Effect of Insertion of a Single Interference Screw on the Mechanical Properties of Porcine Anterior Cruciate Ligament Reconstruction Grafts

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Abstract

The objective of this study was to evaluate the mechanical properties of soft-tissue grafts following a single interference screw insertion of 4 different commercially available bioabsorbable interference screws.

Twenty-four bovine proximal tibiae (12 matched pairs) were prepared and sagittally split to make 48 bone samples for testing. Tibiae were prepared for a 9 mm porcine tendon graft and were instrumented with 1 of 4 commercially available 10 x 35 mm composite screws, each with a different thread design. The samples were tensile loaded to failure at 200 mm/min and values for yield load, maximum load, and stiffness were recorded to quantify any differences on the function of the grafts.

No graft showed macroscopic evidence of laceration following screw insertion and there were no statistically significant differences for yield load ($P = .41$), maximum load ($P = .35$), or stiffness ($P = .68$) among the different screw types.

There is no significant difference in the mechanical properties of an anterior cruciate ligament graft following insertion of the 4 bioabsorbable screws tested in this study, in terms of yield load, stiffness, or failure load.

Although bone-patellar tendon-bone (BPTB) autograft has been the gold standard for anterior cruciate ligament (ACL) reconstruction the past few decades, its use has been accompanied by reports of anterior knee pain, quadriceps weakness, patella fracture, patella tendon rupture, and infrapatellar contracture.[1,2] Autologous hamstring tendon, which is another graft used in ACL reconstruction, continues to gain in popularity; compared with BPTB graft, hamstring tendon graft has a lower postoperative morbidity rate and fewer donor-site complications.[1,2]

In a meta-analysis of clinical outcomes, Samuelsson and colleagues[1] found no difference between BPTB and hamstring tendon grafts in terms of laxity, clinical outcome, time to return to sport, patellofemoral crepitations, 1-leg hop, and anterior knee sensory deficit.

In biomechanical studies, BPTB grafts have demonstrated 168% of the strength of the ACL,[3] and 4-strand hamstring grafts more than 250%.[4] Nevertheless, graft fixation remains the weak point in ACL reconstruction.[5] Many techniques, including use of metal and bioabsorbable interference screws, have been applied to fixating hamstring grafts to the bone tunnel.[5]

Concerns about graft laceration caused by metal interference screws led Zantop and colleagues[6] to investigate the mechanical properties of soft-tissue grafts after insertion of a single bioabsorbable or titanium screw. Mechanical properties of the grafts were significantly decreased after insertion of a titanium screw than after insertion of a bioabsorbable screw.[6] In addition, stiffness, yield load, and maximum failure load were significantly increased after insertion of a bioabsorbable screw made of poly-D,L-lactide-tricalcium phosphate (PLDLA-TCP) than after insertion of a screw made of poly-D,L-lactide (PLDLA).[6]

We conducted a study to expand on that finding and to compare the mechanical properties (yield load, stiffness, maximum failure load) of soft-tissue ACL grafts after insertion of a single screw, 1 of 4 different commercially available bioabsorbable interference screws, in a porcine tendon and bovine tibia model. We hypothesized that after insertion of a single screw, the mechanical properties of the grafts would be similar, regardless of which of the 4 commercially available screws was used for instrumentation.

Materials and Methods

Twenty-four bovine knees (12 matched pairs) and porcine flexor digitorum tendons were used in this comparative study.

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Specimens were screened for gross anatomical defects; specimens with abnormalities were excluded from the study. The bovine tibia samples were supplied wrapped in gauze, individually identified, and suitably preserved (frozen). Specimens were kept at -20°C until approximately 24 hours before preparation. Then they were thawed to room temperature. The proximal tibia was freed from the surrounding soft tissues. A sagittal cut was made in the middle of the tibia such that each tibia would provide 2 bone samples for testing. Each bone sample was large enough to accommodate drilling of a 35-mm tunnel for graft fixation.

The 4 screw types were the BioComposite (Arthrex Inc, Naples, Florida), made of biphasic calcium phosphate/poly-DL-lactic acid; the Milagro (DePuy Mitek Inc, Raynham, Massachusetts), made of β-tricalcium phosphate/poly(lactic-co-glycolic acid); and the Biosteon HA/PLLA (Stryker Corp, Mahwah, New Jersey) and the Biosure HA/PLLA (Smith & Nephew, Memphis, Tennessee), both made of hydroxyapatite/poly-L-lactic acid (**Figure 1**).

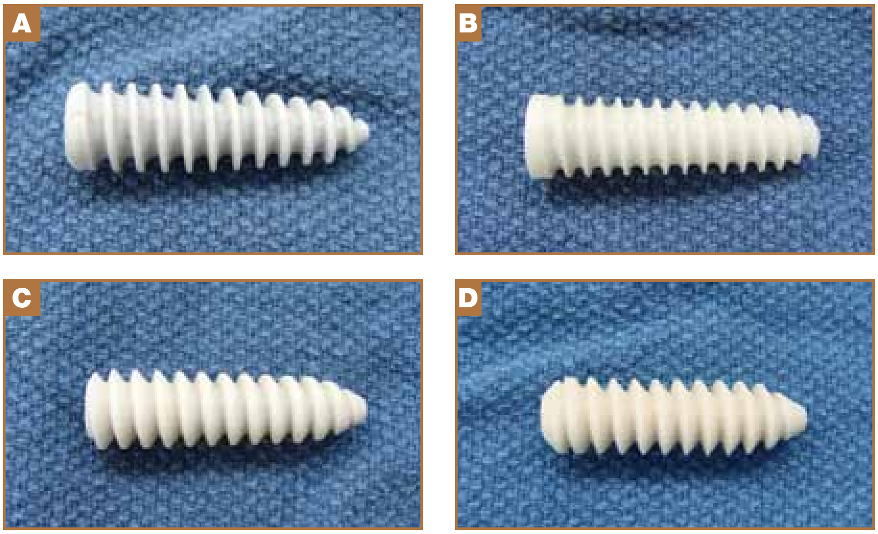


Figure 1. Four types of interference screw: (A) Biosteon (Stryker Corp, Kalamazoo, Michigan), (B) Biosure HA (Smith & Nephew, Memphis, Tennessee), (C) BioComposite (Arthrex Inc, Naples, Florida), (D) Milagro (DePuy Mitek, Raynham, Massachusetts).

All screws were 10 mm in diameter and 35 mm in length. Each of the 4 screw types was tested in 12 bone samples, yielding 48 graft samples for mechanical testing. One screw type was randomly assigned to each bone sample. A soft-tissue graft 9 mm in diameter was created from the porcine flexor digitorum tendon and prepared, as is routine for this procedure.[6] In all cases, 2 strands of tendon were paired and their diameter measured. If needed, another piece was used to augment the sample, producing grafts 9 mm in diameter using a standard ACL graft-sizing block. Both ends of the graft sample were secured with heavy-braided suture in a Krackow stitch. A 7.5-mm extraction drill was used initially to create the bone tunnel in each bone sample (**Figure 2**). For each treatment, the bone tunnel was serially dilated (7.5, 8.0, 9.0 mm) using the dilation system specific to the brand of the interference screw to be inserted into the bone sample. The graft was inserted into the tunnel and the interference screw was placed over a guidewire engaging the middle 35 mm of the graft. The grafts were long enough to allow for 25 to 30 mm of free graft at either end to facilitate later clamping into the testing apparatus. After insertion of the interference screw and graft, the surrounding bone was removed with careful dissection to avoid further damage of the soft-tissue graft. The specimens were kept moist with a wrapping of saline-soaked gauze throughout preparation and testing,

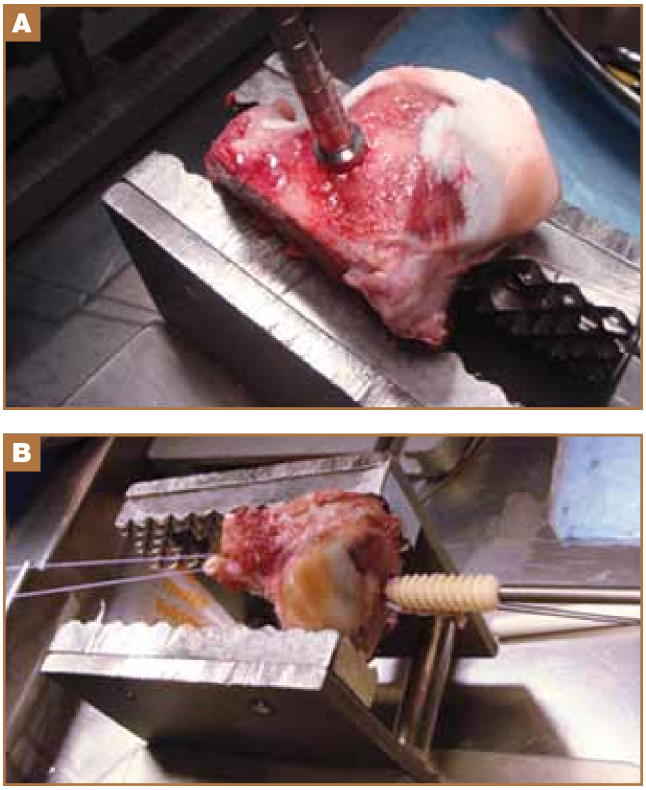


Figure 2. (A) Cut bovine tibia bone sample undergoing serial dilation. (B) Instrumentation of porcine graft (already placed in tunnel) with interference screw in bovine tibia bone sample.

Each tendon was removed from the bone and monotonically loaded in axial tension in an MTS 810 servohydraulic load frame (MTS Systems Corp, Eden Prairie, Minnesota; **Figure 3**). Each graft was secured in a cryoclamp with dry ice, leaving an unsupported gauge length of 35 mm. Proximally, the cryoclamp was mounted on a universal joint and rigidly attached to the load frame. All testing was performed in air. Each tendon was preconditioned for 20 cycles at 5 to 50 N of tension at a test frequency of 1 Hz. After preconditioning, tension was applied at a rate of 200 mm/min to failure.[6] Data were acquired at 100 Hz. Maximum failure load, stiffness, and yield load were recorded. A 1-factor analysis of variance was performed to determine if the treatment groups differed significantly on any of these measures. In all cases, the level of statistical significance was set to .05 a priori. All data are presented as means (SD).

Results

Although gross inspection revealed a screw impression on each graft, there was no macroscopic evidence of laceration. There were no statistically significant differences among treatment groups in yield load (P = .414), stiffness (P = .681), or maximum failure load (P = .353). **Table I** lists the mean (SD) yield loads: 2400 (448) N for Biosteon, 2060 (735) N for Biosure HA, 2354 (401) N for Biocomposite, and 2329 (507) N for Milagro. **Table II** lists the mean (SD) linear stiffness values: 285.2 (59.4) N/mm for Biosteon, 282.2 (144.3) N/mm for Biosure HA, 310.7 (92.2) N/mm for Biocomposite, and 322.3 (59.6) N/mm for Milagro. **Table III** lists the mean maximum failure loads: 2599 (442) N for Biosteon, 2218 (727) N for Biosure HA, 2453 (443) N for Biocomposite, and 2552 (565) N for Milagro.

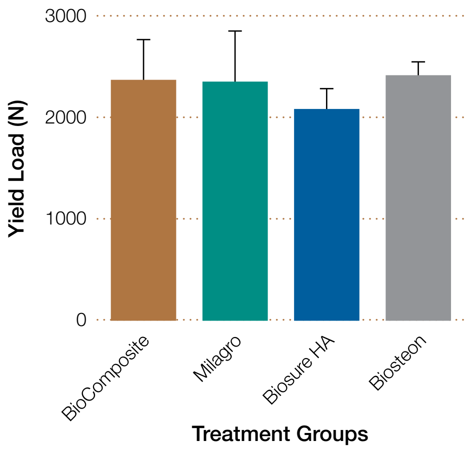
Figure 3. Graft positioned for testing in cryoclamps proximally and distally. Unsupported gauge length (35 mm) used for each sample. Indentations from placement of interference screw are visible on graft.

Discussion

We conducted this study to determine if the mechanical properties of ACL grafts would differ after insertion of a single screw, 1 of 4 different commercially available composite screws. The grafts secured with these 4 screws showed no

Table I. **Yield Loads of Grafts Instrumented With Each of the 4 Interference Screws**

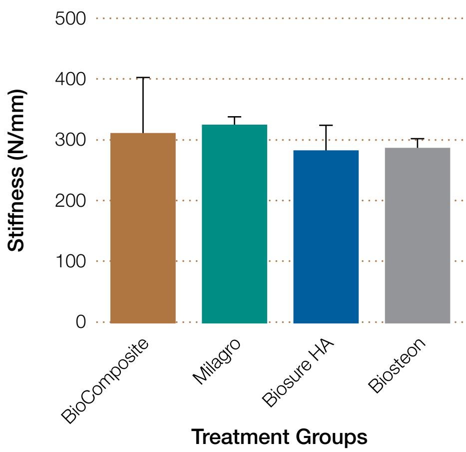
	BioComposite	Milagro	Biosure HA	Biosteon
Mean Yield Load (N)	2354	2329	2060	2400
SD	401.0	506.5	734.5	448.2
Range	1507-2950	1648-3362	1022-3161	1790-3085
95% CI	2099-2608	2007-2650	1594-2527	2115-2685
P	.414	—	—	—
1–β	.049	—	—	—



Abbreviations: SD, standard deviation; CI, confidence interval; HA, hydroxyapatite.
BioComposite (Arthrex Inc), Milagro (DePuy Mitek), Biosure HA (Smith & Nephew, Memphis, Tennessee), Biosteon (Stryker Corp). No. of samples for power 1–β = .8 is 9319.

Table II. **Stiffness of Grafts Instrumented With Each of the 4 Interference Screws**

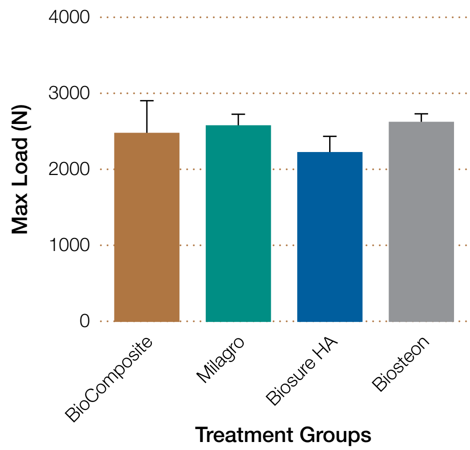
	BioComposite	Milagro	Biosure HA	Biosteon
Mean Stiffness (N/mm)	310.7	322.3	282.2	285.2
SD	29.21	60.62	144.3	59.46
Range	183.2-478.5	186.9-394.6	126.5-613.2	179.6-372.0
95% CI	252.1-369.2	284.4-360.2	190.6-373.9	247.5-322.9
P	.681	—	—	—
1–β	.049	—	—	—



Abbreviations: SD, standard deviation; CI, confidence interval; HA, hydroxyapatite.
BioComposite (Arthrex Inc), Milagro (DePuy Mitek), Biosure HA (Smith & Nephew), Biosteon (Stryker Corp). No. of samples for power 1–β = .8 is 1273.

Table III. **Maximum Failure Loads of Grafts Instrumented With Each of the 4 Interference Screws**

	BioComposite	Milagro	Biosure HA	Biosteon
Mean Maximum Load (N)	2453	2552	2218	2599
SD	443.0	564.7	727.7	442.3
Range	1557-3041	1703-3986	1047-3289	1835-3219
95% CI	2171-2734	2193-2911	1755-2680	2318-2880
P	.353	—	—	—
1–β	.068	—	—	—



Abbreviations: SD, standard deviation; CI, confidence interval; HA, hydroxyapatite.
BioComposite (Arthrex Inc), Milagro (DePuy Mitek), Biosure HA (Smith & Nephew), Biosteon (Stryker Corp). No. of samples for power 1–β = .8 is 2827.

significant differences in mechanical properties, confirming our hypothesis. There were no graft lacerations on macroscopic visualization and no significant differences in yield load, stiffness, or maximum failure load among the grafts instrumented with the 4 screws.

Zantop and colleagues[6] conducted a similar study focused on graft lacerations caused by titanium and bioabsorbable interference screws. The mechanical properties of grafts after insertion of titanium screws were significantly reduced compared with the properties of grafts after insertion of bioabsorbable screws. There were differences among bioabsorbable screws as well—this finding prompted our study. For grafts instrumented with PLDLA-TCP screws, mean (SD) yield load was 714.0 (333) N, mean (SD) stiffness value was 138.35 (54) N/mm, and mean (SD) maximum failure load was 830.04 (333) N. These values were higher than those for grafts instrumented with both titanium screws and PLDLA screws.

The yield loads, maximum failure loads, and stiffness values in our study were higher than those reported by Zantop and colleagues.[6] For the 4 screws in our study, mean yield load was 2285 N (**Table I**), mean stiffness value was 300 N/mm (**Table II**), and mean maximum failure load was 2455 N (**Table III**). There are several possibilities for the differences. The screws used in the studies may have had designs that damaged the grafts to different degrees. In addition, securing the tendons to the testing apparatus is challenging, and any slippage of the graft in the cryoclamp could have affected results. Zantop and colleagues inserted the bare tendon ends into the cryofixation device. In our study, the tendons were whip-stitched with size 2 suture at each end. That suture may have increased fixation in the cryoclamp, and decreased slippage, leading to higher biomechanical property values.

Graft fixation is the weak point in ACL constructs after surgery.[5] Post–ACL-reconstruction rehabilitation protocols focus on immediate full range of motion, return of neuromuscular function, proprioception, and early weight-bearing up the kinetic chain.[5] Graft fixation methods must be able to withstand these rehabilitation principles immediately after surgery. One aspect of the ACL reconstruction construct is the integrity of the graft itself. An interference screw that reduces the mechanical properties of the graft could compromise the integrity of the entire fixation construct. Clinical results have shown no significant differences in the outcomes associated with the bioabsorbable screws and metal screws used in ACL reconstruction.[7] In addition, use of bioabsorbable screws eliminates the need for screw removal, and postoperative imaging can be easier to interpret, both of which make this fixation method appealing.[7] We found that the 4 types of bioabsorbable screws used in our study had similar effects on the mechanical properties of the grafts.

Our study had several limitations. First, the grafts were tested after being removed from the ACL reconstruction model. Results may have been different if the pull-out strength of the intact screw–tendon–bone construct had been measured. Second, this comparative study did not have a control group of grafts that did not undergo screw insertion. Third, we did test bioabsorbable screws at time 0, meaning there was no time for them to go through their natural degradative cycle. However, this should not present a problem, as we wanted to evaluate initial graft laceration, which is not dependent on the degradative properties of the screw. Fourth, using porcine tendon and bovine tibiae to fabricate an ACL reconstruction model could be a limitation. Use of these materials was based on the work of Zantop and colleagues.[6] In addition, bovine tibiae produced adequate results in similar applications,[8-10] and other studies have shown that the material properties of porcine flexor digitorum tendons are similar to those of human hamstring tendon.[11] Fifth, we made some grafts from 2 strands of tendon and others from 3 strands. We thought it was more important to have grafts of uniform size rather than grafts made with the same number of tendons. We used a standard ACL graft-sizing block to ensure uniform size. Sixth, this study used a small number of specimens. Using more would have increased the power of the statistical analysis and possibly shown larger differences among screws.

Our study results suggest that none of the 4 different bioabsorbable composite screws that were tested affect a porcine ACL graft to the extent that there is a measurable significant difference in yield load, stiffness, or maximum failure load.

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