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Bioabsorbable versus Titanium Screws in Anterior Cruciate Ligament Reconstruction Using Hamstring Autograft : A Prospective Double Blinded Randomized Controlled Trial with 5 Year Follow-up.

Yuval Arama, Lucy J. Salmon, Kesavan Sri-Ram, James Linklater, Justin P. Roe, and Leo A. Pinczewski

Study performed at North Sydney Orthopaedic and Sports Medicine Centre

Abstract:

Background: Longer term studies of bioabsorbable screws for ACL reconstruction are reported, but results are specific to the exact screw material and design. Titanium and PLLA-HA screw outcomes have been compared only to 2 years.

Purpose: The aim of this study was to compare the clinical and radiological outcomes of PLLA-HA screw (BS) versus a titanium screw (TS), for hamstring tendon anterior cruciate ligament reconstruction over 5 years. We hypothesized that there are no differences in clinical scores, and tunnel widening, between the BS and the TS groups, and that the PLLA-HA screw as seen on MRI should show high grade resorption and ossification response over 5 years.

Methods: 40 patients undergoing ACLR were randomized to receive either a PLLA-HA screw (BS group) or a Titanium screw (TS group) for ACL fixation. Blinded evaluation was performed at 2 & 5 years with IKDC & Lysholm knee score, KT-1000 arthrometer, single legged hop test, and MRI to evaluate tunnel and screw volumes, peri-screw ossification, graft integration and cyst formation.

Results: There was no difference in any clinical outcome measure at 2 or 5 years between the 2 groups. At 2 years, the BS femoral tunnel was smaller than the TS tunnel ($p=0.02$) and at 5 years, there was no difference. At 2 years the femoral BS screw was a mean 76% of its original volume and by 5 years, 36%. At 2 years the tibial BS screw mean volume was 68% of its original volume and by 5 years, 46%. At 5 years BS group 88% of femoral tunnels and 56% of tibial tunnels demonstrated a significant ossification response. There was no increase in cyst formation in the BS group and no screw breakages.

Conclusion: Our study has shown equivalent clinical results between BS and TS groups at 2 and 5 years. This PLLA-HA screw was not associated with increased tunnel widening or cyst formation when compared with the titanium screw. The PLLA-HA screw demonstrated progressive screw resorption and gradual, but incomplete ossification over 5 years.

What is known about the subject: Previous studies comparing bioabsorbable and titanium screws have shown no significant differences with respect to subjective assessments or clinical examination. Bioabsorbable screws have been associated with femoral tunnel widening, knee effusion and screw breakage, but outcomes are specific to the screw material. The outcome of ACL reconstruction comparing a PLLA-HA screw to a titanium screw with MRI over 5 years has not previously been reported.

What this study adds to existing knowledge: This is the first study to report the 5 year clinical and imaging outcomes of a PLLA-HA screw compared to a titanium screw.

Introduction:

Anterior cruciate ligament reconstruction (ACLR) using four stranded ipsilateral hamstrings autograft is a commonly performed procedure, with documented long term excellent results in term of laxity, activity level, function, symptoms, and patient satisfaction. Aperture fixation by bioabsorbable (BS) or titanium (TS) interference screws, during hamstrings (HT) anterior cruciate ligament reconstruction is a well-established technique which allows accelerated rehabilitation[3, 4, 11, 16, 20]. Although metallic interference screws (TS), and bioabsorbable screw (BS) have shown to have the same fixation strength[13], metallic screws have been associated with graft damage[24], hinder subsequent MRI examination due to their ferromagnetic qualities and artifacts[21] , and potentially need to be removed in revision surgery or high tibial osteotomy. To overcome these disadvantages, different designs of bioabsorbable screws were introduced, and are increasingly popular. However, there have been reports of screw breakage, high rates of effusions, and decreased pull out strength with Bio screws compared to RCI.

Bio screw materials include: polyglicolic acid (PGA) poly L-lactic acid (PLLA), poly D,L-lactic acid (PDLA), PDLA with trimethylene carbonate (TMC), PGA with trimethyline carbonate, PLLA with hydroxyapatite (PLLA-HA), and PLLA with β-tricalcium Phosphate. In a recent meta-analysis of 11 randomized controlled studies with 878 subjects comparing bioabsorbable and metallic screws for adverse events and clinical outcomes, following HT ACLR, equal short term (≤2 years) and long term (≥5 years), functional and clinical results were found[14]. Larger tunnel widening on the femoral side and significantly higher rates of effusion and screw breakage were noted with the bioabsorbable screw compared to a metal screw[14]. Meyers et al[18], showed that identically shaped bioabsorbable (HA-PLLA) and metallic screws were equally successful up to 2 years following four strand hamstring autograft for ACLR on clinical and X-ray assessment, but MRI was not performed. Drogset et al[6], found equivalent satisfactory clinical and functional results with a PLLA screw compared to a titanium screw in bone patellar bone tendon (BPBT) ACL reconstruction at 7 years. The outcome of ACL reconstruction comparing a PLLA-HA screw to a titanium screw with MRI over 5 years has not previously been reported.

We performed a prospective randomized double blinded controlled trial of ACLR with either a PLLA-HA screw or titanium screw using four stranded ipsilateral hamstring autograft, with a 5 year MRI follow-up. The purpose of our study was to compare the clinical and radiological outcomes of PLLA-HA screw with a titanium screw for ACLR over 5 years. Our hypotheses was that there are no differences in clinical scores or tunnel widening between the PLLA-HA screw and the titanium screw, and that the PLLA-HA screw as seen on MRI should show high grade resorption and ossification response at 5 years.

MATERIALS AND METHODS:

Patients:

Between June 2002 and October 2003, 40 patients, 29 male and 11 female patients, all with a unilateral, isolated anterior cruciate ligament rupture were prospectively randomized for ACLR using 4 stranded hamstring graft with either PLLA-HA (BioRCI-HA, Smith & Nephew Endoscopy, Andover, Massachusetts, 75% PLLA +25%HA) or titanium (RCI, Smith & Nephew Endoscopy, Andover, Massachusetts) interference screw. These screws are identical apart from their material of manufacture. Inclusion and exclusion criteria are shown in Table 1.

Patients were randomized at the time of consent via computer method. Both PLLA-HA and titanium groups comprised of 20 patients each. All patients had signed an informed consent.

Ethics:

Ethical approval for the study was obtained from the St Vincent's Hospital Human Ethics Committee (Reference No. H02/008). Randomization procedure has been specified as follows: "40 envelopes were created prior to commencement of the study. In blocks of 20, these envelopes contained cards with the word "RCI" or "BioRCI" in equal numbers, in random order. Each envelope was numbered consecutively on the outside. The envelopes were sealed and there was no information on the outside of the envelope as to which card is inside. On the day before the surgery an envelope was chosen from the box in consecutive order by the surgeon's secretary who had no involvement in the study, and inserted into the patients' file which accompanied them to surgery. The envelope was opened once the patient has entered the operating theatre. The surgeon was then instructed with method of fixation will be used."

"Disclosures: Institutional research support has been received from Smith and Nephew, Inc"

Surgical Technique:

General anesthesia and a tourniquet were used. Hamstrings were harvested via a vertical proximal tibial incision. A high anterolateral viewing portal and a low anteromedial working portal were utilized. All ACL reconstructions were performed using an ipsilateral 4 strand autologous gracilis and semitendinosus graft by the senior author (L.A.P). The femoral tunnel was drilled first, via an anteromedial arthroscopic portal, with the knee in maximal flexion and positioned 5 mm anterior to the posterior capsular insertion. The femoral screw was inserted via the anteromedial portal. The tibial tunnel was centered on a line between the anterior tibial spine and the posterior margin of the anterior horn of the lateral meniscus, half a graft diameter lateral along this line. In all cases the femoral fixation consists of a 7x25 mm screw. Tibial fixation consists of different screw diameters. Tibial screw diameter was selected according to tunnel size and bone quality, with softer bone receiving larger diameter screws. Tensioning of the graft was made in extention. The screw type was concealed from the surgeon until the day of the surgery. The same screw type was used for both femoral and tibial fixation.

Postoperative Rehabilitation:

Patients were permitted to bear weight as tolerated on crutches immediately after surgery. They were given oral analgesics for pain control and daily physical therapy. No brace was used. Stage I,acute post-op, aim of wound healing, regain full extension 0-2 weeks. Stage II, the aiming to regain Hamstring and Quadriceps control 2-6 Weeks. Stage III, aim top improve neuromuscular control and proprioception 6-12 weeks. Stage IV, incorporate more sport specific activities. Stage V, from week 12 to 5 months, aiming to improve confidence and skill level. Return to competitive sport involving jumping, pivoting or side stepping was prohibited until 6 months after the reconstruction and only after rehabilitation goals had been met, including stable knee to ligamentous testing, > 90% performance of single leg hop test, and within contralateral 1 cm of thigh circumference at a point 10 cm above the superior pole of the Patella.

Clinical Assessment:

Two independent physical therapists with extensive experience in knee assessment, unaware of the screw type, performed all pre-operative and post-operative clinical assessment. The patients remained blinded throughout the study.

Wound healing was assessed 7-10 days post op. Patients were assessed pre-operatively and then post-operatively at 2 weeks, 6 weeks, and 6 months, then at 1, 2 and 5 years. Ligament laxity was assessed by the Lachman and pivot-shift tests. The Lachman test was graded as a side to side difference, with 0 (less than 3 mm), 1 (3-5 mm), or 2 (more than 5 mm) and the pivot-shift test as 0 (negative), 1 (glide), 2 (clunk), or 3 (gross). Instrumented knee testing was performed using the KT-1000 arthrometer (MEDmetric Corp, San Diego, California) manual maximum test at 30° of flexion.

At 2 and 5 years, the International Knee Documentation Committee assessment (IKDC 2000), Lysholm knee score, KT 1000 arthrometer testing and single-legged hop test were performed.

Radiological Assessment:

At 2 and 5 years, an MRI was performed on a 1.5 Tesla MRI Unit (GE Medical Systems) using an eight channel phased array transmit-receive extremity coil. Oblique short axis Fast spin echo T1 and STIR sequencing was performed perpendicular to the tibial and femoral tunnels and oblique sagittal and coronal fast spin echo proton density weighted sequences were performed oriented along the long axis of the tibial and femoral tunnels. Artefact on the T1 sequence was minimized by using a fast spin echo technique with echo train of 4 and relatively large receiver bandwidth (41.7kHz). A STIR sequence was preferred over frequency selective fat suppression in order to minimize artefact from the metallic screws. Artefact from the screws was minimized on the proton density sequence by utilizing a relatively long echo train (10) and a relatively large receiver bandwidth (41.7kHz). In addition a sagittal fat suppressed proton density sequence was performed through the entire knee. The MRI scans were assessed by a musculoskeletal radiologist. The following parameters were specifically evaluated: 1) Tunnel and screw volumes, 2) Peri-screw ossification, 3) Screw resorption, 4) Graft integration and cyst formation.

Tibial and femoral tunnel volume, were calculated by measuring the cross sectional areas of the tunnel in each transverse image through the tibial and femoral tunnels, adding these up and multiplying this total by the MRI slice thickness. Screw volumes were calculated using the formula $V = \pi[1/2[r1 + r2]]^2 \times h$, where r1 and r2 were the largest and smallest radius respectively and h was the height of the remaining screw, as described by Drogset[6]. Evidence of peri-screw ossification (osteoconductivity) was quantified on MRI using the ossification scale described by Barber et al[1]. Evidence of osteoconductivity was considered to be present when the ossification score was 2 or greater. The extent of screw resorption was classified into 4 grades as described by Drogset[5]: no resorption (1), ill-defined screw (2), partial screw body resorption (3) and complete screw resorption (4). Graft integration was classified as complete in presence of uniform, concentric, low signal graft-tunnel interface, and incomplete in presence of focal high signal intensity at the graft-tunnel interface. No integration of graft was considered in presence of diffuse high signal intensity at the graft-tunnel interface. Cystic change within the tunnels, between graft bundles was classified as present or absent. The presence of peri-graft fibrosis, peri-tunnel bone marrow oedema and peri-tunnel intra-osseous cysts were also documented.

Statistics:

Power calculations determined that in order to detect a 35% variation in tunnel volume, with a power of 0.8 and a significance level of 0.05, 17 patients were required for each group. By over sampling by 3 patients in each group, we accounted for potential withdrawals and losses to follow-up. Statistical comparison was by the chi-square test for categorical data, using A and B against C and D [normal or nearly normal versus abnormal or severely abnormal] in IKDC data. The Mann-Whitney U-test was used for non-parametric data (Lysholm score, KT-1000 arthrometer, screw and tunnel volumes comparison). Association between ordinal variables was assessed with Kendalls Tau B. Change over time of linear non-parametric data was assessed with the Wilcoxon signed ranked test.

RESULTS:

Between June 2002 and October 2003, 40 patients (29 male, 11 female), underwent ACL reconstruction within the study, with 20 patients in each group. The PLLA-HA group comprised of 14 male and 6 female patients, 11 being operated on left and 9 on right side. The titanium group was similar, comprising of 15 male and 5 female patients, 10 being operated on left and 10 on right side. The mean age of patients was 33 years in PLLA-HA and 29 in the titanium group.

Preoperatively, there were no significant differences between the study groups in terms of demographics (Table 2).

In the Titanium group, 1 patient ruptured the graft 7 months post-surgery, whilst playing tennis and underwent revision surgery therefore was excluded and 1 patient was living overseas at 2 years and only completed the subjective review. MRI data was available in 18 patients. In PLLA-HA group, at two years complete subjective and objective data were available in all 20 patients. Two patients did not have an MRI scan. There was no significant difference between the PLLA-HA and Titanium group in terms of graft diameter ($p=0.65$) or tibial screw diameter ($p=0.744$). There were no screw breakages. There were no infections. The participant flow including 5 year review is shown in figure 1.

MRI Results:

Tunnel Volume

In the Titanium group there was no significant change between 2 and 5 years in the femoral tunnel volume ($p=0.58$). In the PLLA-HA group the femoral tunnel enlarged between 2 and 5 years ($p=0.02$). At 2 years, the femoral tunnel volume in the PLLA-HA group was significantly smaller than the Titanium group ($p=0.02$). At 5 years there was no difference in femoral tunnel volume between the 2 groups (p=0.49). There was no difference in tibial tunnel volume between groups at 2 and 5 years (p=0.87 and 0.58). However, over time, the tibial tunnel volume for each group significantly increased (p=0.02 PLLA-HA, p=0.04 Titanium), (Table 3 and Figure 2).

Screw Volume:

The femoral PLLA-HA screw volume significantly decreased between 2 and 5 years [p=0.001] (Figure 3). At 2 years the PLLA-HA screw was 76% of its original volume and by 5 years the screw was 38% of its original volume. The tibial PLLA-HA screw volume decreased significantly from 69% of its original volume at 2 years to 49% at 5 years (p=0.004). Between 2 and 5 years there was no change in either the femoral or tibial titanium screw volume.

Ossification Grade:

Evidence of peri-screw ossification (osteoconductivity) was quantified on MRI using the ossification scale described by Barber et al[1], grade I - Little or no ossification, grade II – some ossification, grade III – ossification with a thin lucent rim, grade IV – good ossification border of tract is vague. Little or no ossification occurred around the titanium screw at 2 or 5 years in either femoral or tibial tunnels (Figure 4). 89% of the femoral tunnels with PLLA-HA screws showed a type 2 or 3 response at 2 years. By 5 years, more advanced ossification was evident around the screw tract with 88% having a type 3 or 4 response. Five tunnels showed good ossification (type 4), filling the screw tract (Figure 4). In the tibial tunnel, less ossification occurred compared to the femoral tunnel at 2 years, with 39% showing a type 2 or 3 response. At 5 years, 59% of tibial tunnels demonstrated a type 3 or 4 response. Two out of 16 tunnels showed good ossification (type 4), filling the screw tract.

Screw Resorption:

The extent of screw resorption was classified into 4 grades as described by Drogset5: no resorption (1), ill-defined screw (2), partial screw body resorption (3) and complete screw resorption (4). The femoral screw had higher rates and grades of ossification compared to the tibial screw and showed better resorption, with 11% complete screw resorption compared to 6% on the tibial side at 5 years.

The classification of screw resorption with the PLLA-HA screw is shown in Figure 5 and 6.

Cyst formation and graft integration:

Visible peritunnel cysts present on MRI scan on the tibial side in 24% (4/17) of the PLLA-HA group and 16% (3/19) of the Titanium group (p=0.56). Visible cysts present on MRI scan on the femoral side in 18% (3/17) of the PLLA-HA group and 11% (2/19) of the Titanium group (p=0.54).

At 2 years, in both groups, the majority of grafts had integrated in the tunnel. Incomplete graft integration (areas of focal high signal) was seen on the tibial side in 18% (3/17) with the PLLA-HA group and 32% (6/19) of the titanium group (p=0.34). Incomplete graft integration (areas of focal high signal) was seen on the femoral side in 6% (1/17) with the PLLA-HA group and 5% (1/19) of the titanium group (p=0.94).

Clinical Results:

No significant differences between the 2 groups were found at 2 years or 5 years for any subjective or objective clinical assessment variables (Table 5). There were no infections or screw breakage during insertion or at follow-up.

Discussion:

Our study shows that there were no clinical, subjective, or objective statistically significant difference between the PLLA screw group and titanium screw group, nor were there any statistically significant differences in knee laxity measurements, cyst formation and graft integration. In concordance to our study, previous studies comparing metal and bio absorbable screws, some with different structural and chemical composition, reported no significant difference in IKDC and Lysholm scores[2, 7, 22], with either patellar tendon autograft[8, 12] or hamstring tendon autograft[15, 17]. This PLLA-HA screw was associated with progressive screw resorption and gradual, but incomplete ossification over 5 years, with no adverse effects. This is the first study to report the 5 year clinical and imaging outcomes of a PLLA-HA screw compared to a titanium screw.

We found no evidence of femoral tunnel widening in the BS group compared to the TS group at 5 years. Although the femoral tunnel volume was significantly smaller in the BS group than in the TS group at two years, no statistically significant difference was present at 5 years. On the tibial side there were no significant differences between the TS and the BS tunnel volume at 2 or 5 years. While in the TS group femoral tunnel volumes at 2 and 5 years were the same, the BS group showed significantly smaller femoral tunnel volumes at 2 years, which were significantly increased between 2 to 5 years to reach the same volumes of the TS group at 5 years. In concordance femoral BS screw volumes decreased significantly between 2 & 5 years. We hypothesize that delayed resorption of the PLLA-HA screw leads to the increase in femoral tunnel volumes in the BS group.

The reason for tunnel widening is unknown. Several mechanical and biological explanations have been suggested, such as different tunnel positioning, necrosis of bone caused by drilling, or toxic products in the tunnel (metal or titanium), graft – tunnel motion[9, 10, 19], and overly aggressive rehabilitation[23]. The process of screw resorption will be specific to the screw material. Only one previous study has compared the PLLA-HA to a titanium screw[18]. Meyers et al[18], utilizing HT, reported a wider middle zone femoral tunnel on radiographs, with a PLLA-HA screw compared to titanium screw at 2 years post operatively, but no difference in the aperture of the tunnel - the most important area for graft fixation. Moisala et al[17] reported statistically significant wider femoral tunnel diameter with measured 2 centimeters from the articular surfaces on MRI scan, using HT with a PDLA-TMC screw, compared to a titanium screw. Laxadal et al[15], reported 2-year results with significantly larger tunnel width with a PLLA screw compared to a titanium screw, in lateral view radiographs at both femoral and tibial sides, using HT autograft. In a recent meta-analysis, evidence of larger tunnel widening on the femoral side was noted, but data could not be pooled because of diverse measurements methods had been used. A possible explanation is the different measuring techniques used to assess tunnel volume or diameter, and the use of different modalities and differing screw materials. To our knowledge none of the other researchers calculated the whole tunnel volume using the summation of MRI cuts. We believe that our measuring technique is accurate in assessing tunnel volumes. In addition, in our study screw size was not constant, but was determined in concordance to the graft size, which may facilitate better graft fixation. Multiple factors will contribute to assessment of tunnel widening with bioresorbable screws, including screw material, screw size, measurement technique, imaging modality and these should be considered when interpreting the results.

Complete resorption of the PLLA-HA screw over 5 years was rare. The femoral screw had higher rates and grades of ossification compared to the tibial screw and showed better resorption, with 11% complete screw resorption compared to 6% on the tibial side at 5 years. The resorption characteristics appear favorable and the Hydroxyapetite component of the screw may stimulate osteoconduction, contributing to these results.

Drogset et al[6] reported complete resorption of the PLLA screw on MRI of 16 patients, 7 years after surgery, but the area of the resorped screw was filled with soft tissue without sign of significant bony ingrowth at the femur or tibia. Moisala[17] reported better resorption of the copolymer PDLA-TMC screw on the femoral side, and replacement of the screw by soft tissue. Similar to our study, Barber et al[1] reported that 10% of the screw sites with a β-TCP-PLLA were completely ossified at a mean of 50 months. A possible explanation for the femoral-tibial discrepancy is that the large screw head and conical shape prevents synovial fluid leakage into the femoral tunnel thus facilitates better biological response than on the tibial tunnel were the larger screw head and cones is directed distally.

We found no statistically significant differences between the BS and TS groups in cyst formation and graft integration. It appears that cyst formation occurs with equivalent frequency with PLLA-HA compared to titanium screws.

The strength of our study is that it is a prospective double blinded randomized controlled study, with one experienced surgeon using the same surgical technique in all patients. The follow up was made by two unbiased physiotherapists that did not take any part in the rehabilitation process, and were unaware of the screw type used.

Conclusion:

Our study has shown equivalent clinical results between BS and TS groups at 2 and 5 years. This PLLA-HA screw provides adequate aperture fixation in ACLR with excellent functional outcomes. This PLLA-HA screw was not associated with femoral tunnel widening or increased cyst formation when compared with the titanium screw. This specific composite and design of PLLA-HA screw was associated with progressive screw resorption and gradual, but incomplete ossification over 5 years, with no adverse effects.

This PLLA-HA screw is a good alternative to a titanium screw in ACLR, which may aid revision procedures and allow for imaging without artifact.

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FIGURES:

Figure 1: Participant flow

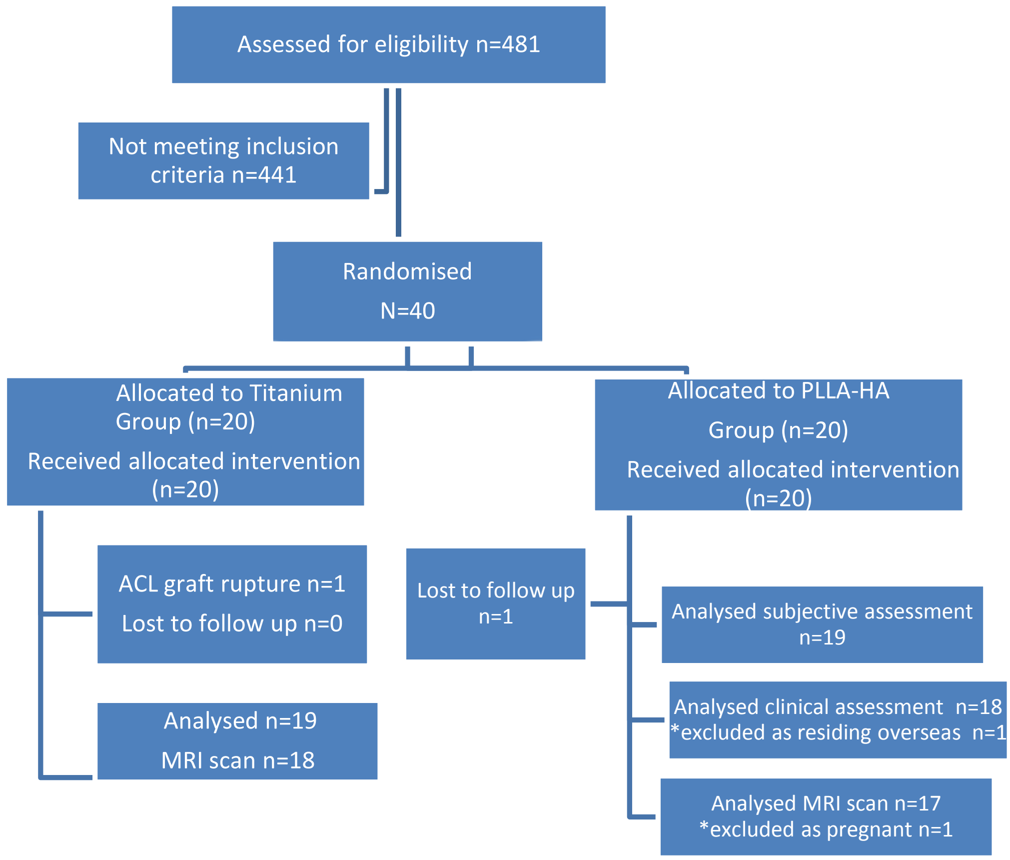

Figure 2: Tunnel volume of PLLA-HA and titanium screw at 2 and 5 years

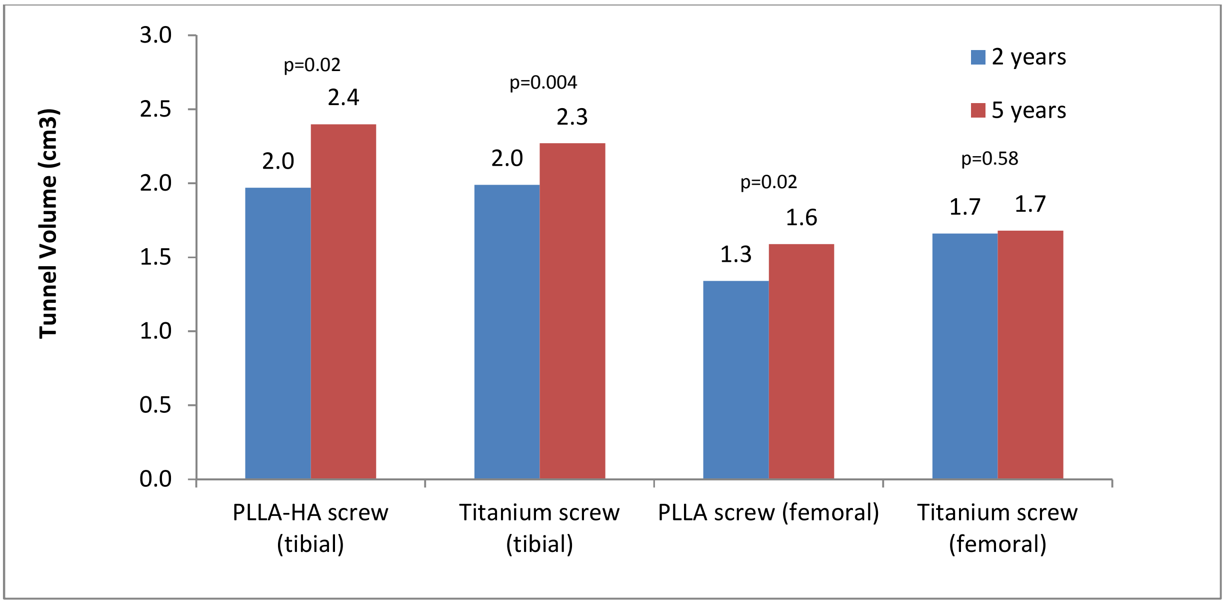

Figure 3: Screw volume of the PLLA-HA and titanium screws at surgery, 2 and 5 years as percentage of its original volume.

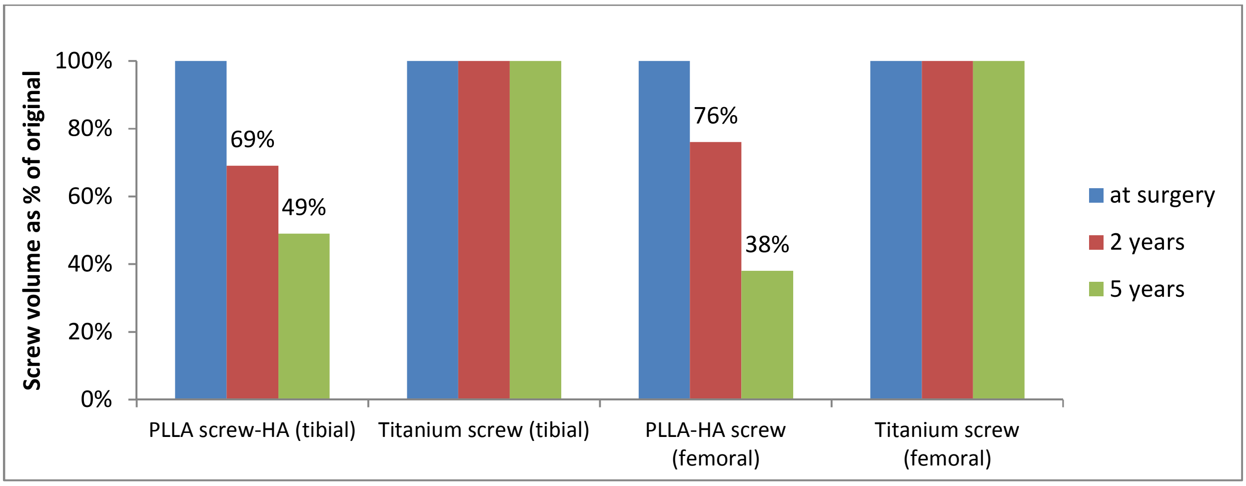

Figure 4: Ossification grade of the PLLA-HA screw at 2 and 5 years using Barber et al classification *[23]*.

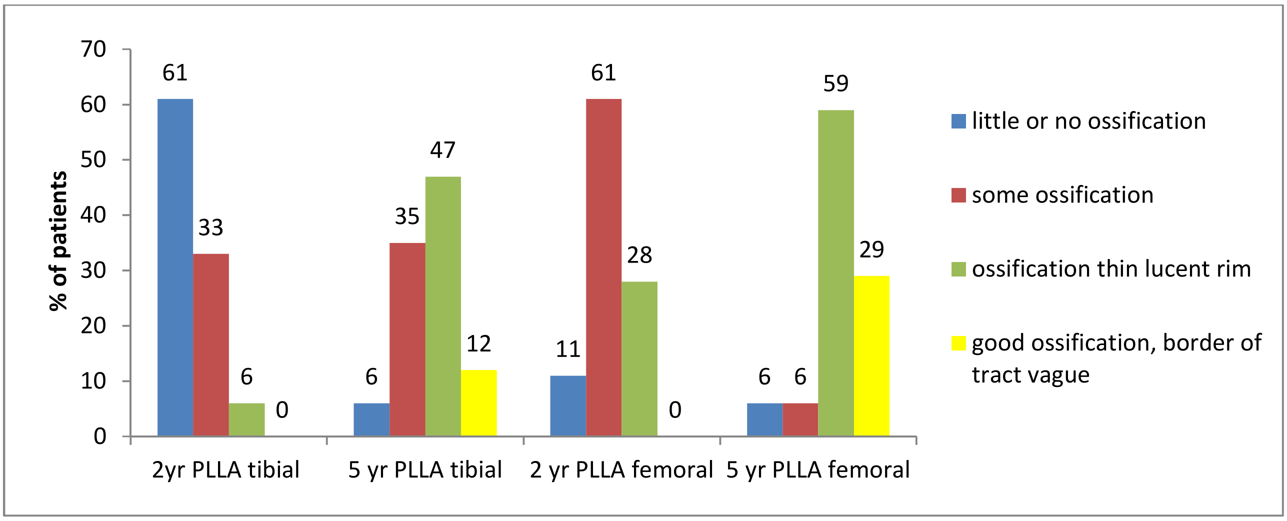

Figure 5: The classification of screw resorption with the PLLA-HA screw at 2 and 5 years.

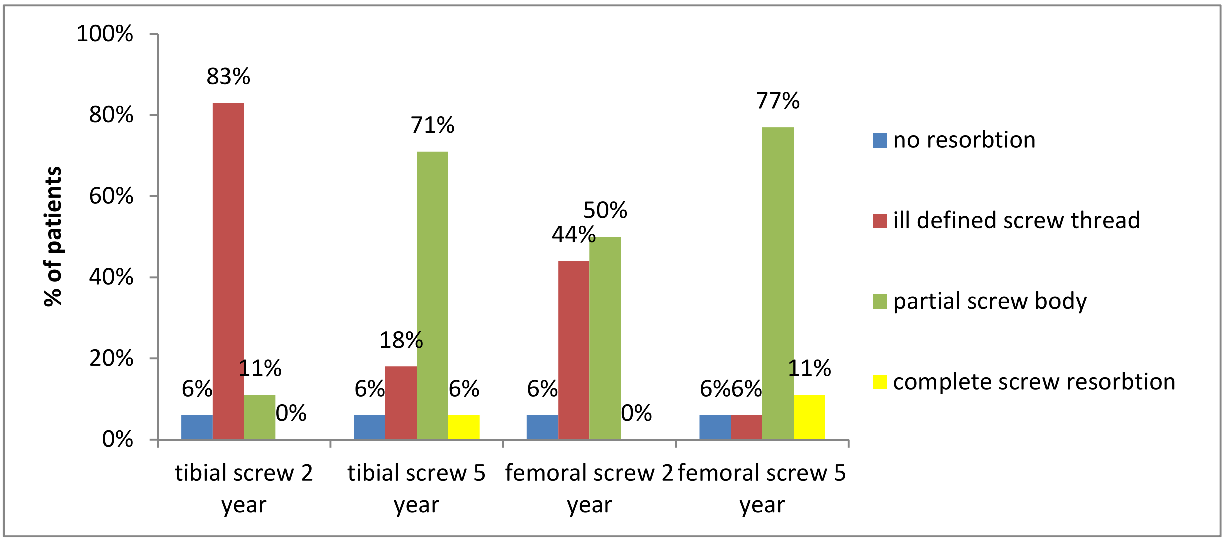

Figure 6: Sagittal fat saturated magnetic resonance images of a left knee. The tibial PLLA-HA screw (arrow) at 2 years (A) shows partial screw resorption and grade 1 ossification and in the same patient at 5 years (B) shows significant screw resorption with grade 4 ossification.

Figure 7: A sagittal fat saturated magnetic resonance image of a left knee showing 2 cysts [arrows] anterior to the femoral portion of the graft at 2 years following ACLR with titanium screws.

TABLES

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Primary ACLR with 4 stranded hamstring graft **Written informed consent to study**	Concurrent significant other ligament injury Chondral injury More than a third meniscectomy Abnormal contralateral knee joint Seeking injury compensation

Table 2. Preoperative demographics of the study groups. sd, standard deviation; NS, not significant.

Variable	PLLA-HA Group	Titanium Group	Significance
Male / Female	14/6	15/5	0.72
Mean [sd]Age at operation [years]	33 [7.2]	29 [6.5]	0.09
Left / Right	11/9	10/10	0.76
Mean Preoperative Lysholm Score (standard deviation)	62 (17)	66 (15)	0.44
Preoperative Overall IKDC Grade (%)			
A	0	0	0.70
B	0	0	
C	74%	79%	
D	26%	21%	

Table 3. Mean femoral and tibial tunnel volume (standard deviation) for PLLA-HA and titanium screws at 2 and 5 years and mean femoral and tibial screw volume [standard deviation]for PLLA-HA and titanium screws at surgery, 2 and 5 years. sd, standard deviation; NS, not significant; S, significant; p = p value

	PLLA-HA (Wilcoxon signed ranks)	Titanium	Significance (Mann Whitney U)
Mean Femoral Tunnel Volume [sd]cm3			
2 yrs	1.34 [0.31]	1.66 [0.41]	0.014
5 yrs	1.59 [0.43]	1.68 [0.27]	0.40
p	0.02	0.58	
Mean Tibial Tunnel Volume [sd]cm3			
2 yrs	1.97 [0.42]	1.99 [0.42]	0.91
5 yrs	2.40 [0.85]	2.27 [0.45]	0.70
p	0.02	0.004	
Mean Femoral Screw Volume [sd]cm3			
At surgery	0.96 [0.0]	0.96 [0.0]	0.99
2 yrs	0.73 [0.14]	0.96 [0.0]	0.001
5 yrs	0.35 [0.18]	0.96 [0.0]	0.001
p	0.001	NS	
Mean Tibial Screw Volume [sd]cm3			
At surgery	1.42 [0.29]	1.35 [0.18]	0.51
2 yrs	0.97 [0.25]	1.35 [0.18]	0.001
5 yrs	0.66 [0.41]	1.35 [0.18]	0.001
p	0.001	NS	

Table 4: Graft integration and cyst formation.

	PLLA-HA	Titanium	Sig
Tibial cyst	4/17 [24%]	3/19 [16%]	0.56
Femoral cyst	3/17 [18%]	2/19 [11%]	0.54
Incomplete graft integration [focal high signal]			
Tibial	3/17 [18%]	6/19 [32%]	0.34
Femoral	1/17 [6%]	1/19 [5%]	0.94

Table 5. Outcome measures at 5 Years. PLLA-HA, poly-L-lactide acid hydroxyapatite; IKDC, International Knee Documentation Committee; NS, not significant; 95% ci, 95% confidence interval; sd, standard deviation.

	PLLA-HA	Titanium	Significance
Lysholm Score Mean [95% CI]	94 [91-98]	92 [85-99]	0.79
IKDC Score Mean [95% CI]	93 [89-96]	93 [87-98]	0.28
Overall IKDC Grade			
A [normal]	10/18	11/19	0.25
B [nearly normal]	8/18	8/19	
Extension Deficit			
<3 degrees	16/18	19/19	0.14
3-5 degrees	2/18	-	
Pivot Shift [grade]			
None [0]	15/18	15/19	0.74
Glide [1+]	3/18	4/19	
Lachman [grade]			
0-2mm [0]	14/18	13/19	0.53
3-5mm [1]	4/18	6/19	
KT-1000 Mean [sd]side to side difference [mm]			
	1.5 [1.6]	2.1 [1.6]	0.27
Effusion			
None	17/18	15/19	0.17
Mild	1/18	4/19	
Single Legged Hop Test			
90-100%	16/18	16/19	0.68
76-89%	2/18	3/19	