Chapter 4

Clinical Performance of the SKI Prosthesis

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4.1 INTRODUCTION

The good clinical performance of a knee prosthesis is what is most important to the patient. A pain-free, stable knee joint, which allows full weight-bearing and has a good range of motion, can lead to unrestricted mobility and fulfillment of a quality lifestyle. To evaluate a knee replacement, many different knee-rating systems are available. Several studies have evaluated the patient's view and used generic health status questionnaires to assess outcome [134].

The Oxford 12-Item Questionnaire [135] was developed in 1998 especially for the evaluation of total knee replacement to record the patients' perception. It is short, practical, reliable, valid and sensitive to clinically important changes over time [135], but this score was not available at the time of our first follow-up study in 1996. Other systems used are The British Association of the Knee Chart [136], The Hospital for Special Surgery Score [137] and The Knee Society Clinical Dual Rating System devised by the American Knee Society [138].

The British Orthopedic Association Score combines subjective and objective variables. The variables are equally weighed. There are however several problems with this system. There are no criteria for determining the category to which the patients belongs. The data are subject to patient bias, i.e. the patients may upgrade their response in order to please the questioner, who may have been the surgeon [139]. The British Orthopedic Association Score has low interobserver and intraobserver variation due to equal weighing of the variables, but this makes the system less likely to detect changes [140].

The Hospital for Special Surgery Score was developed in the 1970s. It combines an evaluation of both the operated knee and the patient's general function in one score. However, this may cause problems. The total score may be reduced if a patient cannot walk due to other medical problems, although he may have no pain or an excellent function.

The Knee Society Clinical Dual Rating System (American Knee Society Score) was a logical outgrowth of the Hospital for Special Surgery Score. It separates findings in the operated knee from findings in the patient's function. According to Miller et al., the "best buy" of outcome studies for knee replacement surgery is the American Knee Society Score [139].

To evaluate pain, the Pain Score of the American Knee Society Score can be used. This is a categorical score. A common complaint of categorical scales is that the number of descriptors is insufficient and that the choice of a particular category is forced and limited [141]. Pain can also be scored with a Visual Analogue Scale. Visual Analogue Scales

were originally developed to measure depression, well-being, sleep and mood in psychology [142], and were adapted to measure pain [143]. It has been shown that straight, horizontal and ungraded lines are the most sensitive [144]. The theoretical advantages of the Visual Analogue Scales are that they are simple, quick to score, do not involve imprecise descriptive terms and provide many points from which to choose [141].

To evaluate the long-term clinical performance of the SKI prosthesis, we studied all available patients in two consecutive follow-up studies, as has been already indicated in previous chapters. The Knee Score, Function Score and Total Score, the factors that may have influence on it and the course in time of all patients in both studies will be analyzed in sections 4.3.1, 4.3.5 and 4.3.6. Pain, the factors that may have influence on it and the course of the pain in time will be analyzed in section 4.3.2 with the Pain Score of the American Knee Society Score, a VAS Score for pain and the presence of anterior knee pain. The range of motion, flexion and flexion contractures, the factors that may have influence on it and the course in time will be analyzed in section 4.3.3. The pre- and postoperative stability and alignment will be described in section 4.3.4. In section 4.3.7 the pre- and postoperative scores of patients with degenerative arthritis and rheumatoid arthritis, and in section 4.3.8 the scores before and after polyethylene exchange will be described.

4.2 MATERIAL AND METHODS

Most patients with an SKI prosthesis are seen at regular intervals at Groningen University Hospital for many years after total knee replacement. To evaluate the clinical performance of the SKI prosthesis, two consecutive large follow-up studies were carried out. The first study was done by observer 1 from January 1996 to November 1997 (Tp). The second study was done by observer 2 from July 1999 to July 2001 (Tc). If patients did not have an appointment to visit the outpatient clinic at Tp or at Tc, they were invited to visit the clinic. If they were not able to visit the clinic, they were seen at home.

Of all 341 SKI prostheses implanted in 255 patients, 194 knees (146 patients) were available for clinical follow-up at Tp and 97 knees (79 patients) at Tc (see Figure 2.2). All patients seen at Tc by observer 2 (Group III) were also seen at Tp by observer 1 (Group II). For details of all patients see Appendix 2. The mean time of follow-up of the patients seen at Tp was 9.8 ± 2.6 years (range 5.1-15.5) and at Tc 14.0 ± 2.6 years (range 9.2-18.7) (see Figure 4.1).

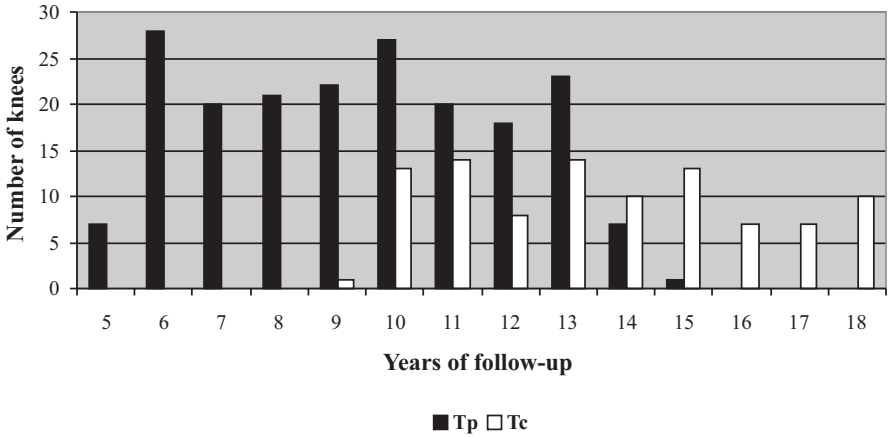

Figure 4.1. *Number of knees and time of follow-up of patients seen at Tp by observer 1 (n=194) and at Tc by observer 2 (n=97).*

Because the patients were seen by two different observers at two separate moments, and because the patients seen at Tc were a selection of all patients seen at Tp, the results of the patients seen at Tp and at Tc will be discussed separately.

At the final follow-up study, 23 knees (21 patients) had had an exchange of the polyethylene insert. In one knee only a PE exchange was performed due to patient morbidity in a knee prosthesis with clinical signs of loosening. This knee was excluded from the analysis. The details of these patients (Group IV) are described in Appendix 2. Of the knees with a PE exchange, 19 were both seen in the first follow-up study before PE exchange and in the second follow-up study after the PE exchange. The mean time of follow-up of these knees was 14.0 ± 2 6 years (range 9.2-18.3) and the mean time of follow-up after PE exchange was 2.6 years ± 1.6 (range 0.1-5.1).

4.2.1. Scoring systems

The American Knee Society Score [138] was used to evaluate the clinical performance of the knee (Knee Score) and patient function (Function Score) pre- and postoperatively and in the course of time (see Appendix 3). The Knee Score considers pain, stability and range of motion, with deductions for flexion contractures, extension lag and malalignment. The Knee Score ranges from 0 to 100 points. A patient with a well-aligned knee with no pain, 125 degrees of motion and no anteroposterior or mediolateral instability has a Knee Score of 100 points. A Knee Score of

100-85 points is considered excellent, a Knee Score of 84-70 points is considered good, one of 60-69 points is considered fair and a score below 60 points is considered poor.

The Function Score ranges from 0 to 100 points. A patient with a Function Score of 100 points has unlimited walking ability, is able to climb stairs up and down normally, and uses no walking aids. The patient function may be undermined by factors other than the knee in question. For this reason, a categorization system is included. Patients in category A have had one or both knees replaced and are relatively healthy. Patients in category B have had one knee replaced with the contralateral knee being symptomatic at the time of evaluation. Patients in category C have multiple joint involvement or other systemic illness that affects their functional status. The Knee Score is independent of multiple joint involvement. The Function Score may decline with multiple joint involvement or generalized debility.

To evaluate the pain pre- and postoperatively and in the course of time, the Pain Score of the American Knee Society Score and a Visual Analogue Score (VAS) were used. In the Pain Score of the American Knee Society Score the score is 50 points if a patient has no pain and 0 points if the patient has severe pain. The Visual Analogue Score was obtained by measuring the distance between the end of a straight horizontal and ungraded line of 10 cm length, which represents no pain and the patients mark (see Figure 4.2). The VAS-Score was only scored at follow-up. The Score ranges from 0 (no pain) to 10 (severe pain).

Figure 4.2. *The VAS Score for pain was obtained by measuring the distance between the end of a 10-cm long straight horizontal and ungraded line, which represents no pain and the patient's mark.*

The presence of anterior knee pain was only registered at follow-up. Anterior knee pain was defined as pain around the patella occurring for example when standing up, climbing stairs or cycling. Range of motion, flexion and flexion contractures were evaluated pre- and postoperatively. Range of motion was measured with a goniometer. All values were expressed in degrees. Stability and alignment were

evaluated using the American Knee Society Score. The score for anteroposterior (AP) stability ranges from 0 (movement > 10 mm) to 10 points (movement < 5 mm). The mediolateral (ML) stability ranges from 0 (movement > 15°) to 15 points (movement < 5°). The score for alignment ranges from 0 (valgus alignment 5° to 10°) to 20 points (varus or valgus alignment > 15°) (see Appendix 3).

4.2.2 Statistical analysis

The pre- and postoperative Knee Score, Pain Score, Function Score and Total Score, range of motion, flexion, flexion contractures, stability and alignment were compared with a paired samples t-test. The difference was considered significant if the p-value was <0.05.

Many factors may influence the clinical performance of the knee joint and patient function after total knee replacement. We considered the factors that might influence clinical performance:

- sex
- the primary diagnosis
- previous high tibial osteotomy
- previous synovectomy
- previous arthrotomy
- body weight
- age at the time of surgery
- time of follow-up
- exchange of the polyethylene insert (only in the second follow-up study)

To study the influence of all above-mentioned factors on the Knee Score, Pain Score, VAS Score, range of motion, flexion, flexion contractures, Function Score and Total Score, a univariate analysis of variance (ANOVA) was performed for each factor separately. A factor was considered significant if the p-value was <0.05. The factors with a significant influence will be mentioned in the text. To correct for the influence of all factors together, a multilevel regression analysis was performed. The analysis was performed as a multilevel analysis because knees are nested within patients. The test statistic F-value and the p-value will be presented in the tables. A factor was considered significant if the p-value was <0 05.

To study the influence of all these factors on the presence of anterior knee pain, a logistic regression analysis was performed for each factor separately. A factor was considered significant if the p-value was <0.05.

The factors with a significant influence will be mentioned in the text. To correct for the influence of all factors together, a multilevel logistic regression analysis was performed. The 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 was <0.05.

The pre- and postoperative scores in patients with rheumatoid arthritis and degenerative arthritis were compared with an independent samples t-test. The difference in anterior knee pain in these patients was evaluated with a logistic regression analysis. Differences were considered significant if the p-value was <0.05.

The scores before and after PE exchange were evaluated with a paired samples t-test. The difference in anterior knee pain was evaluated with a Cochran's Q-test. Differences were considered significant if the p-value was <0.05.

4.3 RESULTS

4.3.1 Knee Score

The mean Knee Score of all patients seen in the first follow-up study at Tp was 26.0 points **±** 15.9 preoperatively and 78.6 points **±** 15.5 at follow-up. The mean Knee Score of all patients seen in the second follow-up study at Tc was 27.6 points **±** 17.1 preoperatively and 69.7 points **±** 19.3 at follow-up (see Table 4.1). In both groups, the improvement of the Knee Score at follow-up was significant compared to the Knee Score preoperatively (paired samples t-test, p<0.001).

Table 4.1. Knee Score preoperatively (n=327) and at follow-up at Tp (n=194) and at Tc (n=97).

	n	**Knee Score (mean ± sd (min-max)) preoperatively**	**Knee Score (mean ± sd (min-max)) at follow-up**	**p-value[1]**
All patients	327	26.7 ± 15.9 (0-76)		
Patients seen at Tp	194	26.0 ± 15.9 (0-70)	78.6 ± 15.5 (23-100)	**<0.001**
Patients seen at Tc	97	27.6 ± 17.1 (0-70)	69.7 ± 19.3 (23-97)	**<0.001**

[1] Paired samples t-test

Preoperatively, none of the knees had an excellent Knee Score and only 4 knees (1.2%) had a good Knee Score. At Tp, 139 knees (71.7%) had an excellent or good Knee Score. At Tc, 59 knees (60.8%) had an excellent or good Knee Score (see Table 4.2).

Table 4.2. Number (%) of patients with an excellent, good, fair or poor Knee Score preoperatively (n=327), at Tp (n=194) and at Tc (n=97).

Knee Score	**Preoperatively** *(n=327)*	**Tp** *(n=194)*	**Tc** *(n=97)*
Excellent	0 (0%)	88 (45.4%)	22 (22.7%)
Good	4 (1.2%)	51 (26.3%)	37 (38.1%)
Fair	6 (1.8%)	33 (17.0%)	11 (11.3%)
Poor	317 (96.9%)	22 (11.3%)	27 (27.8%)

In the group of patients seen at Tp, female patients had a higher Knee Score compared to male patients, and patients with degenerative arthritis had a higher Knee Score on average compared to patients with rheumatoid arthritis and other diagnoses, but the differences were not significant. The Knee Score was lower in patients who had had an arthrotomy or a synovectomy compared to patients who had not, but the differences were not significant. High tibial osteotomy before total knee replacement, body weight and time of follow-up did not have a significant influence on the Knee Score.

In a univariate analysis of variance for each factor separately, patients who had undergone a synovectomy and younger patients had a significantly lower Knee Score on average compared to patients who had not ($F=4.36$, $p=0.038$ and $F=12.61$, $p<0.001$ respectively).

Corrected for all factors in a multilevel regression analysis, the only factor that had a significant influence on the Knee Score was age at the time of surgery. Patients who were younger at the time of surgery had significantly worse Knee Scores at follow-up (see Table 4.3 and Figure 4.3).

In the group of patients seen in the second follow-up study at Tc, male patients, patients with degenerative arthritis and other diagnoses, and patients who had had a PE exchange had a higher Knee Score on average compared to female patients, patients with rheumatoid arthritis and patients who did not have a PE exchange, but the differences were not significant. The Knee Score was lower in patients who had undergone

Table 4.3. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the Knee Score in the group of patients seen in the first follow-up study at Tp (n=194 knees, 146 patients). Age at the time of surgery was the only significant factor.

Factors that may have an influence on the Knee Score	n	Knee Score at Tp mean ± sd (min-max)	F-value	p-value
Sex			0.01	0.917
Male	28	76.1 ± 16.4 (43-99)		
Female	118	79.1 ± 15.3 (23-100)		
Primary diagnosis				
Degenerative arthritis	62	81.2 ± 13.8 (38-100)		
Rheumatoid arthritis	64	78.0 ± 16.5 (23-100)	0.02	0.880
Other	20	72.0 ± 14.5 (43-94)	2.41	0.128
Previous high tibial osteotomy			0.11	0.742
Yes	8	77.8 ± 12.0 (60-95)		
No	186	78.6 ± 15.6 (23-100)		
Previous synovectomy			0.34	0.562
Yes	18	71.4 ± 18.1 (44-97)		
No	176	79.3 ± 15.1 (23-100)		
Previous arthrotomy			0.66	0.421
Yes	25	74.9 ± 16.5 (43-97)		
No	169	79.1 ± 15.3 (23-100)		
Body weight	146		0.02	0.881
Age at the time of surgery	194		5.25	**0.027**
Time of follow-up	194		0.50	0.481

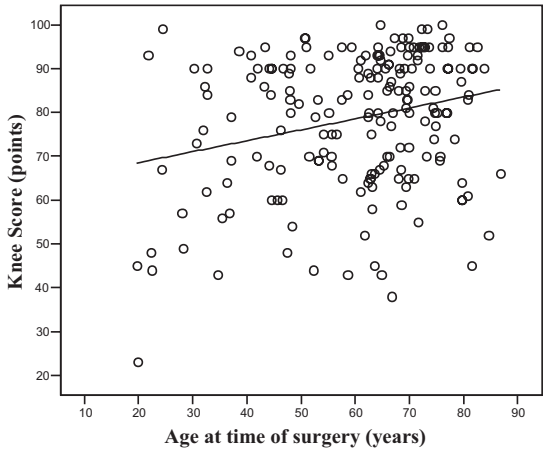

Figure 4.3. *The influence of age at the time of surgery as expressed by the Knee Score at Tp. Patients who were younger at the time of surgery had significantly worse Knee Scores at follow-up.*

Table 4.4. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the Knee Score in the group of patients seen in the second follow-up study at Tc (n=97 knees, 79 patients). None of the factors had a significant influence on the Knee Score.

Factors that may have an influence on the Knee Score	n	Knee Score at Tc mean ± sd (min-max)	F-value	p-value
Sex			0.73	0.407
Male	13	74.2 ± 20.3 (38-97)		
Female	66	68.9 ± 19.1 (23-95)		
Primary diagnosis				
Degenerative arthritis	33	71.8 ± 18.7 (25-95)		
Rheumatoid arthritis	34	67.6 ± 19.1 (23-96)	0.55	0.470
Other	12	72.6 ± 22.3 (30-97)	0.02	0.885
Previous high tibial osteotomy			2.56	0.131
Yes	3	55.7 ± 27.2 (38-87)		
No	94	70.1 ± 19.1 (23-97)		
Previous synovectomy			0.34	0.568
Yes	15	64.9 ± 19.3 (28-94)		
No	82	70.1 ± 19.3 (23-97)		
Previous arthrotomy			1.32	0.269
Yes	13	66.7 ± 19.7 (38-95)		
No	84	70.1 ± 19.3 (23-97)		
PE exchange			0.69	0.418
Yes	22	72.7 ± 19.1 (25-97)		
No	75	68.8 ± 19.4 (23-96)		
Body weight	79		0.09	0.764
Age at the time of surgery	97		0.18	0.680
Time of follow-up	97		0.71	0.412

a high tibial osteotomy, a synovectomy or an arthrotomy compared to patients who had not, but the differences were not significant either. Body weight, age at the time of surgery and time of follow-up did not have a significant influence on the Knee Score in the group of patients seen at Tc (see Table 4.4).

Analyzing the course of the Knee Score in time in the first and second follow-up studies separately shows no deterioration with a longer time of follow-up within each group of patients. The mean Knee Score remained higher than preoperatively even after 18 years of follow-up (see Figure 4.4).

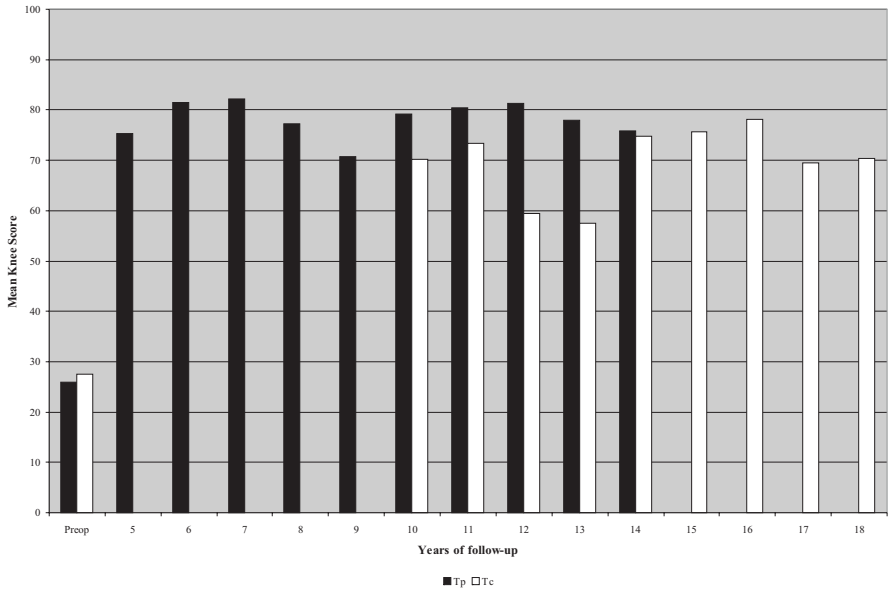

Figure 4.4. *Mean Knee Score preoperatively and at follow-up of patients seen in the first and second follow-up studies. Within each group no deterioration of the Knee Score was seen in time. At follow-up, the mean Knee Score remained higher postoperatively than preoperatively.*

Table 4.5. Pain Scores preoperatively (n=327) and at follow-up at Tp (n=194) and Tc (n=97). A significant reduction in pain was seen at follow-up compared to the preoperative Pain Scores in both groups.

	n	**Pain Score (mean ± sd (min-max)) preoperatively**	**Pain Score (mean ± sd (min-max)) at follow-up**	**p-value[1]**
All patients	327	10.6 ± 8.9 (0-40)		
Patients seen at Tp	194	11.6 ± 8.8 (0-30)	42.2 ± 10.3 (10-50)	< **0.001**
Patients seen at Tc	97	11.3 ± 9.3 (0-30)	38.8 ± 14.2 (0-50)	< **0.001**

[1] Paired samples t-test

4.3.2 Pain

4.3.2.1 Pain Score

Patients seen in the first follow-up study had a mean Pain Score of 11.6 points **±** 8.8 preoperatively and 42.2 points **±** 10.3 at follow-up. Patients seen in the second follow-up study had a mean Pain Score of 11.3 points **±** 9.3 preoperatively and 38.8 points **±** 14.2 at follow-up. In both patient groups the improvement in Pain Score at follow-up was significant compared to the preoperative Pain Score (paired samples t-test, $p<0.001$).

In the group of patients seen at Tp, the Pain Score in male and female patients was equal. Patients with rheumatoid arthritis and other diagnoses had slightly more pain compared to patients with degenerative arthritis, but the differences were not significant. Patients who had had a high tibial osteotomy before total knee replacement did not have significantly more pain compared to patients who had not. Patients who had undergone a synovectomy or an arthrotomy before total knee arthroplasty had slightly more pain compared to patients who had not, but the differences were not significant either. Body weight, age at the time of surgery and time of follow-up did not have a significant influence on the Pain Score (see Table 4.6).

Table 4.6. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the Pain Score in the group of patients seen in the first follow-up study at Tp (n=194 knees, 146 patients). None of the factors had a significant influence on the Pain Score.

Factors that may have an influence on the Pain Score	**n**	**Pain Score at Tp mean ± sd (min-max)**	**F-value**	**p-value**
Sex			0.43	0.517
Male	28	42.2 ± 10.1 (10-50)		
Female	118	42.2 ± 10.5 (10-50)		
Primary diagnosis				
Degenerative arthritis	62	43.2 ± 9.9 (10-50)		
Rheumatoid arthritis	64	41.2 ± 10.7 (10-50)	0.43	0.517
Other	20	41.4 ± 10.6 (20-50)	0.13	0.716
Previous high tibial osteotomy			0.12	0.736
Yes	8	44.4 ± 6.2 (30-50)		
No	186	42.1 ± 10.5 (10-50)		
Previous synovectomy			0.09	0.768
Yes	18	38.9 ± 11.8 (20-50)		
No	176	42.5 ± 10.2 (10-50)		
Previous arthrotomy			0.04	0.841
Yes	25	40.8 ± 12.0 (10-50)		
No	169	42.4 ± 10.1 (10-50)		
Body weight	146		0.75	0.392
Age at the time of surgery	194		1.87	0.179
Time of follow-up	194		0.01	0.941

Among the group of patients seen at Tc, female patients and patients who had had a high tibial osteotomy or an arthrotomy had slightly more pain compared to male patients and patients who had not had prior surgery, but the differences were not significant. Diagnosis, synovectomy before total knee replacement, PE exchange, body weight, age at the time of surgery and time of follow-up did not have a significant influence on the Pain Score (see Table 4.7).

Analyzing the course of the Pain Score in time in the first and second follow-up studies separately shows no increase in pain with a longer time of follow-up within each group of patients. In the course of time, patients continued to have less pain than preoperatively (see Figure 4.5).

Table 4.7. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the Pain Score in the group of patients seen in the second follow-up study at Tc (n=97 knees, 79 patients). None of the factors had a significant influence on the Pain Score.

Factors that may have an influence on the Pain Score	**n**	**Pain Score at Tc mean ± sd (min-max)**	**F-value**	**p-value**
Sex			0.53	0.476
Male	13	41.0 ± 14.7 (10-50)		
Female	66	38.4 ± 14.2 (0-50)		
Primary diagnosis				
Degenerative arthritis	33	37.2 ± 15.9 (0-50)		
Rheumatoid arthritis	34	39.8 ± 13.0 (0-50)	0.40	0.536
Other	12	38.9 ± 15.2 (10-50)	0.01	0.927
Previous high tibial osteotomy			0.89	0.360
Yes	3	30.0 ± 20.0 (10-50)		
No	94	39.0 ± 14.1 (0-50)		
Previous synovectomy			0.02	0.895
Yes	15	41.3 ± 10.4 (10-50)		
No	82	38.3 ± 14.8 (0-50)		
Previous arthrotomy			1.29	0.274
Yes	13	34.6 ± 15.3 (10-50)		
No	84	39.4 ± 14.1 (0-50)		
PE exchange			0.07	0.788
Yes	22	38.0 ± 13.9 (10-50)		
No	75	39.0± 14.4 (0-50)		
Body weight	79		0.73	0.408
Age at the time of surgery	97		0.76	0.397
Time of follow-up	97		0.00	0.953

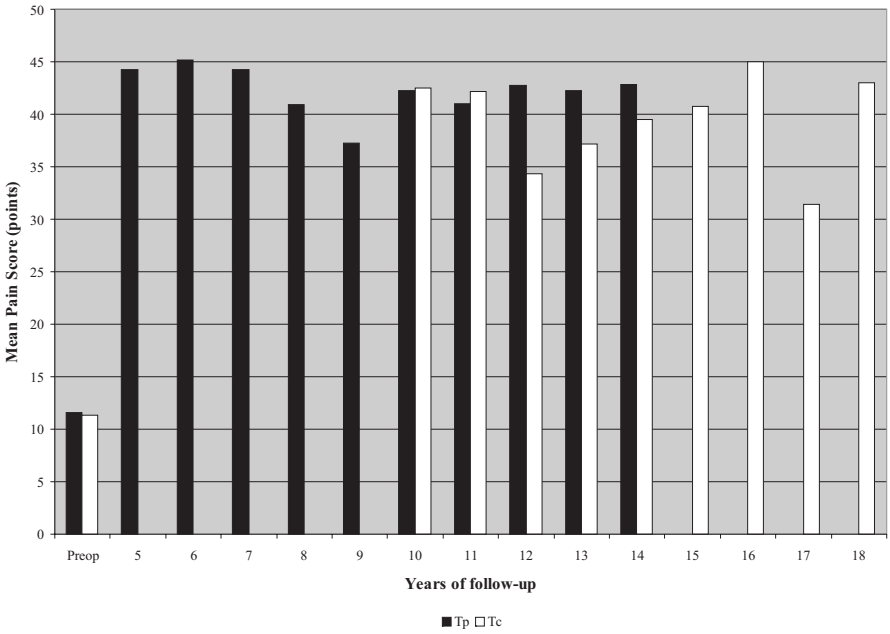

Figure 4.5. *Mean Pain Score preoperatively and at follow-up. Both within the group of patients seen at Tp and at Tc, no increase in pain was seen in time. Patients continued to have significantly less pain than preoperatively.*

4.3.2.2 VAS Score

In the group of patients seen in the first follow-up study at Tp, the mean VAS Score for pain at follow-up was 1.7 points ± 1.9. Male patients, patients with degenerative arthritis and other diagnoses, and patients who had had a high tibial osteotomy, a synovectomy or an arthrotomy before total knee replacement recorded slightly more pain on a VAS Score compared to female patients, patients with rheumatoid arthritis and patients who had not had prior surgery, but the differences were not significant. Age at the time of surgery and time of follow-up did not have a significant influence on the VAS Score for pain.

Heavier patients recorded more pain. In a logistic regression analysis for each factor separately, body weight had a significant influence on the VAS Score ($F=4.12$, $p=0.044$), but corrected for all factors in a multi-level regression analysis the influence was not significant (see Table 4.8).

In the group of patients seen at Tc, the mean VAS Score was 3.0 points ± 2.7 at follow-up. Female patients, patients with degenerative arthritis, patients who had had a high tibial osteotomy, a synovectomy, an

Table 4.8. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the VAS Score for pain in the group of patients seen in the first follow-up study at Tp (n=194 knees, 146 patients). None of the factors had a significant influence on the VAS Score.

Factors that may have an influence on the VAS Score	n	VAS Score at Tp mean ± sd (min-max)	F-value	p-value
All patients		1.7 ± 1.9 (0-9)		
Sex			0.93	0.339
Male	28	1.9 ± 1.9 (0-8)		
Female	118	1.7 ± 1.9 (0-9)		
Primary diagnosis				
Degenerative arthritis	62	1.8 ± 2.1 (0-9)		
Rheumatoid arthritis	64	1.6 ± 1.7 (0-8)	1.19	0.281
Other	20	2.0 ± 2.2 (0-8)	0.03	0.869
Previous high tibial osteotomy			0.00	0.961
Yes	8	2.4 ± 1.4 (0-4)		
No	186	1.7 ± 1.9 (0-9)		
Previous synovectomy			0.77	0.384
Yes	18	2.4 ± 2.0 (0-8)		
No	176	1.6 ± 1.9 (0-9)		
Previous arthrotomy			1.83	0.184
Yes	25	2.4 ± 2.6 (0-9)		
No	169	1.6 ± 1.8 (0-8)		
Body weight	146		2.71	0.107
Age at the time of surgery	194		3.62	0.064
Time of follow-up	194		0.00	0.971

arthrotomy or a PE exchange recorded slightly more pain compared to male patients, patients with rheumatoid arthritis and other diagnoses, and patients who had not had surgery before total knee replacement or a PE exchange, but the differences were not significant. Body weight, age at the time of surgery and time of follow-up did not have a significant influence on the VAS Score (see Table 4.9).

Analyzing the course of the VAS Score in time in the first and second follow-up studies separately shows no increase in pain with a longer time of follow-up within each group of patients (see Figure 4.6).

Table 4.9. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the VAS Score for pain in the group of patients seen in the second follow-up study at Tc (n=97 knees, 79 patients). None of the factors had a significant influence on the VAS Score.

Factors that may have an influence on the VAS Score	n	VAS Score at Tc mean ± sd (min-max)	F-value	p-value
All patients	97	3.0 ± 2.7 (0-10)		
Sex			1.18	0.294
Male	13	2.5 ± 2.7 (0-7)		
Female	66	3.1 ± 2.7 (0-10)		
Primary diagnosis				
Degenerative arthritis	33	3.4 ± 3.0 (0-10)		
Rheumatoid arthritis	34	2.7 ± 2.5 (0-10)	0.11	0.742
Other	12	2.9 ± 2.8 (0-7)	0.13	0.719
Previous high tibial osteotomy			0.99	0.335
Yes	3	4.8 ± 3.3 (1-7)		
No	94	2.9 ± 2.7 (0-10)		
Previous synovectomy			0.43	0.521
Yes	15	3.2 ± 2.0 (0-7)		
No	82	2.9 ± 2.8 (0-10)		
Previous arthrotomy			0.64	0.437
Yes	13	3.6 ± 2.6 (0-7)		
No	84	2.9 ± 2.7 (0-10)		
PE exchange			1.14	0.302
Yes	22	3.7 ± 2.7 (0-9)		
No	75	2.8 ± 2.7 (0-10)		
Body weight	79		2.22	0.157
Age at the time of surgery	97		0.19	0.673
Time of follow-up	97		0.03	0.868

4.3.2.3 Anterior knee pain

Anterior knee pain was recorded at Tp in 32 knees (16.5%). Sex and body weight had no significant influence on the presence of anterior knee pain. Patients who had had a high tibial osteotomy or an arthrotomy before total knee replacement and patients with a larger size prosthesis recorded anterior knee pain more frequently, but the differences were not significant.

In a logistic regression analysis for each factor separately, previous synovectomy (B=1.623, se=0.523, p=0.002), age at the time of surgery

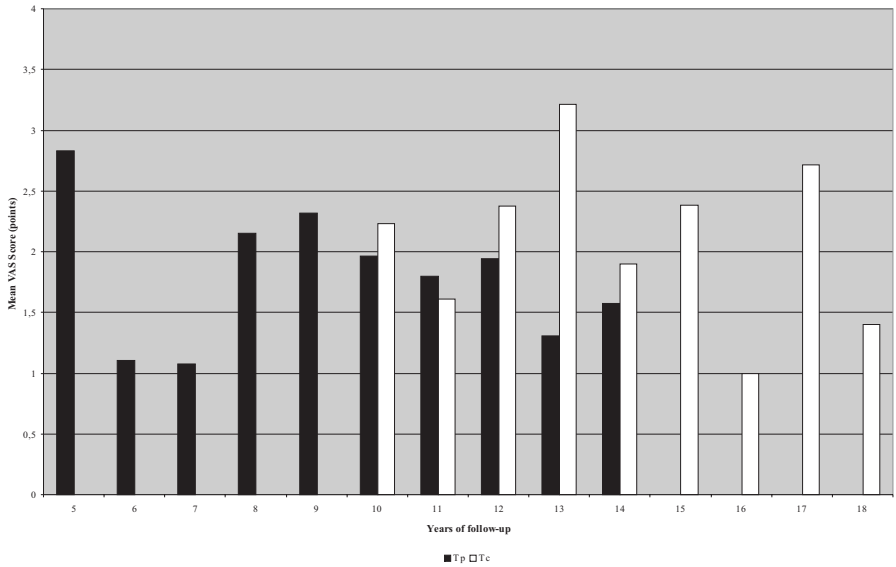

Figure 4.6. *VAS Scores and time of follow-up in patients seen at Tp and at Tc. For both groups, no increase in pain is seen in the course of time.*

(B=-0.033, se=0.012, p=0.006), time of follow-up (B=0.205, se=0.080, p=0.011) and the primary diagnosis had a significant influence on the presence of anterior knee pain.

Corrected for all factors in a multilevel regression analysis, the only factor contributing significantly to the presence of anterior knee pain was the primary diagnosis. Patients with rheumatoid arthritis and other diagnoses had significantly more anterior knee pain compared to patients with degenerative arthritis (18.8% and 35.0% versus 8.1%) (see Table 4.10).

In the group of patients seen at Tc, anterior knee pain was recorded in 22 knees (22.7%). Male patients, patients who had had a high tibial osteotomy or a synovectomy and younger patients recorded anterior knee pain more often compared to female patients, and patients who had not had a high tibial osteotomy or synovectomy, but the differences were not significant. Diagnosis, arthrotomy before total knee replacement, PE exchange, size of the prosthesis, body weight, and time of follow-up did not have a significant influence on the presence of anterior knee pain (see Table 4.11)

Table 4.10. Multilevel logistic regression analysis. Logistic regression coefficient (B), standard error (se) and p-value of the relation between anterior knee pain and the factors that may contribute to the presence of anterior knee pain in the first follow-up study (n=194 knees, 146 patients). Patients with rheumatoid arthritis and other diagnoses had significantly more anterior knee pain compared to patients with degenerative arthritis.

Factors that may influence anterior knee pain	**n**	**Anterior knee pain at Tp**	**No anterior knee pain at Tp**	**B**	**se**	**p-value**
All patients	194	32 (16.5%)	162 (83.5%)			
Sex				0.940	0.779	0.228
Male	28	4 (14.3%)	24 (85.7%)			
Female	118	20 (16.9%)	98 (83.1%)			
Diagnosis						
Degenerative arthritis	62	5 (8.1%)	57 (91.9%)			
Rheumatoid arthritis	64	12 (18.8%)	52 (81.2%)	1.471	0.731	**0.044**
Other	20	7 (35.0%)	13 (65.0%)	1.949	0.845	**0.021**
High tibial osteotomy				0.942	1.089	0.387
Yes	8	3 (37.5%)	5 (62.5%)			
No	186	29 (15.6%)	157 (84.4%)			
Synovectomy				1.168	0.761	0.125
Yes	18	8 (44.4%)	10 (55.6%)			
No	176	24 (13.6%)	152 (86.4%)			
Arthrotomy				0.662	0.697	0.342
Yes	25	7 (28.0%)	18 (72.0%)			
No	169	25 (14.8%)	144 (85.2%)			
Size prosthesis				0.727	0.561	0.195
Unknown	2	0 (0%)	2 (100%)			
2	8	0 (0%)	8 (100%)			
3	130	22 (16.9%)	108 (83.1%)			
4	54	10 (18.5%)	44 (81.5%)			
Body weight (kg) mean ± sd (rmin-max)	146	69.8 ± 12.6 (50-100)	70.9 ± 13.2 (46-102)	0.017	0.023	0.460
Age at the time of surgery (years) mean ± sd (min-max)	194	53.2 ± 16.1 (22-81)	61.7 ± 14.9 (19-86)	-0.012	0.020	0.549
Time of follow-up (years) mean ± sd (min-max)	194	10.9 ± 2.3 (6.6-14.4)	9.6 ± 2.6 (5.1-15.5)	0.128	0.098	0.192

Table 4.11. Multilevel logistic regression analysis. Logistic regression coefficient (B), standard error (se) and p-value of the relation between anterior knee pain and the factors that may contribute to the presence of anterior knee pain in the second follow-up study (n=97 knees, 79 patients). None of the factors had a significant influence on the presence of anterior knee pain.

Factors that may influence anterior knee pain	n	Anterior knee pain at Tc	No anterior knee pain at Tc	B	se	p-value
All patients	97	22 (22.7%)	75 (77.3%)			
Sex				-0.681	0.922	0.460
Male	13	4 (30.8%)	9 (69.2%)			
Female	66	15 (22.7%)	51 (77.3%)			
Diagnosis						
Degenerative arthritis	33	9 (27.3%)	24 (72.7%)			
Rheumatoid arthritis	34	8 (23.5%)	26 (76.5%)	-1.062	0.902	0.239
Other	12	2 (16.7%)	10 (83.3%)	-0.685	1.078	0.525
High tibial osteotomy				0.542	1.466	0.712
Yes	3	1 (33.3%)	2 (66.7%)			
No	94	21 (22.3%)	73 (77.7%)			
Synovectomy				1.124	0.839	0.180
Yes	15	6 (40.0%)	9 (60.0%)			
No	82	16 (19.5%)	66 (80.5%)			
Arthrotomy				-0.718	0.938	0.444
Yes	13	2 (15.4%)	11 (84.6%)			
No	84	20 (23.8%)	64 (76.2%)			
PE exchange				-0.013	0.692	0.985
Yes	22	5 (22.7%)	17 (77.3%)			
No	75	17 (22.7%)	58 (77.3%)			
Size prosthesis				-0.133	0.626	0.832
Unknown	2	1 (50%)	1 (50%)			
2	6	0 (0%)	6 (100%)			
3	65	17 (26.2%)	48 (73.8%)			
4	24	4 (16.7%)	20 (83.3%)			
Body weight (kg) mean ± sd (min-max)	79	68.5 ± 13.6 (50-90)	69.1 ± 12.5 (46-102)	-0.016	0.031	0.606
Age at the time of surgery (years) mean ± sd (min-max)	97	51.5 ± 19.4 (22-83)	56.2 ± 15.5 (19-84)	-0.019	0.025	0.447
Time of follow-up (years) mean ± sd (min-max)	97	13.5 ± 2.5 (9.2-18.0)	14.2 ± 2.6 (10.0-18.7)	-0.133	0.626	0.832

Analyzing the presence of anterior knee pain in time in the first and second follow-up studies separately shows no significant increase in the presence of anterior knee pain with a longer time of follow-up within each group of patients (see Figure 4.7).

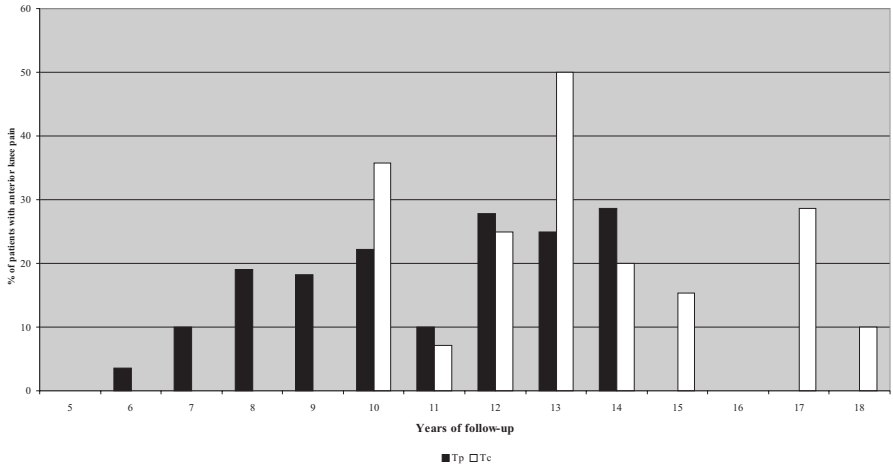

Figure 4.7. *Percentage of patients with anterior knee pain at follow-up in the first follow-up study at Tp and in the second follow-up study at Tc. In the first follow-up study, an increase in the presence of anterior knee pain was seen in the course of time. However, in a multilevel logistic regression analysis the increase was not significant. In the second study no increase in anterior knee pain was seen.*

4.3.3 Range of motion

The mean range of motion of all knees seen at Tp was 84.6° ± 27.2 preoperatively and 94.8° ± 22.6 at follow-up. The improvement in range of motion at follow-up compared to the range of motion preoperatively was significant in the first follow-up study (paired samples t-test, $p<0.001$).

In the group of patients seen at Tc the mean range of motion preoperatively was 83.8° ± 30.4 and 86.6° ± 25.6 at follow-up. In the second study the improvement in range of motion at follow-up compared to the range of motion preoperatively was not significant (paired samples t-test, $p=0.325$) (see Table 4.12).

Table 4.12. Range of motion preoperatively and at follow-up in patients seen at Tp and at Tc. In the group of patients seen at Tp a significant gain in range of motion was seen at follow-up compared to the preoperative range of motion.

	n	Range of motion (°) (mean ± sd (min-max)) preoperatively	Range of motion (°) (mean ± sd (min-max)) at follow-up	p-value[1]
All patients	327	86.1 ± 28.0 (0-140)		
Patients seen at Tp	194	84.6 ± 27.2 (0-135)	94.8 ± 22.6 (0-135)	**<0.001**
Patients seen at Tc	97	83.8 ± 30.4 (0-135)	86.6 ± 25.6 (0-125)	0.325

[1] Paired samples t-test

In the group of patients seen at Tp, female patients, patients with rheumatoid arthritis, patients who had had a high tibial osteotomy or a synovectomy before total knee replacement had less range of motion at follow-up compared to male patients, patients with degenerative arthritis and other diagnoses and patients who had not had a high tibial osteotomy or synovectomy, but the differences were not significant. Arthrotomy prior to total knee replacement and time of follow-up did not have a significant influence on the range of motion.

In a univariate analysis of variance for each factor separately, heavier patients and younger patients had a significantly higher range of motion (F=6.08, p=0.015 and F=8.71, p=0.004 respectively).

Corrected for all factors in a multilevel regression analysis, age at the time of surgery was the only factor that had a significant influence on the range of motion (see Table 4.13 and Figure 4.8).

In the group of patients seen at Tc, female patients, patients with rheumatoid arthritis and patients who had had a synovectomy before total knee replacement had less range of motion compared to male patients, patients with degenerative arthritis and other diagnoses, and patients who had not had a synovectomy, but the differences were not significant. High tibial osteotomy or arthrotomy prior to total knee replacement, age at the time of surgery and time of follow-up did not have a significant influence on the range of motion.

In a univariate analysis of variance for each factor separately, patients who had had a PE exchange had a significantly smaller range of motion compared to patients with the original PE insert in situ, and heavier patients had a significantly higher range of motion (F=4.49, p=0.037 and F=8.50, p=0.004 respectively).

Table 4.13. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the range of motion in the group of patients seen in the first follow-up study at Tp (n=194 knees, 146 patients). Younger patients had a significantly worse range of motion at follow-up.

Factors that may have an influence on the ROM	n	ROM (°) at Tp mean ± sd (min-max)	F-value	p-value
Sex			0.20	0.655
Male	28	97.8 ± 25.5 (40-135)		
Female	118	94.2 ± 22.0 (0-125)		
Diagnosis				
Degenerative arthritis	62	96.0 ± 20.3 (40-125)		
Rheumatoid arthritis	64	93.7 ± 24.4 (0-125)	2.76	0.104
Other	20	96.0 ± 22.3 (40-135)	1.59	0.215
Previous high tibial osteotomy			0.57	0.453
Yes	8	88.8 ± 17.3 (50-100)		
No	186	95.1 ± 22.8 (0-135)		
Previous synovectomy			0.11	0.736
Yes	18	85.6 ± 26.8 (40-125)		
No	176	95.8 ± 22.0 (0-135)		
Previous arthrotomy			0.47	0.495
Yes	25	99.8 ± 21.0 (40-135)		
No	169	94.1 ± 22.8 (0-125)		
Body weight	146		2.01	0.163
Age at the time of surgery	194		8.38	**0.006**
Time of follow-up	194		0.18	0.672

Figure 4.8. *Range of motion and age at the time of surgery in the group of patients seen at Tp. Patients who were younger at the time of surgery had significantly less range of motion at follow-up.*

Corrected for all factors in a multilevel regression analysis, none of the factors had a significant influence on the range of motion (see Table 4.14).

Table 4.14. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the range of motion in the group of patients seen in the second follow-up study at Tc (n= 97 knees, 79 patients). None of the factors had a significant influence on the range of motion.

Factors that may have an influence on the ROM	**n**	**ROM (°) at Tc mean ± sd (min-max)**	**F-value**	**p-value**
Sex			0.76	0.396
Male	13	95.0 ± 22.4 (40-125)		
Female	66	85.1 ± 26.0 (0-125)		
Diagnosis				
Degenerative arthritis	33	91.5 ± 20.8 (20-125)		
Rheumatoid arthritis	34	81.3 ± 28.4 (0-120)	0.10	0.761
Other	12	95.4 ± 22.0 (40-125)	0.27	0.612
Previous high tibial osteotomy			0.46	0.507
Yes	3	103.3 ± 11.5 (90-110)		
No	94	86.1 ± 25.8 (0-125)		
Previous synovectomy			0.44	0.517
Yes	15	81.7 ± 32.2 (15-120)		
No	82	87.5 ± 24.3 (0-125)		
Previous arthrotomy			1.59	0.227
Yes	13	99.6 ± 26.1 (40-125)		
No	84	84.6 ± 25.1 (0-120)		
PE exchange			0.34	0.571
Yes	22	96.6 ± 22.1 (40-125)		
No	75	83.7 ± 26.0 (0-120)		
Body weight	79		1.52	0.236
Age at the time of surgery	97		2.43	0.140
Time of follow-up	97		0.16	0.698

Analyzing the range of motion in time in the first and second follow-up studies separately shows no significant deterioration in range of motion with a longer time of follow-up within each group of patients (see Figure 4.9).

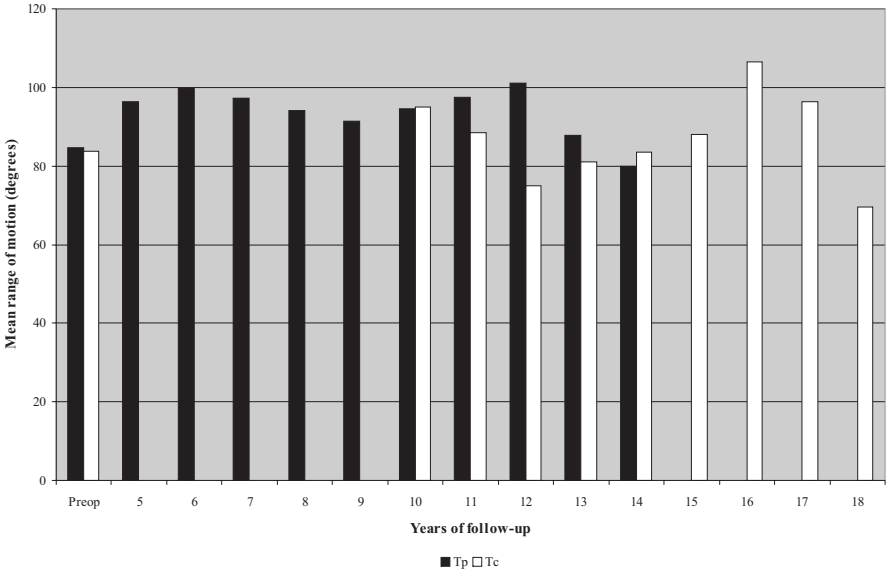

Figure 4.9. *Range of motion and time of follow-up of the patients seen at Tp and at Tc. No significant deterioration in range of motion was seen in the course of time within each group of patients.*

4.3.3.1 Flexion

The mean flexion of all patients seen at Tp was 98.2° ± 20.4 preoperatively and 97.0° ± 20.8 at follow-up. The difference in flexion preoperatively and at follow-up in the first follow-up study was not significant (p=0.452).

In the group of patients seen at Tc, the mean flexion preoperatively was 97.4° ± 23.1 and 91.4° ± 21.5 at follow-up. The loss in flexion at follow-up compared to the preoperative flexion in the group of patients seen in the second follow-up study was significant (paired samples t-test, p=0.021) (see Table 4.15).

Table 4.15. Flexion (°) preoperatively and at follow-up at Tp and at Tc. The loss of flexion at follow-up compared to the preoperative flexion in the group of patients seen at Tc is significant.

	n	Flexion (°) mean ± sd (min-max) preoperatively	Flexion (°) mean ± sd (min-max) at follow-up	p-value[1]
All patients	327	99.0 ± 21.9 (10-140)		
Patients seen at Tp	194	98.2 ± 20.4 (15-140)	97.0 ± 20.8 (0-135)	0.452
Patients seen at Tc	97	97.4 ± 23.1 (15-135)	91.4 ± 21.5 (0-125)	**0.021**

[1] *Paired samples t-test*

In the group of patients seen at Tp, female patients and patients who had had a high tibial osteotomy or a synovectomy before total knee replacement had less flexion at follow-up compared to male patients and patients who had not had a high tibial osteotomy or a synovectomy, but the differences were not significant. Diagnosis, arthrotomy prior to knee replacement and time of follow-up did not have a significant influence on the flexion at follow-up.

In a univariate analysis of variance for each factor separately, heavier patients had significantly more flexion and younger patients had significantly less flexion (F=4.58, p=0.034 and F=7.01, p=0.009 respectively).

Corrected for all factors in a multilevel regression analysis, age at the time of surgery was the only factor that had a significant influence on the flexion at follow-up (see Table 4.16 and Figure 4.10).

Table 4.16. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the flexion in the group of patients seen in the first follow-up study at Tp (n=194 knees, 146 patients). Younger patients had significantly less flexion at follow-up.

Factors that may have an influence on the flexion	**n**	**Flexion (°) at Tp mean ± sd (min-max)**	**F-value**	**p-value**
Sex			0.46	0.500
Male	28	100.2 ± 23.5 (45-135)		
Female	118	96.3 ± 20.2 (0-135)		
Diagnosis				
Degenerative arthritis	62	97.7 ± 19.2 (45-125)		
Rheumatoid arthritis	64	96.2 ± 22.5 (0-135)	2.76	0.104
Other	20	98.3 ± 18.9 (50-135)	1.50	0.227
Previous high tibial osteotomy			1.15	0.290
Yes	8	88.8 ± 17.3 (50-100)		
No	186	97.4 ± 20.9 (0-135)		
Previous synovectomy			0.48	0.492
Yes	18	91.7 ± 20.3 (60-125)		
No	176	97.6 ± 20.8 (0-135)		
Previous arthrotomy			0.89	0.351
Yes	25	102.2 ± 18.4 (50-135)		
No	169	96.2 ± 21.1 (0-135)		
Body weight	146		1.59	0.214
Age at the time of surgery	194		8.59	**0.005**
Time of follow-up	194		0.21	0.646

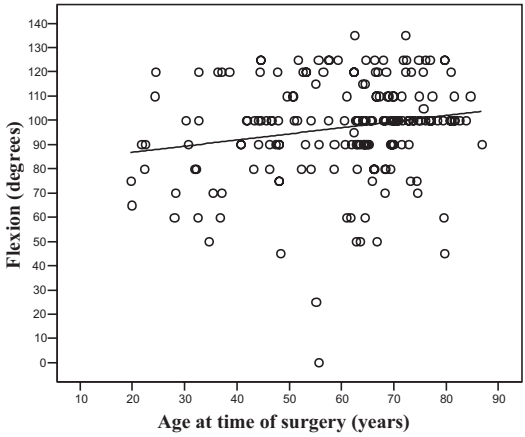

Figure 4.10. *Flexion and age at the time of surgery in the group of patients seen at Tp. Patients who were younger at the time of surgery had significantly less flexion at follow-up.*

Table 4.17. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the flexion in the group of patients seen in the second follow-up study at Tc (n= 97 knees, 79 patients). None of the factors had a significant influence on the flexion.

Factors that may have an influence on the flexion	**n**	**Flexion (°) at Tc mean ± sd (min-max)**	**F-value**	**p-value**
Sex			0.24	0.637
Male	13	96.3 ± 20.7 (50-125)		
Female	66	90.1 ± 21.7 (0-125)		
Diagnosis				
Degenerative arthritis	33	94.1 ± 17.7 (40-125)		
Rheumatoid arthritis	34	87.8 ± 24.0 (0-120)	0.06	0.805
Other	12	99.6 ± 18.3 (50-125)	0.84	0.375
Previous high tibial osteotomy			0.31	0.586
Yes	3	103.3 ± 11.5 (90-110)		
No	94	91.1 ± 21.7 (0-125)		
Previous synovectomy			1.64	0.220
Yes	15	92.7 ± 17.2 (55-120)		
No	82	91.2 ± 22.3 (0-125)		
Previous arthrotomy			1.35	0.264
Yes	13	101.5 ± 22.5 (50-125)		
No	84	89.9 ± 21.1 (0-120)		
PE exchange			0.02	0.902
Yes	22	97.7 ± 21.6 (40-125)		
No	75	89.6 ± 21.3 (0-120)		
Body weight	79		0.85	0.372
Age at the time of surgery	97		0.97	0.341
Time of follow-up	97		0.20	0.659

In the group of patients seen at Tc, female patients and patients with rheumatoid arthritis had less flexion at follow-up compared to male patients and patients with degenerative arthritis or other diagnoses, but the differences were not significant. Patients who had had a PE exchange had more flexion compared to patients with the original PE insert in situ, but the difference was not significant either. High tibial osteotomy, synovectomy or arthrotomy prior to total knee replacement, body weight, age at the time of surgery and time of follow-up did not have a significant influence on the flexion at Tc (see Table 4.17).

Analyzing the flexion in time in the first and second follow-up studies separately shows no significant deterioration in flexion with a longer time of follow-up within each group of patients (see Figure 4.11).

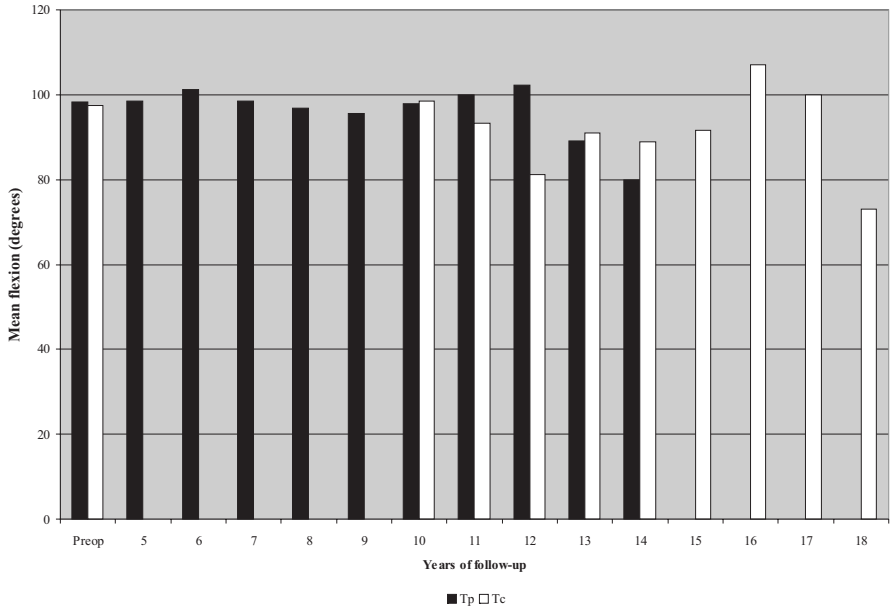

Figure 4.11. *Flexion and years of follow-up in the group of patients seen at Tp and at Tc. No significant deterioration in flexion was seen in the course of time within each group of patients.*

4.3.3.2 Flexion contractures

The knees seen in the first follow-up study at Tp had a mean flexion contracture of 13.6° ± 12.8 preoperatively and 2.2° ± 6.7 at follow-up. The knees seen in the second follow-up study at Tc had a mean flexion contracture of 13.7° ± 14.1 preoperatively and 4.9° ± 9.5 at follow-up.

The decrease in flexion contractures at follow-up compared to the flexion contractures preoperatively was significant, both in the first and in the second follow-up study (paired samples t-test, p<0.001) (see Table 4.18).

Table 4.18. Flexion contractures (°) preoperatively and at follow-up at Tp and at Tc. In both groups of patients, the decrease in flexion contractures at follow-up compared to the preoperative flexion contractures is significant.

	n	Flexion contracture (°) mean ± sd (min-max) preoperatively	Flexion contracture (°) mean ± sd (min-max) at follow-up	p-value[1]
All patients	327	12.9 ± 11.8 (90-0)		
Patients seen at Tp	194	13.6 ± 12.8 (90-0)	2.2 ± 6.7 (45-0)	**<0.001**
Patients seen at Tc	97	13.7 ± 14.1 (90-0)	4.9 ± 9.5 (60-0)	**<0.001**

[1] *Paired samples t-test*

In the group of patients seen at Tp, patients with degenerative arthritis had less flexion contractures compared to patients with rheumatoid arthritis and other diagnoses, but the differences were not significant. Sex, arthrotomy or high tibial osteotomy before total knee replacement, body weight, age at the time of surgery and time of follow-up had no significant influence on flexion contractures.

In a univariate analysis of variance for each factor separately, knees that had had a synovectomy before total knee replacement had significantly higher flexion contractures (F=7.11, p=0.008).

Corrected for all factors in a multilevel regression analysis, none of the factors had a significant influence on flexion contractures at Tp (see Table 4.19).

In the group of patients seen at Tc, male patients and patients with degenerative arthritis had less flexion contractures compared to female patients and patients with rheumatoid arthritis or other diagnoses, but the differences were not significant. Arthrotomy or high tibial osteotomy prior to total knee replacement, body weight and time of follow-up did not have a significant influence on flexion contractures.

In a univariate analysis of variance for each factor separately, knees that had had a synovectomy before total knee replacement, knees with

Table 4.19. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on flexion contractures in the group of patients seen in the first follow-up study at Tp (n=194 knees, 146 patients). None of the factors had a significant influence on flexion contractures.

Factors that may have an influence on flexion contractures	n	Flexion contracture (°) at Tp mean ± sd (min-max)	F-value	p-value
Sex			0.46	0.503
Male	28	2.4 ± 6.5 (30-0)		
Female	118	2.2 ± 6.7 (45-0)		
Diagnosis				
Degenerative arthritis	62	1.7 ± 5.8 (30-0)		
Rheumatoid arthritis	64	2.5 ± 7.5 (45-0)	0.18	0.671
Other	20	2.4 ± 5.4 (20-0)	0.16	0.695
Previous high tibial osteotomy			0.40	0.532
Yes	8	0.0 ± 0.0 (0-0)		
No	186	2.3 ± 6.8 (45-0)		
Previous synovectomy			2.00	0.164
Yes	18	6.1 ± 13.9 (45-0)		
No	176	1.8 ± 5.3 (30-0)		
Previous arthrotomy			0.28	0.601
Yes	25	2.4 ± 6.6 (30-0)		
No	169	2.2 ± 6.7 (45-0)		
Body weight	146		0.89	0.350
Age at the time of surgery	194		0.28	0.600
Time of follow-up	194		0.00	0.995

the original PE insert in situ and younger patients had significantly higher flexion contractures compared to knees that had not had a synovectomy, a PE exchange and older patients (F=8.08, p=0.005, F=4.55, p=0.036 and F=5.89, p=0.017 respectively).

Corrected for all factors in a multilevel regression analysis, age at the time of surgery was the only factor that had a significant influence on flexion contractures at Tc (see Table 4.20 and Figure 4.12).

Analyzing the flexion contractures in time in the first and second follow-up studies separately shows no significant increase in flexion contractures with a longer time of follow-up within each group of patients. The mean flexion contracture at follow-up remained below the mean flexion contracture preoperatively in both patient groups (see Figure 4.13).

Table 4.20. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the flexion contractures in the group of patients seen in the second follow-up study at Tc (n= 97 knees, 79 patients). Younger patients had significantly higher flexion contractures.

Factors that may have an influence on flexion contractures	n	Flexion contracture (°) at Tc mean ± sd (min-max)	F-value	p-value
Sex			1.92	0.186
Male	13	1.3 ± 3.5 (10-0)		
Female	66	5.5 ± 10.1 (60-0)		
Diagnosis				
Degenerative arthritis	33	2.7 ± 5.5 (20-0)		
Rheumatoid arthritis	34	6.5 ± 11.5 (60-0)	0.16	0.697
Other	12	4.2 ± 7.6 (25-0)	0.65	0.433
Previous high tibial osteotomy			0.34	0.570
Yes	3	0.0 ± 0.0 (0-0)		
No	94	5.0 ± 9.6 (60-0)		
Previous synovectomy			1.53	0.235
Yes	15	11.0 ± 18.3 (60-0)		
No	82	3.7 ± 6.3 (25-0)		
Previous arthrotomy			0.51	0.486
Yes	13	1.9 ± 4.8 (15-0)		
No	84	5.3 ± 9.9 (60-0)		
PE exchange			4.07	0.062
Yes	22	1.1 ± 2.6 (10-0)		
No	75	5.9 ± 10.4 (60-0)		
Body weight	79		1.74	0.207
Age at the time of surgery	97		4.99	**0.041**
Time of follow-up	97		0.41	0.522

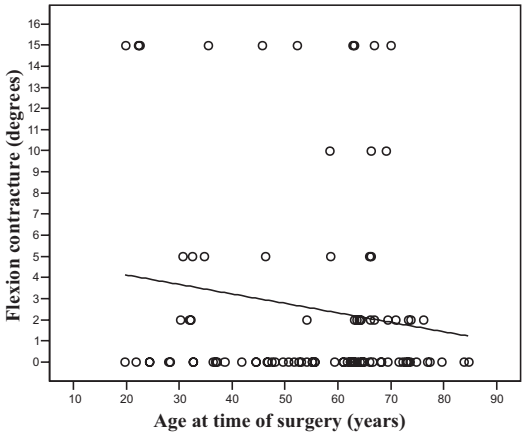

Figure 4.12. *Flexion contractures at Tc and age at the time of surgery. Patients who were younger at the time of surgery had significantly more flexion contractures.*

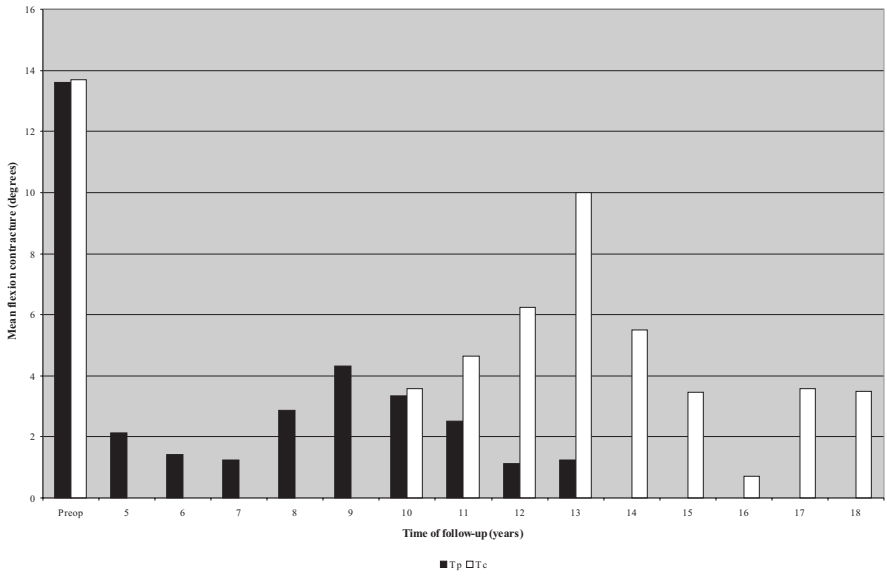

Figure 4.13. *Flexion contractures and time of follow-up. Within the group of patients seen at Tp and at Tc, no significant increase in flexion contracture was seen in time. The mean flexion contracture at follow-up remained below the mean flexion contracture preoperatively in both patient groups.*

4.3.4 Stability and alignment

In the group of patients seen at Tp, the mean score for stability in anteroposterior (AP) direction was 7.6 points ± 2.9 preoperatively and 8.2 points ± 2.9 at follow-up. In the group of patients seen at Tc, the mean score for stability in AP direction was 7.8 points ± 3.0 preoperatively and 8.5 points ± 2.9 at follow-up. In the group of patients seen at Tp, the improvement in stability in AP direction at follow-up compared to the stability pre-operatively was significant (paired samples t-test, p=0.037), in the group of patients seen at Tc this was not significant (p=0.096) (see Table 4.21).

In the group of patients seen at Tp, the mean score for stability in mediolateral (ML) direction was 9.9 points ± 4.3 preoperatively and 12.7 points ± 3.6 at follow-up. In the group of patients seen at Tc, the mean score for stability in ML direction was 10.1 points ± 4.5 preoperatively and 11.9 points ± 4.2 at follow-up. In both groups of patients seen at Tp and at Tc, the improvement in stability in ML direction at follow-up compared to the ML stability preoperatively was significant (paired samples t-test, p<0.001 and p=0.005 respectively) (see Table 4.22).

Table 4.21. Stability score in anteroposterior (AP) direction preoperatively and at follow-up. In the group of patients seen at Tp, the improvement in AP stability at follow-up was significant compared to the AP stability preoperatively.

	n	Stability score AP (points) mean ± sd (min-max) preoperatively	Stability score AP (points) mean ± sd (min-max) at follow-up	p-value[1]
All patients	327	7.7 ± 3.1 (0-10)		
Patients seen at Tp	194	7.6 ± 2.9 (0-10)	8.2 ± 2.9 (0-10)	**0.037**
Patients seen at Tc	97	7.8 ± 3.0 (0-10)	8.5 ± 2.9 (0-10)	0.096

[1] *Paired samples t-test*

Table 4.22. Stability Score in mediolateral (ML) direction preoperatively and at follow-up. In both groups of patients seen at Tp and at Tc, the improvement in ML stability at follow-up was significant compared to the ML stability preoperatively.

	n	Stability score ML (points) mean ± sd (min-max) preoperatively	Stability score ML (points) mean ± sd (min-max) at follow-up	p-value[1]
All patients	327	9.9 ± 4.6 (0-15)		
Patients seen at Tp	194	9.9 ± 4.3 (0-15)	12.7 ± 3.6 (0-15)	**<0.001**
Patients seen at Tc	97	10.1 ± 4.5 (0-15)	11.9 ± 4.2 (0-15)	**0.005**

[1] *Paired samples t-test*

In the group of patients seen at Tp, the mean score for alignment was 11.6 points ± 9.2 preoperatively and 1.9 points ± 5.6 at follow-up. In the group of patients seen at Tc, the mean score for alignment was 10.3 points ± 3.9 preoperatively and 3.9 points ± 7.0 at follow-up. In both groups of patients seen at Tp and at Tc, the improvement in alignment at follow-up compared to the alignment preoperatively was significant (paired samples t-test, $p<0.001$) (see Table 4.23).

4.3.5 Function Score

The mean Function Score of all patients seen at Tp was 20.8 points ± 18.8 preoperatively and 36.2 points ± 30.0 at follow-up. The mean Function Score of all patients seen at Tc was 22.1 points ± 20.6 preoperatively and 37.8 points ± 31.6 at follow-up. The improvement of the Function Score at follow-up compared with the Function Score preoperatively was significant in both follow-up studies (paired samples t-test, $p<0.001$) (see Table 4.24).

Table 4.23. Alignment score preoperatively and at follow-up. Both at Tp and at Tc the alignment had improved significantly compared to the alignment preoperatively.

	n	Alignment score (points) mean ± sd (min-max) preoperatively	Alignment score (points) mean ± sd (min-max) at follow-up	p-value[1]
All patients	327	10.9 ± 9.4 (0-20)		
Patients seen at Tp	194	11.6 ± 9.2 (0-20)	1.9 ± 5.6 (0-20)	**<0.001**
Patients seen at Tc	97	10.3 ± 9.4 (0-20)	3.9 ± 7.0 (0-20)	**<0.001**

[1] Paired samples t-test

Table 4.24. Function Score preoperatively and at follow-up. At Tp as well as at Tc, the Function Score had improved significantly compared to the Function Score preoperatively.

	n	Function Score (points) mean ± sd (min-max) preoperatively	Function Score (points) mean ± sd (min-max) at follow-up	p-value[1]
All patients	327	19.3 ± 18.5 (0-85)		
Patients seen at Tp	194	20.8 ± 18.8 (0-85)	36.2 ± 30.0 (0-90)	**<0.001**
Patients seen at Tc	97	22.1 ± 20.6 (0-85)	37.8 ± 31.6 (0-100)	**<0.001**

[1] Paired samples t-test

In the group of patients seen at Tp, patients who had had a synovectomy before total knee replacement had a higher Function Score on average compared to patients who had not, but the difference was not significant. Body weight did not have a significant influence on the Function Score.

In a univariate analysis of variance for each factor separately, female patients had significantly lower Function Scores compared to male patients (F=9.73, p=0.002) and patients who had had a high tibial osteotomy or an arthrotomy before total knee replacement had a significantly higher Function Score compared to patients who had not (F=7.98, p=0.005 and F=7.85, p=0.006 respectively). These factors were not significant anymore in an analysis corrected for all factors that may have an influence on the Function Score.

Corrected for all factors, patients with rheumatoid arthritis and patients in categories B (symptomatic contralateral knee) and C (multiple joint involvement) had significantly lower Function Scores compared

to patients with degenerative arthritis and patients in category A (unilateral involvement of the knee or successful replacement of the contralateral knee). Younger patients and patients with other diagnoses had significantly higher Function Scores compared to patients with degenerative arthritis (see Figure 4.14). The Function Score decreased significantly with a longer time of follow-up (see Table 4.25 and Figure 4.15).

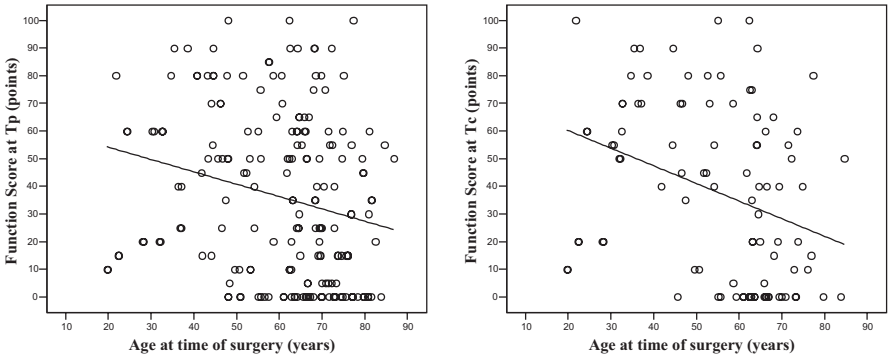

Figure 4.14. *Function Score and age at the time of surgery at Tp (left) and at Tc (right). Both at Tp and at Tc, patients who were younger at the time of surgery had a significantly higher Function Score compared to older patients.*

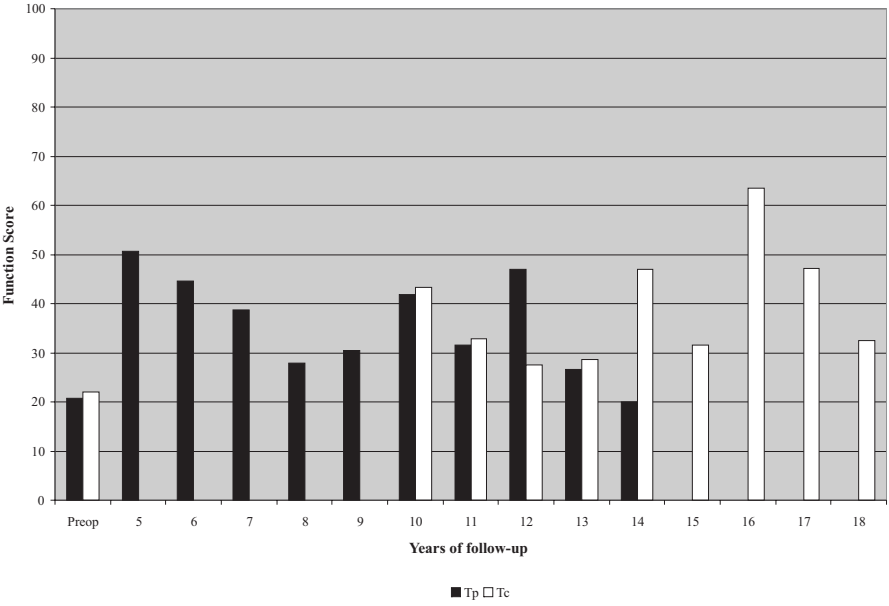

Figure 4.15. *Function Score and time of follow-up. In the group of patients seen at Tp, patients with a longer time of follow-up had a significant decrease in Function Score (Multilevel regression analysis, F=6.22, p=0.017). In the group of patients seen at Tc, no significant deterioration in Function Score was seen (Multilevel regression analysis, F=0.00, p=0.998).*

Table 4.25. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the Function Score in the group of patients seen in the first follow-up study at Tp (n=194 knees, 146 patients). Patients with rheumatoid arthritis and patients in categories B and C had significantly lower Function Scores compared to patients with degenerative arthritis and patients in category A. Younger patients and patients with other diagnoses had significantly higher Function Scores compared to patients with degenerative arthritis. The Function Score decreased significantly with a longer time of follow-up.

Factors that may have an influence on the Function Score	**n**	**Function Score at Tp mean ± sd (min-max)**	**F-value**	**p-value**
Sex			0.48	0.491
Male	28	50.4 ± 33.3 (0-100)		
Female	118	33.2 ± 28.4 (0-100)		
Diagnosis				
Degenerative arthritis	62	37.6 ± 29.7 (0-100)		
Rheumatoid arthritis	64	29.2 ± 28.0 (0-100)	5.52	**0.023**
Other	20	63.8 ± 23.6 (0-90)	5.05	**0.030**
Category			8.33	**0.004**
A	21	60.9 ± 31.1 (0-100)		
B	4	44.2 ± 33.7 (0-90)		
C	116	31.8 ± 28.2 (0-90)		
Unknown	5	42.9 ± 28.5 (5-85)		
Previous high tibial osteotomy			0.97	0.330
Yes	8	65.0 ± 21.5 (20-90)		
No	186	35.0 ± 29.7 (0-100)		
Previous synovectomy			0.23	0.633
Yes	18	41.1 ± 27.9 (0-100)		
No	176	35.7 ± 30.2 (0-100)		
Previous arthrotomy			0.69	0.412
Yes	25	51.6 ± 30.1 (0-90)		
No	169	33.9 ± 29.4 (0-100)		
Body weight	146		0.12	0.730
Age at the time of surgery	194		15.21	**<0.001**
Time of follow-up	194		6.22	**0.017**

In the group of patients seen at Tc, male patients, patients with other diagnoses and patients in category A had a higher Function Score on average compared to female patients, patients with degenerative arthritis and rheumatoid arthritis and patients in categories B and C, but the differences were not significant. Previous high tibial osteotomy or synovectomy, body weight and time of follow-up did not have a significant influence on the Function Score in the group of patients seen at Tc (see Figure 4.15).

In a univariate analysis of variance for each factor separately, patients who had had an arthrotomy before total knee replacement, patients who had had a PE exchange and younger patients had a significantly higher Function Score compared to patients who had not had an arthrotomy or a PE exchange and older patients (F=9.179, p=0.003, F=7.872, p=0.006 and F=11.77, p=0.001 respectively).

Corrected for all factors that may have an influence on the Function Score in a multilevel regression analysis, only age at the time of surgery had a significant influence on the Function Score (see Table 4.26 and Figure 4.14).

Table 4.26. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the Function Score in the group of patients seen in the second follow-up study at Tc (n= 97 knees, 79 patients). Younger patients had significantly higher Function Scores.

Factors that may have an influence on the Function Score	**n**	**Function Score at Tc mean ± sd (min-max)**	**F-value**	**p-value**
Sex			0.15	0.704
Male	13	52.3 ± 34.9 (0-100)		
Female	66	35.1 ± 30.5 (0-100)		
Diagnosis				
Degenerative arthritis	33	32.7 ± 30.3 (0-100)		
Rheumatoid arthritis	34	35.1 ± 30.8 (0-100)	0.21	0.655
Other	12	63.8 ± 28.6 (0-100)	2.94	0.107
Category			0.86	0.357
A	14	54.3 ± 43.2 (0-100)		
B	3	16.0 ± 25.3 (0-60)		
C	62	36.2 ± 28.6 (0-90)		
Previous high tibial osteotomy			0.03	0.866
Yes	3	51.7 ± 46.5 (0-90)		
No	94	37.3 ± 31.3 (0-100)		
Previous synovectomy			0.65	0.431
Yes	15	48.7 ± 23.2 (20-90)		
No	82	35.8 ± 32.7 (0-100)		
Previous arthrotomy			1.19	0.292
Yes	13	61.5 ± 24.2 (0-90)		
No	84	34.1 ± 31.2 (0-100)		
PE exchange			0.59	0.454
Yes	22	53.9 ± 33.8 (0-100)		
No	75	33.1 ± 29.6 (0-100)		
Body weight	79		0.16	0.691
Age at the time of surgery	97		5.83	**0.029**
Time of follow-up	97		0.00	0.998

4.3.6 Total Score

The mean Total Score of all patients seen at Tp was 46.9 points ± 26.1 preoperatively and 114.8 points ± 35.6 at follow-up. The mean Total Score of all patients seen at Tc was 49.6 points ± 26.8 preoperatively and 107.5 points ± 41.8 at follow-up. Both at Tp and at Tc, the improvement in Total Score at follow-up compared with the Total Score preoperatively was significant (paired samples t-test, p<0.001) (see Table 4.27).

Table 4.27. Total Score preoperatively and at follow-up. Both at Tp and at Tc, the improvement of the Total Score at follow-up compared to the Total Score preoperatively was significant.

	n	Total Score (points) mean ± sd (min-max) preoperatively	Total Score (points) mean ± sd (min-max) at follow-up	p-value[1]
All patients	327	46.0 ± 26.7 (0-132)		
Patients seen at Tp	194	46.9 ± 26.1 (0-132)	114.8 ± 35.6 (33-197)	**<0.001**
Patients seen at Tc	97	49.6 ± 26.8 (0-132)	107.5 ± 41.8 (25-197)	**<0.001**

[1] *Paired samples t-test*

In the group of patients seen at Tp, high tibial osteotomy, synovectomy or arthrotomy before total knee replacement, body weight, age at the time of surgery and time of follow-up did not have a significant influence on the Total Score

In a univariate analysis of variance for each factor separately, male patients and patients with degenerative arthritis and other diagnoses had a significantly higher Total Score compared to female patients and patients with rheumatoid arthritis (F=4.60, p=0.033 and F=6.70, p=0.002 respectively).

Corrected for all factors that may have an influence on the Total Score in a multilevel regression analysis, none of the factors had a significant influence (see Table 4.28).

In the group of patients seen at Tc, the Total Score in male patients and patients with other diagnoses was higher compared to female patients and patients with degenerative arthritis and rheumatoid arthritis, but the differences were not significant. High tibial osteotomy, synovectomy or arthrotomy before total knee replacement, PE exchange, body weight, age at the time of surgery and time of follow-up did not have a significant influence on the Total Score in the group of patients seen at Tc (see Table 4.29).

Table 4.28. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the Total Score in the group of patients seen in the first follow-up study at Tp (n=194 knees, 146 patients). None of the factors had a significant influence on the Total Score.

Factors that may have an influence on the Total Score	n	Total Score at Tp mean ± sd (min-max)	F-value	p-value
Sex			0.26	0.612
Male	28	126.6 ± 39.3 (45-189)		
Female	118	112.3 ± 34.4 (33-197)		
Diagnosis				
Degenerative arthritis	62	118.8 ± 35.1 (38-197)		
Rheumatoid arthritis	64	107.2 ± 35.2 (33-193)	3.87	0.055
Other	20	135.8 ± 30.0 (69-183)	1.00	0.322
Previous high tibial osteotomy			0.57	0.454
Yes	8	142.8 ± 25.1 (85-166)		
No	186	113.6 ± 35.6 (33-197)		
Previous synovectomy			0.58	0.449
Yes	18	112.5 ± 37.1 (59-193)		
No	176	115.0 ± 35.6 (33-197)		
Previous arthrotomy			0.59	0.448
Yes	25	126.5 ± 35.9 (45-180)		
No	169	113.0 ± 35.4 (33-197)		
Body weight	146		0.11	0.739
Age at the time of surgery	194		3.72	0.060
Time of follow-up	194		1.85	0.181

Table 4.29. Multilevel regression analysis with the test statistic F-value and p-value of the factors that may have an influence on the Total Score in the group of patients seen in the second follow-up study at Tc (n= 97 knees, 79 patients). None of the factors had a significant influence on the Total Score.

Factors that may have an influence on the Total Score	n	Total Score at Tc mean ± sd (min-max)	F-value	p-value
Sex			0.26	0.618
Male	13	126.5 ± 45.0 (38-197)		
Female	66	104.0 ± 40.5 (25-186)		
Diagnosis				
Degenerative arthritis	33	104.4 ± 41.4 (25-183)		
Rheumatoid arthritis	34	102.7 ± 40.4 (27-186)	0.71	0.412
Other	12	136.3 ± 40.2 (53-197)	1.85	0.194
Previous high tibial osteotomy			0.43	0.520
Yes	3	107.3 ± 60.9 (38-152)		
No	94	107.5 ± 41.5 (25-197)		
Previous synovectomy			0.11	0.741
Yes	15	113.5 ± 35.4 (48-155)		
No	82	106.4 ± 42.9 (25-197)		
Previous arthrotomy			0.16	0.698
Yes	13	128.2 ± 36.7 (53-175)		
No	84	104.3 ± 41.8 (25-197)		
PE exchange			0.16	0.691
Yes	22	126.6 ± 46.4 (25-197)		
No	75	101.9 ± 38.9 (27-186)		
Body weight	79		0.17	0.689
Age at the time of surgery	97		3.38	0.086
Time of follow-up	97		0.02	0.882

Analyzing the Total Score in time in the first and second follow-up studies separately shows no significant deterioration in Total Score with a longer time of follow-up within each group of patients. The Total Score at follow-up remained higher than the preoperative Total Score (see Figure 4.16).

4.3.7 Scores in patients with degenerative arthritis and rheumatoid arthritis

The preoperative Scores and the Scores at follow-up of all patients with degenerative arthritis and rheumatoid arthritis seen in the first and second follow-up study are listed in Tables 4.30 and 4.31. In the group

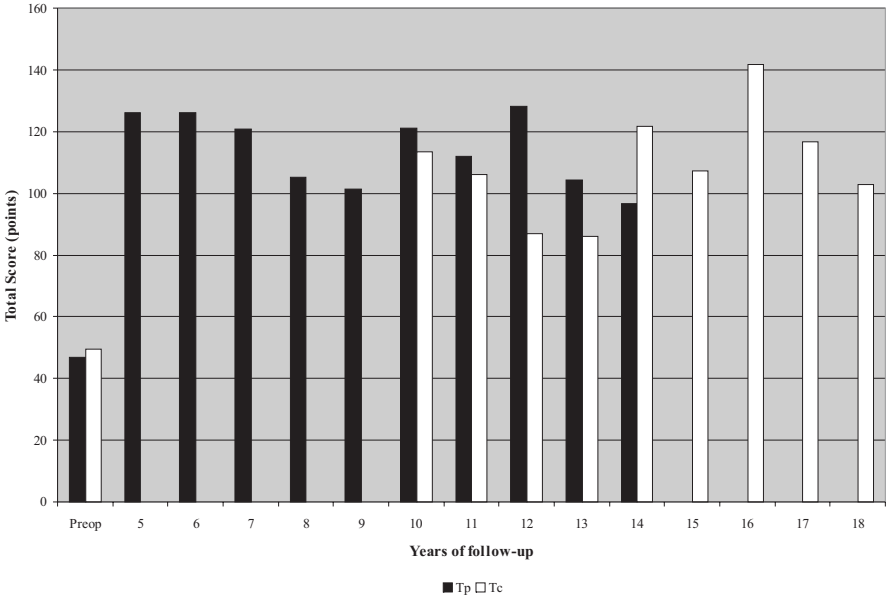

Figure 4.16. *Total Score and time of follow-up. In both the first and second follow-up studies, no significant deterioration in Total Score was seen in the course of time. At follow-up the Total Score remained higher than the preoperative Total Score.*

of patients seen in the first follow-up study at Tp, patients with degenerative arthritis had a significantly better range of motion, flexion, AP stability, Function Score and Total Score, and significantly less flexion contractures preoperatively compared to patients with rheumatoid arthritis. Patients with rheumatoid arthritis had a significantly better alignment preoperatively. At follow-up, patients with degenerative arthritis had a significantly better Total Score and significantly less anterior knee pain. All other Scores were comparable.

In the group of patients seen in the second follow-up study at Tc, patients with degenerative arthritis had a significantly better range of motion, Function Score and Total Score, and significantly less flexion contractures preoperatively compared to patients with rheumatoid arthritis. Patients with rheumatoid arthritis had a significantly better alignment preoperatively.

At follow-up, patients with degenerative arthritis had significantly less flexion contractures and a significantly better AP stability compared to patients with rheumatoid arthritis. All other Scores were comparable.

Table 4.30. Differences in preoperative scores and scores at follow up of all patients with degenerative arthritis and rheumatoid arthritis seen in the first follow-up study at Tp. Preoperatively, patients with degenerative arthritis had a significantly better range of motion, flexion, AP stability, Function Score and Total Score, and significantly less flexion contractures; patients with rheumatoid arthritis had a significantly better alignment. At Tp, patients with degenerative arthritis had a significantly better Total Score and significantly less anterior knee pain compared to patients with rheumatoid arthritis.

PREOPERATIVE SCORE (MEAN ± SD (MIN-MAX))				
	Degenerative arthritis *(n=75)*	**Rheumatoid arthritis** *(n=98)*	**p-value[1]**	
Knee Score	27.2 ± 15.6 (0-70)	25.1 ± 15.7 (0-65)	0.395	
Pain Score	10.9 ± 7.6 (0-30)	11.9 ± 9.4 (0-30)	0.436	
Range of motion (°)	92.7 ± 20.0 (40-130)	77.5 ± 29.6 (0-135)	**<0.001**	
Flexion (°)	101.9 ± 16.5 (45-140)	94.7 ± 21.7 (15-135)	**0.018**	
Flexion contracture (°)	9.3 ± 9.3 (-30-0)	17.2 ± 14.2 (-90-0)	**<0.001**	
Stability AP	8.2 ± 2.4 (5-10)	7.1 ± 3.1 (0-10)	**0.009**	
Stability ML	9.5 ± 4.5 (0-15)	10.3 ± 4.4 (0-15)	0.291	
Alignment Score	14.2 ± 8.4 (0-20)	9.4 ± 9.3 (0-20)	**0.001**	
Function Score	23.6 ± 16.3 (0-70)	14.8 ± 16.1 (0-60)	**0.001**	
Total Score	50.8 ± 26.1 (5-123)	39.9 ± 23.3 (0-120)	**0.005**	
SCORE AT FOLLOW-UP (TP) (MEAN ± SD (MIN-MAX))				
	Degenerative arthritis *(n=75)*	**Rheumatoid arthritis** *(n=98)*	**p-value[1]**	**p-value[2]**
Knee Score	81.2 ± 13.8 (38-100)	78.0 ± 16.5 (23-100)	0.175	
Pain Score	43.2 ± 9.9 (10-50)	41.6 ± 10.7 (10-50)	0.310	
VAS Score	1.8 ± 2.1 (0-9)	1.6 ± 1.7 (0-8)	0.367	
Range of motion **(°)**	96.0 ± 20.3 (40-125)	93.7 ± 24.4 (0-125)	0.505	
Flexion **(°)**	97.7 ± 19.2 (45-125)	96.2 ± 22.5 (0-135)	0.631	
Flexion contracture **(°)**	1.7 ± 5.8 (-30-0)	2.5 ± 7.5 (-45-0)	0.464	
Stability AP	8.3 ± 2.7 (0-10)	8.4 ± 2.6 (0-10)	0.710	
Stability ML	12.7 ± 3.6 (0-15)	13.0 ± 3.4 (0-15)	0.675	
Alignment	1.3 ± 4.8 (0-20)	1.6 ± 5.2 (0-20)	0.713	
Function Score	37.6 ± 29.7 (0-100)	29.2 ± 28.0 (0-100)	0.058	
Total Score	118.8 ± 35.1 (38-197)	107.2 ± 35.2 (33-193)	**0.033**	
Anterior knee pain	6.7%	20.4%		**0.015**

[1] Independent samples t-test [2] Logistic regression analysis

Table 4.31. Differences in preoperative scores and scores at follow up of all patients with degenerative arthritis and rheumatoid arthritis seen in the second follow-up study at Tc. Preoperatively patients with degenerative arthritis had a significantly better range of motion, Function- and Total Score and significantly less flexion contractures and patients with rheumatoid arthritis had a significantly better alignment. At Tc, patients with degenerative arthritis had significantly better AP stability and significantly less flexion contractures compared to patients with rheumatoid arthritis.

PREOPERATIVE SCORE (MEAN ± SD (MIN-MAX))				
	Degenerative arthritis *(n=34)*	**Rheumatoid arthritis** *(n=51)*	**p-value[1]**	
Knee Score	30.7 ± 16.7 (1-64)	25.9 ± 15.9 (0-60)	0.192	
Pain Score AKSS	11.2 ± 8.8 (0-30)	11.2 ± 9.1 (0-30)	1.000	
Range of motion (°)	94.1 ± 21.0 (40-130)	77.3 ± 33.6 (0-135)	**0.006**	
Flexion **(°)**	102.4 ± 18.0 (45-13)	94.7 ± 25.1 (15-135)	0.129	
Flexion contracture (°)	8.2 ± 8.6 (-30-0)	17.5 ± 16.4 (-90-0)	**0.001**	
Stability AP	8.4 ± 2.4 (5-10)	7.4 ± 3.4 (0-10)	0.102	
Stability ML	10.3 ± 4.6 (0-15)	10.1 ± 4.6 (0-15)	0.196	
Alignment Score	13.0 ± 8.9 (0-20)	8.3 ± 9.2 (0-20)	**0.023**	
Function Score	26.8 ± 16.7 (0-70)	15.3 ± 18.0 (0-60)	**0.004**	
Total Score	57.4 ± 26.5 (20-123)	41.2 ± 23.3 (0-100)	**0.004**	
SCORE AT FOLLOW-UP (TC) (MEAN ± SD (MIN-MAX))				
	Degenerative arthritis *(n=34)*	**Rheumatoid arthritis** *(n=51)*	**p-value[1]**	**p-value[2]**
Knee Score	71.8 ± 18.7 (25-95)	67.6 ± 19.1 (23-96)	0.325	
Pain Score AKSS	37.2 ± 15.9 (0-50)	39.8 ± 13.0 (0-50)	0.412	
VAS Score	3.4 ± 3.1 (0-10)	2.7 ± 2.5 (0-10)	0.257	
Range of motion **(°)**	91.5 ± 20.8 (20-125)	81.3 ± 28.4 (0-120)	0.059	
Flexion **(°)**	94.1 ± 17.7 (40-125)	87.8 ± 24.0 (0-120)	0.188	
Flexion contracture (°)	2.7 ± 5.5 (-20-0)	6.7 ± 11.5 (-60-0)	**0.044**	
Stability AP	9.3 ± 2.5 (0-15)	7.8 ± 3.4 (0-10)	**0.028**	
Stability ML	11.9 ± 3.9 (0-15)	11.6 ± 4.5 (0-15)	0.719	
Alignment	3.0 ± 6.3 (0-20)	4.1 ± 7.0 (0-20)	0.450	
Function Score	32.7 ± 30.3 (0-100)	35.1 ± 30.8 (0-100)	0.719	
Total Score	104.4 ± 41.4 (25-183)	102.7 ± 40.4 (27-186)	0.851	
Anterior knee pain	26.5%	21.6%		0.602

[1] Independent samples t-test [2] Logistic regression analysis

4.3.8 Scores before and after polyethylene exchange

An exchange of the polyethylene insert was performed if significant wear was seen radiographically in prostheses that had no clinical or radiographic signs of loosening. After a PE exchange, no significant change in Knee Score, Pain Score, VAS Score, range of motion, flexion, extension, anteroposterior and mediolateral stability, alignment, Function Score or Total Score was seen compared with the scores before exchange (see Table 4.32).

Table 4.32. Clinical performance of the SKI prosthesis before and after exchange of the polyethylene insert. No significant changes were seen after a PE exchange.

	Before PE Exchange *(n=19)*	**After PE Exchange** *(n=19)*	**p-value[1]**	**p-value[2]**
Knee Score	74.8 ± 15.9 (43-97)	73.5 ± 18.2 (25-97)	0.790	
Pain Score AKSS	39.5 ± 10.4 (20-50)	38.7 ± 13.2 (10-50)	0.793	
VAS Score for pain	2.4 ± 2.3 (0-7)	3.5 ± 2.7 (0-8)	0.185	
Range of motion **(°)**	100.8 ± 19.2 (60-135)	98.9 ± 18.0 (60-125)	0.590	
Flexion **(°)**	100.8 ± 19.2 (60-135)	100.0 ± 17.5 (60-125)	0.804	
Flexion contracture **(°)**	0 ± 0 (0-0)	1.1 ± 2.7 (-10-0)	0.104	
Stability AP	7.6 ± 3.1 (0-10)	8.2 ± 3.4 (0-10)	0.542	
Stability ML	11.6 ± 4.1 (5-15)	11.8 ± 4.2 (0-15)	0.853	
Alignment	3.2 ± 7.5 (0-20)	4.4 ± 7.0 (0-20)	0.408	
Function Score	57.1 ± 26.6 (15-100)	55.5 ± 33.6 (0-100)	0.820	
Total Score	131.9 ± 39.3 (58-197)	129.1 ± 44.0 (25-197)	0.776	
Anterior knee pain	26.3%	21.1%		0.705

[1] Paired samples t-test [2] Cochran's Q-test

Analyzing the Knee Score in time before and after a PE exchange shows a slight decrease in Knee Score before the exchange, but the deterioration is not significant (ANOVA, p=0.329). No deterioration of the Knee Score in the course of time was seen after the PE exchange, even after five years of follow-up (ANOVA, p=0.929) (see Figure 4.17).

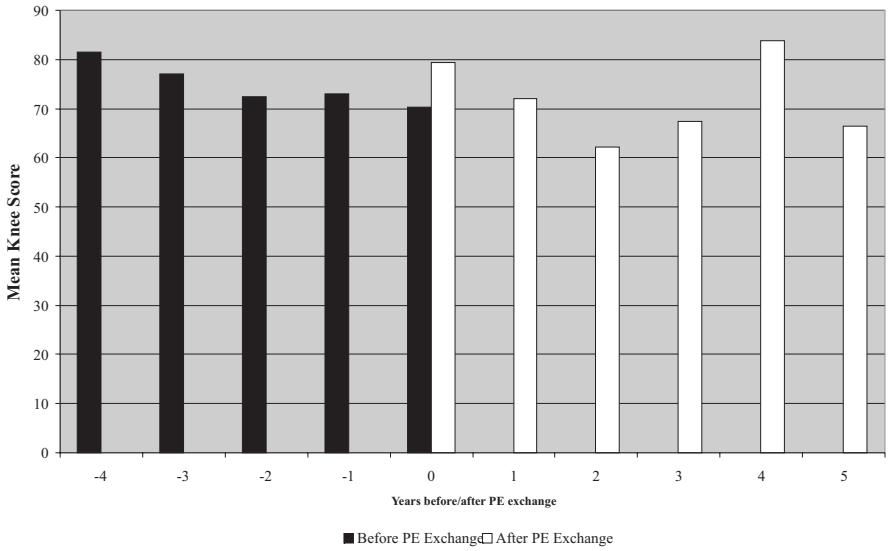

Figure 4.17. *Knee Score before and after PE exchange. A slight decrease in the Knee Score is seen before PE exchange, but the deterioration was not significant (ANOVA, p=0.329). No deterioration in the Knee Score was seen after PE exchange (ANOVA, p=0.929).*

4.4 DISCUSSION

If the results of the first follow-up study at Tp are compared with the results of the second follow-up study at Tc, there seems to be a deterioration in clinical performance in time. Patients seen at Tc had a lower Knee Score and Total Score, a smaller range of motion, an increase in pain on the VAS Score and more flexion contractures compared to the patients seen at Tp. However, these results cannot be compared, because of two reasons:

1. The patients seen in the second follow-up study (Group III) were younger at the time of surgery, they had had more previous surgery, and there were relatively more patients with degenerative arthritis compared to the group of patients who were only seen in the first follow-up study (Group II) (see Appendix 2). Analysis of the results of the group of patients seen in the second follow-up study (Group III), when seen at Tp, showed that these patients already had a significantly lower Knee Score and Pain Score, significantly less range of motion and flexion, and a significantly higher VAS Score for pain at Tp compared to the patients who were only seen in the first follow-up study (Group II-A). The patients in Group III also had a signifi-

cantly higher Function Score at Tp compared to the patients in Group II-A (see Table 4.33). Therefore, the group of patients who were seen in the second follow-up study can be considered a selection of patients who already had a worse clinical performance but a higher Function Score at the first follow-up study.

2. The patients were seen by two different observers at two separate moments. Liow et al. [140] found a high inter-observer variation in the Knee Score of the American Knee Society Score. They stated that if two different observers saw a patient at two visits, a change was real if it exceeded 22 points. However, they included nurses and inexperienced observers in their study. If they were excluded from this study, the inter-observer agreement was fair to moderate.In our study, the interobserver variation of the two investigators was not known. Because time of follow-up and interobserver variation could not be separated in this study, it was not possible to ascribe the deterioration in clinical performance to interobserver variation or to a deterioration of the clinical performance in time.

Table 4.33. Mean scores at Tp of the group of patients only seen in the first follow-up study (Group II-A) and the patients seen at both follow-up studies (Group III). The patients in Group III already had significantly lower Knee Scores and Pain Scores, significantly less range of motion and flexion, and a significantly higher VAS Score for pain at Tp compared to the patients in Group II-A. The patients in Group III also had a significantly higher Function Score at Tp compared to the patients in Group II-A.

	SCORE AT Tp (MEAN ± SD (MIN-MAX))			
	Patients only seen at Tp (Group II-A) (n=97)	**Patients seen at Tp and Tc (Group III) (n=97)**	**p-value[1]**	**p-value[2]**
Knee Score	82.6 ± 12.2 (45-100)	74.6 ± 17.3 (23-99)	**< 0.001**	
Pain Score AKSS	44.5 ± 8.4 (10-50)	39.9 ± 11.6 (10-50)	**0.002**	
Range of motion (°)	99.2 ± 17.9 (45-125)	90.4 ± 25.8 (0-135)	**0.006**	
Flexion (°)	101.4 ± 16.3 (45-135)	92.6 ± 23.8 (0-135)	**0.003**	
Flexion contracture (°)	2.2 ± 6.3 (30-0)	2.2 ± 6.9 (45-0)	0.957	
Function Score	31.0 ± 30.1 (0-90)	41.3 ± 29.2 (0-100)	**0.016**	
Total Score	113.6 ± 33.4 (45-180)	115.9 ± 37.9 (33-197)	0.656	
VAS Score for pain	1.3 ± 1.4 (0-5)	2.1 ± 2.3 (0-9)	**0.001**	
Anterior knee pain	13 (13.4%)	19 (19.6%)		0.248

[1] Independent samples t-test [2] Logistic regression analysis

Analyzing the results in the course of time within the group of patients seen at Tp and at Tc, we only found a significant deterioration of the Function Score in time in the group of patients seen at Tp. This might be caused by ageing of the patients. All other scores showed no significant deterioration in time. All scores were significantly higher at follow-up compared with the preoperative scores, except for the flexion in the group of patients seen at Tp and the range of motion and AP stability in the group of patients seen at Tc.

In this study a univariate analysis of variance and a logistic regression analysis was performed for each factor separately. We also performed a multilevel analysis to correct for the influence of all factors together and to correct for patient factors and knee factors. Several factors that seemed significant in the first analyses turned out to be not significant in the multilevel analyses. This means that the clinical performance of a knee prosthesis is dependent on many different factors, which must be taken into account when analyzing the long-term outcome.

Some authors stated that male patients benefit more from total knee arthroplasty than female patients [145-147]. In the Swedish Knee Arthroplasty Register, men had a higher revision rate than women [148;149]. In our study, male patients had a higher Function Score and Total Score, but in a multilevel regression analysis the difference was not significant. Comparing the clinical performance of the SKI prosthesis in male and female patients shows no significant differences in this study. The differences may have not been detected because there were proportionately more women than men (80.8% of the patients was female at Tp and 83.5% at Tc).

Joint replacement in patients with rheumatoid arthritis is often thought to provide better long-term durability when compared with joint replacement in patients with degenerative arthritis because of the low demand status of patients with rheumatoid arthritis. This is supported by the long-term functional scores documented for these patients when compared with the scores in patients with degenerative arthritis [150-152]. Other authors reported that patients with degenerative arthritis did better than those with rheumatoid arthritis [153;154]. Nafei et al. [155] reported a 97% survivorship of total knee arthroplasty in patients with degenerative arthritis versus a 87% survivorship at 12 years for patients with rheumatoid arthritis. Several authors [156-158] claim no difference exists. In Chapter 3 we found no significant difference in revision rate between patients with rheumatoid arthritis and patients with degenerative arthritis. Comparison of the clinical performance of the SKI prosthesis in patients with rheumatoid arthritis and degenerative arthritis showed that patients with degenerative arthritis seen in the first follow-up study

had significantly less anterior knee pain and a significantly higher Function Score at follow-up. These differences were not seen in the second follow-up study. Preoperatively, patients with rheumatoid arthritis had a significantly smaller range of motion, significantly less flexion, significantly more flexion contractures and significantly lower Function Score and Total Score in both follow-up studies. At follow-up the outcome in patients with rheumatoid arthritis and degenerative arthritis was comparable, although patients with rheumatoid arthritis complained of anterior knee pain more frequently. We have no explanation for the higher amount of anterior knee pain in patients with rheumatoid arthritis. As the preoperative scores in patients with rheumatoid arthritis were significantly worse compared to patients with degenerative arthritis, patients with rheumatoid arthritis benefit more from total knee replacement compared to patients with degenerative arthritis.

Several authors have studied the results of total knee arthroplasty after previous high tibial osteotomy with different results. Total knee replacement after high tibial osteotomy may be technically difficult, because the knee may be tight, the patellar tendon may be short and access to the lateral compartment may be difficult [159-162]. Rotation and inclination of the tibial plateau may be confusing [162;163]. There may be bone loss or overcorrection [164;165], and a quadricepsplasty or other extended exposures may be necessary [166-169]. Some authors report inferior results in patients who have undergone previous high tibial osteotomy [160-162]. Other authors report similar results after total knee replacement with or without a previous high tibial osteotomy [163;170-172]. In our study we found no significant difference between patients who had had a high tibial osteotomy before total knee replacement and patients who had not.

Nelissen [173] found a worse range of motion and a higher percentage of early complications in total knee arthroplasty after synovectomy. In our study, patients who had had a synovectomy prior to total knee replacement had a worse Knee Score on average, more anterior knee pain and more flexion contractures in the first follow-up study. However, in a multilevel regression and a multilevel logistic regression analysis none of these differences appeared to be significant.

An arthrotomy performed before total knee replacement may induce scar tissue formation and consequently cause more complications. In our study, an arthrotomy (excluding a synovectomy) performed before total knee replacement had no significant influence on the clinical performance of the SKI prosthesis at follow-up.

Increased body weight may induce wear, and wear may cause aseptic loosening of the prosthesis (see Chapter 3). Deshmuck et al. [174] and Stickles et al. [175] showed no substantial influence of body weight on short-term outcome. In our study, patients with increased body weight seemed to have more pain on a VAS score, but corrected for all factors we found no significant influence of body weight on the clinical performance of the SKI prosthesis.

Short- to intermediate-term results in patients 55 years or younger have been reported to be in the good-to-excellent range in 98 to 100% of total knee replacements [110;176-178]. Promising results for total knee arthroplasty in young patients were found by other authors [179-181], but this may also be associated with many problems, including patello-femoral symptoms, polyethylene wear and aseptic loosening of the prosthesis in young active individuals [182;183]. In our first follow-up study, younger patients with a SKI prosthesis had significantly lower Knee Scores, and significantly less range of motion and flexion. A multilevel regression analysis showed no significant influence of the diagnosis on the clinical performance. Consequently, the worse clinical performance in younger patients could not be attributed to the higher amount of patients with rheumatoid arthritis in this group of patients. We also found that younger patients had a significantly better Function Score at follow-up. In Chapter 3 we already found that younger patients and patients with a higher activity level had significantly more wear. We also found that wear contributed to aseptic loosening. Younger patients not only have a higher risk of aseptic loosening due to increased activity level which may cause more wear, they also have a worse clinical performance.

In this study no significant difference was found between patients who had had a PE exchange and patients who had the original PE insert in situ. Patients who had had a PE exchange seemed to have a higher Function Score, but corrected for all other factors the difference was not significant. No significant difference in clinical performance was found before and after a PE exchange, except for an increase in anterior knee pain after a PE exchange. We have no explanation for this. However, these latter results must be interpreted with caution, because they were obtained by two different observers and there may be an interobserver variation. Babis et al. [117] found a high rate of early failure after isolated tibial insert exchange. In our study we not only found no aseptic loosening of the prosthesis after a PE exchange (see Chapter 3), we also found no deterioration of the Knee Score in time.

4.5 CONCLUSIONS

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 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. Evaluating the influence of a single factor on the result of total knee replacement may show significant differences, which may not be significant if other factors are taken into account. Evaluation of the long-term clinical outcome at different moments by different observers may affect the outcome not only by interobserver variability, but also by patient selection.

Taking into account all factors that might influence the clinical performance, no significant difference in clinical performance was seen between male and female patients, between patients with degenerative arthritis, rheumatoid arthritis and other diagnoses, or between patients who had had a previous high tibial osteotomy, a synovectomy, an arthrotomy or a PE exchange and patients who had not. Younger patients had a significantly worse clinical performance after total knee replacement with the SKI prosthesis, especially less range of motion and less flexion. Younger patients had a significantly better Function Score at follow-up, which may increase wear and the risk of aseptic loosening.

Patients with rheumatoid arthritis and patients with degenerative arthritis have comparable outcome after total knee replacement with the SKI prosthesis, but patients with rheumatoid arthritis benefit more from total knee replacement with the SKI prosthesis compared to patients with degenerative arthritis.

After a PE exchange, no change in clinical performance of the SKI prosthesis was seen compared to the clinical performance before PE exchange. No significant deterioration of the clinical performance in time was seen after a PE exchange at follow-up.