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A randomised controlled trial of Cemented versus Cementless Oxford Unicompartmental Knee Replacement using Radiostereometric Analysis

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Abstract

The commonest reasons for revision of unicompartmental knee replacement (UKR) in national registers are loosening and pain. Potentially therefore, cementless components may decrease the revision rate. The aim of the study was to assess cementless fixation in the Oxford UKR. 43 patients were randomized to receive either a cemented or cementless Oxford UKR and were followed for 2 years with Radiostereometric analysis (RSA), radiographs aligned with the bone-implant interfaces and clinical scores. The femoral components migrated significantly during the first year (0.2 mm), but not the second. There was no significant difference in migration between cemented or cementless femoral components in either the first and second year. In the first year the cementless tibial component subsided significantly more than the cemented (0.28 mm v 0.09 mm). In the second year, although there was a small amount of subsidence (0.05 mm) there was no difference between cemented and cementless tibial components. There were no femoral radiolucencies. Tibial radiolucencies were narrow (<1 mm) and were significantly less common with cementless compared to cemented components (29% v 62%). There were no complete radiolucencies with cementless components whereas 25% of cemented had complete radiolucencies. The clinical scores were no different. As second year migration is predictive of subsequent loosening and as a radiolucency is suggestive of decreased implant-bone contact, the data suggests that fixation of the cementless components is at least as good, if not better, than cemented.

Introduction

Unicompartmental Knee Replacement (UKR) tends to give better function and a faster recovery with lower morbidity and mortality than Total Knee Replacement (TKR), but overall the revision rate is higher. This needs to be addressed if UKR are to be widely used. Good long term survival rates (98% at ten years[1] and 91% at 20 years[2]) have been reported with cemented Oxford UKR (OUKR), demonstrating that low revision rates can be achieved with this device. However, the National Joint Registry of England and Wales (NJR) reports a revision rate of 9.6% at seven years for the OUKR[3]. The main causes of revisions in the NJR and other registries are pain and component loosening[3,4]. A tibial radiolucent line is common with the cemented OUKR and, although there is no evidence that such a radiolucency, if it is thin and non-progressive, is associated with poor outcome[5,6], it may be a manifestation of sub-optimal fixation. Furthermore there is a concern that it may be misinterpreted as being indicative of loosening and may lead to unnecessary revision. If a cementless OUKR had improved fixation with a decreased incidence of loosening and radiolucency it should help address the high failure rate.

Cementless fixation in Total Knee Replacement (TKR) has had a chequered history and is not routine in most centres as it is associated with high revision rates[7-9]. The NJR reports that only 6.7% of all TKRs in the UK are cementless and there is a significantly increased risk of revision compared to cemented TKR at eight years[3]. The tibial component of a TKR is prone to loosening due to shear forces at the bone-cement interface and due to rocking with eccentric loading leading to tension on the unloaded side of the interface. In contrast, as the OUKR has a mobile bearing almost all the forces transmitted through the implant-bone interface are compressive. Compression is ideal for cementless fixation, whereas shear and tension are not. Therefore, the OUKR may be the ideal knee replacement for cementless fixation.

Radiostereometric analysis, which is designed to measure migration of an implant relative to bone with a high level of accuracy, is the ideal method to assess fixation as continuous migration is predictive of subsequent loosening[10] RSA studies of cemented and cementless components have shown differing results. Nilsson showed, in younger patients, that hydroxyapatite coated cementless TKR tibial components migrated more than cemented components at three months, but then stabilised and migrated less in the subsequent two years[11]. In contrast, Carlsson demonstrated that cemented TKR tibial components were more stable at five years than uncemented components, but also found that the addition of hydroxyapatite to a porous surface improved fiaxtion[12]. A further randomised controlled trial demonstrated that the addition of hydroxyapatite to a porous surface resulted in less migration at two years[13]. Nelissen demonstrated further evidence of the benefit of hydroxyapatite in a RCT where a HA coated tibial component had similar migration to a cemented tray, but significantly less than an uncoated porous tibia.[14] Pijls et al have suggested that migration of less than 0.5 mm in the first post-operative year is encouraging, whereas more than 1.6 mm is associated with an increased revision rate.[15]

A cementless OUKR with a porous titanium and hydroxyapatite coating has been developed. As part of the assessment of this device a randomised controlled trial using RSA and radiographic assessment of the interfaces was undertaken to compare the fixation of the cementless and cemented OUKR. This paper presents the two year results of the study.

Methods

All patients who were due to undergo OUKR for medial compartment osteoarthritis were invited to participate. Exclusion criteria were age greater than 80 years, American Society of Anesthesiologists score of greater than three and previous open surgery or anterior cruciate ligament reconstruction on the same knee. Patients who consented to the trial underwent OUKR by one of four experienced surgeons. Randomisation was performed once patients had undergone arthrotomy and suitability for OUKR was confirmed. Intra-operative evaluation of the ACL and all three compartments was recorded. All patients had full thickness cartilage loss in the medial compartment, an intact ACL and no significant cartilage damage on the weight-bearing portion of the lateral compartment. In addition, no patient had severe damage to the lateral side of the patello-femoral joint with bone loss. All components used in the study were standard Phase 3 Oxford UKR (Biomet, Bridgend, UK)(Figure 1 and Figure 2). In all cemented cases CMW1 Gentamicin impregnated cement (Depuy International Ltd, Leeds, UK) was used according to the manufacturer's instructions. For the cementless components each was examined prior to insertion to ensure that there was good layer of porous titanium and that this had a complete covering of hydroxyapatite and was then implanted according to the recommended surgical technique[16]. Tantalum marker balls with a diameter of 0.8 mm , to provide a reference rigid body were inserted after tibial and femoral preparation was complete. Each set of markers was inserted in predetermined positions using a pre-loaded ball injector (RS-M 08, Tilly Medical Products, Lund, Sweden). Seven markers were inserted in the femur and six in the tibia. The condition number, which is a measure of how well spaced the markers are (where a lower number indicates a better spread of markers with improved accuracy), was calculated for each set of stereo-radiographs. It has been suggested that for large joints a condition number below 100 achieves reliable results[17].

Patients underwent weight-bearing stereoradiographs post-operatively and at three, six, 12 and 24 months. All stereoradiographs were obtained with the patient standing within a calibration frame in a normal two-legged stance. Additional screened radiographs were obtained using fluoroscopy, with the x-ray beam aligned to the tibial tray so as to provide the best image of the component/tibia interface. Furthermore, an Oxford Knee Score was obtained at annual review when each patient attended for radiographs. All stereoradiographs were analysed using model-based RSA (ver 3.21, Medis Specials, Leiden, The Netherlands). Computer aided design models for all implant sizes were provided by the manufacturer (Biomet, Bridgend, UK). All translations were measured in millimeters and rotations in degrees. Migrations for left sided components were converted to those as for a right sided component for analysis of direction of movement as well as magnitude (Table 1). Migrations at each time point were compared to zero migration as well as between fixation groups.

A power calculation to detect a 0.2 mm difference in migration with a power of 80% and a significance of 0.05 required 16 patients in each group. A greater number of patients were recruited to allow for loss to follow up or unusable stereoradiographs. All RSA calculations were conducted following the recommendations of an expert group[17].

The study was approved by the Regional Ethics Committee (C02.101).

Results

47 patients were initially recruited and four were lost to follow up (one bearing dislocation, one death and two withdrawals). Therefore, there were 43 patients with complete data for analysis at two years. Patient recruitment and analysis is presented in the manner recommended by CONSORT[18] (Figure 3). The mean age for cemented components (n=21)

was 65.4 years (sd 8.8 years) and there were 10 male patients and 13 right sided procedures. For cementless components (n=22) the mean age was 67.6 years (sd 7.6 years) with 13 male patients and 13 right sided procedures.

The mean condition number for both femoral and tibial markers at the different time points (3,6,12 and 24 months) was between 35 and 51, with a standard deviation ranging between 9 and 21. No set of rigid body markers had a condition number greater than 95. Therefore, no set of stereoradiographs was discarded for an excessively high condition number.

Femoral Migration

For the femur, there was a significant anterior migration (*z*-axis) of approximately 0.2 mm for both fixation types by six months. This migration remained significant for the two years of the study did not increase further, and there were no significant difference between fixation types (Table 2). Although significant differences between fixation methods were occasionally seen, for example in x-axis migration and rotation around the z-axis at 12 months, none were persistent (Table 3). Between one and two years there was no significant migration of either the cemented or cementless components and no significant difference in migration between the two types of fixation.

Tibial migration

The cemented tibial component tipped into varus (0.3°) by 12 months, with no significant increase by two years (Table 4). There was no other significant migration at any time point. In contrast, the cementless component subsided 0.23 mm by 3 months, which increased to 0.34 mm by two years. This subsidence was combined with a significant increase in posterior slope of 0.4° that was established by 3 months and maintained at two years. In addition, the cementless tibial components appeared initially to rotate around the antero-posterior z-axis into valgus (0.35°), but this corrected by two years to the original position.

There was a significant difference in subsidence between the two methods of fixation at all time points. There was also a difference in posterior slope between fixation methods at 3 and 12 months, but the difference was not maintained at two years (Table 5).

Between the first and second post-operative (PO) years there was no significant difference in migration in any direction between cemented and cementless fixation. However, both fixation types had a small, but significant, amount of subsidence in the second PO year (cemented mean 0.05 mm sd 0.09 mm, cementless mean 0.04 mm 0.08 mm). Five cemented components had greater than 0.15 mm of subsidence whereas only a single cementless component had this amount of subsidence.

Radiographic assessment

All radiographs taken at one and two years postoperatively were assessed. No radiographs were rejected from analysis as all were correctly aligned. A single patient in the cementless group became unwell and did not attend her appointment at two years.

There were no radiolucencies around any femoral component in either group. There were several radiolucencies beneath the tibial component that were all less than 1 mm thick (Table 6).

The overall percentage of patients with a radiolucency around the tibial component in the cemented group was 62% at two years, compared to 29% for the cementless group, which was a significant difference (Chi squared, p = 0.017). At two years no cementless components had complete radiolucencies whereas 25% of cemented components had complete radiolucencies. This difference was statistically significant (Chi squared, p=0.019). The cementless partial RLs at two years were most evident in zone 6 as this was the only area that had a small sclerotic line beneath the radiolucent area.

Among the five cemented tibial components that had more than 0.15 mm of subsidence in the second year there were two complete and two partial radiolucencies and one without a radiolucency. In the single cementless tibial component with more than 0.15mm of subsidence in the second year there was no radiolucency.

Clinical Outcome

There was no difference in Oxford Knee Score between fixation types at either one or two years although the cementless knees maintained their scores at two years and the cemented knees had a slight decrease between one and two years (Table 7).

Discussion

The optimal way to assess the quality of fixation of a new implant is to undertake a randomised controlled trial using RSA, comparing the new implant with what is considered to be the gold standard [REF]. It has therefore been recommended that all new implants should be investigated in this way before being widely used[REF]. The aim of randomisation is to prevent the introduction of bias, and to eliminate the effect of any extraneous factor, such as age, activity level or sex. With the accuracy of RSA it is possible to have sufficient power with only a small number of patients to detect a small difference in migration if there is one. A difference in migration in the second year following implantation is the best predictor of long term loosening rates [REF]. In addition to using RSA we assessed the bone-implant interface with aligned radiographs. In this study there were no differences in patient demographics between groups suggesting that they were well matched. Overall the data suggests that for the OUKR cementless fixation is at least as good if not better than cemented.

Both cemented and cementless femoral components had a small amount of anterior migration, about 0.2 mm, which virtually all occurred in the first three months. This migration occurred anteriorly rather than proximally, presumably because the loads in flexion are greater than extension. The pattern and magnitude of migration was virtually identical between the cemented and cementless groups, and there was no second year migration for either group. No femoral radiolucencies were seen in either group. This demonstrates that cementless femoral fixation is as reliable and is achieved as quickly as cemented femoral fixation.

Significant differences were found between the migration of cemented and cementless tibial components. The main difference was in subsidence. The cemented tibial component had little, if any, subsidence at three months (0.10 mm, $p=0.210$), which had only slight progression over the subsequent time points (0.13 mm, $p=0.120$ at two years). This is to be expected as cement is designed as a grout and achieves its final shape intra-operatively, so any substantial subsidence would have to be the result of collapse of either the cement structure or the underlying bone and would be associated with failure of fixation. In contrast, the cementless components subsided during the first three months (0.23 mm, $p<0.001$) but stabilised over the subsequent time points. This is likely to be due to incomplete seating or bedding in of the component before fixation occurs. In the second post-operative year there was a small, but significant, amount of subsidence for both fixation types of approximately 0.05 mm, but there was no significant difference between the two groups ($p=0.79$). This suggests that the fixation of the cementless tibial component is as good as the cemented component. Furthermore, only a single cementless component subsided more than 0.15 mm in the second year, whereas four cemented components subsided more than 0.15 mm in this time period.

There was a marked difference in incidence of radiolucency between the cemented and cementless components, as has already been reported[15]. At two years no cementless components had complete radiolucencies so all must be securely fixed to bone. 25% of the cemented tibial components had complete radiolucencies. These radiolucencies were less than 1 mm, so should be non-progressive and are not indicative of loosening [5,6]. However, if a patient has pain and a radiolucency many surgeons would revise the knee. Although this type of revision is unnecessary, as the radiolucency is not the source of pain and as the pain tends to settle spontaneously if there is no mechanical problem, it could have been avoided by using a cementless component.

Despite being well designed this study does have limitations. The main limitation relates to the small number of patients studied. Based on the power study there were enough patients to compare fixation using RSA and radiographs but not for a clinical comparison or for complications. So even though there was no difference in Oxford knee scores in this study there may be functional differences between the devices. If loosening was the result of rare surgical errors, such as the surgeon forgetting to put cement in the femoral peg hole, the study would not identify this. However, errors in cementing would be avoided by using cementless components. Furthermore if any cases were likely to loosen it would be those that migrated more than 0.15mm in the second year and had complete radiolucencies. There were two cemented and no cementless components in this group. The other main limitation relates to the assessment of radiolucency. On the tibial side the bone-cement interface is flat so if there is soft tissue at the interface it will be seen on the radiographs. Whereas on the femoral side the interface is convex and if there is radiolucenct material at the interface it will be obscured by the component.

In conclusion, this study shows that the cementless Oxford UKR has a similar second year migration to the cemented, and unlike the cemented has no complete radiolucencies. This suggests that the fixation of the cementless components is at least as good if not better that that of the cemented. This may translate into a decreased revision rate. Large clinical studies are needed to confirm if this is the case.

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	Femur		Tibia	
	+ve	**-ve**	**+ve**	**-ve**
X	Medial	Lateral	Medial	Lateral
Y	Superior	Inferior	Superior	Inferior
Z	Anterior	Posterior	Anterior	Posterior
R*x*	Increased flexion	Decreased flexion	Reduced Slope	Increased Slope
R*y*	Internal rotation	External rotation	Internal rotation	External rotation
R*z*	Valgus	Varus	Valgus	Varus

Table 1. Clinical description of migration or rotation for femoral and tibial components.

	Cemented					**Cementless**				
	3 months	**6 months**	**12 months**	**24 months**	**12 - 24 months**	**3 months**	**6 months**	**12 months**	**24 months**	**12 - 24 months**
X	0.05 (0.40, 0.18)	0.05 (0.28, 0.47)	0.05 (0.28, 0.47)	0.03 (0.34, 0.80)	-0.10 (0.24, 0.15)	-0.01 (0.36, 0.59)	-0.12 (0.31, 0.10)	-0.18 (0.28, 0.01)	-0.05 (0.53, 0.33)	-0.08 (0.25, 0.18)
Y	-0.17 (0.25, 0.01)	-0.02 (0.39, 0.36)	-0.12 (0.25, 0.01)	-0.05 (0.32, 0.46)	0.02 (0.17, 0.67)	-0.10 (0.34, 0.11)	-0.02 (0.39, 0.11)	-0.12 (0.24, 0.06)	-0.04 (0.27, 0.69)	0.06 (0.16, 0.13)
Z	0.14 (0.33, 0.02)	0.16 (0.29, 0.01)	0.24 (0.32, 0.01)	0.22 (0.42, 0.03)	0.00 (0.14, 0.89)	0.26 (0.48, 0.00)	0.24 (0.39, 0.01)	0.26 (0.31, 0.00)	0.21 (0.23, 0.00)	-0.10 (0.20, 0.05)
Rx	0.19 (0.47, 0.08)	0.27 (0.81, 0.18)	0.16 (0.65, 0.40)	0.23 (0.68, 0.18)	0.00 (0.30, 0.97)	0.22 (0.95, 0.57)	0.04 (0.56, 0.85)	0.22 (0.57, 0.04)	0.20 (0.54, 0.16)	0.03 (0.31, 0.66)
Ry	0.10 (0.74, 0.84)	0.05 (0.62, 0.97)	-0.05 (0.63, 0.45)	0.32 (0.52, 0.15)	0.49 (0.57, 0.01)	0.26 (0.55, 0.01)	0.48 (0.79, 0.01)	0.24 (0.52, 0.05)	0.23 (0.52, 0.11)	-0.10 (0.47, 0.36)
Rz	-0.10 (0.95, 0.81)	0.19 (0.76, 0.17)	0.25 (0.80, 0.17)	-0.06 (0.75, 0.69)	-0.24 (0.74, 0.24)	-0.16 (0.89, 0.29)	-0.11 (0.90, 0.60)	-0.26 (0.93, 0.11)	0.00 (1.28, 0.81)	0.14 (0.54, 0.28)

Table 2. 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))

	3 months	6 months	12 months	24 months	12 - 24 months
X	0.285	0.122	0.017	0.178	0.945
Y	0.364	0.844	0.569	0.912	0.945
Z	0.126	0.653	0.748	0.601	0.202
Rx	0.675	0.555	0.539	0.912	1.000
Ry	0.133	0.087	0.079	0.887	0.002
Rz	0.776	0.261	0.026	0.862	0.179

Table 3. 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 and the second post-operative year (Mann-Whitney U).

	Cemented					Cementless				
	3 months	**6 months**	**12 months**	**24 months**	**12 - 24 months**	**3 months**	**6 months**	**12 months**	**24 months**	**12 - 24 months**
X	0.08 (0.28, 0.12)	-0.06 (0.19, 0.14)	0.01 (0.24, 0.91)	0.06 (0.26, 0.37)	0.07 (0.16, 0.08)	-0.09 (0.22, 0.14)	-0.06 (0.19, 0.20)	-0.04 (0.21, 0.57)	0.01 (0.19, 0.61)	0.07 (0.16, 0.07)
Y	-0.10 (0.17, 0.21)	-0.06 (0.18, 0.28)	-0.09 (0.19, 0.28)	-0.13 (0.23, 0.12)	-0.05 (0.09, 0.04)	-0.23 (0.18, 0.00)	-0.28 (0.17, 0.00)	-0.28 (0.19, 0.00)	-0.34 (0.23, 0.00)	-0.04 (0.08, 0.03)
Z	-0.02 (0.26, 0.61)	-0.05 (0.30, 0.88)	0.00 (0.26, 0.48)	0.03 (0.22, 0.48)	0.03 (0.11, 0.29)	-0.03 (0.20, 0.27)	-0.03 (0.13, 0.18)	-0.01 (0.15, 0.53)	-0.02 (0.16, 0.16)	0.02 (0.12, 0.53)
Rx	-0.09 (0.50, 0.59)	-0.25 (0.65, 0.15)	-0.10 (0.70, 0.94)	-0.17 (0.69, 0.43)	-0.01 (0.21, 0.86)	-0.48 (0.88, 0.02)	-0.46 (0.78, 0.01)	-0.38 (0.73, 0.02)	-0.40 (0.76, 0.02)	0.03 (0.19, 0.47)
Ry	-0.08 (0.46, 0.72)	0.07 (0.36, 0.26)	-0.02 (0.45, 0.79)	0.03 (0.44, 0.26)	-0.05 (0.28, 0.42)	0.05 (0.63, 0.99)	0.12 (0.58, 0.64)	0.16 (0.54, 0.18)	0.24 (0.61, 0.19)	-0.01 (0.28, 0.92)
Rz	-0.10 (0.68, 0.23)	0.15 (0.98, 0.88)	-0.29 (0.67, 0.01)	-0.31 (0.68, 0.04)	-0.07 (0.35, 0.36)	0.36 (0.70, 0.04)	0.33 (0.71, 0.04)	0.10 (0.63, 0.34)	-0.01 (0.60, 0.93)	-0.18 (0.29, 0.01)

Table 4. 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))

	3 months	6 months	12 months	24 months	12-24 months
X	0.065	0.940	0.546	0.676	0.979
Y	0.004	0.000	0.000	0.003	0.917
Z	0.234	0.465	0.435	0.192	0.735
Rx	0.120	0.268	0.113	0.144	0.434
Ry	0.961	0.743	0.268	0.651	0.620
Rz	0.025	0.158	0.015	0.192	0.285

Table 5. 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).

	Cemented		**Cementless**	
	One year	**Two years**	**One year**	**Two years**
Full	2 (9.5%)	5 (23.8%)	1 (4.5%)	0 (0%)
Partial	11 (52.4%)	8 (38.1%)	7 (31.8%)	6 (28.7%)
None	8 (38.1%)	8 (38.1%)	14 (63.6%)	15 (71.4%)

Table 6. Number of full and partial radiolucencies beneath the tibial component at each follow up point for both fixation types.

	Cemented	Cementless	p-value
Pre-operative	23.76 (13-37)	23.68 (12-36)	0.968
One year post-operative	39.95 (20-47)	41.27 (28-48)	0.526
Two years post-operative	38.35 (20-47)	41.52 (24-48)	0.197
Change pre-op to one year	16.19 (0-29)	17.14 (4-34)	0.677
Change pre-op to two years	14.69 (-2 - 29)	17.71 (7 - 32)	0.225

Table 7. Mean Oxford Knee Score, with range, for both fixation types at annual review and compared to pre-operative scores and between one and two years. 0 is the minimum score indicating the most poorly performing knee, 48 is the maximum score indicating the best performing knee.

Figures

Figure 1. Clinical photograph showing the undersurface of the hydroxyapatite coated titanium mesh on the cementless femoral component (left) and the uncoated cemented femoral component (right). The cementless component has two pegs while the cemented component has one and all pegs are uncoated. The main peg of the cementless component is oversized to provide a tight initial fit. The cementless component also has an additional 15° radius of curvature to accommodate the additional peg.

Figure 2. Clinical photograph showing the undersurface of the hydroxyapatite coated titanium mesh of the cementless tibial component (left) and the uncoated cemented tibial component (right).

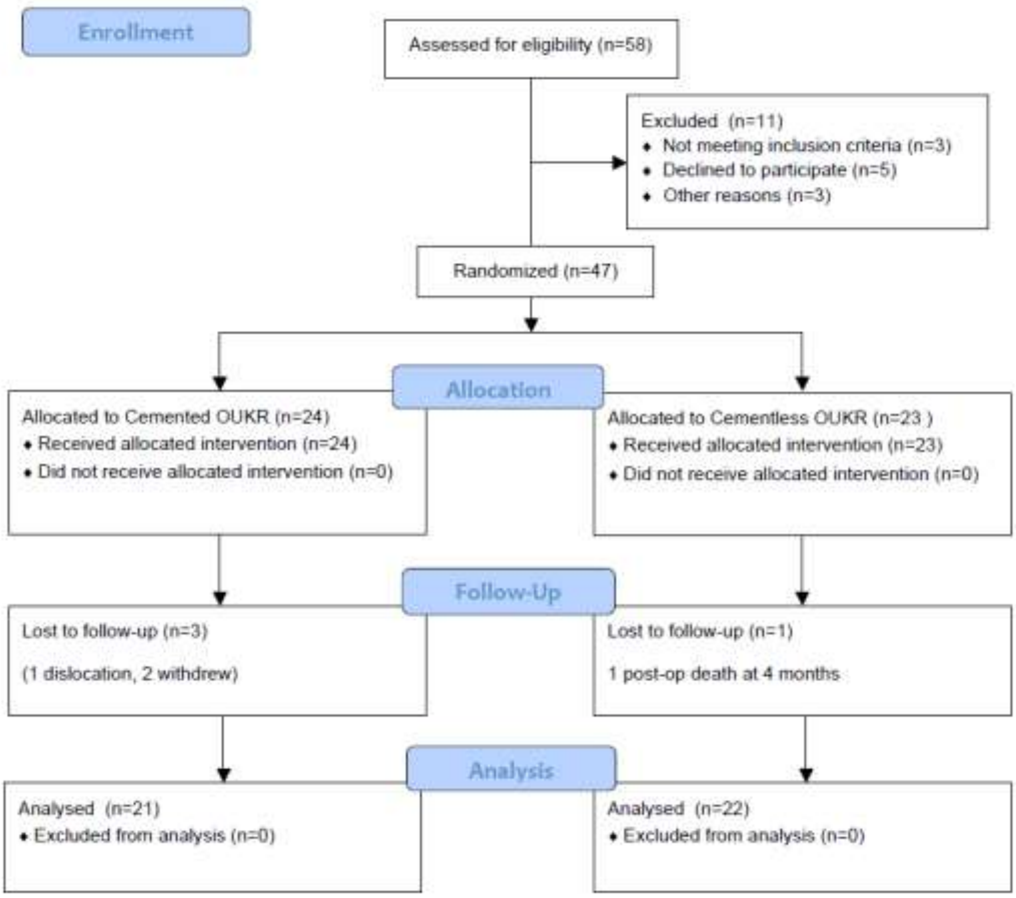

Figure 3. CONSORT diagram for the study.

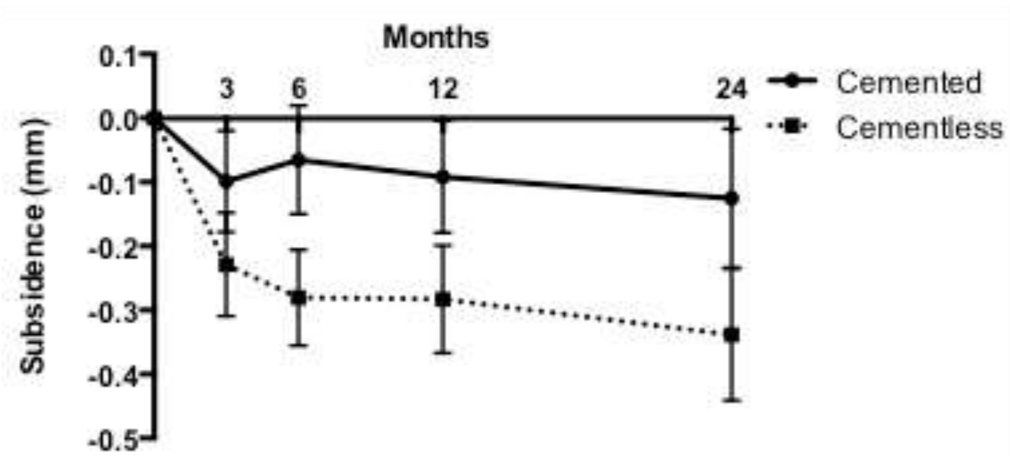

Figure 4. Mean subsidence (migration in the y-axis direction) for the tibial component (cemented: solid line, cementless: dashed line) with 95% confidence intervals.