Chapter 6

Radiographic Examination: the Evaluation of Radiolucency

6.1 INTRODUCTION

As was shown in Chapter 5, the radiographic evaluation of a knee prosthesis can render data that can lead to a proper perspective on its longevity and durability. Whereas up to now wear has been the main subject of the radiographic assessment of the knee prosthesis, we know that the prosthesis-cement-bone construct can show radiographic signs of impending failure at an early stage. Serial radiographic follow-up studies can predict to a large extent the longevity of the arthroplasty by careful evaluation of radiolucencies developing in the interface between prosthesis and bone. The consistent and structured study of the pattern in which radiolucencies appear and expand can tell us to a certain extent whether the arthroplasty is stable or may be in danger of failing. With the first generation of one-piece tibial components, osteolysis was not reported as a clinical problem in cemented knee arthroplasty. The SKI prosthesis is a modular prosthesis. After introduction of modular polyethylene inserts, failure due to osteolysis was recognized as a clinical problem [81;84].

The aim of this study was to determine the radiographic long-term result of the SKI prosthesis. Therefore the presence, increase and patterns of radiolucency around the three components were analyzed on two consecutive, comparable radiographs. To correlate the radiographic result with the clinical performance, the radiolucency around prostheses with clinical signs of loosening (see section 6.4.7) and without clinical signs of loosening (see sections 6.4.1 and 6.4.4) was studied separately. In the group of prostheses without clinical signs of loosening, the factors that might contribute to the presence and increase of radiolucent lines were analyzed (see sections 6.4.5 and 6.4.6). Additionally, the correlation between radiolucency and osteophytes around the patellar component and the presence of anterior knee pain was studied (see sections 6.4.2 and 6.4.3).

6.2 MATERIAL AND METHODS

6.2.1 Patients

The patients seen in the second follow-up study at Tc, with comparable fluoroscopically centralized radiographs of the first follow-up study, were included in the study. All details of the patients (85 knees, 68 patients) are described in Appendix 2. The mean time of follow-up in the first study was 9.9 years ± 2.6 (range 6.1 to 15.5) and in the second

study 14.0 years ± 2.6 (range 10.0 to 19.1). The mean passage of time between both radiographic examinations was 4.1 years ± 0.22 (range 3.6 to 4.8).

At Tc, three patients had clinical signs of loosening of the prosthesis. Two of these knees were revised within four months after radiographic examination. The other knee had an exchange of the polyethylene two months before radiographic evaluation. The surgeon found evidence of loosening of the prosthesis at the time of PE exchange, but decided to change the polyethylene only because of patient morbidity. This prosthesis was considered loose upon further evaluation.

Not all radiographs that were made could be judged, because of extreme flexion contracture of the knee or because the knee was not properly centralized. The numbers of radiographs available for measurement of radiolucency around all components in prostheses with and without clinical signs of loosening are listed in Table 6.1.

Table 6.1. Numbers of radiographs available for measurement of radiolucency in cases with and without clinical signs of loosening.

Radiograph	No clinical signs of loosening	Clinical signs of loosening
Femoral component	78	3
Tibial component AP	80	2
Tibial component lateral	78	3
Patella	75	
Total prosthesis	70	2

6.2.2 Measurement of radiolucency

Section 5.2 describes the method used to fluoroscopically centralize the SKI prosthesis. Radiolucency was defined as a radiolucent zone of any size between the cement and the bone (see Figure 6.1). The radiolucent zone was measured at the maximum width with a goniometer and expressed in millimeters. All radiographs were judged by one observer. The magnification factor of the radiograph was calculated by dividing the measured width of the tibial component by the known width. To correct for magnification, the width of the radiolucent lines measured was divided by the magnification factor of the radiograph.

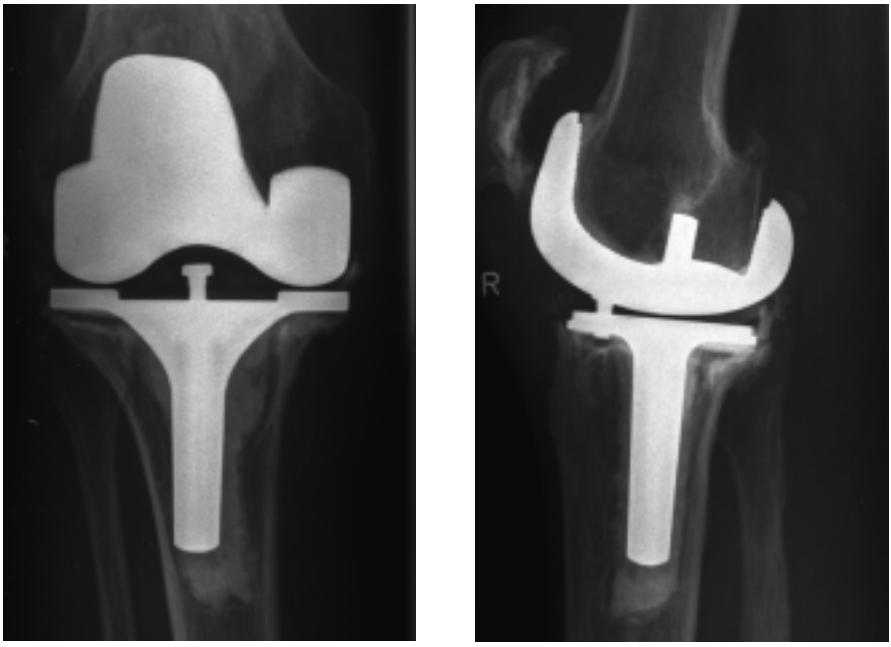


Figure 6.1. *AP and lateral radiograph of a SKI prosthesis in a 56-year old male, 10 years after implantation due to post-traumatic arthritis. The patient had clinical signs of loosening. Marked radiolucency is seen around the tibial component in both the AP and lateral views. Only a slight amount of radiolucency is seen around the femoral component.*

6.2.3 Scoring system

For measurement of the radiolucency around the three components of the knee prosthesis, the roentgenographic evaluation and scoring system of the Knee Society described by Ewald et al. [197] was used. Radiolucency around the femoral component was determined in seven zones on the lateral X-ray. Zones 1 and 2 represent the area behind the anterior flange; zones 5, 6 and 7 represent the fixation of the stem; zones 3 and 4 represent the posterior area (see Figure 6.2).

Radiolucency around the tibial component was determined from both the AP and the lateral view. From the AP view, zones 1 and 2 represent the area beneath the medial plateau, zones 3 and 4 represent the area beneath the lateral plateau, and zones 5, 6 and 7 represent the fixation of the stem (Figure 6.3).

From the lateral view of the tibial component, zone 1 represents the anterior area, zone 2 represents the posterior area and zone 3 represents the distal stem fixation (Figure 6.4).

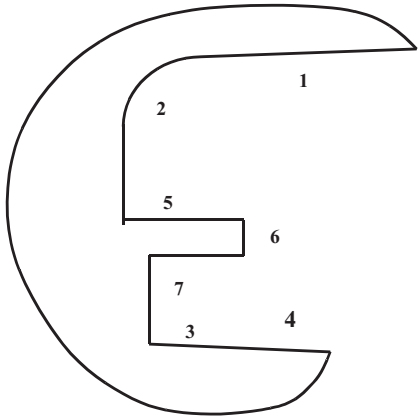


Figure 6.2. *Radiolucency zones 1 to 7 around the femoral component.*

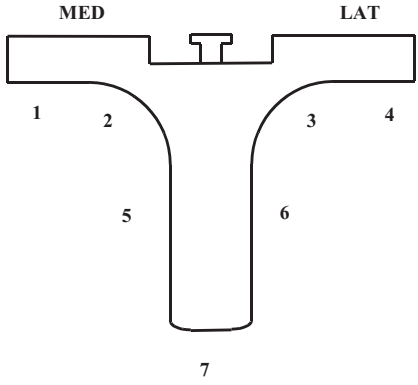


Figure 6.3. *Radiolucency zones 1 to 7 around the tibial component (AP view).*

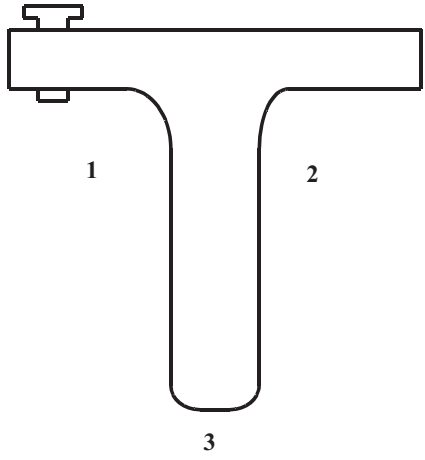


Figure 6.4. *Radiolucency zones 1 to 3 around the tibial component (lateral view).*

Radiolucency around the patellar component was determined in three zones from the skyline view (see section 5.2). Zone 1 represents the medial part, zone 2 represents the lateral part and zone 3 represents the fixation of the patellar button (see Figure 6.5)

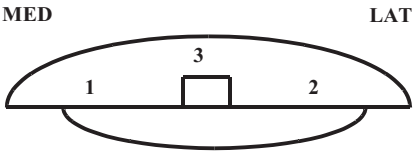


Figure 6.5. *Radiolucency zones 1 to 3 around the patellar component.*

The scoring for each component of the prosthesis was determined by measuring the width of the radiolucent lines for each zone in millimeters and adding the width of all zones. This total produces a numerical score for each component. The radiolucency score of the total prosthesis is obtained by adding the total scores of all three components.

The Knee Society [197] only rated the score for a seven-zone tibial component as follows: a score < 4 and nonprogressive is probably not significant; a score of 5-9 should be closely followed for progression, and a score > 10 signifies possible or impending failure. A rating for the score of the femoral and patellar components or the tibial component from the lateral view was not described in this article.

6.3 STATISTICAL ANALYSIS

To determine the amount and increase of radiolucency, the knees with and without clinical signs of loosening were analyzed separately. The prosthesis was considered loose if the patient had pain upon weight-bearing and/or swelling of the knee joint and/or progressive radiolucency around the prosthesis and/or a change in position or tilting of any of the components. Because none of the patellar components had signs of loosening at revision, all patellar components were analyzed together.

In the group of knees without clinical signs of loosening, the amount of radiolucency in both studies was compared with a paired samples t-test. A difference was considered significant if the p-value was <0.05. We considered the factors that might have influence on the presence and increase of radiolucency:

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

To study the influence of these factors on the amount and increase of radiolucency around the prostheses with no clinical signs of loosening, a univariate analysis of variance (ANOVA) was performed at knee level for each factor separately, and for all factors together. The test statistic F-value and the p-value will be presented in Tables 6.10 to 6.12. A factor was considered significant if the p-value was <0.05.

To study the influence of the presence of radiolucency and osteophytes on the presence of anterior knee pain, a logistic regression analysis at knee level was performed. The regression coefficients (B), standard error (se) and p-value will be presented in Table 6.6. The odds ratio can be calculated with the formula e^B. A difference was considered significant if the p-value was <0.05.

Only three prostheses had clinical signs of loosening. Therefore the amount and increase of radiolucency around these prostheses will only be described.

6.4 RESULTS

6.4.1 Prostheses without clinical signs of loosening

6.4.1.1 Radiolucency around the femoral component

In both the first and the second follow-up studies, most radiolucency around the prostheses without clinical signs of loosening was seen behind the anterior flange in zones 1 and 2 and on the posterior side in zone 4 of the femoral component. Radiolucency was rarely seen behind the fixation stem in zones 6 and 7 (see Figure 6.6). The mean amount of radiolucency of all femoral components without clinical signs of

* *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).*

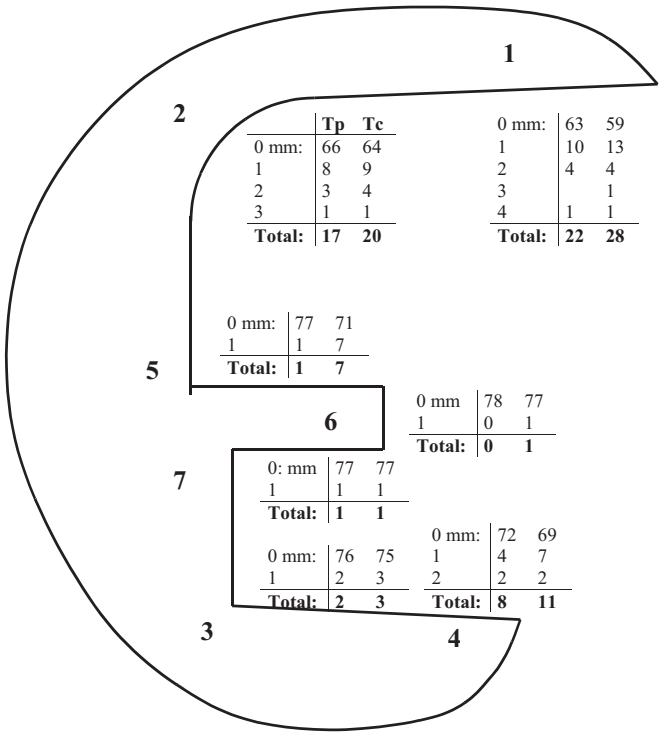


Figure 6.6. *Number of knees and amount of radiolucency in mm around all well-fixed femoral components in the first follow-up study at Tp (first column) and in the second follow-up study at Tc (second column) (n=78). Most radiolucency was seen in zones 1, 2 and 4. A significant increase in radiolucency was seen in zones 1 and 5 (+6 mm).*

loosening was 1.1 mm ± 0.6 (range 0 to 5) at Tp and 1.5 mm ± 0.9 (range 0 to 6) at Tc. In none of the femoral components was a decrease in radiolucency seen at Tc. The increase in radiolucency around the femoral component was significant (paired samples t-test, p=0.001), on the anterior side in zones 1 and 5 (both +6 mm) (paired samples t-test, p=0.013).

In the first follow-up study, 23 knees (29.5%) with a well-fixed femoral component had radiolucency around the femoral component at follow-up (range 1 to 5 mm). In the second follow-up study, 32 knees (41.0%) had radiolucency around the femoral component (range 1 to 6 mm) (see Table 6.2).

Table 6.2. Number of knees and total amount of radiolucency around the femoral component of prostheses with no clinical signs of loosening at Tp and at Tc (n=78). More radiolucency was seen at Tc and around more femoral components.

Total amount of radiolucency (mm)	Tp		Tc	
	n	*(%)*	n	*(%)*
0	55	*(70.5)*	46	*(59.0)*
1	9	*(11.5)*	14	*(17.9)*
2	6	*(7.7)*	6	*(7.7)*
3	4	*(5.1)*	6	*(7.7)*
4	2	*(2.6)*	4	*(5.1)*
5	2	*(2.6)*	1	*(1.3)*
6			1	*(1.3)*

6.4.1.2 Radiolucency around the tibial component (anteroposterior view)

In knees with no clinical signs of loosening, both in the first and the second follow-up study, most radiolucency around the tibial component from the anteroposterior (AP) view was seen at the edges of the tibial plateau in zones 1 and 4 (see Figure 6.7). The mean amount of radiolucency was 1.7 mm ± 1.2 (range 0 to 6) at Tp and 2.0 mm ± 1.5 (range 0 to 10) at Tc. The increase in radiolucency was significant (paired samples t-test, p=0.010). None of these components showed a decrease in radiolucency. Most increase in radiolucency was seen around the tibial stem in zone 6 (+9 mm), in zone 5 (+5 mm) and in zone 7 (+5 mm). The increase in zone 6, on the lateral side of the tibial stem, was significant (paired samples t-test, p=0.012). In all other zones, the increase was not significant.

In the first follow-up study, 38 knees (47.5%) without clinical signs of loosening had radiolucency around the tibial component from the AP view (range 1 to 7 mm). More than 5 mm radiolucency was seen in seven knees (8.8%). In the second follow-up study, 44 knees (55.0%) had radiolucency around the tibial component (range 1 to 10 mm). Eleven knees (13.8%) had more than 5 mm radiolucency (see Table 6.3).

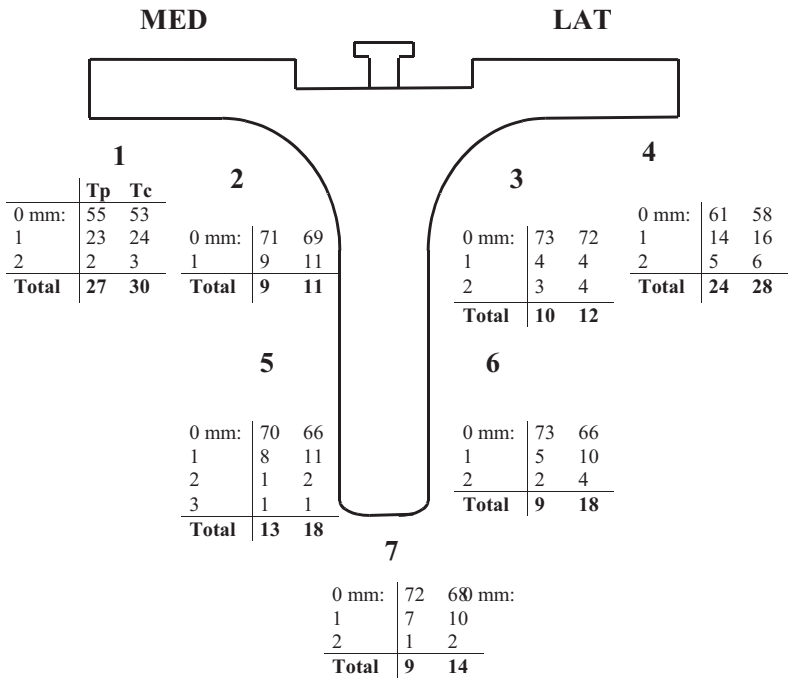


Figure 6.7. *Number of knees and amount of radiolucency in mm around all tibial components without clinical signs of loosening (AP view) in the first follow-up study at Tp (first column) and in the second follow-up study at Tc (second column) (n=80). Most radiolucency was seen at the edges in zones 1 and 4. A significant increase in radiolucency was seen in zone 6 (+9 mm).*

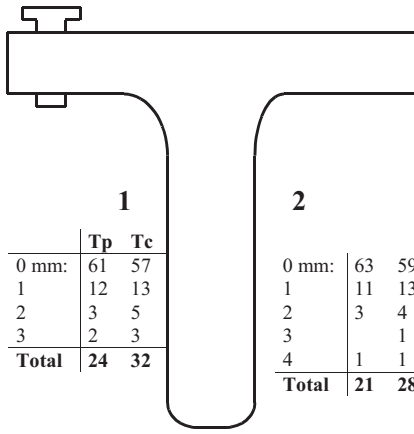
Table 6.3. Number of knees and total amount of radiolucency at Tp and at Tc around the tibial component (AP view) in knees with no clinical signs of loosening (n=80). At Tc, more radiolucency was seen and a higher amount of prostheses was at risk for failure.

Total amount of radiolucency (mm)	Tp		Tc		
	n	*(%)*	n	*(%)*	
0	42	*(52.5)*	36	*(45.0)*	
1	14	*(17.5)*	15	*(18.8)*	
2	9	*(11.3)*	10	*(12.5)*	
3	4	*(5.0)*	6	*(7.5)*	
4	4	*(5.0)*	2	*(2.5)*	
5	2	*(2.5)*	3	*(3.8)*	*impending failure*
6	4	*(5.0)*	4	*(5.0)*	
7	1	*(1.3)*	3	*(3.8)*	
10			1	*(1.3)*	

6.4.1.3 Radiolucency around the tibial component (lateral view)

From the lateral view of the tibial components without clinical signs of loosening, most radiolucency was seen on the anterior side in zone 1 and on the posterior side in zone 2 (see Figure 6.8). The mean amount of radiolucency was 1.2 mm ± 0.7 (range 0 to 6) at Tp, and 1.5 mm ± 1.0 (range 0 to 7) at Tc. In none of these tibial components was a decrease in radiolucency seen at Tc. The increase in radiolucency around the tibial component from the lateral view was significant (paired samples t-test, $p<0.001$). An increase in the total amount of radiolucency of 8 mm was seen at Tc, both on the anterior side in zone 1 and around the distal part of the tibial stem in zone 3. The increase in zones 1 and 3 was significant (paired samples t-test, $p=0.004$ and $p=0.020$ respectively).

In the first follow-up study, 25 knees (32.1%) without clinical signs of loosening had radiolucency around the tibial component from the lateral view (range 1 to 6 mm). Two prostheses had a total amount of radiolucency of more than 5 mm. In the second follow-up study, 34 knees (43.6%) had radiolucency around the tibial component from the lateral view (range 1 to 6 mm). Three knees had a total amount of radiolucency of more than 5 mm (see Table 6.4).

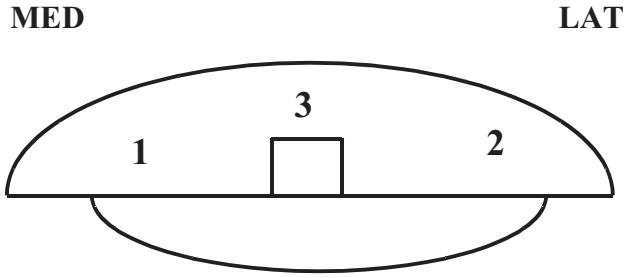


	Tp	Tc
0 mm:	61	57
1	12	13
2	3	5
3	2	3
Total	**24**	**32**

0 mm:	63	59
1	11	13
2	3	4
3		1
4	1	1
Total	**21**	**28**

0 mm:	67	62
1	10	12
2	1	4
Total	**12**	**20**

Figure 6.8. *Number of knees and amount of radiolucency in mm around all fixed tibial components (lateral view) in the first follow-up study at Tp (first column) and in the second follow-up study at Tc (second column) (n=78). Most radiolucency was seen in zones 1 and 2. A significant increase in radiolucency was seen in zones 1 and 3 (+8 mm).*



	Tp	Tc
0 mm:	71	69
1	4	6
Total	**4**	**6**

0 mm:	73	72
1	2	3
Total	**2**	**3**

0 mm:	68	67
1	7	8
Total	**7**	**8**

Figure 6.9. *Number of knees and amount of radiolucency in mm around all patellar components in the first follow-up study at Tp (first column) and in the second follow-up study at Tc (second column) (n=75). An increase in radiolucency was seen at Tc in all zones.*

Table 6.4. Total amount of radiolucency at Tp and at Tc around the tibial component (lateral view) in knees without clinical signs of loosening (n=78). At Tc, more radiolucency was seen and around more prostheses radiolucency was seen.

Total amount of radiolucency (mm)	**Tp**		**Tc**	
	n	***(%)***	**n**	***(%)***
0	53	*(67.9)*	44	*(56.4)*
1	10	*(12.8)*	12	*(15.4)*
2	5	*(6.4)*	10	*(12.8)*
3	6	*(7.7)*	5	*(6.4)*
4	2	*(2.6)*	4	*(5.1)*
5	1	*(1.3)*	1	*(1.3)*
6	1	*(1.3)*	2	*(2.6)*

6.4.2 Radiolucency around the patellar component

Both at Tp and at Tc, most radiolucency was seen around the lateral part of the patellar component (zone 2). At Tp, the mean amount of radiolucency in all knees was 0.1 mm ± 0.5 (range 0 to 3), and at Tc 0.2 mm ± 0.6 (range 0 to 3). The increase in radiolucency around the patellar component was significant (paired samples t-test, p=0.045). The increase was seen in all zones of the patellar component.

Radiolucency was seen around the patellar component at Tp in 9 knees (12.0%) (range 1 to 3 mm) and at Tc in 11 knees (14.7%) (range 1 to 3 mm) (see Table 6.5).

Table 6.5. Number of knees and total amount of radiolucency at Tp and at Tc around all patellar components (n=75).

Total amount of radiolucency (mm)	Tp		Tc	
	n	*(%)*	n	*(%)*
0	66	*(88.0)*	64	*(85.3)*
1	6	*(8.0)*	6	*(8.0)*
2	2	*(2.7)*	4	*(5.3)*
3	1	*(1.3)*	1	*(1.3)*

6.4.3 Anterior knee pain, radiolucency and osteophytes

In the first follow-up study, only one patient (11.1%) with radiolucency around the patellar component had anterior knee pain at Tp, while 13 patients (19.7%) who had no radiolucency around the patellar component had anterior knee pain. In the second study, two patients (18.2%) with radiolucency around the patellar component complained of anterior knee pain, while 17 (26.6%) of the patients who had no radiolucency complained of anterior knee pain. In neither study was a significant relation found between radiolucency around the patellar component and anterior knee pain (p=0.542 and p=0.524) (see Table 6.6).

Table 6.6. Logistic regression analysis with the Logistic regression coefficient (B), standard error (se) and p-value of the relation between radiolucency and osteophytes around the patellar component and anterior knee pain (n=75 and n=71 respectively). No relation was found between radiolucencies or osteophytes around the patellar component and anterior knee pain.

	n	Anterior knee pain	No anterior knee pain	B	se	p-value
Radiolucency around patella at Tp				-0.674	1.105	0.542
No	66	13 (19.7%)	53 (80.3%)			
Yes	9	1 (11.1%)	8 (88.9%)			
Radiolucency around patella at Tc				-0.531	0.832	0.524
No	64	17 (26,6%)	47 (73,4%)			
Yes	11	2 (18.2%)	9 (81.8%)			
Osteophytes around patella				-0.013	0.556	0.981
No	26	6 (26.9%)	19 (73.1%)			
Yes	45	12 (26.7%)	33 (73.3%)			

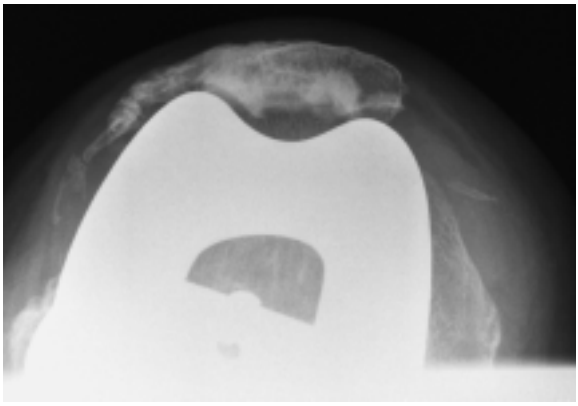


Figure 6.10. *Osteophyte on the lateral side of the patella in a 53-year-old female patient with rheumatoid arthritis, 13.2 years after total knee replacement. This patient had no anterior knee pain.*

Osteophytes were seen around 45 patellar components (63.4%) (see Figure 6.10). No difference in anterior knee pain was seen between patients who had osteophytes and patients who had none (26.9% of the patients with osteophytes had anterior knee pain versus 26.7% of patients with no osteophytes) (p=0.981) (see Table 6.6).

6.4.4 Radiolucency around the total prosthesis

In the group of knees that had no clinical signs of loosening, the mean amount of radiolucency around the total prosthesis was 2.8 mm ± 3.4 at Tp and 3.7 mm ± 3.9 at Tc. The increase in radiolucency was significant (paired samples t-test, p<0.001) (see Table 6.7)

In the first follow-up study, no radiolucency was seen in 21 knees (30.0%). Four knees (5.7%) had a total amount of radiolucency of more than 10 mm. Two of these prostheses had no increase in radiolucency at the second follow-up study, and in two knees an increase of 1 mm was seen. In the second follow-up study no radiolucency was seen in 15 knees (21.4%). Seven knees (10.0%) had a total amount of radiolucency of more than 10 mm, without clinical signs of loosening (see Table 6.8).

Table 6.7. Mean amount of radiolucency of all prostheses seen at Tp and at Tc (n=70). A significant increase in radiolucency was seen at Tc.

	Tp	Tc	p-value[1]
Amount of radiolucency (mm) mean ± sd (min-max)	2.8 ± 3.4 (0-15)	3.7 ± 3.9 (0-16)	**<0.001**

[1] *Paired-samples t-test*

Table 6.8. Number of knees and total amount of radiolucency around the total prosthesis at Tp and at Tc in patients with no clinical signs of loosening (n=70). At Tc, more prostheses had radiolucency. Four knees at Tp and seven knees at Tc had a total amount of radiolucency of more than 10 mm, without clinical signs of loosening.

Total amount of radiolucency (mm)	Tp		Tc	
	n	*(%)*	n	*(%)*
0	21	*30.0*	15	*21.4*
1	12	*17.1*	12	*17.1*
2	11	*15.7*	10	*14.3*
3	4	*5.7*	5	*7.1*
4	6	*8.6*	6	*8.6*
5	4	*5.7*	3	*4.3*
6	5	*7.1*	3	*4.3*
7			2	*2.9*
8	2	*2.9*	4	*5.7*
9	1	*1.4*	3	*4.3*
10	1	*1.4*	4	*5.7*
11	1	*1.4*		
12			1	*1.4*
15	2	*2.9*	1	*1.4*
16			1	*1.4*

Table 6.9. Increase in radiolucency (mm) around prostheses that had no clinical signs of loosening. A mean increase in radiolucency of 2.1 mm ± 1.6 (range 1 to 8) was seen in 30 knees.

Increase in radiolucency (mm)	n	*%*
0	40	*57.1*
1	15	*21.4*
2	7	*10.0*
3	2	*2.9*
4	4	*5.7*
5	1	*1.4*
8	1	*1.4*

An increase in radiolucency was seen in 30 knees (42.9%), with a mean increase of 2.1 mm ± 1.6 (range 1 to 8 mm), or 0.5 mm/year ± 0.4 (range 0.2-2.1). In two knees (2.9%) the increase in radiolucency was of more than 5 mm, without clinical signs of loosening (see Table 6.9).

6.4.5 Factors that may influence the amount of radiolucency

In the first study at Tp, in male patients slightly more radiolucency was seen on average compared to female patients, but the difference was not significant. More radiolucency was seen in knees with wear or screw loosening compared to knees without wear or screw loosening, but the differences were not significant either. Activity level, age at the time of surgery and time of follow-up had no significant influence on the amount of radiolucency.

In a univariate analysis of variance, significantly more radiolucency was seen in patients with degenerative arthritis compared to patients with rheumatoid arthritis and other diagnoses (F=4.12, p=0.021).

Table 6.10. Univariate analysis of variance with the test statistic F-value and p-value of the factors that might influence the amount of radiolucency around the total prosthesis in the first follow-up study (n=70), corrected for all factors. None of the factors had a significant influence.

Factors that may have an influence on the amount of radiolucency	n	Amount of radiolucency (mm) at Tp mean ± sd (min-max)	F-value	p-value
Sex			0.01	0.940
Male	10	3.1 ± 2.2 (0-6)		
Female	60	2.8 ± 3.6 (0-15)		
Diagnosis			1.31	0.278
Degenerative arthritis	26	4.2 ± 3.9 (0-15)		
Rheumatoid arthritis	35	1.8 ± 2.1 (0-8)		
Other	10	2.8 ± 4.8 (0-15)		
Wear			3.66	0.061
Yes	27	4.2 ± 4.4 (0-15)		
No	43	1.9 ± 2.3 (0-9)		
Screw loosening			0.04	0.833
Yes	13	4.2 ± 4.1 (0-15)		
No	57	2.5 ± 3.2 (0-15)		
Body weight (kg)	70		0.00	0.969
Activity level (AKSS Function Score)	70		0.00	0.957
Age at the time of surgery	70		0.00	0.996
Time of follow-up	70		0.13	0.724

Significantly more radiolucency was also seen in heavier patients (F=4.38, p=0.004). Corrected for all factors, none of the factors had a significant influence on the amount of radiolucency (see Table 6.10).

In the second study at Tc, in male patients slightly more radiolucency was seen on average compared to female patients, but the difference was not significant. Activity level, age at the time of surgery and time of follow-up had no significant influence on the amount of radiolucency.

In a univariate analysis of variance, significantly more radiolucency was seen in patients with degenerative arthritis compared to patients with rheumatoid arthritis and other diagnoses (F=3.32, p=0.042). Knees with wear and screw loosening had significantly more radiolucency compared to knees without wear or screw loosening (F=5.81, p=0.019 and F=5.55, p=0.021 respectively), and significantly more radiolucency was seen in heavier patients (F=4.27, p=0.043). Corrected for all factors, none of the factors had a significant influence on the amount of radiolucency (see Table 6.11).

Table 6.11. Univariate analysis of variance with the test statistic F-value and p-value of the factors that might influence the amount of radiolucency around the total prosthesis in the second follow-up study (n=70), corrected for all factors. None of the factors had a significant influence.

Factors that may have an influence on the amount of radiolucency	n	Amount of radiolucency (mm) at Tc mean ± sd (min-max)	F-value	p-value
Sex			0.78	0.379
Male	10	4.8 ± 3.7 (0-10)		
Female	60	3.5 ± 3.9 (0-16)		
Diagnosis			1.00	0.375
Degenerative arthritis	27	5.2 ± 3.9 (0-15)		
Rheumatoid arthritis	35	2.7 ± 3.0 (0-10)		
Other	10	3.7 ± 5.6 (0-16)		
Wear			1.27	0.264
Yes	27	5.1 ± 4.7 (0-16)		
No	43	2.9 ± 3.0 (0-10)		
Screw loosening			1.29	0.261
Yes	13	5.9 ± 4.5 (0-16)		
No	59	3.2 ± 3.6 (0-15)		
Body weight (kg)	70		0.00	0.965
Activity level (AKSS Function Score)	70		0.13	0.724
Age at the time of surgery	70		0.35	0.558
Time of follow-up	70		0.87	0.356

6.4.6 Factors that may influence the increase of radiolucency

The mean increase in radiolucency in all knees without clinical signs of loosening at Tc was 0.9 mm ± 1.5 (range 0 to 8 mm), or 0.2 mm/year ± 0.4 (range 0 to 2.8). Male patients had more of an increase in radiolucency compared to female patients on average, but the difference was not significant. Diagnosis, wear, body weight, activity level and age at the time of surgery had no influence on the increase in radiolucency.

Knees with screw loosening had a significantly higher increase in radiolucency around the prosthesis compared to knees with a fixed screw (1.8 mm ± 2.4 versus 0.7 mm ± 1.2). The difference was even significant in a univariate analysis of variance corrected for all other factors (see Table 6.12).

Table 6.12. Univariate analysis of variance with the test statistic F-value and p-value of the factors that might influence the increase in radiolucency around the total prosthesis (n=70), corrected for all factors. Knees with screw loosening had a significant increase in radiolucency.

Factors that may have an influence on the increase of radiolucency	n	Mean increase in radiolucency (mm)	F-value	p-value
Sex			3.86	0.054
Male	10	1.7 ± 1.8 (0-5)		
Female	60	0.8 ± 1.4 (0-8)		
Diagnosis			0.20	0.818
Degenerative arthritis	26	1.0 ± 1.7 (0-8)		
Rheumatoid arthritis	35	0.9 ± 1.3 (0-4)		
Other	9	0.9 ± 1.7 (0-5)		
Wear			2.30	0.135
Yes	27	0.9 ± 1.2 (0-4)		
No	43	0.9 ± 1.7 (0-8)		
Screw loosening			6.62	**0.013**
Yes	13	1.8 ± 2.4 (0-8)		
No	59	0.7 ± 1.2 (0-5)		
Body weight (kg)	70		0.32	0.573
Activity level (AKSS Function Score)	70		0.55	0.462
Age at the time of surgery	70		1.21	0.276

6.4.7 Prostheses with clinical signs of loosening

6.4.7.1 Radiolucency around the femoral component

Of the three prostheses with clinical signs of loosening, one knee had a total amount of 1 mm radiolucency around the femoral component at

Tp and 3 mm at Tc. One knee had a total amount of 4 mm radiolucency in both studies, and in one knee no radiolucency was seen around the femoral component (see Table 6.13).

Table 6.13. Total amount of radiolucency around the femoral component at Tp and at Tc of the three prostheses with clinical signs of loosening in the second follow-up study.

	Total amount of radiolucency (mm)	
	Tp	**Tc**
Prosthesis 1	1	3
Prosthesis 2	4	4
Prosthesis 3	0	0

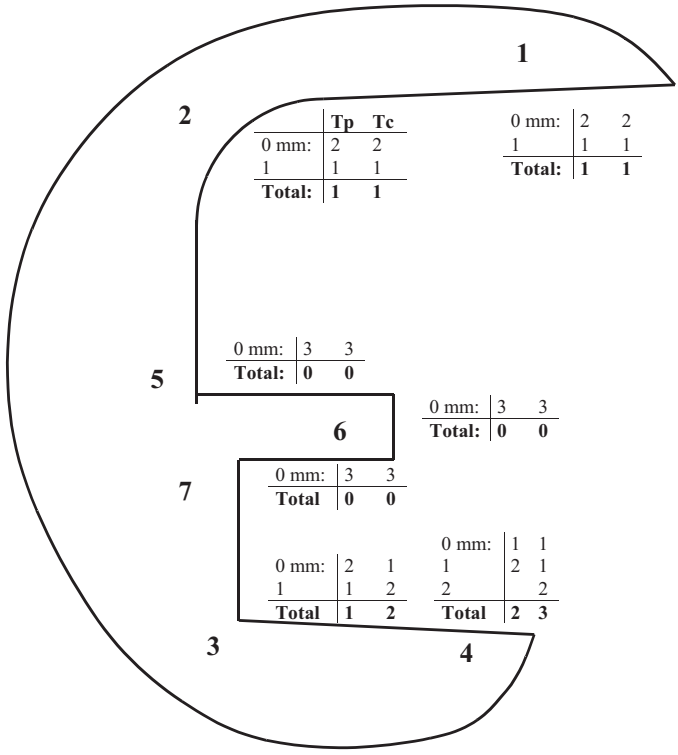


Figure 6.11. *Amount of radiolucency in mm around the loosened femoral components (n=3) in the first follow-up study at Tp (first column) and in the second follow-up study at Tc (second column). Only slight amount of radiolucency was seen in zones 1, 2, 3 and 4. A minor increase in radiolucency was only seen in zones 3 and 4.*

Around the femoral components in knees with clinical signs of loosening, only a slight amount of radiolucency was seen on the posterior side in zones 3 and 4 and behind the anterior flange in zones 1 and 2. No radiolucency was seen around the fixation stem of the femoral components in zones 5, 6 and 7. A slight increase in radiolucency was only seen on the posterior side in zones 3 and 4 (see Figure 6.11).

6.4.7.2 Radiolucency around the tibial component (anteroposterior view)
Of the two prostheses with clinical signs of loosening, one had a total amount of radiolucency around the tibial component from the anteroposterior (AP) view of 2 mm at Tp and 10 mm at Tc (+8mm). In the other prosthesis, the total amount of radiolucency was 13 mm at Tp and 9 mm at Tc (-4 mm) (see Table 6.14).

Table 6.14. Total amount of radiolucency around the tibial component (AP view) at Tp and at Tc of two prostheses with clinical signs of loosening.

	Total amount of radiolucency (mm)	
	Tp	**Tc**
Prosthesis 1	2	10
Prosthesis 2	13	9

In the first prosthesis, an increase in radiolucency of 6 mm was seen beneath the medial plateau in zone 2, and 2 mm at the lateral edge in zone 4. In the other prosthesis, an increase in radiolucency was seen beneath the lateral plateau (+3 mm in zone 3 and +2 mm in zone 4) and a decrease of 3 mm beneath the medial plateau in zones 1 and 2 and in the lateral part of the tibial stem in zone 6 (see Figure 6.12).

6.7.4.3 Radiolucency around the tibial component (lateral view)
Of the three prostheses with clinical signs of loosening, one prosthesis had an increase in radiolucency around the tibial component of 8 mm and two prostheses an increase of 2 mm from the lateral view at Tc (see Table 6.15).

Most radiolucency was seen on the anterior side of the tibial component. A total increase in radiolucency of 5 mm was seen on the anterior side in zone 1 and on the posterior side in zone 2. In zone 3 the increase was of 2 mm.

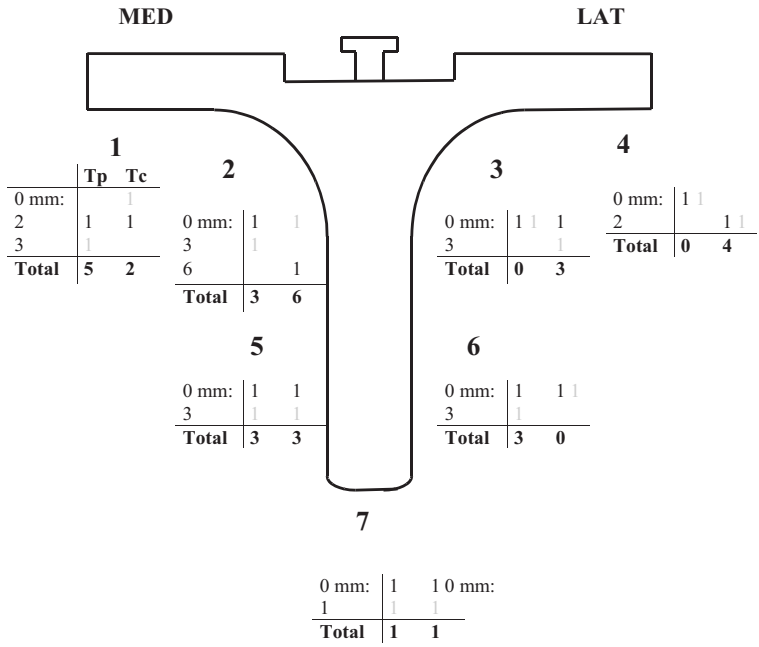


Figure 6.12. *Amount of radiolucency in mm around two tibial components with loosening (AP view) at Tp and at Tc. The amount of radiolucency of prosthesis 1 is printed in black and of prosthesis 2 in grey. In prosthesis 1 an increase in radiolucency was seen in zones 2 and 4. In prosthesis 2 an increase in radiolucency was seen in zones 3 and 4, and a decrease in zones 1, 2 and 6.*

Table 6.15. Total amount of radiolucency around the tibial component (lateral view) at Tp and at Tc of three prostheses with clinical signs of loosening.

	Total amount of radiolucency (mm)	
	Tp	**Tc**
Prosthesis 1	0	8
Prosthesis 2	5	7
Prosthesis 3	7	9

6.4.7.4 Radiolucency around the total prosthesis

Of the prostheses with clinical signs of loosening, one prosthesis had a total increase in radiolucency of 18 mm, the other had a decrease in the total amount of radiolucency of 2 mm at Tc (see Table 6.16).

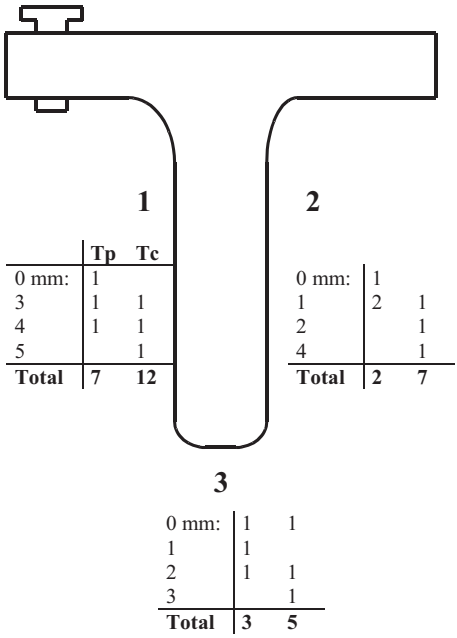


Figure 6.13. *Amount of radiolucency in mm around the three tibial components with clinical signs of loosening (lateral view). The first column represents the amount of radiolucency at Tp, the second column at Tc. Most radiolucency was seen in zone 1. Most of the increase in radiolucency was seen in zones 1 and 2 (+5 mm).*

Table 6.16. Total amount of radiolucency around the components at Tp and at Tc of two prostheses with clinical signs of loosening.

	Total amount of radiolucency (mm)	
	Tp	**Tc**
Prosthesis 1	3	21
Prosthesis 2	22	20

6.5 DISCUSSION

Osteolysis it generally thought to result from a granulomatous response to polyethylene, polymethylmethacrylate or metal particulate debris [84;132;133]. Particulate debris from the prosthetic replacement gains access to the bone-cement interface or the bone prosthesis-interface, and elicits formation of a fibrous tissue membrane that contains macrophage and

foreign body giant cells [209;210]. The foreign body debris is phago-cytosed by the macrophages. In response to this, the macrophages produce inflammatory mediators that stimulate osteoclasts. This results in bone resorption.

Plain radiographs often tend to underestimate or even fail to detect radiolucent lines [89;211;212]. Ecker et al. [89] showed that flexion of more than 4° obscures radiolucent lines in metal-backed components. Nelissen [213] showed that flexion, medial tilting, ventral tilting and rotation had an influence on the measurement of radiolucent lines. Mintz et al. [211] showed that fluoroscopically guided radiographs allow accurate measurement of the presence and extent of radiolucent lines. In this study, fluoroscopically centered radiographs were made in a group of patients with a SKI prosthesis at two consecutive moments. This allowed us to compare the amount of and increase in osteolysis accurately after a mean follow-up of 9.9 years and 14.0 years, with a mean interval of 4.1 years. The examination of radiolucency was only performed in the group of patients that was available for radiographic examination at both follow-up studies. Therefore, the study population might be a selection of all patients with a SKI prostheses. Because none of the other radiographs were fluoroscopically centralized, no comparison could be made with radiographs made on routine outpatient visits or in a larger group of patients.

In prostheses with no clinical signs of loosening, most radiolucency was seen at the edges of the prosthesis (zones 1, 2 and 4 of the femoral component, zones 1 and 4 of the tibial component from the AP view, zones 1 and 2 of the tibial component from the lateral view, and at the medial and lateral edges of the patellar button). A possible explanation might be that wear particles gain access to the interface between the bone and cement at the edge of the prosthesis and cause osteolysis in these zones.

Cadambi et al. [214] found that male sex, younger age, increased patient weight, degenerative arthritis and length of time in situ were statistically significant factors associated with femoral osteolysis. Wear has been associated with osteolysis [215]. On both radiographic examination studies we found more radiolucency in patients with degenerative arthritis and in patients with increased body weight. In the second follow-up study, patients with wear and patients with loosening of the screw also had more radiolucency. However, corrected for all factors none of above-mentioned factors had a significant influence on the amount of radiolucency in our study. The study population might be too small to detect a significant influence on the amount of radiolucency.

Of the prostheses with clinical signs of loosening, only a slight amount of radiolucency was seen around the femoral component, without much progression. Several authors found more osteolysis around the femoral component at revision than previously seen at radiographic examination [212;216;217]. Radiographic review usually leads to under-estimation of the degree of osteolysis around the femoral component, because osteolytic defects may be hidden by the femoral component of the prosthesis on the anteroposterior radiograph, and by the other side of the femoral condyle on the lateral radiograph. Around the tibial component, one prosthesis with clinical signs of loosening showed an increase in radiolucency and the other showed a decrease. The decrease in radiolucency was caused by a change in position and tilting of the tibial component. In none of the prostheses without clinical signs of loosening was a decrease in radiolucency seen.

In this study, no relation was found between anterior knee pain and radiolucency or the presence of osteophytes around the patellar component. However, the skyline view of the patella was taken in one position (45 degrees of flexion) and was not fluoroscopically centralized. The amount of radiolucency might therefore be higher than what we found.

Comparison of the radiographs of both follow-up studies shows a significant increase of radiolucency around all three components in the group of prostheses that had no clinical signs of loosening. In prostheses with an increase in radiolucency (n=30), the mean increase was 2.1 mm ± 1.6 or 0.5 mm/year ± 0.4. This increase in radiolucency must alert the physician of impending loosening at further follow-up of the SKI prosthesis. Most of the increase of radiolucency around the femoral component was seen on the anterior side. From the AP view of the tibial component, most of the increase was seen around the tibial stem in zones 5, 6 and 7; from the lateral view an increase was seen in all zones. The only factor that contributed significantly to the increase in radiolucency was loosening of the screw. In Chapter 3 and section 5.5 we already found more wear and a higher wear rate in knees with screw loosening. Knees with screw loosening may have a different mode of wear. Therefore, the wear characteristics of retrieved knees with and without screw loosening will be analyzed in the next chapter.

6.6 CONCLUSIONS

In prostheses without clinical signs of loosening, most radiolucency was seen at the edges of the prosthesis. More radiolucency was seen in

patients with degenerative arthritis and heavier patients, and in knees with wear and screw loosening, but none of these factors had a significant influence on the amount of radiolucency. A significant increase in radiolucency was seen around prostheses without clinical signs of loosening, which must alert the physician of impending loosening at further follow-up. Screw loosening was the most important factor contributing to the increase in radiolucency.

In prostheses with clinical signs of loosening, only a slight amount and a minor increase in radiolucency was seen around the femoral component. Most changes were detected around the tibial component: one prosthesis showed a significant increase in radiolucency and the other a decrease, due to a change in position and tilting.

No relation between anterior knee pain and radiolucency or the presence of osteophytes around the patellar component could be demonstrated.