Grazette, A., Wylde, V., Dixon, S., Whitehouse, S., Blom, A., & Whitehouse, M. (2018). A 15 to 17-year follow-up of the Kinemax total knee replacement. *Knee*, *25*(6), 1292-1298. https://doi.org/10.1016/j.knee.2018.09.015

A 15 to 17-year follow up of the Kinemax Total Knee Replacement

1 Introduction

Total knee replacement (TKR) is a successful and cost effective operation for the majority of patients, although up to 20% of patients report an unfavourable long-term pain outcome [1]. The number of TKR operations performed continues to rise year on year and large future increases in demand have been predicted [2]. TKR remains the only intervention that has a large effect size for the relief of chronic knee pain [3].

There is a paucity of prospective longitudinally collected data available regarding the outcome of TKR [4]. Long term follow up studies in excess of 10 years often do not include preoperative data or data from the early postoperative period, limiting our ability to determine the success of the intervention regarding long term patient focused outcomes and whether patient satisfaction and improvements in pain and function are maintained in the long term. It has been established that even when collected in the early postoperative period, retrospectively recalled patient data regarding pain and function is not reliable [5], limiting the utility of this approach.

The aim of this study was to determine the mortality, implant survivorship, patient reported function and satisfaction in a cohort of patients who had received a Kinemax total knee replacement more than 15 years ago.

2 Patients and Methods

2.1 Patients

The cohort consisted of 124 Kinemax TKRs (114 patients; 47 males and 67 females) performed in our centre between September 1997 and December 1998, there were no modifications to the polyethylene during this period. Ten patients had both knees replaced during the period of recruitment (5 males and 5 females). Eight of the patients had a diagnosis of rheumatoid arthritis and the remainder had a diagnosis of osteoarthritis. A medial parapatellar approach was used in all but three cases where a subvastus approach was used. Standard cemented femoral and tibial components were used in all cases. The patella was resurfaced in all but two cases, where patellar debridement only was performed. The mean interval between operations in those that had both knees replaced was 3.9 months (range 2.8-6.2). There were six deaths during follow up in the group that had both sides replaced during the recruitment period and 63 deaths amongst the group that only had one side replaced leaving 45 patients alive at final follow up. Four patients were excluded from the cohort due to medical comorbidities (dementia in three patients and a stroke in one patient). The mean age at surgery in the cohort was 72 years (range 48.2-89.8). The mean body mass index (BMI) of the patients at the time of surgery was 28 (range 17.0-41.1). The mean age of the surviving patients at final follow up was 83 years (range 64.4-94.9).

Mortality in the cohort was assessed by a combination of interrogation of hospital records and the NHS National Strategic Tracing Service. Revision of the TKR in deceased patients was assessed by interrogation of hospital and primary care

records. In the surviving patients, the survivorship of the implant was confirmed in the postal questionnaire that was completed by the patients. The median time from surgery to final follow up in the surviving patients was 15.7 years (IQR 15.4-16.3).

2.2 Outcome measures

Patients completed a questionnaire preoperatively, at 3 months, 1 year, 2 years and a minimum of 15 years following surgery. The questionnaire incorporated disease- and joint-specific scores including the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Oxford knee score (OKS). The WOMAC is a 24-item disease-specific measure which includes separate subscales for pain, function and stiffness. Global scores range from 0-96, with 0 being the best score. In this study, WOMAC Pain (0-20) and Function (0-68) subscales were collected at all time points, and the WOMAC Stiffness (0-8) subscale was collected pre-operatively and at 3 months and 15 years postoperation. Therefore, WOMAC global scores were calculated for these time points. The OKS is a 12-item joint-specific questionnaire validated in patients undergoing TKR. Total scores range from 0-48 scale with 48 being the best score. Patient satisfaction with the outcome of surgery was assessed using the Self-Administered Patient Satisfaction Scale for Primary Hip and Knee Arthroplasty (SAPS) and general health was assessed at final follow-up using the EQ-5D. In addition to these validated outcome measures, patients completed questions regarding the occurrence of infection, venous thrombosis, anterior knee pain, numbness, periprosthetic fracture, stiffness, revision and any other postoperative complications at the final follow up.

2.3 Statistics

A D'Agostino and Pearson normality test was performed to determine the distribution of data. Where data were normally distributed, central tendency is described with the mean and range. Where data were not normally distributed, the median and inter-quartile range (IQR) were used. Kaplan-Meier survivorship analysis with 95% confidence intervals (CI) was performed for the endpoints of mortality or revision of the TKR. The numbers at risk at each 5-year interval are expressed in figures 1 and 2. When a patient had undergone bilateral staged TKRs during the recruitment period, the first operation only was considered for the mortality analysis. Analysis of non-parametric data over multiple time points was performed with a Kruskal-Wallis test with Dunn's multiple comparison post-tests.

3 Results

The survivorship of the cohort with death as the endpoint was 34.6% (95% CI 24.4-45.0%) at a follow up of 16.2 years. The median time to death following surgery in the deceased patients was 9.0 years (IQR 4.4-12.8).

The survivorship of the cohort with revision of the TKR as the endpoint was 84.4% (95% CI 62.8-94.0%) at a follow up of 16.3 years. Four cases were revised for wear of the polyethylene liner, three cases for aseptic loosening (femoral and tibial component in one case, femoral component only in one case and tibial component only in one case) and one case was revised for a femoral component periprosthetic

fracture secondary to osteolysis. The mean time until revision in the revised patients was 10.0 years (range 2.4-16.3).

Thirty-nine patients out of the 41 included at final follow-up completed the final outcome questionnaire (43 out of 45 eligible TKRs). The mean EQ5D score was 0.553 (range 0-1). The median and interquartile ranges for the WOMAC subscales, global score, OKS and SAPS are shown in table 1 and longitudinal plots over time shown in figures 3 to 6.

A significant improvement was seen in the WOMAC Pain subscale over time ($p<0.0001$). Dunn's post-test revealed significant differences between the preoperative score and the postoperative score at 3 months, 1 year, 2 years and a mean of 15.7 years ($p<0.0001$). No significant differences were observed between any of the postoperative time points. The same pattern and level of significance was observed for the WOMAC Function subscale. The WOMAC Stiffness subscale and global score demonstrated a significant improvement between the preoperative score and each of the postoperative time points ($p<0.0001$) but no difference between the postoperative time points.

A significant improvement was seen in the OKS over time ($p<0.0001$). Dunn's post-tests revealed significant differences between the preoperative score and the postoperative score at 3 months, 1 year, 2 years and 15.7 years ($P<0.0001$). A significant improvement was also seen between 3 months and 1 year postoperation ($p<0.05$) but not at any of the other postoperative time points.

A significant change was seen in the SAPS over the postoperative follow up period ($p=0.012$). Dunn's post-tests revealed no significant differences between the 3 months score and any of the subsequent time points however a significantly lower score was seen at the 15.7 year follow up when compared to the 1 year and 2 year postoperation follow ups ($p<0.05$). At 1 year following surgery, 102 patients of 110 responders to this part of the questionnaire indicated that overall, they were somewhat or very satisfied with the knee replacement. At final follow up, 28 of the 39 responders indicated that overall, they were somewhat or very satisfied with the knee replacement.

When questioned about complications following their TKR at final follow up, 2 out of 39 responders indicated they had experienced an infection. Neither of these patients indicated they had required a delayed discharge, antibiotics or readmission to hospital or revision. Five of the 39 responders reported they had experienced a DVT, one of which was treated with clexane and the remainder with warfarin. Eleven of the 39 responders indicated they had experienced anterior knee pain, none of which required any reoperations; five patients indicated they had numbness in association with their scar but none reported that this was a concern for them. Other than the previously described revision for a periprosthetic fracture, no patient reported a fracture and no patient reported they had undergone any intervention for stiffness.

4 Discussion

The mortality of this cohort of patients who received a Kinemax TKR over the period studied was similar to that observed in other long term longitudinal studies of TKR [6]. The survivorship of the patients reported in this cohort is in keeping with the national statistics for the country of origin and the age group of the patients [7]. The reported survivorship of the TKRs with revision of the prosthesis as the end point was satisfactory for the period reported (84.4% at 16.3 years). These results are consistent with the reported survivorship of alternative cemented TKR designs from randomised controlled trials [8] and case series [9] with follow up to 15 years. The Kinemax TKR has been shown to have a survivorship equivalent to other prosthesis designs in the Norwegian registry in the short to medium term (5 years) [10]. In the longer term (10 years), the relative risk of revision was shown to be higher for the Kinemax TKR than for some alternative designs in the Swedish registry but this may be influenced by the known temporal trend to decreased revision rates in the Swedish registry and use of the Kinemax stopping in Sweden in 2006 [11]. The components in this study were cemented, the survivorship of the uncemented Kinemax design has been shown to be inferior to cemented fixation [12]. This may not be true for all designs of TKR [8], with one series of uncemented TKR reporting implant survival rates of 97.1% at 20 years [13].

The predominant modes of failure observed in the study were wear and loosening, which is typical of long term follow up of TKR [6, 14, 15]. Rotational malalignment is known to effect implant survivorship [16], but there is no evidence to suggest this effects the Kinemax TKR more than other implants.

The maintenance of patient reported function in the medium term has been reported for the Kinemax TKR [17]. Few long term follow up studies incorporating patient reported function and preoperative data are available [4]. Long term follow up studies of TKR are often limited by the lack of preoperative or longitudinal patient reported functional scores [15]. The results of such long term follow up have shown good or excellent function or pain scores in 75-90% of patients. Marked preoperative functional limitation, severe pain, low mental health scores and multiple comorbid conditions are predictive of short term outcomes following TKR [18]. Short term postoperative pain and function may be predicted by different preoperative factors [19]. Differences in outcome predicted by baseline psychosocial factors are however, not maintained in the medium term [20]. Given the mortality rates in this study, we would not have achieved sufficient power to determine if the same effect was present in the long term, although the lack of change in the functional outcome scores in the long term suggests this may be the case. Due to the limited size of the subgroups, we were unable to analyse patients with rheumatoid and osteoarthritis separately to determine if there were any differences in outcome relative to the underlying pathology.

In this series, the WOMAC score was not significantly different between any of the postoperative time points suggesting that recovery from TKR, as assessed by the WOMAC, plateaus at around three months after surgery. In contrast, the OKS improved significantly from three months to one year postoperation. This suggests that three months would appear to be too early a time point to judge the outcome

of TKR when measured by the OKS. This supports data suggesting that the 6 month outcome according to the OKS is an acceptable time point to assess patient reported outcomes after TKR [21]. The patients in this reported cohort achieved absolute changes in OKS (>11) and final OKS scores (>30) in the early postoperative period which are correlated with high levels of satisfaction and these outcomes were maintained in the long term [21]. Despite this, we observed a significant decline in patient satisfaction over the period of the study. Whilst our interpretation of this phenomenon is limited by the small final sample size, it suggests that patient satisfaction is a more complex outcome than may be assumed and it may not be accurately determined or substituted for by the use of outcome scores such as the WOMAC or OKS. It has been suggested that patient related outcome scores may be a more sensitive measure for pain and quality of life in TKR [22].

The most frequent complication observed in the series was anterior knee pain with 11 out of 39 patients reporting this at final follow up. The majority of patients in this study had their patella resurfaced at the time of the primary surgery but there were no revisions performed due to patellar component failure alone in contrast to other series [23]. The incidence of anterior knee pain in our series was higher than in Ewald et al.'s study. The resurfacing or not of the patella is not the sole determinant of anterior knee pain and related function following TKR; femoral component design, malrotation of components, oversizing and offset errors are correlated with anterior knee pain [24].

Weaknesses of this study include the small number of patients from the original cohort alive at the time of the final follow up, which limits our ability to interpret certain changes over time such as the decline in patient reported satisfaction despite well maintained functional scores. For patients that were deceased, we queried local hospital and primary care records to ascertain of a revision had occurred. In the NHS, the primary care clinician acts as a gatekeeper for access to secondary care services and there is an obligation for secondary care clinicians to inform the primary care clinician of treatment and interventions. Whilst we are confident that this method allows for robust data capture of revision episodes, this is not a formally validated method and there is the possibility that we may have missed revision episodes, this is reflected in the confidence intervals of our survival estimates. The implantations predate the National Joint Registry in the NHS and there was no alternative suitable national database available to determine if revision had occurred. We were required to exclude a small number of patients due to comorbidities that rendered them incapable of completing the postal questionnaire but our follow up proportion of surviving patients is comparable to other long terms follow up studies [6]. A further strength of the study was the inclusion of preoperative and early postoperative scores. Radiological assessment was not performed as part of this study; this leaves the possibility that there may be some patients that would be classified as radiological failures of whom we are unaware. Of note, none of the patients in the final follow up cohort indicated that they had any problems with their TKR that they would seek further treatment for or requested further clinical review rendering revision surgery in this elderly population unlikely. Range of motion (ROM) was not assessed at final follow-up but ROM is known to have only moderate correlation

with functional scores and to correlate poorly with patient satisfaction and improvements in quality of life [25].

5 Conclusion

We observed an 84% survivorship of the Kinemax TKR at a follow up of 16.3 years. The predominant modes of failure were wear and loosening. Functional scores were in excess of the identified thresholds that correlate with high levels of patient satisfaction in large sample sizes and these improvements were maintained in the long term although satisfaction did decline with time.

6 Declaration of Interests

During the initial phase of the study Dr S Whitehouse received a grant from Stryker UK for recruitment and short term follow up. Dr V Wylde, Dr S Whitehouse, Professor Blom and Mr M Whitehouse have received grants from Stryker UK outside the submitted work. Dr M Whitehouse has received other funding from Heraeus & DePuy outside the submitted work.

7 Acknowledgements

This study was supported by the NIHR Biomedical Research Centre at the University Hospitals Bristol NHS Foundation Trust and the University of Bristol.

The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

Table 1

	Preop	Postop			
		3 months	**1 year**	**2 years**	**15.7 years**
WOMAC pain subscale	12 (10-14)	4 (2-6)	2 (0-6)	2 (0-5)	5 (0.75-7.25)
WOMAC function subscale	37 (29-44)	21 (11.25-29.75)	17 (6.25-30)	15 (8-30.5)	24 (5.75-35.25)
WOMAC stiffness subscale	4 (3-5)	3 (2-4)	*	*	2 (1-4)
WOMAC global score	52 (44-63)	27 (16.5-38)	+	+	33 (10.5-42.5)
OKS	16 (12-22)	30 (19.5-34.5)	34 (28-41.25)	34 (26.5-41)	31.5 (23-39.5)
SAPS	!	93.75 (81.25-100)	93.75 (81.25-100)	100 (81.25-100)	75 (50-100)

Table 1: WOMAC, OKS and SAPS preoperatively, at 3 months, 1 year, 2 years and 15.7 years postoperation (* WOMAC stiffness subscale unavailable at 1 and 2 years postoperation; $^{+}$ WOMAC global score not calculated at 1 and 2 years due to lack of stiffness subscale; $^{!}$ SAPS not relevant preoperatively)

8 References

1. Beswick AD, Wylde V, Gooberman-Hill R, Blom A, Dieppe P (2012) What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. BMJ Open 2:e000435. DOI 10.1136/bmjopen-2011-000435

2. Kurtz S, Ong K, Lau E, Mowat F, Halpern M (2007) Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am 89:780-785. DOI 10.2106/jbjs.f.00222

3. Juni P, Reichenbach S, Dieppe P (2006) Osteoarthritis: rational approach to treating the individual. Best Pract Res Clin Rheumatol 20:721-740. DOI 10.1016/j.berh.2006.05.002

4. Ethgen O, Bruyere O, Richy F, Dardennes C, Reginster JY (2004) Health-related quality of life in total hip and total knee arthroplasty. A qualitative and systematic review of the literature. J Bone Joint Surg Am 86-a:963-974

5. Lingard EA, Wright EA, Sledge CB (2001) Pitfalls of using patient recall to derive preoperative status in outcome studies of total knee arthroplasty. J Bone Joint Surg Am 83-a:1149-1156

6. Loughead JM, Malhan K, Mitchell SY, Pinder IM, McCaskie AW, Deehan DJ, Lingard EA (2008) Outcome following knee arthroplasty beyond 15 years. Knee 15:85-90. DOI 10.1016/j.knee.2007.11.003

7. **Office for National Statistics** (2014) National Life Tables, United Kingdom, 2011-2013. In., Newport.

8. Baker PN, Khaw FM, Kirk LM, Esler CN, Gregg PJ (2007) A randomised controlled trial of cemented versus cementless press-fit condylar total knee replacement: 15-year survival analysis. J Bone Joint Surg Br 89:1608-1614. DOI 10.1302/0301-620x.89b12.19363

9. Victor J, Ghijselings S, Tajdar F, Van Damme G, Deprez P, Arnout N, Van Der Straeten C (2014) Total knee arthroplasty at 15–17 years: Does implant design affect outcome? International Orthopaedics 38:235-241. DOI 10.1007/s00264-013-2231-8

10. Furnes O, Espehaug B, Lie SA, Vollset SE, Engesaeter LB, Havelin LI (2002) Early failures among 7,174 primary total knee replacements: a follow-up study from the Norwegian Arthroplasty Register 1994-2000. Acta Orthop Scand 73:117-129. DOI 10.1080/000164702753671678

11. The Swedish Knee Arthroplasty Register (2013) Swedish Knee Arthroplasty Register: Annual Report 2012. 1st ed. In., http://www.myknee.se/pdf/117_SKAR_2012_Engl_1.0.pdf.

12. Cloke DJ, Khatri M, Pinder IM, McCaskie AW, Lingard EA (2008) 284 press-fit Kinemax total knee arthroplasties followed for 10 years: poor survival of uncemented prostheses. Acta Orthop 79:28-33. DOI 10.1080/17453670710014725

13. Epinette J-A (2014) Long lasting outcome of hydroxyapatite-coated implants in primary knee arthroplasty: a continuous series of two hundred and seventy total knee arthroplasties at fifteen to twenty two years of clinical follow-up. International Orthopaedics 38:305-311. DOI 10.1007/s00264-013-2246-1

14. The NJR Editorial Board (2017) National Joint Registry for England, Wales and Northern Ireland: 14th Annual Report. In., www.njrreports.org.uk.

15. Wright RJ, Sledge CB, Poss R, Ewald FC, Walsh ME, Lingard EA (2004) Patient-reported outcome and survivorship after Kinemax total knee arthroplasty. J Bone Joint Surg Am 86-a:2464-2470

16. Kim Y-H, Park J-W, Kim J-S, Park S-D (2014) The relationship between the survival of total knee arthroplasty and postoperative coronal, sagittal and rotational alignment of knee prosthesis. International Orthopaedics 38:379-385. DOI 10.1007/s00264-013-2097-9

17. Back DL, Cannon SR, Hilton A, Bankes MJ, Briggs TW (2001) The Kinemax total knee arthroplasty. Nine years' experience. J Bone Joint Surg Br 83:359-363

18. Lingard EA, Katz JN, Wright EA, Sledge CB (2004) Predicting the outcome of total knee arthroplasty. J Bone Joint Surg Am 86-a:2179-2186

19. Wylde V, Dixon S, Blom AW (2012) The role of preoperative self-efficacy in predicting outcome after total knee replacement. Musculoskeletal Care 10:110-118. DOI 10.1002/msc.1008

20. Wylde V, Trela-Larsen L, Whitehouse MR, Blom AW (2017) Preoperative psychosocial risk factors for poor outcomes at 1 and 5 years after total knee replacement. Acta Orthop 88:530-536. DOI 10.1080/17453674.2017.1334180

21. Judge A, Arden NK, Kiran A, Price A, Javaid MK, Beard D, Murray D, Field RE (2012) Interpretation of patient-reported outcomes for hip and knee replacement surgery: identification of thresholds associated with satisfaction with surgery. J Bone Joint Surg Br 94:412-418. DOI 10.1302/0301-620x.94b3.27425

22. Sasaki E, Tsuda E, Yamamoto Y, Meada S, Otsuka H, Ishibashi Y (2014) Relationship between patient-based outcome score and conventional objective outcome scales in post-operative total knee arthroplasty patients. International Orthopaedics 38:373-378. DOI 10.1007/s00264-013-2064-5

23. Ewald FC, Wright RJ, Poss R, Thomas WH, Mason MD, Sledge CB (1999) Kinematic total knee arthroplasty: a 10- to 14-year prospective follow-up review. J Arthroplasty 14:473-480

24. Petersen W, Rembitzki IV, Brüggemann G-P, Ellermann A, Best R, Koppenburg AG, Liebau C (2014) Anterior knee pain after total knee arthroplasty: a narrative review. International Orthopaedics 38:319-328. DOI 10.1007/s00264-013-2081-4

25. Wylde V, Lenguerrand E, Brunton L, Dieppe P, Gooberman-Hill R, Mann C, Blom AW (2014) Does measuring the range of motion of the hip and knee add to the

assessment of disability in people undergoing joint replacement? Orthop Traumatol Surg Res 100:183-186. DOI 10.1016/j.otsr.2013.09.016