Chapter 8

General Overview of Results and Conclusions

In this chapter a general overview of the results of this study will be given with the answers to the questions as described in section 2.2. The results already have been discussed in the previous chapters. References to the concerning discussions will be given in the text.

8.1 LONG-TERM SURVIVAL AND CLINICAL PERFORMANCE OF THE SKI PROSTHESIS

The long-term survival of the SKI prosthesis is good. We found a cumulative survival rate of 86.6% ± 3.2 at 19 years, with removal of the prosthesis or recommended revision due to mechanical problems or aseptic loosening as an endpoint, and 83.4% ± 3.5 if removal of the prosthesis due to infection was included as an endpoint. Significantly more aseptic loosening was seen in patients with a higher activity level and in knees with wear (see section 3.4).

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. Increased mobility after knee replacement may reduce social isolation and have other benefits, such as improved cardiovascular fitness [234]. 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. Some of these factors may appear to be significant if analyzed separately, but they are not significant in an analysis corrected for all factors. Besides, knees are nested within patients, which also may affect the outcome. To select the factors that are really important, analyses of long-term outcome should be performed as multilevel analyses to correct for all factors that might influence the clinical performance, and to correct for patient factors (for example body weight or diagnosis) and knee factors (for example previous surgery or time of follow-up). Considering all factors that might influence the clinical performance of the SKI prosthesis, age at the time of surgery was the most important factor determining the outcome. Younger patients had significantly worse Knee Scores, significantly less range of motion and significantly less flexion. Younger patients had a higher activity level compared to older patients, which may explain the higher amount of wear seen in these younger patients. Wear and a higher activity level may increase the risk of aseptic loosening of the prosthesis in younger patients. No significant difference in clinical

performance was seen between male and female patients or between patients who had had previous surgery (high tibial osteotomy, synovectomy or an arthrotomy) and patients who had not. The outcome in patients with rheumatoid arthritis and patients with degenerative arthritis is comparable, but patients with rheumatoid arthritis had a worse clinical performance before total knee replacement and therefore benefit more from total knee replacement (see section 4.4).

8.2 COMPLICATIONS

Thromboembolic complications were seen in 1.5% of all procedures (one DVT and four non-fatal pulmonary embolisms). Transient peroneal nerve palsy was seen in six procedures (1.8%). Excessive hematoma was seen in 15 knees (4.4% of all procedures), five of which required evacuation of the hematoma. Delayed wound healing or superficial infection was seen in 12 knees (3.5%). No factor could be identified that increased the risk of developing delayed wound healing or a superficial infection.

Deep infection was seen in 12 knees (3.5%). In case of deep infection, the prosthesis could not be maintained in seven (58.3%) of the cases. In case of previous ulceration of the leg, patients had a significantly higher risk of developing a deep infection. Delayed wound healing was another factor increasing the risk of deep infection.

Manipulation of the knee was performed in 32 knees (9.4%). Patients with flexion contractures pre-operatively and patients with degenerative arthritis needed a manipulation more often. No difference in range of motion was seen at follow-up between patients who had had a manipulation and patients who had not.

Patellofemoral complications requiring surgery were seen in 15 knees (4.4%): four patellar fractures, three ruptures of the extensor mechanism, and eight knees had an exploration because of patellar pain. Anterior knee pain was seen in 16.5% of the patients in the first follow-up study and in 22.7% of the patients in the second follow-up study. Patients with rheumatoid arthritis and other diagnoses and patients who had had a PE exchange had significantly more anterior knee pain. We have no explanation for this. We found no relation between anterior knee pain and osteophytes around the patellar component. Patellar instability was not a clinical problem in our study. The raised lateral border of the femoral component, which prevents the patella from dislocation, might explain this (see section 3.4).

8.3 SCREW LOOSENING: INCIDENCE, FACTORS CONTRIBUTING TO IT AND CONSEQUENCES

One of the weak points in the design of the SKI prosthesis is the locking mechanism of the tibial insert with a screw. 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). Activity level was the only factor that contributed significantly to screw loosening. Patients with a higher activity level had significantly more screw loosening (see section 3.4).

In the total population available for clinical follow-up, knees with screw loosening had significantly more wear. At radiographic follow-up, knees with screw loosening had an annual wear rate of 0.39 mm ± 0.45. This was more than four times higher compared to knees that had no screw loosening. Wear is unlikely to cause the screw loosening, because screw loosening was already seen within two years after implantation of the prosthesis in knees that had no signs of wear. Besides, the screw is fixed in the central part of the insert, where no wear was seen.

At retrieval analysis, knees that had had screw loosening showed a significantly higher wear rate and significantly more damage. In knees with screw loosening, significantly more abrasion, surface deformation, delamination and scratching were seen, especially in sections 1 and 5. Only in knees with screw loosening was a rotational pattern of wear seen on the backside of the tibial insert and on the metal tibial baseplate. This backside wear could not be quantified. In knees with screw loosening, the polyethylene insert probably rotates in the metal tibial tray, causing more articular wear due to abnormal loading and backside wear. The backside wear may cause wear debris with smaller particles, which may explain the significant increase in radiolucency seen in knees with screw loosening (see section 7.5).

8.4 SURVIVAL AND CLINICAL PERFORMANCE AFTER POLYETHYLENE EXCHANGE

No significant difference in clinical performance or wear rate was seen before and after PE exchange. No deterioration of the clinical performance in time was seen after PE exchange (see section 4.4).
In our study, no aseptic loosening was seen after PE exchange after a mean follow-up of 2.6 years ± 1.6. Other studies showed a high rate of

failure after isolated tibial insert exchange [117;118]. Engh et al. [119] found a deterioration in locking mechanism in time in modular knee prostheses. In case of PE exchange of the SKI prosthesis, the fixation mechanism of the tibial insert beneath the raised border of the metal tibial baseplate is probably not compromised. After PE exchange, the screw was locked with a locking pin (see Chapter 1). This might provide a better fixation of the insert after PE exchange compared to the deteriorated locking mechanisms in other studies. Besides, thicker PE inserts were used in case of a PE exchange. Studies with a longer follow-up time will have to be performed to show if isolated PE exchange in the SKI prosthesis is a durable procedure (see section 3.4).

Bert et al. [235] reviewed 62 revision total knee arthroplasties performed secondary to modular insert failure. In 88.7%, significant damage to the femoral and/or tibial component occurred, necessitating revision of one or both components. In our study, only one prosthesis (3.6%) needed a revision of all components due to damage of the metal parts, while the prosthesis was still well-fixed. The small amount of damaged metal parts in our series is probably due to regular outpatient visits and early recognition of wear and subsequent exchange of the polyethylene. In knees with damage of the metal parts 95% of the prostheses showed signs of aseptic loosening. Metal-on-metal contact may contribute to aseptic loosening of the prosthesis. We recommend regular radiographic examination of modular prostheses to avoid damage due to metal-on-metal contact, preferably with fluoroscopically centralized radiographs (see section 7.5).

8.5 DETERMINING THE AMOUNT OF WEAR IN VIVO

Wear is the abrasion of material that occurs as a result of the relative motion between two opposing surfaces under load. By measuring the distance between the metal femoral and tibial components of a knee prosthesis on a radiograph, the remaining PE thickness can be calculated after correction for the magnification factor. Because the SKI prosthesis has a raised border on the metal tibial tray, it can be centralized fluoroscopically with accuracy by rotating the leg and the X-ray tube until the X-ray beam is perfectly parallel to the metal tibial tray. By measuring the PE thickness of different unused inserts with a Vernier calliper and on a radiograph, we calculated an intraclass correlation coefficient of 0.999 between both measurements. The PE thickness of the SKI prosthesis can be measured accurately on a fluoroscopically

centralized radiograph. Because most knee prostheses do not have marks to centralize the knee prosthesis, we advise manufacturers to add a marker to the polyethylene. This will allow the clinician to determine of the amount of wear in vivo, provided that fluoroscopically centralized radiographs are used. In this study we were not able to determine the course of wear (see section 5.4.3).

8.6 WEAR CHARACTERISTICS AND FACTORS CONTRIBUTING TO WEAR

In the group of patients available for radiographic examination of the SKI prosthesis, the mean annual wear rate was 0.14 mm ± 0.25. This means a full thickness wear of the thinnest available insert in 14 years. Knees with wear had an annual wear rate of 0.29 mm ± 0.33. At retrieval analysis, the annual wear rate was 0.19 mm ± 0.11.

Most damage at retrieval analysis was seen on the posteromedial and to a lesser extent on the posterolateral side. Especially abrasion, which may be caused by eccentric loading by the condyles of the femoral component associated with rotational torques [85]; delamination, which may be caused by the high shear stresses occurring beneath the surfaces [226]; and surface deformation, presumably caused by cold flow and/or creep [85] were seen in these sections. The higher amount of damage on the posterior side might be caused by the design of the prosthesis. The femoral component has a sharply curved posterior side and the tibial component is relatively flat. Both factors may cause localized areas of high-pressure wear and deformation of the polyethylene on the posterior side. Another factor that may play a role is retention of the posterior cruciate ligament (PCL). If the PCL is too tight, the knee may "open like a book" instead of allowing a femoral rollback. This may deform the polyethylene on the posterior side [236] (see section 7.5).

In the clinical follow-up study, younger patients, more active patients and knees with screw loosening showed significantly more wear (see section 3.4). At radiographic examination, significantly more wear and a significantly higher wear rate was seen in knees with screw loosening (see section 5.5.4). At retrieval analysis 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 (see section 7.5).

8.7 DETERMINING ALIGNMENT ON A SHORT RADIOGRAPH

In this study, alignment of the leg could not be determined on short radiographs. Measuring the FTA on a short radiograph may differ 3.0° ± 3.1 or 3.2° ± 2.8 from the FTA measured on a full-length leg radiograph, depending on the positioning of the anatomical axes of the femur and tibia.

8.8 ALIGNMENT OF THE PROSTHESIS AND THE LEG

With an intramedullary guidance instrument, a knee prosthesis is not aligned through the real anatomical axis of the femur and tibia. The point of intersection of the anatomical axis of the femur and tibia generally crosses above the knee joint. The FTA determined with an intramedullary guidance instrument is significantly different from the FTA through the anatomical axis of the femur, with an average difference of 1.8° ± 2.0 (see section 5.4.2).

8.9 ALIGNMENT OF THE PROSTHESIS AND THE LEG AND WEAR

In the selected group of patients available for radiographic examination of the SKI prosthesis, we found a malalignment of the femoral component in the AP view and the tibial component in both the AP and lateral views in almost one quarter of the knees, and a malalignment of the femoral component in the lateral view in 55.6%. Malalignment of the leg was seen in 74.1% of the knees. Although the alignment of the prosthesis or the leg may have been changed in time, the external guidance instruments used in the SKI prosthesis probably did not align the components accurately (see sections 5.6.4 and 5.7.4).

At radiographic follow-up, 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. To study the influence of the alignment of the prosthesis and the alignment of the leg on the wear rate, an analysis among a larger group of patients with documentation of the initial alignment should be performed (see sections 5.6.4 and 5.7.4).

8.10 RADIOGRAPHIC LONG-TERM RESULTS

Osteolysis was not reported as a clinical problem in cemented knee arthroplasty with the first generation of one-piece tibial components [81;84]. The AGC knee, for example, with a nonmodular, compression moulded tibial component, showed no radiolucency after 4 to 15 years of follow-up [237]. The SKI prosthesis is a modular prosthesis. After introduction of modular polyethylene inserts in the mid-1980s, failure due to osteolysis was recognized as a major clinical problem. Evaluation of the radiolucency around the SKI prosthesis showed radiolucency in 78.6% of the knees at final follow-up. 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. Screw loosening was the only factor contributing to the increase significantly. None of the knees without clinical signs of loosening had a decrease in radiolucency. The increase was seen on the anterior side around the femoral component, around the stem of the tibial component from the AP view, and in all zones around the tibial component from the lateral view and the patellar component. The increase in radiolucency must alert the physician of impending loosening at further follow-up of the SKI prosthesis.

In prostheses with clinical signs of loosening, only a slight amount of radiolucency was seen around the femoral component, with minor progression, probably because the radiolucent zones are obscured by the other femoral condyle. Most changes in radiolucency were seen around the tibial component: one prosthesis had a significant increase in radiolucency and the other prosthesis had a decrease, due to a change in position and tilting of the component.

More radiolucency was seen in patients with degenerative arthritis, heavier patients and knees with wear or screw loosening, but corrected for all factors none of these factors had a significant influence on the amount of radiolucency.

No relation was found between radiolucency around the patellar component and anterior knee pain (see section 6.6).

8.11 LESSONS WE CAN LEARN FROM THE SKI PROSTHESIS

Total knee replacement should provide a pain-free, stable knee joint, which allows full weight-bearing and has a good range of motion. Wear of the polyethylene and disruption of the bonding between the

prosthesis, the cement and the bone may lead to the development of instability and loosening of the prosthesis, necessitating revision procedures. When osteolysis is present, the loss of bone at revision surgery may challenge the surgeon to achieve the above-mentioned goals.

Because many new designs are developed nowadays, it is important to review the reasons of failure of former designs. Only by carefully analyzing the reasons for failure can the weak points of a design be evaluated and the good properties of the design developed further. One of the weak points of the design of the SKI prosthesis was the locking mechanism of the tibial insert with a screw. In this study, knees with screw loosening showed more wear, a higher wear rate and a significant increase in radiolucency. In the retrieval study, knees with screw loosening had a rotational pattern of wear at the backside of the insert and at the tibial baseplate. In case of screw loosening the tibial insert may rotate, causing more wear and backside wear with smaller particles, which may explain the increase in radiolucency. To evaluate if smaller particles play a role in the increase in radiolucency, the wear debris of knees with and without screw loosening should be analyzed. Although the fixation mechanism of the PE insert had a poor design, the cumulative survival rate of this prosthesis is high and it provided a durable decrease in pain as well as 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. The high survival rate might be due to the fact that the design of the stabilizing "Totalplateau" of the SKI prosthesis used at Groningen University Hospital is similar to the total condylar design, which proved to be reliable [50].

The thickness of the polyethylene of the SKI prosthesis turned out to be far below the recommended eight to ten millimeters. However, no relation was found in this study between PE thickness and wear, radiolucency, loosening or failure of the prosthesis. The relation may not have been detected because proportionally many thin PE inserts were used (sizes 7 and 9 with a thickness of 2.0 and 4.0 mm in 93% of the cases).

By measuring the alignment of the leg and of the prosthesis in the bone, malalignment was found in the majority of the knees. Because the alignment was not measured shortly after implantation of the prosthesis, it may have changed in time. On the other hand, placement with the extramedullary guidance instruments of the SKI prosthesis (see Fig. 1.3a-b) is probably not very accurate. Contemporary guidance instruments for prosthetic knee replacement allow a better positioning

of the components than the external guidance instruments of the SKI prosthesis did. With the high survival rates in poorly placed knee prostheses, the gain of perfecting the alignment with computer navigation in routine knee replacement should be questioned.

Modular implants offer the advantage of isolated exchange of the polyethylene in case of wear. In this study no aseptic loosening or deterioration in clinical outcome were seen after isolated insert exchange. After introduction of modular implants, osteolysis became a clinical problem. Recent studies ascribe this phenomenon to micromotion between the polyethylene and the metal tibial tray, which may cause small wear particles. In this study a high amount of progressive radiolucency was seen around the modular SKI prostheses, especially in knees with screw loosening. Radiolucency is not seen in prostheses with a fixed bearing [237;238]. Although modularity offers a quick and relatively simple solution to full thickness wear of the polyethylene, the use of modular implants must be reconsidered with regard to the signs of disruption of the bonding between the prosthesis, the cement and the bone at longer follow-up.

Clinical performance after total knee replacement is influenced by many different factors. To select the factors that are really important, analyses of long-term outcome should evaluate all factors that might influence the outcome together. In total knee replacement with the SKI prosthesis, age at the time of surgery turned out to be the most important factor determining the outcome. Younger patients had a significantly worse clinical performance after total knee replacement with the SKI prosthesis. They were also more active and had more wear, and are therefore at a higher risk of aseptic loosening. Total knee replacement in younger patients should be considered thoroughly.

In this study a retrospective analysis of the clinical performance was done at two separate moments by two different observers. The patients seen in the second follow-up study were a selection of the patients seen in the first follow-up study. The patients seen in the second follow-up study seemed to have a worse clinical performance at follow-up compared to the patients seen in the first follow-up study. This may be ascribed to deterioration of the clinical performance in time or it may be due to interobserver variability. Further analysis showed that the patients seen in the second follow-up sudy already had a worse clinical performance in the first follow-up study. Therefore retrospective studies evaluating the long-term results of a surgical intervention at a single moment in time should be interpreted with caution. Because patients may die or may be lost to follow-up, long-term follow-up studies are

performed in a selected group of patients, which may affect the outcome. The long-term outcome of prosthetic replacement is best evaluated in a prospective study, with regular follow-up and standardized questionnaires.

The SKI prosthesis showed that the amount of wear could be determined accurately in vivo, because it can be centralized fluoroscopically due to a raised border of the metal tibial tray. Adding a marker to the polyethylene will allow other prostheses to be centralized fluoroscopically too. Because different patient factors may influence polyethylene wear and different designs of knee prostheses may have different wear characteristics, determination of the amount of wear in vivo should be studied to show which factors are most important and which designs have the least wear.

Regular radiographic follow-up, preferably with fluoroscopically centralized radiographs, may recognize full thickness wear of the PE insert at an early stage. In modular prostheses, early exchange of the PE insert may avoid damage due to metal-on-metal contact, which may cause aseptic loosening of the prosthesis. However, with the greater numbers of prosthetic joint replacements, surveillance of these patients becomes more time-consuming [239].