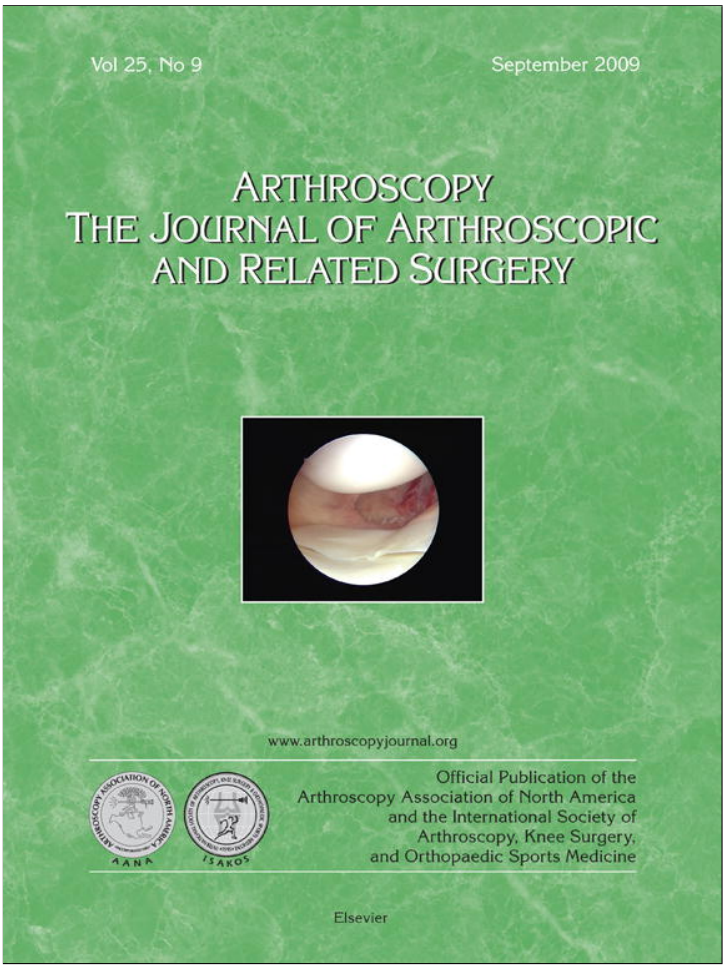

Biomechanical Evaluation of a 1-Stage Revision Anterior Cruciate Ligament Reconstruction Technique Using a Structural Bone Void Filler for Femoral Fixation

Zackary D. Vaughn, M.D., Josh Schmidt, M.D., Derek P. Lindsey, M.S., and Jason L. Dragoo, M.D.

Purpose: The purpose of this study was to develop a method of femoral fixation for complex revision anterior cruciate ligament (ACL) reconstructions that would avoid a staged bone grafting approach. We evaluated the use of a calcium phosphate cement as a structural bone void filler that would allow for a single-stage revision ACL reconstruction with initial biomechanical properties equivalent to standard autologous bone–patellar tendon–bone primary ACL reconstruction. **Methods:** We tested 11 matched pairs of fresh-frozen cadaveric knees (N = 22). Controls were treated with autologous bone–patellar tendon–bone primary ACL reconstruction fixed with bioabsorbable interference screws with a 1-mm back wall. The contralateral knee of each pair had a large bone void created that would hamper subsequent femoral fixation to simulate revision ACL reconstruction conditions. This defect was filled with calcium phosphate cement arthroscopically. After solidification, the femoral tunnel was drilled through the bone void filler and native bone with a 1-mm back wall, allowing anatomic positioning. The autologous graft was then placed and fixed with a bioabsorbable interference screw. Specimens were then tested in an MTS machine (MTS Systems, Eden Prairie, MN) for load to failure according to a standard protocol and compared with matched controls. **Results:** Failure loads for the control group averaged 312 N (standard deviation [SD], 127 N) and were not significantly different compared with the calcium phosphate cement revision group, which averaged 301 N (SD, 95 N) (P = .80). Failure occurred at the femoral bone block in both groups but without screw pullout. **Conclusions:** Statistical analysis failed to show a significant difference between the control group and the group undergoing structural bone void filler revision in this biomechanical evaluation of initial fixation strength. **Clinical Relevance:** This technique may allow surgeons to perform a single-stage revision ACL reconstruction in the presence of a contained bone void and avoid the need for a staged procedure if clinical studies verify long-term incorporation of the bone void filler. **Key Words:** ACL—Reconstruction—Revision—Calcium phosphate cement—Tunnel widening—Biomechanical study.

Reconstruction of the anterior cruciate ligament (ACL) is one of the most common procedures in orthopaedic surgery, with a success rate greater than 90%.[1-4] However, failures of the index procedure occur most commonly because of surgeon error in femoral tunnel placement or widening of tunnels leading to graft failure.[1-4] Revision ACL reconstruction often requires a staged approach because of the need for bone grafting of the void that is created by the previously misplaced tunnel, osteolysis, or removal of previous fixation. Bone grafting procedures usually require greater than 4 months for incorporation of the graft before a new ACL graft can be placed. This delay may be detrimental to the rehabilitation process and potentially harmful to the knee joint itself because of the lengthened period of relative instability.[5-8] This emphasizes the need to find strategies and biomaterials that can allow for a successful 1-stage revision reconstruction with comparable strength to the gold

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standard primary bone–patellar tendon–bone (BPTB) graft with interference screw fixation. The use of calcium phosphate cements as bone void fillers, which have been used in cases of orthopaedic trauma and spinal instrumentation to augment fixation strength, presents a possible solution for complex ACL graft fixation.

The purpose of this study is to evaluate whether filling femoral defects with a structural calcium phosphate cement (Callos Impact; Skeletal Kinetics, Cupertino, CA) will allow placement of an anatomically positioned revision ACL reconstruction in a single procedure and maintain fixation strength that is equivalent to the gold standard primary BPTB ACL reconstruction.

METHODS

Implant Material

Callos Impact is a bioactive moldable calcium phosphate cement with a putty-like consistency that is ideal for this application. It cures in an aqueous environment and solidifies in vivo at standard body temperature such that it can be drilled for screw fixation after 6 minutes.[9] It reaches 98% of its final strength by 24 hours when in the human body at 37°C.[9,10] The solidified state of this particular calcium phosphate cement has structural support, as well as consistency, that is slightly stronger than cancellous bone and therefore would not be subject to toggling, creep, windshield-wiper effects, or further compression when compared with the surrounding cancellous bone. It is biocompatible and is remodeled, not resorbed, by an osteoclastic cell-mediated process, gradually being replaced at the same rate by cancellous bone over several months without loss of integrity or strength.[9,11-13]

Procedure

We tested 22 fresh-frozen adult cadaveric knees as 11 matched pairs. Cadavers were obtained through a nonprofit research foundation (LifeLegacy Foundation, Tucson, AZ). The age range of the specimens was 43 to 65 years. There was no evidence of underlying bone disorder or prior knee surgery in any of the specimens. All specimens were equally randomized based on sidedness to either the control group or the structural bone void filler test group. Specimens were thawed appropriately for a minimum of 24 hours before any use and were otherwise stored at –20°C. Autologous BPTB grafts were harvested from the central 10 mm of patellar tendon in each specimen with 9 × 30–mm bone blocks. Bone blocks were prepared by use of rongeurs only, without crimping, and with the ends bulleted for ease of passage. Standard transosseous sutures were placed through 2 drill holes for graft passage. Each specimen underwent full arthroscopic evaluation and had complete resection of the native ACL.

The control group underwent standard primary ACL reconstruction with BPTB autograft. A notchplasty was performed when necessary to prevent graft impingement on the sidewall and roof. The tibial tunnel was drilled and prepared in standard fashion. The knee was then hyperflexed, and a 6-mm over-the-top-guide was introduced through the anteromedial portal. A 10-mm-diameter femoral tunnel was drilled over a transfemoral guidewire at the corresponding 10- or 2-o'clock position with a 1-mm back wall. The graft was placed with the knee in hyperflexion and was fixed in the femoral tunnel with an 8 × 25–mm LactoSorb bioabsorbable interference screw (Biomet, Warsaw, IN). The interference screw was placed superolateral to the bone block, compressing the graft against the more posterior aspect of the bone tunnel according to standard protocol.

In the structural bone void filler treatment group, we simulated a failed ACL reconstruction scenario resulting from the 2 most common failure modes: (1) improperly placed tunnels or (2) widened tunnels due to a windshield-wiper effect. A 12-mm femoral over-the-top guide (Biomet, Warsaw, IN) and guide pin were used in each test specimen to help create a femoral bone void that would be of reproducible size and location and that would overlap the anticipated site for the proper anatomic reconstruction (at the 10- or 2-o'clock position) (Fig 1). Therefore a large contained bone void was created in this "too anterior" location with a cannulated 12-mm drill over the guide pin to a depth of approximately 35 mm. This bone void interfered with fixation at the time of revision, simulating either a previously malpositioned tunnel, a void generated from removal of prior graft or fixation materials, or a widened tunnel resulting from a windshield-wiper effect of the graft. Callos Impact was then prepared according to the manufacturer's recommendations for technique and timing and was packed into a modified 10-mL syringe. The tip of the syringe was cut off to allow a larger orifice for injecting the bone void filler because of its putty-like consistency. With the plunger of the syringe temporarily removed, the filler was manually placed into the syringe, followed by replacement of the plunger for delivery. The

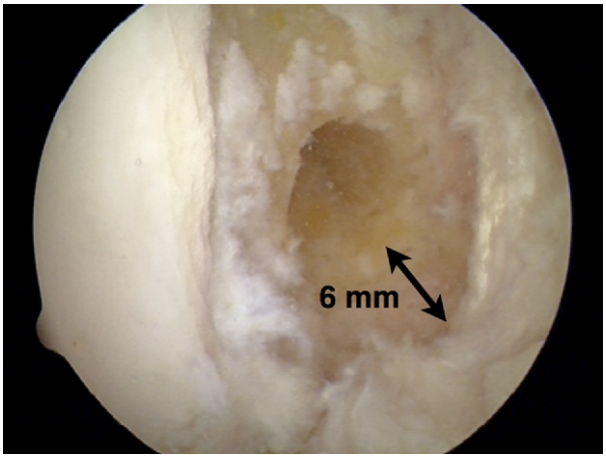

FIGURE 1. Arthroscopic view of an improperly placed anterior "tunnel" as a simulated bone void with a 6-mm back wall for the experimental model as created with a 12-mm over-the-top guide for consistency of placement between specimens. Arrow demarks 6 mm size of back wall as measured from back wall of femur to edge of bone void.

syringe was then placed through the anteromedial portal with the knee in hyperflexion, after this portal site had been slightly widened to approximately 2 cm in length, and was visualized with the arthroscope as the filler was delivered directly into the bone void with the saline pump flow off. A total of approximately 3 to 5 mL of Callos was injected and then manually impacted into the bone void by holding pressure for approximately 2 minutes (Fig 2) with the saline pump flow on. This was accomplished by gentle pressure with appropriately sized tunnel dilators from our ACL

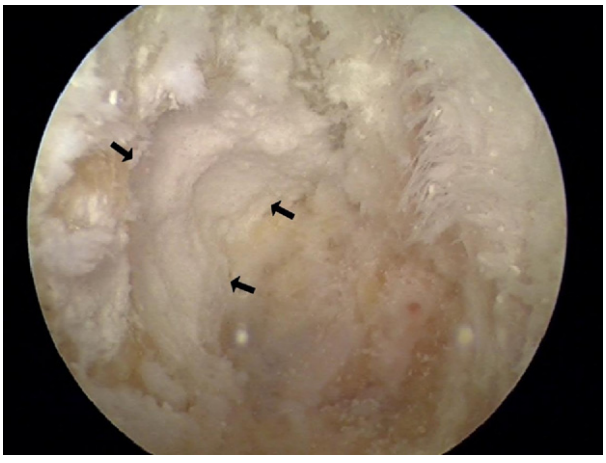

FIGURE 2. Bone void filled with Callos after packing and solidification. Arrows demark the interface of implanted Callos with native cancellous bone.

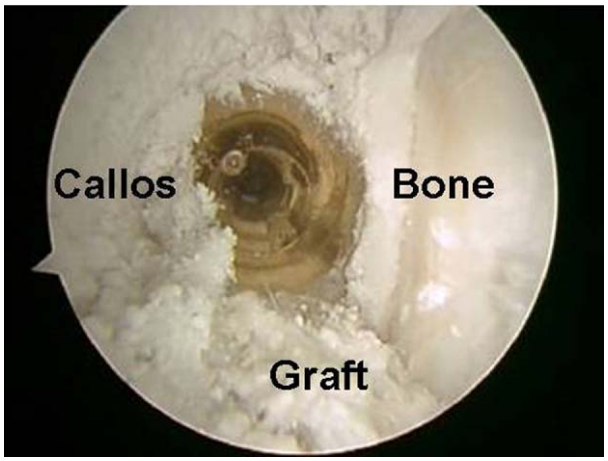

FIGURE 3. ACL graft passage through new, properly placed femoral tunnel. Half of the tunnel was drilled through structural bone void filler and half through native bone. An interference screw was placed at the junction of structural bone void filler and native bone.

reconstruction set or bone tamps. The knees were then placed into a 37°C water bath to simulate normal body temperature for an additional 18 minutes for proper curing of the Callos. Thereafter the filled bone void was probed to show solidification. The mixing procedure, timing of incubation, and method of application were determined in consultation with the manufacturer to optimize the functionality of the product and were modified as appropriate for the cadaveric scenario.

Excess structural bone void filler was then removed easily with a combination of simple egress of fluid through the widened portal site with 50 mm Hg of pump pressure inflow, minimal use of a 4.5-mm shaver with suction, and arthroscopic graspers. The enlarged arthrotomy was partially closed with suture after completion of the grafting procedure to help maintain fluid pressure for the reconstruction. These specimens then underwent revision reconstruction by the identical technique used in the primary BPTB autograft technique as described previously, by use of a 6-mm over-the-top guide and a 10-mm femoral tunnel in the 10- or 2-o'clock position. The new tunnel was placed in the correct anatomic position by a transportal technique through an approximately 50:50 composite of native cancellous bone and the newly implanted structural bone void filler (Fig 3). The graft was then placed in the new tunnel with equal circumferential contact with native bone and structural filler and was fixed with the identical 8 × 25–mm interference screw construct used in the control group. The interference screw was placed superolateral to the

graft, at the interface of native cancellous bone and implanted graft (Fig 3), in the identical location to the control group mentioned previously. The tibial-sided bone block remained within the tibial tunnel without formal fixation for ease of later removal. The specimens were then incubated at 37°C overnight before testing.

Mechanical Testing

All of the matched pairs had the tibia and supporting soft tissue removed to avoid confounding variables in testing and to adhere to previously established loading protocols. The tibia was removed as all soft tissue attachments were cut, leaving only the ACL graft intact and fixed to the femur. The bone block on the tibial side was easily extracted through the proximal aspect of the tibial bone tunnel without damaging the graft. This isolated the distal femur with fixed ACL graft and the free, intact tibial-sided bone block to affix to the loading apparatus. Each specimen was then potted in polymethyl methacrylate bone cement on the femoral shaft side and mounted on the hydraulic MTS Bionix frame (MTS Systems, Eden Prairie, MN) (Fig 4). The shaft of the femur was fixed in bone cement in metal mounting jigs with long bicortical screws placed transversely in different planes through the femoral shaft, with a minimum excess of 5 mm of screw threads prominent on both cortices, to interdigitate with the cement to prevent motion. This mounting jig with the femur potted upside down at a 45° angle was then fixed solidly to the MTS loading apparatus to allow for a force vector in direct line with the femoral bone tunnel that would create a "worst-case scenario" for slippage and shear forces with the interference screw. The free end of the ACL graft with the tibial bone block intact was fixed to a corrugated metal clamp that firmly grasped the bone block to allow for tensile distraction (Fig 4). All tests were performed at room temperature after a minimum of 24 hours of specimen thawing. Loading occurred in a vertical tensile fashion at 50 mm/min until failure. Failure was defined as loss of fixation including pullout of the graft or interference screw, fracture of femur, or rupture of graft. Failure was observed visually and reflected by an abrupt change in continuous force measurements from the MTS mechanical data. This biomechanical testing protocol has been used in prior studies evaluating load-to-failure force of ACL grafts at time 0 with standard fixation methods.[14-18]

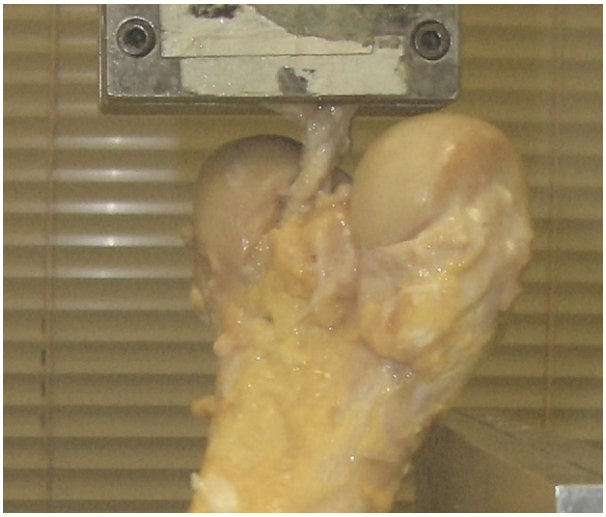

Figure 4. MTS setup for testing load to failure. The line of pull was directed in line with the graft and interference screw fixation to create the "worst-case scenario" of direct failure, oblique to lateral condyle and approximately 45° to the shaft.

Statistical Methods

Identification of the respective pairs of knees was retained throughout the experiment. This allowed for the difference in pullout force and stiffness for the 2 conditions to be calculated as a function of knee pairs rather than simply comparing mean values between groups. Although an ideal experimental design would show equivalency, the number needed to obtain significance by use of equivalency testing, based on standard assumptions for adequate power (0.8), was 358 paired specimens, as derived from our pilot data collection of the initial 4 pairs. This quantity of specimens for testing is not achievable because of specimen procurement issues. A post hoc power analysis for our 11 matched pairs (N = 22) showed a power of 0.5, indicating that the study is underpowered to statistically prove equivalence of the 2 groups. The differences between the conditions were analyzed by use of both a paired t test and a single-sample, 1-tailed t test. This 1-tailed t test was selected because it allowed us to examine the differences between the individual pairs, rather than group means, and allowed more stringent and accurate evaluation of the data. Significance was defined as $P \leq .05$. Statistical consultation was obtained through the Bone and Joint Center for Biomechanical Research at the Palo Alto VA Medical Center, Palo Alto, California.

RESULTS

All failures occurred at the femoral-sided bone block with destruction and fragmentation of the bone

block itself as the mode of failure. In each case the bone block eventually failed by cracking or shearing past the fixation without dislodging the interference screw and without damaging the implanted calcium phosphate. There were no instances of screw pullout or disruption of the structural bone void filler. This showed that the limiting factor for failure was the underlying bone quality and strength rather than the Callos or interference screw fixation. The mean load-to-failure strength of the control group was 312 N (standard deviation [SD], 127 N), whereas that in the structural bone void filler revision group was 301 N (SD, 95 N) (Table 1, Fig 5). These values are consistent with pullout strengths obtained in other previously reported studies using human cadaveric specimens.[15] We were unable to show a significant difference between the 2 groups ($P = .80$), with a mean pullout strength difference of only 11 N of greater load for the control specimens. This mean 11-N difference within each set of paired specimens is negligible overall, because it represents less than one tenth of an SD of the entire specimen population. In addition, when we evaluated the specimens through a direct head-to-head comparison, the structural bone void filler group had a higher maximum load to failure in 5 of 11 pairs.

TABLE 1. *Load-to-Failure Data for All Matched-Pair Specimens*

Knee No.	Maximum Load (N)	Slope (N/mm)
Control specimens		
1	359.7	75.4
2	298.0	45.3
3	313.8	41.4
4	247.2	30.9
5	337.1	37.9
6	149.2	10.7
7	304.0	36.3
8	155.7	11.9
9	214.3	37.9
10	530.7	46.6
11	526.2	60.0
Callos test specimens		
1	263.0	36.4
2	333.3	51.6
3	455.7	58.1
4	179.5	26.5
5	268.8	30.8
6	238.7	15.9
7	417.7	42.6
8	327.1	32.4
9	178.6	73.1
10	242.0	17.8
11	413.1	45.2

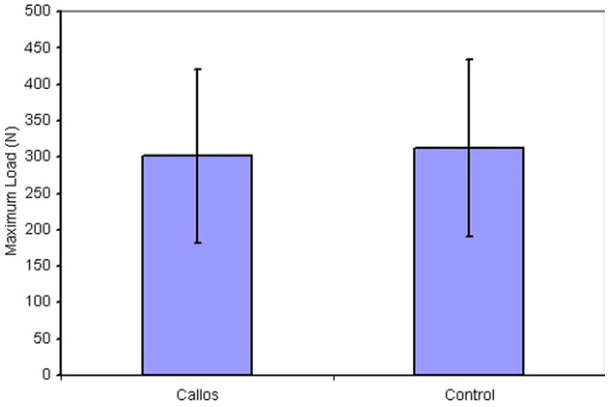

FIGURE 5. Comparison of mean load to failure (in Newtons) for both groups.

The mean stiffness, a value derived from the slope of the curve representing the change in length of the graft as it relates to the force applied, was 39.5 N/mm (SD, 18 N/mm) in control specimens versus 39.1 N/mm (SD, 17 N/mm) in structural bone void filler–treated specimens ($P = .50$) (Fig 6). The mean difference between these groups was 0.36 N/mm (SD, 21.6 N/mm). Again, the structural bone void filler group had a higher maximal stiffness in 6 of 11 pairs, further showing the inability to detect a significant difference between the pairs.

DISCUSSION

This study shows that a specific calcium phosphate cement can be used to fill femoral-sided bone defects after failed ACL reconstructions to allow for anatomic revision reconstructions without sacrificing tunnel po-

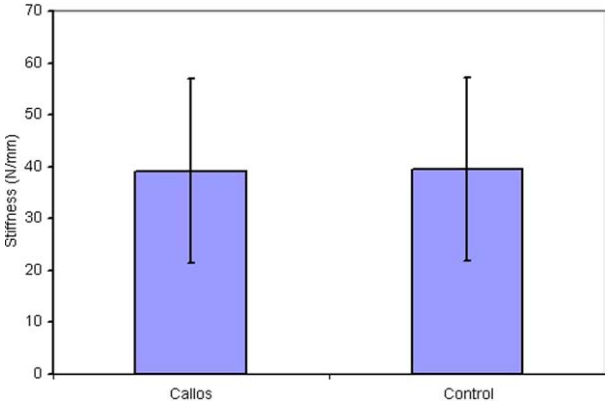

FIGURE 6. Comparison of mean stiffness (in Newtons per millimeter) for both groups.

sition and without a statistically significant loss of immediate fixation strength. Recent publications have addressed the need for creative use of alternative grafting options to avoid staged reconstructions using preformed allograft or synthetic bone dowels.[19,20] These strategies have been successful for discrete cylindrical bone voids; however, the potential use of calcium phosphate cements could be more amenable in variably sized or shaped defects and without concern over appropriate tunnel placement. The use of this technique may allow avoidance of a staged reconstruction and the sequelae of continued instability such as meniscal tears and pain.[21,22]

Chaudhari and colleagues[23] have shown increased cartilage damage in ACL-deficient knees, which may lead to osteoarthritis resulting from alterations in cartilage morphology and contact pressures. ACL reconstructions are occurring with increasing frequency due in part to this evolving body of literature as well as the overall activity of the population. Despite our improving techniques and technologic advances, failures of ACL reconstructions do occur.

The vast majority of failures occur because of technical error, with over 70% resulting from improper tunnel placement, typically on the femoral side, which can lead to bone defects within the femur that are problematic for revision surgery because of location, shape, and size.[1-4] These bony defects may result from tunnel widening, misplaced tunnels, or residual voids after removal of previous graft fixation.

We hypothesize that the ability to perform a complex revision ACL reconstruction in a single operation may be possible using certain types of osteobiological bone void fillers. Calcium phosphate cements would be ideal for this application because they have shown an ability to remodel similarly to both cortical and cancellous bone by an osteoclastic cell–mediated process, such that the stability is not compromised during the course of the remodeling.[11] In addition, these compounds have been shown to have 4 to 10 times the compressive strength of cancellous bone grafts and other bone graft substitutes, providing excellent compressive stability and the ability to maintain their structural integrity when drilled for screw fixation.[11,24-27] Trenholm et al.[24] showed increased stiffness in stabilization of tibial plateau fractures with a compressive load. The trauma literature has also shown increased resistance against screw cutout by up to 16% in instrumented peritrochanteric femur fractures with compression screws.[25] Pedicle screw pullout strength has also been shown to be augmented with the use of such cements in the spine literature.[26,27] Animal studies have been conducted showing the remodeling process with no evidence of structural integrity loss, as well as showing incorporation of surrounding host bone, making calcium phosphate cement an ideal compound for initial as well as long-term stability.[12] This, however, has not been specifically tested in humans or in this method of use. Concerns about potential side effects of intra-articular use of this compound have been raised; however, no complications have been reported in the recent literature with its use in distal radius fracture stabilization at 2 years of follow-up.[13]

This procedure is straightforward and reproducible if the manufacturer's recommendations are followed and proper surgical planning is performed. Caution should be exercised when using other calcium phosphate cements, which were not tested in this study, because the physical and chemical properties vary widely among manufacturers.[11] Each separate formulation of structural bone void filler should undergo testing, and inference of data between different products is not recommended.

The primary limitation in our study is not statistically proving equality between the groups, which is because of the limited number of specimens that can be tested. Statistical analysis requires testing of 358 pairs of specimens to make an equivalence claim. Because this is not technically feasible given procurement constraints, we limited our evaluation to a single time 0 load to failure for each specimen to evaluate initial fixation strength. Despite our study being underpowered, this allowed for our initial evaluation of technical feasibility and stability of the construct. In retrospect, given that the only visible mode of failure occurred by destruction of the femoral-sided bone block and with nearly identical stiffness calculations, it is likely that the limiting factor for mode of failure was the bone quality of the bone block itself. Although the standard technique was followed for the autograft harvest and the grafts were all standard sizes and were prepared in identical fashion, the bone density of the grafts was not controlled for or evaluated with a dual-energy x-ray absorptiometry bone density scan, because this was not available. Although this may explain the variability in the data across multiple specimens, it also further shows that the structural bone void filler was not a limiting factor for load-to-failure force testing.

Other limitations to be addressed include the long-term graft incorporation with the calcium phosphate filler in place. Although supporting literature exists for remodeling of the filler itself without resorption and

maintaining strength greater than that of cancellous bone,[12] our specific biomechanical testing method does not fully evaluate its clinical applicability in humans. Despite the available data in the animal model regarding stability of the calcium phosphate cement, currently, there is an absence of human clinical data to prove long-term stability of the graft. In addition, the ability of the implanted ACL graft to incorporate over time in conjunction with the implanted bone void filler has not been evaluated and would require additional study. Therefore verifying this incorporation of the graft in an animal model along with performing cyclic loading testing will be necessary before clinical use of this technique is accepted.

Although this specific testing model may not mimic every feasible type of graft failure, it does re-create the most common modes of failure with a residual bone void that can be prepared and filled with this calcium phosphate cement to allow a single-stage revision. This could be adapted to most foreseeable revision reconstruction scenarios when a femoral bone void is present.

CONCLUSIONS

Statistical analysis failed to show a significant difference between the control group and the structural bone void filler revision group in this biomechanical evaluation of initial fixation strength. This technique may provide the means to perform a single-stage revision ACL reconstruction in the presence of a contained bone void and avoid the need for a staged procedure if clinical studies verify long-term incorporation of the bone void filler.

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