Computed Tomography Imaging of BioComposite Interference Screw After ACL Reconstruction With Bone–Patellar Tendon–Bone Graft

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Background: Bioabsorbable interference screws tend to have high resorption rates after anterior cruciate ligament (ACL) reconstruction; however, no studies have examined screws composed of 30% biphasic calcium phosphate and 70% polylactide (30% BCP/70% PLDLA).

Purpose: To evaluate femoral and tibial tunnel widening and resorption of 30% BCP/70% PLDLA interference screws and replacement with bone at 2 to 5 years after ACL reconstruction using bone–patellar tendon–bone (BTB) autograft.

Study Design: Case series; Level of evidence, 4.

Methods: Included were 20 patients who had undergone ACL reconstruction using BTB autograft and were reevaluated 2 to 5 years after surgery using computed tomography scans. Tunnel measurements were obtained from computed tomography scans in the sagittal and coronal planes and were compared with known tunnel measurements based on operative reports. These images and measurements were used to assess tunnel widening, resorption of the 30% BCP/70% PLDLA screw, its replacement with bone, and possible cyst formation. Paired t tests were used to compare initial and final femoral and tibial tunnel measurements.

Results: The cross-sectional area of the femoral tunnel decreased at the aperture ($P = .03$), middle ($P = .0002$), and exit ($P < .0001$) of the tunnel compared with the initial femoral tunnel size, and the tibial tunnel cross-sectional area decreased at the aperture ($P < .0001$) and exit ($P = .01$) of the tunnel compared with the initial tibial tunnel size. Bone formation was observed in 100% of femoral tunnels and 94.7% of tibial tunnels. Screw resorption was 100% in the femur and 94.7% in the tibia at the final follow-up. Cysts were noted around the femoral tunnel in 2 patients (5.1%).

Conclusion: The 30% BCP/70% PLDLA interference screws used for ACL reconstruction using BTB autograft had high rates of resorption and replacement with bone, and there were no increases in tunnel size at 2 to 5 years postoperatively. The authors observed a low rate of cyst formation and no other adverse events stemming from the use of this specific biointerference screw, suggesting that this type of screw is a reasonable option for graft fixation with minimal unfavorable events and a reliable resorption profile.

Keywords: bioabsorbable; interference screw; anterior cruciate ligament; reconstruction

Approximately 300,000 anterior cruciate ligament (ACL) reconstructions are performed each year in the United States.18 Typically, autogenous bone-ligament-bone grafts, hamstring tendon grafts (semitendinosus with or without gracilis), or quadriceps tendon grafts are used to reconstruct the ACL.8 Traditionally, metallic interference screw fixation of the graft has been used, but these implants have the potential for migration and become artifacts on both computed tomography (CT) and magnetic resonance imaging (MRI) scans, making accurate postoperative imaging difficult. Additionally, metal interference screws remain permanently embedded in the bone, which can complicate revision surgery.26 Metal screws can also lead to graft laceration during implantation.

Bioabsorbable screws were developed as an alternative to metal interference screws and have become a popular choice among surgeons because of their unique characteristics when compared with metal implants.18,26 Bioabsorbable screws are made of polymers or copolymers that degrade over time and ideally become replaced by bone, while still providing sufficient mechanical fixation.11 Unlike metal screws, bioabsorbable screws can facilitate...
revision surgery because they resorb over time or the surgeon can drill through them if they fail to resorb and place new screws without the need for hardware removal. They also create minimal imaging artifact, making planning for revision surgery easier.\textsuperscript{2-4,13,21,26}

Resorption rates for bioabsorbable screw fixation have varied in the literature, with Drogset et al\textsuperscript{7} showing 60\% or more resorption at 2 years and complete resorption by 7 years in poly-l-lactide (PLLA) bioabsorbable screws. Barber\textsuperscript{2} and Barber et al\textsuperscript{3} demonstrated faster degradation in screws with a \( \beta \) isomer composition and found complete screw resorption on CT scans by 38 months after surgery. However, another study demonstrated no significant resorption at 4 years, indicating heterogeneity in the literature, which may potentially be related to specific screw composition.\textsuperscript{19}

Despite the large body of literature on bioabsorbable interference screws, there have been no studies that have looked specifically at screws with a unique composition of 30\% biphasic calcium phosphate and 70\% poly-\( \beta \)-lactide (30\% BCP/70\% PLDLA; BioComposite bioabsorbable screw; Arthrex). This material is thought to be capable of being resorbed and replaced with bone, with minimal tunnel widening. There have been no studies of which we are aware that have involved bioabsorbable fixation and have performed imaging studies at a follow-up of at least 2 years using CT scans to assess screw resorption, bone growth into the tibial and femoral tunnels, and the effect on tunnel size.

The purpose of this study was to examine tunnel size changes, screw resorption, and replacement with bone with use of 30\% BCP/70\% PLDLA screws in patients who had undergone ACL reconstruction using bone–patellar tendon–bone (BTB) graft. We hypothesized that the screws would dissolve and be replaced by bone. If bone replacement was incomplete, the maximum diameter of the defect would be less than or equal to the initial tunnel size at the time of surgery.

**METHODS**

**Sample Selection**

We used billing records to generate a list of 146 patients undergoing ACL reconstruction by 2 surgeons (L.J.B., M.S.F.) at our institution between 2009 and 2014. Patients meeting the study inclusion criteria were contacted by telephone to determine if they were willing to undergo CT scanning of their treated knee. Eligible patients were contacted until 5 patients were enrolled from each of 4 follow-up intervals (2, 3, 4, and 5 years postoperatively), for a total of 20 participants. This study was approved by our institutional review board and participants provided informed consent.

The inclusion criteria were age between 18 and 50 years, primary ACL reconstruction using BTB autograft fixed at both the femur and the tibia via 30\% BCP/70\% PLDLA interference screws, an isolated ACL tear, a minimum 2-year follow-up, and no advanced (grade 3 or 4) degenerative joint disease noted on preoperative weightbearing radiographs (ie, >50\% joint space loss and/or presence of osteophytes). Exclusion criteria were revision ACL reconstruction, ACL tears with concomitant pathology (ie, meniscal or other ligamentous pathology because of the association of these pathologies with higher graft forces), other graft types besides BTB autograft (eg, hamstring graft or allograft), significant degenerative changes on preoperative radiographs, other graft fixation besides the 30\% BCP/70\% PLDLA interference screws for either the femoral or tibial tunnel, ACL reconstruction performed <2 years or >5 years from the time of enrollment in the study, pregnancy, >grade 2 laxity of other ligaments, and the use of any additional fixation.

A total of 107 patients were excluded because of ACL reconstruction using hamstring graft (n = 22), concomitant pathology (n = 69), revision ACL reconstruction (n = 4), or medical records not available (n = 12). This resulted in 39 eligible patients, who were called for enrollment until 20 patients agreed to participate. Four patients were found to have metal rather than BioComposite screws present in both the femur and the tibia via their CT scan; these patients were excluded, and 4 more patients were enrolled to replace them. One of the final 20 patients had a BioComposite screw in the femur and a metal screw in the tibia (this patient was included).

**Data Collection**

Follow-up CT scans were obtained for those enrolled, and the images were reviewed and measured once each by a single orthopaedic surgery sports medicine fellow (B.S.). Measurements from the CT scans were obtained perpendicular to the long axis of the femoral and tibial tunnels at the aperture, middle, and exit of each tunnel. The aperture and exit measurements were made 5 mm from the termination of the tunnels. Each measurement was taken from both the coronal and the sagittal views, and all data were acquired at 0.625-mm thickness. These measurements were used to...
the calculate the cross-sectional area (CSA) at each of the 3 tunnel locations: CSA = \[\text{radius (coronal)} \times \text{radius (sagittal)} \times \pi\] (Figure 1). No imaging was available immediately postoperatively, so the initial CSA was calculated for tibial and femoral tunnel sizes using the reamer diameter selected during surgery, which was taken from the operative reports and assumed to be consistent at all 3 locations in the tunnel. This is a similar method to one previously described by Weber et al.26 The images were reviewed for screw resorption and replacement with bone. We also recorded any cyst formation, as this has been noted to be a complication of bioabsorbable screws in previous studies.5,9,17,23,24

Clinical Assessment

Physical examination information including assessment of knee stability and range of motion was obtained from medical records. Knee stability as it pertained to the ACL reconstruction was graded using a Lachman test. This was graded in comparison with the contralateral knee, with a grade of 0 (<3-mm difference), 1 (3-<5 mm), 2 (5-10 mm), or 3 (>10 mm). This was a subjective measurement by the physician and not an instrumentation measurement. The information was acquired from the last available follow-up appointment that specifically pertained to the treated knee. This was done before inclusion in the study and before the CT scans.

Statistical Analysis

Descriptive statistics were calculated for patient characteristics (age, sex, laterality), femoral and tibial tunnel size (based on operative reports and on measurements obtained at 2 to 5 years postoperatively in the coronal and sagittal planes that were used to calculate CSA), postoperative assessment of screw resorption and replacement with bone, and cyst formation. One of the 20 patients did not have tibial measurements because of a long graft requiring another form of fixation and thus was excluded from analyses involving tibial measurements. Paired t tests were used to compare the immediate postoperative (based on operative reports) and follow-up femoral and tibial tunnel measurements. Pearson correlations were calculated to examine if age and length of follow-up were correlated with the change in each of the femoral and tibial tunnel CSA measurements. Data are reported as means and standard deviations or absolute values and percentages. Statistical analyses were performed using SAS Version 9.4 (SAS Institute).

RESULTS

Patient Characteristics

The mean age at follow-up was 36 ± 10.51 years, and there were an equal number of men (n = 10) and women (n = 10). The mean length of follow-up from the time of surgery to postoperative imaging was 45.7 ± 15.69 months. There were 8 right-sided ACL reconstructions and 12 left-sided ACL reconstructions.

Screw Resorption

CT scans of the femoral and tibial tunnels demonstrated complete resorption of the 30% BCP/70% PLDLA screws in 20 of the 20 femoral tunnels (100%) and 18 of the 19 tibial tunnels (94.7%) where screws were used. The single screw without complete resorption was in a tibial tunnel, although it was not completely intact and did have some identifiable resorption. The follow-up CT scan on this patient with incomplete screw resorption was performed 27 months from the index procedure. Twenty of the 20 femoral interference screws (100%) and 18 of the 19 tibial interference screws (94.7%) had some degree of replacement with bone, clearly distinctive from the bone blocks of the autografts (Figure 2).

Femoral and Tibial Tunnel Measurements

The initial femoral and tibial tunnel measurements were obtained from operative reports and based on the dictated reamer size used for the femoral and tibial tunnels. Final measurements were obtained from CT scans taken 2 to 5 years postoperatively and are presented in Table 1. At the time of surgery, the mean femoral tunnel diameter was 9.95 ± 0.22 mm, and the mean tibial tunnel diameter was 10.05 ± 0.22 mm. The mean intraoperative CSA was assumed to be equal at all 3 tunnel locations (aperture, middle, and exit). The mean initial femoral and tibial CSAs were 77.79 mm² and 79.36 mm², respectively. Compared with the initial femoral CSA, there were significant decreases in CSA at the femoral tunnel aperture (P =
Initial tibial CSA was compared with follow-up measurements at the aperture, middle, and exit of the tunnel. Compared with the initial tibial CSA, there were significant decreases in CSA at the tibial aperture ($P < .0001$) and exit ($P < .0001$) of the tunnel. However, there was no difference in CSA at the middle of the tibial tunnels ($P = .57$) compared with the initial tibial CSA.

Cyst Formation/Clinical Results

No cysts were identified in any of the 19 tibial tunnels where interference screws were utilized (Table 2). In 2 of the 20 femoral tunnels (10%), small cysts were noted.

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**Table 1**

| Femoral and Tibial Tunnel Measurements (N = 20) | Mean ± SD | P Value$^a$ |
|----------------------------------------------|-----------|-------------|
| **Femoral tunnel measurements**              |           |             |
| Initial tunnel diameter, mm                  | 9.95 ± 0.22 | Referent    |
| Postoperative tunnel diameter, mm            |           |             |
| Aperture, coronal width                      | 8.75 ± 1.30 | .001        |
| Middle, coronal width                        | 7.98 ± 1.19 | <.0001      |
| Exit, coronal width                          | 7.65 ± 0.90 | <.0001      |
| Aperture, sagittal width                     | 10.00 ± 1.51 | .89        |
| Middle, sagittal width                       | 9.59 ± 1.61 | .34        |
| Exit, sagittal width                         | 8.47 ± 1.04 | <.0001      |
| Initial cross-sectional area, mm$^2$         | 77.79 ± 3.34 | Referent   |
| Postoperative cross-sectional area, mm$^2$   |           |             |
| Aperture                                     | 69.16 ± 15.49 | .03       |
| Middle                                       | 60.45 ± 15.61 | .0002     |
| Exit                                         | 50.79 ± 8.05 | <.0001     |
| **Tibial tunnel measurements**$^b$           |           |             |
| Initial tunnel diameter, mm                  | 10.05 ± 0.22 | Referent    |
| Postoperative tunnel diameter, mm            |           |             |
| Aperture, coronal width                      | 8.06 ± 1.23 | <.0001      |
| Middle, coronal width                        | 9.02 ± 1.41 | .004        |
| Exit, coronal width                          | 8.69 ± 1.17 | <.0001      |
| Aperture, sagittal width                     | 8.32 ± 0.93 | <.0001      |
| Middle, sagittal width                       | 10.84 ± 1.34 | .01       |
| Exit, sagittal width                         | 10.37 ± 1.71 | .40      |
| Initial cross-sectional area, mm$^2$         | 79.36 ± 3.69 | Referent   |
| Postoperative cross-sectional area, mm$^2$   |           |             |
| Aperture                                     | 53.17 ± 11.95 | <.0001    |
| Middle                                       | 77.29 ± 17.89 | .57      |
| Exit                                         | 70.70 ± 14.61 | .01      |

$^a$P values were calculated using paired t tests comparing postoperative measurements versus initial measurements (referent). Bolded P values indicate statistical significance ($P < .05$).

$^b$One patient did not have a tibial screw.

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**Table 2**

| Frequencies of Bone Formation, Screw Resorption, and Cysts | n (%) |
|-----------------------------------------------------------|-------|
| Femoral bone formation                                    |       |
| Yes                                                       | 20 (100) |
| No                                                        | 0 |
| Tibial bone formation                                     |       |
| Yes                                                       | 18 (94.7) |
| No                                                        | 1 (5.3) |
| Overall bone formation, femoral and tibial tunnels        | 38/39 (97.4) |
| Femoral screw resorption                                  |       |
| Yes                                                       | 20 (100) |
| No                                                        | 0 |
| Tibial screw resorption$^a$                                |       |
| Yes                                                       | 18 (94.7) |
| No                                                        | 1 (5.3) |
| Overall screw resorption, femoral and tibial tunnels      | 38/39 (97.4) |
| Femoral cyst                                              |       |
| Yes                                                       | 2 (10) |
| No                                                        | 18 (90) |
| Tibial cyst                                               |       |
| Yes                                                       | 0 |
| No                                                        | 19 (100) |

$^a$One patient did not have a tibial screw.
TABLE 3
Physical Examination Follow-up Data

| Stability, n (%) | Range of motion |
|-----------------|-----------------|
|                 | Lachman grade 0 | Range of motion |
|                 | 20 (100)        | 0° to 110° |
|                 |                 | 0° to 130° |
|                 |                 | 0° to 135° |
|                 |                 | −3° to 140° |
|                 |                 | 0° to 140° |
|                 |                 | 1° to 140° |

(Figure 3). The overall rate of cyst formation was 2 of 39 tunnels (5.1%). Clinical results are presented in Table 3. At their last follow-up, at 1 and 1.5 years, respectively, neither of the 2 patients with cyst formation had instability, loss of motion, or other complications attributed to the femoral cysts.

DISCUSSION

Our study demonstrated that use of 30% BCP/70% PLDLA interference screws did not result in increased tunnel diameter and, in most measurements, led to a significantly reduced size of the femoral and tibial tunnels based on CSA. The interference screws also underwent substantial resorption at 2 to 5 years postoperatively, exhibiting remodeling and bone formation. Additionally, there were only 2 cases of cyst formation in 2 femoral tunnels, without residual instability or loss of motion. Despite the large body of ACL literature that exists, postoperative outcomes of the 30% BCP/70% PLDLA screws at a minimum of 2 years after surgery have not been assessed.

Our finding of 97.4% screw resorption at 2 to 5 years postoperatively is consistent with previous studies by Barber et al3,4 who showed complete degradation of bioabsorbable screws at 3 years postoperatively. The single screw in a tibial tunnel without complete resorption was observed 27 months after the index procedure. This relatively early follow-up imaging may be the reason we did not see complete resorption as we did in other patients with follow-up closer to 5 years. Additionally, the timing of resorption at 2 to 5 years represents a better resorption rate than that seen in previous studies that reported resorption took up to 7 years or in some cases no significant resorption was present at 4 years.7,19 Barber2 showed that varying the composition of bioabsorbable screws, in their case using a D isomer, can affect resorption rate. This may in part explain why 30% BCP/70% PLDLA interference screws, with a poly-D-L-lactide makeup, had earlier resorption rates than those seen in previous studies.

We also evaluated each femoral and tibial tunnel at 3 locations to assess for widening, as this can be associated with the use of bioabsorbable screws. Notably, we found that there was no significant tunnel widening in any of the measurements. Instead, there were significant decreases in tunnel size at all measurement locations in the femoral tunnels and 2 of the 3 (aperture and exit) in the tibial tunnels. We also saw a decrease in the measurements for the middle of the tibial tunnels, although this was not significant.

Ultimately, our hypothesis that there would be no significant increases in tunnel size at any measured site was confirmed. Having no significant increase in tunnel size stands in contrast to a study by Lind et al,16 who compared metal with bioabsorbable screws and demonstrated appreciable widening with PLLA screws on radiographs.16 It should be noted that this study was performed at 12 months and used radiographs only, so it is unclear whether tunnel widening would have continued to decrease over time or would better be evaluated using CT scans. A study by Myers et al,19 using hydroxyapatite-coated PLLA screws, also showed slight but significant widening of femoral and tibial tunnel sizes of 1 mm using bioabsorbable screws when compared with titanium implants, but we did not see these increases with the use of the 30% BCP/70% PLDLA screw. Although not directly evaluated in this study, our finding of no significant tunnel widening could be attributed to the unique composition of this interference screw.

While relatively uncommon, a variety of complications have been noted in case reports after implantation of bioabsorbable screws. Reported complications include bone cysts,5,9,17,24 pseudocysts,23 infection,15,20 extrusion,3 abscess,6, and pre-tibial pain and swelling.15,22 There have also been 2 case reports of broken screws with associated pathology, either ulceration or chondral lesions.10,12 Complications were reported anywhere from 11 weeks to 10 years postoperatively, although most were reported within 1 year postoperatively. The cause of these complications could not be discerned from case reports alone, but an inflammatory reaction to the bioabsorbable screw might have played a role in some cases. The only observed radiographic complication in our patients was cysts seen around 2 femoral tunnels. These did not have any effect on stability of the knee or on range of motion based on information obtained at the final follow-up appointments. It may prove useful to have repeat imaging at a future date to assess whether the cysts have stabilized or resolved. A previous study of PLLA bioabsorbable screws found that 5% of patients developed painful tibial cysts after ACL reconstruction, which was similar to the frequency of cysts observed in our study.22 However, we suspect that the cysts observed in our study were purely incidental because no other apparent complications were found for these patients. Finally, although the last clinically recorded flexion for 1 patient was listed as 110° (Table 3), this was obtained from the electronic medical record at a 6-week follow-up visit, and the patient had an abnormal radiographic finding at the time of CT scan 5 years after surgery.

There are several limitations of this study including a lack of volumetric measurements of tunnel size. While our measurement technique has been used in previous studies, a volumetric measurement of tunnel size might give a better understanding of how much tunnel ossification is occurring.25,27 Additionally, a recent study by Sundaraj et al25 utilized both MRI and CT scans for the evaluation of tunnel volume and screw resorption, concluding that both imaging studies ultimately provided a more accurate assessment of tunnel size and screw integrity. While our study had a midterm follow-up of 2 to 5 years, one study from Kiekara...
et al. showed tunnel ossification starting closer to 5 years, so for some of our patients, the imaging may have been too early to see the full extent of ossification. In addition, this was a radiographic study and, although we collected clinical measurements of laxity and range of motion, we did not collect patient-reported outcomes, which may be correlated with radiographic outcomes. Finally, we had a relatively small number of study participants, and a power analysis was not conducted.

The next generation of biointerference screws maintains the same 30% BCP/70% PLDLA composition, with the addition of fenestrations designed to promote bone ingrowth. Although the newer screws were not included in this research, given that they are composed of the same chemical makeup and would have a presumed similar resorption and incorporation profile, this research should continue to be applicable. Longer follow-up with imaging may provide a more accurate assessment of true tunnel ossification potential.

CONCLUSION

In this study, 30% BCP/70% PLDLA interference screws used for ACL reconstruction using BTB autograft had high rates of resorption and replacement with bone as well as no increased tunnel size at 2 to 5 years postoperatively. We observed a low rate of cyst formation and no other adverse events stemming from the use of this specific biointerference screw, suggesting that this type of screw is a reasonable option for graft fixation with minimal unfavorable events and a reliable resorption profile.

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