Chapter 2

Study Population and Aims of the Study

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2.1 STUDY POPULATION

In the period between January 1982 and July 1991, 345 SKI-type cemented knee prostheses were implanted at Groningen University Hospital. In three cases a separate tibial plateau was used, and in one case a revision of a unicondylar prosthesis was performed. These cases were excluded from the analysis, leaving 341 primary SKI prostheses (255 patients) available for analysis. Each year a mean of 36 SKI prostheses was implanted, varying from 29 in 1982 to 46 in 1984. In the first six months of 1991, only 9 SKI prostheses were implanted (see Figure 2.1).

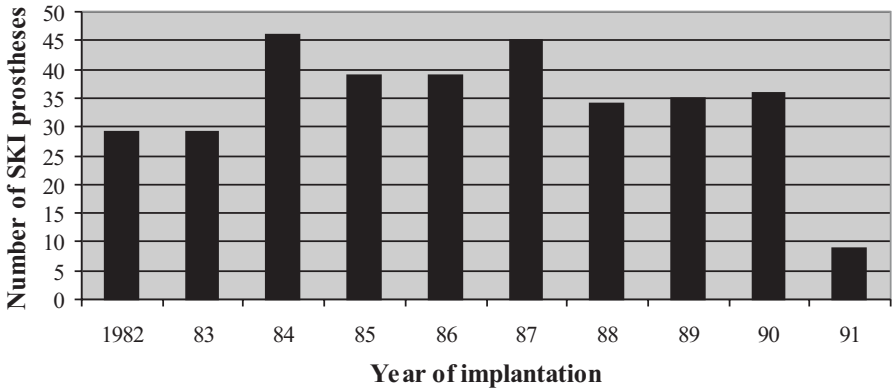

***Figure 2.1**. Number of TKAs implanted each year between January 1982 and July 1991.*

All implantations of the SKI knee prosthesis were performed by four different consultants or under direct supervision of the consultant by three different registrars. The consultants performed 310 operations and the registrars 31. The number of operations each surgeon performed ranged from 2 to 93.

The size of the prostheses used is listed in Appendix 1. Size 1 was not used, size 3 (206 knees) and size 4 (109 knees) were mostly used. In seven cases the size of the prosthesis was not known. At the time of implantation of the SKI prosthesis there used to be no overall registration

of the implants used, so it was not possible to find out the size of the prosthesis used in those cases. At that time, bone was resected as minimally as possible in order to allow performing an arthrodesis if the prosthesis failed. For this reason, insert sizes 7 (273 knees) and 9 (44 knees) were mostly used. Overall, size 3 x 7 (171 knees) and 4 x 7 (89 knees) were mostly used.

All patient characteristics are listed in Appendix 2. There were 194 women (261 knees) and 61 men (80 knees). The right knee was involved in 179 cases, the left knee in 162. The primary diagnosis can be divided into three major groups: rheumatoid arthritis (135 patients, 201 knees), degenerative arthritis (94 patients, 112 knees) and other diagnoses (26 patients, 28 knees). The 'other diagnoses' consist of posttraumatic arthritis (14 patients, 14 knees), hemophilia (four patients, five knees), psoriatic arthritis (three patients, four knees), Gaucher disease (two patients, two knees), Osteochondritis Dissecans (one knee), aneurysmatic bone cyst (one knee), and one knee was affected by osteomyelitis in the past. The mean age at the time of surgery was 64.3 years ± 13.2 (range 20-87). Male patients were younger than female patients on average. The mean age of patients with degenerative arthritis at the time of surgery was higher compared to patients with rheumatoid arthritis and other diagnoses. The mean body weight of the patients was 71.2 kg ± 11.9 (range 36-102). Male patients were heavier compared to female patients, and patients with degenerative arthritis and other diagnoses were heavier compared to patients with rheumatoid arthritis on average.

To find out what had happened to all the patients with a SKI-type knee prosthesis implanted between 1982 and 1991 (Ti), two large follow-up studies were done. The first study was carried out from January 1996 to November 1997 (Tp), the second study from July 1999 to July 2001 (Tc). To analyze the results, the population was divided into different groups (see Figure 2.2). A total of 255 patients underwent 341 total knee arthroplasties (Group I) at Ti. At Tp, 146 patients with 194 prostheses were seen by observer 1 (Group II). Three of these patients (3 knees) had had an exchange of the polyethylene insert. At Tc, 79 patients with 97 prostheses were seen by observer 2 (Group III). Twenty of these patients (22 knees) had had an exchange of the polyethylene insert (Group IV). Group II-a represents the patients seen at Tp by observer 1, but not at Tc by observer 2 (97 knees). The fate of the knee prosthesis in 3 patients (4 knees) at Tp and in another 11 patients (14 knees) at Tc was not known. These patients were considered lost to follow-up.

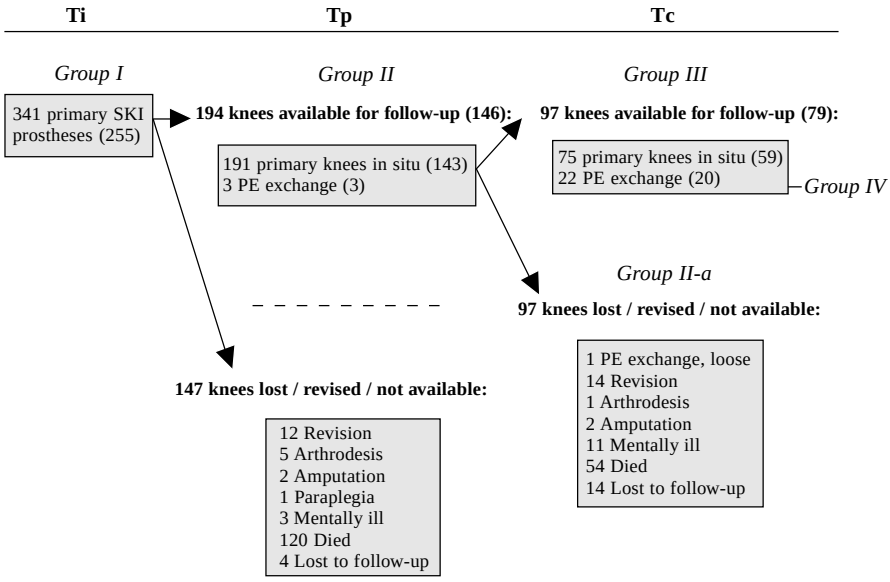

***Figure 2.2**. Number of knees (patients) in different patient groups and fate of all SKI knee prostheses implanted at Groningen University Hospital.*

2.2 AIMS OF THE STUDY

The goals of total knee replacement are to obtain pain relief and to restore function and mobility. Total knee replacement is expected to be a durable procedure lasting at least 10 to 15 years. Demographic changes are likely to increase the demand for total knee replacement by 40% over the next 30 years [80]. Therefore, evaluation of the clinical performance and long-term survival of former designs are of the utmost importance to the development of future designs. The SKI knee prosthesis was used in the period between January 1982 and July 1991 at Groningen University Hospital. The long-term results of the SKI prosthesis were studied in two large follow-up studies with a mean follow-up of 9.8 years ± 2.6 (range 5.1-15.5) and 14.0 years ± 2.6 (range 9.2-18.7).

In this study we aimed at finding answers to the following questions:

1. What is the long-term survival and clinical performance of the SKI prosthesis, and which factors influence the clinical performance? (see sections 3.3.1, 3.3.2 and Chapter 4)

2. What complications occurred, which factors contributed to these complications, and to what extent did they influence long-term survival? (see sections 3.3.4 to 3.3.10)

The polyethylene insert of the SKI prosthesis is fixed with a screw. In case of wear, the PE insert can be exchanged without having to sacrifice the fixation of the tibial component. One of the main problems of the SKI prosthesis was loosening of the locking screw of the polyethylene insert. The main reason to start these follow-up studies was to find an answer to the following questions:

3. In how many knees was loosening of the locking screw of the PE insert seen? Which patients had screw loosening and what were the consequences of screw loosening? (see sections 3.3.8 and 7.4.1.14 to 7.4.1.16)

After isolated exchange of the polyethylene insert, the prosthesis should stay well-fixed in the bone to preserve a pain-free, mobile and stable joint allowing full weight-bearing. However, some studies showed high rates of failure after isolated PE exchange [117;118]. We tried to find answers to the following question:

4. How is the survival and the clinical performance after revision of the polyethylene insert? (see sections 3.3.3 and 4.3.8)

Wear of a polyethylene surface is a multifactorial process [63;85;86]. Malalignment, increased body weight, increased activity level, poor quality of the polyethylene and probably other factors may increase wear, and wear may induce loosening of the knee prosthesis [87-90]. The potential for generation of polyethylene debris at the articular surface is substantially higher in the prosthetic knee than in the prosthetic hip. Surface incongruity, point-loading of the polyethylene and the likelihood of third-body wear from debris in the joint are responsible for this [60;71]. In recent years, researchers have observed wear on the backside of retrieved polyethylene inserts of modular knee prostheses (91;92). Most studies on polyethylene wear in total knee arthroplasty are retrieval analyses [93-96]. There is little information about in vivo wear measurement, due to practical issues related to the patient's positioning and reproduction of the X-ray beam projection [97]. Therefore we tried to answer the following questions:

5. Is it possible to determine the amount of wear in vivo? (see sections 5.2 to 5.3)
6. What are the wear characteristics, and which factors contribute to this phenomenon the most in the SKI prosthesis? (see sections 3.3.9, 5.5 and Chapter 7)

Alignment of the leg can be determined on full-length leg and short radiographs. Some studies found no significant difference between measurements on long and short radiographs [3], but other studies found significant differences [173;188;189]. To study the influence of alignment of the leg and the prosthesis on wear and wear rate, we tried to answer the following questions:

7. Is it possible to determine the alignment of the leg on a short radiograph? (see section 5.4)
8. Is the knee prosthesis aligned through the real anatomical axis with an intramedullary guidance instrument? (see section 5.4)
9. To what extent did the alignment of the leg and the prosthesis influence wear and wear rate? (see section 5.6 to 5.7)

The polyethylene insert of the SKI prosthesis is replaceable. Problems of accelerated implant wear with modular components were identified in 1992 by Engh et al. [81]. The biological response that is elicited in the surrounding tissue by particles of polyethylene can cause endosteal bone resorption and deterioration of the bone-implant interface [82;83]. Osteolysis was not reported as a clinical problem in cemented knee arthroplasty with the first generation of one-piece tibial components. After introduction of modular polyethylene inserts in the mid-1980s, failure due to osteolysis was recognized as a clinical problem [81;84]. In this study we evaluated the presence, increase and patterns of radiolucency around the SKI prosthesis in order to find an answer to the following questions:

10. What are the radiographic long-term results of the SKI prosthesis, and how do they relate to the clinical performance? (see Chapter 6)