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ORIGINAL PAPER

All-polyethylene tibial components in TKA in rheumatoid arthritis: a 25-year follow-up study

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Abstract

Purpose There is renewed interest in the all-polyethylene tibial component in total knee arthroplasty (TKA). Long-term results of this prosthesis in rheumatoid arthritis (RA) patients, however, are limited. Therefore, we studied 104 primary cemented all-polyethylene tibial TKA in 80 consecutive RA patients for up to 25 years to determine the long-term survival of all-polyethylene tibial components in patients suffering from end stage RA.

Methods We estimated revision rates according the revision rate per 100 observed component years used in national joint registries. Kaplan–Meier was used to estimate survival curves.

Results During the 25-year follow-up, three revisions for tibial component loosening were performed. The mean revision rate of all-polyethylene tibial components with revision for aseptic loosening as the endpoint was 0.09 per 100 observed component years. This corresponds to a revision rate of 0.9% after ten years and 2.25% after 25 years. Survivorship according to Kaplan–Meier was 100% at ten years and 87.5% at 25 years [95% confidence interval (CI) 64.6–100)].

Department of Orthopaedics, Leiden University Medical Center, Leiden, The Netherlands Universal Trial Number (UTN) U1111-1113-6472; Dutch Trial Registry (NTR) TC 2218

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R. G. H. H. Nelissen e-mail: R.G.H.H.Nelissen@lumc.nl *Conclusion* This study shows good long-term results of allpolyethylene tibial TKA in patients with RA. RA patients with multiple-joint inflammation may be less physically active than osteoarthritis patients, resulting in a lower demand on the prosthesis, and these patients may, indeed, be good candidates for all-polyethylene tibial TKA. Our results suggest that all-polyethylene tibial TKA could be a successful and cost-saving treatment for end-stage knee arthritis in RA patients.

Introduction

All-polyethylene tibial (APT) total knee arthroplasty (TKA) has gained renewed interest [1]. An important concern is the combination of durability with cost reduction compared with metal-backed tibial (MBT) components. Implant costs can decrease by 20-50% using APT components [1]. This prosthesis is recommended for patients who are less physically demanding [2]. RA patients in general are more physically impaired compared with those suffering from osteoarthritis (OA) patients. This is partially due to the polyarticular involvement of the disease. TKA has proven to be a successful surgical intervention that reduces pain and enhances physical function of RA patients [3]. Additionally, primary TKA is one of the most frequently performed orthopaedic interventions in such patients [3]. One of the first total knee prostheses with an APT design was the total condylar knee prosthesis (Zimmer, Warsaw, IN, USA). This prosthesis showed excellent clinical results at long-term follow-up of mainly OA patients [4]. Over time, this implant was modified to an MBT component because in vitro studies indicated improved load distribution to the proximal tibia [5, 6]. Despite biomechanical evidence, this has not been demonstrated in clinical studies.

Few studies have been performed on TKA with an APT component in patients with rheumatoid arthropathy, as identified with a search in the PubMed library using the following key words: total knee arthroplasty, rheumatoid arthritis, polyethylene and relevant abbreviations and synonyms [7–9]. Therefore, long-term results of this type of TKA in this specific population are scarce. Knowledge of long-term outcomes is necessary to evaluate efficacy and durability of joint replacements, especially in patients with RA because of their relatively young age [10]. Therefore, our aim was to determine the long-term survival (up to 25 years) of APT components in TKA in patients suffering from end-stage RA.

Patients and methods

From 1979 to 1990, 104 primary cemented APT (ultrahigh-molecular-weight polyethylene) tibial TKA with the semiconstrained cruciate-ligament-sacrificing total condylar (type I) knee prosthesis (Zimmer) were performed in a generalised academic institute in 80 consecutive patients with RA. In 24 patients, bilateral TKA was performed. The diagnosis of RA was assessed by a rheumatologist using the nomenclature and classification of arthritis and rheumatism [11]. Previously, the four to ten year survival rate of some of these patients and the basic operative technique were described by the senior author [12]. The procedure is performed through a standard midline skin incision and a medial parapatellar arthrotomy. It includes measures for proper patellar tracking, releases for fixed deformities, balancing the tension in the medial and lateral collateral ligaments and restoring the proper mechanical axis of the lower extremity.

Data-collection procedure

The study was conducted after approval of the hospital ethical committee (reference number P09.244). All patients were followed up at predefined visits at our orthopaedic department. We collected information regarding possible failure of the prosthesis from the hospital database. We also checked databases of the two nearest hospitals to rule out possible revisions. In case of an incomplete follow-up, we contacted the patient's general practitioner (GP) to enquire about revisions elsewhere or problems with the prosthesis. In The Netherlands, GPs receive all medical correspondence related to a particular patient and are the centre in the medical network: e.g. a patient must be referred by a GP when a consultation by a specialist is required. Therefore, in the event of problems with the prosthesis or if a revision was performed in another hospital, the GP will have the record. Finally, we consulted the community registry to check possible date of death of all patients to determine the endpoint of follow-up. For 63 patients (81 TKAs), information was collected until death or revision. After the 25-year follow-up, revision in 17 patients (23 TKAs) could not be ruled out with absolute certainty, and these patients were nominated as being lost to follow-up (Figure 1). There were no relevant differences between patients lost to follow-up and other patients regarding demographics (Table 1).

Clinical evaluation of all patients was performed using the Hospital for Special Surgery (HSS) knee scoring system [13]. Of TKA instability at one year follow-up was examined.



Table 1 Parameters of all patients		Complete FU ($n=63$)	Lost to FU $(n=17)$	Total (<i>n</i> =80)
	Follow-up (years)	11 (1–25) [7.8]	10 (1–21) [4.9]	11 (1–25) [7.3]
	Age (at index operation)	66 (30-82) [9.8]	69 (53–78) [6.4]	67 (30-82) [9.3]
	Female (%)	78	87	80
Range (); standard deviation []	BMI	25 (19–35) [3.6]	26 (20-32) [3.0]	25 (19-35) [3.5]
<i>FU</i> follow-up, <i>BMI</i> body mass index, <i>ROM</i> range of motion	Femorotibial alignment ^a ROM at 1 year	175 (166–181) [3.1] 95 (45–130) [15 3]	177 (173–186) [3.1] 94 (50–140) [20 6]	176 (166–186) [3.1] 95 (45–140) [16 5]
^a Determined on 89% of cases	icolui al 1 your	95 (15 150) [15.5]	51 (00 110) [20:0]	<i>(13</i> 140)[10.5]

Instability was defined according to the HSS: none, mild $0-5^\circ$, moderate $5-15^\circ$, severe $\geq 15^\circ$ [13]. Radiological evaluation, including assessing alignment, radiolucent lines and possible loosening was performed using the Knee Society TKA radiographic evaluation and scoring system [14].

Statistical analysis

The primary endpoint was revision or removal of the tibial component for aseptic loosening. The secondary endpoint was revision or removal of the tibial component for any reason. We calculated revision rates according to the Australian Arthroplasty Register and a recent systematic review using revisions per 100 observed component years [15]. This method gives outcomes that are easier to than using national joint registries. The traditional Kaplan-Meier method is inappropriate because it overestimates the risk of revision, especially when the incidence of competing risks is high [16]. This risk is very likely in long-term follow-up studies of joint replacements because there is a high incidence of the competing risk of death. We included a worst-case-scenario analysis (i.e. every patient lost to follow-up was considered as a revision). This represents the lowest possible survival rate. The revision rates were compared with revision rates of annual reports in national joint registries of several countries. Despite the fact that the Kaplan-Meier method overestimates the risk of revision, we also estimated survival curves according to the Kaplan-Meier method to allow comparison with clinical studies. Calculations and survival curves were performed using the multi state (mstate) library in R version 2.12 [17].

Results

Follow-up for the 80 patients was up to 25 years, and mean duration of follow-up until death or revision of the 63 patients was 11 (range 1–25) years. For the 17 patients without complete follow-up, this period was ten (range one to 21) years (Table 1). Mean revision rate of the APT component with revision for aseptic loosening as endpoint for the 25 year follow-up was 0.09 per 100 observed

component years. This corresponds to a revision rate of 0.9% after ten years and 2.25% after 25 years. Survivorship according to Kaplan–Meier was 100% at ten years (n=47)

25 years (n=3) (Figure 2). The mean revision rate with revision for any reason was 0.27 per 100 observed component years. This corresponds to a revision rate of 2.7% after ten years and 6.75% after 25 years. Survivorship according to Kaplan–Meier is 98.9% (95% CI: 96.7–100) at ten years (n=47) and 79.3% (95% CI: 54.3–100%) at 25 years (n=3) (Fig. 3). When radiological failures are included the mean revision rate was 0.53 per 100 observed component years.

and 87.5% [(95% confidence interval (CI) 64.6-100%)] at

Clinical follow-up

Mean HSS was 76 [range 28–93, standard deviation (SD) 11.6] and mean range of motion (ROM) was 97° (range 50–130, SD 16.2) at a follow-up of six (range 2–10, SD 3.0) years. At one year follow-up, 93% of prostheses had no



Fig. 2 Survivorship curve (*black line*) showing revision for aseptic loosening of the all-polyethylene tibial (APT) component with 95% confidence intervals (*dotted lines*)



Fig. 3 Survivorship curve (*black line*) showing revision for any reason of the all-polyethylene tibial (APT) component with 95% confidence intervals (*dotted lines*)

instability, 6% had mild instability and 1% had moderate instability.

Radiological follow-up

Postoperative femorotibial alignment was 176° (range 168– 186, SD 3.1). Mean beta (tibial) joint-line angle was 88° (range 80–94, SD 2.3). Mean sagittal tibial angle was 88° (range 69–96, SD 4.1) A radiolucent line of 1 mm under the tibial component was observed in 47.5% of patients in the first ten postoperative years. In 5%, a radiolucent line of 2 mm was observed under the tibial component. During follow-up, three TKAs in three patients showed radiographic loosening (13.2, 18.3 and 19.8 years postoperatively). However, these patients did not undergo revision surgery. One patient with radiographic loosening at 13.2 years postoperatively refused revision. The remaining

Fig. 4 Revision rates (endpoint revision for any reason) of the best- and worst-case scenarios (all cases lost to follow-up are considered as revision) of the all-polyethylene tibial (APT) component and revision rates after total knee arthroplasty (TKA) in six countries

two patients did not undergo revision surgery because the complaints were relatively mild and they suffered from severe immobility caused by end stage RA that affected multiple joints.

Worst-case scenario

Mean revision rate in the worst-case scenario for the APT component with revision for any reason as endpoint was 2.4 per 100 observed component years. Revision rates of primary TKA according to annual reports of several national joint registries range from 0.71 to 2.51 [15]. The revision rate in the worst-case scenario of our cohort was within this range (Figure 4).

Complications

Three revisions for loosening were performed: one for aseptic loosening (23 years postoperative). This patient underwent complete revision. Perioperatively, only the tibial component was found to be loose. There were large bony deficits, so augmentations of the tibial and femoral component were necessary. Nine years after this revision procedure, the patient was still satisfied with the prosthesis. One patient underwent revision for septic loosening due to a Staphylococcus aureus infection (3.7 years postoperatively). This patient underwent prosthesis removal and had six weeks of antibiotic therapy prior to TKA reimplantation. Twenty-five months after revision, the infection recurred and an arthrodesis was performed. On the contralateral side, this patient also had a TKA with an APT component. Throughout the study period, there were no complications with this prosthesis. Another patient experienced septic loosening due to a coagulase-negative S. aureus infection (20.8 years postoperative). No revision TKA was performed for this patient due to multiple comorbidities. There were no signs of infection at the contralateral TKA, so it remained in situ.



No revision was performed for loosening of femoral or patellar components as a primary indication. There were five traumatic fractures of the distal femur (5.2; 8.3; 11.3; 14.6; 17.8 years postoperatively), two traumatic patellar fractures (0.3; 11.9 years postoperatively), one nontraumatic patellar fracture (2.3 years postoperatively) and one aboveknee amputation for vascular complications (8.8 years postoperatively). All fractures were treated conservatively with plaster cast and immobilisation. Two patients with bilateral TKA experienced a distal femur fracture on both sides at different times. No patient with a periprosthetic fracture underwent TKA revision. One patient died 11 days after TKA due to gram-negative sepsis of unknown origin.

Discussion

As this study offers the longest follow-up for a single APT component in RA, it provides greater insight into long-term survival rates of APT TKA. The study shows good long-term survival, and revision rates are comparable with TKA revision rates as noted in several national joint registries [15]. Previous reports of APT TKA in RA patients show results comparable with our study. Kristensen and Laskin showed survival rates ranging from 81% to 89% at the ten year follow-up [8, 9]. Rodriquez reported a 91% survival rate at 15 years, with endpoint as revision for any reason [7].

Our study has some limitations: First, some patients were lost to follow-up. To account for these patients, we included a worst-case scenario to give an absolute lower limit of the revision rate. The worst-case scenario assumes all patients lost to follow-up were revised. The revision rate of the worst-case scenario lies in the range of revision rates according several national joint registries, as illustrated in Fig. 4 [15]. Despite thorough attempts to collect complete follow-up of all patients, revision in some patients could not be ruled out with absolute certainty. The most important reason for this lack of information was the limited storage time of medical files, which are destroyed ten years after the patient has died. Consequently, medical information for patients who died more than ten years prior to our study was almost impossible to trace. We checked the community registry to determine the end of study time of each patient and found that many patients died during the follow-up. At the time of analysis, information of the patients who died not long after TKA could therefore not be retrieved. Of these patients, we ruled out revision in our hospital and in the two nearest hospitals by gathering information from their databases. Additionally, that group was comparable with the complete follow-up group regarding several patient demographics, as seen in Table 1. A second limitation was that the APT total condylar knee prosthesis used in this study is no longer used in today's orthopaedic practice. As

the modern polyethylene types are expected to be superior to the APT in our study, the revision rate of a modern APT may even be lower than the revision rate of the total condylar knee prosthesis, which had an excellent long-term track record [4].

RA is a chronic inflammatory disease that leads to varying degrees of functional impairment and disability [7]. Many RA patients still require total joint arthroplasty despite improvements in pharmacological treatment [3]. Functional status after TKA is inferior to that of OA patients treated with TKA [7]. A reason is the polyarticular involvement and the declining functional status due to the disease. In the literature, patients who are relatively sedentary and less active are classified as low demand, are frequently elderly (>70-75 years old) or have RA [2, 7]. Low-demand patients generally place lower stress on their TKA and thus reduce the wear rate and risk of revision. According to the literature, APT TKA can be an acceptable treatment for such low-demand patients and a cost-saving treatment option [2, 18]. Many studies have compared APT with MBT TKA. These studies investigated possible superiority of MBT components. None of these studies showed significant differences in favour of MBT TKA [18-24]. In addition, a meta-analysis favours the use of a nonstabilised APT component over an MBT component [25]. Although all these studies show good results for APT designs, one study showed high revision rates of one specific APT design with low conformity [26]. This study mainly reviewed OA patients (93%); our study, on the other hand, reviews RA patients. Additionally, the design of this tibial component differs from the APT design of the total condylar prosthesis by conformity of the prosthesis between the femoral and tibial components. The APT design of the total condylar has a higher conformity. In conclusion, our results suggest that APT TKA could be a successful and cost-saving treatment for end-stage knee arthritis in rheumatoid patients.

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Conflict of interest The authors declare that they have no conflict of interest.

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