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## A randomized controlled trial of PEEK versus titanium interference screws for anterior cruciate ligament reconstruction with 2-year follow-up

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Shumborski, S., Heath, E., Salmon, L.J., Roe, J.P., Linklater, J.P., Facek, M., and Pinczewski, L.A. (2019) A randomized controlled trial of PEEK versus titanium interference screws for anterior cruciate ligament reconstruction with 2-year follow-up. *American Journal of Sports Medicine*, 47(10), 2386-2393. doi: 10.1177/0363546519861530

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

3  
4 **ABSTRACT**

5  
6 **Background:** Graft fixation with interference screws for anterior cruciate ligament  
7 reconstruction is a highly successful technique. Polyether ether ketone (PEEK) is a novel  
8 thermoplastic polymer with high biocompatibility, mechanical properties that mimic native  
9 bone, and can be imaged on CT or MRI without signal flare.

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

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

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

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

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

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

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

37 Word count: 350

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

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

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

48

49

50 **INTRODUCTION**

51

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

62

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

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

83

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

90

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



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

102

### 103 **METHODS**

104

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

115

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

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

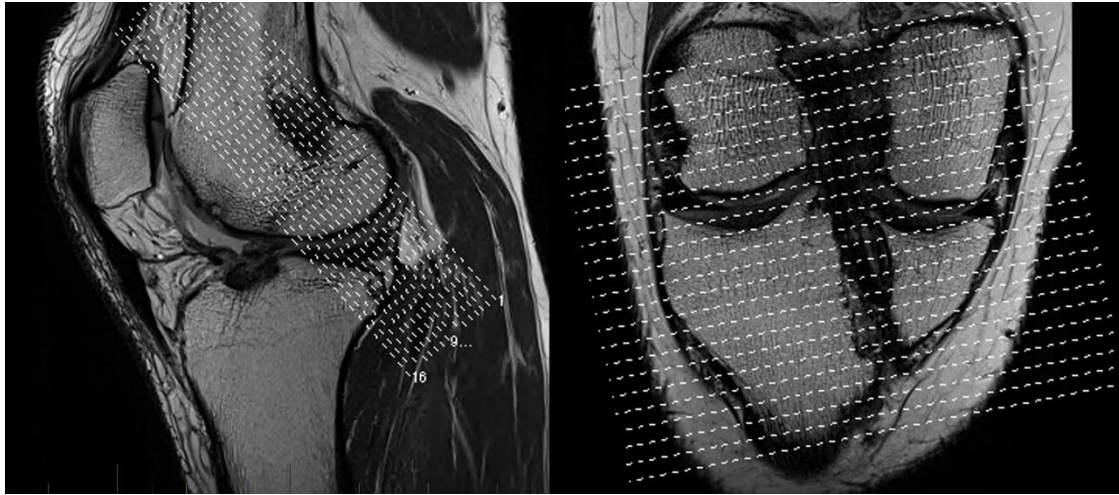
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126 All patients received 4-strand hamstring autograft with tunnels prepared by single incision  
127 endoscopy technique, utilising the anteromedial portal for femoral tunnel drilling. The graft  
128 was fixed at the femur and the tibia by either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

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

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

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



160  
161 Figure 1: Orientation of modified oblique sagittal (1a) and modified oblique coronal (1b)  
162 MRI slices for the purposes of accurate tunnel volume assessment

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

176

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

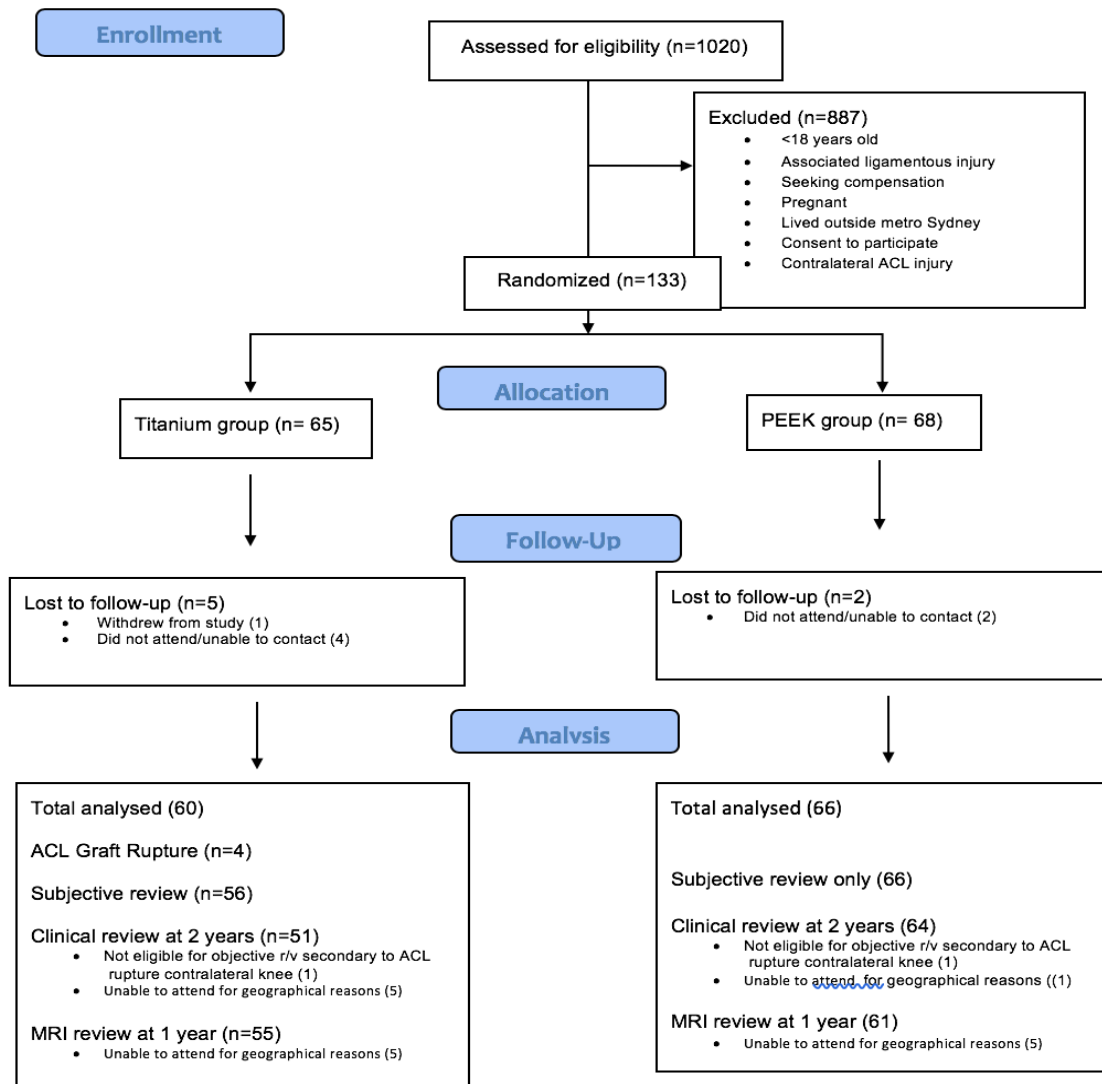
179 and power of 80%, a sample size of 53 in each group was calculated to be required to detect  
180 a difference of 10%, based on a one-sided test. The sample size includes 20% oversampling  
181 to allow for potential withdrawals and losses to follow-up. Statistical analysis was performed  
182 with SPSS software for Windows (IBM, Armonk, NY). Statistical significance was set at P =  
183 0.05. Comparison of variables between groups was analyzed with  $\chi^2$  tests for categorical  
184 data and independent-samples t-test. For data elements where a count of less than 5 was  
185 present in a particular category, a Fisher's Exact test was used. Linear variables were  
186 summarized by the mean, and categorical variables were summarized by the frequency. To  
187 assess inter-observer reliability of MRI assessment of volumes of both the femoral and tibial  
188 tunnels, the intraclass correlation coefficient (ICC) was calculated. For interpretation of the  
189 ICC, we used the subjective guidelines established by Landis and Koch (1977) for  
190 coefficients, suggesting that values from 0.61 to 0.80 indicate "substantial" agreement  
191 between observers, and values from 0.81 to 1.00 indicate "almost perfect" agreement <sup>14</sup>.

## 192 **RESULTS**

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

200

201 Figure 2: Consort flow diagram



202

203

204 Table 1: Patient Demographics and injury profile

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

205

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

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

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

220 Table 2: Subjective Outcomes

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

221

222 Objective evaluation was performed only on patients with intact graft and contralateral  
 223 native ACL, this included 63 patients in the PEEK group (94%) and 53 in the titanium group  
 224 (88%). Forty-two patients (79%) in the titanium group and forty-three (68%) in the PEEK  
 225 group had a normal knee according to the IKDC knee examination (p=0.2). No patients were  
 226 found to have an abnormal or severely abnormal knee. There was no significant difference  
 227 in regards to effusion, range of movement, functional ability or degree of laxity based on  
 228 Lachman’s, Pivot Shift test and KT-1000. Table 3.

229



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

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

231

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

239

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

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

241

242 Regarding the inter-observer reliability of tunnel volumes performed on the post-operative  
 243 MRI, the intra-class coefficient (ICC) was high for the PEEK screw group; for the tibial tunnels  
 244 the ICC was 0.868, and for femoral tunnels 0.689. By comparison, for the titanium screws,  
 245 the ICC values were 0.768 for tibial tunnels and 0.531 for femoral tunnels. The tunnel  
 246 volumes on the tibia measured an average of 3.5mm<sup>3</sup> for the titanium group and 3.8mm<sup>3</sup>  
 247 for the PEEK group (p=0.054). There was a significant difference in the volume of the  
 248 femoral tunnels with the titanium group measuring an average of 3.3mm<sup>3</sup> compared to  
 249 2.8mm<sup>3</sup> in the PEEK group (p=0.002).

250

251 **DISCUSSION**

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

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

266 Another result which neared statistical significance was no pain with strenuous or very  
267 strenuous activity (p=0.08). To determine significance of this variable would have required  
268 70 subjects in each group and thus we are underpowered to appropriately examine this  
269 variable. Cohort size is certainly a limitation and we are unable to conclude a difference on  
270 this variable. However, without any significant differences in examination including effusion,  
271 range of movement or stability as well as that an equivalent number of patients returned to,

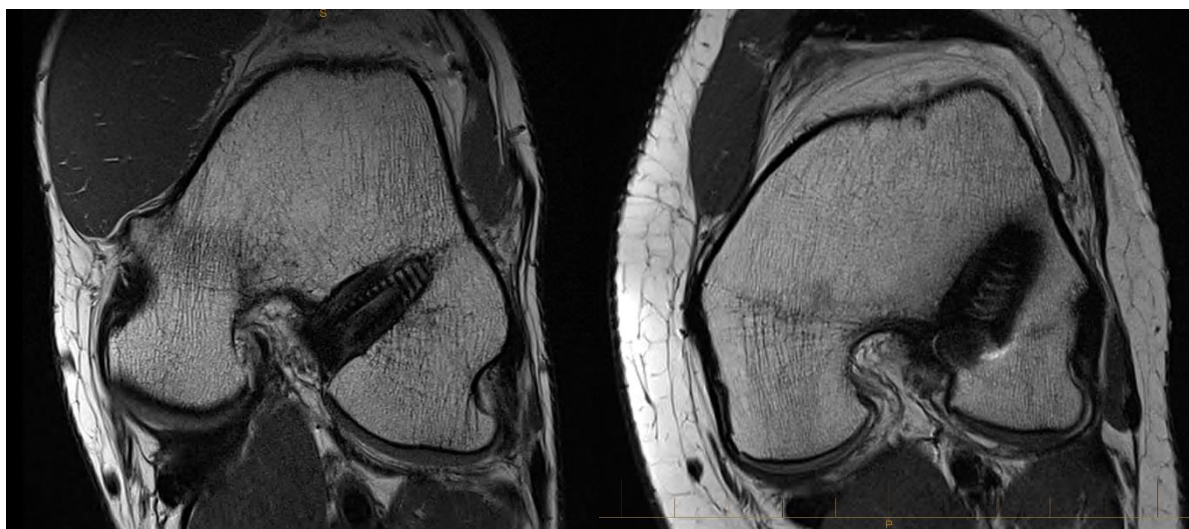
272 at a minimum, strenuous level activity, it is difficult to determine what the source of pain  
273 may be for 17% of patients in the PEEK group.

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

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

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

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



310

311 Figure 3: Comparison of MRI appearance of bone adjacent to a PEEK (3a) and titanium (3b)  
312 screw, highlighting interference phenomenon caused by metallic properties of titanium  
313 which reduces the ability to visualise the adjacent tunnel and ACL graft  
314

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

325

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

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

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

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