Bioabsorbable Versus Titanium Interference Screws With Hamstring Autograft in Anterior Cruciate Ligament Reconstruction: A Prospective Randomized Trial With 2-Year Follow-up

Peter Myers, M.B.B.S., F.R.A.C.S., F.A.Orth.A.,
Martin Logan, M.B.Ch.B., M.R.C.S., M.D., F.R.C.S.(Tr&Orth),
Andy Stokes, M.B.B.S., F.R.A.C.S.(Tr&Orth), Kevin Boyd, M.B.B.S., F.R.C.S.(Tr&Orth),
and Mark Watts, B.Sc.App.H.M.S.(Ex-Sc), M.Phil.

Purpose: The purpose of this study was to prospectively assess the outcome of hamstring autograft anterior cruciate ligament (ACL) reconstruction by use of identically shaped bioabsorbable and titanium interference screws in a randomized trial. **Methods:** One hundred patients were randomized to have either bioabsorbable or titanium interference screws used for graft tunnel fixation in hamstring autograft ACL reconstruction. Patients were objectively and subjectively assessed preoperatively and 3, 6, 12, and 24 months postoperatively. Radiographs at 12 months postoperatively were also assessed for tunnel width. **Results:** There were no differences in clinical outcome by use of Lysholm and International Knee Documentation Committee scores between the 2 groups at any stage of follow-up to 2 years. Tibial tunnel widths were the same between the 2 groups. There was slightly more tunnel widening in the femur when bioabsorbable interference screws were used. **Conclusions:** Identically shaped bioabsorbable interference screws and titanium interference screws used for hamstring autograft ACL reconstruction are equally successful up to 2 years postoperatively. **Level of Evidence:** Level I, prospective randomized trial with more than 80% follow-up. **Key Words:** Anterior cruciate ligament—Interference screws—Hamstring autograft—Bioabsorbable.

Interference screws have been successfully used for graft fixation in anterior cruciate ligament (ACL) reconstruction by use of both patellar tendon and hamstring autografts.[1] Traditionally, interference screws have been metallic—steel or titanium—but, more recently, bioabsorbable materials such as poly-L-lactic acid have become available. Animal studies[2] and human case reports[3] emphasize the relative redundancy of interference screws as early as 12 weeks postoperatively, and hence a bioabsorbable material is an attractive option, provided that the fixation of graft to bone is adequate. The shape and mechanical aspects of the interference screw are integral to its capacity to achieve adequate fixation strength without damage to the graft. It remains unclear whether it is the shape or the material of the screw that is the critical factor in providing graft-bone fixation.

We present a prospectively randomized study of 2 groups of patients who underwent 4-strand hamstring autograft ACL reconstruction using either titanium

From the Brisbane Orthopaedic and Sports Medicine Centre (P.M., M.L., A.S., K.B., M.W.), Brisbane Private Hospital, Brisbane, Australia, and the Institute of Health and Biomedical Innovation (M.W.), Queensland University of Technology, Brisbane, Australia.

M.W. was partially funded for this project by Smith & Nephew. The authors report no conflict of interest.

Received November 7, 2007; accepted February 17, 2008.

Address correspondence and reprint requests to Martin Logan, B.Sc., M.B.Ch.B., M.R.C.S., M.D., F.R.C.S.(Tr&Orth), Brisbane Orthopaedic and Sports Medicine Centre, Brisbane Private Hospital, 259 Wickham Terr, Brisbane QLD 4000, Australia. E-mail: martinlogan@doctors.net.uk

0749-8063/08/2407-7564$34.00/0
doi:10.1016/j.arthro.2008.02.011

(RCI; Smith & Nephew, Andover, MA) or bioabsorbable hydroxyapatite poly-L-lactic acid (HA-PLLA) composite (RCI; Smith & Nephew) interference screws for both tibial and femoral tunnel fixation. Both screws have an identical shape, and the purpose of our study was to prospectively compare the outcomes of both types of screws in a randomized trial. Our hypothesis was that bioabsorbable screws would be as effective as titanium screws in terms of patient outcome and radiographic features.

METHODS

Between February 2002 and January 2005, 114 patients awaiting ACL reconstruction agreed to participate and were recruited into the study. Ethical committee approval was obtained. At the time of screw insertion, patients were assigned by use of block randomization with consecutively numbered sealed envelopes to receive either titanium or bioabsorbable (HA-PLLA) interference screws for both tibial and femoral tunnel graft fixation. All interference screws were identical in shape and size (7 × 25 mm), having blunt threads to reduce the risk of graft laceration and large round heads to optimize aperture fixation of the graft in the bony tunnels. The surgical technique using arthroscopically assisted single-incision 4-strand hamstring autograft (gracilis/semitendinosus) was the same for all patients, differing only in the type of interference screw used. Femoral tunnels were prepared in a standard fashion through the anteromedial portal in all cases. Size 7 screws were used in all tunnels because we believe this size is more than adequate for graft fixation in both the femur and the tibia, as also used by other authors,[1] and it would allow meaningful comparison of tunnel sizes in all patients. We routinely leave the hamstring graft attached to its insertion on the pes anserinus, providing further fixation to the tibia. Grafts were manually tensioned at 15° of flexion. Meniscal sutures were placed by an inside-out technique with No. 2 monofilament sutures. All operations were performed by the senior author.

Exclusion criteria were skeletal immaturity, multiligament injury, contralateral knee ligament injury, previous knee ligament surgery, and advanced degenerative joint disease (Outerbridge grade IV).

Patients were assessed preoperatively and at 3, 6, 12, and 24 months postoperatively. Assessment included clinical examination, instrumented laxity tests (Rolimeter; Aircast, Vista, CA), and knee function scores (Lysholm and International Knee Documentation Committee [IKDC]). The Rolimeter has been previously validated compared with the KT-1000 arthrometer (MEDmetric, San Diego, CA).[4] The clinical assessors were blinded to the type of interference screw used in each case. All patients underwent the same standard closed-chain rehabilitation program aiming for return to contact sports at 9 months postoperatively.

Radiographic analysis of standard anteroposterior and lateral films was undertaken at 12 months postoperatively and consisted of assessment of graft tunnel widths (tibial and femoral) in each group (Fig 1). Assessment of bone tunnel widths by this method has previously been validated with computed tomography[5]; the assessor was blinded to the clinical outcome in each case.

Statistical analysis was performed with SPSS software, version 13.0 (SPSS, Chicago, IL). An ad hoc power analysis was performed, estimating that a minimum of 80 patients (40 in each group) would be required for the study. A power of 0.8 was accepted. The Student t test was used to compare the 2 groups. $P < .05$ was accepted as being statistically significant. Odds ratios were also used to quantify effect size between the 2 groups.

RESULTS

We originally recruited 114 patients into the study. Complete data were available for 100 patients who were randomized to either titanium or HA-PLLA RCI screws, with 50 patients in each group. The mean age of the patients receiving the titanium screws was 30.7 ± 9.3 years, with that in the HA-PLLA group being 29.6 ± 9.4 years. Table 1 summarizes the patient details and the surgical procedures, which were similar in both groups in terms of tourniquet time, concomitant meniscal surgery, and bone tunnel diameters.

One patient in the HA-PLLA group sustained breakage of the screw head during insertion; this titanium screw was overdrilled, and the patient was excluded from the study. There were 2 ruptures of autograft, 1 in each group, occurring at 6 months in the HA-PLLA group (bodysurfing) and at 14 months in the titanium group (soccer).These 2 patients were excluded from the final analysis. One patient had persistent swelling postoperatively and was subsequently diagnosed with systemic lupus erythematosus and excluded. A further 10 patients failed to attend the follow-up assessment. Therefore 50 patients were prospectively randomized into each group receiving ei-

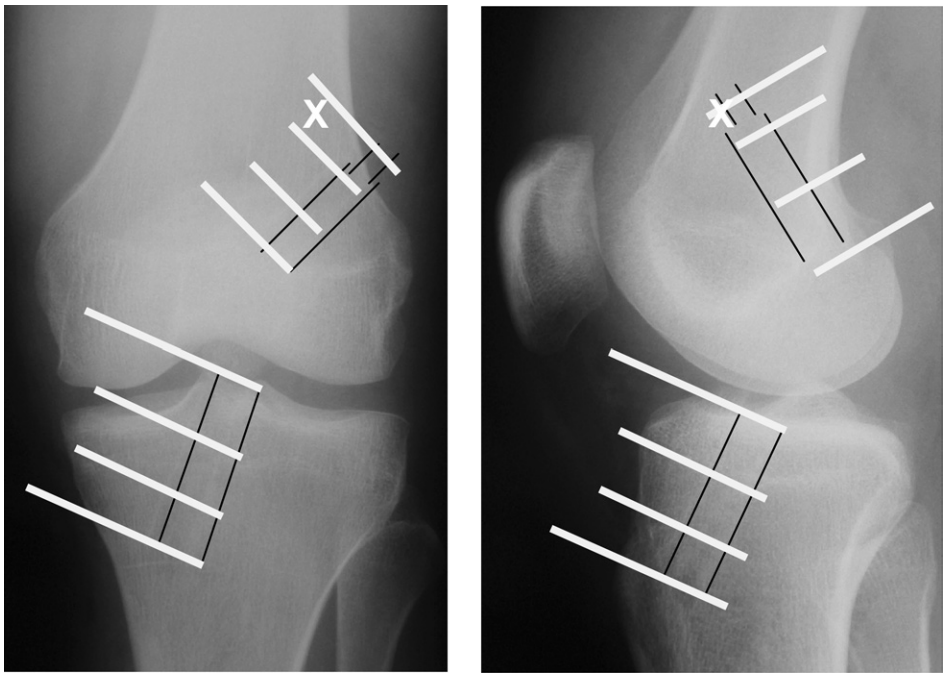

Figure 1. The sclerotic margins of each tunnel were measured in 3 zones in the tibia (proximal, middle, and distal) and 2 zones in the femur (middle and distal) with a vernier caliper. Measurements were made on both anteroposterior and lateral digital radiographs for all patients in each group. Webster et al.[5] previously showed that plain radiographs were satisfactory for assessment of tunnel width. X, marks proximal part of the femoral tunnel not measured in this study.

ther titanium or HA-PLLA interference screws for both tibial and femoral tunnels during ACL reconstruction.

Scoring Systems

At 24 months postoperatively, the mean Lysholm scores were 91.7 in the titanium group and 90.5 in the HA-PLLA group. The IKDC scores were also very similar at 24 months: 85.2 and 87.5, respectively. As shown in Figures 2 and 3, there were no significant differences by use of the IKDC and Lysholm scores between the 2 groups of patients throughout the follow-up period to 2 years. Specifically, by use of the IKDC scores, there were no differences regarding effusion, range of motion, or instrumented laxity between the 2 groups. No statistically significant differences were identified in the individual components of both the Lysholm and IKDC scores. Figure 4 shows no statistical significance in the sagittal laxity of the 2 groups studied in our trial, emphasizing the success of both screws.

Looking at the pivot-shift test in both patient groups compared with the contralateral normal knees, we found no difference postoperatively using either the titanium or HA-PLLA screw (Fig 5).

Tunnel Widths

Tibial tunnel widths at each of the proximal, middle, and distal measurement points were similar in

Table 1. *Summary of Patients and Operative Procedures*

	Titanium	HA-PLLA
No. of Patients	50	50
M/F	50%/50%	66%/34%
Age (yr) (mean ± SD)	30.7 ± 9.3	29.6 ± 9.4
Right side/left side (%)	60%/40%	56%/44%
Median time between injury and surgery (mo)	5.0	6.0
Tourniquet time (min) (mean ± SD)	64.8 ± 20.5	61.8 ± 13.4
No. of deranged menisci (repaired/resected)	31 (62%/38%)	31 (42%/58%)
Femoral tunnel drill diameter (mm) (mean ± SD)	7.5 ± 0.5	7.6 ± 0.5
Tibial tunnel drill diameter (mm) (mean ± SD)	7.5 ± 0.5	7.7 ± 0.5

NOTE: There were no significant differences between the 2 groups.

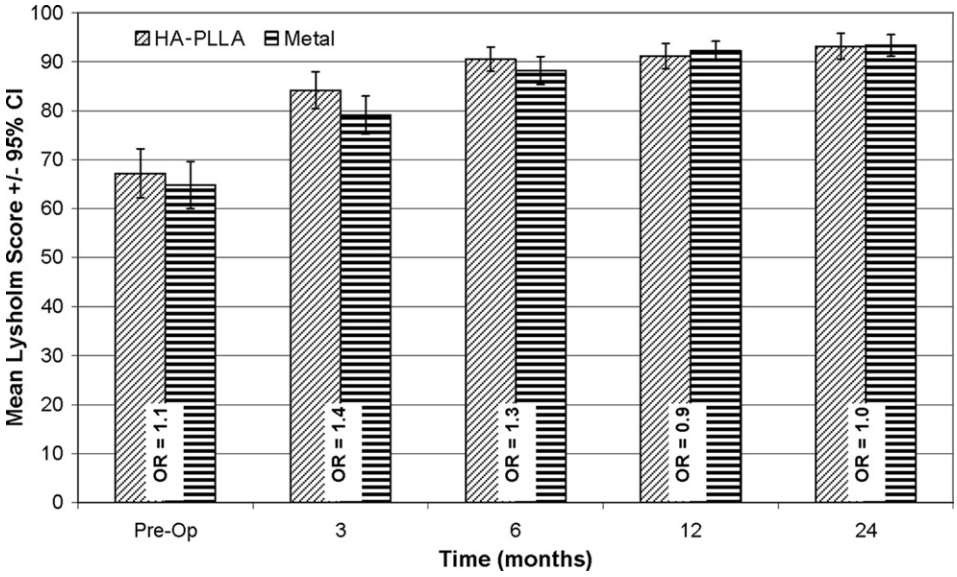

Figure 2. Comparison of IKDC scores between the 2 groups. The scores were similar between the 2 groups throughout the follow-up period of 24 months. (Pre-Op, preoperatively; OR, odds ratio; CI, confidence interval.)

both groups. The middle femoral tunnel measurement was different in the 2 groups, with the HA-PLLA tunnels being wider on both anteroposterior ($P = .05$) and lateral ($P = .003$) films (Fig 6). The distal femoral tunnel sizes were similar in both groups.

DISCUSSION

Interference screws provide a stable construct to allow graft-to-bone healing. To our knowledge, this is the first prospectively published series comparing identically shaped and sized bioabsorbable interference screws with metal interference screws by use of 4-strand hamstring autograft for ACL reconstruction. The possible advantages of a bioabsorbable screw include potentially easier revision surgery, minimal interference with future imaging such as magnetic resonance imaging, and the theoretically reduced risk of late hematogenous infection to metal. Previous publications using bioabsorbable interference screws with bone–patellar tendon–bone autograft have shown conflicting results, with similar outcomes to metal screws in one series[6] and inferior results in another.[7] Bone-to-bone healing should theoretically be quicker

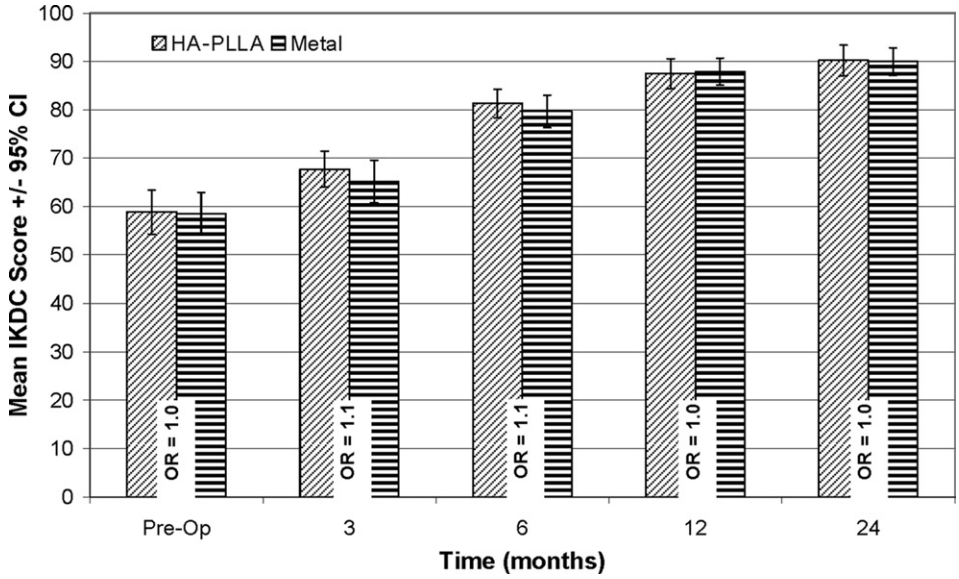

Figure 3. Comparison of Lysholm scores between the 2 groups. The scores were similar between the 2 groups throughout the follow-up period. (Pre-Op, preoperatively; OR, odds ratio; CI, confidence interval.)

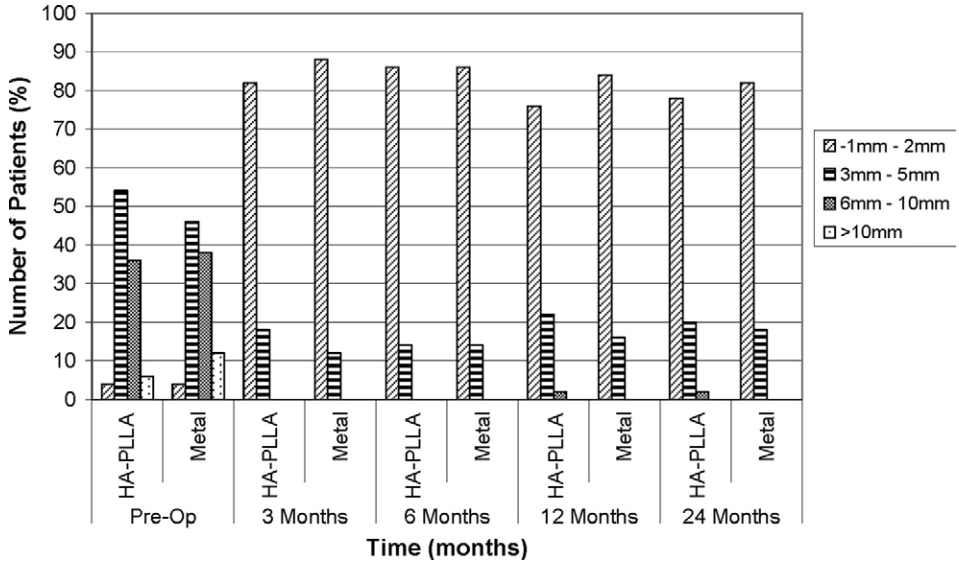

FIGURE 4. Side-to-side difference (between ipsilateral reconstructed ACL and contralateral normal knee as control) in sagittal laxity results by use of Rolimeter in both groups of patients, showing reduction of anteroposterior laxity after ACL reconstruction throughout follow-up period of 24 months. (Pre-Op, preoperatively.)

and more predictable than tendon-to-bone healing. Therefore adequate and reliable fixation of graft to bone by use of hamstring autograft is an essential component of the procedure and depends, at least in part, on stability provided by the interference screws. This stability is determined by the mechanical shape of the screw. A recent study using a bovine knee model suggested that bioabsorbable poly-D,L-lactide screws were superior to titanium screws for soft-tissue graft fixation in terms of stiffness, yield load, and maximum load.[8] Two studies have shown equal pull-out strengths of titanium versus bioabsorbable RCI screws.[9,10] Both Zantop et al.[8] and Brand et al.[9] suggested that bioabsorbable screws, being materially softer than titanium, were less likely to lacerate the soft-tissue graft during insertion. Our study emphasizes the success of both titanium screws and HA-PLLA screws in vivo in terms of functional outcome and a low rate of graft rupture. There were no cases of graft injury during insertion of interference screws in our study. A potential disadvantage of bioabsorbable screws is screw fracture during insertion, which occurred in only 1 patient in our series.

The perceived advantages of bioabsorbable screws resorbing and being replaced with bone have yet to be convincingly shown in vivo. Although some investi-

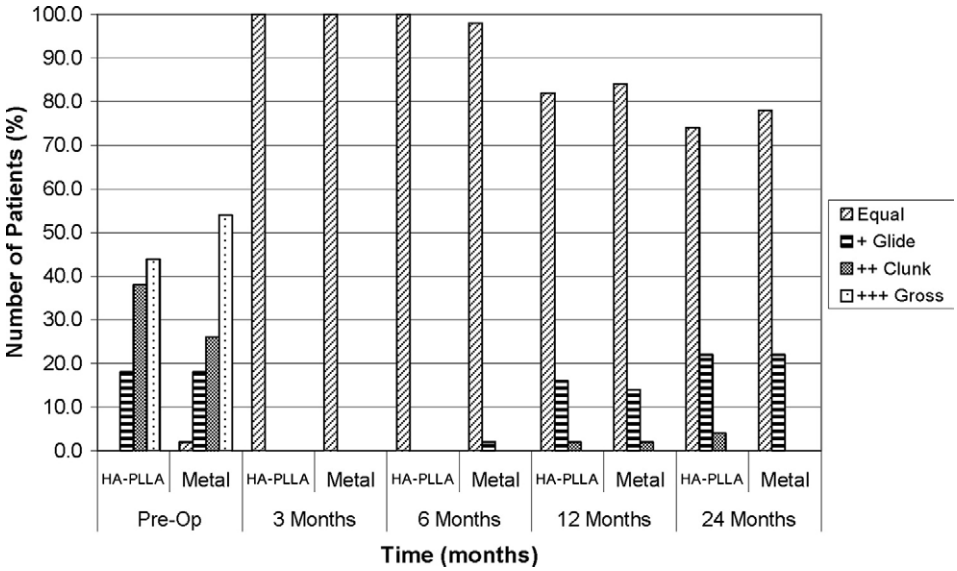

FIGURE 5. Results of pivot-shift test in both groups compared with contralateral normal knee. There is no difference postoperatively for the titanium or HA-PLLA group. (Pre-Op, preoperatively.)

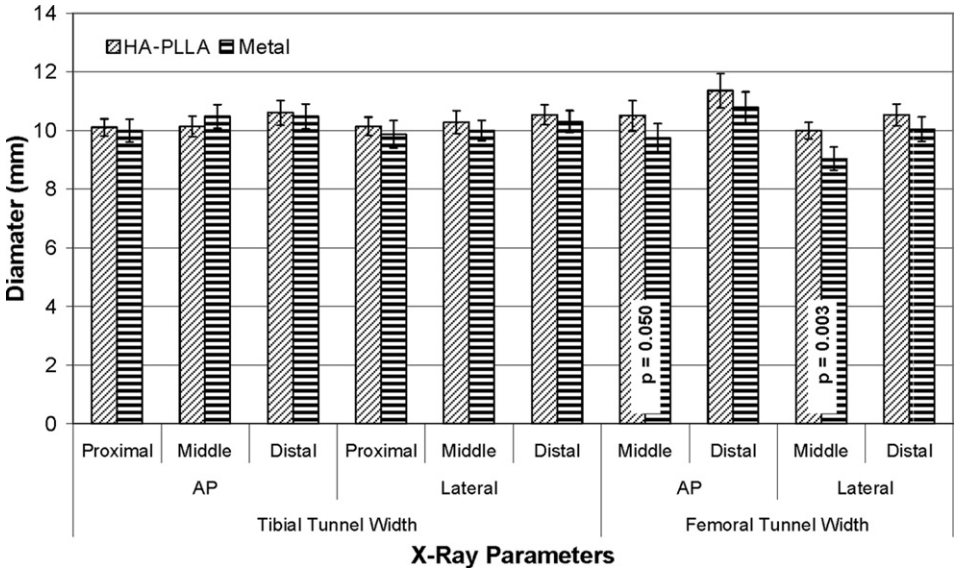

FIGURE 6. Comparison of tibial and femoral tunnel widths between 2 groups. As indicated by the *P* values, the middle section of the femoral tunnels was slightly wider in the bioabsorbable screw population. (AP, anteroposterior.)

gators have found screw dissolution and even new bone formation at the site of polylactic acid/polyglycolic acid bioabsorbable screw placement,[11] others have found no evidence of screw resorption up to 4 years postoperatively[12] and no evidence of new bone formation in the tunnels.[13] Indeed, a recent case report with 10-year follow-up magnetic resonance imaging scans showed that all cases had intraosseous cysts with resorption of the biodegradable screws but no new bone formation resulting in a possible stress riser.[14] Therefore it is questionable whether revision surgery would be easier with bioabsorbable screws. HA-PLLA screws are also significantly more expensive than titanium screws. We believe that the shape of the interference screw is the most important factor for graft-bone stability rather than the actual material property of the screw.

Synovitis with biodegradable implants has been reported.[15-17] This was not a problem in our series; however, we accept that our study had only 2 years' follow-up, and therefore very little degradation of HA-PLLA screws had probably occurred up to that point.

In our study the femoral tunnels in the HA-PLLA group were statistically wider in the middle zone compared with the titanium group (by 1 mm). There was, however, no difference in terms of clinical outcome between the 2 groups. We are unsure as to the significance of this finding. Hydroxyapatite coating of the screws has been shown to reduce tunnel wall sclerosis.[18] Perhaps this factor could explain our findings by apparently increasing tunnel width compared with tunnels with titanium screws, which have a more sclerotic appearance. In addition, the most important area for graft fixation is at the aperture of the tunnel, and this was not different between the 2 groups.

Our study is limited, however, in that follow-up is only to 2 years and we used only 2 different types of screw material and only 1 design of screw.

CONCLUSIONS

Our study has convincingly demonstrated the success of identically shaped bioabsorbable and titanium interference screws using hamstring autograft for ACL reconstruction up to 2 years. The shape of the RCI screws worked very successfully in our series in providing graft-tunnel fixation.

REFERENCES

1. Pinczewski LA, Lyman J, Salmon LJ, Russell VJ, Roe J, Linklater J. A 10-year comparison of anterior cruciate ligament reconstructions with hamstring tendon and patellar tendon autograft: A controlled, prospective trial. *Am J Sports Med* 2007;35:564-574.
2. Weiler A, Hoffmann RFG, Bail HJ, Rehm O, Sudkamp NP. Tendon healing in a bone tunnel. Part II. *Arthroscopy* 2002; 18:124-135.
3. Logan M, Williams A, Myers P. Is bone tunnel osseointegration in hamstring tendon autograft anterior cruciate ligament reconstruction important? *Arthroscopy* 2003;19:E1-E3.
4. Schuster AJ, McNicholas MJ, Wachtl SW, McGurty DW, Jakob RP. A new mechanical device for measuring anteroposterior knee laxity. *Am J Sports Med* 2004;32:1731-1735.

5. Webster KE, Feller JA, Elliott J, Hutchison A, Payne R. A comparison of bone tunnel measurements made using computed tomography and digital plain radiography after anterior cruciate ligament reconstruction. *Arthroscopy* 2004;20:946-950.
6. Kaeding C, Farr J, Kavanaugh T, Pedroza A. A prospective randomized comparison of bioabsorbable and titanium anterior cruciate ligament interference screws. *Arthroscopy* 2005;21:147-151.
7. Drogset JO, Grontvedt T, Tegnander A. Endoscopic reconstruction of the anterior cruciate ligament using bone-patellar tendon-bone grafts fixed with bioabsorbable or metal interference screws: A prospective randomized study of the clinical outcome. *Am J Sports Med* 2005;33:1160-1165.
8. Zantop T, Weimann A, Schmidtko R, Herbort M, Raschke MJ, Petersen W. Graft laceration and pullout strength of soft-tissue anterior cruciate ligament reconstruction: In vitro study comparing titanium, poly-D,L-lactide, and poly-D,L-lactide-tricalcium phosphate screws. *Arthroscopy* 2006;22:1204-1210.
9. Brand JJC, Nyland J, Caborn DNM, Johnson DL. Soft-tissue interference fixation: Bioabsorbable screw versus metal screw. *Arthroscopy* 2005;21:911-916.
10. Weiler A, Windhagen HJ, Raschke MJ, Laumeyer A, Hoffmann RFG. Biodegradable interference screw fixation exhibits pull-out force and stiffness similar to titanium screws. *Am J Sports Med* 1998;26:119-128.
11. Lajtai G, Schmiedhuber G, Unger F, et al. Bone tunnel remodeling at the site of biodegradable interference screws used for anterior cruciate ligament reconstruction. *Arthroscopy* 2001;17:597-602.
12. Radford MJ, Noakes J, Read J, Wood DG. The natural history of a bioabsorbable interference screw used for anterior cruciate ligament reconstruction with a 4-strand hamstring technique. *Arthroscopy* 2005;21:707-710.
13. Bach FD, Carlier RY, Elis JB, et al. Anterior cruciate ligament reconstruction with bioabsorbable polyglycolic acid interference screws: MR imaging follow-up. *Radiology* 2002;225:541-550.
14. Warden WH, Chooljian D, Jackson WD. Ten-year magnetic resonance imaging follow-up of bioabsorbable poly-L-lactic acid interference screws after anterior cruciate ligament reconstruction. *Arthroscopy* 2008;24:370.e1-370.e3. Available online at www.arthroscopyjournal.org.
15. Bostman O, Hirvensalo E, Makinen J, Rokkanen P. Foreign-body reactions to fracture fixation implants of biodegradable synthetic polymers. *J Bone Joint Surg Br* 1990;72:592-596.
16. Friden T, Rydholm U. Severe aseptic synovitis of the knee after biodegradable internal fixation. A case report. *Acta Orthop Scand* 1992;63:94-97.
17. Weiler A, Helling HJ, Kirch U, Zirbes TK, Rehm KE. Foreign-body reaction and the course of osteolysis after polyglycolide implants for fracture fixation: Experimental study in sheep. *J Bone Joint Surg Br* 1996;78:369-376.
18. Robinson J, Huber C, Jaraj P, Colombet P, Allard M, Meyer P. Reduced bone tunnel enlargement post hamstring ACL reconstruction with poly-L-lactic acid/hydroxyapatite bioabsorbable screws. *Knee* 2006;13:127-131.