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Original Article

Prospective randomised clinical trial assessing subsidence and rotation, using radiostereometric analysis, of two modular cementless femoral stems (Global K2 and Apex)

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ABSTRACT

Aims: To accurately assess subsidence, rotation and clinical scores in two cementless femoral stems.

Methods: 260 patients received either K2 or Apex femoral stems and were studied over 2y, with RSA and clinical scores.

Results: Mean Oxford Hip score for both stems was excellent (45.78 and 46.76). Very little subsidence or rotation were noted on RSA in either stem. There were no statistically significant differences in clinical scores, or radiological motion between stems. Revision rate was 0.8% over the study period.

Conclusion: Excellent clinical and RSA scores over the 2y study period predict good long term outcomes for these stems.

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1. Introduction

We present a prospective randomised clinical outcome study assessing migration patterns, rotational stability, bone remodelling, clinical and radiological outcomes after primary modular hip arthroplasty with 2 different femoral stems. We analysed the K2 (Global Orthopaedic Technology, Sydney Australia) and Apex Modular (Global Orthopaedic Technology, Sydney Australia). K2 (Global Orthopaedic Technology, Sydney Australia) modular hip system's geometry comprises a dual

longitudinal taper with rectangular cross-section. This has been modelled on the shape of the very successful Zweymüller design.¹ Apex Global Modular Hip system's geometry comprises a modular titanium construction with circumferential proximal porous coating of the "fit and fill" body section.²

Both these stems have recently been recalled by the TGA based on the 2012 NJRR report which indicated that the cumulative revision rate for the Apex K2 Modular Hip Replacement System was 5.5% at 1 year from the time of implantation and 9.3% at 3 years.³

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Migration patterns and rotation stability in the two implants were assessed using Radiostereometric analysis (RSA) at 6 weeks, 6 months, 1 and 2 years post op. The change in bone remodelling next to a porous coated femoral stem, was assessed using Dual Energy X-ray Absorptiometry (DEXA). Clinical outcomes were measured using Harris Hip Scores and Oxford Hip Scores. The cohort were followed up for 2 years after the hip arthroplasty procedure.

Radiostereometric analysis (RSA) is a highly accurate radiographic technique and is the gold standard in Europe for assessing the stability of implants within bone.^{4–7} It is at least ten times more accurate than conventional radiography.⁸ The pattern of micromotion exhibited by various prostheses and fixation techniques within the first post-operative year has been shown to be predictive of the long term fixation of the component to bone.^{5,7–12,20–22} The value of this precise radiographic technique is that new technologies and techniques can be introduced *in vivo* while limiting their exposure to as few patients as possible. RSA is a proven, safe and invaluable method for assessing methods of knee component fixation as well as different design concepts.^{13–19} Furthermore, the use of this extremely precise method of evaluation of micromotion means that small numbers are required to produce statistically significant results in a short period of time.¹³ Standard RSA films accurately demonstrate subsidence and micromotion over time (secondary stability), while stress RSA films demonstrate instantaneous micromotion at the prosthesis bone interface thus assessing primary stability.

Dual X-ray Absorptiometry (DEXA) has been widely used to quantify the extent of periprosthetic bone loss around joint implants.¹⁰ Detailed bone mineral density information in combination with RSA micromotion data provides a comprehensive assessment of bone in-growth and fixation processes that determine long term implant stability and survival.

2. Patients and methods

Sample size for two-sample comparison of means (at $\alpha = 0.01$, with an effect size of 0.5 and power at 0.9) equates to a sample size 120 for each group. We added 10 (8%) to each group for attrition. The total number of patients equals 130 for each group or 260 in total.

We identified 260 patients over a 12 month period that met the inclusion criteria for our study (see [Appendix 1](#)).

Preoperatively patients were computer randomised to receive either the K2 or Apex stem. Surgery was performed by the senior author, via a mini posterior approach. 4–5 RSA beads were inserted intraoperatively into the femur around the stem. Post-operatively patients underwent a standardised exercise rehab protocol. They were followed up for 24-months post-op, during this time they were assessed at the following intervals: pre-op., 6 week, 3 months, 12 months and 24 months post-op. They were assessed clinically using Harris Hip Score, Oxford Hip Score, and SF-12. They were assessed radiologically in a subset of 30 patients (Fifteen K2, and fifteen Apex stems) using standard and stress Radio Stereometric Analysis (RSA) films, and DEXA scanning to assess prosthetic migration and bone density in different Gruen zones.

2.1. RSA

Translation was measured in mm in relation to the 1st X-ray, performed 1 week post op. Motion in all three planes was assessed: x = mediolateral (medial positive), y = craniocaudal (proximal positive), z = anteroposterior (anterior positive). Rotation was assessed in degrees from original post op X-ray: clockwise (+ve) and anticlockwise (–ve) around the translational axis x, y and z: e.g rotation around the y axis is what is commonly referred to as anteversion/retroversion, rotation around the z axis varus/valgus and so on. Stress RSA were performed to show instantaneous movement when loading the prosthesis to demonstrate primary stability, whereas standard RSA were performed to demonstrate secondary stability.

2.2. Data and statistical analysis

A series of repeated measures ANOVAs were used to investigate the progression of clinical, DEXA and RSA outcomes between the two groups and, in the occurrence of significant main or interaction effects, independent t-tests were used to investigate differences in each dependent variable at the specific assessment time points. Statistical analysis was performed using SPSS software (SPSS, Version 17.0, SPSS Inc., USA), while statistical significance was determined at $p < 0.05$.

3. Results

3.1. Clinical outcomes

For all hips, the mean pre-op. Oxford Hip Score was 26.5, by 6 weeks this had improved to 36.7, at 3 months was 44, at 1 year and 2 years the mean was 46. The mean pre-op. Harris Hip Score was 59.4, at 6 weeks 82.8, at 3 months 93.6 at 1y 95.9 and at 2y 96.1. The mean SF-12 (physical component score) improved in both Apex and K2 groups from pre-op. of 38.5–44 by 6 weeks, and to 51 by 3 months, and 52 at 1y. The Mean scores when separating out for the different stems is illustrated in [Table 1](#) and [Fig. 1](#).

Post-hoc t-tests indicated that both groups significantly improved ($p < 0.05$) from pre-surgery to 6-weeks post-operatively, and again from 6-weeks to 3-months, though there was no further significant improvement ($p > 0.05$) from 3-months to 12-months post-surgery. Comparing the stems with each other, there was no statistically significant difference between clinical scores at each stage for either stem ($p > 0.05$).

3.2. RSA (see [Tables 2 and 3](#), and [Fig. 2](#))

The K2 stem demonstrated motion in any direction of less than 2 mm over the 24 month study period (even while stressing). The Apex stem subsided up to 2.5 mm by 1y, however by 24 months the mean apex stem subsidence was <2 mm (1.66 mm).

In the K2 group the difference between the mean inducible translation in any plane was no greater than 0.15 mm, in the Apex group the greatest difference was 0.48 mm in the y and z axis (at the 1y stage). However, the stress testing did not reveal such a large motion change at the 2y stage (mean 0.08 mm).

Table 1 – ANOVA results summary for clinical outcomes throughout the pre- and post-operative timeline. Shown are means (SE).

Time-point	Stem	OHS	HHS	PCS	MCS
Pre-surgery	K2	25.78 (1.24)	58.79 (2.40)	38.32 (1.51)	52.35 (1.59)
	Apex	28.31 (1.22)	60.93 (2.40)	39.50 (1.49)	57.13 (1.57)
6-weeks	K2	36.07 (1.04)	81.69 (2.04)	43.73 (1.33)	57.11 (1.30)
	Apex	37.05 (1.03)	83.02 (2.01)	44.96 (1.31)	56.76 (1.28)
3-months	K2	43.61 (0.76)	92.64 (1.33)	51.58 (1.30)	55.67 (1.12)
	Apex	44.38 (0.75)	94.29 (1.31)	51.55 (1.28)	57.85 (1.11)
12-months	K2	45.78 (0.45)	94.96 (1.18)	51.73 (1.30)	56.10 (1.34)
	Apex	46.76 (0.44)	96.83 (1.17)	52.28 (1.28)	56.17 (1.33)
Time Effect (<i>p</i> value)		<0.0001	<0.0001	<0.0001	0.272
Group Effect (<i>p</i> value)		0.094	0.281	0.58	0.263
Interaction Effect (<i>p</i> value)		0.387	0.963	0.676	0.112

There was a mean rotation of upto 3.57° in the K2 group at 1y however this reduced to 0.69° by 2y. The Apex group had a maximal mean rotation of 3.61° at the 2y mark.

Mean Induceable rotation was less than 1° at every stage post op.

Post-hoc t-tests indicated that there were no significant group differences (*p* > 0.05) in any of the translation or rotation based measures, as indicated by RSA, from early post-surgery to 3-months, or 3-months to 12-months post-surgery.

3.3. DEXA

The DEXA scanning revealed that the bone density was maximal preoperatively. Post-operatively in every zone the density was returning to preoperative levels, however none of the zones reached preoperative levels during the study period. There did not seem to be a predilection for certain zones to increase in density more than others.

We analysed the density between stems at different Gruen zones at the pre-op. 1y and 2y mark (Figs. 3 and 4).

When looking at the 1 and 2 year stage (Figs. 4 and 5), we see that the Apex had increased Bone mineral content in Zone G1,2,6,7 compared to the K2 – whereas the K2 had higher density in zones G3,4,5 than the Apex. This was a statistically significant finding (*p* < 0.05).

4. Discussion

These stems have recently been recalled (October 2012) by the TGA based on the 2012 NJRR report which indicated that the cumulative revision rate for the Apex K2 Modular Hip

Fig. 1 – Oxford and Harris Hip Scores for each stem.

Replacement System was 5.5% at 1 year from the time of implantation and 9.3% at 3 years.³ Our results using these two stems have been generally good and the RSA results appear to predict good long term stability for both of these stems.

4.1. Complications

We lost 8 patients to follow up (3%), no patients died. There was a complication rate of 1.5%. The 4 complications (detailed in Table 5) were 1 dislocation, 2 infections (requiring revision) and a DVT during the study period (Table 4).

Our revision rate was 0.8% over the 2 year period (significantly less than the reported 5% in the NJRR).

4.2. Clinical scores

Both stems had a significant improvement in scores from pre-op. to post-op. at every studied stage using the OHS and HHS. Interestingly there was no significant difference between the scores when comparing the two stems with each other. We believe that both these implants produce good results and convey similar clinical outcomes at every stage post-operatively over this timeframe.

4.3. RSA

The accuracy and prognostic importance of RSA X-rays make it the ideal mode for assessing new implants and picking up early probable failures. It is an extremely accurate measure when used to look at motion of a prosthesis in bone and has an accuracy of upto 0.2 mm.^{6–8} Significant subsidence in a stem measured by RSA is reported to be > 2 mm at 2y, with subsidence of 0.5–1 mm at 1 year is a bad prognostic sign, with 25–50% failure within 10 y.^{4,7,8,22,23} It is also known that stems often migrate within the first 6 months and then stabilise and this has no effect on long term stability.^{24,25} With regards to rotation it is felt that displacement of <2° is acceptable, although its effect on long term stability has not been reported.^{24,25}

In our study, as expected, the maximal motion occurred in translation along the y axis (subsidence). The K2 stem demonstrated motion in any direction of less than 2 mm over the 24 month study period (even while stressing). The Apex stem subsided up to 2.5 mm by 1y. This would be expected to predict a poor outcome, however by 24 months the mean apex stem subsidence was <2 mm (1.58 mm). There was a significant

Table 2 – ANOVA results summary for standard RSA changes (translation in mm, and rotation in degrees) from pre-surgery to 3-months post-surgery (3-months) and pre-surgery to 12-months post-surgery (12-months). Shown are mean changes (SE).

Time-point	Stem	TXA	TYA	TZA	RXA	RYA	RZA
3-months	K2	0.252 (0.066)	1.280 (0.352)	1.174 (0.376)	0.432 (0.112)	1.831 (0.646)	0.493 (0.133)
	Apex	0.211 (0.052)	2.119 (0.567)	0.660 (0.190)	0.775 (0.276)	1.699 (0.552)	0.304 (0.109)
12-months	K2	0.265 (0.076)	1.917 (0.604)	0.716 (0.283)	0.477 (0.140)	1.846 (0.595)	0.615 (0.235)
	Apex	0.273 (0.052)	2.509 (0.540)	1.054 (0.322)	0.303 (0.055)	2.878 (0.656)	0.383 (0.117)
Time Effect (p value)		0.507	0.058	0.372	0.133	0.192	0.256
Group Effect (p value)		0.837	0.385	0.987	0.641	0.556	0.331
Interaction Effect (p value)		0.672	0.976	0.062	0.074	0.203	0.832

Table 3 – ANOVA results summary for stress RSA changes (translation in mm, and rotation in degrees) from pre-surgery to 3-months post-surgery (3-months) and pre-surgery to 12-months post-surgery (12-months). Shown are mean changes (SE).

Time-point	Stem	TXA	TYA	TZA	RXA	RYA	RZA
3-months	K2	0.276 (0.071)	1.276 (0.353)	1.210 (0.435)	0.482 (0.110)	2.798 (0.961)	0.465 (0.100)
	Apex	0.250 (0.062)	2.468 (0.586)	0.892 (0.252)	0.498 (0.079)	2.508 (0.732)	0.379 (0.100)
12-months	K2	0.282 (0.087)	1.854 (0.608)	0.886 (0.257)	0.542 (0.124)	2.509 (0.784)	0.685 (0.267)
	Apex	0.273 (0.081)	2.136 (0.529)	0.801 (0.094)	0.354 (0.094)	2.403 (0.898)	0.400 (0.156)
Time Effect (p value)		0.991	0.656	0.594	0.751	0.968	0.343
Group Effect (p value)		0.976	0.331	0.932	0.490	0.747	0.478
Interaction Effect (p value)		0.922	0.108	0.682	0.263	0.449	0.370

Fig. 2 – RSA analysis of subsidence and rotation for both stems, and induced motion (suffix s).

Fig. 4 – DEXA Results for Apex stem at different periods post op.

Fig. 3 – DEXA Results for K2 stem at different periods post op.

Fig. 5 – DEXA Results for both stems at different periods post op.

Table 4 – ANOVA results summary for DEXA gruen zones from pre-surgery to 12-months post-surgery. Shown are means (SE).

Time-point	Stem	G1	G2	G3	G4	G5	G6	G7
Pre-surgery	K2	0.879 (0.162)	1.498 (0.300)	1.793 (0.298)	1.881 (0.276)	1.872 (0.296)	1.593 (0.259)	1.094 (0.203)
	Apex	0.936 (0.154)	1.610 (0.249)	1.870 (0.259)	1.909 (0.274)	1.973 (0.259)	1.651 (0.253)	1.159 (0.179)
12-months	K2	0.912 (0.165)	1.119 (0.219)	1.228 (0.214)	1.739 (0.185)	1.467 (0.272)	1.242 (0.201)	1.005 (0.190)
	Apex	1.005 (0.151)	1.446 (0.364)	1.426 (0.534)	1.790 (0.228)	1.366 (0.576)	1.438 (0.351)	1.073 (0.209)
Time Effect (p value)		0.002	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	0.002
Group Effect (p value)		0.126	0.275	0.475	0.683	0.002	0.350	0.029
Interaction Effect (p value)		0.332	0.010	0.456	0.819	0.046	0.035	0.797

outlier in the apex group who subsided by 5.4 mm – when this one is excluded the mean subsidence was only 1.07 mm.

Stress testing is thought to test the primary stability of the stem within the first year. Ideally the stem should not move more than 0.15 mm (so as not to interfere with osseointegration). In the K2 group the difference between the mean translation in any plane with stress applied was no greater than 0.15 mm, in the Apex group the greatest difference was 0.48 mm in the y and z axis at the 1y stage. However, the stress testing did not reveal a such a large motion change at the 2y stage – at this stage the mean was 0.08 mm. We noted that stabilisation of the stem occurred beyond 6 months this is not in keeping with previous reports.^{24,25} This suggests that the Apex stem continues to stabilise after 1y, despite this when looking at the translation (without stress) at the 2y mark the Apex had less subsidence than the K2 stem. Either the primary stability of the stem doesn't need to be as good as expected for osseointegration to occur or (we believe more likely) that the stem subsides and in so doing wedges in more tightly over time and stabilises in this way. We question the ability to truly significantly test primary stability (with regards to affecting osseointegration) using RSA which has an accuracy of 0.2 mm when we are looking for motion of <0.2 mm (0.15 mm) as the figure at which osseointegration occurs. Is it possible that osseointegration is not the important factor in their long term stability?

Table 5 – Adverse events.

Patient ID#	Complication	Adverse event description
85	Dislocation	Hip dislocation when playing lawn bowls, resulted in admission to Sir Charles Gairdner Hospital, confirmed via X-ray, relocated under anaesthetic with no further surgery
39	Deep infection	Patient presented 15 months post-surgery, washout and 2-stage right hip revision performed following initial washout, no further issues
88	DVT	6 cm soleal clot left lower limb, patient was Warfarinised and re-assessed at 2 weeks – clot had resolved warfarin was stopped, no further issues
43	Deep infection	Patient presented 18 months post-surgery with persistent hip pain following a throat infection, later diagnosed as a clinically infected hip. This proceeded to a 2-stage right hip revision, no further issues

The maximal mean rotation in both groups was found to be in the y axis (version). There was a mean rotation of upto 3.57° in the K2 group at 1y however this reduced to 1.53° by 2y. The Apex group had a maximal mean rotation of 3.61° at the 2y mark. It is probable that the stems rotation changes slightly as the stems subside into the host bone over time, and it would be interesting to see what the rotation was at later intervals than 2y. It is also noteworthy that the inducible rotation becomes less over time in both stems, suggesting stability is improving. However as already mentioned the significance of rotation with regards to prognosis is uncertain.^{24,25}

4.4. DEXA

The DEXA scanning revealed that the bone density was maximal preoperatively. Post-operatively in every zone the density was returning to preoperative levels, however none of the zones reached preoperative levels during the study period. There did not seem to be a major predilection for certain zones to increase in density more than others. When looking at the 2 year mark only (Fig. 5) and comparing, we see that the Apex had increased density in Zone G1,2,6,7 compared to the K2 suggesting more proximal loading, whereas the K2 had higher density in zones G3,4,5 suggesting more distal loading than the Apex. This may suggest that the differing stem design does have a bearing on the functional loading of the bone, however we believe that a longer study period is required to see any obvious changes in bone density to comment on.

5. Conclusion

We believe that both stems produce similar excellent clinical outcomes in the short term. Both stems displayed minimal motion (<2 mm) in subsidence, and rotation as assessed by RSA over the study period, which bodes well for their long term survival.

There was no significant difference between the outcome scores of each stem when compared. Furthermore there was no significant difference in the RSA analysis for translation or rotation between the two stems. We noted that stabilisation of the Apex stems continued to occur beyond 6 months (up to 1 year).

Our revision rate was significantly lower than the reported rate in the NJRR. We wonder if perhaps there were some centres/individuals that have had particularly bad results with these stems and have therefore skewed the results?

Conflicts of interest

All authors have none to declare.

Appendix 1. Inclusion and exclusion criteria

Inclusion criteria

1. The individual has signed a Patient Informed Consent (PIC), specific to this study, and approved by the Institutional Ethics Review Board.
2. The individual is between the ages of 21 and 75 years.
3. The individual is not classified as morbidly obese.
4. The individual clinically qualifies for total hip arthroplasty surgery based on physical examination and medical history.
5. The individual is diagnosed with a primary diagnosis of Non-Inflammatory Degenerative Joint Disease (osteoarthritis, traumatic arthritis, avascular necrosis, slipped capital epiphysis, pelvic fracture, femoral fracture, failed fracture fixation or diastrophic variant).
6. The individual does not have an active infection within the affected hip joint.
7. The individual has not had a previous total hip replacement or hip fusion of the affected hip joint.
8. The individual is physically and mentally willing and able to comply with post-operative scheduled clinical and radiographic evaluations and rehabilitation (i.e., not currently being treated for a psychiatric disorder, senile dementia, Alzheimer's disease, presence of alcohol or substance abuse).
9. The individual does not have a neuromuscular nor neurosensory deficiency which limits the ability to evaluate the safety and effectiveness of the device.
10. The individual does not have a diagnosed systemic disease that would affect the subject's welfare or overall outcome of the study (i.e., moderate to severe osteoporosis, Paget's disease, renal osteodystrophy), is not immunologically suppressed, or receiving steroids in excess of physiologic dose requirements.
11. The individual is skeletally mature.
12. The individual is not pregnant.
13. The individual is not a prisoner.
14. The individual has no plans to relocate to another geographic area before the completion of the study.

6.2 Exclusion criteria

1. The individual is unable or unwilling to sign the Patient Informed Consent (PIC), specific to this study, and approved by the Institutional Ethics Review Board.
2. The individual is less than 21 or greater than 75 years of age.
3. The individual is classified as morbidly obese (>40 BMI).
4. The individual does not clinically qualify for total hip arthroplasty surgery based on physical examination and medical history.

5. The individual is physically or mentally compromised (i.e., currently being treated for a psychiatric disorder, senile dementia, Alzheimer's disease, presence of alcohol or substance abuse), and is unwilling or unable to comply with post-operative scheduled clinical and radiographic evaluation and rehabilitation.
6. The individual has a neuromuscular or neurosensory deficiency which limits the ability to evaluate the safety and effectiveness of the device.

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