A 15-year follow-up study of 4606 primary total knee replacements

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This is a 15-year follow-up observational study of 4390 patients with 4606 primary total knee replacements (TKRs) implanted in the Trent health region between 1990 and 1992. The operations were performed in 21 hospitals, including both district general and teaching hospitals, with 77 different surgeons as named consultant.

The main objective was to analyse the survival of the patients and of the prostheses, and to evaluate what impact different variables have on survival. In addition, the 1480 patients (33.7%) (1556 TKRs) alive at 15 years following operation were sent a self-administered questionnaire which examined their level of satisfaction, of pain, and their quality of life at 15 years. Completed responses were received from 912 TKRs (58.6%).

Three survival curves were constructed: a best-case scenario based on the patients entered into the life tables, another included failures not reported in the revision database, and a third worst-case scenario based on all patients lost to follow-up presumed to have had a failed primary TKR. In the best-case scenario survival at 15 years was 92.2%, and in the worst-case scenario was 81.1%. Survival was significantly increased in women and older patients (Mantel-Cox log-rank test, p < 0.005 and p < 0.001, respectively).

Revision as a result of infection was required in 40 TKRs (18.8%) representing 0.87% of the original cohort.

The limited information available from the questionnaire indicated that satisfaction was less frequent among men, patients with osteoarthritis and those who required revision (chi-squared test, p < 0.05, p < 0.05 and p < 0.0001, respectively). With regard to pain, older patients, females and patients who still had their primary replacement in place at 15 years, reported the least pain (chi-squared test for trends, p < 0.0005, p < 0.005 and p < 0.0001, respectively). The reported quality of life was not affected by any variable.

There have been several studies of European origin which have examined cumulative survival of total knee replacement (TKR) at ten years. However, there is very little information on the survival of primary TKR in the longer term. We analysed the survival of primary TKRs performed in the United Kingdom at 21 hospitals and by 77 different consultant surgeons, using information stored on a regional arterioplasty database. The survival of the prostheses was analysed at five, ten and 15 years post-operatively.

Previous studies have found that the age of the patient at the time of surgery has a significant effect on survival, with older patients less likely to require a revision procedure, but that neither gender nor the primary disease had a significant effect on cumulative revision rates. Accordingly, we examined the effect of these variables on our patient cohort. We also examined the rate of infection resulting in revision procedures.

Patient satisfaction following TKR has been reported to range between 75% and 85%. We evaluated the proportion of patients who were satisfied at 15 years following primary TKR, the frequency of pain, and the quality of life, and attempted to determine which variables contributed to these results.

Patients and Methods
The Trent (and Wales) Regional Arthroplasty Audit Group was established to assess the outcome of joint replacement in one United Kingdom health region. Since the beginning of 1990, and with the agreement of all consultant orthopaedic surgeons in the Trent region, all primary TKRs and total hip replacements (THR) performed have been recorded prospectively and the details registered on the
A database at the University of Leicester. The information recorded by the surgeon (not an author) at the time of the operation includes demographic, medical and operative details for each patient and implant. All information is validated by a peripatetic clerk visiting each unit. Since 1992, a similar database has been established for all revision procedures.

Between 1990 and 1992, a total of 4606 primary TKRs in 4390 patients were performed in the region. Patients were traced using the NHS Strategic Tracing Service. A self-administered postal questionnaire was sent to all surviving patients at a mean of 15.2 years (13.8 to 16.7) post-operatively. This questionnaire sought the patients’ opinion of their TKR. It asked about their level of satisfaction, whether they experienced pain, if they have encountered any problems or required further operations, and used a visual analogue scale (VAS) to measure their quality of life.

Any patients who had undergone a revision procedure were identified using the revision arthroplasty database. The cause of failure as stated by the surgeon, and the length of time until failure of the primary TKR, were established from this database. Failure was defined as any revision procedure.

A total of 3989 TKRs (86.6%) were cemented but there was no information available concerning whether the patella was resurfaced.

The tracing service was unable to trace 460, patients 20 of whom had bilateral TKRs (480 TKRs lost to follow-up). A total of 1480 patients (33.7%) with 1556 TKRs were alive at a mean of 15.2 years (13.8 to 16.7) post-operatively, 76 of whom had undergone bilateral TKR.

The mean age of the 4390 patients in this study at the time of operation was 69.5 years (19 to 92), which is comparable to the results of both Swedish and Norwegian joint registers, and 2800 (63.8%) were female which is also comparable with the Swedish joint register. The principal disorder leading to joint replacement was osteoarthritis (OA) with rheumatoid arthritis (RA) the next most common cause, involving 3398 (77.4%) and 814 (18.5%) patients, respectively.

Statistical analysis was performed using SPSS version 14 (SPSS Inc., Chicago, Illinois) to assess the survival of the original population cohort, survival of the prostheses, infection rate, and the opinion of the patients at 15 years of follow-up. The Kaplan-Meier method was used for survival analysis.

Results

Survival analysis showed that at one month the mortality rate was 0.4%, and at one year was 1.8%, which is comparable with the results of the National Joint Register (1.3% and 0.4%, respectively). Further analyses showed that five years after replacement 85.7% (3795) of patients were alive; after ten years, this figure was 65.6% (2873); and after 15 years 47.2% (2068) (Fig. 1).

Women were statistically more likely than men to be alive 15 years post-operatively (Mantel-Cox log-rank test, p < 0.00001). The survival curves for the different age groups showed statistically significant differences between the groups (Mantel-Cox log-rank test, p < 0.00001) (Fig. 2).

Prosthesis survival. In total, 30 identifiable prostheses were used, but in 356 TKRs (7.7%), the manufacturer’s information was not available. However, six prostheses alone were used for 3577 TKRs (77.7%). These were Freeman-Samuelson, 229 (5%) (Sulzer Orthopaedic Baar, Switzerland); Insall Burstein II, 406 (8.8%) (Zimmer, Swindon, United Kingdom); Kinematic, 677 (14.7%) (Howmedica, London, United Kingdom); Kinemax, 1270 (27.6%) (Howmedica); Omnifit, 185 (4%) (Osteonics, Rutherford, New Jersey) and Press Fit Condylar, 810 (17.6%) (Johnson and Johnson Inc, Raynham, Massachusetts).

A total of 239 TKRs (5.2%) had been revised at a mean of 76 months (1 to 185). From the questionnaires, a further 29 patients (0.62%) reported undergoing a revision of their primary prosthesis, but no information was available to validate this on the revision database.

Three survival curves have been constructed. One is based on those patients entered into the life tables and is a best-case scenario. Another included the additional 29 patients who stated that they have required a revision but had not been registered on the revision database. In this scenario, failure of the prosthesis was recorded as occurring before five years. The third curve is the worst-case scenario, in which all patients who could not be traced are assumed to have had a revision within five years of their primary TKR.
The best-case scenario of cumulative implant survival is shown in Figure 3. After five years, 97.5% (standard error (SE) 0.3%) of prostheses were in situ. At ten years, the figure was 94.4% (SE 0.4%); and at 15 years, 92.2% (SE 0.5%).

In the second scenario, the survival at five years was 96.6% (SE 0.3%), at ten years was 94.3% (SE 0.4), and at 15 years was 91.1% (SE 0.5%). However, in the final worst-case scenario, survival at ten years was 83.1% (SE 0.6) and at 15 years was 81.1% (SE 0.7).

All subsequent analysis of survival of the implants, and the impact of different variables, is based upon life tables and the ‘best-case scenario’.

No statistical significance was observed in the relationship between survival and diagnostic indication for TKR, either OA or RA (Mantel-Cox log-rank test, p = 0.207). However, on plotting separate survival curves for gender, there was a significant difference in the survival of the prostheses (Mantel-Cox log-rank test, p < 0.001), with female patients undergoing fewer revisions (Fig. 4).

Age at the time of the primary procedure also had a significant inverse relationship on survival of the prostheses (Mantel-Cox log-rank test, p < 0.001), with younger patients requiring more revision procedures (Fig. 5).

Separate survival curves were plotted for each of the six most commonly-implanted prostheses, revealing that there was a significant difference in survival depending on the prosthesis used Mantel-Cox log-rank test (p < 0.05) (Fig. 6). However, separate analysis of other identified variables associated with a reduced survival was not undertaken for each implant design. Therefore, these results may have been confounded.

**Cause of failure.** Revision was a result of aseptic loosening in 81 TKRs (34%), to infection in 40 TKRs (16.7%) and to wear of polyethylene in 33 TKRs (13.8%). The remaining 85 failures were caused by instability, patellofemoral pain, technical problems, peri-prosthetic fractures, or the cause was unknown.

Failure attributed to aseptic loosening occurred at a relatively constant rate over the 15-year follow-up (Fig. 7).
Infection as a cause of failure, however, occurred most commonly within the first 12 months, whereas implant failure or failure of the polyethylene occurred most commonly at around eight years post-operatively.

It is possible to consider the infection rate as a percentage of surviving or presumed surviving patients, or as a percentage of the original cohort. This gives two different results, a worst-case and a best-case scenario, respectively. By three years post-operatively, 12 patients had required revision because of infection, representing 0.28% of surviving TKRs, or 0.26% of the original cohort. By five years, 19 TKRs had been revised for infection representing 0.49% of surviving TKRs, or 0.41% of the original cohort of 4606. By 15 years, 40 patients had undergone a revision for infection, representing 2.57% of surviving TKRs or 0.87% of the original cohort of TKRs.

**Population outcome measures.** The 15-year follow-up questionnaire sought the opinion of 1480 surviving patients (1556 TKRs) regarding their operation; the responses concerning 912 TKRs were returned (58.6%). The three main outcome measures used were satisfaction, frequency of pain, and quality of life. Of the respondents 778 patients (85.3%) were satisfied, which is comparable to other studies. However, contrary to other studies, the results indicated that the patients’ satisfaction was not affected by their age at primary surgery but was affected by gender, the diagnosis leading to TKR, and the need for revision. Men, patients who had OA, and those who had undergone a revision procedure were statistically more likely to be dissatisfied (chi-squared test, p < 0.05, p < 0.05 and p < 0.0001, respectively).

With respect to the frequency of pain, age, gender and failure of the primary TKR had a significant effect on the results. The results indicate that older patients, females, and patients whose primary prosthesis was still in situ at 15 years experienced pain less often (chi-squared test for trends, p < 0.0005, < 0.005, and < 0.0001, respectively).

Patients’ quality of life, as measured on the VAS (mean VAS 58.9 (0 to 100)), was not affected by any variable. Therefore, gender, age at primary replacement, failure of
TKR and diagnosis leading to TKR did not have any bearing on quality of life at 15 years following TKR.

The relationships between different variables and the outcome measurements of satisfaction, pain, and quality of life are presented in Table I.

Discussion

The survival analysis of cohort showed that women and younger patients were statistically more likely to survive to 15 years following TKR. The mortality rates at both three months and one year post-operatively, are comparable to contemporary results for England and Wales.11

The best-case survival curve at 15 years following TKR showed that 92.7% of prostheses were still in situ. In the worst-case survival, 81.1% were in situ. However, our best-case scenario findings differed from those of the Swedish Knee Arthroplasty register5,6 with respect to the influence of gender, with 89.5% of prostheses surviving to 15 years in males and 93.5% in females.

Survival of the prosthesis was significantly affected by the age of the patient, as concluded in previous studies.4-6 In patients aged less than 55 years at the time of surgery, only 87.0% of prostheses survived to 15 years; but as age at the time of TKR increased survival of the TKR also improved (Fig. 5). The infection rates at three, five and 15 years based on the whole cohort were 0.26%, 0.41% and 0.74%, respectively. These findings were comparable with those of other long-term studies.11

Although limited by the large number of non-responders, a high level of satisfaction with the TKR was still felt 15 years following the replacement. Males and patients who had undergone a revision were statistically more likely to be dissatisfied. Similarly, men reported pain from their TKR more often than did women.

It was disappointing that 29 of the revisions (0.62%) had not been documented on the database. This may have occurred when patients in the original cohort moved out of the region. This is one of the first long-term studies from the United Kingdom to look at the survival of primary TKR in one simultaneous cohort without selecting specific prostheses.7 It shows that survival at five and ten years is comparable to the results of similar studies from other countries.1-3 However, there is very little information on the survival of knee prostheses beyond ten years but the results from the Trent Regional Arthroplasty Study are better than have been previously published, with more than 90% of prostheses surviving to 15 years.2,6

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References


