Chapter 3

Survival and Complications

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3.1 INTRODUCTION

Total knee replacement is expected to be a durable procedure with as few complications as possible. To learn from designs used in the past, all revisions, causes for revision and complications should be analyzed. To study the long-term results of the SKI prosthesis, all revisions and complications of the SKI prostheses implanted at Groningen University Hospital were studied. The number of revisions, the revision time and the causes for revision were analyzed retrospectively (see section 3.3.1). To determine the long-term survival of the SKI prosthesis, a survival analysis with three different endpoints was performed (failure due to mechanical problems, failure due to mechanical problems and infection, and failure due to mechanical problems, infection and PE exchange as endpoints) (see section 3.3.2).

After isolated exchange of the PE insert, the prosthesis is expected to be well-fixed for a longer period of time. However, in some studies the benefit of isolated exchange of the PE insert is questioned because of high rates of failure shortly after the exchange [117; 118]. We performed a survival analysis of the SKI prosthesis after exchange of the polyethylene insert with two different endpoints (failure due to loosening and infection of the prosthesis, and failure due to loosening, infection and re-exchange of the PE as endpoints) (see section 3.3.3).

All complications after total knee replacement with the SKI prosthesis that were related or unrelated to the knee or knee prosthesis will be described in sections 3.3.4.1 and 3.3.4.2. Of the complications related to the knee or prostheses, the following complications will be described in more detail:

1. A much-feared complication in prosthetic replacement surgery is deep infection. The factors that might contribute to the development of wound problems and deep infection were analyzed (see sections 3.3.5 and 3.3.6).
2. Sometimes a knee has a small range of motion after total knee replacement and needs to be manipulated under anesthesia. The factors that may influence the need for manipulation were analyzed, and the range of motion at follow-up between knees that had undergone a manipulation and knees that had not were compared (see section 3.3.7).
3. One of the complications of the SKI prosthesis was loosening of the screw that locked the polyethylene insert on the tibial baseplate. The incidence of screw-loosening in all patients with a SKI prosthesis

was determined. The characteristics of the patients with screw loosening were also analyzed (see section 3.3.8).
4. Different factors that may contribute to wear and aseptic loosening of the prosthesis were analyzed (see sections 3.3.9 and 3.3.10).

3.2 MATERIAL AND METHODS

3.2.1 Patients

We retrospectively analyzed all patient records on 341 knees (255 patients) with a SKI prosthesis operated at Groningen University Hospital. All patient characteristics are listed in Appendix 2. A questionnaire was sent to the general practitioner of every patient that was mentally ill or had died, asking for any problems or revisions at any other hospital. Fourteen patients (18 knees) were lost to follow-up in the survival analysis.

Analysis of the factors that might contribute to delayed wound healing or superficial infection and manipulation was performed in the total population of 341 knees. Analysis of the factors that might contribute to deep infection was performed in the population of patients with rheumatoid arthritis and degenerative arthritis (n=313), because none of the patients with other diagnoses developed a deep infection. Analysis of the factors that might contribute to screw loosening, wear and aseptic loosening was performed in a population of 214 knees (163 patients). The analysis was performed in this group of patients because information was missing in 127 knees (92 patients) at Tp due to the following reasons:

- 87 patients (120 knees) had died
- in one patient both legs were amputated
- one patient became paraplegic (one knee)
- three patients (four knees) were lost to follow-up

3.2.2 Revisions and survival analysis

The use of actuarial methods to construct life tables enables both the annual and overall failure rates to be determined for a group of patients with varying periods of follow-up. Monitoring starts at the time of operation and ends at a chosen point, for example the date of removal of the prosthesis. The method to analyze survivorship was described by Dobbs in 1980 [98]. This method assumes that patients who are lost to follow-up are no more or less likely to be at risk of failure of an operation than are patients who are still being followed. Dorey et al. [99] showed

that survivorship analysis is a valid technique to use in the long-term evaluation of patients who have had a joint replacement. We performed five different survival analyses of the SKI prosthesis:

1. Survival with revision or clinical and/or radiographic signs of loosening of the prosthesis due only to mechanical problems as an endpoint.
2. Survival with revision, clinical and/or radiographic signs of loosening due to mechanical problems and infection of the prosthesis as an endpoint.
3. Survival with revision, clinical and/or radiographic signs of loosening due to mechanical problems, infection and exchange of the PE insert as an endpoint.
4. Survival after PE exchange with revision, clinical and/or radiographic signs of loosening and infection of the prosthesis as an endpoint.
5. Survival after PE exchange with revision, clinical and/or radiographic signs of loosening, infection of the prosthesis and re-exchange of the PE insert as an endpoint.

3.2.3 Complications

All events that caused a new intervention, a longer or a new stay at the hospital, and the events that may have caused deterioration in functioning of the knee were considered complications. The complications not related to the prosthesis and complications related to the knee or prosthesis will be described separately.

Of all complications related to the knee or prosthesis, we analyzed the factors that may influence the development of wound problems and deep infection, manipulation of the knee under anesthesia, screw loosening, wear and aseptic loosening.

Wound problems and deep infection: Several factors that might increase the risk of wound problems and deep infection have been described (100). In this study we considered the factors that may contribute to the development of wound problems (prolonged drainage for more than two weeks or superficial infection) and deep infection:

- the primary diagnosis
- sex
- age at the time of surgery
- diabetes mellitus
- obesity (Body Mass Index $\geq$ 30)
- previous surgery

- ulcerations of the legs in history
- use of steroids perioperatively
- other risk factors (a previous history of septic arthritis of the knee, splenectomy, Reflex Sympathetic Dystrophy, liver dysfunction, kidney dysfunction and the use of immunosuppressive drugs)
- delayed wound healing (only for deep infection)

Manipulation under anesthesia: After total knee replacement, most patients can flex the knee more than 90 degrees within one or two weeks postoperatively. If the range of motion is not sufficient, the surgeon may decide to manipulate the knee under anesthesia. We considered the factors that may contribute to a small range of motion necessitating manipulation under anesthesia:
- the primary diagnosis
- sex
- body weight
- age at the time of surgery
- previous surgery
- flexion of the knee preoperatively
- extension of the knee preoperatively

Screw loosening: The polyethylene insert of the SKI prosthesis is fixed with a screw to the tibial baseplate. This screw may loosen in the course of time. We determined the incidence of screw loosening, and considered the factors that may contribute to it:
- the primary diagnosis
- sex
- body weight
- age at the time of surgery
- activity level*
- previous surgery
- PE thickness
- time of follow-up

Wear: A prosthesis with wear was defined as a prosthesis that was revised or needed a revision because of wear, a prosthesis that had had or needed an exchange of the polyethylene insert, and a prosthesis with a loss in height of the PE insert of $\geq$ 2 mm in the weight-bearing area radiographically. The method to determine the amount of wear radiographically will be described in Chapter 5. The limit was set at 2 mm, because this means a full thickness wear of the thinnest available

insert. A loss in height of less than 2 mm might be caused by creep or surface deformation and not necessarily by wear [101;102]. Wear of a polyethylene surface is a multifactorial process [63;85;86]. We considered the factors that may contribute to wear:

- the primary diagnosis
- sex
- body weight
- age at the time of surgery
- activity level*
- previous surgery
- PE thickness
- time of follow-up
- screw loosening

In Chapter 5 the influence of the alignment of the prosthesis and the leg on wear will be described.

Aseptic loosening: Aseptic loosening of a prosthesis was defined as a prosthesis with clinical and/or radiographic signs of loosening without clinical signs of infection. Many factors that may contribute to aseptic loosening of a prosthesis are described [88;103;104]. We considered the following factors:

- the primary diagnosis
- sex
- body weight
- age at the time of surgery
- activity level *
- previous surgery
- PE thickness
- time of follow-up
- screw loosening
- wear

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* *To determine the activity level of the patients we used the Function Score of the American Knee Society Score (see Appendix 3 and Chapter 4). The Function Score ranges from 0 to 100 points. A patient with a Function Score of 100 points has an unlimited walking capacity, is able to climb stairs up and down normally, and uses no walking aids.*

3.2.4 Statistical analysis

To analyze all factors that might influence the development of wound problems and deep infection, manipulation of the knee postoperatively, screw loosening, wear and aseptic loosening, a logistic regression analysis at knee level was performed. Regression coefficients (B), standard error (se) and p-value will be presented in the tables. The odds ratio can be calculated with the formula e^B. A factor was considered significant if the p-value <0.05. Data were extracted from 341 knees in 255 patients. Knees are nested within patients, therefore a multilevel analysis was performed too [105;106]. The results of the multilevel analysis are presented in Appendix 4.

3.3 RESULTS

3.3.1 Revisions

At Tc, 30 prostheses (8.8%) were removed due to mechanical problems or infection and three prostheses (0.9%) had clinical signs of loosening. These three knees were revised within three months after examination and were considered revisions due to aseptic loosening upon further analysis.

Of the 33 knees with mechanical problems or infection, a revision of the prosthesis was performed in 26 cases, an arthrodesis was performed in six cases and in one case an amputation of the leg was done.

Of the 26 revisions of the prosthesis, 19 revisions were done because of aseptic loosening, one revision was done due to a severe valgus instability after a trauma, one revision was done due to wear of the metal parts without loosening of the prosthesis, and in one case the reason for revision could not be traced. In four cases a 2-stage revision was performed due to infection. Of the six arthrodeses, five were performed due to infection. In one case an arthrodesis was performed because of an irreducible dislocation of the prosthesis. The amputation was performed because of extensive infection of the prosthesis.

An exchange of the polyethylene insert was performed in 27 cases (7.9%). One of these knees had radiographic signs of loosening. Because of patient morbidity, the surgeon decided to change the insert only. This prosthesis is recorded as an aseptic loosening of the prosthesis in further analysis (see Table 3.1).

Table 3.1. Number of revisions and polyethylene insert exchanges and reasons for revision.

Removal of the prosthesis	**n**	***% Knees***
Total revision:		
Total revision due to aseptic loosening	19	*5.6*
2-stage revision due to infection	4	*1.2*
Total revision due to (valgus) instability	1	*0.3*
Total revision due to wear	1	*0.3*
Total revision, reason unknown	1	*0.3*
(Subtotal)	*(26)*	
Arthrodesis:		
Arthrodesis due to infection	5	*1.5*
Arthrodesis due to instability (dislocation)	1	*0.3*
(Subtotal)	*(6)*	
Amputation:		
Amputation due to infection	1	*0.3*
(Subtotal)	*(1)*	
Total removal of prostheses	33	9.7
Change of the polyethylene insert	**n**	***% Knees***
Prosthesis fixed	26	*7.6*
Prosthesis with signs of loosening*	1	*0.3*
Total changes of polyethylene inserts	27	7.9

** This prosthesis had radiographic signs of loosening, but was not totally revised because of patient morbidity. This prosthesis was considered loose in further analysis*

3.3.2 Survival analysis

In the survival analysis the endpoint of 20 knees was aseptic loosening (19 total revisions and one PE exchange in a prosthesis with clinical and radiographic signs of loosening), the endpoint of 10 knees was infection (five arthrodeses, four two-stage revisions and one amputation), the endpoint of two knees was instability (one total revision and one arthrodesis), the endpoint of one knee was wear of the metal parts without loosening, and in one case the reason for revision was unknown.

The mean time from the insertion of the prosthesis to removal due to mechanical problems or infection (n=33) or aseptic loosening without removal of the prosthesis (n=1) was 8.8 years (range 0.5 to 17.9 years). Aseptic loosening (n=20) was seen after a mean period of 11.1 years (range 2.2 to 17.9). Infections leading to revision, arthrodesis or amputation (n=10) occurred after a mean period of 5.4 years (range 0.5 to 13.6 years). The two knees with instability were revised at 6.0 and 8.9 years after insertion. The mean time from the insertion of the prosthesis to exchange of the polyethylene (n=26) was 11.8 years (range 6.2 to 17.8 years) (see Table 3.2 and Figure 3.1).

Table 3.2. Number and mean time from insertion of the prosthesis to revision or removal of the prosthesis and polyethylene exchange.

	n	% Revisions	% Knees	Years ± sd (range)
Revision or removal of prosthesis				
Aseptic loosening	20	58.8	5.9	11.1 ± 4.5 (2.2-17.9)
Infection	10	29.4	2.9	5.4 ± 4.8 (0.5-13.6)
Instability	2	5.9	0.6	7.4 ± 2.1 (6.0-8.9)
Wear of metal parts	1	2.9	0.3	9.1
Unknown	1	2.9	0.3	1.0
Total	34		10.0	8.8 ± 5.1 (0.5-17.9)
PE exchange	**26**		**7.6**	**11.8 ± 2.9 (6.2-17.8)**

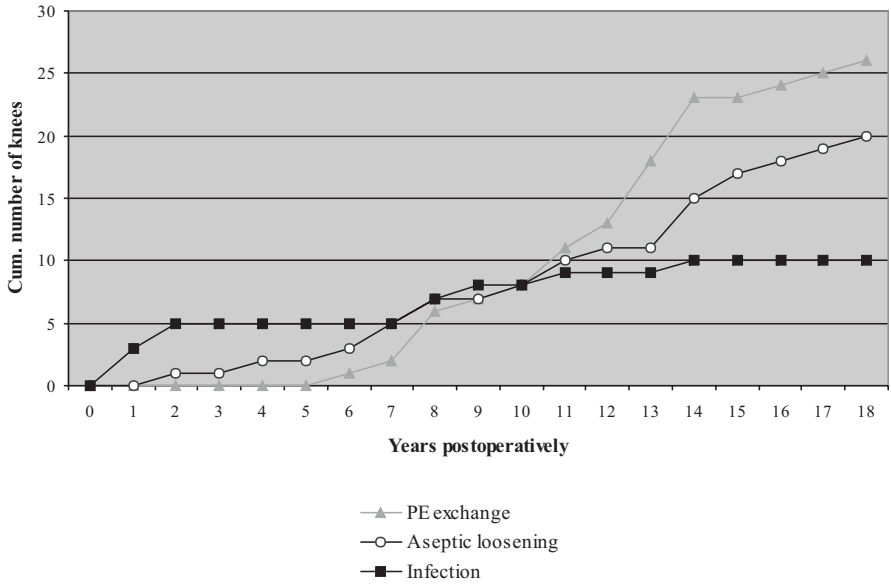

Figure 3.1. *Cumulative number of knees versus time from implantation to polyethylene exchange or removal of the prosthesis due to aseptic loosening or infection.*

The cumulative survival rate of the SKI prosthesis with removal of the prosthesis only due to mechanical problems (n=23) or aseptic loosening without removal of the prosthesis (n=1) as an endpoint is 86.6% ± 3.2 at 19 years. The cumulative survival rate of the SKI prosthesis with removal of the prosthesis due to mechanical problems (n=23) or aseptic loosening without removal of the prosthesis (n=1) and infection

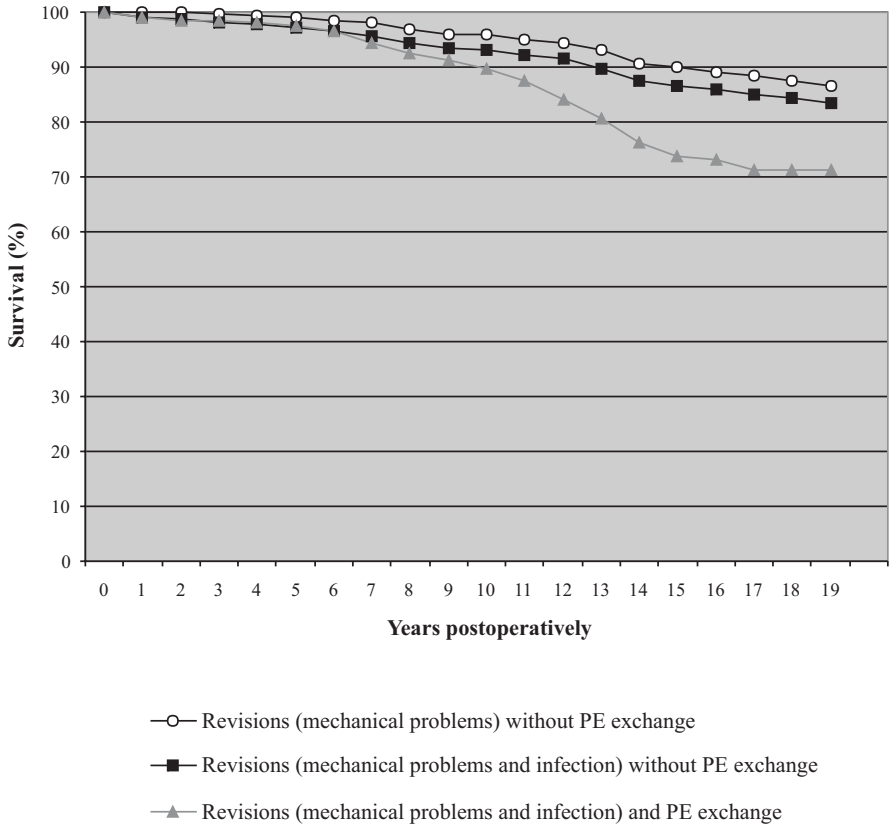

Figure 3.2. *Survival curves of the SKI knee prosthesis with revision due to mechanical problems as an endpoint, revision due to mechanical problems and infection as an endpoint, and all revisions including PE exchange as an endpoint.*

(n=10) as an endpoint is 83.4% ± 3.5 at 19 years. The cumulative survival rate of the SKI prosthesis with removal of the prosthesis due to mechanical problems (n=23), aseptic loosening without removal of the prosthesis (n=1), infection (n=10) and exchange of the polyethylene (n=26) as an endpoint is 71.3% ± 4.5 at 19 years (see Figure 3.2).

3.3.3 Survival of the SKI prosthesis after exchange of the polyethylene

At Tc, 26 exchanges of the PE insert had been performed in prostheses that were well fixed at the time of exchange. One knee with a PE exchange was lost to follow-up. The mean time of follow-up after PE exchange was 2.6 ± 1.6 years (range 0.1 to 5.5).

No aseptic loosening or infection was seen at Tc after exchange of the PE insert. In one knee the PE insert was exchanged a second time

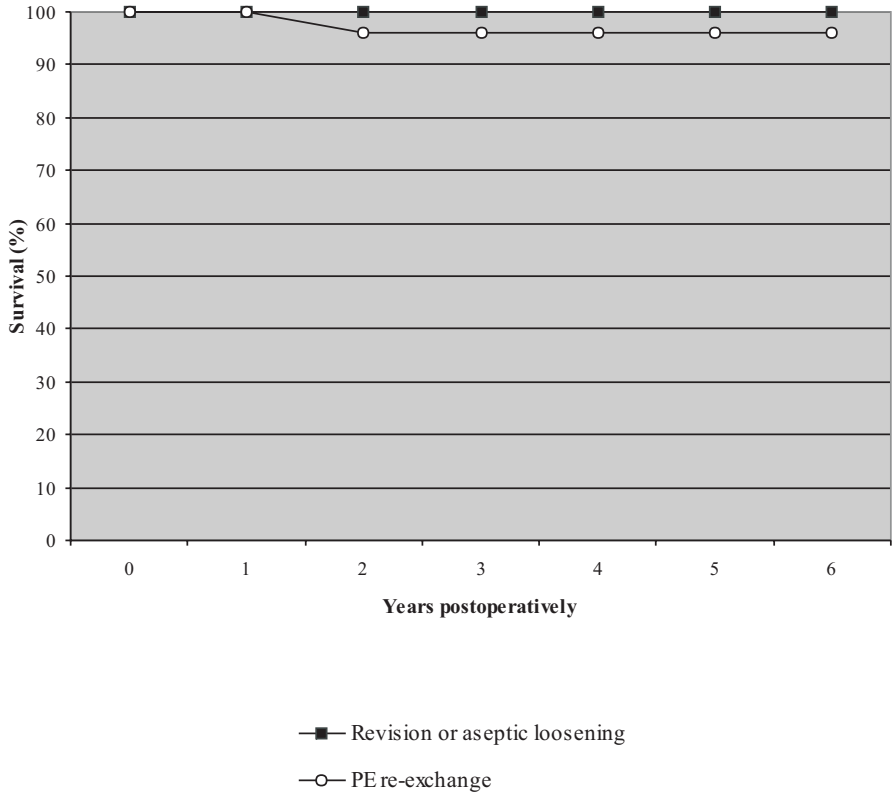

Figure 3.3. *Survival curves of the SKI knee prosthesis after PE exchange with revision or aseptic loosening as an endpoint and re-exchange of the PE insert as an endpoint.*

1.9 years after the first exchange. In this case, at the time of the first revision the prosthesis required a PE insert > 12 mm, but this size was not available at the time of exchange. The patient continued to be troubled by instability and therefore a second exchange was performed with a 17-mm thick insert. This prosthesis showed no clinical or radiographic signs of loosening 3.5 years after the second PE exchange.

The cumulative survival rate of the SKI prosthesis after PE exchange with revision or aseptic loosening as an endpoint is 100.0% at 6 years. The cumulative survival rate of the SKI prosthesis after PE exchange including re-exchange of the PE insert is 96.2% ± 3.7 (see Figure 3.3).

3.3.4 Complications

Of all 341 procedures, no complications were seen in 157 procedures (46.0%). A total of 284 complications were seen in 184 knees. In 83 cases the complication was not related to the prosthesis, and in 201 cases the

complication was related to the prosthesis or knee. Three complications were recorded during the operation (a fissure of the tibial plateau, a patellar tendon rupture and a failure of instruments). None of these peroperative complications had serious consequences. Complications not related to the prosthesis and compli-cations related to the prosthesis or knee will be discussed in the following sections.

3.3.4.1 Complications not related to the prosthesis

Most of the complications not related to the prosthesis were urinary tract infections (12.6% of all procedures) and decubitus (6.5%). Six patients (1.8%) had gastrointestinal complications (peptic ulcer or gastric hemorrhage). Thromboembolic complications were seen in five patients (1.5%): pulmonary embolism in four patients and deep vein thrombosis in one patient. None of the thromboembolic complications were fatal.

Four patients had an amputation of the whole leg or the lower leg: two because of trauma and two due to circulation problems. One patient became paraplegic after trauma (see Table 3.3).

Table 3.3. Complications not related to the prosthesis (number of procedures /% of all procedures).

Complications not related to the prosthesis	n	%
Urinary tract infection	43	*12.6*
Decubitus	22	*6.5*
Peptic ulcer / gastric hemorrhage	6	*1.8*
Pulmonary embolism	4	*1.2*
Amputation of the leg	3	*0.9*
Pneumonia	2	*0.6*
Deep vein thrombosis	1	*0.3*
Amputation of the lower leg	1	*0.3*
Paraplegia after trauma	1	*0.3*

3.3.4.2 Complications related to the prosthesis or knee

All complications related to the prosthesis or knee are listed in Table 3.4. Peroneal nerve palsy was seen in six cases (1.8% of all procedures). One patient with rheumatoid arthritis had a bilateral peroneal nerve palsy. Four of these patients had a valgus deformity of more than 15º, the other two patients had a flexion contracture of 15º. All peroneal nerve palsies were transient.

Patellar problems were seen in twelve cases (3.5%): eight patients had patellar pain requiring exploration, and in four cases a patellar fracture was seen.

Table 3.4. Complications related to the prosthesis (number of knees /% of all prostheses implanted).

Complications related to the prosthesis or knee	**n**	**%**
Peroneal nerve palsy	6	*1.8*
Patellar pain requiring exploration	8	*2.3*
Patellar fracture	4	*1.2*
Varus/valgus instability of the knee	2	*0.6*
Dislocation of the prosthesis	2	*0.6*
Periprosthetic fracture	6	*1.8*
Rupture of the quadriceps tendon due to trauma	2	*0.6*
Rupture of the patellar tendon due to trauma	1	*0.3*
Avulsion fracture of the MCL	1	*0.3*
Wound problems and infections:		
Excessive hematoma	10	*2.9*
Excessive hematoma with evacuation	5	*1.5*
Delayed wound healing	11	*3.2*
Superficial infection	1	*0.3*
Deep infection	12	*3.5*
Manipulation:		
Manipulation under anesthesia	32	*9.4*
Screw loosening:		
Screw loosening	38	*11.1*
Screw loosening after locking screw	2	*0.6*
Screw loosening after tightening screw	1	*0.3*
***Wear*:**		
PE exchange	27	*7.9*
Revision	18	*5.3*
Radiographic $\geq$ 2 mm	10	*2.9*
Aseptic loosening of prosthesis	20	*5.9*

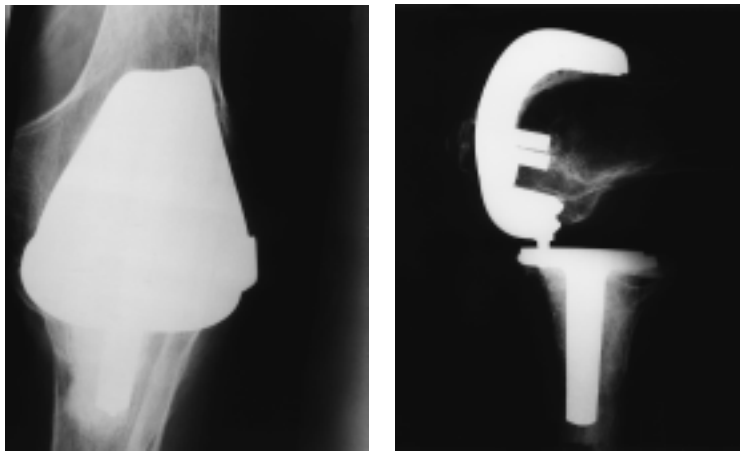

Figure 3.4. *AP and lateral radiograph of a dislocated SKI prosthesis in a 61-year old male patient with rheumatoid arthritis.*

Instability was a problem in four cases (1.2%). One patient had a varus instability and one patient had a valgus instability requiring revision. Dislocation of the prosthesis was seen two times in one patient (see Figure 3.4). This was a 61-year old patient with rheumatoid arthritis with bilateral knee dislocation five and six years postoperatively. Preoperatively both knees had an anteroposterior instability of 5-10 mm, a mediolateral instability of 10-14° and a range of motion of 80°. After dislocation one knee was repositioned under general anesthesia. The

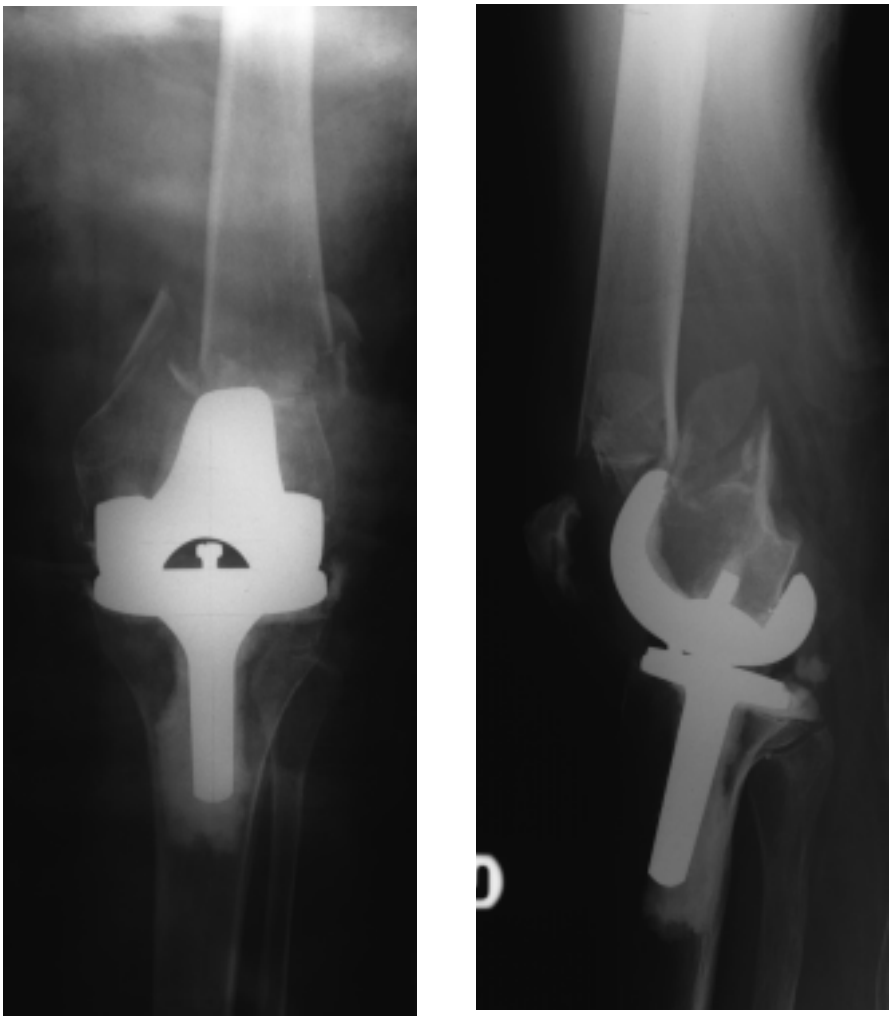

Figure 3.5. *AP and lateral radiograph of a periprosthetic fracture in a 77-year old female patient. Open reduction and fixation was performed.*

other knee remained in a dislocated position even after tenolysis of the hamstrings. Finally an arthrodesis of this knee was performed.

Six patients (1.8%) had a periprosthetic fracture, five of the distal femur (see Figure 3.5) and one of the tuberositas tibiae. In two knees an open reduction and internal fixation was done. The other fractures were treated conservatively. Two patients had a rupture of the quadriceps tendon, one of the patellar tendon and one patient had an avulsion fracture of the medial collateral ligament due to trauma. Wound problems (excessive hematoma, delayed wound healing or superficial infection) were seen in 27 knees (7.9%). Deep infection was seen in 12 knees (3.5%).

Manipulation of the knee under anesthesia was performed in 32 knees (9.4%). Screw loosening was seen in 38 knees (11.1%). One screw loosened again after tightening and two screws loosened after locking of the screw (see Figure 3.6).

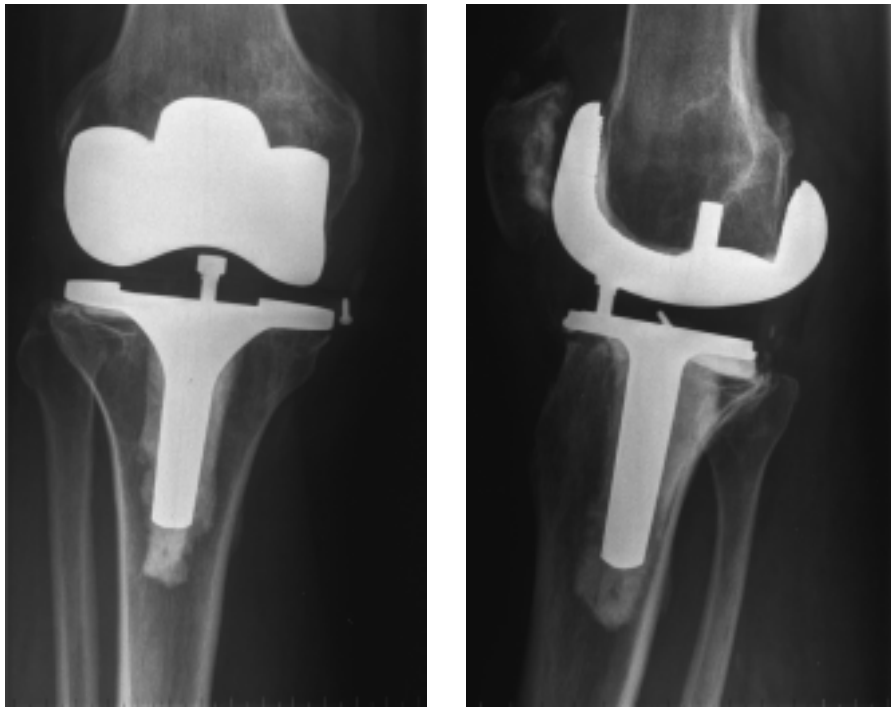

Figure 3.6. *AP and lateral radiograph of a SKI prosthesis with loosening of the locking pin 3.5 years after locking of the screw in a 73-year old male patient.*

Wear was seen in 55 knees (16.1%). Aseptic loosening of the prosthesis was seen in 20 knees (5.9%). The factors that might contribute to wound problems, deep infection, manipulation of the knee postoperatively, screw loosening, wear and aseptic loosening will be discussed in the following sections.

3.3.5 Wound problems and superficial infection

Excessive hematoma was seen in 15 knees (4.4% of all procedures), five of which required evacuation of the hematoma. One of the patients with an excessive hematoma, which was not evacuated, developed a deep infection. Patients with rheumatoid arthritis had more excessive hematomas compared to patients with degenerative arthritis (5.0% versus 2.7%), but the difference was not significant (p=0.337).

Delayed wound healing was seen in 11 knees (3.2%), and in one knee a superficial infection (0.3%) was seen. Patients with rheumatoid arthritis and patients with other diagnoses had more wound problems compared to patients with degenerative arthritis, but the difference was not significant. An equal rate of wound problems was seen in male and female patients. Patients with wound problems were younger on average compared to patients with no wound problems, but the difference was not significant. Patients with diabetes mellitus, obese patients, patients who had had previous surgery or other risk factors did not have significantly more wound problems compared to patients without these risk factors. None of the patients who had ulcerations of the legs in history or patients who had used steroids perioperatively had delayed wound healing or developed a superficial infection (see Table 3.5).

3.3.6 Deep infection

Deep infection was seen in 12 patients (3.5% of all procedures). In four patients a 2-stage revision was performed, and in one patient the prosthesis was maintained after thorough irrigation. In five patients the infection resulted in an arthrodesis, in one patient an amputation was performed, and one patient died of sepsis probably arising from an infection of the knee prosthesis ten years after implantation.

Patients with rheumatoid arthritis had a higher rate of deep infection compared to patients with degenerative arthritis, but the difference was not significant. Male and female patients had an equal rate of deep infection. Patients with a deep infection were younger at the time of surgery, but the difference was not significant either. Patients with diabetes mellitus, obese patients and patients who had had previous surgery did not have significantly more deep infections compared to patients without these risk factors. Patients who used steroids perioperatively

Table 3.5. Logistic regression coefficient (B), standard error (se) and p-value of the relation between delayed wound healing or superficial infection and the factors that may increase the risk of delayed wound healing or superficial infection in all knees (n=341). None of the risk factors lead to a statistically significant increase of either delayed wound healing or superficial infection.

	n	Delayed wound healing/ superficial infection	No delayed wound healing/ superficial infection	B	se	p-value
All knees	341	12 (3.5%)	329 (96.5%)			
Diagnosis						
Degenerative arthritis	112	2 (1.8%)	110 (98.2%)			
Rheumatoid arthritis	201	8 (4.0%)	193 (96.0%)	0.487	0.876	0.578
Other	28	2 (7.1%)	26 (92.9%)	1.047	1.116	0.348
Sex						
Male	80	3 (3.8%)	77 (96.3%)			
Female	261	9 (3.4%)	252 (96.6%)	-0.261	0.750	0.728
Age at the time of surgery (mean ± sd (range))	341	57.2 ± 17.6 (24-78)	63.7 ± 13.6 (19-86)	-0.031	0.023	0.181
Diabetes mellitus						
Yes	25	1 (4.0%)	24 (96.0%)			
No	316	11 (3.5%)	305 (96.5%)	-0.472	1.126	0.675
Obesity (BMI ≥ 30)						
Yes	56	1 (1.8%)	55 (98.2%)			
No	285	11 (3.9%)	274 (96.6%)	0.516	1.124	0.646
Previous surgery						
Yes	59	2 (3.4%)	57 (96.6%)			
No	282	10 (3.5%)	272 (96.5%)	0.467	0.872	0.592
Other risk factors						
Yes	7	1 (14.3%)	6 (85.7%)			
No	334	11 (3.3%)	323 (96.7%)	-0.963	1.186	0.417
Ulcerations in history						
Yes	11	0 (0%)	11 (100%)			
No	330	12 (3.6%)	318 (96.4%)			
Use of steriods						
Yes	32	0 (0%)	32 (100%)			
No	309	12 (3.9%)	297 (96.1%)			

had a higher rate of deep infection, but the difference was not significant either.

Patients with ulcerations of the legs in history had significantly more deep infections compared to patients without ulcerations in history (20.0% versus 3,3%). Another factor that contributed significantly to the development of a deep infection was delayed wound healing (30.0% of the patients with delayed wound healing developed a deep infection,

versus 3.0% of the patients who did not have delayed wound healing) (see Table 3.6).

3.3.7 Manipulation of the knee under anesthesia

Manipulation of the knee under anesthesia was carried out in 32 knees (9.4%). Significantly more manipulations of the knee were done in

Table 3.6. Logistic regression coefficient (B), standard error (se) and p-value of the relation between deep infection and the factors that may increase the risk of deep infection in patients with rheumatoid arthritis or degenerative arthritis (n=313). Patients with ulcerations of the legs in history and patients with delayed wound healing had a statistically significant increased risk of developing a deep infection.

	n	Deep infection	No deep infection	B	se	p-value
All knees	313	12 (3.8%)	301 (96.2%)			
Diagnosis						
Degenerative arthritis	112	2 (1.8%)	110 (98.2%)			
Rheumatoid arthritis	201	10 (5.0%)	191 (95.0%)	1.232	0.920	0.180
Sex						
Male	69	2 (2.9%)	67 (97.1%)			
Female	244	10 (4.1%)	234 (95.9%)	-0.794	0.889	0.372
Age at the time of surgery (mean ± sd (range))	313	60.9 ± 12.7 (38-79)	63.6 ± 13.8 (19-86)	0.014	0.025	0.574
Diabetes mellitus						
Yes	24	1 (4.2%)	23 (95.8%)			
No	289	11 (3.8%)	278 (96.2%)	0.668	1.241	0.590
Obesity (BMI ≥ 30)						
Yes	52	2 (3.8%)	50 (96.2%)			
No	261	10 (3.8%)	251 (96.2%)	-0.606	0.911	0.506
Previous surgery						
Yes	48	3 (6.2%)	45 (93.8%)			
No	265	9 (3.4%)	256 (96.6%)	-1.411	0.799	0.077
Use of steroids						
Yes	32	2 (6.3%)	30 (93.8%)			
No	281	10 (3.6%)	271 (96.4%)	-1.253	0.959	0.192
Ulcerations in history						
Yes	10	2 (20.0%)	8 (80.0%)			
No	303	10 (3.3%)	293 (96.7%)	-2.506	0.936	**0.007**
Delayed wound healing						
Yes	10	3 (30.0%)	7 (70.0%)			
No	303	9 (3.0%)	294 (97.0%)	-3.309	0.946	**<0.001**
Other risk factors						
Yes	5	1 (20.0%)	4 (80.0%)			
No	308	11 (3.6%)	297 (96.4%)	-1.663	1.590	0.296

patients with degenerative arthritis compared to patients with rheumatoid arthritis (13.4% versus 5.5%).

Female patients had more manipulations compared to male patients, patients who had a manipulation of the knee were younger compared to patients who did not have a manipulation, and patients who had had surgery before total knee replacement required manipulation of the knee more often compared to patients without previous surgery, but the differences were not significant. No difference in body weight was found between patients who had a manipulation of the knee and patients who had not.

There was no difference in flexion pre-operatively between patients who had a manipulation and patients who had not, but patients who needed a manipulation had a significantly worse extension pre-operatively compared to patients who did not need a manipulation (-18.3° versus -12.3°) (see Table 3.7).

Table 3.7. Logistic regression coefficient (B), standard error (se) and p-value of the relation between manipulation and the factors that may influence the need of a manipulation in all knees (n=341). In patients with rheumatoid arthritis, significantly fewer manipulations were done compared to patients with degenerative arthritis. Patients who needed a manipulation had a significantly worse extension preoperatively.

	n	Manipulation	No manipulation	B	se	p
All knees	341	32 (9.4%)	309 (90.6%)			
Diagnosis						
Degenerative arthritis	112	15 (13.4%)	97 (86.6%)			
Rheumatoid arthritis	201	11 (5.5%)	190 (94.5%)	-1.783	0.558	**0.001**
Other	28	6 (21.4%)	22 (78.6%)	0.389	0.617	0.528
Sex						
Male	80	5 (6.3%)	75 (93.8%)			
Female	261	27 (10.3%)	234 (89.7%)	-1.016	0.607	0.094
Body-weight (kg) (mean ± sd (range))	341	70.9 ± 12.6 (49-100)	70.6 ± 12.5 (36-102)	-0.003	0.017	0.855
Age at the time of surgery (mean ± sd (range))	341	61.0 ± 15.4 (22-81)	63.8 ± 13.6 (19-86)	-0.026	0.017	0.112
Previous surgery						
Yes	59	7 (11.9%)	52 (88.1%)			
No	282	25 (8.9%)	257 (91.1%)	0.180	0.554	0.745
Flexion preoperatively (°) (mean ± sd (range))	341	98.0 ± 22.7 (35-135)	99.3 ± 21.5 (10-140)	0.008	0.011	0.446
Extension preoperatively (°) (mean ± sd (range))	341	-18.3 ± 17.3 (-90-0)	-12.3 ± 10.8 (-40-0)	-0.057	0.019	**0.003**

In both follow-up studies, patients who had had a manipulation of the knee had a slightly better flexion and a slightly worse extension at follow-up compared to patients who did not undergo manipulation, but the differences were not significant (see Table 3.8).

Table 3.8. Flexion and extension (°) at follow-up (Tp and Tc) in patients who had had a manipulation and patients who had not. No significant differences were seen.

	Manipulation	**No manipulation**	**p-value***
First follow-up study (n=197)	*n=32*	*n=165*	
Flexion at follow-up (°)	97.4 ± 19.1 *(45-125)*	96.9 ± 21.2 *(0-135)*	0.910
Extension at follow-up (°)	-4.1 ± 9.8 *(-40-0)*	-1.8 ± 5.9 *(-45-0)*	0.233
Second follow-up study (n=97)	*n=16*	*n=81*	
Flexion at follow-up (°)	95.6 ± 17.9 *(55-120)*	90.6 ± 22.2 *(0-125)*	0.398
Extension at follow-up (°)	-6.9 ± 11.8 *(-40-0)*	-4.4 ± 8.9 *(-60-0)*	0.350

** Independent samples t-test*

3.3.8 Screw loosening

Screw loosening was seen in 38 knees (17.8% of all prostheses that were available for follow-up or revised) (see Figure 3.7).

In patients with degenerative arthritis and other diagnoses, more screw loosening was seen compared to patients with rheumatoid arthritis, but the difference was not significant. Male patients had a higher rate of screw loosening compared to female patients, but the difference was not significant either. Patients with screw loosening were younger at the time of surgery, they were heavier and they had had more previous surgery than patients with a fixed screw, but the differences were not significant. A higher rate of screw loosening was seen in knees with a thicker PE insert, but the PE thickness was not a significant factor influencing screw loosening. The only factor that contributed significantly to screw loosening was the Function Score. Patients with screw loosening had a significantly higher activity level compared to patients with a fixed screw (mean Function Score 55.7 ± 27.5 versus 32.9 ± 29.2 points) (see Table 3.9 and Figure 3.8).

Figure 3.7. *AP and lateral radiograph of a SKI prosthesis with a loosened screw in a 76 year-old female patient, 6.7 years after total knee replacement. Wear of the polyethylene is seen at the medial side.*

Table 3.9. Logistic regression coefficient (B), standard error (se) and p-value of the relation between screw loosening and the factors that may contribute to screw loosening in 214 knees. Only a high Function Score contributed significantly to screw loosening.

	n	Aseptic loosening	No aseptic loosening	B	se	p-value
All knees	214	38 (17.8%)	176 (82.2%)			
Diagnosis						
Degenerative arthritis	82	17 (20.7%)	65 (79.3%)			
Rheumatoid arthritis	111	15 (13.5%)	96 (86.5%)	-0.044	0.636	0.944
Other	21	6 (28.6%)	15 (71.4%)	0.043	0.705	0.952
Sex						
Male	40	12 (30.0%)	28 (70.0%)			
Female	174	26 (14.9%)	148 (85.1%)	-0.149	0.615	0.808
Body weight (mean ± sd (range))	214	75.5 ± 12.8 (52-100)	70.1 ± 12.9 (46-102)	0.038	0.021	0.065
Age at the time of surgery (mean ± sd (range))	214	57.7 ± 13.2 (24-81)	61.0 ± 15.3 (19-86)	-0.008	0.020	0.678
Function Score (mean ± sd (range))	194	55.7 ± 27.5 (0-100)	32.9 ± 29.2 (0-100)	0.023	0.009	**0.008**
Previous surgery						
Yes	49	12 (20.3)	37 (62.7)			
No	165	26 (9.2)	139 (49.3)	-0.240	0.498	0.629
PE thickness				0.151	0.140	0.281
Unknown	3	0 (0%)	3 (100%)			
7	170	29 (17.1%)	141 (82.9%)			
9	29	5 (17.2%)	24 (82.8%)			
11	9	2 (22.2%)	7 (77.8%)			
13	3	2 (66.7%)	1 (33.3%)			
Time of follow-up (mean ± sd (range))	214	11.0 ± 3.8 (1-18)	10.8 ± 3.1 (1-18)	0.062	0.077	0.417

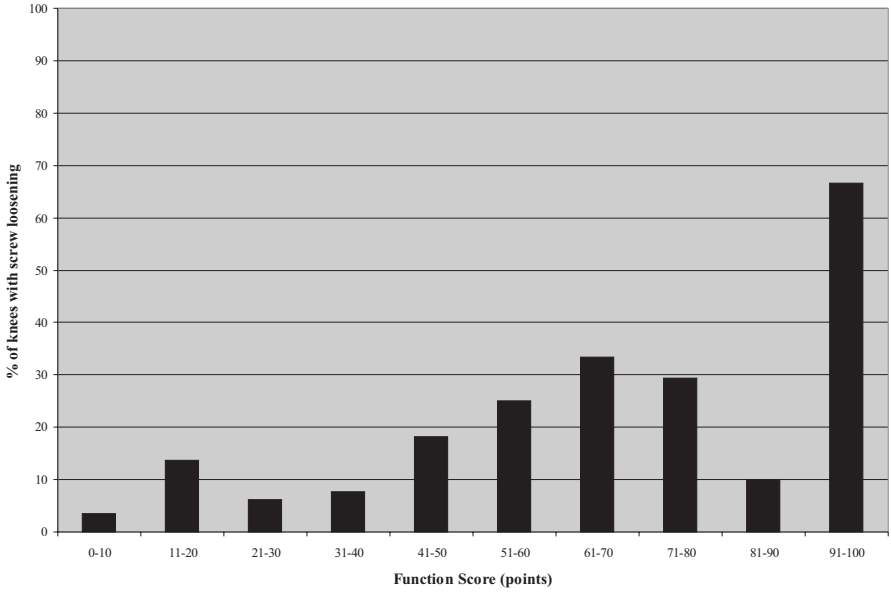

Figure 3.8. *Screw loosening and Function Score. A significantly higher rate of screw loosening was seen in patients with a higher Function Score (logistic regression analysis, B=0.023, se=0.009, p=0.008).*

3.3.9 Wear

Wear was seen in 55 prostheses (25.7% of all knees that were available for follow-up or revised) (See Figure 3.9). Among these, 27 knees had an exchange of the polyethylene insert because of wear, 18 knees had wear at the time of revision, and in 10 knees wear was seen upon radiographic examination at follow-up.

In patients with degenerative arthritis and other diagnoses, more wear was seen compared to patients with rheumatoid arthritis, but the difference was not significant. Male patients had more wear compared to female patients, patients with previous surgery had more wear compared to patients without previous surgery, and in patients with a thicker PE insert more wear was seen, but the differences were not significant.

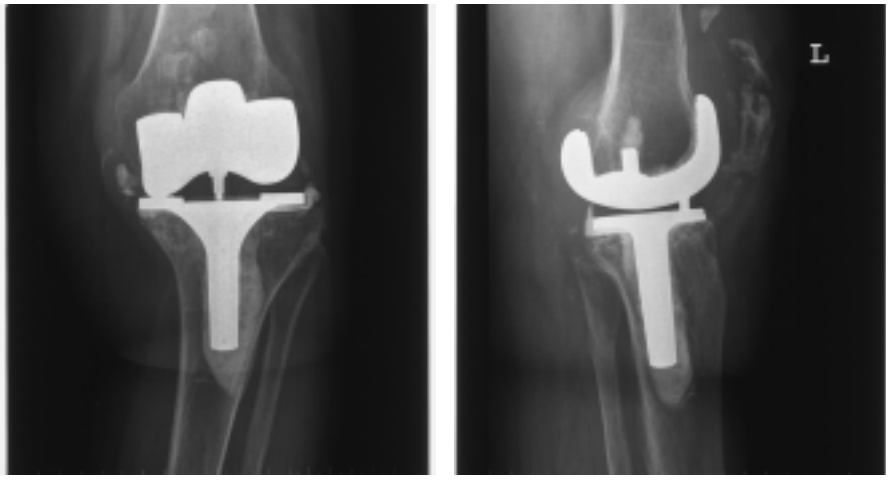

Figure 3.9. *AP and lateral radiograph of a SKI prosthesis with full thickness wear at the medial side in a 64-year old female patient with screw loosening. This patient had a Function Score of 100 points.*

Patients with wear were heavier compared to patients without wear (mean body weight 76.9 ± 13.6 versus 69.0 ± 12.3 kg). In a logistic regression analysis, this difference was significant ($p<0.001$), but corrected for all other factors, $p=0.053$. Patients with wear were significantly younger at the time of surgery (mean age 55.0 ± 14.0 versus 62.2 ± 14.9 years) (see Table 3.10 and Figure 3.10). Patients with wear had a significantly higher activity level compared to patients who had no wear (mean Function Score 58.2 ± 24.8 versus 28.5 ± 27.8 points) (see Table 3.10 and Figure 3.11).

Knees with screw loosening had significantly more wear compared to knees with a fixed screw (68.4% of the knees with screw loosening had wear compared to 16.5% of the knees without screw loosening) (see Table 3.10).

3.3.10 Aseptic loosening of the prosthesis

Aseptic loosening of the prosthesis was seen in 20 patients (9,3% of all knees that were available for follow-up or revised) (See Figure 3.12). In patients with degenerative arthritis and patients with other diagnoses, more aseptic loosening of the prosthesis was seen compared to patients with rheumatoid arthritis, but the difference was not significant. Male patients had a higher rate of aseptic loosening compared to female patients, but this difference was not significant either. Patients with

Table 3.10. Logistic regression coefficient (B), standard error (se) and p-value of the relation between wear and the factors that may contribute to wear in 214 knees. Younger age, a higher Function Score and screw loosening contributed significantly to increased wear. Increased body weight contributed significantly to increased wear (p<0.001), but corrected for all other factors p=0.053.

	n	Wear	No wear	B	se	p-value
All knees	214	55 (25.7%)	159 (74.3%)			
Diagnosis						
Degenerative arthritis	82	25 (30.5%)	57 (69.5%)			
Rheumatoid arthritis	111	19 (17.1%)	92 (82.9%)	-0.946	0.677	0.162
Other	21	11 (52.4%)	10 (47.6%)	-0.259	0.700	0.712
Sex						
Male	40	16 (40.0%)	24 (60.0%)			
Female	174	39 (22.4%)	135 (77.6%)	0.296	0.610	0.628
Body weight (mean ± sd (range))	214	76.9 ± 13.6 (46-102)	69.0 ± 12.3 (46-100)	0.041	0.021	0.053
Age at the time of surgery (mean ± sd (range))	214	55.0 ± 14.0 (21-84)	62.2 ± 14.9 (19-86)	-0.053	0.020	**0.008**
Function Score (mean ± sd (range))	194	58.2 ± 24.8 (0 -100)	28.5 ± 27.8 (0-90)	0.027	0.008	**0.001**
Previous surgery						
Yes	49	20 (40.8)	29 (59.2)			
No	165	35 (21.2)	130 (78.8)	-0.272	0.492	0.580
PE thickness				0.150	0.146	0.305
Unknown	3	0 (0.0%)	3 (100%)			
7	170	41 (24.1%)	129 (75.9%)			
9	29	7 (24.1%)	22 (75.9%)			
11	9	5 (55.6)	4 (44.4%)			
13	3	2 (66.7%)	1 (33.3%)			
Screw loosening						
Yes	38	26 (68.4%)	12 (31.6%)			
No	176	29 (16.5%)	147 (83.5%)	-2.416	0.556	**<0.001**
Time of follow-up (mean ± sd (range))	214	10.9 ± 3.2 (5-18)	10.7 ± 3.9 (1-18)	0.020	0.074	0.788

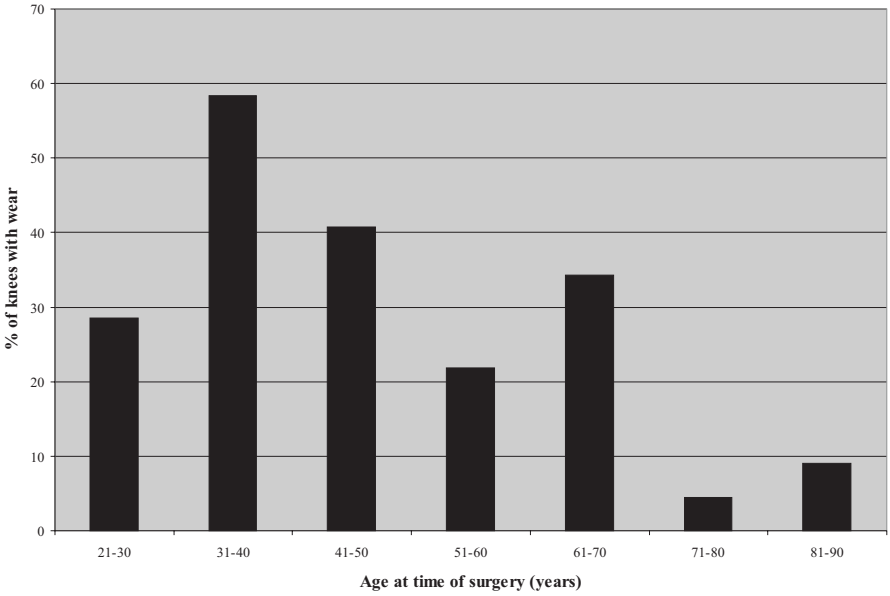

***Figure 3.10**. Wear and age at the time of surgery. Significantly more wear is seen in patients who were younger at the time of surgery (logistic regression analysis, B=-0.053, se=0.020, p=0.008).*

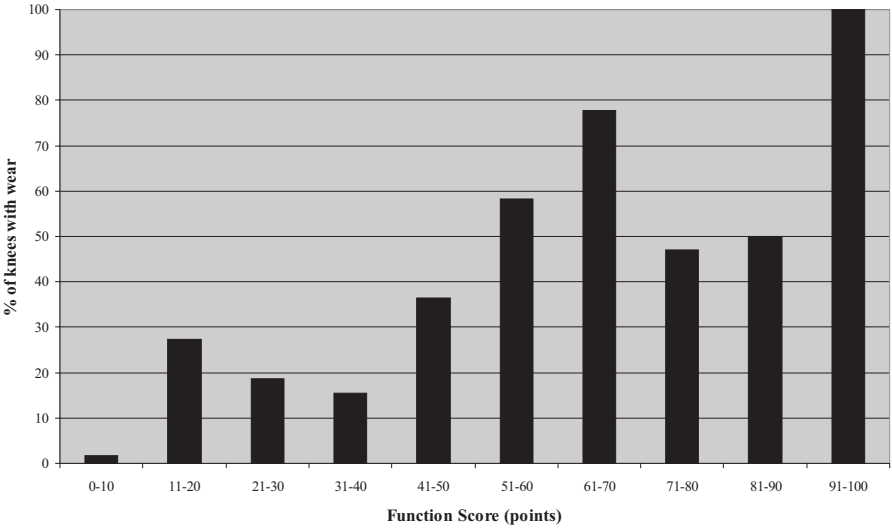

***Figure 3.11**. Wear and Function Score. Significantly more wear is seen in patients with a higher Function Score (logistic regression analysis, B=0.027, se=0.008, p=0.001).*

Figure 3.12. *AP and lateral radiograph of a SKI prosthesis with screw loosening, wear and aseptic loosening in a 54-year old male patient with rheumatoid arthritis, seven years after implantation.*

aseptic loosening had more body weight, they were younger at the time of surgery and they had had more previous surgery compared to patients who had no aseptic loosening of the prosthesis, but all these factors did not contribute to aseptic loosening of the prosthesis significantly. The thickness of the PE insert had no significant influence on aseptic loosening. More aseptic loosening of the prosthesis was seen in knees with screw loosening, but screw loosening was not a significant factor contributing to aseptic loosening. (see Table 3.11).

Table 3.11. *Logistic regression coefficient (B), standard error (se) and p-value of the relation between aseptic loosening of the prosthesis and the factors that may contribute to aseptic loosening in 214 knees. A higher Function Score and increased wear were significantly associated with aseptic loosening.*

	n	Aseptic loosening	No aseptic loosening	B	se	p-value
All knees	214	20 (9.3%)	194 (90.7%)			
Diagnosis						
Degenerative arthritis	82	8 (9.8%)	74 (90.2%)			
Rheumatoid arthritis	111	7 (6.3%)	104 (93.7%)	0.332	1.144	0.772
Other	21	5 (23.8%)	16 (76.2%)	1.050	0.981	0.285
Sex						
Male	40	7 (17.5%)	33 (82.5%)			
Female	174	13 (7.5%)	161 (92.5%)	0.046	0.978	0.963
Body weight (mean ± sd (range))	214	79.3 ± 13.3 (58-102)	70.2 ± 12.7 (46-102)	0.031	0.042	0.457
Age at the time of surgery (mean ± sd (range))	214	57.4 ± 11.2 (37-80)	60.8 ± 15.3 (19-86)	-0.009	0.031	0.756
Function Score (mean ± sd (range))	194	70.0 ± 16.4 (25-85)	33.6 ± 29.2 (0-100)	0.033	0.016	**0.041**
Previous surgery						
Yes	49	6 (12.2)	43 (87.8)			
No	165	14 (8.5)	151 (91.5)	0.099	0.752	0.895
PE thickness				-0.218	0.214	0.309
Unknown	3	0 (0.0%)	3 (100%)			
7	170	16 (9.4%)	154 (90.6%)			
9	29	1 (3.4%)	28 (96.6%)			
11	9	3 (33.3%)	6 (66.7%)			
13	3	0 (0.0%)	3 (100.0%)			
Screw loosening						
Yes	38	11 (28.9%)	27 (71.1%)			
No	176	9 (5.1%)	167 (94.9%)	-1.332	0.756	0.078
Wear						
Yes	55	17 (30.9%)	38 (69.1%)			
No	159	3 (1.9%)	156 (98.1%)	-2.873	1.144	**0.012**

Patients with aseptic loosening of the prosthesis had a significantly higher activity level compared to patients who had no signs of aseptic loosening (mean Function Score 70.0 ± 16.4 versus 33.6 ± 29.2 points) (see Table 3.11 and Figure 3.13). Significantly more aseptic loosening was seen in knees with wear (30.9% of the prostheses with wear had aseptic loosening compared to 1.9% of the prostheses that had no wear) (see Table 3.11).

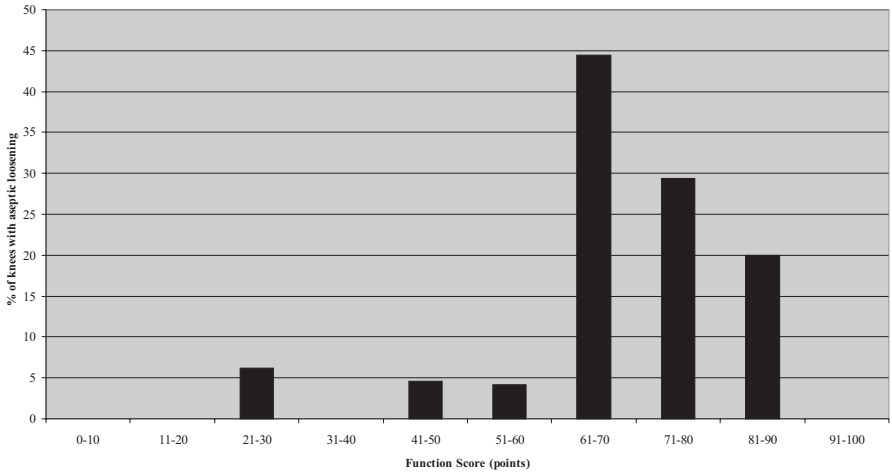

Figure 3.13. *Aseptic loosening of the prosthesis and Function Score. A significantly higher rate of aseptic loosening of the prosthesis is seen in patients with a higher Function Score (logistic regression analysis, B=0.033, se=0,016, p=0.041).*

3.4 DISCUSSION

Differences in patient population, length of follow-up and different definitions of endpoints make a comparison of the results of joint replacement difficult. Survivorship of total knee prostheses varies from 82% at 14 years [107] to 100% at 10 years [108]. Only a few studies with a follow-up of more than 15 years are published. Ritter et al. [109] found a cumulative survival rate of 98.86% at 15 years for the AGC total knee replacement, Gill et al. [110] found a cumulative survival rate of 92.6% at 17 years for the Kinematic Condylar total knee replacement, and Font-Rodriguez [50] found a cumulative survival rate of 90.8% at 21 years for the Total Condylar total knee replacement (see Table 3.12).

Table 3.12. Survivorship of different types of knee prostheses with the number of knees included in the study and definition of the endpoint.

Type prosthesis	Author	Number of knees	Survivorship	Endpoint
AGC	Ritter (109)	4585	98.86% at 15 years	Revision or loosening
AGC	Worland (111)	562	97% at 14 years	Revision for any reason
Kinemax	Back (112)	422	96.5% at 9 years	Revision
Kinematic Condylar	Ritter (49)	394	94.7% at 10 years	Revision or recommended revision
Kinematic Condylar	Gill (110)	404	92.6% (87.6-95.6) at 17 years 84.9% (76.5-90.5) at 17 years	Removal or revision Worst case scenario
Kinematic	van Loon CS (107)	102	82% (67-92) at 14 years 62% (46-77) at 14 years	Revision Worst case scenario
Kinematic	Malkani (113)	168	96% at 10 years	Revision
Kinematic	Weir (114)	208	92 (95-87) at 10 years	Revision
Kinematic	Ansari (115)	445	96% at 10 years	Revision or recommended revision
Total Condylar	Ranawat (116)	112	94.1 % at 11 years	Revision or recommended revision
Total Condylar	Ritter (15)	394	96.8% at 12 years	Prosthetic removal excluding infection
Total Condylar	Font-Rodriguez (50)	215	90.8% at 21 years	
Miller Galante I	Berger (108)	172	84.1% ± 4.1 at 10 years	Revision
Miller Galante II	Berger (108)	109	100 % at 10 years	Revision

In our study, the majority of the procedures (58.9%) was performed in knees affected by rheumatoid arthritis. We found a cumulative survival rate of the SKI knee prosthesis of 83.4 % ± 3.5 at 19 years with revision, loosening of the prosthesis or infection as endpoint and 86.6% ± 3.2 at 19 years with revision, or loosening only due to mechanical failure as an endpoint. There are no other long-term studies of the SKI prosthesis to compare the results.

Babis et al. [117] found a cumulative survival rate of 63.5% at 5.5 years after isolated tibial insert exchange. Engh et al. [118] advised not to perform an isolated insert exchange in cases with accelerated wear within ten years after the index surgery. In our series, only one PE insert was exchanged a second time due to instability. No aseptic loosening was seen following PE exchange after a mean follow-up of 2.6 years. Thanks to regular outpatient visits, wear was recognized early and the PE insert was exchanged in time. In most cases the exchange was performed with a thicker PE insert. Engh et al. found a deterioration of the tibial baseplate locking mechanism in modular total knee components [119]. In our study, most screws were locked with a locking pin to prevent the screw from loosening again (see Chapter 1). This might explain the high cumulative survival rate after PE exchange in this study. However, the time of follow-up after PE exchange was short, and studies with a longer follow-up time will have to be done to show whether isolated exchange of the PE insert in the SKI prosthesis is a durable procedure.

More than half of the procedures (54%) had one or more complications. Of these complications 70.6% were related to the prosthesis or knee. Thromboembolic disease is not an uncommon occurrence after total knee arthroplasty. According to venographic data, the incidence of deep vein thrombosis (DVT) ranges from 50 to 70% [120]. DVT based on clinical diagnosis is reported in 1-10% of the patients after total knee replacement [121]. In this series, clinically apparent DVT was only seen in one patient (0.3%). As the clinical diagnosis of DVT is difficult, this may be an underestimation of the real number of DVTs in this series. Asymptomatic pulmonary embolism may occur in up to 10-18% of the patients after total knee replacement. Symptomatic pulmonary embolism is reported in 1.0-1.9% of the patients, and fatal pulmonary embolism in 0.2-0.7% [120;122]. In this series, pulmonary embolism was seen in four (1.2%) patients. None of the pulmonary embolisms was fatal.

Peroneal nerve injury has been reported in 0.3-2.0% of patients after total knee arthroplasty [123]. It is frequently associated with a preoperative flexion contracture, valgus deformity and prior knee surgery, especially tibial osteotomy [124]. In this series, transient peroneal nerve palsy was

seen in six (1.8%) patients. Four of these patients had a valgus deformity of more than 15°, the other two patients had a flexion contracture of 15°. Peroneal nerve palsy was not seen in patients who had had a tibial osteotomy.

The patellofemoral joint is exposed to high loads. In activities such as squatting, the patellofemoral joint is loaded seven times the body weight, and during stair-climbing three to four times the body weight [125]. The patellofemoral joint is the most common source of pain and dysfunction after total knee replacement. Excessively thin or thick patellae, decreased circulation to the patella and patella maltracking have been associated with patellar fractures [126]. Patellar maltracking may be related to prosthetic design, asymmetric patellar resection, malrotation of the femoral or tibial component, or patellar malpositioning [124]. Complications of the extensor mechanism are reported in 8-35% of the patients [125]. In this study, complications of the extensor mechanism were seen in 15 (4.4%) knees. Of these patients, eight (2.3%) had patellar pain requiring a reoperation, four (1.2%) had a patellar fracture and three (0.9%) had a rupture of the extensor mechanism. The incidence of patellar pain will be described in Chapter 4. Patellar instability was not a clinical problem in this series. This is probably due to the asymmetric femoral component with a raised lateral border (see Figure 3.14).

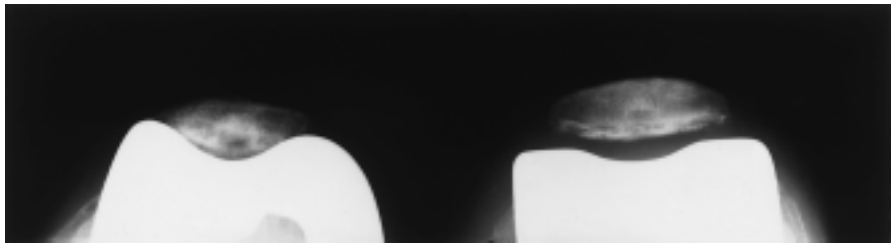

***Figure 3.14**. Skyline view of a SKI prosthesis (left) and an AGC knee prosthesis (right). The SKI prosthesis has a raised lateral border, which may prevent patellar dislocation.*

Wound healing problems (marginal wound necrosis, sinus tract formation, wound dehiscence and hematoma formation) is reported in 2-37% of the cases (average 1-10%) [127]. In this series, wound problems (superficial infection, delayed wound healing and excessive hematoma) were seen in 7.9% of all procedures. No risk factor could be identified that contributed significantly to delayed wound healing or superficial infection.

Deep infection rates range from 0-7.0%, with the average at about 3% [127]. In this series, deep infection was seen in 12 (3.5%) procedures. Patients with rheumatoid arthritis, diabetes mellitus or previous surgery had a higher rate of deep infection, but the main prognostic factor to develop a deep infection was previous ulceration of the leg and delayed wound healing. Deep infection is a serious complication. In the group of patients with a deep infection, the prosthesis could not be maintained in seven cases (58.3%).

Manipulation of the knee under anesthesia may be performed to increase the range of motion and to facilitate early rehabilitation. Fox and Poss [128] found that manipulation was more likely to be necessary if patients were female, if the primary diagnosis was degenerative arthritis or if they were over 70 years of age. In this series, manipulation of the knee was done in 32 (9.4%) knees. More manipulations were done in female patients, younger patients and patients with previous surgery, but the main predictive factor for manipulation of the knee was preoperative flexion contracture or the diagnosis degenerative arthritis. The long-term benefits of manipulation under anesthesia after total knee replacement have been questioned [128]. Esler et al. [129] found a mean gain of active flexion of 33º one year after manipulation. Because this was a retrospective study we were not able to calculate the gain in range of motion after manipulation under anesthesia, but we found no significant difference in flexion or extension at follow-up between patients who had undergone a manipulation of the knee and patients who had not.

A weak point in the design of the SKI prosthesis is the locking mechanism of the tibial insert with a screw. The screw that has to prevent rotation of the polyethylene insert on the tibial baseplate appeared to have the possibility to loosen and to become a loose body in the knee. At the final follow-up study, screw loosening had occurred in 38 knees (11.1% of all SKI prostheses implanted and 17.8% of the knees that were available for follow-up or revised). The most important factor contributing to screw loosening was the Function Score. In patients with a higher Function Score, significantly more screw loosening was seen. In this study we used the Function Score of the American Knee Society Score to determine the activity level of the patient. The Function Score rates the walking distance of the patient, the ability to climb stairs and the use of walking aids. We realize that there may be a high degree of variability in load on the prosthesis between patients with equal Function Scores, but in this retrospective study we believe the activity level is best estimated with this score.

In this study, significantly more wear was seen in patients with a higher Function Score, in younger patients, and in prostheses with screw

loosening. In laboratory studies the rate of wear is proportional to load [130;131]. Younger patients probably have a higher Function Score and load their knee prosthesis more, which causes more wear. Patients with screw loosening had a significantly higher Function Score and significantly more wear compared to patients with a fixed screw. A higher activity level may cause loosening of the screw, but it also may cause increased wear. The wear in knees with screw loosening may therefore be caused because these patients were more active, because of damage to the polyethylene by the screw itself, or maybe due to other factors. The differences in wear rate and damage of retrieved polyethylene inserts in knees with and without screw loosening will therefore be analyzed in Chapters 5 and 7.

Aseptic loosening of the prosthesis was seen in 5.9% of all SKI knee prostheses and in 9.3% of all knees that were available for follow-up or revised. The main factors contributing to aseptic loosening were activity level and wear. Patients with a higher activity level load their prosthesis more, which causes more wear. Increased wear may activate osteoclasts by the production of inflammatory mediators by macrophages that phagocytose polyethylene debris [84;132;133]. Mirra et al. [82] already found that excessive polyethylene wear correlated well with the incidence of loosening.

3.5 CONCLUSIONS

The long-term results of the SKI prosthesis are good. The cumulative survival rate with removal of the prosthesis only due to mechanical problems or aseptic loosening as an endpoint is 86.6% ± 3.2 at 19 years and 83.4% ± 3.5 if infections were included as an endpoint. After PE exchange, no aseptic loosening of the prosthesis was seen after a mean follow-up of 2.6 ± 1.6 years.

No risk factor could be identified that contributed significantly to delayed wound healing or superficial infection. The most important factors increasing the risk of developing a deep infection in this study were previous ulceration of the leg and delayed wound healing.

Patients with degenerative arthritis and other diagnoses needed a manipulation of the knee more often compared to patients with rheumatoid arthritis, and patients who needed a manipulation had a significantly worse extension pre-operatively. The pre-operative flexion was the same in patients who needed a manipulation and patients who did not need a manipulation. At follow-up, no difference in flexion and

extension was seen between patients who had had a manipulation and patients who had not.

Increased activity level was the most important factor that contributed to screw loosening. Increased activity level, younger age at the time of surgery and screw loosening were the most important factors contributing to wear. Increased activity level and increased wear were the most important factors contributing to aseptic loosening of the SKI prosthesis (see Figure 3.15).

Because screw loosening was an important factor contributing to wear, and wear was an important factor contributing to aseptic loosening, the cumulative survival rate of the SKI prosthesis might have been higher if the fixation of the PE insert to the tibial baseplate had been better. *

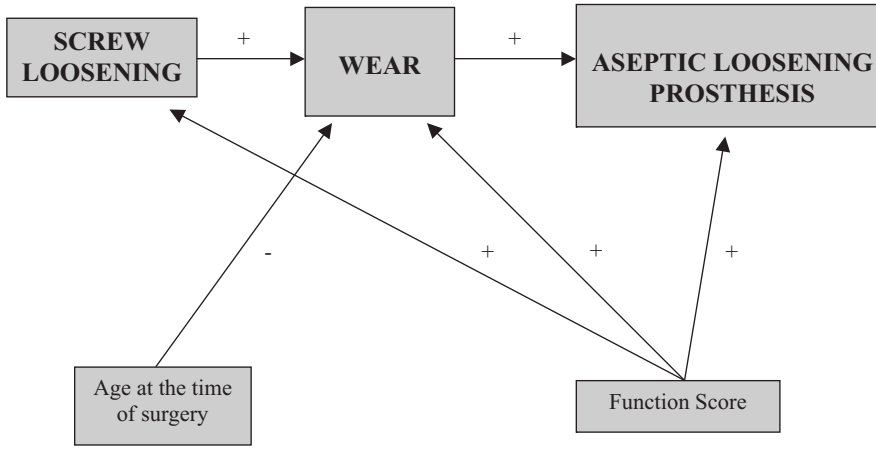

Figure 3.15. *The relation of the factors that contributed significantly to screw loosening, wear and aseptic loosening of the prosthesis.*

* *If patients with screw loosening were excluded from the survival analysis the cumulative survival rate would have been 91.5% ± 3.0 excluding infection as an endpoint and 88.0 ± 3.5% including infection as an endpoint. However, it must be mentioned that patients with a higher activity level were also excluded from this analysis.*