Do Newer-Generation Bioabsorbable Screws Become Incorporated into Bone at Two Years After ACL Reconstruction with Patellar Tendon Graft?

A Cohort Study

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Background: Bioabsorbable interference screws are used frequently for graft fixation in ACL (anterior cruciate ligament) reconstruction. The resorption properties of many available screws that are marketed as bioabsorbable are not well defined. The CALAXO (Smith & Nephew Endoscopy) and MILAGRO (DePuy Synthes) bioabsorbable screws contain polymers of poly(lactic-co-glycolic acid) (PLGA) plus additives to encourage osseointegration over time. The purpose of this study was to evaluate radiographic and magnetic resonance imaging (MRI) properties and compare patient-reported outcomes at a minimum of two years of follow-up after ACL reconstruction using CALAXO or MILAGRO bioabsorbable interference screws.

Methods: A cohort of patients who underwent ACL reconstruction in which the fixation used was either CALAXO or MILAGRO screws returned for repeat radiographs for evaluation of tunnel widening, repeat MRI for evaluation of graft integrity and screw breakdown, and completion of the pain and symptom items of the KOOS (Knee injury and Osteoarthritis Outcome Score) questionnaire.

Results: At a mean of three years (range, 2.5 to 4.0 years) after surgery, thirty-one patients with sixty-two CALAXO screws and thirty-six patients with seventy-two MILAGRO screws returned for repeat evaluation. Two blinded, independent reviewers found no significant differences between the two screw types when comparing radiographs for tibial or femoral tunnel widening or MRIs for graft integrity, tibial and femoral foreign body reactions, or femoral screw degradation. Both reviewers found a significant difference between the two screw types when comparing tibial screw degradation properties ($p < 0.01$). All analyzed CALAXO screws were rated as partially intact or degraded; the MILAGRO screws were more likely to be rated as intact. No significant differences were noted between the two screw types when comparing the two KOOS subscales.

Conclusions: CALAXO screws in the tibial tunnel were more likely to be rated as degraded or partially degraded compared with MILAGRO screws at a mean of three years after implantation for ACL reconstruction. Although these newer-generation bioabsorbable screws were designed to promote osseointegration, no tunnel narrowing was noted, and in the majority of cases the remains of the screws were present at approximately three years.

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

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Bioabsorbable interference screws are used extensively in orthopaedic procedures, and they are frequently used for graft fixation in ACL (anterior cruciate ligament) reconstruction. Like titanium screws, these screws secure the ACL graft, but they offer the added potential benefits of allowing magnetic resonance imaging (MRI), decreasing stress shielding from gradual transfer of load during degradation, and theoretically minimizing the difficulty of revision surgery as

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there are no implants to remove. Numerous studies[1-6] analyzing clinical outcomes after use of bioabsorbable screws have demonstrated graft stability throughout screw resorption.

The CALAXO osteoconductive interference screw (Smith & Nephew Endoscopy, Andover, Massachusetts) was released for clinical use in August 2006. This bioabsorbable screw was composed of polylactide carbonate (PLC), an amorphous polymer consisting of 65% poly(D,L-lactic-co-glycolic acid) and 35% calcium carbonate[7,8]. It was hypothesized that this bioabsorbable material would also display osteoconductive properties, thereby providing a scaffold for new bone formation during its degradation.

The senior surgeon (K.P.S.) subsequently changed his standard practice for fixation in ACL reconstruction to use of a nonmetallic implant, in part because of his desire to later be able to use MRI to assess the development of structural markers of knee osteoarthritis in patients concurrently enrolled in a prospective longitudinal cohort study of ACL reconstruction outcomes. The CALAXO screw was chosen for its properties that would potentially result in rapid resorption, osseointegration, and MRI compatibility.

In August 2007, the CALAXO screw was removed from the market by the manufacturer because of increasing reports[8-12] of postoperative complications related to the screw degradation properties; these complications included screw swelling and prominence noted at the tibial bone tunnel used for graft fixation from two to thirty-six weeks after implantation. As a result of this development, the MILAGRO bioabsorbable screw (DePuy Synthes, Warsaw, Indiana) was used by the senior author thereafter. The MILAGRO screw, which has been available for clinical use since 2004, consists of 30% β-tricalcium phosphate and 70% poly(lactic-co-glycolic acid) (PLGA). This screw is marketed as bioabsorbable, with ossification occurring at the screw site within several years after surgery[13].

Most studies evaluating bioabsorbable screws have consisted of small, retrospective case series. There is a paucity of prospective clinical studies with sufficient sample size and/or follow-up (more than two years) to understand the absorption properties and bone tunnel reaction to these newer-generation screws. Furthermore, to our knowledge, no comparative study between these two newer-generation screws has been published previously.

The purpose of the present study was to evaluate MRI and radiographic properties and compare patient-reported outcomes at a minimum of two years after ACL reconstruction using CALAXO or MILAGRO bioabsorbable interference screws. To our knowledge, previous studies evaluating bioabsorbable screws and degradation properties following ACL surgery have consisted of case series, and this study represents the first comparative cohort in a retrospective analysis of prospectively collected data.

Materials and Methods

All patients underwent unilateral primary ACL reconstruction by the senior surgeon utilizing almost exclusively bone-patellar tendon-bone autograft (a two-incision approach utilizing 10-mm bone blocks). Fixation was performed with either the CALAXO screw (in earlier patients) or the MILAGRO screw (in later patients). All patients were prescribed the same postoperative ACL rehabilitation guidelines. The patients included in this study had sustained a unilateral ACL injury during sports, had undergone ACL reconstruction a minimum of two years earlier, had not had surgery involving the contralateral knee, and were less than thirty-six years of age. This study was designed to utilize patients returning for testing as part of a cohort study to evaluate the future risk of osteoarthritis after ACL reconstruction, and the age restriction was part of the larger study in order to minimize the presence of preexisting osteoarthritis.

Exclusion criteria included concomitant ligamentous injuries requiring surgery, simultaneous bilateral ACL reconstructions, revision ACL reconstruction at any time, and ineligibility for MRI. A small subset of the patients who underwent ACL reconstruction with CALAXO screws from August 16 to December 1, 2006, were not included in the nested cohort because of a hiatus in enrollment, and these patients were identified on the basis of the CPT (Current Procedural Terminology) code for the procedure. Forty-six patients treated with CALAXO screws were eligible for enrollment. Fourteen of these patients were identified on the basis of the CPT code. The remaining thirty-one patients treated with CALAXO screws and all eligible patients treated with MILAGRO screws had been enrolled in the cohort study with onsite follow-up at two years and were invited to participate in the present study as well. Testing was then combined with the onsite testing related to the other study. The patients treated with MILAGRO screws underwent surgery from September 2007 to October 2008 and were included in this study serially as they returned for the other testing until we reached a total of thirty-six patients, a conservative number chosen to match the number in the CALAXO group after accounting for an estimated 20% dropout. All patients completed the pain and symptom sections of the KOOS (Knee injury and Osteoarthritis Outcome Score) questionnaire at the time of the return visit for imaging.

MRI scans of all operatively treated knees were acquired at our institution with use of a Philips Achieva 3.0T instrument (Philips Medical Systems, Best, The Netherlands) with a single-channel body coil for transmission and an eight-channel knee coil for reception. Three sequences utilizing multislice turbo spin echo were used: (1) sagittal proton-density-weighted (TR/TE =2931/30 ms) without fat saturation, (2) sagittal proton-density-weighted (TR/TE = 2270/30 ms) with SPIR (spatially selective fat saturation), and (3) axial proton-density-weighted (TR/TE = 3269/30 ms) with SPIR. Only partial MRI data, sufficient for determining graft integrity, were obtained for one patient because of instrument problems, and another patient did not pass the final safety clearance for undergoing MRI and did not participate in the imaging.

Bilateral standing anteroposterior and non-weight-bearing full-extension lateral radiographs of the operatively treated knee were made. The anteroposterior view was taken with the patient standing and facing the tube with the popliteal surface of the legs against the cassette, the patella centered in the image, and the knees extended with equal weight on each foot.

Two independent reviewers, a senior orthopaedic surgery resident and an orthopaedic sports medicine fellow, evaluated the radiographs and MRI scans for features of the interference screws. Blinded digital images were analyzed with use of the Philips DICOM viewer (R2.5 version 1 level 1).

ACL graft integrity, femoral and tibial screw integrity (Fig. 1), and foreign body reactions due to the femoral and tibial screws were rated on the MRI scans (Fig. 2). ACL graft integrity was classified as "intact" or "not intact" primarily on the basis of sagittal cuts of T1-weighted images. An intact graft displayed continuity of fibers from the femoral to the tibial tunnel. The integrity of the femoral and tibial screws was classified as "degraded," "partially intact," or "intact." An intact screw displayed sharp, well-defined threads, visualized on multiple cuts on the MRI scans. A partially intact screw demonstrated blunted threads or remnants of a screw, whereas the location of a degraded screw exhibited an absence of any residual screw material. Foreign body reactions were identified as "not present," "edema," or "cyst" formation. If uniform signal comparable with that of the adjacent screw and/or bone was seen on T2-weighted images, the reaction was classified as not present. Edema was characterized by an amorphous increased signal in the bone surrounding the femoral and tibial tunnels on T2-weighted images. Increased T2 signal that exhibited a more structured, sac-like structure was classified as cyst formation.

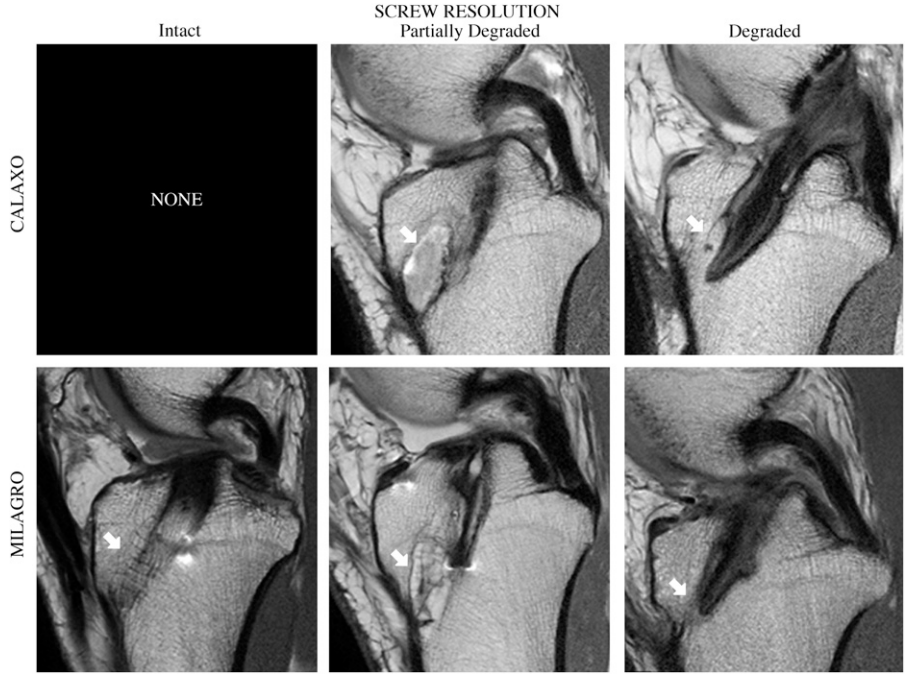

Fig. 1

Representative sagittal proton-density-weighted MRI scans without fat saturation demonstrating intact, partially degraded, and degraded screws (arrows) of each type. The upper panels show CALAXO screws and the lower panels show MILAGRO screws. There were no CALAXO screws rated as intact.

The diameters of the femoral and tibial tunnels were measured on radiographic images made with a Hologic DR instrument (Bedford, Massachusetts). The femoral tunnel diameter was calculated from the anteroposterior radiograph of the knee, and the tibial tunnel diameter was calculated from both the anteroposterior and lateral radiographs (Fig. 3). The tunnel borders were identified by an outside source on a copy of the images and printed for the

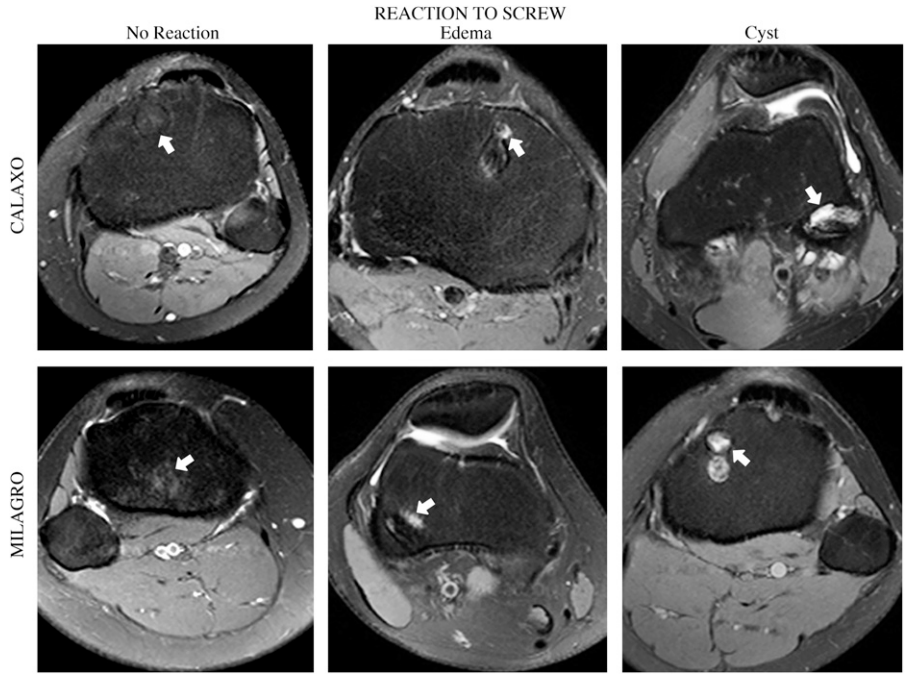

Fig. 2

Representative axial proton-density-weighted MRI scans with spatially selective fat saturation (SPIR) demonstrating no reaction, edema, and cyst formation within the tunnel in response to each type of screw. The arrows point to the reactions (or to the screws in the images without reaction). The upper panels show CALAXO screws and the lower panels show MILAGRO screws.

TABLE I Demographics*

	MILAGRO Group			CALAXO Group		
	25th Percentile	Median	75th Percentile	25th Percentile	Median	75th Percentile
Age *(yr)*	19	21	29	19	21	28
Weight *(kg)*	63	74	85	64	73	83
Height *(m)*	1.65	1.73	1.80	1.69	1.73	1.78

*The MILAGRO group was 50% male (18 M, 18 F), and the CALAXO group was 48% male (15 M, 16 F).

reviewers, and the widest diameter was measured regardless of the location of the graft bone block.

Agreement between the reviewers was assessed on the basis of the Bland-Altman agreement for tunnel width measurements and on the basis of the agreement percentage and kappa statistic for each of the remaining categorical variables. Differences between the two screw types were calculated for each reviewer independently, using Wilcoxon tests for the tunnel width variables and KOOS pain and symptom subscales and chi-square statistics for the categorical variables. All statistical analyses were performed with use of open-source R software[14].

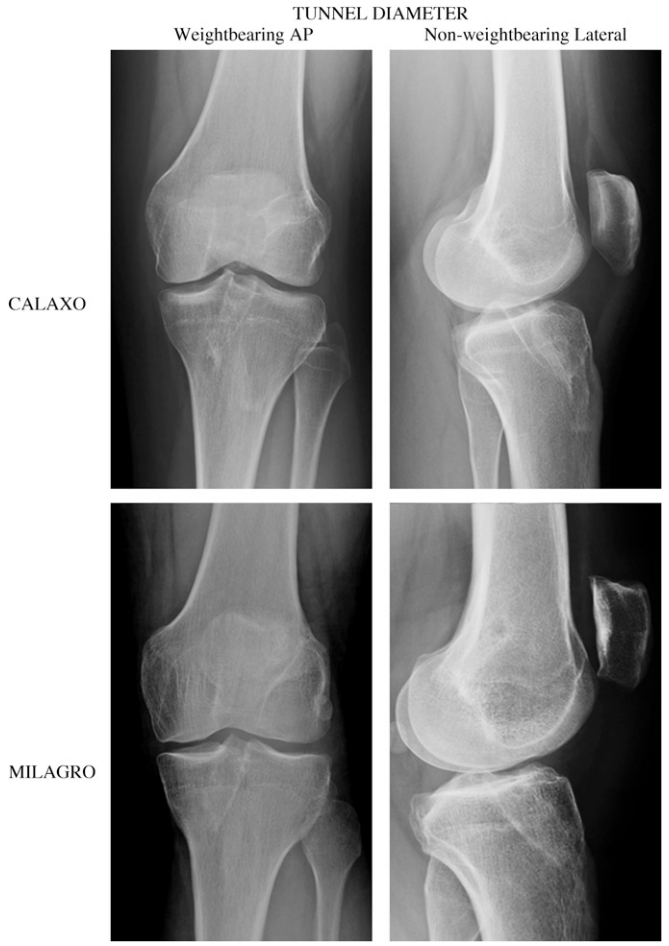

Fig. 3

Representative standing anteroposterior (AP) and non-weight-bearing lateral radiographs are shown for each type of screw. The upper panels show CALAXO screws and the lower panels show MILAGRO screws.

After the reviewers completed a tutorial explaining each property and how to consistently appraise it, ten MRI scans and four radiographs were evaluated to assess measurement reliability. Interobserver agreement on the sample images was ≥70% for the categorical variables, and the Bland-Altman limits of agreement were within approximately 2 mm for the coronal radiographic measurements. The study images were then evaluated, and each reviewer was blinded to the screw type and to the assessments of the other reviewer. An interim analysis for agreement was performed after thirty images had been assessed. Agreement was deemed acceptable for all measurements except bone block incorporation, a measurement that was then dropped, and the rest of the images were analyzed.

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Results

The overall rate of follow-up in the study was 67% in the CALAXO group and 78% in the MILAGRO group. Nine of the forty-six patients in the CALAXO group declined to participate and six could not be contacted by telephone. The remaining thirty-one patients (six of the fourteen identified on the basis of the CPT code and twenty-five [78%] of the thirty-two cohort patients) returned for additional testing and imaging studies (which yielded radiographs for all thirty-one patients and MRI scans for thirty). Twenty-eight of the thirty-one patients had received ipsilateral patellar tendon autografts, and the remaining three had received patellar tendon allografts. Fifty-four patients in the MILAGRO group met the inclusion criteria and underwent surgery in the time period covered by the study. Eight of these declined to participate and four could not be contacted by telephone. The remaining forty-two patients (78%) returned for onsite testing as part of the cohort; however, only the first thirty-six also participated in this study. All thirty-six patients in the MILAGRO group had received ipsilateral patellar tendon autografts. The mean duration of follow-up was 3.1 years (median, 3.1 years; range, 2.8 to 4.0 years) for the CALAXO implants and 2.9 years (median, 2.9 years; range, 2.5 to 3.2 years) for the MILAGRO implants.

The sex distribution, age, weight, and height were nearly identical in the two groups (Table I). Agreement between reviewers was >80% for graft integrity and for screw degradation and foreign body reaction at both femoral and tibial sites (see Appendix). The limits of agreement between reviewers were <2.9 mm for tunnel width (see Appendix).

TABLE II Categorical MRI Results According to Screw Type and Observer

	Reviewer A			Reviewer B		
	MILAGRO	CALAXO	P Value	MILAGRO	CALAXO	P Value
Tibial screws			<0.001			0.002
Degraded	3	3		3	1	
Partially intact	18	27		22	29	
Intact	14	0		10	0	
Femoral screws			0.36			0.35
Degraded	2	1		0	0	
Partially intact	31	29		34	30	
Intact	2	0		1	0	
Tibial foreign body reaction			0.29			0.37
Not present	18	21		19	18	
Edema	8	5		8	9	
Cyst	9	4		8	3	
Femoral foreign body reaction			0.98			0.87
Not present	20	17		19	17	
Edema	11	10		11	10	
Cyst	4	3		5	3	

At a minimum of two years after implantation, only a few screws in either location were completely degraded (Table II, Fig. 1). Both Reviewer A ($p < 0.001$) and Reviewer B ($p < 0.002$) found a significant difference in tibial screw degradation between the two screw types. All of the CALAXO screws at this location were at least partially degraded; in contrast, nearly one-half of the MILAGRO screws were rated as intact. There were no significant differences for the femoral screw location. There were no significant differences in foreign body reaction between screws at either location. No foreign body reaction was seen in >50% of the subjects, with the remaining subjects demonstrating either edema or cyst formation with approximately equal frequency (Table II, Fig. 2). There were no significant differences in tunnel widening between the screw types, and the median tunnel widths in the sagittal and coronal views in the two groups ranged from 10.75 to 12.40 mm (Table III, Fig. 3). Thus, clinically relevant tunnel widening did not occur in this sample of 134 bioabsorbable screws (sixty-two CALAXO and seventy-two MILAGRO) at a minimum of two years of follow-up.

No clinically important or statistically significant differences in the validated patient-reported outcomes (KOOS symptom and pain subscales) were observed between the screw types (Table III). (The minimum clinically important difference on the KOOS is 8 points.)

One patient in the MILAGRO group underwent reoperation to remove a prominent tibial screw because of pain, and

TABLE III Radiographic and KOOS Results According to Screw Type and Observer

	MILAGRO			CALAXO			
	25th Percentile	Median	75th Percentile	25th Percentile	Median	75th Percentile	P Value
Reviewer A, tunnel width *(mm)*							
Tibial coronal	10.57	11.50	12.20	10.85	12.40	13.10	0.14
Tibial sagittal	10.30	11.15	12.55	11.10	11.90	13.40	0.22
Femoral coronal	9.80	10.50	11.72	10.50	11.00	12.05	0.09
Reviewer B, tunnel width *(mm)*							
Tibial coronal	10.47	11.40	12.50	10.55	11.90	12.70	0.61
Tibial sagittal	10.28	10.90	12.48	10.40	11.90	12.95	0.36
Femoral coronal	9.40	10.75	11.55	10.05	10.90	13.00	0.25
Patient-reported outcome at min. 2 yr							
KOOS symptom	82.14	89.29	93.75	78.57	85.71	94.65	0.44
KOOS pain	91.67	97.22	97.22	88.89	94.44	100.00	0.89

a partially resorbed screw was found during the surgery. No patients in the CALAXO group underwent reoperation for screw-related complications.

Discussion

The development of cysts related to tibial fixation with bioabsorbable screws after ACL surgery is not a new finding, having been described in a previous case report and several case series. Simonian et al. previously reported on four patients with pretibial ganglion formation at a mean of forty-four months after surgery[15]. Likewise, Tsuda et al. reported a case of a multiloculated cyst arising from the tibial bone tunnel two years after surgery[16]. Victoroff et al. described four cases of cyst formation at the tibial tunnel aperture at six to twenty-nine months after surgery[17]. Gonzalez-Lomas et al. reported seven cases of foreign body reactions and cyst formation, all involving poly(L-lactic acid) (PLLA) tibial interference screw fixation, after ACL surgery. The three-year incidence in that series was 5% of 140 ACL reconstructions performed during 2003 to 2006[18].

Previous case series have employed advanced imaging to evaluate biocompatible PLLA interference screws after their use in ACL surgery. Radford et al. analyzed eight patients to assess the absorption properties of bioabsorbable PLLA interference screws (Arthrex, Naples, Florida) on MRI scans acquired at one, two, and four years postoperatively[19], and found no evidence of screw resorption at any time point. One patient developed a small cyst in the tibial tunnel, but no tunnel edema was noted in any patient. Barber and Dockery reviewed twenty patients with bioabsorbable PLLA interference screws (BioScrew; Linvatec, Largo, Florida)[20]. Computed tomography (CT) scans obtained at a minimum of seven years after surgery demonstrated that all screws had degraded completely but no bone ingrowth had occurred. Drogset et al. performed repeat MRI evaluations of PLLA screws (Linvatec) in nineteen patients at a mean of 26.5 months[21]. They reported that 16% of the femoral screws and none of the tibial screws showed osteolysis, concluding that approximately 33% of the screw volume remained in the tunnels at a mean of two years after surgery.

Because of failure of bone ingrowth after use of PLLA interference screws, manufacturers have tried incorporating various additives into the screw composition to encourage faster resorption and bone formation. Such additives include β-tricalcium phosphate, hydroxyapatite, and calcium carbonate, and previous case series have reported the resulting outcomes. Barber and Dockery followed twenty patients for a minimum of forty-four months[22]. Repeat CT scans showed the Bilok interference screws (ArthroCare Sports Medicine, Sunnyvale, California), which are composed of PLLA and β-tricalcium phosphate, to be completely resorbed, with a calcified trabecular tissue noted in place of the screws. In another case series, Johnston et al. obtained CT scans at five years postoperatively[23]. With 54% follow-up, the authors found that all of the Biosteon interference screws (Stryker, Mahwah, New Jersey), composed of hydroxyapatite-PLLA, had been resorbed and density in the screw tracks was comparable with that in the surrounding bone. Macarini et al. evaluated thirty-one patients using MRI over a forty-month period after surgery[24]. The authors found evidence of edema and cyst formation in a group of fifteen patients ten to thirteen months after implantation of hydroxyapatite-PLLA interference screws, but this resolved over time and was absent, having been replaced by fibrous tissue, on repeat MRI scans in a separate group of sixteen patients thirty to forty months after surgery. The authors concluded that cyst formation and edema in the early postoperative period did not represent an adverse reaction but rather an expected finding that resolved over time.

As noted previously, numerous studies have utilized repeat radiography, CT, and/or MRI to evaluate imaging properties of implanted screws and tunnels after ACL surgery. However, our review of the published literature identified no validation studies in which the reliability of techniques to assess screw properties was determined. Marchant et al. did evaluate twelve patients undergoing revision ACL reconstruction and assessed the reliability of various imaging modalities (radiography, CT, and MRI) by means of interobserver and intraobserver testing[25]. They found CT to be the most reliable method for identification and cross-sectional analysis of bone tunnels, with radiography and MRI being less reliable. In the present study, we did not include CT as an imaging modality because of its additional cost and radiation exposure to the study subjects. Prior to the analysis of the study group, we validated our techniques for assessing categorical variables of tunnel properties on radiographs and screw properties on MRI scans by assessing ten previous patients and calculating interobserver and intraobserver agreement. Osseointegration demonstrated poor agreement and was not included in the present study, but tunnel width measurements on radiographs were included.

The present study compared two PLGA screws containing additives to encourage bone ingrowth; the MILAGRO screws were composed of PLGA and β-tricalcium phosphate, and the CALAXO screws were composed of PLGA and calcium carbonate. On the basis of our review of the literature, this represents the largest cohort treated with these implants and followed over time to determine degradation properties using MRI and tunnel changes using radiography. Clinically, no differences were noted with respect to the KOOS pain and symptom subscales, indicating that both screw types can contribute to a stable fixation construct and patient satisfaction. On the MRI scans, the CALAXO screws appeared to lose structural integrity faster than the MILAGRO screws in the tibial tunnel, but no differences in degradation were noted in the femoral tunnels. Although the present study cannot account for the differences in screw degradation between the tibial and femoral tunnels, the surgical technique may have contributed to this finding because of possible differences involving the mean tunnel length, depth of screw placement in the bone, and soft-tissue envelope covering the tunnel. It is possible that further screw resorption might occur over time in both tibial and femoral tunnels. Although no differences in tunnel widening were found on radiographs, the clinical ramifications of this finding are unclear. Bioabsorbable screws offer the potential advantages of compatibility with repeat MRI, gradual degradation over time, and less difficulty during

revision surgery. Taking into account the results of the present study, one could argue that the lack of complete screw degradation at a mean of three years after implantation does not justify the increased cost of these screws compared with traditional titanium screws. However, the partial degradation noted could allow for simpler revision surgery, and further study is needed to answer this question.

In conclusion, this retrospective comparative study of prospectively collected data from patients evaluated with MRI, radiography, and a validated patient-reported outcome instrument revealed only one significant or clinically relevant difference between patients who had undergone ACL reconstruction utilizing CALAXO or MILAGRO screws at approximately three years after implantation. That difference involved tibial screw degradation, with MILAGRO screws being significantly more likely to be rated intact compared with CALAXO screws at three years after surgery. The two groups were otherwise similar with respect to tunnel widening on radiographs, other properties on MRI scans, and KOOS outcomes. Even though these newer-generation bioabsorbable screws were designed to promote osseous integration, no tunnel narrowing was noted, and in the majority of cases the remains of the screws were present at approximately three years.

Appendix

eA Tables summarizing the interobserver agreement for the screw results are available with the online version of this article as a data supplement at jbjs.org. ■

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