A Prospective Randomized Comparison of Bioabsorbable and Titanium Anterior Cruciate Ligament Interference Screws

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Purpose: To compare the Phantom bioabsorbable polymer interference screw (DePuy, Warsaw, IN) with a titanium metal interference screw when used in fixation of femoral and tibial bone blocks in central third bone–patellar tendon–bone autograft anterior cruciate ligament (ACL) reconstructions. **Type of Study:** Multicentered prospective randomized study. **Methods:** Two surgeons performed primary ACL reconstructions at different locations. Preoperatively, the patients were randomly assigned. One group received a titanium cannulated interference screw. The second group received the cannulated poly-L-lactic bioabsorbable Phantom screw. Data included subjective evaluation of activity level and International Knee Documentation Committee scores. Objective measures were made using the KT-1000 arthrometer (MedMetric, San Diego, CA), range of motion, presence of effusions, and complications intraoperatively or postoperatively. Measurements were made at 1 year and 2 years. Radiographic evaluation was carried out at least 2 years from the initial surgical date and interpreted by 2 independent orthopaedic surgeons. **Results:** At the 1-year follow-up (N = 97), pain was reported more during moderate activity in the Phantom screw group (6) compared with the titanium screw group (0) ($P = .03$). No statistical difference between range of motion ($P = .45$), activity level ($P = .83$), swelling with activity ($P = .95$), partial ($P = .13$) or full ($P = .31$) giving way, knee effusions ($P = .33$), or KT-1000 side-to-side difference ($P = .53$) were found. At the 2-year follow-up (N = 65), more subjects (18) in the Phantom interference screw group reported activity levels in the strenuous category compared with those in the titanium interference screws (7) group ($P = .02$). No differences were reported with respect to pain ($P = .97$), effusion ($P = .17$), partial ($P = .28$) or full ($P = .27$) giving way, swelling with activity ($P = .21$), range of motion ($P = .64$), or KT-1000 side-to-side difference ($P = .96$). Radiographic inspection showed no change in bone plug position, osteolysis, adverse effect, or complication caused by the bioabsorbable material. Some evidence of tunnel widening was seen in both groups. **Conclusions:** Use of a poly-L-lactic bioabsorbable interference screw can provide clinical results equal to that of a metal interference screw for fixation of a central third bone–patellar tendon–bone graft in ACL reconstruction. **Level of Evidence:** Level II, therapeutic. **Key Words:** Absorbable implants—Anterior cruciate ligament—Arthroscopy—Reconstructive surgical procedures.

Anterior cruciate ligament (ACL) tears are very significant and common injuries among the physically active population. Approximately 95,000 new injuries occur each year. Of these, approximately 50,000 reconstructions are performed in the United States alone. Traditionally, the gold standard graft for ACL reconstruction was considered to be the central third patellar tendon autograft.[1] This graft has excellent inherent strength, easy availability, and secure fixation obtained by bony plugs.[1] Because of its superior fixation strength, over the last decade the bony plugs have classically been fixed with interference screws.[2] These interference screws can be made of metallic or bioabsorbable materials. The fixation must remain secure for at least 6 to 8 weeks.[3] By this time, graft bone and host bone trabeculation can appear to be in continuity and biologic fixation is achieved in most cases.

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0749-8063/05/2102-3554$30.00/0

doi:10.1016/j.arthro.2004.09.012

The advantages of using metallic interference screws are that they are a proven method of solid fixation using material that has a long track record of being well tolerated by the body. The disadvantage of using metallic screws is 3-fold: (1) they can cause a laceration of the graft while being inserted,[4] (2) their potential interference with future surgery in the knee, such as revision ACL reconstruction,[5] and (3) interference with any future magnetic resonance imaging (MRI) of the knee.[6] In addition, there is the consideration of trying to avoid unneeded foreign material retained in the body.

With respect to bioabsorbable interference screws, the advantage is their disappearance after they are no longer needed. They cause no interference with imaging studies, such as a future MRI, and also would not interfere with any subsequent knee surgery. There is also no long-term foreign material retained within the body. The disadvantages associated with this type of screw are potential fracture of the implant during insertion and a potential adverse reaction to the bioabsorbable material.

The objective of this study was to compare the Phantom absorbable polymer (poly-L-lactic acid, PLLA) interference screw (DePuy, Warsaw, IN) with a titanium metal interference screw when used in fixation of femoral and tibial bone blocks in central third bone–patellar tendon–bone autograft ACL reconstructions. Our hypothesis is that the bioabsorbable interference screw will be no different than the titanium interference screw on all outcome measures.

METHODS

This study was designed as a multicenter prospective randomized study. Two surgeons were involved at 2 different locations. All patients had ACL reconstructions performed using central third patellar tendon autografts. All patients were randomized into 1 of 2 groups according to the last digit of their hospital identification number. These numbers are assigned by the hospital randomly, thus creating an equal probability that the last digit could be even or odd. If the last digit was even (0, 2, 4, 6, 8) the patient received the bioabsorbable interference screw. If the last digit was odd (1, 3, 5, 7, 9) the patient received the titanium interference screw. One group had titanium interference screws used for fixation of both sides of the graft. The second group had bioabsorbable PLLA interference screws used for fixation of both sides of their grafts. All surgeries were primary ACL reconstructions. Exclusion criteria included previous ACL or posterior cruciate ligament (PCL) reconstruction, multiple-ligament injured knees, active infection, morbid obesity, PCL insufficiency, skeletal immaturity, history of rheumatoid arthritis or gout, prior articular or patellar fractures, multiligament-injured knees, recent steroid therapy to the joint, or severe degenerative joint disease. Subjective, objective, and radiographic evaluations were performed.

The clinical data examined included evaluation of activity level as well as subjective evaluation of knee function by the patient using the International Knee Documentation Committee (IKDC) rating scale. These evaluations were reported at 1 year and at 2 years.

Objective measures were made using the KT-1000 arthrometer (MedMetric, San Diego, CA), range of motion, presence of effusions, and complications intraoperatively or postoperatively. These measurements were also reported at 1 and 2 years. Radiographic evaluation was carried out looking at anteroposterior and lateral films taken at least 2 years after the surgical date and were interpreted by 2 orthopaedic surgeons not involved in the study. These 2 surgeons independently reviewed all the radiographs and came to a mutual agreement on the reported findings.

Surgical technique differed between the 2 groups only in the material of the interference screw. Preoperatively, the patients were randomly assigned to 1 of 2 groups. One group received a titanium cannulated interference screw. The second group received the cannulated poly-L-lactic bioabsorbable Phantom screw. The bioabsorbable screws were all 7×25 mm. The titanium screws were all 7×20 mm in length. Surgical technique involved a single-incision arthroscopic technique with ipsilateral harvest of bone–patellar tendon–bone autograft and creation of 10-mm femoral and tibial tunnels. The bone plugs of the autograft were fashioned to fit snugly through a 10-mm sizing sleeve. The graft was then inserted under arthroscopic visualization and held in place using femoral and tibial interference screws. The screws were all cannulated and placed over a guide pin. All patients underwent a standardized rehabilitation protocol following the reconstructive surgery.

Student t tests and Pearson χ-square tests were used on continuous or discrete data, respectively, to determine significance of differences between the groups. Significance was set a priori at $P < .05$.

TABLE 1. *One- and Two-Year Follow-up Statistics*

		1-Year Follow-up			2-Year Follow-up		
		Phantom Screw (%)	Titanium Screw (%)	*P* Value	Phantom Screw (%)	Titanium Screw (%)	*P* Value
Activity level	Strenuous	49.0	44.7		58.1	20.6	
	Moderate	29.4	25.5		25.8	44.1	
	Light	13.7	19.1		16.1	29.4	
	Sedentary	7.8	10.6	.830	0.0	5.9	.015*
Pain with activity	Strenuous	86.7	97.6		86.2	88.2	
	Moderate	13.3	0.0		10.3	8.8	
	Sedentary	0.0	2.4	.031†	3.4	2.9	.971
Swelling with activity	Strenuous	97.7	97.5		89.3	97.0	
	Moderate	2.3	2.5		3.6	0.0	
	Light	0.0	0.0		0.0	3.0	
	Sedentary	0.0	0.0	.946	7.1	0.0	.214
Partial giving way	Strenuous	23.3	33.3		96.7	100.0	
	Moderate	14.0	28.6		3.3	0.0	
	Light	46.5	31.0		0.0	0.0	
	Sedentary	16.3	7.1	.125	0.0	0.0	.283
Full giving way	Strenuous	97.6	100.0		96.4	100.0	
	Moderate	2.4	0.0	.309	3.6	0.0	.267
Effusion	None	98.0	100.0		83.3	94.1	
	Mild	2.0	0.0	.330	16.7	5.9	.168

*Two-year follow-up activity level significantly different between Phantom and titanium screws, $P < .05$.
†One-year follow-up pain with activity significantly different between Phantom and titanium screws, $P < .05$.

RESULTS

One-Year Follow-up

Ninety-seven patients with 1 year or more of follow-up made up the study group. A total of 48 patients had bioabsorbable interference screws for fixation and 49 patients had titanium metal cannulated interference screws for fixation. There were 65 men (32 bioabsorbable, 33 titanium) and 32 women (16 bioabsorbable, 16 titanium). Their average age at time of surgery was 26.9 years.

Preoperatively, there was no statistical difference between the 2 groups with respect to age, gender, time from injury to surgery, range of motion, activity level, or subjective knee function.

Postoperatively, there was no statistical difference between groups in range of motion, activity level, or knee function. There was also no difference between the 2 groups in the presence of an early postoperative knee effusion. The 1-year evaluation for knee effusions also showed no difference between the 2 groups. No difference was shown by the KT-1000 scores, which were reported as side-to-side differences. Additionally, scores were evaluated to identify between groups any difference in success versus failure rates. Criteria for failure was set as a side-to-side difference ≥ 4 because, traditionally, a KT-1000 side-to-side difference of 0 to 3 mm has been considered good or excellent. Both groups had similar failure rates (Phantom screw, 20.7%; titanium screw, 14.3%; $P = .53$). All statistical information can be found in Tables 1 and 2.

Two-Year Follow-up

A total of 65 patients (33% were lost to follow-up) had a minimum of 2-year follow-up; 31 had Phantom interference screws placed and 34 had titanium interference screws placed. The participating population included many young, active college-aged students who moved with no forwarding address, thus making it impossible to track all at 2 years. There were 43 men and 22 women (average age, 26.9 years) available for a 2-year follow-up. There was no change in bone plug position or osteolysis seen in either group. No radiographic evidence of significant adverse effect or complication caused by the bioabsorbable material was detected. Some evidence of tunnel widening was seen in both types of screws.

More subjects (18) who had Phantom interference screws placed reported activity levels in the strenuous category when compared with the subjects who had

Table 2. *Objective Test Results One and Two Years Postoperatively*

	1-Year Follow-up			2-Year Follow-up		
	Phantom Screw (mean ± SD)	Titanium Screw (mean ± SD)	*P* Value	Phantom Screw (mean ± SD)	Titanium Screw (mean ± SD)	*P* Value
KT-1000 (side-to-side diff)	1.3 ± 2.7	0.6 ± 1.8	.28	1.0 ± 3.0	0.7 ± 2.9	.73
KT-1000 (% failure rate)	20.1 ± 7.5	14.3 ± 6.6	.53	16.7 ± 10.7	17.4 ± 7.9	.96
ROM flexion limit*	127.9 ± 38.8	121.2 ± 47.8	.45	139.2 ± 4.9	138.7 ± 5.4	.64
ROM hyperextension limit*	2.3 ± 3.3	3.4 ± 4.1	.17	2.1 ± 2.4	3.8 ± 2.7	.02

*Measurement in degrees.

titanium interference screws placed (7). No differences were reported with respect to pain, swelling, partial or full giving way, effusion, or range of motion. The KT-1000 scores, reported as side-to-side differences showed no difference. The Phantom screw group showed a failure rate of 16.7% and the titanium screw group showed a failure rate of 17.3%. The difference between groups was not significant ($P = 0.96$). All statistical information can be found in Tables 1 and 2.

Complications

There were 10 effusions that required aspirations in the early postoperative period. Six of these were in the bioabsorbable group and 4 were in the metal group. This was not statistically significant. There was an average of 41 mL of serosanguineous fluid aspirated. There were 2 infections (1 bioabsorbable, 1 titanium) and 1 deep peroneal nerve palsy, which resolved on its own. There was no screw breakage on insertion.

DISCUSSION

It is well accepted that, immediately after surgery, the weakest part of the ACL graft is the fixation site.[2] Bioabsorbable screws have been found to provide initial fixation strength comparable to that of traditional metal screws. Rupp et al.[7] compared the initial fixation strength of 3 different bioabsorbable screws and compared them with a titanium screw. All screws withstood more than the 200-N forces believed to be placed on the graft during accelerated rehabilitation.[7] Cyclic loading tests also support the statement that bioabsorbable screws are as strong as traditional metal screws.[8] Our study is in line with these mechanical studies as we had no early complications associated with graft fixation failure.

Poly-L-lactic acid has a resorbable half-life of approximately 6 months.[9] Complete reabsorption should take place in approximately 3 to 5 years.[10] This long resorbable half-life has several clinical advantages over the more rapid resorption of other resorbable polymers. First, this allows the screw to retain its fixation strength until well after biologic healing is complete.[11] Second, there is a very gradual decline of strength over time, which allows for a similar slow decrease in stress shielding that is transferred to the biologic healing process. This successful transfer of fixation to biologic incorporation is confirmed by our 1- and 2-year results that show persistent good stability. No loss of stability over time was reported in either of the study groups. KT-1000 testing and subjective reports show positive results for both the Phantom screw and the titanium screw.

A third advantage of the slow resorption of PLLA is its low rate of inflammatory reactions. This is in distinct contrast to polyglycolic acid (PGA), which has a rapid resorption rate. Bostman and Pihlajamaki[4] found that 107 of 2,037 patients (5.3%) who received a PGA implant had a clinically significant foreign-body reaction. Conversely, only 1 in 491 patients (0.2%) who received a PLLA implant had a similar reaction.[4] This low incidence of inflammatory reaction is likely due to the slower rate of degradation. The incidence of mild effusion in the present study is consistent with past research and was not found to be statistically significant.

A potential complication associated with using bioabsorbable screws is occasional breakage during insertion. Various studies report no screw breakage,[12] 2 of 32,[13] to 12 of 103.[14] Overall, the risk is minimal and poses no increase in risk to the patient. No screw breakage was reported in our study.

Clinical advantages of PLLA screws are that they are bioabsorbable and are degraded into nontoxic products. A local sterile inflammatory reaction is not

associated with PLLA. These screws do not interfere with any imaging studies, such as an MRI. PLLA screws should present a minor interference with any future surgery, although this was not studied in this present series. These advantages, coupled with few and minor complications, make PLLA interference screws a safe, reliable way to fix a central third bone–patellar tendon–bone autograft in ACL reconstruction.

CONCLUSION

Use of a PLLA bioabsorbable interference screw can provide clinical results equal to that of a metal interference screw when used for fixation of a central third bone–patellar tendon–bone graft in an ACL reconstruction.

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