Biomechanical Comparison of Interference Screws and Combination Screw and Sheath Devices for Soft Tissue Anterior Cruciate Ligament Reconstruction on the Tibial Side

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Biomechanical Comparison of Interference Screws and Combination Screw and Sheath Devices for Soft Tissue Anterior Cruciate Ligament Reconstruction on the Tibial Side

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Background: The tibial fixation site has been reported to be the weakest point in anterior cruciate ligament (ACL) reconstructions. Numerous interference screws and combination screw and sheath devices are available for soft tissue fixation, and a biomechanical comparison of these devices is necessary.

Hypothesis: Combination screw and sheath devices would provide superior soft tissue fixation properties compared with interference screws in a porcine model.

Study Design: Controlled laboratory study.

Methods: Eight different intratunnel tibial soft tissue fixation devices were biomechanically tested in a porcine model with bovine tendons, with 10 specimens per group. The soft tissue fixation devices included 3 interference screws—the Bio-Interference Screw, BIOSURE PK, and RCI Screw—and 5 combination screw and sheath devices (combination devices)—the AperFix II, BIOSURE SYNC, ExoShape, GraftBolt, and INTRAFIX. The specimens were subjected to cyclic (1000 cycles, 50-250 N, 0.5 Hz) and pull-to-failure loading (50 mm/min) with a dynamic tensile testing machine. Ultimate failure load (N), cyclic displacement (mm), pull-out stiffness (N/mm), displacement at failure (mm), load at 3 mm displacement (N), and mechanism of failure were recorded.

Results: The ultimate failure loads were highest for the GraftBolt (1136 ± 115.6 N), followed by the INTRAFIX (1127 ± 155.0 N), AperFix II (1122 ± 182.9 N), BIOSURE PK (990.8 ± 182.1 N), Bio-Interference Screw (973.3 ± 95.82 N), BIOSURE SYNC (829.5 ± 172.4 N), RCI Screw (817.7 ± 113.9 N), and ExoShape (814.7 ± 178.8 N). The AperFix II, GraftBolt, and INTRAFIX devices were significantly stronger than the BIOSURE SYNC, RCI Screw, and ExoShape. Although the 3 strongest devices were combination screw and sheath devices, no significant differences were observed between the ultimate failure strengths of the screw and combination devices when compared as groups. The least amount of cyclic displacement after 1000 cycles was observed for the GraftBolt (1.38 ± 0.27 mm), followed by the AperFix II (1.58 ± 0.21 mm), Bio-Interference Screw (1.61 ± 0.22 mm), INTRAFIX (1.63 ± 0.15 mm), ExoShape (1.68 ± 0.30 mm), BIOSURE PK (1.72 ± 0.29 mm), BIOSURE SYNC (1.92 ± 0.59 mm), and RCI Screw (1.97 ± 0.39 mm). The GraftBolt allowed significantly less displacement than did the BIOSURE SYNC and RCI Screw. Similarly, no significant differences were observed between the cyclic displacements of the screws and combination devices when compared as groups.

Conclusion: The combination screw and sheath devices did not provide superior soft tissue fixation properties compared with the interference screws alone in a porcine model. Although the highest ultimate failure loads and least amounts of cyclic displacement were observed for combination devices, group comparisons of screw and combination devices did not result in any significant differences for ultimate failure load and cyclic displacement.

Clinical Relevance: It is important to consider that these results represent device performance in an in vitro animal model and are not directly transferrable to an in vivo clinical situation. The combination of a sheath and screw did not consistently result in improved fixation characteristics compared with interference screw fixation.

Keywords: anterior cruciate ligament; ACL reconstruction; soft tissue graft; tibial fixation; hamstring graft; interference screw; sheath; intratunnel fixation; graft fixation; biomechanical testing

The tibial graft fixation site has been reported to be the weakest point in anterior cruciate ligament (ACL) reconstructions.[17,26] This has been reported to be due to the lower bone mineral density (BMD) of the proximal tibia compared with the distal femur and the angle at which the forces are applied to the graft on the tibial side.[2] In knee extension, the force vector of the ACL is in line with the tibial tunnel, which places maximal forces on the tibial graft fixation.[2] In addition, the healing process of tendon

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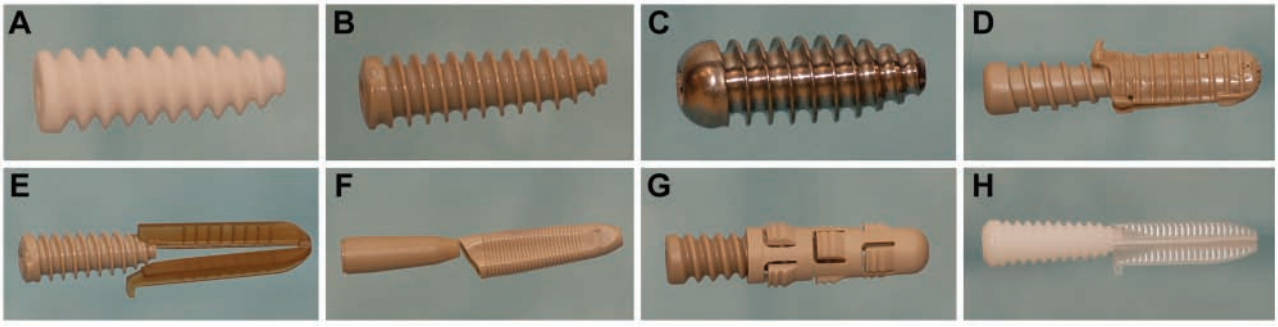

Figure 1. Soft tissue tibial fixation devices: (A) Bio-Interference Screw, (B) BIOSURE PK, (C) RCI Screw, (D) AperFix II, (E) BIOSURE SYNC, (F) ExoShape, (G) GraftBolt, and (H) INTRAFIX.

to bone in soft tissue graft fixation is slower than direct bone-to-bone healing, which can result in an increase in the potential for graft slippage.[9,34] The intratunnel fixation has been shown to be more anatomically and biomechanically similar to the native ACL,[17] although some studies have reported inferior biomechanical properties by this fixation method.[2,18,34] The stiffness of the graft has been reported to be higher with intratunnel fixation,[26] but the fixation technique is highly dependent on the BMD.[18] Concerns regarding the biomechanical properties of soft tissue graft fixation have resulted in the recommendation of maintaining a conservative rehabilitation protocol in the early postoperative period.[13]

Although numerous soft tissue tibial tunnel fixation devices exist, few studies have compared their biomechanical properties. Current research lacks a thorough analysis and comparison of interference screws and combination screw and sheath devices. The purpose of this study was to biomechanically compare 3 interference screws and 5 combination screw and sheath devices for intratunnel tibial soft tissue fixation in response to cyclic and pull-to-failure loading at time zero. We hypothesized that the combination screw and sheath devices would provide superior soft tissue fixation properties compared with the interference screws in a porcine model.

MATERIALS AND METHODS

Eight soft tissue tibial tunnel fixation devices were biomechanically evaluated in response to cyclic and pull-to-failure loading. Selected devices for testing included 3 interference screws—the Bio-Interference Screw (Arthrex Inc, Naples, Florida), BIOSURE PK (Smith & Nephew Inc, Andover, Massachusetts), and the RCI Screw (Smith & Nephew)—and 5 combination screw and sheath devices (combination devices)—the AperFix II (Cayenne Medical Inc, Scottsdale, Arizona), BIOSURE SYNC (Smith & Nephew), ExoShape (MedShape Inc, Atlanta, Georgia), GraftBolt (Arthrex), and INTRAFIX (DePuy Mitek Inc, Raynham, Massachusetts) (Figure 1).

Specimen Preparation

Testing was performed in 80 fresh-frozen porcine tibias with 80 bovine extensor tendons (Innovative Medical Device Solutions, Logan, Utah). Bovine digital extensor tendons have been reported to have similar viscoelastic, structural, and material properties to human hamstring tendons.[7] Specimens were stored at –20°C and thawed at room temperature before insertion of the devices and biomechanical testing. The specimens were randomly divided into 8 groups, with 10 specimens per group. The porcine model was used because previous studies have reported similar biomechanical properties to that of the young adult human knee.[20,25,33] The tibia diaphysis was cut 14 cm distal to the joint line, and 3 screws were inserted orthogonally into the distal tibia before potting to ensure rigid fixation. The distal end of the tibia was potted in line with the tibial axis in a custom-made cylinder with polymethylmethacrylate (Fricke Dental International Inc, Streamwood, Illinois), 3 cm distal to the predetermined exit of the tibial tunnel.

On the day of preparation, grafts were thawed for 2 hours before device insertion. Each tendon was shortened to a length of 200 mm, and 50 mm of each end was split to create an intratunnel 4-stranded graft similar to human

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TABLE 1
Corresponding Device, Material, and Tunnel Sizes for Use With a 9-mm Graft[a]

Device	Screw Length, mm	Diameter, mm	Tunnel Diameter, mm	Material
Bio-Interference Screw[b]	28.0	9.0	9.0	PLDLA
BIOSURE PK[b]	30.0	9.0	9.0	PEEK
RCI Screw[b]	25.0	9.0	9.0	Titanium
AperFix II[c]	30.0	11.0	10.0	PEEK
BIOSURE SYNC[c]	32.5	11.0	9.0	PEEK
ExoShape[c]	30.0	9.0	9.0	PEEK
GraftBolt[c]	30.0	10.0	9.0	PEEK
INTRAFIX[c]	30.0	10.5	9.0	polyethylene (sheath) and acetal (screw)

[a]PEEK, polyetheretherketone; PLDLA, bioabsorbable poly-LD-lactic acid.
[b]Screw device.
[c]Combination device (screw and sheath).

hamstring tendons. The grafts were doubled over and adjusted to 9 mm in diameter with a graft sizing block. Those that were smaller than 9 mm were excluded, and those that were larger than 9 mm were trimmed in line with the fiber orientation. Thirty millimeters of all 4 strands were whip-stitched with nonabsorbable polybraided propylene suture (Fiberloop No. 2; Arthrex).[5] The grafts were wrapped in 0.9% saline-soaked gauze until use.

Device Insertion Techniques

All devices were inserted by a single surgeon according to the manufacturers' specifications with their recommended instruments. The device dimensions, material, and their corresponding tunnel sizes are listed in Table 1. An industry representative was present for pilot testing only for each device to ensure the correct manufacturer's insertion technique. Tibial tunnels were prepared using a tibia drill guide set at a 45° angle. The guide pin was advanced from the anteromedial proximal tibia through the footprint of the native ACL. The tunnel length was confirmed to be 40 mm with a depth gauge. All tibial tunnels were reamed to a diameter of 9 mm unless the manufacturer's recommendation was otherwise. The graft was manually pulled through the tibial tunnel from distal to proximal until approximately 50 mm of the graft had advanced through the proximal aperture. Proximally, the graft was looped over a rigid dowel, to simulate femoral fixation, while insertion of the respective devices in the tibial tunnel was performed. During the entirety of the procedure, 60 N of tension was applied to the graft distally and in line with the tunnel, as measured by a force gauge. All excess graft material and sutures were excised before testing.

AperFix II. In accordance with the manufacturer, a 10-mm diameter tibial tunnel was reamed for the 9-mm graft. The grafts were spread, and the sutures were fixed to a tendon expander. A guide wire was placed concentric between the grafts, and a 10-mm sheath implant was inserted over the guide wire. The sheath's tab was set at the 12-o'clock position. Then, the screw was inserted over the guide wire and flush with the cortical bone while the tab remained secured outside the cortex.

Bio-Interference Screw. A 1.1-mm diameter guide wire was placed in the tibial tunnel concentric between the grafts, and a 9-mm screw was inserted over the guide wire until it was flush with the cortical bone.

BIOSURE PK. A 1.2-mm diameter guide wire was placed concentric and a 9-mm screw was inserted over the guide wire until it was flush with the cortical bone.

BIOSURE SYNC. A 9- to 10-mm dilator was inserted into the distal 35 mm of the tibial tunnel with a mallet. The guide wire was placed concentric between the grafts. Then, a 9- to 10-mm sheath and a 9-mm screw were inserted over the guide wire, and the sheath's tab was positioned at the 12-o'clock position. The screw was inserted flush with the cortical bone, and the tab was removed.

ExoShape. A guide wire was inserted concentric between the grafts, and the tunnel diameter was dilated sequentially from 7 to 9 mm. The sheath was inserted over the guide wire into the tunnel, and the tibial insert was introduced into the sheath. All devices were inserted flush to the cortical bone.

GraftBolt. A 1.1-mm diameter guide wire was placed concentric between the grafts, and the 6-mm dilator was inserted over the wire. The tunnel diameter was dilated sequentially from 6 to 9 mm in diameter. Then, the 9-mm combined sheath and screw device was inserted until the screw was flush with the cortical bone.

INTRAFIX. First, a dilator was used to adjust the tunnel, and then a guide wire, with concentric placement between the grafts, was used to guide an 8- to 10-mm sheath and an 8- to 10-mm screw into the tibial tunnel. The sheath's tab was orientated to the 12-o'clock position. The screw was inserted flush with the cortical bone.

RCI Screw. A 2.1-mm diameter guide wire was placed concentric between the grafts. The 9-mm screw was inserted over the guide wire until it was flush with the cortical bone.

Biomechanical Testing

Screws and combination devices were evaluated in response to cyclic and pull-to-failure loading with a dynamic tensile testing system (Instron ElectroPuls

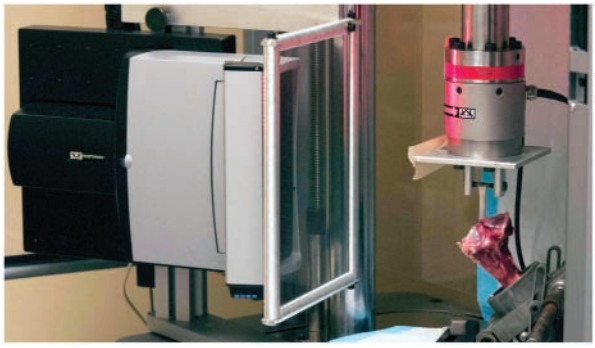

Figure 2. Biomechanical test setup with the advanced video extensometer (left) and customized alignment fixture (bottom right), which allowed for the force vector to be applied in line with the tibial tunnel.

E10000; Instron Systems, Norwood, Massachusetts). The proximal 50-mm portion of the graft was looped over a 4.5-mm diameter stainless steel pin and rigidly fixed to the actuator, while the tibia was secured to the base plate of the test frame with a custom jig (Figure 2).[33] The jig was adjusted and positioned so that the tensile force applied to the tendon was in line with the tibial tunnel to mimic the worst-case scenario for both pullout and displacement. Tracking markers were placed on the tibial plateau, at a distance representative of the inserted device's end point within the tibial tunnel, and at the center of the pin pulling the graft on the actuator. An advanced video extensometer (Instron Systems) tracked the markers and recorded tendon extension relative to the proximal surface of the device, independent of any bone deflection.

Test parameters for the cyclic and pull-to-failure testing protocol were selected after a literature search and synthesis of common parameters from the various protocols. As a result, the graft was first preloaded in tension from 10 to 50 N at 0.1 Hz for 10 cycles, then loaded between 50 and 250 N for 1000 cycles at a frequency of 0.5 Hz.[3,22,23,33] This simulated the reported forces in the ACL during passive extension while walking and the early rehabilitation protocol of flexion-extension loading on the reconstructed graft.[19] After the cyclic loading protocol, grafts were further displaced at 50 mm/min until failure[16] to simulate a sudden overload event at the knee. Cyclic loading data were recorded by the Instron WaveMatrix software, and load-to-failure data were recorded by the Instron Bluehill 2 software (Instron Systems). Biomechanical measurements, including ultimate failure load (N), pull-out displacement (mm), load at 3-mm displacement (N), energy at failure (J), pull-out stiffness (N/mm), and cyclic displacement (mm), were measured and recorded. Pull-to-failure displacement was measured as the total elongation at ultimate failure and accounted for tendon elongation, graft slippage or tearing, and device pullout. The cyclic displacement was determined as the displacement from the initial 50 N ramp-up position after the preconditioning cycles to the final position at 50 N after the thousandth cycle. Stiffness was calculated from the same linear portion of the load-elongation curves from the pull-to-failure raw data. The mechanism of failure (graft slippage, graft tear, device pullout, etc) was observed and recorded.[31,33]

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics, version 20 (SPSS Inc, Chicago, Illinois). The biomechanical results were analyzed using 1-way analyses of variance, and post hoc Tukey tests were performed to determine if there was a difference among the fixation devices and the group comparisons between screws and combination devices for each of the measured quantities of interest. P values less than .05 were deemed statistically significant. The observed effect sizes (f) for overall comparison of the 8 devices with respect to ultimate failure load and cyclic displacement were 8.67 and 3.33, respectively. Both values are much larger than the threshold for a "large" effect size defined by Cohen in 1988,[6] leading us to conclude that our sample size was sufficient to provide very high statistical power for the overall comparison tests we performed.

RESULTS

Test results from the pull-to-failure loading and cyclic loading are reported in Table 2 (mean ± standard deviation), and P values for device comparisons are reported in Table 3.

Pull-to-Failure Loading

Average ultimate failure loads for the AperFix II, GraftBolt, and INTRAFIX were significantly higher than loads for the BIOSURE SYNC, RCI Screw, and ExoShape ($P < .05$). No significant differences in ultimate failure load were found when comparing the screw group and combination group. In addition, there were no significant differences among the devices for pull-out displacement, load at 3 mm of displacement, energy at failure, or pull-out stiffness. The recorded failure modes were classified as slippage, tear at the tendon-screw interface, or pullout of the screw. There were no differences between the devices in their mode of failure. All the devices failed at the tibial fixation site.

Cyclic Loading

All specimens survived preloading and cyclic testing. The GraftBolt displaced significantly less than the RCI Screw and BIOSURE SYNC after 1000 cycles ($P < .05$). All devices displaced less than 2 mm. No significant differences in cyclic displacement were observed when comparing the screw group and combination group.

DISCUSSION

The results of the current study did not support our hypothesis that combination screw and sheath devices would provide superior soft tissue fixation properties compared with

TABLE 2
Biomechanical Properties of Tibial Soft Tissue Fixation Devices[a]

Device	Cyclic Displacement, mm	Ultimate Failure, N	Displacement at Failure, mm	Load at 3-mm Displacement, mm	Pull-Out Stiffness, N/mm	Energy at Ultimate Failure, J
Bio-Interference Screw[b]	1.61 ± 0.22	973.3 ± 95.82	5.31 ± 0.51	703.8 ± 74.50	343.0 ± 46.43	2.92 ± 0.51
BIOSURE PK[b]	1.72 ± 0.29	990.8 ± 182.1	5.65 ± 1.35	721.2 ± 92.45	352.3 ± 42.73	3.45 ± 1.40
RCI Screw[b]	1.97 ± 0.39	817.7 ± 114.0	4.80 ± 2.07	676.3 ± 157.2	384.3 ± 105.2	4.80 ± 2.07
AperFix II[c]	1.58 ± 0.21	1122 ± 182.9	5.43 ± 1.54	782.8 ± 171.0	366.4 ± 40.76	3.66 ± 1.05
BIOSURE SYNC[c]	1.92 ± 0.59	829.5 ± 172.4	6.54 ± 2.90	632.0 ± 154.9	326.9 ± 74.51	6.54 ± 2.90
ExoShape[c]	1.68 ± 0.30	814.7 ± 178.8	5.27 ± 1.25	663.8 ± 125.5	342.3 ± 51.47	2.80 ± 1.10
GraftBolt[c]	1.38 ± 0.27	1136 ± 115.6	5.98 ± 1.47	767.6 ± 146.0	402.3 ± 58.89	4.00 ± 1.47
INTRAFIX[c]	1.63 ± 0.15	1127 ± 155.0	6.43 ± 1.24	709.9 ± 118.4	372.5 ± 50.02	4.38 ± 1.64

[a]Data are shown as means ± standard deviations.
[b]Screw device.
[c]Combination device (screw and sheath).

the interference screws in a porcine model. The 3 devices with the highest ultimate failure loads were the AperFix II, GraftBolt, and INTRAFIX, all of which were combination devices. However, the lowest and third lowest ultimate failure loads were observed for the ExoShape and BIOSURE SYNC, both combination devices. The cyclic displacement results were more dispersed when comparing the combination devices and interference screws, with mixed results for both types of devices. Comparing the screw and combination device groups, we could not definitively conclude any significant difference between the biomechanical properties of these devices.

There are multiple factors reported to improve tibial intratunnel biomechanical fixation: ensuring tunnel diameter is within 0.5 mm of the graft size,[29] increasing screw length,[14,27,34,35] using a screw diameter sized according to the tunnel size,[14,34,35] and concentric placement of the screw in the tunnel.[28] Combination devices, which incorporate an interference screw with a sheath, attempt at improving fixation characteristics by increasing radial force and compression on the graft against the tunnel wall.[30,31] The purpose of the sheath is to reportedly separate the grafts, secure concentric placement of the screw, and provide homogeneous friction between the tendon and bone.[30]

Devices were inserted according to the manufacturers' recommendations, and some differences in insertion techniques were observed between devices. Some insertion techniques have incorporated additional tunnel dilations, in addition to simple tunnel reaming, in an effort to create impaction of the surrounding cancellous bone, increase tunnel wall bone volume, and subsequently increase fixation strength.[8] Serial dilation up to the desired tunnel diameter can have different effects on the bone surrounding the tunnel than simply reaming the desired diameter. Contrary to cortical bone, the cancellous bone that surrounds the tunnel is less dense and contains a structural framework that can be compressed. Dunkin et al[8] reported that performing a serial dilation up to the desired tunnel diameter results in increased bone volume when compared with extraction drilling. This implies that the device can obtain a more rigid fixation within the reconstruction tunnel wall and possibly influence soft tissue fixation strength; however, studies have demonstrated conflicting results. Dunkin et al[8] reported that serial dilation in porcine tibias did not significantly improve biomechanical fixation properties. Rittmeister et al[24] reported similar findings using cadaveric human tibias. However, 2 studies using cadaveric human and animal specimens have reported some beneficial effects of dilation on fixation properties.[4,10] Dunkin et al[8] have reported that dilation has less effect in bone with high BMD, which may explain why a beneficial effect was observed in studies such as Cain et al,[4] which used human cadaver specimens much older than the typical population that receives an ACL reconstruction.[4,8] Four of the tested devices in this study used tunnel dilation at the time of insertion. To maintain the integrity of the intended insertion of each device, standardization of the insertion techniques was deemed to be outside the scope for this study. This decision was supported by the lack of a clear distinction of whether serial dilation could definitively improve fixation strength for all devices. Devices were inserted according to the manufacturers' recommended technique for optimal fixation with that device. Although the reported effects of tunnel dilation on fixation strength are mixed, in the present study, we did not observe any correlation between dilation of tunnel diameter and improved fixation properties. Screw diameter has been reported to significantly influence fixation strength.[34,35] Four of the tested devices had larger diameters than the corresponding bone tunnels. Consistent with the results reported by Weiler et al,[34] 3 of these devices—the AperFix II, GraftBolt, and INTRAFIX—produced the highest ultimate failure loads observed in this study. In addition, we did not observe any correlation between the material of the device and its biomechanical properties, which is supported by similar results that have been reported in the literature.[15]

Within the past decade, multiple studies have performed biomechanical comparisons of specific interference screws and combination screw and sheath devices. The present study was the first to evaluate more than one combination device. In 2003, a study by Kousa et al[16] compared the biomechanical properties between 3 interference screws, a combination screw and sheath device, and 2

TABLE 3
P Values of Device Comparisons for Ultimate Failure Load and Cyclic Displacement[a]

Ultimate Failure Load

	Bio-Interference Screw[b]	BIOSURE PK[b]	RCI Screw[b]	AperFix II[c]	BIOSURE SYNC[c]	ExoShape[c]	GraftBolt[c]	INTRAFIX[c]
Bio-Interference Screw[b]	—	1.000	.324	.379	.426	.300	.272	.339
BIOSURE PK[b]	1.000	—	.201	.543	.280	.184	.416	.497
RCI Screw[b]	.324	.201	—	**.001**	1.000	1.000	**<.001**	**.001**
AperFix II[c]	.379	.543	**.001**	—	**.001**	**.001**	1.000	1.000
BIOSURE SYNC[c]	.426	.280	1.000	**.001**	—	1.000	.001	**.001**
ExoShape[c]	.300	.184	1.000	**.001**	1.000	—	**<.001**	**.001**
GraftBolt[c]	.272	.416	**<.001**	1.000	**.001**	**<.001**	—	1.000
INTRAFIX[c]	.339	.497	**.001**	1.000	**.001**	**.001**	1.000	—

Cyclic Displacement

	Bio-Interference Screw[b]	BIOSURE PK[b]	RCI Screw[b]	AperFix II[c]	BIOSURE SYNC[c]	ExoShape[c]	GraftBolt[c]	INTRAFIX[c]
Bio-Interference Screw[b]	—	.995	.235	1.000	.411	1.000	.772	1.000
BIOSURE PK[b]	.995	—	.690	.974	.868	1.000	.302	.999
RCI[b]	.235	.690	—	.144	1.000	.484	**.004**	.309
AperFix II[c]	1.000	.974	.144	—	.277	.997	.887	1.000
BIOSURE SYNC[c]	.411	.868	1.000	.277	—	.699	**.010**	.507
ExoShape[c]	1.000	1.000	.484	.997	.699	—	.489	1.000
GraftBolt[c]	.772	.302	**.004**	.887	**.010**	.489	—	.682
INTRAFIX[c]	1.000	.999	.309	1.000	.507	1.000	.682	—

[a] *P* values $\leq$.05 were considered significant and are in bolded text.
[b] Screw device.
[c] Combination device (screw and sheath).

extracortical devices, using pull-to-failure and cyclic loading in porcine tibias with human hamstring tendon grafts. This study reported that the combination device (INTRAFIX) provided significantly higher ultimate failure strength and lower displacement compared with the other devices. The reported ultimate failure load and displacement for the INTRAFIX device were comparable with our results. Halewood et al[11] compared the soft tissue fixation properties on the tibial side of the EZ KneeSpan (EZ Orthopedics Ltd) with those of a titanium interference screw in human cadaver specimens with bovine digital extensor tendon grafts. The EZ KneeSpan reportedly resulted in significantly less graft slippage but did not significantly improve ultimate failure strength on the tibial side when compared with interference screw fixation. The reported ultimate failure strength of the titanium screw was approximately 70% of the ultimate failure strength reported for the RCI Screw in the present study. However, the age of the cadaver specimens used by Halewood et al[11] ranged from 62 to 71 years. The lower BMD associated with older cadaver specimens and higher BMD associated with young porcine specimens may elucidate the differences in results. Device design, loading rate, and device, graft, and tunnel diameters are additional factors to consider. In 2009, Walsh et al[33] biomechanically compared a retrograde bioabsorbable screw, suture button suspension apparatus, and a combination of the 2 devices in porcine tibias with bovine digital extensor tendons. Reported ultimate failure loads for the retrograde screw and combined retrograde screw and suture button were similar to the results observed for the tested devices in the present study. However, the present study focused on antegrade fixation and did not specifically test a retrograde screw. Caborn et al[3] performed a biomechanical comparison of the INTRAFIX device and a bioabsorbable interference screw in human cadaver tibias and human hamstring tendon grafts. The INTRAFIX was reported to fail on average at 796 N, which was about 30% less than what was observed in the present study. Caborn et al[3] performed testing in human cadaver tibias with a reported average BMD of 0.74 g/cm^3, which is much less than what has been reported for young human bone (1.30 g/cm^3).[20] Differences in results may be explained by our use of porcine bone in the present study, which reportedly has similar BMD to young human bone,[33] and the use of human bone by Caborn et al[3] with BMD not representative of the young population, which typically would receive this procedure clinically.

One of the strengths and innovative qualities of this study was the use of an advanced video extensometer (AVE) to record displacement during cyclic and pull-to-failure testing. We believe that this improves upon previous studies that relied on actuator positions to report displacement. With the nature of the construct, the tibia diaphysis adds an elastic deflection between the potting and the device insertion when the load is applied at an angle relative to the axis of the tibia. Displacements

recorded by the actuator include displacements of the fixture, bone, and tendon. Even though all the tibias were cut to a similar length, differences in the inherent properties of each specimen could influence the amount of displacement recorded by the actuator. Use of the AVE allowed for isolated displacement of the tendon to be recorded, independent of bone deflection and fixture slippage. This might explain our smaller displacement values compared with previous studies.[16,33]

We do acknowledge the presence of limitations within our study design. The results achieved through an in vitro biomechanical study in an animal model cannot be transferred to a clinical setting. From previous research, it is known that the porcine model has a higher BMD in the proximal tibia compared with human cadavers.[1,2,21] All tested devices are dependent on dense bone stock, and the pull-out strength and stiffness could be overestimated compared with an in vivo model.[1,18,21] Although the findings of Bailey et al,[1] Magen et al,[18] and Nurmi et al[21] suggest that porcine models should not be used for the evaluation of tibial interference fixation devices, there are also findings that promote their use. Previous studies have reported that the mean BMD in young porcine bone (24 months) is 1.42 g/cm,[2,33] which is similar to the average BMD of young humans aged 20 to 29 years (1.30 $\pm$ 0.11 g/cm^2).[20] Since the mean age of a patient undergoing ACL reconstruction has been reported to be about 26 years,[12] young porcine bone can serve as an acceptable substitute. In addition, obtaining cadaveric specimens within this age range is often not possible, forcing studies to use older specimens with lower BMD, which may underestimate the fixation strength of the devices.[3,11,32] In studies testing a limited number of specimens, dual x-ray absorptiometry (DEXA) scans can be useful for equally dividing high BMD specimens between groups and preventing biased outcomes.[33] Although the BMD of the tested specimens in our study was unknown, the inclusion of a high number of specimens (n = 10) compared with previous studies, as well as the random distribution of specimens between groups, helped to prevent disproportional bone quality between groups.[3,8,23,31,33,35] Last, as is the case with any study performed in an in vitro biomechanical model, the in vivo biologic aspects for healing were not present, and the results were predictive of time zero fixation.

CONCLUSION

The combination screw and sheath devices did not provide superior soft tissue fixation properties compared with the interference screws alone in a porcine model. Although the highest ultimate failure loads and least amounts of cyclic displacement were observed for combination devices, some of the combination devices provided inferior fixation properties compared with interference screw fixation. Group comparisons of screw and combination devices did not show any significant differences. The combination of a screw and sheath did not consistently result in improved fixation characteristics compared with interference screw fixation. Although use of a porcine model had anatomic, biologic, and clinical limitations, this study used a consistent and reproducible biomechanical model to compare the fixation characteristic of these devices and appropriately investigated the hypothesis of the study.

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