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A Randomized Controlled Trial of PEEK vs. Titanium Interference Screws for Anterior Cruciate Ligament Reconstruction with Two-year Follow-up

ABSTRACT

Background: Graft fixation with interference screws for anterior cruciate ligament reconstruction is a highly successful technique. Polyether ether ketone (PEEK) is a novel thermoplastic polymer with high biocompatibility, mechanical properties that mimic native bone, and can be imaged on CT or MRI without signal flare.

Purpose: To compare the clinical performance of anterior cruciate ligaments (ACL) reconstruction using PEEK and titanium interference screws at two years and to evaluate a novel method of measuring of tunnel volume.

Study design: Randomised controlled trial; Level of evidence, 1.

Methods: 133 patients underwent arthroscopic ACL reconstruction with 4-strand hamstring autografts and were randomised to have titanium or PEEK interference screws for both the femoral and tibial tunnel fixation. At two years, subjective Lysholm and IKDC scores were assessed, and clinical examination performed. At 12 months, MRI was performed to assess graft incorporation and cyst formation, and a novel technique employed to measure tunnel volumes..

Results: There were no significant difference in graft re-rupture rate, contralateral ACL rupture rate, subjective outcomes or objective outcomes. In both the titanium and PEEK

groups, MRIs demonstrated high overall rates of graft integration (96-100% and 90-93%) and ligamentization (89% and 84%), and low rates of synovitis (22% and 10%) and cyst formation (0-18% and 13-15%). There is a higher proportion of patients with incomplete graft integration within the femoral tunnel in the PEEK group compared with the titanium group (10% vs 0%, p=0.03), however we suggest that metal artifact precluded proper assessment by MRI of the graft in the titanium group. Tunnel volumes also appeared to be equivalent in the two groups and measured using a novel technique which was highly reproducible in the PEEK group secondary to the absence of flare.

Conclusion: Two-year clinical analysis of PEEK interference screws for femoral and tibial fixation of ACL reconstructions showed equivalent clinical performance to titanium interference screws. Given the excellent mechanical characteristics, biological compatibility and absence of metal artifact on MRI, PEEK has become our material of choice for interference screw fixation in ACL reconstruction.

Key words: Anterior cruciate ligament reconstruction, interference screw, Polyether ether ketone (PEEK), Titanium

Word count: 350

What is known about the subject: Although there are several options available for fixation, the use of interference screws has been shown to be highly successful and a reproducible technique with excellent long-term outcomes. Polyether ether ketone (PEEK) is a thermoplastic polymer which is widely used in spinal and non-orthopaedic surgery. It is clinically inert, has an elastic modulus similar to bone, does not create signal flare on MRI and insoluble. The use of PEEK interference screws in ACL reconstruction has not yet been

studied. Previous studies in cadavers and pigs have shown equivalent results in pull out strength compared to Titanium interference screws.

What this study adds to existing knowledge: This study represents the first randomized controlled trial to compare the clinical outcomes of PEEK and titanium interference screws.

INTRODUCTION

One of the fundamental aims of anterior cruciate ligament (ACL) reconstruction is secure fixation of the graft. Although there are several options available for fixation including compression, as in the use of interference screws, expansion, as in the cross-pin technic and suspension with a button, there remains no definitive gold standard. This is particularly true for fixation in the femoral tunnel. The use of interference screws has been shown to be highly successful and a reproducible technique with excellent long-term outcomes[4]. Traditionally titanium screws were used, however, due to their metallic properties, they cause significant signal artifact on MRI imaging, making post-operative assessment challenging[6]. Also, due to the hardness of titanium screws, damage can occur to the graft during screw insertion[22, 27].

As the search for the ideal material has continued, "bioresorbable" interference screws were theorised to solve two issues. Firstly, the material is radiologically inert and thus allows for superior post-operative MRI assessment. Secondly, the bioresorbable screw would allow for solid fixation, without damage to the graft as it gradually resorbs and is replaced by cancellous bone. Although bioresorbable screws have been associated with good clinical outcomes and do not cause MRI signal flare, resorption has proven unreliable and complete replacement by bone rare[5]. This is largely due to the acidic nature of the materials and the hydrolytic pathway for their dissolution resulting in bony destruction and cyst formation [3, 20].

Another option is polyether ether ketone (PEEK), a thermoplastic polymer which is widely used in spinal and maxillofacial surgery and is becoming increasingly popular in orthopaedic surgery. PEEK is chemically inert, insoluble, has a modulus of elasticity closer to human cortical bone, is compatible with MRI, and, for sterilization purposes, has high resistance to radiation [13]. When compared to other commonly used materials for graft fixation, there has also been shown to be no difference in tunnel widening or cyst formation[9, 26] PEEK itself does not encourage bone ingrowth or ongrowth, but it can be reinforced with elements such as hydroxyapatite, carbon and tricalcium phosphate, which can encourage bony incorporation. Hence PEEK represents a stable and biocompatible material that may address the issues of graft damage due to material hardness, and interference with imaging, that is present with titanium screws.

Previous studies in human and porcine models have shown equivalent results in pull out strength between PEEK and titanium screws [2, 21]. Similarly, a study performed on dogs found that PEEK with tricalcium phosphate fixation showed bony incorporation at six months and was stable through biomechanical evaluation [16]. To date the majority of the literature on the use of PEEK surgical material in live humans has come from spinal and maxillary-facial literature.

At present there are no prospective randomised controlled trials comparing the outcomes of PEEK and titanium interference screws for ACL reconstruction. The purpose of this study was to compare titanium interference screws to a novel PEEK polymer screw by randomized controlled trial. The primary outcome was patient reported outcomes assessed with IKDC and Lysholm score at two years. Secondary outcomes included objective measures of laxity

by clinical evaluation and instrumentation by KT-1000, incidence of graft rupture and MRI appearance of graft integration, cyst formation and tunnel volume. We hypothesized that there will be no difference in patient reported outcomes, ACL graft re-rupture rate, or objective outcomes between the PEEK and titanium subjects. However, we suspected that the absence of signal flare from PEEK screws will allow for more accurate MRI assessment, compared to titanium screws.

METHODS

A parallel two group randomized controlled trial was performed on 133 patients undergoing primary ACL reconstruction between September 2013 and December 2015. Patients were over the age of 18, had no concomitant ligamentous injuries to the operative knee or the contralateral knee, lived in the local metropolitan area and gave informed consent to participate. Exclusion criteria included associated ligamentous injury to the knee, if they were seeking compensation for their injury or if they were pregnant. This study was performed at a high volume, private orthopaedic practice in Sydney, Australia. The surgery was performed by two orthopaedic surgeons (LP, JR), using the same technique. Ethics approval was sought and granted by a local ethics committee (St Vincent's Hospital, Sydney, Australia).

Randomization was achieved by computer generated numbers. Prior to commencement of the trial, envelopes were consecutively numbered from one to 140 with cards that contained the words "TITANIUM RCI" or "PEEK RCI". Randomisation was restricted to multitudes of 10 with a 1:1 allocation ratio by one researcher. On the day prior to surgery,

an envelope was placed into the patient's file by an administrative assistance and this was opened just prior to surgery by the operating surgeon. The card was then replaced inside the envelope and sealed, only to be re-opened at the conclusion of the study. Whilst the surgical operator could not be blinded to the treatment group, the patient and clinical assessors were.

All patients received 4-strand hamstring autograft with tunnels prepared by single incision endoscopy technique, utilising the anteromedial portal for femoral tunnel drilling. The graft was fixed at the femur and the tibia by either a PEEK RCI HA screw (Smith & Nephew, Andover, Massachusetts) or Titanium RCI screw (Smith & Nephew, Andover, Massachusetts). On the femoral side, a 7 X 25 mm screw was used in all patients excepting one, who received an 8 X 25 mm screw. On the tibial side an 8 x 30 mm or 9 x 30 mm screw was used depending on the patient's bone quality which was assessed intra-operatively by manually gauging resistance when reaming. Patients in both groups were discharged home on the day of surgery and underwent an accelerated rehab protocol, commencing formal physiotherapy on post-operative day 0 for weight bearing and range of movement exercises. Return to competitive sports was prohibited until 6-9 months after the reconstruction and then was allowed only after rehabilitation goals had been met. Achievement of these goals was assessed by the surgeon and the physiotherapist and includes range of movement, strength and agility.

Standard clinical reviews took place at one week, six weeks, and six months. At 12 and 24 months, subjective evaluation was performed with the Lysholm questionnaire and International Knee Documentation Committee (IKDC). Ligament stability was assessed with

a full IKDC examination, including Lachman's test, pivot-shift test and KT-1000 arthrometer (MEDmetric, San Diego, California). Assessment was performed by two specialist research physiotherapists, who were blinded to screw allocation.

MRI was performed at one year to evaluate graft integration, the presence of effusion or synovitis, cyst formation and assess tibial and femoral tunnel volumes. MRIs were performed at a single imaging centre with musculoskeletal specialist MRI radiologists, and modified oblique and coronal sequences chosen to optimise post-operative tunnel volume measurement. If patients were unable to attend the nominated imaging centre, MRI was still performed at alternate imaging centres, and all assessments were carried out by one musculoskeletal radiologist except for tunnel volume measurement. Graft integration was assessed on both the femoral and tibial sides by observing the graft adjacent to the interference screw to have uniform, concentric low signal interface ("complete integration") or focal or diffuse high signal ("incomplete integration") [19]. The modified MRI sequences were designed so that slices would be exactly perpendicular (tibial) or parallel (femoral) to the long axis of the tibial and femoral tunnels; axial imaging slices were aligned perpendicular to the tibial tunnel axis ("oblique axial"), and modified coronal ("oblique coronal") slices were taken parallel to the femoral tunnels (Figure 1).

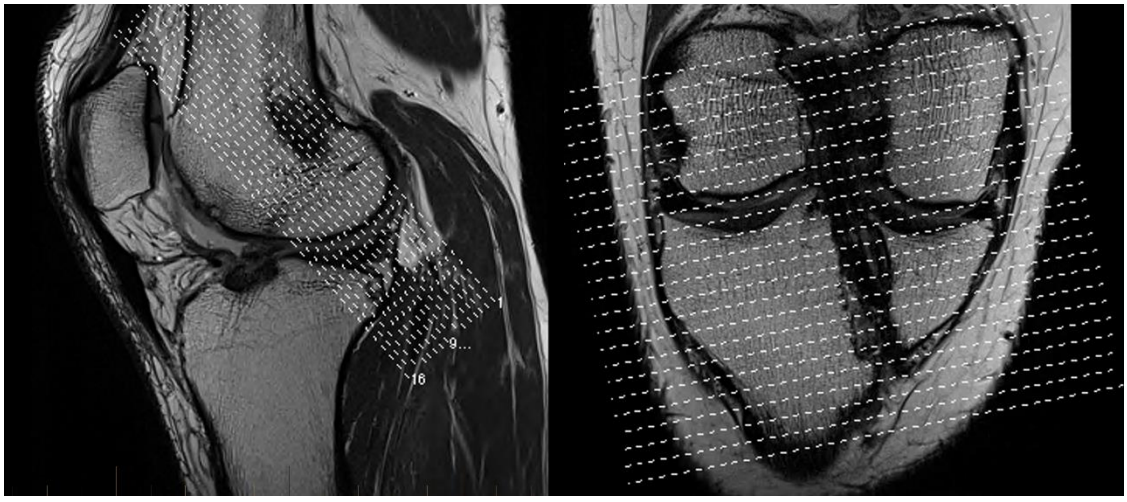

Figure 1: Orientation of modified oblique sagittal (1a) and modified oblique coronal (1b) MRI slices for the purposes of accurate tunnel volume assessment

The technique of interpretation of tunnel volume was discussed with a musculoskeletal radiologist and agreed upon, then measurements were made independently by an orthopaedic surgeon and an orthopaedic registrar using a computer-based volume assessment tool (Inteliviewer, Intelerad Systems, Montreal, Canada). For each imaging slice positioned perpendicular to the femoral or tibial tunnel, the border of the tunnel was traced using a stylus on a digital pen tablet device (Intuos Art, Wacom) and the cross-sectional area of the enclosed region calculated. Consistent brightness and contrast ratios were established (contrast/width = 1000, brightness/length = 600) such that tunnel borders were clearly defined on 3mm thick proton density (PD) image slices. The tunnel cross sectional area was calculated only if the full circumference of the tunnel was visible on that slice. By incorporating the known slice thickness, the "Volume of Interest" tool converted adjacent cross-sectional areas into a total tunnel volume (mm^3) for both the tibia and femur. The technique of measurement is novel and has not previously been reported.

This study was designed to test equivalence of PEEK screws compared to titanium for the primary outcome variable of mean subjective IKDC score. For a level of significance of 5%

and power of 80%, a sample size of 53 in each group was calculated to be required to detect a difference of 10%, based on a one-sided test. The sample size includes 20% oversampling to allow for potential withdrawals and loses to follow-up. Statistical analysis was performed with SPSS software for Windows (IBM, Armonk, NY). Statistical significance was set at P = 0.05. Comparison of variables between groups was analyzed with $\chi 2$ tests for categorical data and independent-samples t-test. For data elements where a count of less than 5 was present in a particular category, a Fisher's Exact test was used. Linear variables were summarized by the mean, and categorical variables were summarized by the frequency. To assess inter-observer reliability of MRI assessment of volumes of both the femoral and tibial tunnels, the intraclass correlation coefficient (ICC) was calculated. For interpretation of the ICC, we used the subjective guidelines established by Landis and Koch (1977) for coefficients, suggesting that values from 0.61 to 0.80 indicate "substantial" agreement between observers, and values from 0.81 to 1.00 indicate "almost perfect" agreement [14].

RESULTS

A total of 68 patients were enrolled in the PEEK group and 65 in the titanium group. At two-year review, 64 (94%) in the PEEK group and 51 (90%) in the titanium group had complete subjective and objective evaluation. Two patients in the PEEK group and five in the titanium group were lost to follow up and unable to be contacted. One patient in the titanium group withdrew from the study, the other patients did not attend follow up or were unable to be contacted. Figure 2. There was no statistical difference between groups for any of the baseline patient demographics or injury profile. (Table 1).

201 Figure 2: Consort flow diagram

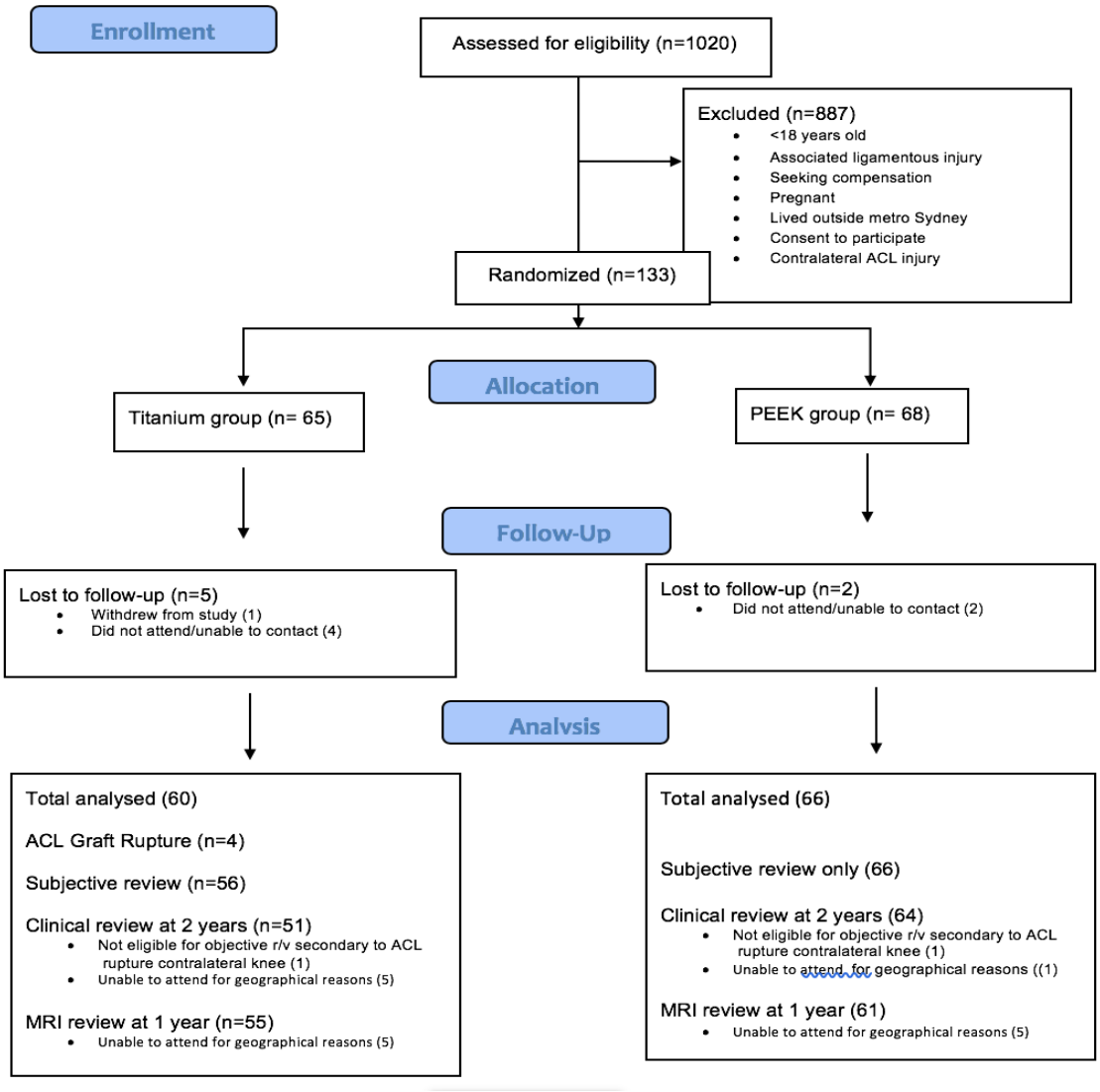

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Table 1: Patient Demographics and injury profile

	Titanium	PEEK	p-value
Number of patients	65	68	
Mean age	33.3 (+/- 10) years	35.2 (+/- 9) years	0.26
Female	29 (44.6%)	30 (44.1%)	0.95
Left sided ACL rupture	36 (55.4%)	32 (47.0%)	0.34
Lateral meniscus injury	19 (29.2%)	17 (25%)	0.81
Medial meniscus injury	14 (21.5%)	15 (22.1%)	0.37

There was also no significant difference between titanium and PEEK groups in regards to operative tunnel volume and screw size. The mean femoral tunnel sizes at time of surgery were 7.5mm in the titanium and 7.6mm in the PEEK group (p=0.3), and the mean tibial tunnel sizes at time of surgery were 7.4mm in the titanium group and 7.5mm in the PEEK group (p=0.3).

There were four ACL graft ruptures over the two-year period in the titanium group, and none in the PEEK group (p=0.054). The graft ruptures occurred at three, five, nine, and 24 months post-surgery, and the respective causes were fall whilst intoxicated, soccer, soccer, and fall from a ladder. Contralateral ACL rupture occurred in one patient in both the PEEK and titanium arms of the study.

For subjective analysis, only patients with intact ACL in the operated knee were included. This resulted in 56 patients undergoing review in the Titanium group and 66 patients in the PEEK group. There was found to be no significant difference between the two groups in regards to subjective outcomes. See Table 2.

Table 2: Subjective Outcomes

	Titanium Group	PEEK Group	p-value
Mean IKDC score	90 (+/- 8.9)	89 (+/- 9.1)	0.33
Mean Lysholm Knee score	94 (+/- 6.5)	94 (+/-7.2)	0.98
Return to strenuous or very strenuous activity	44 (79%)	47 (71%)	0.77
Return to pre-injury sport	42 (75%)	42 (64%)	0.16
No or mild pain with kneeling	51 (91%)	58 (88%)	0.49
No pain with strenuous or very strenuous activity	51 (91%)	48 (73%)	0.08
No swelling with strenuous or very strenuous activity	47 (84%)	53 (80%)	0.43
No giving way with strenuous or very strenuous activity	50 (89%)	57 (86%)	0.70

Objective evaluation was performed only on patients with intact graft and contralateral native ACL, this included 63 patients in the PEEK group (94%) and 53 in the titanium group (88%). Forty-two patients (79%) in the titanium group and forty-three (68%) in the PEEK group had a normal knee according to the IKDC knee examination (p=0.2). No patients were found to have an abnormal or severely abnormal knee. There was no significant difference in regards to effusion, range of movement, functional ability or degree of laxity based on Lachman's, Pivot Shift test and KT-1000. Table 3.

Table 3: Comparison of 2 year Clinical Outcomes in the Titanium and PEEK Groups

	Titanium Group	PEEK Group	p-value
IKDC ligament grade A	42 (80%)	43 (68%)	0.18
No effusion	50 (94%)	54 (86%)	0.09
Negative Lachman test	47 (89%)	50 (80%)	0.18
Negative Pivot shift	49 (93%)	52 (83%)	0.11
KT-1000 <3mm	42 (79%)	44 (70%)	0.88
Full extension	51 (96%)	62 (98%)	0.46
Full flexion	53 (100%)	63 (100%)	1.0
Hop test >90%	40 (76%)	44 (73%)	0.32

MRIs were performed in 116 of the 133 patients (87%). Of the patients with a completed MRI, 93 (70%) had the novel modified format that allowed accurate assessment of tunnel volumes. The remaining 23 patients had MRIs performed at alternative imaging centres, with standard technique. There was no significant difference between titanium and PEEK groups in the presence of an effusion, synovitis, bone oedema adjacent to the tunnels or cyst/ganglion formation. There was a statistically significant higher rate of complete femoral graft integration in the Titanium group. Compared to the PEEK group. Table 4.

Table 4: Comparison of MRI evaluation in the Titanium and PEEK Groups

	Titanium Group (n=55)	PEEK Group (n=61)	p-value
Effusion	42 (76%)	41 (67%)	0.28
Synovitis	12 (22%)	6 (10%)	0.75
Ligamentization	49 (89%)	51 (84%)	0.39
Complete tibial integration	53 (96%)	57 (93%)	0.48
Complete femoral integration	55 (100%)	55 (90%)	0.03*
Bone oedema adjacent to tibial screw	7 (13%)	9 (15%)	0.75
Bone oedema adjacent to femoral screw	4 (7%)	7 (12%)	0.44
Cyst/ganglion tibia	10 (18%)	8 (13%)	0.45
Cyst/ganglion femur	0 (0%)	9 (15%)	0.25
Tunnel volume tibia	3.5 mm^3	3.8 mm^3	0.05
Tunnel volume femur	3.3 mm^3	2.8 mm^3	0.002*

Regarding the inter-observer reliability of tunnel volumes performed on the post-operative MRI, the intra-class coefficient (ICC) was high for the PEEK screw group; for the tibial tunnels the ICC was 0.868, and for femoral tunnels 0.689. By comparison, for the titanium screws, the ICC values were 0.768 for tibial tunnels and 0.531 for femoral tunnels. The tunnel volumes on the tibia measured an average of 3.5mm^3 for the titanium group and 3.8mm^3 for the PEEK group (p=0.054). There was a significant difference in the volume of the femoral tunnels with the titanium group measuring an average of 3.3mm^3 compared to 2.8mm^3 in the PEEK group (p=0.002).

DISCUSSION

The results of this study show equivalence when comparing PEEK with titanium interference screws when used for ACL reconstruction, in regards to mean subjective IKDC and Lysholm knee scores, re-rupture rate, and objective examination with IKDC ligament exam grades. Furthermore, PEEK screws did not show any difference in rates of synovitis, oedema or cyst formation on MRI compared to titanium screws at 12 months.

Over the 24 months there were no re-ruptures within the PEEK group. The titanium group did have four patients who ruptured their graft. This result nearly approached statistical significant with a p-value of 0.054. The graft ruptures from the titanium screw cohort occurred at three, five, nine, and 24 months post-surgery, and the respective causes were fall whilst intoxicated, soccer, soccer, and fall from a ladder. It is probable that the failures were related to the nature of the mechanism of injury or ill-advised early return to sport, however there is also concern that titanium screws may damage to the graft when inserted and thus may contribute to early failure[11]. A larger cohort size may have further exposed this.

Another result which neared statistical significance was no pain with strenuous or very strenuous activity (p=0.08). To determine significance of this variable would have required 70 subjects in each group and thus we are underpowered to appropriately examine this variable. Cohort size is certainly a limitation and we are unable to conclude a difference on this variable. However, without any significant differences in examination including effusion, range of movement or stability as well as that an equivalent number of patients returned to,

at a minimum, strenuous level activity, it is difficult to determine what the source of pain may be for 17% of patients in the PEEK group.

One of the benefits of PEEK is that it does not interfere with post-operative imaging on MRI. This is indicated in the superior inter-observer reliability in measuring tunnel volumes for PEEK compared to titanium screws. Particularly on measuring the femoral tunnels with titanium, the reliability was graded as moderate agreement as per Landis and Koch criteria compared to substantial in the PEEK group. This is likely secondary to the degree of scatter artifact caused by metal material. A further benefit is that compared to bioabsorbable screws, PEEK does not cause cysts or inflammatory change due to degradation, showing comparable results to titanium. Furthermore, in the case of revision surgery the PEEK screw can be removed with the same ease of titanium as, unlike bioabsorbable screws, PEEK does not lose structural integrity over time.

There was noted to be a high rate of effusion identified on MRI in the titanium and PEEK groups at 76% and 67% (p=0.3). Effusions were graded to be small and the incidence of associated synovitis was relatively low, 22% and 10% for Titanium and PEEK groups respectively. It has previously been reported that at 12-months only 11% of patients will have a knee joint effusion back to baseline [15]. Therefore, this rate of MRI reported effusion may be expected at 12-month review. It is noted that at clinical review at 24 months, 94% and 86% of patients in the Titanium and PEEK group had no clinically apparent effusion.

There was found to be a significant difference between the titanium and PEEK screw groups in regards to the proportion of patient who demonstrated incomplete graft integration on the femoral side. This finding was seen in six of the 61 patients (10%) in the PEEK group, and

none of the 55 patients from the titanium group. Incomplete integration was defined as focal or diffuse high signal in the graft adjacent to the interference screw, if this was not observed then it was categorized as complete integration. It is likely that the difference in femoral integration is attributable to the inability to assess graft signal in the presence of metal artifact caused by the titanium screw, despite the use of suppression software. This concept can be seen below by comparing representative MRI slices from a titanium and PEEK screw patient (Figure 3). It can be seen that the graft is directly adjacent to the screw and obscured by metal artifact in the titanium screw group.. There was, however, no significant difference in the rates of complete integration for the tibia. Artifact produced by metal in MRI scan is related to, amongst other things, the orientation of the implant in the magnetic field[23]. It is believed that the oblique orientation of the screw in the femoral tunnel results in a greater degree of artifact and difficulty in visualizing the graft. It is our impression that the result of incomplete integration of the graft at the femur in the PEEK group is unlikely to accurately represent a true difference in behaviour of the grafts about the two screw types, but rather an inferior ability to accurately view the graft adjacent to the metal screws.

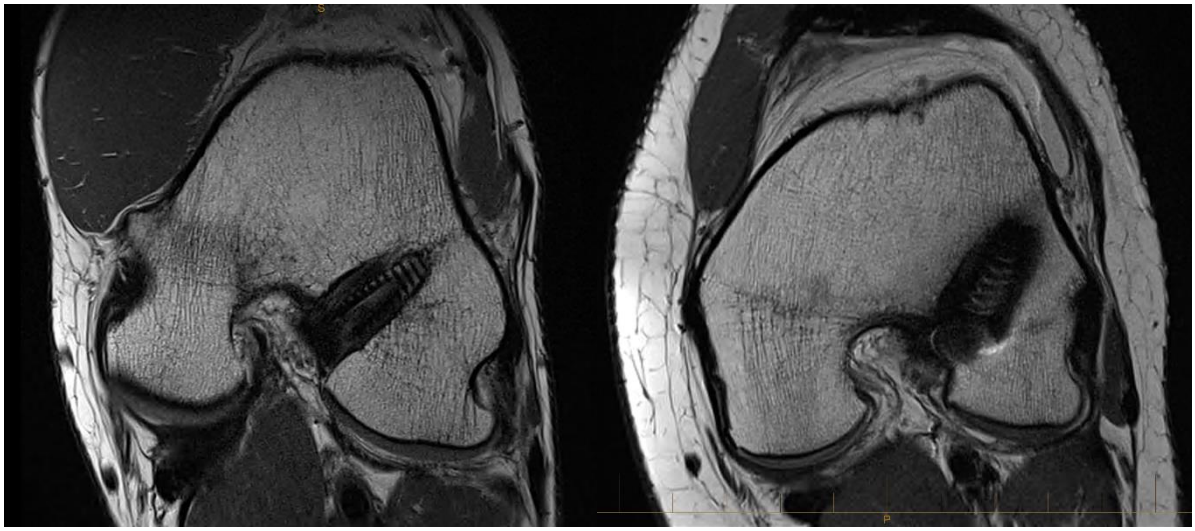

Figure 3: Comparison of MRI appearance of bone adjacent to a PEEK (3a) and titanium (3b) screw, highlighting interference phenomenon caused by metallic properties of titanium which reduces the ability to visualise the adjacent tunnel and ACL graft

It was also found that there was a significant difference in the tunnel volume of the femur with the titanium tunnel being significantly wider (p=0.002). As with the difficulty of interpreting complete femoral integration, it was particularly difficult to measure the true volume of the femoral tunnel with the metal artifact. This can also be illustrated with the rates of inter-observer reliability. There was less consistence in measuring of the femoral tunnels compared to the tibial tunnels; 0.689 and 0.531 for PEEK and titanium on the femur, compared to 0.868 and 0.768 on the tibia. Measurement of the femoral tunnel with the titanium screw had only a moderate ICC, this is possibly due to the obliquity of the tunnel within the femur and its tangential course to the cortical margin. The tibial tunnel runs deeply with the tibal and thus is easier to define.

This study demonstrates a novel volume assessment technique for tibia and femoral tunnels and show that the absence of signal flare on MRI from the PEEK screws greatly improved inter-observer reliability. There are several techniques suggested in the literature for the assessment of tunnel size [1, 7, 10-12, 17, 24, 25] with CT scan typically seen as the gold standard[8, 17]. However, ICC for CT scan has previously been reported as only 0.49-0.76 for intra and inter-observer reliability[18]. In most clinical settings, sufficient information regarding tunnel size and widening can be gathered from plain radiographs to allow planning of revision surgery. Where quantitative volume assessment is important, for example in the setting of research, given the combination of higher accuracy, absence of radiation, and additional soft tissue information garnered, we feel tunnel volume assessment is best done with MRI. Mayr et. al

also measured tunnel volume on 1.5T MRI however with measurements off of the axial slice, rather than our technique of slices perpendicular to the tunnel [17]. For the tibia they found almost identical ICC of 0.869. Similar to our findings, the ICC for the femur was lower than that of the tibia. Although they reported a higher rate of ICC, we feel that due to the trajectory of the femoral tunnel, a perpendicular oblique view on a 3T scanner shows a greater number of slices with the tunnel visible and better reflects the true tunnel volume. The technique presented here can be used with standard MRI scanners and requires only modification of the orientation of the acquired slices.

From this study we conclude equivalent clinical outcomes of PEEK interference screws compared to titanium. The use of PEEK interference screws in ACL reconstruction provides a stable, reliable method of fixation. There is no significant difference in subjective measures, objective examination or graft reinjury at two year follow up when compared with titanium interference screws. MRI assessment at one year showed equivalent rates of effusion, synovitis, ligamentization and cyst formation, and the absence of signal flare on PEEK MRI images allowed for reproducible tunnel volume measurements and adequate assessment of the graft in the tunnels. The PEEK screw is an alternative to the gold standard of titanium screw in ACL reconstruction, may simplify revision procedures and allow for superior imaging of the tunnel and graft. PEEK interference screws are now our preferred method of fixation for ACL reconstruction.

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