Implant design influences the joint-specific outcome after total knee arthroplasty

data from a randomized controlled trial at a minimum 12 years' follow-up

From Edinburgh Orthopaedics, Royal Infirmary of Edinburgh, Edinburgh, UK

Correspondence should be sent to N. Clement
nickclement@doctors.org.uk

Cite this article:
Bone Jt Open 2024;5(10):
911–919.

DOI: 10.1302/2633-1462.
510.BJO-2024-0111.R1

N. Clement,[1,2] D. J. MacDonald,[2] D. F. Hamilton,[2,3] P. Gaston[1,2]

[1]Edinburgh Orthopaedics, Royal Infirmary of Edinburgh, Edinburgh, UK
[2]Department of Orthopaedics, University of Edinburgh, Edinburgh, UK
[3]Research Centre for Health, Glasgow Caledonian University, Glasgow, UK

Aims
The aims were to assess whether joint-specific outcome after total knee arthroplasty (TKA) was influenced by implant design over a 12-year follow-up period, and whether patient-related factors were associated with loss to follow-up and mortality risk.

Methods
Long-term follow-up of a randomized controlled trial was undertaken. A total of 212 patients were allocated a Triathlon or a Kinemax TKA. Patients were assessed preoperatively, and one, three, eight, and 12 years postoperatively using the Oxford Knee Score (OKS). Reasons for patient lost to follow-up, mortality, and revision were recorded.

Results
A total of 94 patients completed 12-year functional follow-up (62 females, mean age 66 years (43 to 82) at index surgery). There was a clinically significantly greater improvement in the OKS at one year (mean difference (MD) 3.0 (95% CI 0.4 to 5.7); p = 0.027) and three years (MD 4.7 (95% CI 1.9 to 7.5); p = 0.001) for the Triathlon group, but no differences were observed at eight (p = 0.331) or 12 years' (p = 0.181) follow-up. When assessing the OKS in the patients surviving to 12 years, the Triathlon group had a clinically significantly greater improvement in the OKS (marginal mean 3.8 (95% CI 0.2 to 7.4); p = 0.040). Loss to functional follow-up (53%, n = 109/204) was independently associated with older age (p = 0.001). Patient mortality was the major reason (56.4%, n = 62/110) for loss to follow-up. Older age (p < 0.001) and worse preoperative OKS (p = 0.043) were independently associated with increased mortality risk. An age at time of surgery of ≥ 72 years was 75% sensitive and 74% specific for predicting mortality with an area under the curve of 78.1% (95% CI 70.9 to 85.3; p < 0.001).

Conclusion
The Triathlon TKA was associated with clinically meaningful greater improvement in knee-specific outcome when compared to the Kinemax TKA. Loss to follow-up at 12 years was a limitation, and studies planning longer-term functional assessment could limit their cohort to patients aged under 72 years.

Take home message
- Implant designed was associated with clinically meaningful greater improvement in knee-specific outcome.
- Loss to long-term follow-up was a limitation and was greater in those aged 72 years and older at the time of randomization.

Bone & Joint Open

Introduction
Total knee arthroplasty (TKA) is one of the most effective treatment options for end-stage arthritis of the knee, and is associated with improvement in both knee-specific function and health-related quality of life.[1] TKA is established as one of the most cost-effective procedures available in the NHS

with a cost per quality-adjusted life year of £2,761 at ten years.[2] A marker of the longer-term success of TKA is implant survival, with registry data suggesting a revision risk of 3.2% at ten years for all cemented TKAs.[3] Therefore, the majority of patients will continue to have a well-functioning TKA in the medium to longer term, but there is a paucity of data assessing knee-specific function. Williams et al[4] demonstrated, with cross-sectional Oxford Knee Score (OKS)[5,6] data, that knee-specific function peaks in the first three years following TKA, then gradually deteriorates to ten years. However, Scott et al,[7] using a patient-linked dataset over a 15-year postoperative period following TKA, showed that the OKS peaked at five years then deteriorated to 15 years. However, both studies showed a clinically meaningful improvement in the OKS at all timepoints postoperatively relative to baseline scores.[8]

There are comparatively few randomized studies evaluating implant design, and even fewer have evaluated longer-term patient functional outcomes.[9–14] Those that do tend to report outcome data at a single final follow-up timepoint and analyze this at one timepoint.[9,10,12,13] This form of analysis does not account for any temporal change which can offer a more complete picture of recovery and outcome trajectories.[15] The authors have reported a randomized controlled trial (RCT) that contrasted a modern implant design employing a single radius "patella friendly" design (Triathlon; Stryker, USA) against an older model employing a J-shaped curve multi radius design (Kinemax; Stryker). The Triathlon group outperformed the Kinemax group in terms of range of motion (ROM) and pain relief in longitudinal models over eight years.[16] However, at the eight-year timepoint there was no difference in knee-specific outcome despite earlier significant differences observed at one year.[17] One of the potential reasons for this was the limited number of patients available for functional assessment due to loss to follow-up in the longer term, as the study was powered to the OKS at the one-year endpoint. An alternative method is assessing functional change over time with inclusion of all assessment timepoints over the follow-up period.[15] In addition, for future studies powering to a longer-term endpoint, knowledge of factors associated with loss to follow-up may aid improved retention of the study cohort with defined inclusion and exclusion criteria for the cohort.

The primary aim was to assess whether joint-specific outcome after TKA was influenced by implant design over a 12-year follow-up period. The secondary aims were to assess whether patient-related factors were associated with loss to follow-up and mortality risk.

Methods

This study follows a cohort of 212 patients who were recruited to a prospective, double-blinded RCT to assess the influence of TKA prosthesis design on patient functional outcome; full methodological details are presented in the initial study report.[17] The study was registered on the International Standard Randomized Controlled Trial Number Register (ISRCTN85418379). Ethical approval was granted by the Lothian Research Ethics Committee 03 (ref: 06/S1103/50). Patients were recruited between February 2008 and August 2009 and followed up for a minimum of 12 years. The patient and researcher were blinded to implant allocation up to three years postoperatively, when patients could request to know their randomization group. Patients were randomized (by computer) to either a Kinemax or Triathlon TKA. The Kinemax TKA is an older implant that was non-sided and had a traditional multiradius design. In contrast, the Triathlon TKA is a sided patella-friendly implant that adopts a single radius of curvature, and the femoral component has shorter posterior femoral condyles and a thinner-sided anterior femoral condyle (to limit overstuffing the patella femoral joint). Surgery and postoperative care for all patients in the study was standardized as per the study centre's routine protocols. Implants were inserted via the same surgical technique employing cemented, cruciate-retaining, fixed-bearing implants in all cases. Patients underwent a standard mechanically aligned TKA using manual jigs (intramedullary femoral jig and extramedullary tibial jig). The aim for the femoral component was 5° to 7° of valgus relative to the anatomical axis of the femur, with 8 mm measured resection and 3° of external rotation. The aim for the tibial alignment was 0° varus/valgus and a 3° slope. The patella was not resurfaced, which was standard practice in the study centre.

Mortality

Patient mortality was obtained from their medical notes within the study centre, which is the only medical centre serving the population. In addition, the Scottish Office for Births and Deaths were contacted to confirm mortality status, but this would only capture patients who were within Scotland. Therefore, patients who moved out of Scotland may have been overlooked.

Revision

Survival analysis was undertaken for the 204 patients that received the assigned implant (97 Kinemax and 108 Triathlon). Patients undergoing revision were identified from their medical notes at the study centre and the questionnaires during the course of their follow-up. In addition, the national picture archiving system (Carestream Health (formerly Kodak Health), USA) for Scotland was used the review each patient's radiological history, and therefore if they had undergone revision in the NHS within Scotland they would have been identified.

Patients

From the original 212 patients who were randomized to the study, 94 patients (37 Kinemax and 57 Triathlon) were available for functional analysis at a mean 13 years' follow-up (12.0 to 14.3) (Figure 1). This represents a loss to follow-up of 118 patients in total, of whom eight were lost to follow-up early in the study follow-up as they did not receive the correct trial implants. Of the remaining 110 patients, reasons for this loss included death (n = 62), comorbidity preventing further evaluation (n = 15), failed to contact or refused further evaluation (n = 24), and revision of implant (n = 9) (Table I).

Outcomes

The OKS was used to assess knee-specific outcome and was administered preoperatively and at one, three to eight, and 12 years postoperatively via a postal questionnaire. Patients who did not return the questionnaire, or missed responses to specific questions, were contacted via telephone to complete the OKS. This has been shown to be a valid data collection

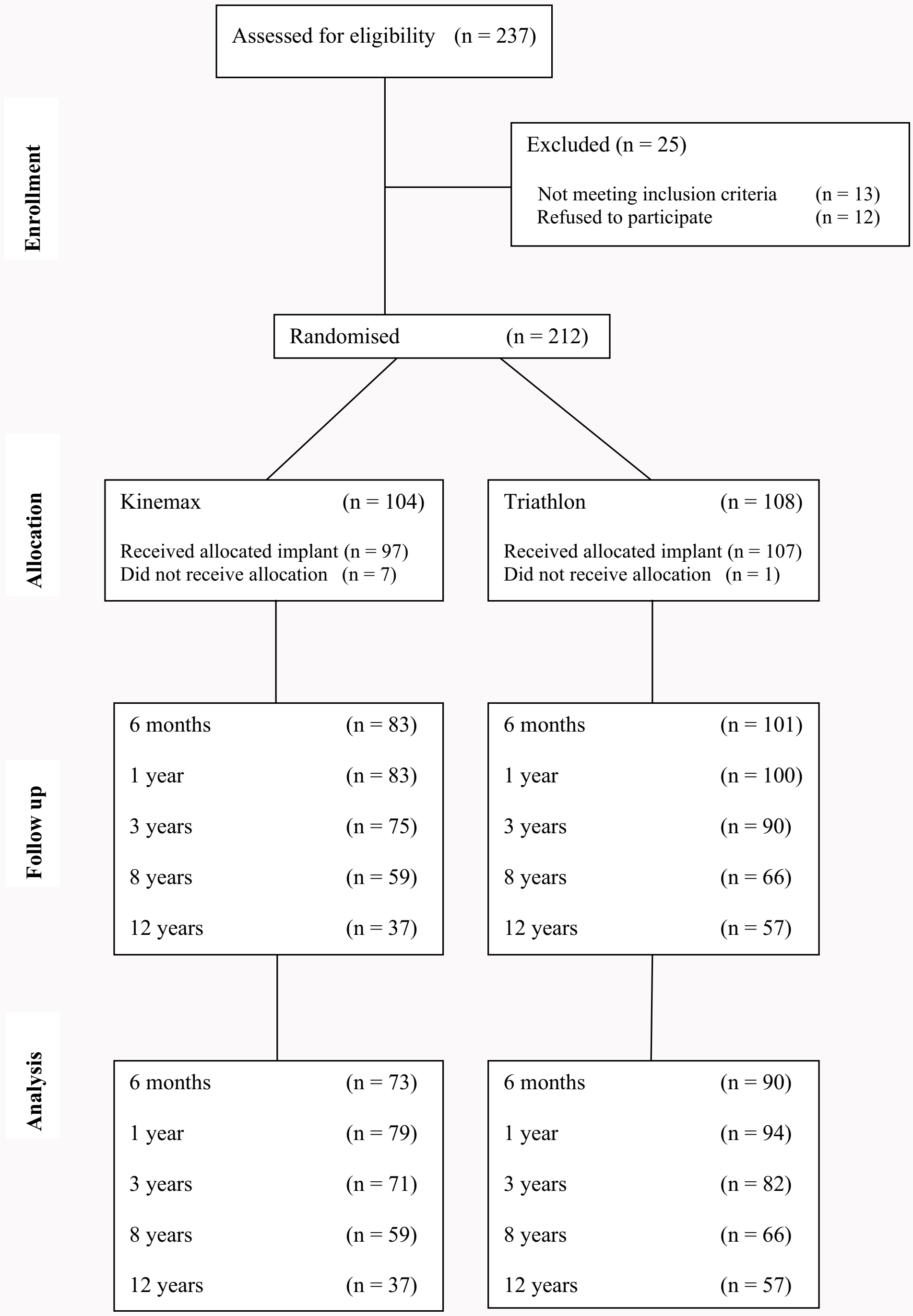

Fig. 1

Trial participation CONSORT flow diagram for functional assessment (Oxford Knee Score).

method for the OKS.[18] The responses to each of the OKS questions were scored from 0 to 4.[5,6] A summative score of 48 is the best possible score (least symptomatic) and 0 is the worst possible score (most symptomatic). The minimal clinically important difference (MCID) is the smallest difference in the OKS that is clinically perceived by the patient following their TKA. This has been defined to be between three and five points;[6,8,19] the authors therefore chose the lower value of three points to define the MCID for the current study being the minimal value.

Statistical analysis

Data were analyzed using SPSS v. 16 (SPSS, USA). Means are presented with SDs or 95% CIs if the mean represented a difference. An independent-samples *t*-test was used to assess differences between groups. Chi-squared tests were used to assess differences in categorical variables. Repeated measures analysis of variance (ANOVA) was used to the assess the difference in the OKS over time during the postoperative period (one to 12 years) with a Bonferroni correction for multiple testing. Kaplan-Meier methodology was used to estimate the survival of the patient and the prosthesis. Log rank (Mantel-Cox) test was used to assess differences in survival between the two groups. Logistic regression analysis

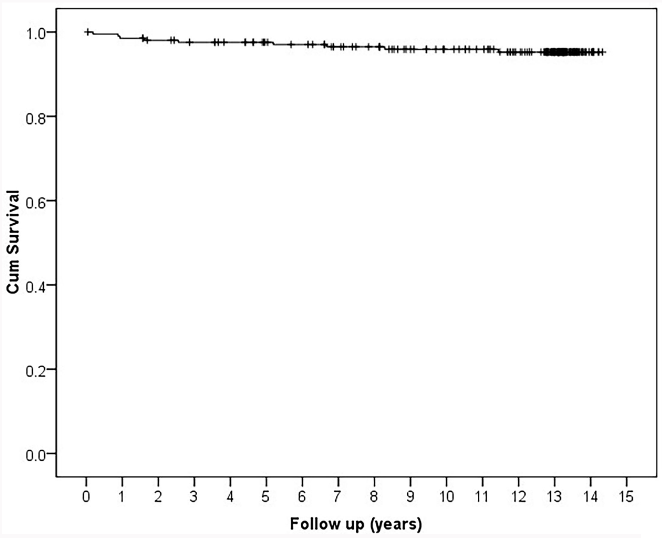

Fig. 2
Kaplan-Meier curve for implant survival. There were nine revisions during the 15 years' follow-up period.

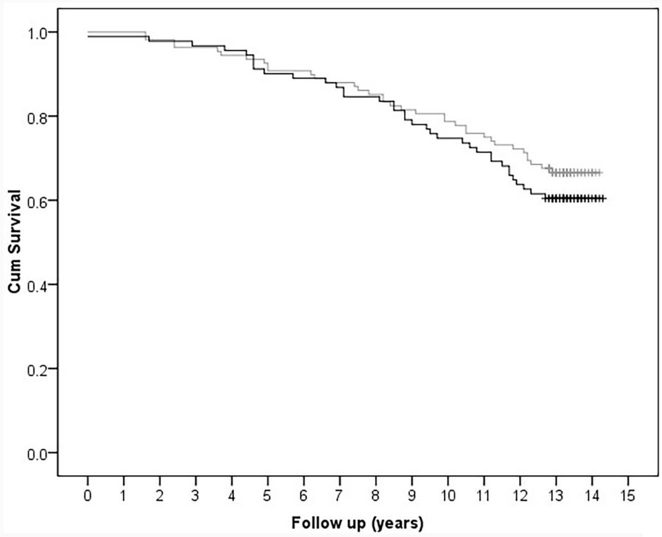

Fig. 3
Kaplan-Meier curve for patient survival for the Triathlon (grey) and Kinemax (black) groups (Stryker, USA). There were 72 deaths during the follow-up period.

was undertaken to assess the impact of preoperative variables

Table I. Loss to follow-up according to timepoint assessed and group.

Time period	Reason for loss to follow-up	Kinemax, n (%)	Triathlon, n (%)
Surgery	Operation delayed/cancelled	5 (4.8)	1 (0.9)
	Non-trial surgeon reallocation	2 (1.9)	0 (0)
1 year	Death	1 (1.0)	0 (0)
	Revised	2 (1.9)	1 (0.9)
	Not contactable/refused follow-up	9 (8.7)	4 (3.7)
	Impaired health prohibited assessment	2 (1.9)	2 (1.9)
3 years	Death	5 (4.8)	8 (7.4)
	Revised	3 (2.9)	1 (0.9)
	Not contactable/refused follow-up	11 (10.6)	6 (5.6)
	Impaired health prohibited assessment	3 (2.9)	2 (1.9)
8 years	Death	15 (14.4)	16 (14.8)
	Revised	4 (3.8)	4 (3.7)
	Not contactable/refused follow-up	13 (12.5)	13 (12.0)
	Impaired health prohibited assessment	6 (5.8)	8 (7.4)
12 years	Death	33 (31.7)	29 (26.9)
	Revised	5 (4.8)	4 (3.7)
	Not contactable/refused follow-up	14 (13.5)	10 (9.3)
	Impaired health prohibited assessment	8 (7.7)	7 (6.5)

on the likelihood that patients were lost to follow-up during the study period following TKA. Cox regression analysis was used to identify independent variables associated with mortality risk during the study follow-up period. Receiver operating characteristic curve analysis was used to assess the predictive value of age and baseline OKS as predictors of mortality. This is reported as an area under the curve (AUC), where 0.5 equates to no discrimination, 0.5 to 0.7 has poor discrimination, 0.7 to 0.8 has acceptable discrimination, 0.8 to 0.9 has excellent discrimination, and more than 0.9 has outstanding discrimination.[20] A cutoff value that offered the highest specificity and sensitivity was identify for age a predictor of mortality. Significance was accepted at $p \leq 0.05$. A

Table II. Mean changes in the Oxford Knee Score at the assessment timepoints relative to preoperative baseline score.

Timepoint and variable	Triathlon	Kinemax	p-value
1 yr			
Implants, n	100	83	
Sex (M:F), n	36:64	34:49	0.493*
Mean age at surgery, yrs (range)	68.9 (46 to 92)	67.6 (46 to 84)	0.707†
Mean baseline OKS (SD)	18.7 (7.1)	20.6 (7.7)	0.384†
3 yrs			
Implants, n	90	75	
Sex (M:F), n	31:59	29:46	0.571*
Mean age at surgery, yrs (range)	68.2 (46 to 92)	68.1 (46 to 84)	0.762†
Mean baseline OKS (SD)	18.6 (7.0)	20.0 (7.9)	0.266†
8 yrs			
Implants, n	66	59	
Sex (M:F), n	24:42	25:34	0.493*
Mean age at surgery, yrs (range)	66.8 (43 to 82)	68.1 (52 to 84)	0.373†
Mean baseline OKS (SD)	19.1 (7.3)	20.2 (7.6)	0.170†
12 yrs			
Implants, n	57	37	
Sex (M:F), n	20:37	12:25	0.791*
Mean age at surgery, yrs (range)	66.0 (43 to 82)	68.1 (56 to 80)	0.207†
Mean baseline OKS (SD)	18.6 (6.7)	21.5 (6.8)	0.055†

*Chi-squared test.
†Independent-samples *t*-test.
OKS, Oxford Knee Score.

Table III. Mean changes in the Oxford Knee Score at the assessment timepoints relative to preoperative baseline score.

	Mean change in OKS (SD)			
Timepoint	**Triathlon**	**Kinemax**	**Mean difference (95% CI)**	**p-value***
1 yr	20.0 (8.8)	17.0 (9.0)	3.0 (0.4 to 5.7)	0.027
3 yrs	19.5 (8.2)	14.9 (9.3)	4.7 (1.9 to 7.5)	0.001
8 yrs	14.0 (10.5)	12.0 (11.7)	2.0 (-1.9 to 6.0)	0.311
12 yrs	15.4 (11.3)	12.0 (12.0)	2.6 (-1.6 to 8.5)	0.181

*Independent-samples *t*-test.
OKS, Oxford Knee Score.

post-hoc power calculation for the repeated measures ANOVA demonstrated 99.9% power using the partial eta of 0.050 (effect size 0.229) an α of 0.05, using four measurements (one, three, eight, and 12 years postoperatively), in two groups (total 94 patients at 12 years), with a correlation of 0.5 and non-sphericity correction of 1.

Results

At 12 years' follow-up, 94 patients completed functional follow-up, with a mean age of 66 years (43 to 82) at time of primary surgery, and 62 (66.0%) of whom were female. There were no significant differences in sex, age, or baseline OKS between the groups at one, three, eight, or 12 years (Table II). There were nine revisions during the follow-up period, of which six were for aseptic reasons and three were for septic reasons, and the implant survival at 12 years was 95.2% (95% CI 92.1 to 98.3) (Figure 2). There was no difference in survival between the two groups (p = 0.721, log rank). There were 78 deaths during the full follow-up period (12.0 to 14.3 years), which equated to a 67.5% (95% CI 61.3 to 73.7) survival at 12 years (Figure 3). Of the 78 deceased patients, ten had completed functional assessment prior to their death. No patient was lost to follow-up in relation to their mortality status.

Primary aim: improvement in knee-specific outcome

There was a significantly greater improvement in the OKS at one and three years for the Triathlon group, which was also clinically significant (Table III), but no differences were observed at eight or 12 years' follow-up. When assessing the OKS over four timepoints assessed postoperatively, the Triathlon group had significantly (p = 0.040, partial eta squared 0.050) greater improvement in the OKS (mean difference 3.8, 95% CI 0.2 to 7.4) over the postoperative period (one, three, eight, and 12 years) which was also clinically significant (Figure 4).

Secondary aim: factors associated with loss to follow-up

The logistic regression model for factors associated with loss to follow-up contained four preoperative variables that met the assumptions of the model. The full model containing all predictors was statistically significant (p = 0.001, chi-squared test), indicating the model was able to distinguish between patients who were and were not lost to follow-up. The model as a whole explained between 10% (Cox and Snell R squared) and 14% (Nagelkerke R squared) of the variance in patient loss to follow-up and correctly classified 50.6% of the cases. Hosmer and Lemeshow test was non-significant (p = 0.149), which supports the goodness of fit of the model. Older age (odds ratio (OR) 1.06, 95% CI 1.03 to 1.11; p = 0.001) was the only variable that was independently associated with all-cause loss to follow-up. More specifically, older age (p < 0.001, Cox regression) and a worse baseline OKS (p = 0.043, Cox regression) were independently associated with an increased mortality risk during the follow-up period (Table IV). The patient's age at time of index surgery was shown to be an acceptable discriminator of mortality risk with an AUC of 78.1% (95% CI 70.9 to 85.3; p < 0.001), whereas baseline OKS was a poor discriminator with an AUC of 45.9% (95% CI 36.9 to 54.8; p = 0.366) (Figure 5). Using an age cutoff of 72 years was 75% sensitive and 74% specific for predicting mortality (Figure 6).

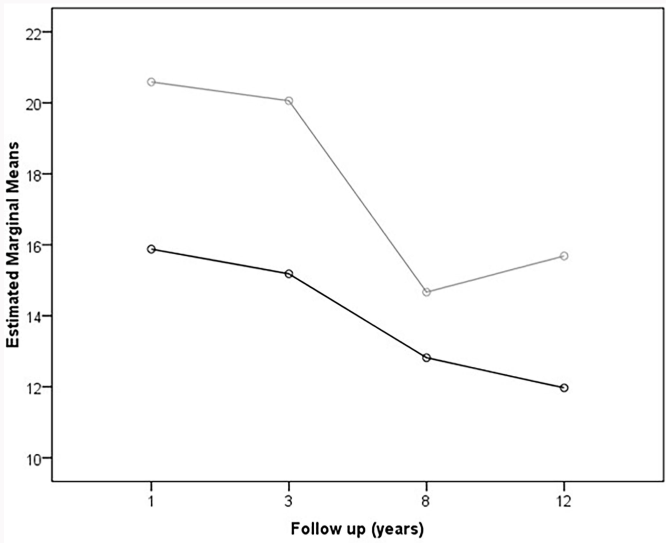

Fig. 4
Repeated measures analysis of variance for change in the Oxford Knee Score over the study period (one to 12 years) for the Triathlon group (grey) and Kinemax group (black).

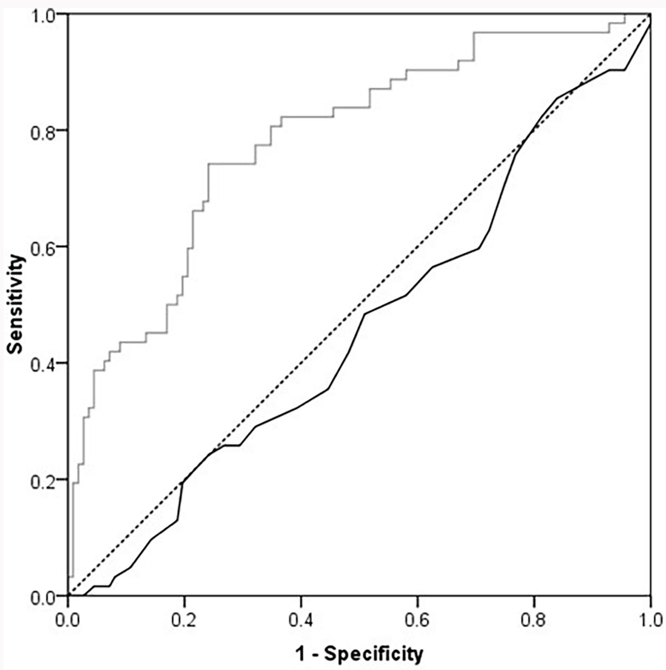

Fig. 5
Receiver operating characteristic curve for age at time of surgery (grey line) and baseline Oxford Knee Score (black solid line) for predicting mortality over the study period (12 to 15 years).

Discussion

The Triathlon implant with a single-radius and thinner (patella-friendly) sided anterior flange would seem to result in a clinically significant greater improvement in the OKS over the 12-year follow-up period when compared to the J-shaped curve design philosophy of the Kinemax TKA. However, when assessing individual timepoints, only one- and three-year assessments had significantly greater improvements in the OKS. This was possibly due to the limited number of patients with longer follow-up at eight and 12 years, which was predominately due to patient mortality. When assessing the OKS between the two groups over the study period (all four assessment points) there was a clinically significantly greater improvement in the OKS in the Triathlon group (marginal mean of 3.8 points). There was a relatively high attrition rate at 12 years of 53% (n = 109/204) which was independently associated with older patient age. Patient mortality was the major reason (56.4%, n = 62/110) for loss to follow-up, and older age and worse preoperative OKS were shown to be independently associated with mortality risk.

The limitations of the study should be acknowledged. The major limitation was the loss to follow-up, with only 94 patients (46%) of the original 204 who received the allocated implant being assessed for functional outcome at 12 years; however, this simply reflects the reality of clinical practice and subsequent patient attrition. The original study was powered to show a difference in the OKS of three points with an endpoint of one year, which required at least 200 patients when accounting for a 10% loss to follow-up at one year.[17] In contrast, the current study did not show a statistically significant or clinically meaningful difference when assessed at the 12-year endpoint in isolation. This non-significant difference may be due to the loss to follow-up with time, as to show a significant different for the 2.6-point difference observed at 12 years between the groups would have required 464 patients (with an assumed SD of ten points). The current study employed repeated measures ANOVA which allowed assessment of OKS over the four postoperative timepoints assessed for those followed up to 12 years. This employs more efficient use of data as compared to independent measures designs, which are often assessed at a single endpoint.[15] Therefore, the repeated measures ANOVA increases the statistical power because individual differences are often reduced, making it easier to detect the effects of the independent variable, i.e. the intervention of interest.[15] When performing a post-hoc power analysis for the repeated measures ANOVA, a power of 99.9% was demonstrated for the study cohort suggesting the significant difference of 3.8 points in the OKS over the 12 years was not a type 1 error. Another limitation was the assessment on knee-specific function using one outcome measure. In the original study, ROM of knee and leg extensor power were also assessed. At the 12-year postoperative timepoint it was felt that patient engagement may be limited with these additional assessments and may have resulted in poor follow-up. The decision was therefore made to assess the OKS in isolation at the 12-year assessment to try and limit patient fatigue, and maximize completion and return.

Both groups demonstrated a clinically meaningful improvement, of more than seven points,[8] in their OKS at all timepoints relative to their baseline score. However, patients in the Triathlon group had statistically significantly greater improvements in the OKS at one and three years with a mean difference of 3.0 and 4.7 points, respectively. The MCID, the clinically meaningful difference between two groups of patients, in the OKS following TKA is thought to range between three and five points.[6,8,19] The current study employed the lower MCID of three points to represent a clinically meaningful difference between the two groups assessed, which was observed at one year and had previously

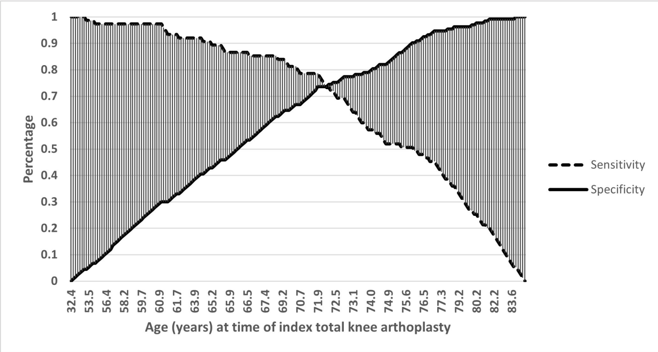

Fig. 6

A plot of specificity and sensitivity for age as a predictor of mortality over the follow-up period (12 to 15 years) for patients undergoing total knee arthroplasty.

Table IV. Cox regression model to assess the association of sex, age, baseline Oxford Knee Score and study group with postoperative mortality during the follow-up period (12.0 to 14.3 years).

Variable	Hazard ratio	95% CI	p-value
Sex			
Male	Reference		
Female	0.62	0.37 to 1.05	0.069
Age*	1.13	1.08 to 1.17	< 0.001
Baseline OKS*	0.96	0.93 to 0.999	0.043
Group			
Triathlon	Reference		
Kinemax	1.21	0.73 to 1.99	0.469

*The hazard ratio is for each year/point increase in age at time of surgery and baseline OKS.
OKS, Oxford Knee Score.

been reported.[17] The 2.0- and 2.6-point differences observed at eight and 12 years, respectively, are less than the MCID and may therefore not be clinically meaningful. However, assessing the OKS over all four timepoints for those followed up to 12 years, the marginal mean difference between the groups was 3.8 points, suggesting that those patients undergoing a Triathlon TKA had a clinically meaningful greater improvement in their knee-specific outcome. The reasons for this may be due to the differences in the implant design. A recent review demonstrated that a single-radius TKA was associated with greater patient satisfaction and better sit-to-stand testing when compared to patients undergoing a multiradius TKA.[21] The patella-friendly design of the Triathlon has also been shown to be associated with reduced anterior knee pain and patella complications in TKA when the patella has not been routinely resurfaced,[14] which was the case in the current study. It would therefore seem that modern implant design does offer patients a clinically meaningful greater improvement in their knee-specific outcome, which is a novel finding with "little to no evidence" showing an effective benefit according to the implant employed over the past 40 years.[22]

Loss to follow-up is a factor that needs to be considered when powering any prospective study. A RCT is typically considered as a level 1 study, but if the loss to follow-up is more than 20%, it may be considered as poor-quality and assigned as a level 2 study.[23] However, a loss to follow-up of more than 20% is acceptable if the natural history of the patient cohort is known, for example in hip fracture patients where there is an approximate 30% mortality rate at one year,[24] and the study can be powered for the anticipated loss accordingly. It is also recognized that approximately 10% of patients will not respond or refuse to continue follow-up. Non-responding patients who are alive are more likely to be younger, and have a higher BMI and worse preoperative patient-reported outcome come measures (PROMs).[25] The association between worse preoperative PROMs and loss to follow-up is consistent with the current study.

The observed mortality rates at eight and 12 years are similar to that observed from registry data for the population at risk, with an overall survival at ten years of 73%.[26] The current study highlighted that older age was independently associated with loss to follow-up due to the associated increasing mortality risk. Studies that are aiming to achieve a longer-term functional follow-up should perhaps consider using an upper age limit of 72 years for their inclusion criteria, which was shown in the current study to be an acceptable discriminator of mortality at 12 to 15 years following TKA. This is also supported by a RCT of patients following TKA that only included those aged younger than 60 years, which demonstrated an overall loss to follow-up of 7.9% (n = 23: five lost and 18 died) in their cohort of 291 patients at a mean of 26 years' follow-up.[11] Long-term follow-up rates must be balanced with the need in pragmatic trials to recruit representative samples and to recruit efficiently in a timely manner. It may be that different strategies should be employed depending on the end goal, however there should be clear consideration regarding this in study protocols.

There was no difference observed in the implant survival between the two groups. However, there is a recognized difference in the implant revision risks between the Kinemax and Triathlon TKA.[3] The National Joint Registry of England, which uses data from England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey, reported the ten-year revision risk for the Triathlon of 2.3% (95% CI 2.2 to 2.5) and 2.9% (95% CI 2.8 to 3.1), whereas the Kinemax revision risk was 4.7% (95% CI 4.3 to 5.3) and 5.4% (95% CI 4.8 to 6.0) for those with and without patella resurfacing, respectively.[3] This suggests a significant difference between these two implants.

In conclusion, the Triathlon TKA was associated with clinically meaningful greater improvement in knee-specific outcome when compared to the Kinemax. Loss to follow-up at eight and 12 years was a limitation, and studies planning longer-term functional follow-up up to 12 years could limit their cohort to patients aged less than 72 years.

References

1. **Sabah SA**, **Knight R**, **Alvand A**, **Beard DJ**, **Price AJ**. Early patient-reported outcomes from primary hip and knee arthroplasty have improved over the past seven years: an analysis of the NHS PROMs dataset. *Bone Joint J*. 2022;104-B(6):687–695.

2. **Chen B**, **Clement ND**, **MacDonald D**, **Hamilton DF**, **Gaston P**. Cost-utility analysis of total knee arthroplasty using 10-year data from a randomised controlled trial: implant design influences quality-adjusted life year gain. *Knee*. 2023;44:79–88.
3. **Ben-Shlomo Y**, **Blom A**, **Boulton C**, **et al**. The National Joint Registry 18th Annual Report 2021, London: The National Joint Registry. 2021. https://www.ncbi.nlm.nih.gov/books/NBK576858/
4. **Williams DP**, **Blakey CM**, **Hadfield SG**, **Murray DW**, **Price AJ**, **Field RE**. Long-term trends in the Oxford knee score following total knee replacement. *Bone Joint J*. 2013;95-B(1):45–51.
5. **Dawson J**, **Fitzpatrick R**, **Murray D**, **Carr A**. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Joint Surg Br*. 1998;80-B(1):63–69.
6. **Murray DW**, **Fitzpatrick R**, **Rogers K**, **et al**. The use of the Oxford hip and knee scores. *J Bone Joint Surg Br*. 2007;89-B(8):1010–1014.
7. **Scott CEH**, **Snowden GT**, **Cawley W**, **et al**. Fifteen-year prospective longitudinal cohort study of outcomes following single radius total knee arthroplasty. *Bone Jt Open*. 2023;4(10):808–816.
8. **Beard DJ**, **Harris K**, **Dawson J**, **et al**. Meaningful changes for the Oxford hip and knee scores after joint replacement surgery. *J Clin Epidemiol*. 2015;68(1):73–79.
9. **Beyer F**, **Pape A**, **Lützner C**, **Kirschner S**, **Lützner J**. Similar outcomes in computer-assisted and conventional total knee arthroplasty: ten-year results of a prospective randomized study. *BMC Musculoskelet Disord*. 2021;22(1):707.
10. **van den Boom LGH**, **Brouwer RW**, **van den Akker-Scheek I**, **et al**. No difference in recovery of patient-reported outcome and range of motion between cruciate retaining and posterior stabilized total knee arthroplasty: a double-blind randomized controlled trial. *J Knee Surg*. 2020;33(12):1243–1250.
11. **Kim YH**, **Park JW**, **Jang YS**. Long-term (up to 27 years) prospective, randomized study of mobile-bearing and fixed-bearing total knee arthroplasties in patients <60 years of age with osteoarthritis. *J Arthroplasty*. 2021;36(4):1330–1335.
12. **Sappey-Marinier E**, **Swan J**, **Maucort-Boulch D**, **et al**. No significant clinical and radiological differences between fixed versus mobile bearing total knee replacement using the same semi-constrained implant type: a randomized controlled trial with mean 10 years follow-up. *Knee Surg Sports Traumatol Arthrosc*. 2022;30(2):603–611.
13. **Cip J**, **Obwegeser F**, **Benesch T**, **Bach C**, **Ruckenstuhl P**, **Martin A**. Twelve-year follow-up of navigated computer-assisted versus conventional total knee arthroplasty: a prospective randomized comparative trial. *J Arthroplasty*. 2018;33(5):1404–1411.
14. **Karachalios T**, **Komnos G**, **Hantes M**, **Varitimidis S**. Evaluating the "patella-friendly" concept in total knee arthroplasty: a minimum 15-year follow-up outcome study comparing constant radius, multiradius cruciate-retaining, and nonanatomical cruciate-retaining implants. *J Arthroplasty*. 2021;36(8):2771–2778.
15. **Schober P**, **Vetter TR**. Repeated measures designs and analysis of longitudinal data: if at first you do not succeed-try, try again. *Anesth Analg*. 2018;127(2):569–575.
16. **Hamilton DF**, **Burnett R**, **Patton JT**, **et al**. Reduction in patient outcomes but implant-derived preservation of function following total knee arthroplasty: longitudinal follow-up of a randomized controlled trial. *Bone Joint J*. 2020;102-B(4):434–441.
17. **Hamilton DF**, **Burnett R**, **Patton JT**, **et al**. Implant design influences patient outcome after total knee arthroplasty. *Bone Joint J*. 2015;97-B(1): 64–70.
18. **Makaram N**, **Lee T**, **Macdonald D**, **Clement ND**. The verbal Oxford Knee Score is not clinically different from the written score when assessed before or after total knee arthroplasty. *Knee*. 2020;27(5):1396–1405.
19. **Clement ND**, **MacDonald D**, **Simpson A**. The minimal clinically important difference in the Oxford knee score and Short Form 12 score after total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2014; 22(8):1933–1939.
20. **Mandrekar JN**. Receiver operating characteristic curve in diagnostic test assessment. *J Thorac Oncol*. 2010;5(9):1315–1316.
21. **Lei T**, **Jiang Z**, **Qian H**, **Backstein D**, **Lei P**, **Hu Y**. Comparison of single-radius with multiple-radius femur in total knee arthroplasty: a meta-analysis of prospective randomized controlled trials. *Orthop Surg*. 2022;14(9):2085–2095.
22. **Carr AJ**, **Robertsson O**, **Graves S**, **et al**. Knee replacement. *Lancet*. 2012;379(9823):1331–1340.
23. **Burns PB**, **Rohrich RJ**, **Chung KC**. The levels of evidence and their role in evidence-based medicine. *Plast Reconstr Surg*. 2011;128(1):305–310.
24. **Clement ND**, **Penfold RS**, **Duffy A**, **Murthy K**, **MacLullich AMJ**, **Duckworth AD**. Completion of the emergency department "Big 6" in patients with an acute hip fracture is associated with a lower mortality risk and shorter length of hospital stay. *J Clin Med*. 2023;12(17):5559.
25. **Ross LA**, **O'Rourke SC**, **Toland G**, **MacDonald DJ**, **Clement ND**, **Scott CEH**. Loss to patient-reported outcome measure follow-up after hip arthroplasty and knee arthroplasty : patient satisfaction, associations with non-response, and maximizing returns. *Bone Jt Open*. 2022;3(4):275–283.
26. **Yapp LZ**, **Clement ND**, **Moran M**, **Simpson A**, **Scott CEH**. Long-term mortality rates and associated risk factors following primary and revision knee arthroplasty: 107,121 patients from the Scottish Arthroplasty Project. *Bone Joint J*. 2022;104-B(1):45–52.

Author information

N. Clement, MBBS, MD, PhD, FRCS Ed (Tr&Orth), Orthopaedic Consultant, Honorary Clinical Senior Lecturer
P. Gaston, FRCS Ed (Tr&Orth), Orthopaedic Consultant, Honorary Reader
Edinburgh Orthopaedics, Royal Infirmary of Edinburgh, Edinburgh, UK; Department of Orthopaedics, University of Edinburgh, Edinburgh, UK.

D. J. MacDonald, BA, Database and Clinical Research Manager, Department of Orthopaedics, University of Edinburgh, Edinburgh, UK.

D. F. Hamilton, PhD, Reader in Musculoskeletal Health, Department of Orthopaedics, University of Edinburgh, Edinburgh, UK; Research Centre for Health, Glasgow Caledonian University, Glasgow, UK.

Author contributions

N. Clement: Conceptualization, Formal analysis, Methodology, Writing – original draft.
D. J. MacDonald: Data curation, Investigation, Project administration, Software, Writing – review & editing.
D. F. Hamilton: Funding acquisition, Investigation, Methodology, Writing – review & editing.
P. Gaston: Conceptualization, Methodology, Project administration, Resources, Supervision, Writing – review & editing.

Funding statement

The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: an unrestricted grant for the trial was provided to the University of Edinburgh by Stryker UK, which had no role in the design, collection, analysis and interpretation of the data or in the writing of the article and the decision to submit it.

ICMJE COI statement

N. Clement, D. MacDonald, P. Gaston, and D. Hamilton declare that an unrestricted educational grant for the trial was provided to the University of Edinburgh by Stryker UK, which had no role in the design, collection, analysis and interpretation of the data or in the writing of the article and the decision to submit it. Some of the surgical authors (D. Hamilton and P. Gaston) have previously acted as faculty on Stryker funded educational courses. Although none of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article, benefits have been or will be received but will be directed solely to a research fund, foundation, educational institution, or other non-profit organization with which one or more of the authors are associated. N. Clement is an editorial board member of *The Bone & Joint Journal* and *Bone & Joint Research*. D. Hamilton is an editorial board member of *The Knee*.

Data sharing

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

Acknowledgements

The authors would like to thank all the patients that participated in the study over the 12-year period for their time in delivering this study. We would also like to thank all of our colleagues at Edinburgh Orthopaedics as without their support, this research would not be possible.

Ethical review statement

Ethical approval was granted by the Lothian Research Ethics Committee 03 (ref: 06 /S1103/50) and South-East Scotland Research Ethics Service, Scotland (20/SS/0125).

Open access funding

This was funded from the Stryker grant recieved by Edinburgh University, Edinburgh, UK.

Trial registration number

International Standard Randomized Controlled Trial Number: ISRCTN85418379