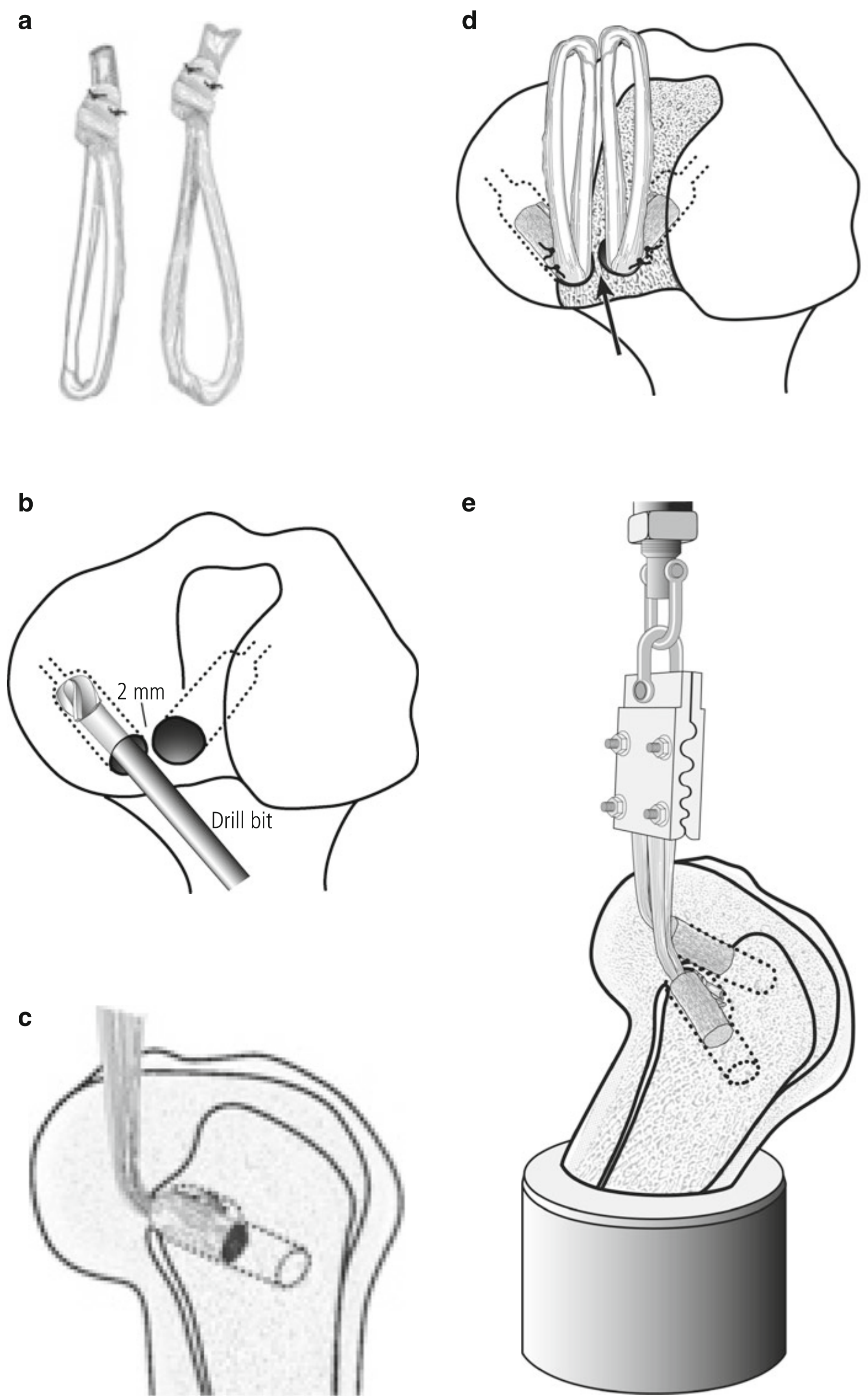

Fig. 1 Fixation techniques that were investigated: SG grafts were prepared as loops with knots that were secured by sutures (SG; **a**). For all groups, a bottleneck-shaped tunnel with an internal diameter of the bone block or the knot was created by enlarging the tunnel with a reamer by 2 mm on the inferior (distal) side (**b**). For better illustration of the tunnel position, also see Fig. 2. The external diameter matched the size of the knots or the bone block/tendons (**c**, **d**). The grafts were inserted from the inside and came to rest against the cortical wall of the tunnel. Then, a bone block was inserted from the inside of the tunnel and the graft was pushed against the wall. All constructs were mounted on a platform of a biomechanical testing machine. The bone tunnel–force direction angle was 30 degrees (Lachman position, **e**)

until their diameter fit into a drill hole that exceeded the diameter of the tendon with a maximum of 4 mm.

Bone block: patellar tendon grafts (PT)

The bone blocks of the patellar tendon grafts were trimmed to fit into a 6- to 7-mm drill hole and to create a cone. A central 2-mm drill hole was placed within each bone block, and a nonresorbable suture (Ethibond 3, Ethicon GmbH, Norderstedt, Germany) was advanced through the hole in order to insert the graft inside the femoral tunnel.

Femoral tunnel preparation

The positioning of the two tunnels was equal for all three techniques. For the anteromedial tunnel, a bottleneck-

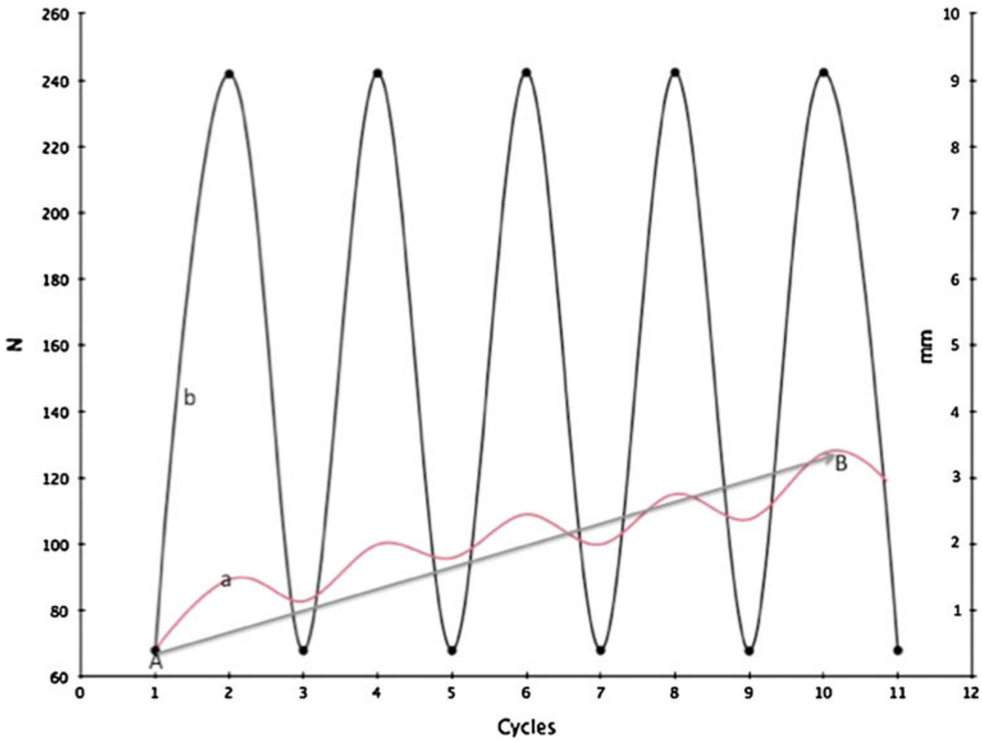

Fig. 2 The length changes (*a*) were reported between the minimum of the 1st (15th, 20th) [*A*] and the maximum of the 5th (20th, 500th) [*B*] cycle (*b*). We chose this log to ensure to report the biggest increase in length changes

shaped femoral tunnel was created using a drill bit with the diameter of the maximum size of the graft. The tunnel entrance matched the diameter of the bone block of the QU and PT grafts or the knot of SG grafts. Behind the cortical tunnel entrance, the tunnel was enlarged 2 mm using a reamer (Fig. 1b). The posterolateral tunnel was adjacent to the cartilage of the femoral lateral condyle in the same way the anteromedial tunnel was created. The grafts were inserted from the inside out. A compactor was used in order to enlarge the bone tunnel and to push the knot and the bone blocks to the posterior aspect of the bone tunnel (Fig. 1c). The size of the compactor determined the size of the additional bone block that was used for fixation. A diamond bone cutting system (DBCS®, Fa. Articomed Ltd., Schlüchtern, Germany) was used in order to fabricate a bone cylinder matching the size of the enlarged tunnel containing the fixation side of the grafts. The bone block was inserted into the anterior side of the bone tunnel (Fig. 1d). Simultaneously, the grafts were pulled to the entry of the bone tunnel. Care was taken in order to obtain alignment of the graft angulated 20° with respect to the femoral shaft in the sagittal plane.

Mechanical testing

The constructs were thawed at 4°C for 24 h prior to mechanical testing and kept moist using saline spray during the entire procedure. A material testing machine (Mini Bionix 858, MTS Systems Co., Minneapolis, USA) was used for the mechanical evaluation of the constructs. The potted femora were rigidly fixed in a base platform at 0°, setting the bone tunnel–force direction angle to 60°. This represents a simulation of human ACL reconstructs with a knee flexion angle of 30° (Lachman position [37], Fig. 1e). There was a distance of 30 mm between the grafts and the clamp, the total length of all tendons was trimmed to 50 mm, leaving 20 mm for fixation in a custom-made, s-shaped clamp (Fig. 1e).

The constructs were pretensioned with 60 N for 30 s prior to testing. Then, 500 cycles of mechanical loading in between 60 and 260 N were applied at a repetition rate of 1 Hz. The increase in construct length was recorded. Length changes are reported between the minimum of the 1st (15th, 20th) and the maximum of the 5th (20th, 500th) cycle (Fig. 2). After a decreasing preload from 60 to 10 N, an pausing for 30 s, a failure test with a ramp speed of 1 mm/s was performed. The maximum failure load, failure mode, and stiffness of the constructs were analyzed.

The tests were recorded with a digital video camera (frame rate: 25 pictures/s). Constructs were photo-optically marked at intervals of 10 mm starting at the ridge of the femoral drill hole. One marker was attached to the bone and three markers within the tendons with a distance of 10 mm in between each marker. Markers A and B were used to investigate length changes within the tendon, markers C and D to analyze changes between tendon and bone (Fig. 3).

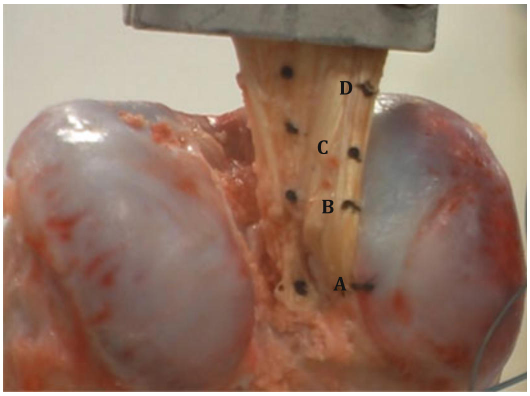

Fig. 3 Photo-optical markers were used in order to analyze length changes of the constructs. The distance between two markers attached to the tendon [*AB*] and between tendon and entrance of the bone tunnel [*CD*] was evaluated. Note the tunnel position on the lateral femoral condyle similar to the human ACL insertion

An image-analyzing software (ImageJ, NIH) was used to determine length changes. The measurements are reported in percent of the initial length. We analyzed the length change in between tendon–bone and tendon–tendon markers. The procedure was executed from the smallest length observed during the 1st (15th) (20th) loading cycle to the maximum length attained during the 5th (20th) (500th) loading cycle. Moreover, lengthening in between the beginning and end of failure testing was examined.

These data were compared with the length changes that were recorded by the mechanical testing machine.

Statistical analysis

All mean values are reported with standard deviations, such as maximum and minimum. The three groups were compared using a one-way ANOVA. Normality and equal variance tests were conducted. If normality test failed, a Kruskal–Wallis ANOVA on ranks was executed with a post hoc Scheffe Test. If normality tests were passed, an equal variance test was conducted. Comparison of two groups was conducted using a nonparametric *t*-test. Power tests were applied for nonsignificant findings (nQuery Advisor Version 5.). Appropriate power was assumed if beta exceeded 0.80. All operations were performed using Sigma Stat 15.0 (SPSS-company, Chicago, IL 60606, USA). A significance level of $P < 0.05$ was assumed.

Results

The maximum diameter of the drill hole was 7.0 ± 0 mm in the PT group, 7.0 ± 0 mm in the QU group, and 8.2 ± 1.7 mm (range: 6–12 mm) in the SG group. ANOVA indicated that there was no statistical difference between these groups ($P = 0.35$; Table 1). There were 2 (20%) pullouts of a graft during cyclic loading in the PT group, one (10%) in the SG group, none in the QU group. The failure mode in the PT group was a bone plug pullout in 3/10 (30%) and a rupture of the tendon at the insertion to the bone block in 7/10 (70%) of the cases. SG fixations failed as a result of pullout of the knot of the semitendinosus tendon in 7/10 (70%) and a pullout of the knot of the gracilis tendon in 3/10 (30%). In the QU group, a rupture of the tendon at the insertion to the bone block was the mode of failure in 9/10 (90%) and a pullout of the bone block in 1/10 (10%).

These results are mirrored in the data obtained from video analysis of the load to failure experiments. The elongation during failure testing between tendon–bone markers was significantly larger for all fixations than between markers placed on the tendons ($P = 0.026$; Table 2).

Maximum failure loads observed were 656 ± 127 N (range: 866–525 N) for the PT fixation, 703 ± 136 N (range: 901–499 N) for the SG group, 632 ± 130 N (range: 739–320 N) for the QU technique. The loads between these groups were not significantly different (ANOVA on ranks, $P = 1.0$; Fig. 4; Table 1).

Stiffness of QU grafts was 159 ± 75 N/mm (range: 312–74 N/mm), the PT reached 154 ± 50 N/mm (range: 255–78 N/mm) and SG 138 ± 26 N/mm (range: 167–90 N/mm). These differences were not significant (power: 11%, β: 0.89; Table 1).

The cyclical loading elongation, determined by optical tendon–bone markers in between the 1st and the 5th cycles,

Table 1 Structural differences and results determined by the testing machine

	PT	OU	SG	Significance
Diameter of the drill holes (mm)	7.0 ± 0	7.0 ± 0	8.2 ± 1.7	NS
Maximum load to failure (*N*)	656 ± 127	632 ± 130	703 ± 136	NS
Stiffness (*N*/mm)	154 ± 50	159 ± 70	138 ± 26	NS
Elongation from the 1st to the 5th cycle (mm)	1.0 ± 0.6	2.0 ± 1.4	1.2 ± 1.4	NS
Elongation from the 15th to the 20th cycle (mm)	0.26 ± 0.15	0.5 ± 0.3	0.38 ± 0.21	NS
Elongation from the 20th to the 500th cycle (mm)	1.0 ± 1.2	1.2 ± 0.8	1.1 ± 0.5	NS

Table 2 The elongation during failure testing between tendon–bone markers was significantly larger for all fixations than between markers placed on the tendons ($P = 0.026$)

	PT (%)	QU (%)	SD (%)
Tendon–Tendon	3.5 ± 3.3	15.8 ± 29.2	1.8 ± 1.0
Tendon–Bone	35.4 ± 30.5	42.1 ± 27.9	53.5 ± 30.8

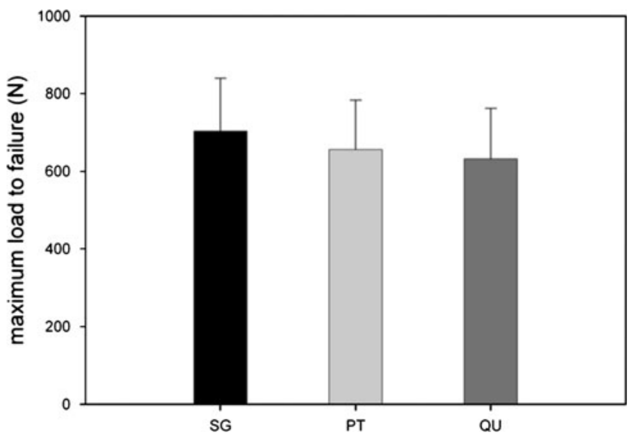

Fig. 4 Maximum load to failure of the three techniques investigated in this study: the three fixation techniques were not significantly different in this parameter (power: 16%, β: 0.84)

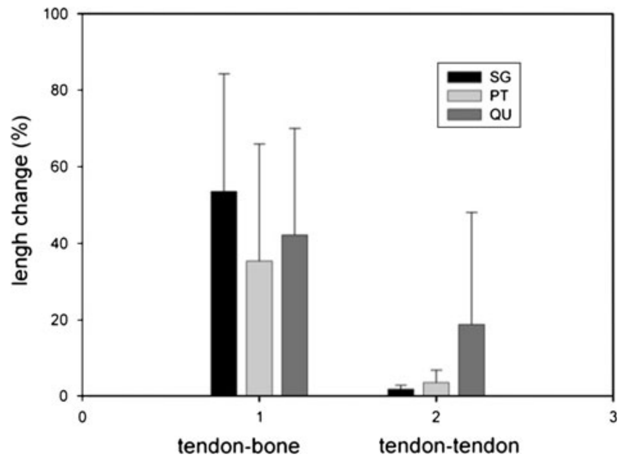

Fig. 5 Stretching of optical markers (compare Fig. 3) located on the tendon and bone of the constructs during failure testing. The amount of cyclical loading elongation was significantly larger between tendon and bone than between tendon–tendon markers ($P < 0.021$)

was significantly larger for all fixations than between markers placed on the tendons ($P < 0.014$). The cyclical loading elongation, determined by optical tendon–bone markers in between the 15th and the 20th loading cycles, was significantly larger for all fixations than between markers placed on the tendons ($P < 0.021$). The cyclical loading elongation, determined by optical tendon–bone markers in between the 15th and the 500th loading cycles, was not significantly different between the groups (Fig. 5; Table 3).

The cyclical loading elongation determined by the mechanical testing machine in between the 1st and the 5th loading cycles showed no significant difference between the groups (power: 38%; beta: 0.62). From the 15th to the 20th loading cycle, the elongation was not significantly different between the groups (power = 52%; beta = 0.48). Length changes between 15th and 500th loading cycle were not significantly different between the groups (power = 6%; beta = 0.94; Fig. 6; Table 1).

Discussion

The techniques used for the fixation of soft tissue ACL reconstruction grafts need hardware for graft fixation [26]. The techniques developed in this study show comparable biomechanical properties to implant using fixation devices. This study explores the biomechanical properties of femoral double-bundle press-fit fixations using human tendons and porcine femora. Care was taken to harvest the tendons shortly postmortem (1.7 ± 0.7 days). The mechanical properties of the tendons of this collective were different from young human tendons; however, most failures were observed as a result of fixation failure rather than from tendon rupture. The first limitation of this study is the fact that one component of our setup was animal tissue. Porcine femora are smaller in size than human femora. Creation of a 10-mm bone tunnel creates a greater stress riser than it does in human bone. This may explain the incidence of bone fracture (8%) that was seen in this study. Although the use of animal specimens has been criticized, we chose porcine femora because of their availability and the fact that due to the same age of the donors, we have a more uniform bone quality [23]. The second limitation is due to the fact that we stretched the complex along the tunnel axis, we are not able to say anything about the flexion–extension motion. Moreover, this controlled laboratory study just reflects on the mechanical properties of femoral press-fit fixation without any biological healing or remodeling responses.

In contrast to other investigators, we used a single graft–bone tunnel angle for mechanical testing (60°). This represents a simulation of human ACL reconstructs at a knee flexion angle of 30° (Lachman position [28]). In vivo, tunnel angles vary according to surgical technique and knee flexion angle. Increasing knee extension may lead to more tension of the graft [25]; however, the graft–femoral bone tunnel angle increases at the same time, which has been demonstrated to increase pullout forces [37]. Thus, it can be assumed that the results for mechanical tests such as failure loads would have been exceeded if further tests

Table 3 The cyclical loading elongation, determined by the optical tendon–bone markers from the 1st (15th) to 5th (20th) cycle, was significantly larger compared to the markers placed on the tendons ($P < 0.021$)

	PT (%)	QU (%)	SG (%)
Tendon–Tendon (1st to the 5th cycle)	0.4 ± 0.9	0.1 ± 0.5	0.5 ± 0.9
Tendon–Bone (1st to the 5th cycle)	5.4 ± 3.0	5.1 ± 3.9	7.1 ± 6
Tendon–Tendon (15th to the 20th cycle)	1.1 ± 1.1	0.4 ± 0.9	1.6 ± 1.2
Tendon–Bone (15th to the 20th cycle)	5.5 ± 2	6.2 ± 6.0	9 ± 3
Tendon–Tendon (15th to the 500th cycle)	1.9 ± 1.9	1.1 ± 1.3	1.4 ± 0.5
Tendon–Bone (15th to the 500th cycle)	9 ± 11	5 ± 1	12 ± 8

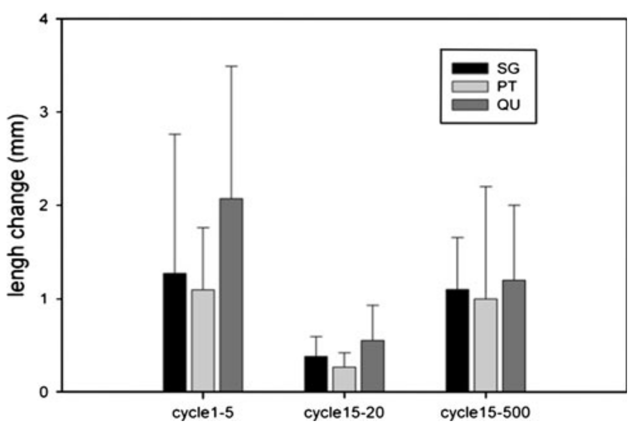

Fig. 6 The cyclical loading elongation determined by the testing machine did not show significant differences between the groups from the 1st (15th) (20th) cycle to the 5th (20th) (500th) loading cycle

were performed with increased graft–bone tunnel angles. Other authors who have investigated press-fit fixations have used an angulation of the femoral tunnel and the graft of 60 degrees and more on experimental testing [28].

Higher strain rates have been investigated by other authors (30 mm/s) [2, 24]. The strain rate used in this study (1 mm/s) was most commonly used in recent investigations [13, 22, 40]. Various different numbers of cycles, recovery periods, and strain magnitudes have been used in order to determine the biomechanical properties of graft fixations [2, 13, 26, 28]. In our view, several thousand cycles would have biased the measurements obtained for SG, because tendon knots are affected more by dehydration than bone blocks. In vivo, dehydration is less likely to occur. Thus, we decided to limit the number of cycles to 500.

The maximum loads to failure forces found in this study exceed the values (for 60° of graft–force angle) and demonstrate smaller standard deviations than published data for single-bundle PT press-fit fixation: Seil et al. [37] found a maximum pullout force of 455 ± 131 N for a graft–force angle of 45° and of 708 ± 211 for an angle of 80°. Similar pullout forces have been reported for interference screw fixation [40], even with a bone tunnel–force angle of 0°. Furthermore, standard deviations in this study population were lower than in comparable studies investigating the biomechanical safety of single-bundle press-fit fixation techniques [16]. Unlike previous experiments, this study demonstrates that there is no biomechanical difference in terms of initial elongation, if a press-fit technique with knots or bone blocks and a bottleneck-shaped tunnel is used in an inside out fashion.

Other investigators found a difference in fixation creep between patellar tendon and hamstring grafts [1]. These differences were not seen in this study. This may have been a result of the close to tunnel fixation with special emphasis on a secure bone block fixation. Still, cyclic preconditioning before final fixation is critical for reproducible results. The results for cyclical loading elongation obtained from video analyses were consistent with the lengthening recorded by the mechanical testing machine. This proves that the clamp and femoral fixation used in this study were sufficient and did not have an impact upon the results.

All fixation techniques investigated in this study do not require additional femoral incisions (unlike some other techniques, e.g. cross-pins and Bone Mulch Screw) [23]. In a previous investigation, a single-bundle press-fit technique with the graft wrapped around a bone block was found not to be biomechanically equivalent [16]. Paessler et al. [20, 33] have described a technique that utilizes a bottleneck-shaped femoral tunnel and a knot in the hamstring grafts in order to achieve implant-free press-fit fixation of the tendons. The pullout strength of this technically challenging procedure is reported to be equivalent to interference screw fixation [16].

To our knowledge, this study is the only investigation that reports data for a double-bundle femoral press-fit fixation. Other authors have analyzed interference screw fixation of hamstring grafts wrapped around a bone block [40]. They found this technique biomechanically equivalent compared with a pure tendon fixation. We found the same biomechanical stability for all investigated press-fit procedures examined in this study. However, the potential advantages of the investigated approach are clear: Since bone tunnel widening and insufficient tendon to bone healing have been associated with hamstring but not with BPTB grafts [10], a bone block that is rigidly included in the fixation may help to avoid these adverse effects.

Good long-term results have been achieved with the single-bundle PT press-fit technique followed by an aggressive rehabilitation program [3]. Good mechanical and functional outcome analyses after 5 and 10 years have also been published following the BPTB press-fit technique [8, 12].

The double-bundle techniques introduced in this study have promise for a similar approach, as comparable mechanical properties were found regardless of whether hamstring, patellar tendon-bone or quadriceps tendon-bone grafts were used. While the results of this study are promising, clinical investigations will be necessary to follow up on the healing process of a femoral press-fit fixation in patients. These investigations should include a careful analysis of bone tunnel enlargement.

Conclusion

In this in vitro evaluation, reconstructions with three soft tissue grafts exhibited very similar biomechanical properties and our hypothesis was supported.

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Conflict of interest statement The authors declare that they have no conflict of interest.

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