Stacked Biocomposite Screws in a Single-Stage Revision Anterior Cruciate Ligament Reconstruction Has Acceptable Fixation Strength in a Porcine Cadaveric Model

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Background: Stacked screws is a commonly used technique in single-stage revision anterior cruciate ligament (ACL) reconstruction in the setting of bone loss, but there are limited data to support its use.

Hypothesis: Two configurations of a biocomposite stacked screws construct have similar fixation strength and linear stiffness as a primary ACL reconstruction construct in a biomechanical model.

Study Design: Controlled laboratory study.

Methods: A total of 30 porcine legs were divided into 3 groups. Group 1 underwent primary ACL reconstruction with a patellar tendon graft fixed into the femur, with an 8-mm biocomposite interference screw of beta-tricalcium phosphate and poly lactide-co-glycolide. For a revision ACL reconstruction model, groups 2 and 3 had bone tunnels created and subsequently filled with 12-mm biocomposite screws. New bone tunnels were drilled through the filler screw and the surrounding bone, and the patellar bone plug was inserted. Group 2 was fixed with 8-mm biocomposite screws on the side of the graft opposite the filler screw, while group 3 had the interference screw interposed between the graft and the filler screw. The construct was loaded at 1.5 mm/s in line with the tunnel until failure. Load to failure, linear stiffness, and mode of failure were recorded.

Results: The mean pullout strength for groups 1, 2, and 3 was 626 ± 145 N, 653 ± 152 N, and 720 ± 125 N, respectively (P = .328). The mean linear stiffness of the construct in groups 1, 2, and 3 was 71.4 ± 9.9 N/mm, 84.1 ± 11.1 N/mm, and 82.0 ± 10.8 N/mm, respectively. Group 2 was significantly stiffer than group 1 (P = .037).

Conclusion: Two configurations of a biocomposite stacked screws construct for a single-stage revision ACL reconstruction in the setting of bone loss show a similar fixation strength and linear stiffness to a primary ACL reconstruction at time zero in a porcine model.

Clinical Relevance: In the setting of bone loss from tunnel malpositioning, a single-stage revision ACL reconstruction using a stacked screws construct may provide adequate fixation strength and linear stiffness.

Keywords: anterior cruciate ligament reconstruction; revision; bone loss; tunnel malposition; biomechanics; stacked screws

Anterior cruciate ligament (ACL) reconstruction is increasingly common, with over 100,000 reconstructions performed annually in the United States.[13,24] The failure rate of ACL reconstruction ranges between 5% and 25%, with revisions becoming increasingly common in parallel with the rise in primary reconstructions.[9]

Failure of primary ACL reconstruction is multifactorial.[9] Malpositioned femoral tunnels have been shown to be the most common cause of failure.[7,27] Tunnel widening can occur independently or in conjunction with other causes of failure, and it is a frequent finding after ACL reconstruction.[21] Both increase the complexity of a revision procedure, compromise proper positioning of tibial and femoral tunnels, and may decrease fixation strength.[3]

Bone loss is a particularly challenging problem in the revision setting. Optimal treatment of malpositioned and/or widened tunnels that overlap with new tunnel placement remains controversial.[21] Some authors recommend a 2-stage procedure, beginning with bone grafting, in the setting of clinically important tunnel widening[9] or over 16 mm of tunnel expansion.[17] The major concerns with 2-stage reconstruction are the added morbidity, prolonged rehabilitation, and cost of 2 procedures.[17] Multiple techniques for a single-stage revision reconstruction in the setting of bone loss have been described, including filling

The American Journal of Sports Medicine
2021;49(8):2144–2149
DOI: 10.1177/03635465211015192

tunnels with an allograft or bone cement, or employing an over-the-top construct.[4,6,8,28,29] These have varying levels of cost and complexity.

Stacked screws is one of the simplest techniques for a single-stage revision reconstruction. This construct involves removal of the old screw, placement of a bioabsorbable screw to fill the void of the previous tunnel, drilling through bone and this filler screw, and inserting the graft alongside a second interference screw in the new tunnel. It was originally described using a metal interference screw for final graft fixation.[14] Bioabsorbable screws have predominantly replaced metal screws for interference fixation in ACL surgery, given the benefits of osteointegration, less graft damage on insertion, and less interference with magnetic resonance imaging or future surgery.[16] In the senior author's practice (T.G.), revision ACL surgery has been performed almost exclusively as a single-stage procedure with a stacked screws configuration.

Very few studies have validated this method despite its common use. Previous studies evaluated earlier generation bioabsorbable screws, tibial fixation only, and only a single graft-screw configuration.[3,25] The strength of newer generation biocomposite stacked screws in the femur, where most osteolysis occurs, is unknown.[20] An optimal or acceptable screw-graft configuration is also unclear.

The purpose of this study was to evaluate the fixation strength of a stacked biocomposite screws construct in a single-stage revision ACL reconstruction in the setting of bone loss. Our hypotheses were that there would be no difference in load to failure between stacked biocomposite screws and primary ACL reconstruction, and there would be no difference in load to failure between the 2 different stacked screws configurations.

METHODS

This was a controlled laboratory study. No institutional review board approval was required at our institution. A total of 30 young adult porcine lower extremities were used. The study was divided into a control group and 2 experimental groups, each with 10 knees. Group 1 underwent a primary ACL reconstruction with a patellar tendon graft. Groups 2 and 3 were 2 separate configurations of stacked screws constructs in a revision ACL reconstruction. Group 2 had an interference screw on the side of the graft opposite the filler screw, while group 3 had the interference screw interposed between the graft and filler screw (Figure 1).

Specimen Preparation

Porcine legs were harvested within 24 hours of sacrificing the donor swine. The legs were harvested with the skin and the surrounding soft tissue envelope in place to eliminate the risk of bone and tendon damage. The legs were stored fresh frozen at a temperature of -20°C in sealed plastic bags. The legs were thawed at room temperature overnight before the experiment.

The specimens were prepared within 24 hours of testing to minimize the risk of graft damage and desiccation and to ensure uniformity. All specimens were prepared by the same board-certified orthopaedic surgeon (H.B.). Two types of screws were used: 8 × 23–mm biocomposite fixation screws and 12 × 30–mm biocomposite filler screws, both made from beta-tricalcium phosphate (ß-TCP) and poly lactide-co-glycolide (PLGA) (MILAGRO; DePuy Mitek).

All soft tissues surrounding the femur, the tibia, and the patella were removed except for the patellar tendon. The femur was isolated from the patella and the tibia by cutting the muscles, menisci, and collateral and cruciate ligaments. The patella–patellar tendon–tibia construct was harvested while the tendon remained attached to both the patella and the tibia. The patella was then cut with an oscillating saw to create a 35–mm long triangular patellar bone plug. The central 10 mm of the tendon was cut down to the tibia to create the ACL graft. The tendon was left attached to the tibia. The bone plug was trimmed to pass through a 10-mm sizer. A hole was drilled in the bone plug for attachment of a No. 2 Ethibond suture (Ethicon, Johnson and Johnson). After specimen preparation, the tendon was preserved and kept moist with saline during the procedure.

In group 1, a 10-mm tunnel was drilled with a core reamer to a depth of 35 mm into the femoral condyle. The 10-mm bone plug was pulled into the tunnel, and an 8-mm screw provided final fixation. In groups 2 and 3, a 10-mm tunnel was drilled, followed by placement of

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Submitted May 30, 2020; accepted January 28, 2021.

One or more of the authors has declared the following potential conflict of interest or source of funding: This study was aided by a donation of interference screws from DePuy Orthopaedics, Inc. This entity was not involved in the conduct of the research, analysis, or interpretation of the data or in writing the manuscript. H.B. has received speaking and hospitality fees from Arthrex; and consulting fees from Linvatec Corporation. M.J.S. has received education support from Arthrex; and hospitality payments from Smith & Nephew. T.J.G. has received consulting fees from Medical Business Devices, Olympus America, and DePuy Orthopaedics; speaking fees from DePuy Mitek and Linvatec Corporation; education support from Arthrex; and hospitality payments from Stryker Corporation, Vericel Corporation, Kairos Surgical, and Olympus Corporation. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.

Figure 1. Study groups. The rectangle is a patellar graft. The small donut is an 8 x 23–mm biocomposite interference screw. The large donut is a 12 x 30–mm biocomposite filler screw. Group 1: control group simulating primary ACL reconstruction. Graft with an adjacent interference screw. Group 2: simulating revision ACL reconstruction. Graft interposed between an interference screw and a filler screw. Group 3: simulating revision ACL reconstruction. Interference screw interposed between the graft and the filler screw. ACL, anterior cruciate ligament.

a 12-mm biocomposite filler screw to simulate filling of the primary ACL tunnel. A 10-mm tunnel was chosen, given that this is often the size of the previous tunnel to be grafted. The screw was oversized by 2 mm to maximally compress the surrounding bone. A guidewire was placed just off the margin of the filler screw, and around this a second 10-mm tunnel (revision tunnel) was drilled for placement of the patellar bone plug and the interference screw. This led to removal of roughly 25% of the 12-mm filler screw. For group 2, the bone plug was interposed between the 12-mm filler screw and a newly placed 8-mm interference screw. For group 3, the interference screw was placed between the filler screw and the bone plug (Figure 1). All screws were placed parallel to the tunnels.

Robotic Testing

After preparation, the femur and the tibia were cut 15 cm from the joint line, potted in polymethyl methacrylate cement, and mounted to the robot (Figure 2). The robotic testing system consisted of a 6 degrees of freedom (DOF) manipulator (Kawasaki UZ150; Kawasaki Heavy Industry), with a 6 DOF force sensor (JR3) and a pedestal. The force sensor was mounted on the end effector of the robot. The tibia and the femur were mounted from the potted side to a fixture attached to the force sensor and the pedestal, respectively (Figure 2). After fixing the femur and the tibia, a nitinol wire was inserted into the graft tunnel to orient the robot end effector with the tibia-tendon construct, allowing the robot to pull the tibia and the attached graft away from the femur in a vector colinear with the femoral bone tunnel. Using this vector ensured that the graft would be pulled out with the minimum possible force.[23]

A digitizer (Microscribe; Solution Technologies Inc) was used to register the initial position of the knee joint and create the required coordinate systems of the knee joint in space relative to the testing apparatus. Before pulling out the graft, an initial graft tension of 5 N was applied to make sure the graft was not slack. The pullout velocity of the robot was set at 1.5 mm/s.

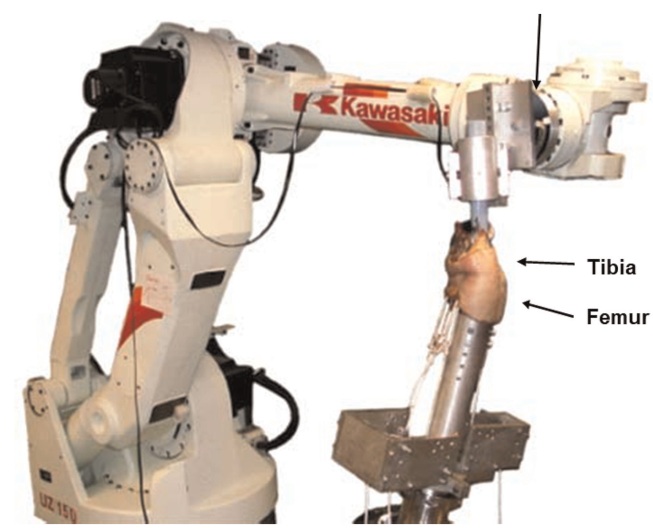

Figure 2. Testing apparatus. The femur is mounted to a fixture attached to a stationary pedestal. The tibia is mounted to a fixture attached to the force sensor. Force in line with the graft is applied to the tibia and recorded.

Data Collection and Statistics

Elongation (mm), force (N), and time (sec) were recorded from the beginning of movement to graft failure. Videos of each test were made to determine the type of failure and the quality of the pullout test. The force corresponding to graft elongation and fixation failure was obtained. Failure was defined as ultimate failure due to graft rupture or pullout. The initial toe region and the linear region of the force-displacement curve were determined. The linear stiffness of the construct was determined by the slope of the linear region of the curve.

The mean values of graft force at failure and linear stiffness were determined by group. The analysis of variance was applied for the statistical analysis of load to failure and linear stiffness. If significant, an independent 2-tailed

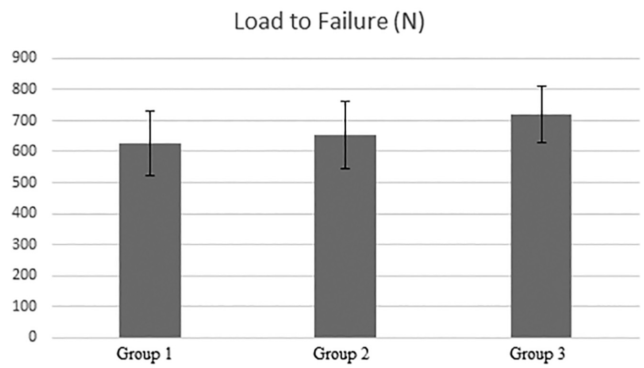

Figure 3. Mean load to failure (N) of the anterior cruciate ligament (ACL) reconstruction construct by study group. Error bars represent 95% CIs.

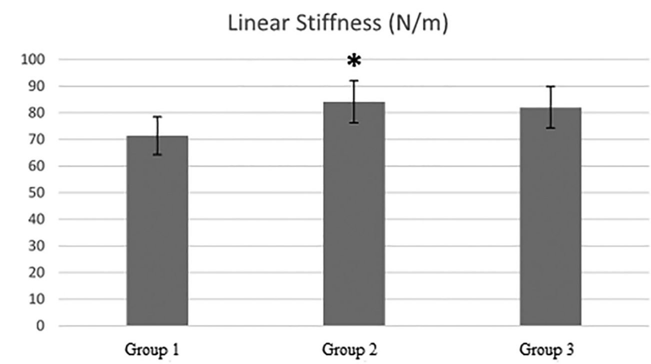

Figure 4. Linear stiffness of the anterior cruciate ligament (ACL) reconstruction construct by study group (N/mm). * denotes statistically significant differences between groups 1 and 2. Error bars represent 95% CIs.

t test was performed between groups with a Bonferroni correction for multiple comparisons. Level of significance was set at $P < .05$.

RESULTS

The mean pullout strength for groups 1, 2, and 3 was 626 ± 145 N, 653 ± 152 N, and 720 ± 125 N, respectively (Figure 3). There was no significant difference in the load to construct failure between the 3 groups (P = .328).

The mean linear stiffness of the construct in groups 1, 2, and 3 was 71.4 ± 9.9 N/mm, 84.1 ± 11.1 N/mm, and 82.0 ± 10.8 N/mm, respectively (Figure 4). Group 2 was 18% stiffer than group 1, a significant difference (P = .037). There were no significant differences between groups 1 and 3 (P = .099) or groups 2 and 3 ($P \geq .999$).

Failure mode was analyzed after graft pullout. In both groups 1 and 2, no bone plug-tendon interface failure occurred. In group 3, a total of 4 tested grafts failed at the bone-tendon interface (Figure 5A). Both the interference screw and the graft were pulled out in 7, 7, and 3 specimens in groups 1, 2, and 3, respectively (Figure 5B). There was graft pullout without screw pullout in 3 specimens in each group (Figure 5C).

A postfailure visual analysis was conducted on the femoral tunnel site and the patellar tendon plug. In groups 1, 2, and 3, respectively, 7, 7, and 1 specimens showed bony damage of the femur near the tunnel site (Figure 6A). In group 1, no patellar bone plug fracture was observed. In groups 2 and 3, patellar bone plug fractures were observed in 1 and 6 specimens, respectively (Figure 6B). The remaining specimens were pulled out without damage to the bone plug or the femur (Figure 6C).

DISCUSSION

Our results show that the time-zero fixation strength of stacked bioabsorbable screws is comparable with time zero fixation of a primary ACL reconstruction in the porcine model. Both stacked screws constructs had similar load to failure and similar or greater linear stiffness than the primary reconstruction model. Bony voids encountered at revision surgery, resulting from malpositioned tunnels, may steer surgeons away from anatomic ACL reconstruction in a single setting.[21,26] This biomechanical study shows that even in such a case, a single-stage procedure may be considered by using a biocomposite screw to graft the bony defect, followed by standard interference screw fixation, to secure the revision ACL graft.

Revision ACL reconstruction poses several challenges, perhaps the greatest being the management of malpositioned or widened tunnels.[17] The Multicenter ACL Revision Study cohort required staging for bone grafting in 25% of patients.[5] Adding a second procedure is not benign, with added risk from anesthesia, cost, and prolonged rehabilitation time. Although it can be a successful operation and may be warranted in the right clinical scenario,[26] avoiding a 2-stage revision is preferable.[17]

Stacked screws is a commonly known technique for 1-stage revision ACL reconstruction, yet it has not been investigated sufficiently. Multiple technique guides for management of bone loss in revision ACL reconstruction mention it as an option with minimal literature supporting its merits.[12,20] Herbenick and Gambardella[14] initially described a technical note on the stacked screws construct with a biocomposite filler screw and a metal interference screw. No biomechanical testing or clinical follow-up were reported. Fullick et al[11] examined the load to failure for a stacked screws construct with a metal interference screw in a synthetic bone with a synthetic bone plug. They found that when 10% or 25% of the filler screw was removed, there was no difference from a screw in bone without a revision tunnel, simulating a primary ACL reconstruction. When 50% of the filler screw was removed, there was a significantly decreased load to failure.

Since the original technique paper, there has been increased use of bioabsorbable screws over metal interference screws, given multiple advantages. Biocomposite screws provide excellent initial fixation, stability through the resorption phase, and osteointegration.[1,18] Additionally,

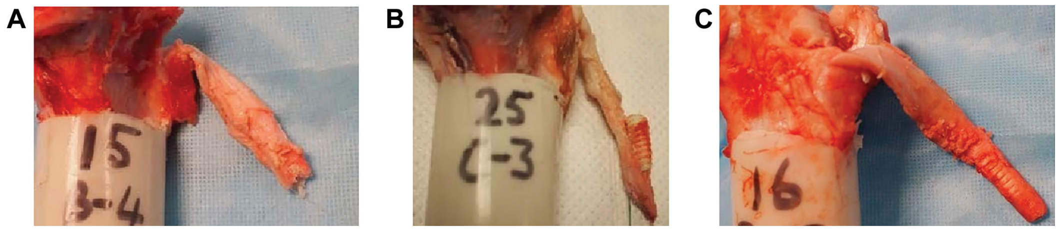

Figure 5. Modes of graft pullout failure observed. (A) Failure at graft bone plug-tendon interface. (B) Graft pullout with interference screw pullout. (C) Graft pullout without interference screw pullout.

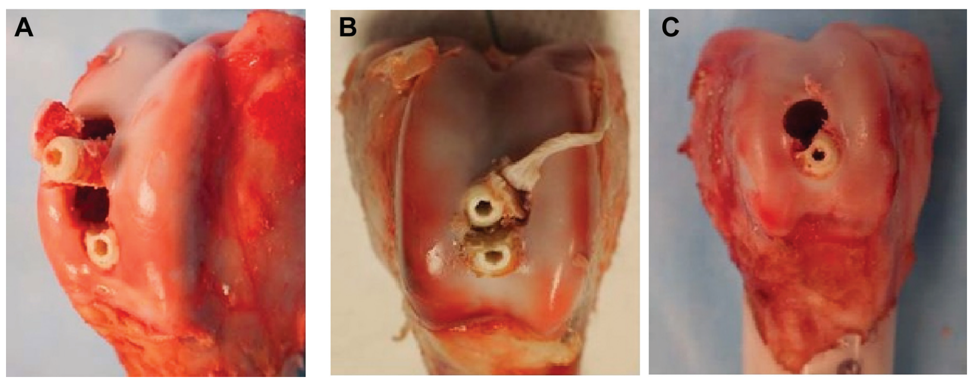

Figure 6. Post failure appearance of the femoral tunnel site. (A) Bony damage to the femur near the tunnel site. (B) Patellar bone plug fracture. (C) No visible damage to the femur and no remaining patellar bone plug.

they do not interfere with postoperative imaging and can be drilled through in revision surgery.

Two studies have evaluated the stacked screws construct with bioabsorbable screws in the tibia. Of note, osteolysis seen in revision ACL reconstruction is less common in the tibia than in the femur.[20] Schliemann et al[25] used a porcine model to show that a stacked screws construct had similar load to failure and linear stiffness as primary ACL reconstruction but increased elongation during testing. They used nonbiocomposite poly-DL-lactide bioabsorbable screws and backed up their interference screw fixation with a cortical button. Behrens et al[3] evaluated a single-stacked screws configuration with biocomposite poly-L-lactic acid (PLLA)/calcium hydroxyapatite screws in a porcine tibia. Their revision construct was drilled through a primary reconstruction biocomposite interference screw that was tested for load to failure but did not pull out in their first round of testing.

Unlike the above literature, PLGA ß-TCP biocomposite screws were used in this study. PLGA has been shown to reabsorb faster than the several years required for PLLA, which may be preferable.[1] Biocomposite screws, which contain calcium salts, such as ß-TCP, have been shown to be osteoconductive, whereas pure PLGA or PLLA screws are not.[1] This is clinically important given the purpose of the filler screw in the stacked screws construct as both a robust bone void filler and a stimulus for bony ingrowth, leaving behind bone after its degradation. Although there has been concern about inflammation,[19] incomplete degradation,[15] tunnel widening,[21] effusion, or cyst formation with biodegradable screws, this has been shown to be uncommon with PLGA/ ß-TCP implants.[2] They show good biocompatibility, resorption, and osteoinductivity.[10]

Our data show that in a porcine biomechanical model, load to failure of the revision constructs had similar load to failure as primary ACL reconstruction. There was also higher linear stiffness in the stacked screws configuration with the graft sandwiched between the 2 screws compared with the primary construct. This may be explained by the filler screw being denser than porcine bone or by multiple screws leading to bone compression, increasing the linear stiffness of the construct. Group 3 was the only configuration to fail at the bone plug-tendon interface (4/10 specimens), suggesting that in some cases the fixation construct was stronger than the graft. Therefore, the mean load to failure of the construct itself may be even higher than measured.

This study shows that either tested stacked screws configuration has adequate strength and linear stiffness in a single-stage revision ACL reconstruction in the setting of bone loss in the porcine model. Previous tunnel location or osteolysis in revision surgery varies; thus, this finding may provide surgeons the flexibility to place the graft and the new interference screw in whichever orientation they think is best in a given patient.

Limitations

A primary limitation of this in vitro biomechanical study is the evaluation of time zero mechanics in cadaveric bones. We were unable to evaluate in vivo bone properties with associated healing, screw resorption, and possible change in fixation over time. Clinical trials of the stacked screws construct would be helpful in addressing these issues and evaluating patient outcomes using a stacked screws construct. Another limitation is the use of porcine bone, although this is a commonly used and acceptable alternative to human cadaveric bone in biomechanical ACL studies, given that the bone quality is very consistent and is similar to that of a human knee.[3,22,25] We did not cycle the graft before testing to allow for loosening or graft relaxation. Although this was true for each study group, it could have affected groups differently. We selected a 10-mm tunnel for grafting, as this is a common size seen in revision ACL reconstruction. Some tunnels will be larger in the setting of tunnel widening, in which case the surgeon could consider less screw oversizing, multiple screws, or a different grafting technique.

CONCLUSION

A biocomposite stacked screws construct for a single-stage revision ACL reconstruction in the setting of bone loss showed adequate biomechanical strength and linear stiffness when compared with primary ACL reconstruction at time zero in a porcine model.

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