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Five-year results of a randomised controlled trial comparing cemented and cementless Oxford unicompartmental knee replacement using radiostereometric analysis

Campi, S.; Kendrick, B.J.L.; Kaptein, B.L.; Valstar, E.R.; Jackson, W.F.M.; Dodd, C.A.F.; ... ; Murray, D.W.

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1 **FIVE-YEAR RESULTS OF A RANDOMISED CONTROLLED TRIAL COMPARING**
2 **CEMENTED AND CEMENTLESS OXFORD UNICOMPARTMENTAL KNEE**
3 **REPLACEMENT USING RADIOSTEREOMETRIC ANALYSIS**
4

5 S Campi¹, B JL Kendrick², BL Kaptein³, ER Valstar³, WFM Jackson², CAF Dodd², AJ Price^{1,2}, DW
6 Murray^{1,2}
7
8

- 9 1. Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of
10 Oxford, UK
11 2. Nuffield Orthopaedic Centre - NHS Foundation Trust, Oxford, UK
12 3. Biomechanics and Imaging Group, Department of Orthopaedics, Leiden University Medical Center,
13 Leiden, The Netherlands
14
15
16
17

18 **Corresponding author:**

19 Stefano Campi
20 Botnar Research Centre,
21 Windmill Road
22 OX3 7LD
23 Oxford, United Kingdom
24

25 E-mail: stefano.campi@gmail.com

26 Mobile: +39 347 1814777
27
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31 **Introduction**

32 The cemented Oxford unicompartmental knee replacement (OUKR) has been in clinical use since
33 the late 1970s and has good outcomes reported by the designer surgeons [1] and independent groups
34 [2-5]. However National Joint Registries report high revision rates, with the commonest causes for
35 revision being aseptic loosening and pain [6] [7] [8]. Assessing whether a component is loose can
36 be difficult as thin radiolucent lines beneath the cemented OUKR tibial components are common
37 [9]. Although they are not a cause of pain or indicative of loosening, surgeons, who are not familiar
38 with the OUKR, may revise the knee if there is pain and a radiolucent line.

39
40 The cementless OUKR was introduced to try and improve fixation so as to decrease the revision
41 rate for aseptic loosening and pain. The cementless implants are similar to the cemented, except
42 they have porous titanium with a hydroxyapatite coating on the under-surface and a second, smaller,
43 peg on the femoral component. As part of the early assessment of the cementless device a two year
44 randomised study comparing it and cemented OUKR with radiostereometric analysis (RSA) was
45 undertaken[10]. In the first year the cementless migrated more than the cement, however in the
46 second year the migration was similar. Furthermore the incidence of radiolucent lines was
47 substantially lower with the cementless. These finding suggested that the fixation of the cementless
48 device was at least as good as the cemented and justified its increased use. However during the
49 second year there was a small but significant amount of subsidence of the cementless tibial
50 component, so there remains some uncertainty about the long term fixation. The aim of this study
51 was therefore to extend the follow up of this randomised controlled trial of the cemented and
52 cementless OUKR using RSA to five years.

53

54 **Materials and Methods**

55 The study was approved by the Regional Ethics Committee (C02.101). A consecutive series of
56 patients who were due to undergo OUKR for medial compartment osteoarthritis were invited to

57 participate in the study. Patient older than 80 years, with an American Society of Anesthesiologists
58 (ASA) score greater than three or having had previous open surgery or anterior cruciate ligament
59 reconstruction on the same knee were excluded from the study. After enrolment and assessment for
60 eligibility, 47 patients gave their consent and were included in the study. All the operations were
61 performed by one of four experienced surgeons at the [REDACTED]. Block
62 randomisation with closed envelopes was performed once patients had undergone arthrotomy and
63 suitability for OUKR was confirmed. Intra-operative evaluation of the ACL and all three
64 compartments was recorded. All patients fulfilled the recommended indication for OUKR [11]. All
65 cases were performed through a minimally invasive approach. All components used in the study
66 were standard Phase 3 Oxford UKR (Biomet, Bridgend, UK). In all cemented cases CMW1
67 Gentamicin impregnated cement (Depuy International Ltd, Leeds, UK) was used according to the
68 manufacturer's instructions. For the cementless components each was examined prior to insertion to
69 ensure that there was good layer of porous titanium and that this had a complete covering of
70 hydroxyapatite and was then implanted according to the recommended surgical technique. To
71 provide a reference rigid body for RSA, seven tantalum marker balls with a diameter of 0.8 mm
72 were inserted in the femur and six in the tibia after bone resections were performed. Each set of
73 markers was inserted in predetermined positions using a pre-loaded ball injector (RS-M 08, Tilly
74 Medical Products, Lund, Sweden). The condition number, which is a measure of how well spaced
75 the markers are (where a lower number indicates a better spread of markers with improved
76 accuracy), was calculated for each set of stereo-radiographs. It has been suggested that for large
77 joints a condition number below 100 achieves reliable results [12].

78 Patients underwent weight-bearing stereoradiographs post-operatively and at three, six, 12, 24 and
79 60 months after the operation. All stereoradiographs were obtained with the patient standing within
80 a calibration frame in a normal two-legged stance. Additional screened radiographs were obtained
81 using fluoroscopy, with the x-ray beam aligned to the tibial tray so as to provide the best image of

82 the bone-implant interface. All stereoradiographs were analysed using model-based RSA (ver 3.21,
83 Medis Specials, Leiden, The Netherlands) (Figure 1).

84 Computer aided design models for all implant sizes were provided by the manufacturer (Biomet,
85 Bridgend, UK). All translations were measured in millimeters and rotations in degrees. Migrations
86 for left sided components were converted to those for a right-sided component for analysis of
87 direction of movement as well as magnitude. Table 1 describes in clinical terms the migration or
88 rotation of the components on each axis. Migrations at each time point were compared to zero
89 migration as well as between fixation groups.

90 The Oxford Knee Score was obtained at annual review when each patient attended for radiographs
91 [13].

92 *Statistical analysis*

93 A power calculation to detect a 0.2 mm difference in migration with a power of 80% and a
94 significance of 0.05 required 16 patients in each group. Forty-seven patients were recruited to
95 allow for loss to follow up or unusable stereoradiographs. All RSA calculations were conducted
96 following the recommendations of an expert group[12]. Initially the the migration was determined
97 at different time points by comparing the RSA measurements at that time point with those from the
98 immediate post-operative radiographs.

99

100 Wilcoxon rank sum test was used for migration against zero, Mann–Whitney for migration between
101 fixation methods and t-test for comparison of clinical outcome. The Chi-squared test was used to
102 compare categorical variables between the groups. All values are expressed as means unless stated
103 otherwise. Statistical significance was set at $p < 0.05$. Statistical analysis was performed using
104 PASW Statistics version 22.0 (SPSS Inc, Chicago, USA).

105

106

107

108 **Results**

109 Of the 47 patients initially included in the study, 24 were allocated in the cemented group and 23 in
110 the cementless group. At the five-year follow-up, 5 patients had withdrawn the study, one patient
111 had died and one patient had a bearing dislocation. In addition, one patient's stereoradiographs
112 could not be analysed because of a calibration issue (Figure 2). Thirty-nine patients were available
113 for analysis, 19 in the cemented group and 20 in the cementless group. The two groups had
114 homogeneous age, gender, laterality and preoperative OKS as reported in Table 2.

115

116 *Femoral migration*

117 At five years, the femoral components had significant anterior migration (z-axis) of 0.20 mm (SD
118 0.3, $p=0.02$) in the cemented group and 0.14 mm (SD 0.31, $p=0.02$) in the cementless group,
119 without significant difference between the two groups ($p = 0.79$). The anterior migration was
120 significant at all time points (3, 6, 12, 24 and 60 months) when compared to zero migration, without
121 a significant difference between the two groups (Tables 3 and 4). The anterior migration occurred
122 almost entirely in the first three months and remained stable up to five years (Figure 3).

123 The cemented femoral components also had significant inferior migration (y-axis) of 0.16 mm (SD
124 0.19, $p=0.005$) at five years. This occurred almost entirely in the first postoperative year and did not
125 progress after that. The cementless femoral components had no significant inferior migration at any
126 stage however, during the first year its inferior migration was similar to that of the cemented. There
127 was no significant difference between cemented and cementless inferior migration.

128 Occasional significant differences were encountered between cemented and cementless
129 components, although none of them was persistent at the five years follow-up.

130 The femoral component showed no significant migration in any other direction at five years, and no
131 difference between cemented and cementless components.

132 There was no significant migration in any direction after the first year.

133

134 *Tibial migration*

135 During the first year the distal migration of the cementless tibial components was 0.28 mm (SD
136 0.19, $p < 0.001$), which was significantly ($p < 0.001$) more than that of the cemented tibial
137 components (0.09 mm, SD 0.19). In the second year, both the cementless and cemented groups had
138 small but significant distal migration of 0.04mm (SD 0.08, $p < 0.03$) and 0.05 mm (SD 0.09, $p < 0.04$)
139 mm respectively and there was no significant difference between the groups (Figure 4). There was
140 no further distal migration in either group after the second year (Table 5 and 6).

141 The cemented tibial component tipped into a mean varus of 0.29 degrees (SD 0.67) by 12 months
142 (Rz axis). The varus subsidence was 0.45 degrees by 5 years (SD 0.80, $p = 0.01$), although the
143 progression after the second year was not statistically significant. On the same axis, the cementless
144 components initially showed a valgus subsidence of 0.33 degrees (SD 0.71, $p = 0.04$) at 6 months.
145 There was no significant difference at the subsequent time points compared to zero migration,
146 although there was a minimal but significant varus subsidence in the 12-24 and 24-60 months
147 intervals, which led the components in 0.13 degrees of varus (SD 0.68, $p = 0.5$) at five years.

148 After the second year, there was no significant migration or rotation in any other direction in either
149 group. In addition after the second year, there was no significant difference in migration or rotation
150 between the groups.

151

152 *Radiological assessment*

153 Five-years radiographs were available for 18 patients in the cemented group and 19 patients in the
154 cementless group. All the x-rays were correctly aligned and allowed a satisfactory evaluation of the
155 bone-implant interface of the tibial component.

156 There were 7 radiolucent lines on 18 patients in the cemented group (37%) and one on 19 patients
157 in the cementless group (5%) at five years. There were no complete radiolucencies around the
158 cementless components, while one case in the cemented group had a complete radiolucent line
159 (Figure 5a and 5b). This difference was statistically significant ($p = 0.01$).

160 There was no significant difference in the maximal total point motion (MTPM) between patients
161 with partial or total RL and those with no RL (p=0.23).

162

163 *Clinical outcome*

164 At five years, the mean OKS was 37 (SD 12) in the cemented group and 41 (SD 7) in the
165 cementless group. This difference was not significant (p = 0.26).

166

167 **Discussion**

168 Second year migration has been shown to be a good predictor of long term loosening [14]. When
169 the two-year data was first analysed it was found that there was no significant difference between
170 the migration of the cementless and cemented components in the second year (12 to 24 months). It
171 was concluded that cementless fixation was as good as the cemented and therefore that it was safe
172 for the device to be generally used. There was however still a concern about cementless tibial
173 fixation as in the second year there was small but statistically significant amount of subsidence and
174 during the first two years the cementless tibia subsided more than the cemented. It was therefore
175 important to continue the study and reassuring that between the second (24 months) and fifth (60
176 months) year there was no significant migration of either the cementless femoral or tibial
177 components. Furthermore the mean migration of the components over this three year period in
178 every direction was substantially less than 0.1mm, which is the accuracy of the RSA system. This
179 suggests that the cementless components reliably achieve secure fixation and that this should persist
180 for the patient's life time, unless there are external events such as infection or excessive
181 polyethylene wear. Both of these events are unlikely as the risk of infection following UKR is low
182 and the wear rate of the mobile bearing is low.

183 Between the second and fifth year the only statistically significant migration of the cemented or
184 cementless components was that the cemented tibial component developed 0.27 degrees of varus
185 rotation. This is likely to be the effect the multiple testing as, relative to implantation, at the end of

186 the first year the tibial component was in 0.1 degrees of valgus ($p=0.3$), and at the end of the fifth
187 year it was in 0.13 degrees of varus ($p=0.5$). In contrast, the cemented components showed a varus
188 subsidence of 0.45 degrees at five years ($p = 0.01$), which occurred almost entirely in the first year,
189 without further progression. Even if the rotation of the cementless tibia between the second and fifth
190 year was real it was small and probably clinically irrelevant. Before starting the study we
191 deliberately set the significance level at 0.05 so as not to miss any important differences. As we
192 were undertaking multiple testing we could have set a lower level, this would however, not have e
193 changed the conclusions.

194 At five-years there was no significant difference between cementless and cemented femoral or tibial
195 component migration and rotation in any direction, with one exception. The exception was tibial
196 component subsidence: At five years, the mean cemented tibial subsidence was 0.14 mm (SD 0.29),
197 whereas the mean cementless subsidence was 0.28 mm (SD 0.19). The difference occurred almost
198 entirely during the first three months. It is perhaps not surprising that the cemented components
199 hardly subside as cement achieves its final shape intra-operatively. It is however commonly
200 observed that during the operation the cementless tibial components do not fully seat and can be
201 half a millimetre proud. The study suggests that this does not matter as the components seem to
202 reliably subside to a stable position and then secondary fixation occurs. This observation has an
203 important clinical implication: if a cementless tibial component does not fully seat it is best to leave
204 it slightly proud rather than impacting them hard. Hard impaction probably increases the risk of
205 tibial plateau fracture.

206

207 There were 7 radiolucent lines (6 partial, 1 complete) in the cemented group and one (partial) in the
208 cementless group. The only partial RL in the cementless group was hardly visible (Figure 4.4b) and
209 many surgeons would not even consider it to be a radiolucent line. The difference between the two
210 groups was statistically significant, which confirms the results of previous studies and suggests that
211 cementless fixation may be better than cemented [10,15,16]. This should also decrease the number

212 of unnecessary revisions resulting from misinterpretation of RL. The incidence of RLs is lower than
213 that reported when this cohort of patients was reviewed at two years and is also lower than
214 previously reported for similar cohorts of patients, both among the cemented and cementless
215 groups. The assessment of the x-rays was performed in conjunction with the first author of the two-
216 year evaluation, to minimise inter-observer error. The different incidence of RLs could be related to
217 a less accurate alignment of the radiographs as a small difference in the alignment of the beam can
218 hide or reveal a radiolucent line. The decrease in incidence of cemented RL may also relate to
219 improved cementing technique [17].

220 There was no significant difference in the mean OKS, which was 37 (SD 12) for the cemented
221 group and 41 (SD 7) for the cementless group. However, this study is underpowered to detect a
222 significant difference in the OKS, which was not the primary outcome measure of the study. It is
223 interesting to note that in two separate RCTs, one in our institution and one in Denmark, cementless
224 had a superior OKS than cemented OUKRs [15]. If all the 150 patients included in these two studies
225 were taken together, this difference would probably be statistically significant.

226 This is the first study comparing the stability of cemented and cementless OUKR components using
227 RSA. Randomised controlled trials using RSA is considered the best way to compare the stability of
228 a new implant to what is considered the gold standard [18]. This study does however have some
229 limitations. First, the study was only single blinded as the observer was able to detect from the
230 radiographs whether the components were cemented or cementless. Second, the study was powered
231 to detect a difference in migration. Therefore the number of patients was too small to assess a
232 difference in the clinical outcome and complications. However other studies have investigated these
233 outcomes [16,19,20][21], and in combination with this study confirm the safety, efficacy and
234 reliability of the fixation of the cementless OUKR.

235

236

237

238 **Conclusions**

239 The five-year results of this randomised controlled trial demonstrate that the fixation of cementless
240 components is at least as good as that of cemented components, with a lower incidence of
241 radiolucent lines.

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308 **Figure legends**

309

310 **Figure 1.** Model based RSA.

311 **Figure 2.** Consort chart.

312 **Figure 3:** Mean migration in the z-axis (anterior migration) of the femoral component in the
313 cemented and cementless groups with 95% confidence intervals.

314 **Figure 4:** Mean migration in the y-axis (subsidence) of the tibial component in the cemented and
315 cementless groups with 95% confidence intervals.

316 **Figures 5a, 5b.** Complete radiolucent line around a cemented tibial component (a); small partial
317 radiolucent line around a cementless tibial component (b).

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319

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332

333 **Tables**

334

335 **Table 1:** Clinical description of migration or rotation for femoral and tibial components using three
336 axes.

	Femur		Tibia	
	+ve	-ve	+ve	-ve
X	Medial	Lateral	Medial	Lateral
Y	Superior	Inferior	Superior	Inferior
Z	Anterior	Posterior	Anterior	Posterior
Rx	Increased flexion	Decreased flexion	Reduced slope	Increased slope
Ry	Internal rotation	External rotation	Internal rotation	External rotation
Rz	Valgus	Varus	Valgus	Varus

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338

339 **Table 2:** Distribution of patients and characteristics of the two groups.

	Cemented	Cementless	p
Cases	19	20	-
Age	65 (49-79, SD: 9)	67 (49-79, SD: 7)	0.48
M:F	8:11	11:9	0.42
Right:Left	11:8	12:8	0.58
Pre-op OKS	24 (13-37, SD: 6)	24 (12-36, SD: 7)	0.98

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Table 3. Mean femoral migration for each axis or rotation around an axis at each time point (standard deviation, p-value when mean compared to zero migration (Wilcoxon rank)).

	Cemented					Cementless				
	Follow-up (months)									
	12	24	60	12-24	24-60	12	24	60	12-24	24-60
X	0.05 (0.28, 0.47)	0.03 (0.34, 0.80)	0.10 (0.35, 0.21)	-0.10 (0.24, 0.15)	-0.16 (0.31, 0.19)	-0.18 (0.28, 0.01)	-0.05 (0.53, 0.33)	-0.02 (0.46, 0.41)	-0.08 (0.25, 0.18)	0.07 (0.23, 0.20)
Y	-0.12 (0.25, 0.01)	-0.05 (0.32, 0.46)	-0.16 (0.19, 0.005)	0.02 (0.17, 0.67)	-0.01 (0.18, 0.19)	-0.12 (0.24, 0.06)	-0.04 (0.27, 0.69)	-0.07 (0.29, 0.33)	0.06 (0.16, 0.13)	-0.06 (0.21, 0.15)
Z	0.24 (0.32, 0.01)	0.22 (0.42, 0.03)	0.20 (0.30, 0.02)	0.00 (0.14, 0.89)	0.02 (0.24, 0.78)	0.26 (0.31, 0.00)	0.21 (0.23, 0.00)	0.14 (0.31, 0.04)	-0.10 (0.20, 0.05)	0.03 (0.21, 0.49)
Rx	0.16 (0.65, 0.40)	0.23 (0.68, 0.18)	0.16 (0.54, 0.33)	0.00 (0.30, 0.97)	-0.05 (0.50, 0.87)	0.22 (0.57, 0.04)	0.20 (0.54, 0.16)	0.35 (0.44, 0.01)	0.03 (0.31, 0.66)	0.04 (0.42, 0.99)
Ry	-0.05 (0.63, 0.45)	0.32 (0.52, 0.15)	-0.34 (2.07, 0.98)	0.49 (0.57, 0.01)	0.11 (0.75, 0.87)	0.24 (0.52, 0.05)	0.23 (0.52, 0.11)	0.29 (0.79, 0.19)	-0.10 (0.47, 0.36)	0.11 (0.37, 0.24)
Rz	0.25 (0.80, 0.17)	-0.06 (0.75, 0.69)	0.25 (0.88, 0.25)	-0.24 (0.74, 0.24)	-0.11 (0.87, 0.73)	-0.26 (0.93, 0.11)	0.00 (1.28, 0.81)	-0.17 (1.14, 0.44)	0.14 (0.54, 0.28)	-0.11 (0.79, 0.39)

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Table 4. P-value for migration in each axis or rotation around an axis between cemented and cementless fixation for the femoral component at each time point (Mann-Whitney U).

	12 months	24 months	60 months	12 - 24 months	24 - 60 months
X	0.02	0.18	0.15	0.94	0.12
Y	0.57	0.91	0.45	0.94	0.39
Z	0.75	0.60	0.79	0.20	0.54
Rx	0.54	0.91	0.21	1.00	0.81
Ry	0.08	0.89	0.27	0.00	0.66
Rz	0.03	0.86	0.14	0.18	0.73

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Table 5. Mean tibial migration for each axis or rotation around an axis at each time point (standard deviation, p-value when mean compared to zero migration (Wilcoxon rank)).

	Cemented					Cementless				
	Follow-up (months)									
	12	24	60	12-24	24-60	12	24	60	12-24	24-60
X	0.01 (0.24, 0.91)	0.06 (0.26, 0.37)	0.03 (0.22, 0.42)	0.07 (0.16, 0.08)	-0.12 (0.25, 0.07)	-0.04 (0.21, 0.57)	0.01 (0.19, 0.61)	-0.03 (0.21, 0.68)	0.07 (0.16, 0.07)	-0.03 (0.14, 0.35)
Y	-0.09 (0.19, 0.28)	-0.13 (0.23, 0.12)	-0.14 (0.29, 0.01)	-0.05 (0.09, 0.04)	-0.02 (0.11, 0.49)	-0.28 (0.19, 0.00)	-0.34 (0.23, 0.00)	-0.28 (0.19, 0.00)	-0.04 (0.08, 0.03)	-0.01 (0.07, 0.77)
Z	0.00 (0.26, 0.48)	0.03 (0.22, 0.48)	0.01 (0.31, 0.57)	0.03 (0.11, 0.29)	-0.03 (0.14, 0.26)	-0.01 (0.15, 0.53)	-0.02 (0.16, 0.16)	0.00 (0.11, 0.88)	0.02 (0.12, 0.53)	-0.02 (0.12, 0.79)
Rx	-0.10 (0.70, 0.94)	-0.17 (0.69, 0.43)	-0.34 (1.19, 0.13)	-0.01 (0.21, 0.86)	-0.08 (0.56, 1.00)	-0.38 (0.73, 0.02)	-0.40 (0.76, 0.02)	-0.28 (0.80, 0.22)	0.03 (0.19, 0.47)	0.04 (0.18, 0.65)
Ry	-0.02 (0.45, 0.79)	0.03 (0.44, 0.26)	0.07 (0.40, 0.36)	-0.05 (0.28, 0.42)	0.05 (0.48, 0.90)	0.16 (0.54, 0.18)	0.24 (0.61, 0.19)	0.28 (0.47, 0.04)	-0.01 (0.28, 0.92)	0.04 (0.29, 0.31)
Rz	-0.29 (0.67, 0.01)	-0.31 (0.68, 0.04)	-0.45 (0.80, 0.01)	-0.07 (0.35, 0.36)	-0.11 (0.34, 0.24)	0.10 (0.63, 0.34)	-0.01 (0.60, 0.93)	-0.13 (0.68, 0.50)	-0.18 (0.29, 0.01)	-0.27 (0.15, 0.00)

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Table 6. P-value for migration in each axis or rotation around an axis between cemented and cementless fixation for the tibial component at each time point (Mann-Whitney U).

	12 months	24 months	60 months	12-24 months	24 – 60 months
X	0.55	0.68	0.48	0.98	0.44
Y	0.00	0.00	0.003	0.92	0.50
Z	0.43	0.19	0.65	0.73	0.38
Rx	0.11	0.14	0.95	0.43	0.69
Ry	0.27	0.65	0.28	0.62	0.70
Rz	0.01	0.19	0.21	0.28	0.04

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