Reduction in patient outcomes, but implant derived preservation of function 8-years following total knee arthroplasty

Longitudinal follow-up of a randomised controlled trial

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Reduction in patient outcomes but implant-derived preservation of function following total knee arthroplasty: longitudinal follow-up of a randomized controlled trial

D. F. Hamilton,
R. Burnett,
J. T. Patton,
G. J. MacPherson,
A. H. R. W. Simpson,
C. R. Howie,
P. Gaston

From University of Edinburgh, Edinburgh, UK

Aims

There are comparatively few randomized studies evaluating knee arthroplasty prostheses, and fewer still that report longer-term functional outcomes. The aim of this study was to evaluate mid-term outcomes of an existing implant trial cohort to document changing patient function over time following total knee arthroplasty using longitudinal analytical techniques and to determine whether implant design chosen at time of surgery influenced these outcomes.

Methods

A mid-term follow-up of the remaining 125 patients from a randomized cohort of total knee arthroplasty patients (initially comprising 212 recruited patients), comparing modern (Triathlon) and traditional (Kinemax) prostheses was undertaken. Functional outcomes were assessed with the Oxford Knee Score (OKS), knee range of movement, pain numerical rating scales, lower limb power output, timed functional assessment battery, and satisfaction survey. Data were linked to earlier assessment timepoints, and analyzed by repeated measures analysis of variance (ANOVA) mixed models, incorporating longitudinal change over all assessment timepoints.

Results

The mean follow-up of the 125 patients was 8.12 years (7.3 to 9.4). There was a reduction in all assessment parameters relative to earlier assessments. Longitudinal models highlight changes over time in all parameters and demonstrate large effect sizes. Significant between-group differences were seen in measures of knee flexion (medium-effect size), lower limb power output (large-effect size), and report of worst daily pain experienced (large-effect size) favouring the Triathlon group. No longitudinal between-group differences were observed in mean OKS, average daily pain report, or timed performance test. Satisfaction with outcome in surviving patients at eight years was 90.5% (57/63) in the Triathlon group and 82.8% (48/58) in the Kinemax group, with no statistical difference between groups (p = 0.321).

Conclusion

At a mean 8.12 years, this mid-term follow-up of a randomized controlled trial cohort highlights a general reduction in measures of patient function with patient age and follow-up duration, and a comparative preservation of function based on implant received at time of surgery.

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Correspondence should be sent to D. F. Hamilton; email: d.f.hamilton@ed.ac.uk

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Introduction

Total knee arthroplasty (TKA) is highly effective at reducing the morbidity associated with osteoarthritis.[1] Over 100,000 TKAs are carried out annually in the United Kingdom,[2,3] and although results are generally satisfactory, up to 20% of recipients report a less than favourable outcome.[4,5] As such, implants for knee arthroplasty continually

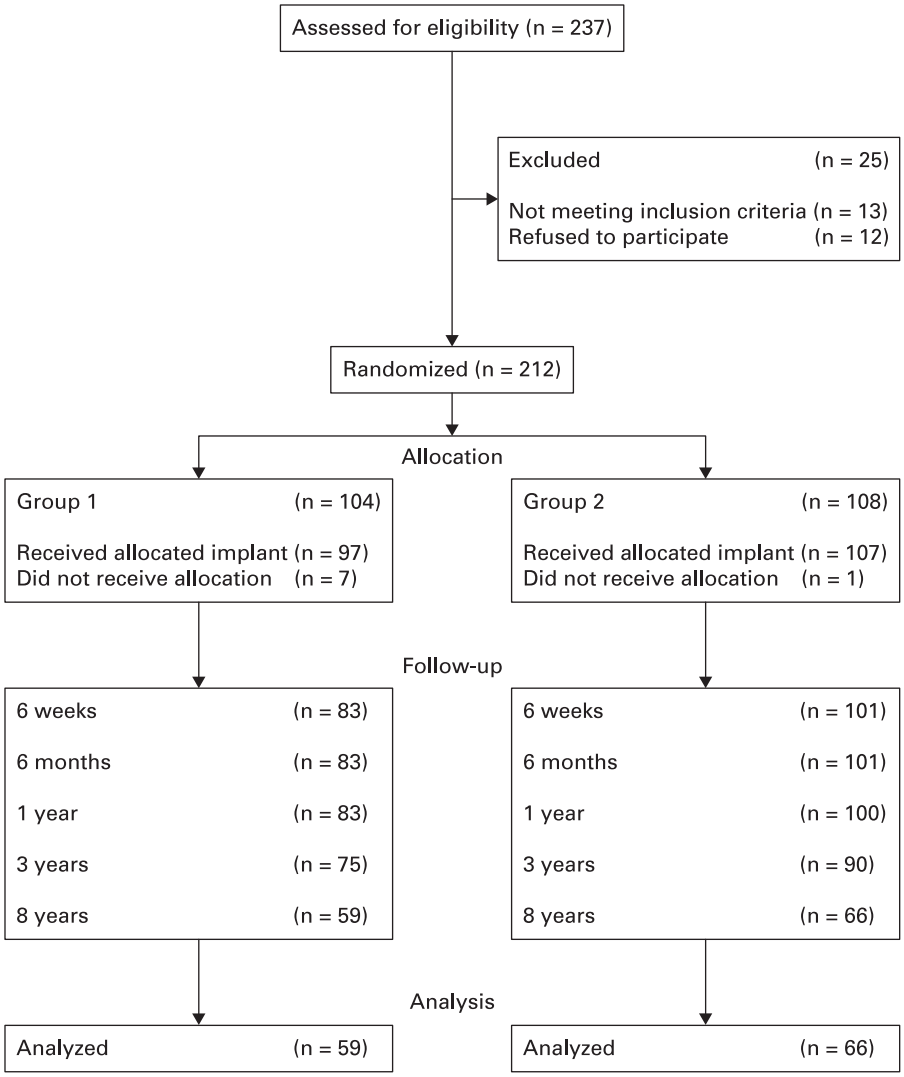

Fig. 1

Flowchart showing trial CONSORT participation.

evolve in efforts to enhance patient outcomes. A plethora of developments in prosthesis kinematics have promised enhanced function. However, Carr et al[6] noted that while the number of implants available had increased substantially in recent years, little or no evidence had been published of increased effectiveness.

Survivorship analysis is the standard evaluation of implant success. This identifies the revision rate of an implant but does not comment on patients' quality of life or function. Additionally, revision surgery is comparatively rare within ten-year follow-up of primary TKA, with UK national datasets reporting implant survival of > 95%.[2,3] Accordingly trials evaluating patient outcomes are necessary, in conjunction with survival analysis, to provide comprehensive information on the performance of implants. There are comparatively few randomized studies evaluating implant technologies, and fewer still that evaluate longer-term patient functional outcomes. Those that do tend to report minimal outcomes data at a single final follow-up timepoint and analyze this by simple two-way analysis with reference to the baseline data. This form of analysis does not account for any temporal change which can offer a more complete picture of recovery and outcome trajectories. We have reported a randomized controlled trial[7] that contrasted a modern implant design (Triathlon, Stryker, Mahwah, New Jersey, USA), against a previous model, that was routinely used at our department (Kinemax, Stryker). In the first three years post-surgery, the Triathlon group outperformed the Kinemax group in terms of knee flexion achieved, lower limb power output achieved, reported levels of 'worst daily pain' felt, and overall satisfaction with surgery.[7]

The aim of this follow-up study was to evaluate the outcomes of this implant trial cohort to chart changing patient function over time following TKA using longitudinal analytical techniques and to determine if any between group differences in patient outcome remained at longer term follow-up.

Table I. Summary of trial loss to follow-up.

Reason for loss to follow-up	Kinemax, n	Triathlon, n
Surgery		
Operation delayed/cancelled	5	1
Non-trial surgeon reallocation	2	N/A
Six weeks postoperatively		
Death	1	N/A
Revised (infection)	2	1
Patient withdrew (local follow-up)	9	3
Impaired health prohibited assessment	2	2
One year postoperatively		
Not contactable/refused follow-up	N/A	1
Three years postoperatively		
Death	4	8
Revised	1	N/A
Not contactable/refused follow-up	2	2
Impaired health prohibited assessment	1	N/A
Eight years postoperatively		
Death	10	8
Revised	1	3
Not contactable/refused follow-up	2	7
Impaired health prohibited assessment	3	6

N/A, not applicable.

Table II. Comparative group characteristics of the surviving cohort.

	Kinemax	Triathlon	p-value
Implants, n	59	66	N/A
Mean follow-up, yrs (range)	8.08 (7.89 to 8.78)	8.11 (7.31 to 9.24)	N/A
Female, n (%)	34 (58%)	42 (63%)	0.58*
Mean age, yrs (SD)	74.8 (8.3)	75.4 (7.6)	0.69†
Mean baseline OKS (SD)	20.19 (7.6)	19.11 (7.3)	0.16†
Mean baseline 'average' pain (SD)	5.41 (1.6)	5.36 (1.6)	0.87†
Mean baseline 'worst' pain (SD)	8.04 (1.6)	8.52 (1.3)	0.09†
Mean baseline ROM, ° (SD)	105.38 (15.4)	105.71 (15.2)	0.93†
Mean baseline timed function, (SD)	32.72 (10.5)	32.50 (10.5)	0.82†
Mean baseline power output, % cont. limb (SD)	51.13 (37.9)	49.77 (32.9)	0.74†

*Chi-squared test.
†Independent samples *t*-test.
OKS, Oxford Knee Score; ROM, range of movement; SD, standard deviation.

Methods

This study follows a cohort of 212 patients (mean age 69, 131 (62%) female) who were recruited to a prospective, double-blind, randomized control trial to assess the influence of TKA prosthetic design on patient functional outcome. The study was registered with the International Standard Randomized Controlled Trial Number Register (ISRCTN85418379).

Full methodological details are presented in the initial study report.[7] Ethical approval was granted by the Lothian Research Ethics Committee 03 (ref: 06/S1103/50). Recruitment took place between February 2008 and August 2009. Patients were recruited through informed consent. Implant allocation was by internet-based computer randomization, both patient and researcher were blinded to implant allocation, and remained so up to reporting at three years. It was initially hoped to review this cohort at five years, but logistical delays resulted that sequential review was facilitated at a later time period. All 'new' timepoint functional tests were carried out by the same researcher independent of the surgical teams blinded to implant allocation; however, we assume continued participant blinding has been lost. We did not formally unblind the trial, but it was ethically unreasonable (and logistically impractical) to attempt to maintain secrecy about implant allocation beyond the original study period and we assumed patients had become aware of their allocation.

The intervention implants were the Kinemax and Triathlon prostheses. Surgery and postoperative care for all patients in the study was standardized as per our unit's routine protocols. Implants were inserted via the same surgical technique employing cemented, cruciate-retaining, fixed-bearing implants in all cases. The patella was not resurfaced in accordance with the units' standard practice.

Outcome assessments. Efforts were made to contact all patients (including those previously reported lost to follow-up), and local health records checked for death and revision of implant. Patients were evaluated using the same equipment at the same clinical testing facility. Evaluation comprised the battery of assessment parameters previously reported. Initially as part of this study we also collected the Western Ontario and McMaster Universities Osteoarthritis Index[8] (WOMAC) score, but use of this questionnaire was abandoned during the first year of follow-up due to poor patient compliance with completion and resultant unusable data. We instead focussed our efforts on collecting the primary outcome questionnaire and functional testing data, which were well tolerated by the participants.

The Oxford Knee Score (OKS), is a 12-item response questionnaire designed to assess the patient's perceived pain and functional ability.[9] Scores range from 0 (representing severe symptoms and dysfunction) to 48 (representing a well-functioning knee joint).Global knee-pain severity was assessed using an 11 point (0 to 10) numerical rating scale (NRS), where 0 represents no pain and 10 the worst possible pain. Separate assessments were made of 'worst pain' and 'perceived average daily pain' to provide more realistic and meaningful measurements of pain intensity.[10] Active measures of flexion were determined using a standardized universal goniometry testing protocol as described by Jakobsen et al.[11] Testing was conducted supine, with no encumbrance from clothing, using a long-arm goniometer with measurements recorded to 1° intervals. The patient's lower limb power was determined with a Leg Extensor Power Rig (Nottingham University, Nottingham, UK). Output is expressed as a proportion of the measured result obtained preoperatively from the contralateral limb to act as an internal control, and to guard against the confounding influence of progressive disease pathology in the contralateral limb. Those not able to complete the test were assigned a score of zero as advocated by Lamb and Frost.[12] The ability to perform daily functional tasks was assessed with the aggregated locomotor function (ALF) score; a composite timed measure of observed tests of walking, stair ascent/decent, and chair transfers.[13] Time was recorded using a handheld stopwatch (Zeon, London, United Kingdom). Patient satisfaction with outcome at eight years was assessed with a five-point Likert scale; response

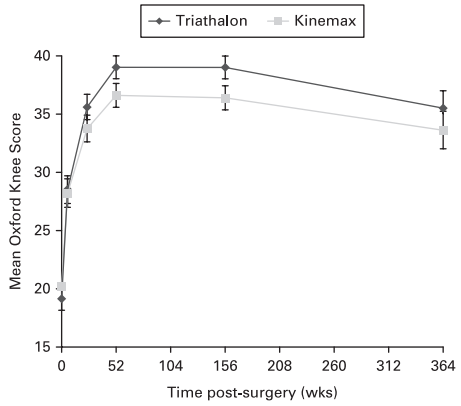

Fig. 2

Chart showing mean Oxford Knee Score (eight-year cohort) with 95% confidence intervals.

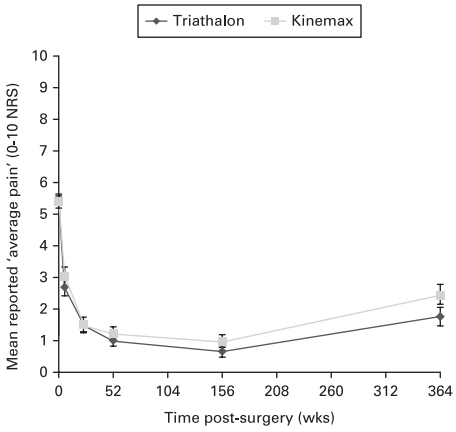

Fig. 3

Chart showing reported mean 'average daily pain' experienced (eight-year cohort) with 95% confidence intervals.

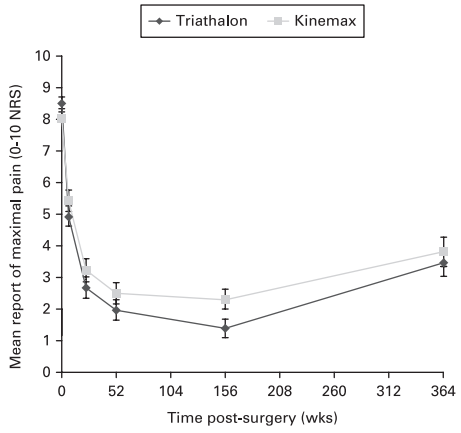

Fig. 4

Chart showing report of worst mean daily pain experienced (eight-year cohort) with 95% confidence intervals.

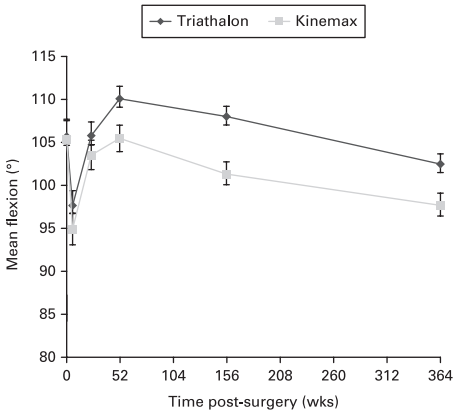

Fig. 5

Chart showing mean maximal knee flexion (eight-year cohort) with 95% confidence intervals.

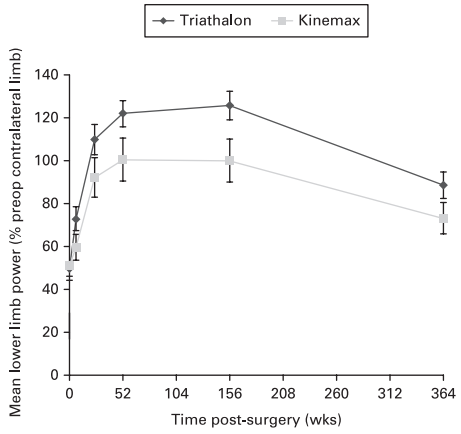

Fig. 6

Chart showing mean lower limb power output (eight-year cohort) with 95% confidence intervals.

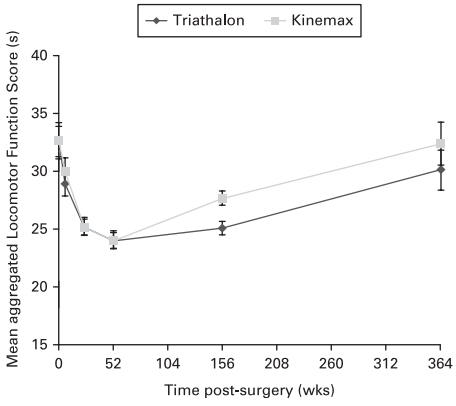

Fig. 7

Chart showing timed mean functional performance score (eight-year cohort) with 95% confidence intervals.

Table III. Satisfaction with outcome by group: eight-year cohort.*

Satisfaction response	Kinemax, n	Triathlon, n	Total, n
Very satisfied	36	38	74
Satisfied	12	19	31
Uncertain	8	3	11
Dissatisfied	1	3	4
Very dissatisfied	1	0	1
Total	58	63	121

*Missing data/no response n = 4.

options were very satisfied, satisfied, unsure, dissatisfied, and very dissatisfied.

The patients. From the originally recruited patients, a total of 125 patients (59 Kinemax and 66 Triathlon) were available for analysis at a mean 8.12 years follow-up (7.31 to 9.24) (Figure 1). This represents a loss to follow-up of 40 patients in the five years since last data reporting. Reasons for this loss include death (n = 18), comorbidity preventing further evaluation (n = 9), failed to contact or declined further evaluation (n = 9), and revision of implant (n = 4). Overall loss to follow-up was now 41% (87 of 212 patients) and full trial loss to follow-up is detailed in the study CONSORT flowchart (Figure 1) with patient attrition by review timepoint summarized in Table I.

Statistical analysis. Analysis was undertaken of the surviving patients who we were able to review eight years after the primary surgery. Means are presented with standard deviations (SDs) or 95% confidence intervals (CIs) as a measure of dispersion. Baseline data comparisons were evaluated with chi-squared and independent samples *t*-tests as appropriate. Final timepoint data were contrasted using unpaired *t*-tests and chi-squared test for the satisfaction data. Primary analysis was evaluation of change in outcome assessment parameters over time (encompassing the earlier outcome timepoints), with subsequent between group implant-time interactions using repeated measures analysis of variance (ANOVA) generalized linear mixed models. Statistical significance was set at a p-value ≤ 0.05. ANOVA effect size is interpreted according to Cohen's benchmarks.[14] Data were collated and analyzed using SPSS v. 21 (IBM, Chicago, Illinois, USA).

Results

The overall all-cause revision rate from the originally recruited 212 patients is equivalent between groups at 3.8% (n = 4) in the Kinemax group and 3.7% (n = 4) in the Triathlon group. We previously reported three early septic revisions (two Kinemax and one Triathlon) and one aseptic revision for persistent pain by three years (Kinemax). The four 'new' revisions occurring between three and eight years were all aseptic failures; two were documented as being aseptic loosening of the tibial component (one per implant group), one as pain and instability secondary to femoral component rotational malalignment (Triathlon) and one as pain following a fall (Triathlon).

To ensure the remaining patients represent a balanced cohort, considering the loss to follow-up by eight-year review, comparative analysis was performed on demographic indicators and baseline scores of evaluable patients (Table II). There are no differences between groups in presenting case-mix in the remaining cohort of 125 patients.

Table IV. Longitudinal assessment of outcome parameter incorporating change across all time point evaluations.

Outcome parameter	Change over time*	Between-group difference†
Oxford Knee Score	$F = 152.7$, $p < 0.001$, $\eta p^2 = 0.58$	$F = 1.7$, $p = 0.14$, $\eta p^2 = 0.15$
Mean 'average daily pain'	$F = 132.5$, $p < 0.001$, $\eta p^2 = 0.53$	$F = 0.7$, $p = 0.74$, $\eta p^2 = 0.07$
Worst daily pain	$F = 66.6$, $p < 0.001$, $\eta p^2 = 0.58$	$F = 2.8$, $p = 0.04$, $\eta p^2 = 0.21$
Knee flexion	$F = 27.6$, $p < 0.001$, $\eta p^2 = 0.20$	$F = 1.9$, $p = 0.05$, $\eta p^2 = 0.12$
Proportional lower limb power	$F = 66.7$, $p < 0.001$, $\eta p^2 = 0.45$	$F = 2.9$, $p = 0.01$, $\eta p^2 = 0.33$
Timed performance test	$F = 34.1$, $p < 0.001$, $\eta p^2 = 0.24$	$F = 1.2$, $p = 0.29$, $\eta p^2 = 0.11$

*Longitudinal mixed model.
†Analysis of variance implant time interaction.
F = F-ratio, ηp^2= partial Eta squared (measure of effect size).

Functional outcomes at eight years. All outcome parameters, which had been broadly stable between six months and three years, now show signs of worsening in the five years since last follow-up (Figures 2 to 7). At eight years, mean OKS in the Kinemax group is 33.6 (95% CI 31.4 to 36.8), and 35.5 (95% CI 32.5 to 38.5) in the Triathlon group (p = 0.140, independent samples *t*-test). Mean 'average daily pain' experienced is 2.5 (95% CI 1.8 to 3.1) in the Kinemax group and 1.8 (95% CI 1.2 to 2.3) in the Triathlon group (p = 0.066, independent samples *t*-test). Mean worst daily pain experienced is 3.8 (95% CI 2.9 to 4.7) in the Kinemax group and 3.4 (95% CI 2.6 to 4.3) in the Triathlon group (p = 0.470, independent samples *t*-test). Mean maximal active flexion is 97.7° (95% CI 95.1 to 100.3) in the Kinemax group and 102.5° (95% CI 100.1 to 104.9) in the Triathlon group (p = 0.003, independent samples *t*-test). Mean proportional lower limb power output is 73.2% (95% CI 61.7 to 84.8) in the Kinemax group and 88.6% (95% CI 76.1 to 101.2) in the Triathlon group (p = 0.137, independent samples *t*-test). Mean aggregated timed functional performance test is 32.4 seconds (95% CI 28.7 to 36.1) in the Kinemax group and 30.1 seconds (95% CI 26.6 to 33.5) in the Triathlon group (p = 0.307, independent samples *t*-test).

Generally high levels of satisfaction with outcome were seen in the cohort with 82.8% (48/58) of the Kinemax group and 90.5% (57/63) of the Triathlon reporting a positive satisfaction response (either satisfied or very satisfied). However, between-group difference in satisfaction response at eight-year assessment did not reach statistical significance (p = 0.321, chi-squared test), Table III.

Longitudinal analysis. Longitudinal models highlight changes over time in all longitudinal parameters and demonstrate large effect sizes. Significant between-group differences were seen in measures of knee flexion (with a medium effect size), lower limb power output (large effect size), and report of worst daily pain experienced (large effect size) favouring the Triathlon group. No longitudinal between-group differences were observed in mean OKS, report of average daily pain report, or timed performance test (Table IV, Figures 2 to 7).

Discussion

The main finding of this study was that patient outcomes, as assessed by a variety of parameters, generally deteriorated over time following knee arthroplasty, with a notable dip in performance occurring between the early follow-ups and the eight-year review. Implant design also seems to influence facets of patient functional outcome in the medium term.

At a mean of 8.12 years (7.3 to 9.4) follow-up, the Triathlon group demonstrate statistically significantly superior results, across all trial timepoints, to the Kinemax group in measures of knee flexion, proportional lower limb power output and report of worst daily pain experienced; demonstrating medium to large effect sizes for these differences. There were no statistically significant between-group differences seen in OKS, average daily pain experienced, or timed performance assessment of activities of daily living. A single timepoint evaluation of satisfaction demonstrated no statistical difference between the groups.

Historically, implant survival has been the usual method of comparing different implant designs over time. The survivorship of modern implants (including those employed in this study) is high regardless of fixation, constraint, and bearing type. Indeed, the most recent data in the National Joint Registry for England, Wales, Northern Ireland and Isle of Man (NJR) highlights both implants to have > 96% survival at ten years.[2] Another recognized problem with focussing on revision rate in isolation is that it does not comment on the quality of patient function or health status prior to revision of the implant. Assuming prosthesis benchmarking standards are met, 'survival' of the implant is something of a poor differentiator of outcome. We have previously highlighted that patient attrition among arthroplasty cohorts are not particularly well reported when considering implant survival.[7] In total, 183 patients were active on this study at one-year review; it is perhaps sobering that since then, 58 patients have been lost to follow-up (32% of the one-year cohort) with only five of these being implant-related. A total of 31 are now dead and a further nine have impaired health to the extent they cannot be actively reviewed (e.g. residential nursing home care with pathologies such as vascular dementia). The active cohort is now 59% of those initially recruited (125 of 212 participants).

It is of note that the outcome scores across the cohort have generally deteriorated between three- and eight-year reviews. We assume that the worsening outcome scores simply reflect an ageing study cohort eight years following surgery; the five-year advancement in time from last review sees the mean age of our cohort rise from early- to mid-70s. Williams et al[15] reported reduced OKS with advancing age using cross-sectional data. It is unsurprising that the physical measures (lower limb power output, time to perform functional activities, and maximal knee flexion) would reduce somewhat, perhaps regressing to a level appropriate to the demands of the patient's lifestyle. Large scale cohort studies documenting physical changes with ageing note the reduction of lower limb muscle strength in older age,[16] and the association between this decline in lower limb strength and increased impairment in mobility.[17] We report lower limb power output relative to that of the contralateral limb collected at preoperative baseline assessment to act as a stable internal control across all future measurements. The trial arms demonstrated the same proportional power output preoperatively (approximately 50% of the control limb). However, the Triathlon group recovered differently and reports greater power compared to the preoperative control value by one year. We hypothesize that this may be mechanically supported via an increased moment arm in the quadriceps group as a result of the differing point of rotation in the knee joint (the Triathlon has a more posterior point of rotation than the Kinemax implant).[7] It is important to highlight that the absolute lower limb power output values recorded in this study are below those of healthy age matched controls;[18] the Triathlon group reports a comparative preservation of lower limb power compared with the Kinemax group and not an improvement compared to healthy populations.

Despite remaining generally low, pain scores have increased compared with previous values; whether this also reflects the ageing process or new pathology is unknown. The mean OKS has correspondingly reduced by around 2 points over this time, representing about half of the accepted minimum clinically detectable change in the score.[19] It could be argued that, in terms of this key outcome parameter, there is a broadly stable outcome recorded between six months and eight years post-operation supporting the longer-term benefits of knee arthroplasty. Alternatively, these data could be seen to point to a blunted measurement range and highlight the benefit of more detailed functional analyses of patients. The same argument applies to the timed performance test, which showed no difference between groups but the clustering of responses around the mean suggests a similar blunting of measurement range. This suggests that the between-group differences we report may relate to higher levels of function than are required for simple daily tasks such as 'getting around the house' and highlights the challenge faced by the orthopaedic community in choosing the most appropriate patient reported outcome measure and functional test to gather relevant information across generic cohorts and highly performing groups.

In this study, the patients who received the more modern of the two implants demonstrate an overall comparative preservation of function at mean 8.12-year (7.3 to 9.4) review. Across the period since surgery, modest differences are evident between groups in absolute flexion (approximately 5°), report of worst pain experienced (approximately 10%), and ability to generate lower limb power in contrast to the control leg (approximately 20%). The implant-derived differences persisting over multiple timepoint evaluation into the medium-term post arthroplasty is an interesting finding, suggesting these are absolute differences and the between-group change over time is proportional. The clinical relevance of the functional differences detected is hard to determine, particularly as they relate to the combined longitudinal change as opposed to any specific timepoint difference. These changes cannot be readily interpreted with reference to a specific minimally important change in a metric, as such parameters have not been calculated over these longer periods. It can be speculated though that the modest reductions in reports of maximal pain, enhanced range of knee flexion, and greater ability to generate muscle power with the lower limb would be broadly beneficial and advantageous to both particularly frail and higher performing individuals.

Strengths of this study were the original randomized controlled trial (RCT) design and both range and consistency of outcome measures employed, over a relatively long follow-up period.

The limitations of this study are that the cohort is from a single centre and that the ability to extrapolate the data to other settings is assumed but unknown. The longitudinal modelling we employ asks whether there is any change over time in the various metrics, and secondarily, whether there are any between-group differences across all the timepoints.

This trial was originally powered to detect a difference in OKS between preoperative and 12-month scores. Clearly the power of the study to detect differences between implant groups is reduced by both applying a longitudinal analysis (incorporating six evaluation times) and the continuing reduction in patient numbers at subsequent assessments. This increases the uncertainty around our point estimates and suggests that we are at increased risk of a type-II error in interpretation (i.e. failing to identify a positive result). We feel this analysis to be the most appropriate and conservative methodology to employ in evaluating the general effects over time; evaluating whether the overall temporal trajectory of outcomes differ between groups as opposed to focussing on any specific individual timepoint differences. A further limitation is that we cannot be sure that the study remains double-blind. Though the assessor was blind to implant allocation, the participants may have had this disclosed. We did not formally unblind the trial, however it is ethically unreasonable (and logistically impractical) to try to hide the implant allocation from patients beyond the original study protocol. With five years having passed since last study visit, it is likely many patients would have seen various other orthopaedic clinical teams and may have had the implant name revealed. Although the patient reported scores could be influenced by confirmation bias, we think it unlikely that the physical evaluations (such as measures of knee flexion and power output) could have been meaningfully influenced by this knowledge.

In conclusion, at a mean 8.12-year follow-up, this randomized controlled trial cohort highlights a general reduction in measures of patient function with time following TKA and a comparative difference in function over time that is attributable to implant received at time of surgery.

Take home message

- We demonstrate a comparative reduction in measures of patient physical function with increasing time following total knee arthroplasty.
- In this RCT, we found that the implant used at time of surgery influenced outcome, with a modern design lineage implant moderating this functional decline.

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Author information:

D. F. Hamilton, PhD, MCSP, Research Fellow
R. Burnett, FRCS Orth (Ed), Consultant Orthopaedic Surgeon
J. T. Patton, FRCS Orth (Ed), Consultant Orthopaedic Surgeon
G. J. MacPherson, FRCS Orth (Ed), Consultant Orthopaedic Surgeon
A. H. R. W. Simpson, DPhil, FRCS Orth (Eng and Ed), Professor of Orthopaedic Surgery
C. R. Howie, FRCS Orth (Ed and Gla), Professor of Orthopaedic Surgery
P. Gaston, FRCS Orth (Ed), Consultant Orthopaedic Surgeon
Department of Orthopaedics and Trauma, University of Edinburgh, Edinburgh, UK.

Author contributions:

D. F. Hamilton: Designed the trial, Collected, analyzed and interpreted the data, Drafted and approved the manuscript.
R. Burnett: Designed the trial, Revised and approved the manuscript.
J. T. Patton: Designed the trial, Revised and approved the manuscript.
G. J. MacPherson: Collected the data, Revised and approved the manuscript.
A. H. R. W. Simpson: Designed the trial, Revised and approved the manuscript.
C. R. Howie: Designed the trial, Revised and approved the manuscript.
P. Gaston: Conceived the project, Designed the trial, Revised and approved the manuscript.

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