Summary

Since the 1970s, the development of total knee replacement has evolved thanks to the incorporation of the low-friction concept and materials proven in the development of total hip arthroplasty during the 1960s. Many new designs have been developed since then, all of them in laboratories. The only way to evaluate the function of a design is to evaluate the long-term results thoroughly. This study describes the long-term results of the SKI knee prosthesis; this is a prosthesis of the condylar type, with a replaceable polyethylene insert. The condylar type knee prosthesis is mostly used nowadays. The insert of the SKI prosthesis is fixed with a screw. One of the main reasons to start this follow-up study was because loosening of this screw was seen in several patients. The SKI prosthesis was available in three types. The type with a stabilizing "Totalplateau" was originally designed for knees with ACL and PCL instability (see Figure 1.1c). This type of prosthesis was used as a standard prosthesis in all cases at Groningen University Hospital from January 1982 to July 1991, with resection of the ACL only.

Chapter 1 presents a brief history of the development of total knee arthroplasty. General design criteria are described, as well as the design of the SKI prosthesis.

Chapter 2 describes the aims of the study and the study population. In two consecutive follow-up studies, the survival, clinical performance, complications and radiographic long-term results of 341 cemented SKI-type knee prostheses (255 patients) implanted at Groningen University Hospital were analyzed.

The goal of the study in **Chapter 3** was to describe the long-term results of the SKI prosthesis by analyzing all revisions, reasons for revision and complications. At final follow-up, 33 revisions (9.8%) had been performed:

- 19 due to aseptic loosening
- 10 due to infection
- one due to (valgus) instability after a trauma
- one due to an irreducable dislocation of the prosthesis
- one due to wear in a well-fixed prosthesis
- and in one case the reason for revision was unknown

An exchange of the PE insert had been performed in 27 cases (7.9%). One of these prostheses had radiographic signs of loosening and was considered as an aseptic loosening of the prosthesis in further analysis.

The cumulative survival rate of the SKI prosthesis is 86.6% ± 3.2 at 19 years, with removal of the prosthesis due to mechanical problems or aseptic loosening as an endpoint. If removal of the prosthesis due to

infection was included as an endpoint the cumulative survival rate was 83.4% ± 3.5. No aseptic loosening was seen subsequent to a PE exchange after a mean follow-up of 2.6 years ± 1.6.

Delayed wound healing was seen in 12 knees (0.5%). No factor could be identified that increased the risk of delayed wound healing or superficial infection. Deep infection was seen in 12 knees (3.5%). In case of previous ulceration of the leg or in case of delayed wound healing, patients had a significantly higher risk of developing a deep infection. Manipulation of the knee was performed in 32 knees (9.4%). Patients with flexion contractures preopertively and patients with degenerative arthritis needed a manipulation more often. Patellofemoral complications requiring surgery were seen in 15 knees (4.4%):

- four patellar fractures
- three ruptures of the extensor mechanism
- eight knees had an exploration because of patellar pain.

Screw loosening was seen in 38 knees (11.1% of all SKI prostheses implanted and 17.8% of the knees that were available for follow-up or revised). Patients with a higher activity level had significantly more screw loosening. Significantly more wear was seen in younger patients, patients who were more active and knees with screw loosening. Significantly more aseptic loosening was seen in patients with a higher activity level and in knees with wear. Aseptic loosening was seen in 95% of the knees with damage of the metal parts of the prosthesis. Metal-on-metal contact may contribute to aseptic loosening of the prosthesis.

The clinical outcome after knee replacement with the SKI prosthesis and after a PE exchange is described in **Chapter 4**. To evaluate the clinical outcome, the Knee Society Clinical Dual Rating System (American Knee Society Score) was used, in which knee and patient function are described separately. To evaluate pain a Visual Analogue Score was used additionally and the presence of anterior knee pain was recorded. Total knee replacement with the SKI prosthesis provides a significant decrease in pain and a significant improvement in range of motion, stability, alignment and patient function in patients with both primary and secondary knee arthritis. The improvement in clinical performance is durable, except for a slight decrease in patient function in time.

The clinical performance after total knee replacement is influenced by many different factors. Some factors may be interconnected and may influence the clinical performance in different ways. To select the factors that are really important, analyses of long-term outcome should evaluate all factors that might influence it together. Evaluation of the long-term clinical outcome at different moments by different observers may also

affect the outcome because of interobserver variability and patient selection. In this study, the outcome of knee replacement with the SKI prosthesis in patients with rheumatoid arthritis and patients with degenerative arthritis is comparable, but patients with rheumatoid arthritis benefit more from total knee replacement because they have worse preoperative scores. Younger patients had a significantly worse clinical performance after total knee replacement with the SKI prosthesis. Besides, they were more active and had more wear. Younger patients are therefore at a higher risk of aseptic loosening. Sex, previous surgery (high tibial osteotomy, synovectomy or arthrotomy), body weight and PE exchange had no significant influence on the clinical outcome. Anterior knee pain was seen more frequently in patients with rheumatoid arthritis and other diagnoses and in patients who had had a PE exchange. Patellar instability was not a clinical problem. No deterioration of the clinical performance in time was seen after exchange of the PE insert.

Most studies on polyethylene wear are retrieval analyses. To evaluate the process of wear and the factors that might have influence on it, wear should be analyzed in vivo. In **Chapter 5** the methods to quantify wear of the SKI prosthesis in vivo are described. Because the SKI prosthesis has a raised metal border on the tibial tray, it can be fluoroscopically centralized, with the X-ray beam perfectly parallel to the tibial tray. To determine the reliability of measuring the amount of wear radiographically, we calculated the intraclass correlation coefficient between measurements on a radiograph and with a Vernier calliper of different unused tibial inserts. The PE thickness of the SKI prosthesis could be determined radiographically with accuracy (intraclass correlation coefficient 0.999).

To determine the alignment of the leg, we first compared measurements of the femoro-tibial angle (FTA) on short and full-length leg radiographs. In this study the FTA could not be measured on a short radiograph. Furthermore, a significant difference, with a mean of 1.8° ± 2.0, was found between measurements of the FTA through the real anatomical axes of the femur and tibia and the axis determined with an intramedullary guidance instrument. With accurate measurements of the PE thickness in vivo, factors that may influence the wear and wear rate – including alignment of the prosthesis in the bone and alignment of the leg – could be studied. In the selected group of patients available for radiographic follow-up, significantly more wear and a significantly higher wear rate were seen in knees with screw loosening. Knees with screw loosening had a wear rate that was more than four times higher

compared to knees without screw loosening. No significant change in wear rate was seen after a PE exchange.

After a mean follow-up of 14.0 years, 20.4% of the knees had malalignment of the femoral component in the AP view and 55.6% in the lateral view. In 27.7% of the knees, malalignment of the tibial component was seen in the AP view and in 16.7% in the lateral view. On full-length leg radiographs, 74.1% had malalignment of the leg. Although the position of the prosthesis or the alignment of the leg may have been changed in time, the prosthesis was probably placed with an inaccurate external guidance instrument. Knees with the femoral component placed in flexion and especially placed in extension, and knees with increased backslope or an upslope seemed to have a higher wear rate, but the relation was not significant. Knees with a valgus and especially a varus alignment seemed to have a higher wear rate, but the relation was not significant either. The course of the wear rate and the influence of the initial alignment of the leg on the wear rate could not be studied in this retrospective analysis.

In **Chapter 6** the radiographic long-term results of the SKI prosthesis were studied by analyzing the presence, changes and patterns of radiolucency around all three components on two consecutive, fluoroscopically centralized, comparable radiographs. At final follow-up radiolucency was seen in 78.6% of the knees. More radiolucency was seen in patients with degenerative arthritis and in heavier patients, and in knees with wear and screw loosening, but none of these factors had a significant influence on the amount of radiolucency. In knees with no clinical signs of loosening, most radiolucency was seen at the edges of the prosthesis. In 42.9% of the knees without clinical signs of loosening, an increase in radiolucency was seen around all components. The increase was seen on the anterior side around the femoral component, around the stem of the tibial component on the AP view, in all zones around the tibial component in the lateral view, and around the patellar component. None of the knees without clinical signs of loosening had a decrease in radiolucency. Screw loosening was the only factor contributing significantly to the increase in radiolucency.

In knees with clinical signs of loosening, only a slight amount of radiolucency was seen around the femoral component, with minor progression. Most changes were seen around the tibial component. A significant increase in radiolucency was seen around one prosthesis.

Around the other knee a decrease was seen due to a change in position and tilting.

No relation was found between anterior knee pain and radiolucency or osteophytes at the patellar component.

The wear characteristics of retrieved implants were studied in **Chapter 7**. Most damage was seen on the posteromedial and to a lesser extent on the posterolateral side. Heavier patients had a higher wear rate, knees with screw loosening had a higher wear rate compared to knees without screw loosening, and patients with degenerative arthritis had a higher wear rate compared to patients with rheumatoid arthritis.

Only in knees with screw loosening was a rotational pattern of wear seen at the backside of the insert and at the metal tibial baseplate. In case of screw loosening, the polyethylene insert probably rotates in the metal tibial tray, causing more articular wear due to abnormal loading, and more backside wear. The backside wear, which could not be quantified in this study, may cause wear debris with smaller particles; this may explain the significant increase in radiolucency seen in knees with screw loosening.

In **Chapter 8** a general overview of the results is given with the answers to the questions as described in section 2.1. Although the thickness of the polyethylene of the SKI prosthesis was far below the recommended eight to ten millimeters, the locking mechanism of the tibial insert with a screw had a poor design and the alignment of the prosthesis with the external guidance instruments was far from optimal, the cumulative survival rate of this prosthesis is high and it provides a durable decrease in pain as well as a significant improvement in range of motion, stability, alignment and patient function. Had the fixation mechanism of the PE insert been better, the survival rate might have been even higher.

Modularity of a prosthesis may offer the advantage of a quick and relatively simple revision procedure in case of wear. In this study no aseptic loosening or deterioration of clinical outcome was seen after an isolated insert exchange. However, because of the high amount of progressive radiolucency, which is not seen in prostheses with a fixed bearing [237;238], the use of modular prostheses should be reconsidered. Because a significant increase in radiolucency was seen in knees with screw loosening, (micro)motion between the polyethylene and the metal tibial baseplate probably plays a role in the development of these radiolucent lines.

To evaluate the clinical performance after total knee replacement, all factors that may affect the outcome should be analyzed together. Evaluating the long-term clinical outcome at one single moment may affect the outcome due to patient selection. The most important factor

determining the outcome of the SKI prosthesis was age at the time of surgery. Younger patients have a significantly worse clinical performance, they are more active and they have more wear, and are therefore at a higher risk of aseptic loosening. Patients with rheumatoid arthritis benefit more from total knee replacement with the SKI prosthesis compared to patients with degenerative arthritis, but the final outcome is comparable.

Because of the raised border on the metal tibial plateau of the SKI prosthesis, accurate measurement of the amount of wear in vivo was possible. Adding a marker to the polyethylene in new designs will allow future studies of factors that may affect wear and wear rate in vivo.

Regular radiographic follow-up, preferably with fluoroscopically centralized radiographs of modular prostheses, may recognize full thickness wear of the polyethylene at an early stage and prevent damage due to metal-on-metal contact, which may cause loosening of the prosthesis. However, with the greater numbers of prosthetic joint replacements, surveillance of these patients will become more time-consuming.