Fifteen-year prospective longitudinal cohort study of outcomes following single radius total knee arthroplasty

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Fifteen-year prospective longitudinal cohort study of outcomes following single radius total knee arthroplasty

PATIENT-REPORTED OUTCOME MEASURES, RESPONSE ATTRITION, AND SURVIVAL

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Aims

This prospective study reports longitudinal, within-patient, patient-reported outcome measures (PROMs) over a 15-year period following cemented single radius total knee arthroplasty (TKA). Secondary aims included reporting PROMs trajectory, 15-year implant survival, and patient attrition from follow-up.

Methods

From 2006 to 2007, 462 consecutive cemented cruciate-retaining Triathlon TKAs were implanted in 426 patients (mean age 69 years (21 to 89); 290 (62.7%) female). PROMs (12-item Short Form Survey (SF-12), Oxford Knee Score (OKS), and satisfaction) were assessed preoperatively and at one, five, ten, and 15 years. Kaplan-Meier survival and univariate analysis were performed.

Results

At 15 years, 28 patients were lost to follow-up (6.1%) and 221 patients (51.9%) had died, with the mean age of the remaining cohort reducing by four years. PROMs response rates among surviving patients were: one-year 63%; five-year 72%; ten-year 94%; and 15-year 59%. OKS and SF-12 scores changed significantly over 15 years ($p < 0.001$). The mean improvement in OKS was 18.8 (95% confidence (CI) 16.7 to 19.0) at one year. OKS peaked at five years (median 43 years) declining thereafter ($p < 0.001$), though at 15 years it remained 17.5 better than preoperatively. Age and sex did not alter this trajectory. A quarter of patients experienced a clinically significant decline (≥ 7) in OKS from five to ten years and from ten to 15 years. The SF-12 physical component score displayed a similar trajectory, peaking at one year ($p < 0.001$). Patient satisfaction was 88% at one, five, and ten years, and 94% at 15 years. In all, 15-year Kaplan-Meier survival was 97.6% (95% CI 96.0% to 99.2%) for any revision, and 98.9% (95% CI 97.9% to 99.9%) for aseptic revision.

Conclusion

Improvements in PROMs were significant and maintained following single radius TKA, with OKS peaking at five years, and generic physical health peaking at one year. Patient satisfaction remained high at 15 years, at which point 2.4% had been revised.

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Introduction

Patient-reported outcome measures (PROMs) are essential quantitative measures in evaluating the "success" of total knee arthroplasty (TKA). PROMs capture the patient's own subjective evaluation of the outcome of their surgery at a specific timepoint in a single quantifiable score providing an 'objective'

evaluation that quantifies the pain, function, or disease severity as perceived by the patient.

Following TKA, both joint-specific and generic health scores are typically used to assess changes in functional ability and health-related quality of life (HRQoL). The Oxford Knee Score (OKS)[1,2] is a validated knee-specific score of pain and function. It is widely used, including by the NHS Digital PROMs database where postoperative scores are reported at six months.[3] A quarter of patients go on to experience clinically significant improvements in OKS from six to 12 months,[4] and the OKS has previously been demonstrated to increase up to two years after TKA.[5] Though there is a wealth of data regarding early PROMs following TKA, there is a paucity of longer-term patient-linked longitudinal outcomes. Though Williams et al[5] reported mean OKSs to ten years to provide normal reference values at different follow-up timepoints, this was not patient-linked and did not represent longitudinal follow-up on the same patient cohort. Therefore, how a patient's OKS changes over time remains unclear. Such benchmark values are required for surgeons to audit accurately and compare their results.[5]

We have previously reported good survival and functional outcomes at five and ten years using the Triathlon TKA (Stryker, USA).[6,7] This TKA design incorporates single radius theory with deep flexion adaptations and patellofemoral friendly features. Implant survival is reported out to 15 years with a revision rate of 3.79 (95% confidence interval (CI) 3.42 to 4.19) across the Triathlon portfolio in the National Joint Registry (NJR) of England, Wales, Northern Ireland and the Isle of Man.[8] This registry data does not include the competing risk of death and can also lack granularity. Joint registry data can suffer from within brand camouflage,[9] and the NJR does not include PROMs.

This study aims to report longitudinal within patient PROMs over a 15-year period following cemented single radius TKA. Secondary aims included reporting the individual PROMs trajectory according to age and sex, expected attrition rates over 15 years, and the 15-year survival of a single radius TKA for the endpoints 'any revision' and 'any reoperation'.

Methods

Ethical approval was obtained for this prospective cohort study (Scotland (A) Research Ethics Committee 16/SS0026). From 2006 to 2007, data was recorded for consecutive patients undergoing Triathlon TKAs (Stryker Orthopaedics, USA) performed or supervised by seven consultant surgeons at a single large orthopaedic centre (Royal Infirmary of Edinburgh, UK) within a university teaching hospital. Cemented, cruciate-retaining TKAs were performed in all cases via a medial para-patella approach. The patella was not routinely resurfaced. All patients followed standardized postoperative rehabilitation.

Prior to surgery, a postal questionnaire,[10] including the 12-item Short Form Survey (SF-12) general health questionnaire[11] and the knee-specific OKS,[1,2] was sent to all patients. The SF-12 is a validated health questionnaire with physical component summary (PCS) and mental component summary (MCS) components. The OKS is a validated knee-specific outcome measure of 12 questions with five possible answers giving a score from 0 to 48. Higher scores represent better function. The minimum clinically important difference (MCID) for the OKS is five points, and the minimal important change (MIC) is seven points. Completed questionnaires were collected at a nurse-led pre-assessment clinic.

Postoperative questionnaires were sent to patients at six months, and one, five, ten, and 15 years. In addition to the SF-12 and OKS, questionnaires at and beyond one year included measures of patient satisfaction.[12] Patients were asked how satisfied they were with their knee arthroplasty with the options "very satisfied", "satisfied", "uncertain", "dissatisfied". At five, ten, and 15 years, patients were asked if they had undergone any reoperations and the nature of these. Collection of data was independent of the routine clinical care of the patient. Patients who did not respond to the 15-year questionnaire were contacted by telephone and were asked to participate over the phone.

Medical and operation notes were examined for each patient. The patient demographics, indication for surgery, consultant in charge of care, date of surgery, and side of surgery were recorded. All intraoperative, early and late complications, and their nature were recorded. In those patients who had undergone revision surgery, the mode of implant failure confirmed at revision was noted. Any other reoperation was also noted. Deceased patients were identified and date of death confirmed.

Statistical analysis. Data were analyzed using SPSS version 24.0 (IBM, USA). Repeated measures analysis of variance (ANOVA) was used to examine changes in parametric variables over the 15-year study period. Significance set at $p < 0.008$, incorporating a Bonferroni correction to adjust for multiple testing at six points over 15 years. Univariate analysis was performed using parametric (paired and unpaired *t*-test) and non-parametric (Mann-Whitney U test) as appropriate to assess continuous variables for significant differences between responders and non-responders, to compare PROMs at sequential timepoints, and to compare improvements in PROMs between older and younger patients (cut off aged 60 years), and by sex. Nominal categorical variables were assessed using chi-squared test or Fisher's exact test. A p-value < 0.05 was considered to be statistically significant. Survival analysis was undertaken with life tables and Kaplan-Meier

analysis. The endpoints used were failure for any reason and any reoperation.

Results

In the study period, 462 consecutive cemented cruciate-retaining Triathlon TKAs were implanted in 426 patients. Median age was 69 years (21 to 89; mean 68.7 years (standard deviation 9.7)), and 290 patients (62.7%) were female. The indication for surgery was primary osteoarthritis in 406/462 patients (87.9%). Standard primary implants were used in all but one patient, where a medial tibial plateau fracture nonunion required a medial augment and a tibial stem. The patella was resurfaced at the index procedure in 24 patients (5.2%) at the discretion of the surgeon. Of the 36 patients who underwent bilateral TKAs, nine had 18 TKAs performed as simultaneous bilateral procedures.

PROMs. By 15 years, 221 patients (51.9%) had died (Figure 1), leaving 188 patients with 204 TKAs potentially available for PROMs follow-up. Responses were obtained from 121/188 patients. Non-responders to PROMs questionnaires were significantly older than responders at both ten and 15 years ($p < 0.001$, Mann-Whitney U test; Table I). The mean PCS and MCS scores of the SF-12 and OKS for the cohort changed significantly over the 15-year follow-up period ($p < 0.001$, two-way ANOVA; Table II). PCS and OKS improved significantly following surgery (Table II, Figures 2 and 3). Over the 15-year study period (after correcting for multiple testing), the PCS showed a statistically significant improvement in the first six months ($p < 0.001$, paired *t*-test) and a significant decline from ten to 15 years ($p < 0.001$, paired *t*-test) (Figure 2a). The MCS demonstrated a significant decline from five to ten years ($p = 0.001$, paired *t*-test; Figure 2b). The OKS demonstrated statistically significant improvements to six months and again from six to 12 months, but there were statistically significant declines from five to ten and ten to 15 years ($p < 0.001$, paired *t*-test; Figure 3). Despite small declines with time, 15-year scores remained significantly better than preoperative scores ($p < 0.001$, paired *t*-test): within patient OKS mean improvement 16.1; cohort OKS mean improvement 17.53; and cohort PCS mean improvement 10.1.

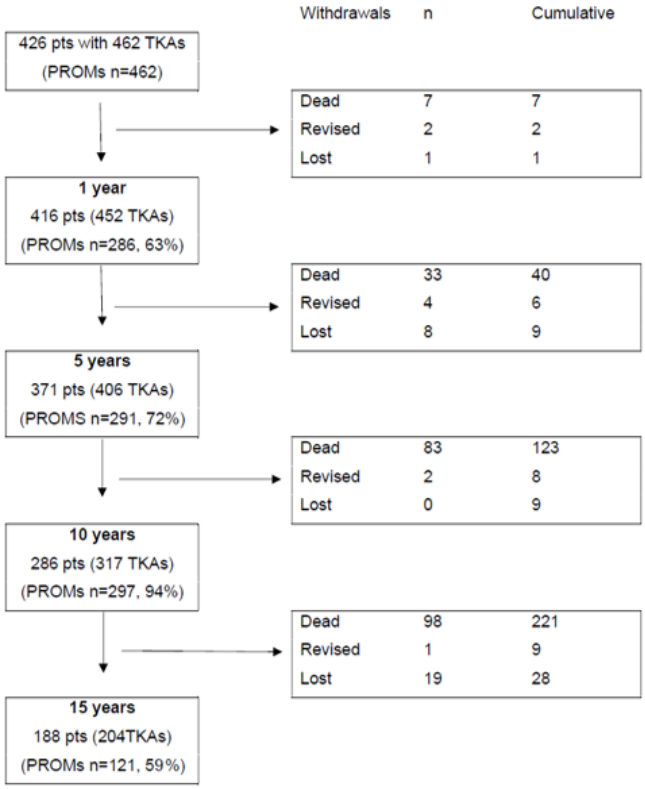

Fig. 1
Patient cohort.

The mean within-patient improvement in OKS was 18.78 (95% CI 16.74 to 19.04) from preoperative to one-year levels (Table II). OKS improvement peaked at five years, with a statistically significant decline thereafter of

Table I. Patient characteristics of responders to PROMs at ten and 15 years, and those who did not (or could not) respond.

	10 years			15 years		
Variable	**Responder**	**Non-responder**	**p-value**	**Responder**	**Non-responder**	**p-value**
Age at TKA, yrs						
Median	66.5	75.8	< 0.001*	65.0	71.1	< 0.001*
IQR	(59.5 to 72.2)	(67.7 to 80.4)		(58.2 to 69.5)	(63.1 to 78.0)	
Sex						
Female	187 (64)	103 (36)	0.909†	66	224	0.491†
Male	110 (64)	62 (36)		44	128	
Indication						
Inflammatory arthropathy	21 (68)	10 (32)	0.620†	4	27	0.189‡
Osteoarthritis	257 (63)	149 (37)		99	307	

*Mann-Whitney U test.
†Chi-squared test.
‡Fisher's exact test.
PROMs, patient-reported outcome measures.

Table II. PROMs at each timepoint.

PROMs	Timepoint	Median	Mean (95% CI)	p-value*	
				All timepoints	Postoperative only
PCS	Preoperative	28.16	30.32 (28.48 to 32.18)	< 0.001	
	Six months	43.36	43.21 (41.02 to 45.40)		0.027
	1 year	45.27	44.67 (42.28 to 47.07)		
	5 years	47.29	44.15 (44.59 to 46.72)		
	10 years	45.19	42.90 (40.50 to 45.31)		
	15 years	41.09	40.45 (37.78 to 43.12)		
MCS	Preoperative	55.39	51.44 (48.78 to 54.11)	0.004	
	Six months	56.56	53.61 (51.41 to 55.81)		0.002
	1 year	57.69	53.61 (51.19 to 56.04)		
	5 years	54.95	53.07 (50.91 to 55.23)		
	10 years	54.42	51.17 (48.96 to 53.38)		
	15 years	48.91	49.05 (46.42 to 51.69)		
OKS	Preoperative	17.50	18.51 (17.02 to 20.00)	< 0.001	
	Six months	38.00	35.82 (33.54 to 38.09)		< 0.001
	1 year	40.00	37.29 (35.07 to 39.51)		
	5 years	43.00	39.75 (37.89 to 41.61)		
	10 years	40.00	37.67 (35.61 to 39.73)		
	15 years	38.50	36.04 (33.82 to 38.26)		
	Preoperative to 1 year	20	18.78 (16.74 to 19.04)	< 0.001	
	1 to 5 years	2	2.46 (0.69 to 4.23)		< 0.001
Within patient change in OKS	5 to 10 years	-1	-3.5 (-0.68)		
	10 to 15 years	-1	-1.63 (-3.23 to -0.03)		

*Two-way analysis of variance reflect changes over time between values.
CI, confidence interval; MCS, mental component summary; OKS, Oxford Knee Score; PCS, physical component summary; PROMs, patient-reported outcome measures.

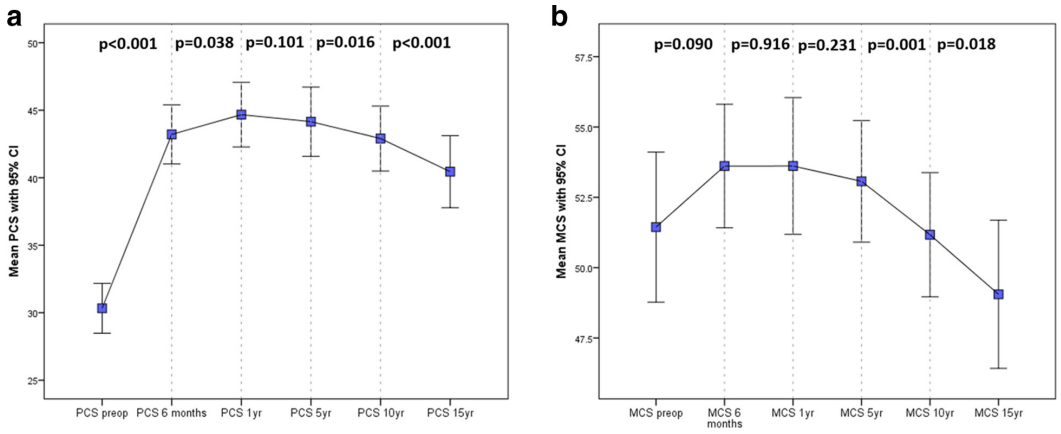

Fig. 2

Mean 12-Item Short Form Survey in a) physical, and b) mental component scores from preoperative to 15 years in linked patients. All p-values are paired *t*-tests between consecutive timepoints.

a mean of 4.13 points to 15 years (Table II). The MIC for individual patients for the OKS is 7 points.[13] From five to ten years, 52/205 (25.4%) experienced a decline in OKS of ≥ 7 points. From ten to 15 years, 28/104 (26.9%) experienced a decline of ≥ 7 points. Patient satisfaction remained high among responders, with 88% of patients satisfied or very satisfied with their knee arthroplasty at one, five, and ten years. Among 15-year responders, 94% of patients were satisfied or very satisfied with their TKA (Table III).

There were no significant differences in absolute scores at any timepoint according to age above or below 60 years, sex, or indication (p > 0.050, unpaired *t*-test). Nor were there significant differences in the trajectory of absolute OKSs or improvements therein between

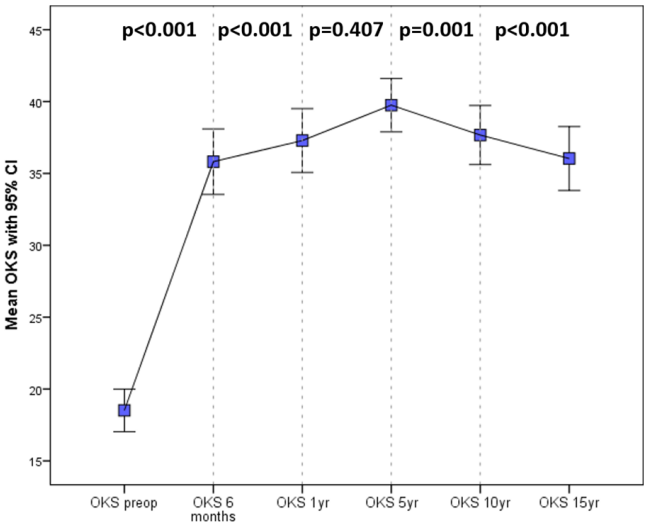

Fig. 3

Mean Oxford Knee Score at each timepoint from preoperative to 15 years in linked patients. All p-values are paired *t*-tests between consecutive timepoints.

of follow-up. There were no differences in underlying indication or sex between responders and non-responders at either ten- or 15-year follow-up (Table I).

Survival. Over the study period, nine TKAs were revised: five for infection and four for mechanical reasons, including two cases of aseptic loosening of the tibial component. The life table for all revisions is given in Table IV and reoperations are detailed in Table V. The 15-year Kaplan-Meier survival for the endpoint any revision was 97.6% (95% CI 96.0% to 99.2%) and for aseptic revision was 98.9% (95% CI 97.9% to 99.9%), as demonstrated in Table VI and Figure 6.

Discussion

This prospective longitudinal cohort study of a single radius cemented cruciate-retaining TKA demonstrates the trajectory of both a knee-specific (OKS) and general health PROMs over 15 years following knee arthroplasty surgery. Large initial within-patient improvements in OKS of a mean of 18.8 points occurred within the first

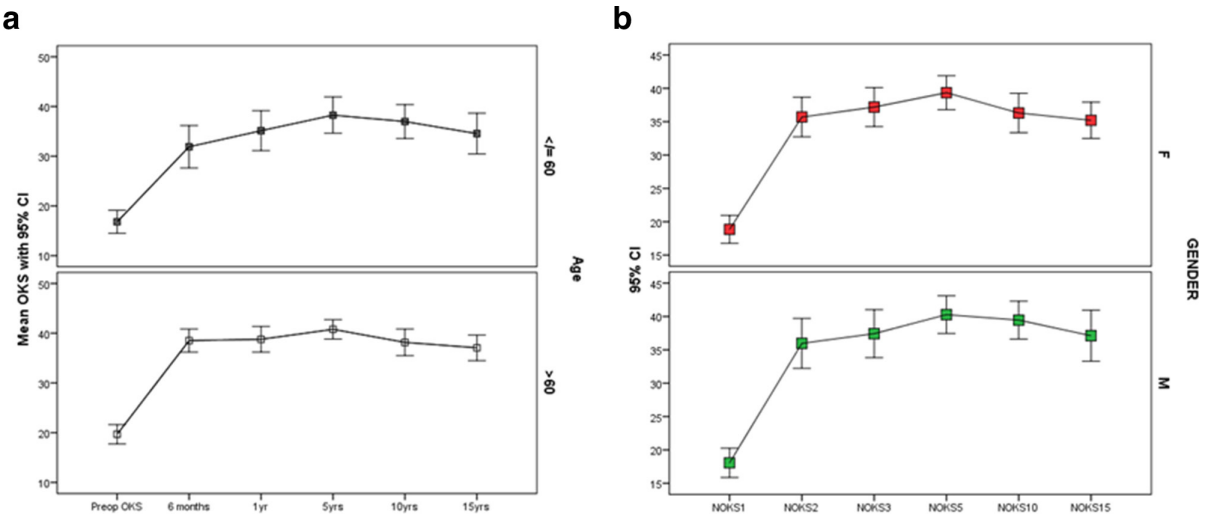

Fig. 4

Fifteen-year linked Oxford Knee Score in patients aged ≤ 60 years and in those older than aged 60 years according to a) age, and b) sex.

timepoints by age above and below 60 years (Figure 4a) or by sex (Figure 4b) (p > 0.050, ANOVA).

Attrition. Reasons provided for non-response to 15-year PROMs included true loss to follow-up in 19 patients who had moved away and were uncontactable; 15 were contacted and were happy with their knee but unwilling to complete questionnaires; ten had dementia and were unable to complete questionnaires; and the remaining 23 patients were multiply comorbid and could not or did not want to complete questionnaires. Figure 5 demonstrates the attrition over 15 years due to death and loss to follow-up and the mean age of the remaining cohort, which reduced by a mean of four years over the 15 years

Table III. Patient satisfaction with their knee arthroplasty.

Time period	PROMs responders, n	Response rate, %	Very satisfied/ satisfied, n(%)
1 year	286	69	252 (88.3)
5 years	291	79	256 (88.0)
10 years	233	85	206 (88.4)
15 years	119	57	112 (94.1)

PROMs, patient-reported outcome measures.

year, and absolute OKS means peaked at five years. A statistically significant decline occurred thereafter from

Table IV. Life table.

Interval, yrs	Number	Withdrawals, n	At risk, n	Failures, n	Failure rate, %	Cumulative survival, %	95% CI
0	458	27	444.5	3	1		
2	428	12	422	0	0	99.3	98.5 to 100
4	416	26	403	3	1	99.3	98.5 to 100
6	387	30	372	0	0	98.6	97.4 to 99.8
8	357	40	337	2	1	98.6	97.4 to 99.8
10	315	40	295	1	0.5	98.0	96.6 to 99.4
12	274	40	254	0	0	97.6	96.0 to 99.1
14	234	185	141.5	0	0	97.6	96.0 to 99.1
16	49	49	24.5	0	0	97.6	96.0 to 99.1

CI, confidence interval.

Table V. Reoperations.

Reoperation	Indication	N (%)
Revision arthroplasty	Deep infection	5 (1.1)
	Instability	2 (0.4)
	Tibial loosening	2 (0.4)
Manipulation under anaesthetic	Early stiffness	10 (2.2)
Secondary patella resurfacing	Persistent anterior knee pain	5 (1.1)
Debridement and implant retention	Acute infection	4 (0.9)
Periprosthetic fracture fixation	Distal femur fracture	3 (0.6)
	Proximal tibial fracture	1 (0.2)
Wound closure	Early dehiscence	1 (0.2)
Arthrolysis	Stiffness	1 (0.2)
Arthroscopic biopsy	Investigation of infection	1 (0.2)

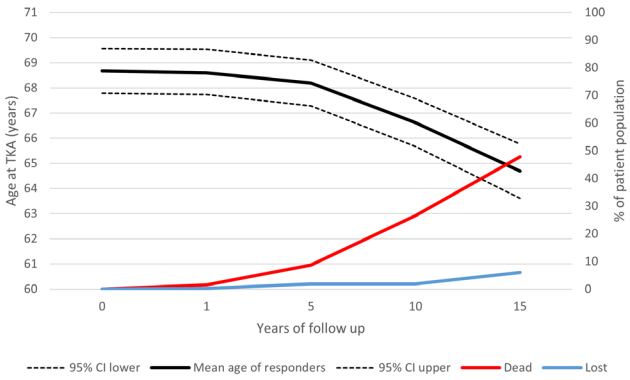

Fig. 5

Mean age at total knee arthroplasty of the cohort available for follow-up at each timepoint with attrition for death and loss.

five to 15 years, with a quarter of patients experiencing a clinically significant decline in OKS that exceeded the individual MIC. Age and sex did not alter this pattern significantly. However, 94% of patients remained satisfied or very satisfied with their TKA at 15 years. The SF-12 PCS displayed a similar trajectory, though the peak occurred earlier at one year with a statistically significant decline from ten to 15 years. The MCS displayed less change following TKA with a lesser improvement following TKA surgery and a decline to preoperative levels by ten years.

Table VI. Fifteen-year Kaplan Meier survival functions for different end points.

End point	n	Survival % (95% CI)
Any revision	9	97.6 (96.0 to 99.2)
Aseptic revision	4	98.9 (97.9 to 99.9)
Any reoperation (including revisions)	35	91.4 (88.7 to 94.1)

CI, confidence interval.

There is a paucity of long-term PROMs data following TKA and trends therein. Williams et al[5] reported trends in the OKS up to ten years, but this was not linked for longitudinal patient outcomes (i.e. the same patient followed up over the time period). Patients were included even if only one score had been obtained, and though 1,547 patients in total were included, the number at each timepoint was far fewer: the maximum number of patients was 737 at year three with 219 at year ten. In contrast to the current study, Williams et al[5] reported worse absolute postoperative OKSs among females and patients aged < 60 years, although changes in scores were not significantly different across these different demographics. Similarly, changes in satisfaction over time have rarely been examined. Nilsdotter et al[14] studied 102 patients over five years, finding satisfaction to be unchanged from one to five years. Clement et al[15] identified three groups of dissatisfied patients following TKA: those with early dissatisfaction at one year only; those with persistent dissatisfaction at five years; and those with late dissatisfaction only. The attrition of patients that occurs over the duration of long-term studies makes it difficult to interpret small changes in satisfaction rates over the long-term when patients with multiple comorbidities that may affect function and HRQoL are often deceased or unable to complete PROMs in the longer-term. Absolute HRQoL scores are known to decline with age.[16] This is reflected in both elements of the SF-12 score in the current study. Though responders

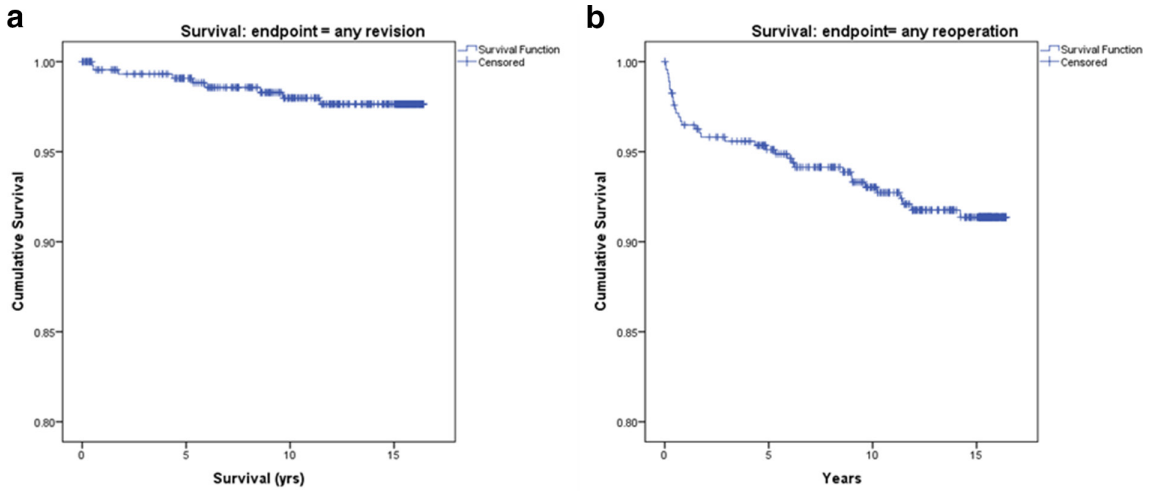

Fig. 6

Kaplan-Meier survival analysis for the endpoint a) any component revision, and b) any reoperation (including revision).

reduced in age by a mean of four years over the study period due to the competing risk of death, the 15-year length of follow-up period resulted in a mean increase in age of responders of 11 years over the study period.

We have previously reported both functional outcomes and survivorship of this cohort previously at five and ten years.[6,7] The single common flexion-extension axis used by the Triathlon TKA conveys several theoretical biomechanical advantages, including ligament isometry, reduced mid-flexion instability, and a longer quadriceps moment arm. These features are thought to improve extensor efficiency and reduce patellofemoral joint reaction forces. Clinically, this has been shown to increase knee extension power.[17] The improvements in knee-specific pain and function following this TKA implant measured using the OKS compare favourably to that reported by the national PROMs database: difference in preoperative and six-month OKS of 20.5 points in the current study compared to 16.8 points in the 2020 to 2021 national PROMs.[3] Satisfaction remained high throughout follow-up with 88% satisfied or very satisfied up to ten years and 94% at 15 years, again comparing favourably with satisfaction rates of 81% consistently reported in the literature.[12] Selective patella resurfacing was performed with 24 patients (5.2%) undergoing primary resurfacing, and a further five (1.1%) undergoing secondary resurfacing for persistent anterior knee pain. Previous studies have demonstrated that patella cartilage loss does not affect OKS or Kujala scores with the cruciate-retaining Triathlon when performed without patella resurfacing.[18] It has also been demonstrated that flexing the CR femoral component is associated with reduced anterior knee pain,[19] and better kneeling ability following TKA.[20] The current study demonstrates this implant to be durable to fifteen years with survival of 97.6 for the endpoint any revision.

During the 15-year follow-up, the patient cohort changed significantly. Attrition of the cohort occurs due to the competing risk of death (tending to remove older patients) and relocation (tending to remove younger patients). This attrition of patients significantly affected the patient characteristics of responders to long-term follow-up. At 15 years, though fewer than 0.5% of patients (19/426) had been lost due to relocation, half of the initial cohort had died and the mean age of patients able to respond had reduced by four years. Though the standardized mortality rates of patients undergoing TKA is lower than the general population, one in four patients are expected to die within ten years of TKA.[21] The risk of dying is affected by certain demographics thus altering the population over long term follow-up. Male sex has been demonstrated to be associated with both an increased risks of revision and of death after TKA,[22] which in larger cohorts may alter the relative proportions of males and females over time. Patients with a greater number of comorbidities unsurprisingly have a higher risk of death after TKA and are therefore removed from longer follow-up.[22] Severe comorbidities also affect both ability and willingness to participate in PROMs follow-up, and this further excludes them from longer term follow-up studies. In this study, 7.7% (33/426) were unable or unwilling to complete 15-year PROMs due to other comorbidities. An indication for TKA of inflammatory arthropathy is associated with an increased risk of death, but not revision.[22] It was not possible to perform any meaningful subgroup analysis of the effect of indication on longitudinal PROMs in the current study due to the small number of inflammatory arthropathy cases included in the cohort (n = 27/462). Though both knee-specific and general health PROMs demonstrated a gradual decline with length of follow-up, patient

satisfaction changed from 88% to 94% among patients able and willing to respond to 15-year questionnaires.

This study has a number of limitations. It was commenced in 2006 prior to the development or common usage of other PROMs scores, such as the Forgotten Joint Score, and so these scores were not available to report at all timepoints. As this study highlights, long-term longitudinal follow-up is associated with significant attrition, even with a fairly geographically static population. This means that the population being examined changes over time and this may affect mean PROMs values. However, this represents a linked account of how PROMs can be expected to change over time with both whole population and within-patient changes. The influence of age and sex on PROMs trajectory were investigated, but other variables, such as indication for TKA and BMI, that may influence PROMs were not possible to examine due to sample size. There was no clinical or radiological examination at 15 years.

This independent study has demonstrated both excellent PROMs and survival for this widely used TKA implant up to 15 years. Both the PCS and MCS components of the SF-12 general health questionnaire peaked at one year and gradually declined thereafter. In contrast, the joint-specific OKS peaked at five years, with a quarter of patients experiencing a decline greater than the seven-point individual MIC for this score every five years thereafter. Despite this, patient satisfaction among responders peaked at 94% at 15 years.

Take home message

- Following single radius total knee arthroplasty (TKA), joint-specific function (Oxford Knee Score) peaked at five years, with clinically important declines in a quarter of patients every five years thereafter.
- The cemented cruciate-retaining Triathlon TKA provided high patient satisfaction at all timepoints (88%), peaking at 94% satisfied at 15 years, and was durable with 15-year all-cause survival of 97.6% (95% confidence interval 96.0% to 99.2%).
- Long-term follow-up changes the demographics of the study population available and able to be followed-up.

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