

Chapter 5

Radiographic Examination: Alignment and Wear

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5.1 INTRODUCTION

Next to the clinical performance of an arthroplasty, which relies on symptoms such as pain at rest and during walking, range of motion and stability, the value of radiographic analysis is of prime importance. Correlating the clinical symptoms with the radiographic findings can render a rather accurate estimate of the (stable) fixation of the prosthesis in the bone and the (change of) position of the components of the prosthesis relative to each other, inside the bone and relative to the loading axis of the extremity. To this end, in this chapter and the next a description will be offered of the way wear, alignment of the prosthesis, the loading axis of the extremity and radiolucencies can be studied radiographically *in vivo*.

Wear is the abrasion of material that occurs as a result of the relative motion between two opposing surfaces under load. Most studies on polyethylene wear in total knee replacement are analyses of failed prostheses in retrieval analyses (93-96). To analyze the factors that might influence wear and wear rate, studies should not only be performed in failed prostheses, but also in the remaining group of patients with the knee prosthesis *in situ*. To analyze the factors that may have an influence on wear and wear rate in patients with the knee prosthesis *in situ*, the amount of wear must be quantified first. Radiographically, the distance between the metal femoral and tibial components represents the remaining PE thickness. By subtracting the remaining PE thickness from the original PE thickness, the amount of wear can be quantified. The remaining PE thickness can only be measured on a true AP radiograph in a weight-bearing patient, with the X-ray beam perfectly parallel to the metal tibial tray. On most radiographs at routine outpatient visits, these conditions are not fulfilled. In this chapter we will first describe the methods used to fluoroscopically centralize the SKI knee prosthesis (section 5.2).

In section 5.3 the reliability of the radiographic measurements of the PE thickness was determined by comparing the original thickness of different unused inserts with radiographic measurements of the PE thickness of these unused inserts.

The alignment of the leg can be determined by measuring the femorotibial angle (FTA), which represents the varus or valgus angle of the lower extremity. To determine the influence of the alignment of the leg on wear and wear rate after total knee replacement, the measurements of the FTA on short and full-length leg radiographs were compared first (see section 5.4). The FTA can be drawn through the true anatomical

axes of the femur and tibia and through the knee center. Intramedullary guidance instruments, used to align a knee prosthesis, are entered into the knee center. Therefore we also compared the difference with measuring the FTA through the true anatomical axes of the femur and tibia and through the knee center (see section 5.4).

In section 3.3.9 the factors that might contribute to wear were already described. In section 5.5 the factors that might contribute to wear and wear rate were analyzed in the selected group of patients with fluoroscopically centralized radiographs seen at Tc. In section 5.6 the influence of the alignment of the prosthesis in the bone on the wear rate will be described. Finally, the influence of the alignment of the leg on the wear rate will be described in section 5.7.

5.2 TECHNIQUE OF RADIOGRAPHIC EXAMINATION

At follow-up four radiographs were taken of each knee:

1. A standing, full-length leg radiograph of the lower extremity taken with the patella facing forward.
2. A fluoroscopically centralized anteroposterior (AP) radiograph. To centralize the knee prosthesis, the leg was rotated on a board under fluoroscopic control, until the anterior and posterior sides of the raised border were projected in parallel fashion (see Figure 5.1a-c). After this, the fluoroscopic beam was rotated in the saggital plane until it was parallel with the surface of the tibial tray. When the beam was perfectly parallel with the tibial tray, the X-ray was taken (see Figure 5.1d).
3. A fluoroscopically centralized lateral radiograph. To centralize the knee prosthesis in the lateral view, the leg was rotated on a board until the fixation pegs of the femoral component were parallel. The fluoroscopic beam was then moved in the coronal plane until it was parallel with the tibial tray. When the beam was perfectly parallel with the tibial tray, the X-ray was taken (see Figure 5.2a-b).
4. An axial view of the patella with the knee in 45° flexion (skyline view) ¹⁸⁴ (see Figure 5.3).



Fig. 5.1a



Fig. 5.1b



Fig. 5.1c



Fig. 5.1d

Figure 5.1a-d. Fluoroscopic centralizing of the knee prosthesis in the AP view. On a standard X-ray that is not centralized, it is not possible to determine the amount of wear (Figure 5.1a). To centralize the knee prosthesis, the leg was rotated on a board under fluoroscopic control (Figure 5.1b) until the anterior and posterior sides were projected in parallel fashion (see arrow) (Figure 5.1c). After this, the fluoroscopic beam was rotated in the saggital plane until it was parallel with the surface of the tibial tray. When the beam was perfectly parallel with the tibial tray, the X-ray was taken (Fig 5.1d).



Fig. 5.2a



Fig. 5.2b

Figure 5.2a-b. Fluoroscopic centralizing of the knee prosthesis in the lateral view. On a standard X-ray that is not centralized, the position of the components cannot be determined accurately (Figure 5.2a). To centralize the radiograph, the leg was rotated on a board and the fluoroscopic beam was moved in the coronal plane until the fixation pegs of the femoral components were parallel and the X-ray beam was perfectly parallel with the tibial tray (Figure 5.2b).

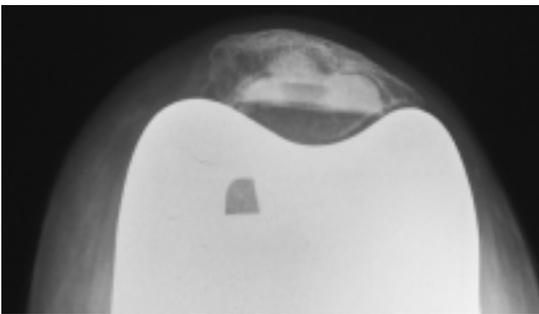


Figure 5.3. Skyline view of the patella. The knee is bent at 45° and the X-ray beam is directed axially toward the patella.

5.3 RELIABILITY OF THE RADIOGRAPHIC MEASUREMENTS

With a fluoroscopically centralized radiograph, the thickness of the PE can be determined radiographically, by measuring the distance between the metal femoral and tibial components of the prosthesis. To determine the reliability of the measurements of the PE thickness on a radiograph, we first determined the original thickness of unused PE inserts. With the radiographic measurements and the original thickness of these unused inserts, an intraclass correlation coefficient could be calculated to determine if the thickness of the PE measured on a radiograph corresponded with the true thickness.

5.3.1 Determination of the original thickness of the polyethylene insert

To determine the original thickness of the polyethylene insert, we first measured the loaded area of different unused PE inserts with a Vernier calliper. We found an actual thickness of the loaded portion of the polyethylene of 2.0 ± 0.04 mm for size 7, a thickness of 4.0 ± 0.03 mm for size 9, a thickness of 6.0 ± 0.04 mm for size 11 and a thickness of 8.0 ± 0.08 mm for size 13 (see Table 5.1).

Table 5.1. Actual thicknesses of different unused PE inserts as measured with a Vernier calliper.

| Size | Original thickness mean \pm sd | n |
|------|-------------------------------------|----|
| 7 | 2.0 ± 0.04 | 5 |
| 9 | 4.0 ± 0.03 | 12 |
| 11 | 6.0 ± 0.04 | 6 |
| 13 | 8.0 ± 0.08 | 13 |

5.3.2 Radiographic measurement of the thickness of the polyethylene insert

To determine the thickness of the unused PE inserts radiographically, we made X-rays of different unused SKI prostheses positioned in an empty bottle. The prosthesis was centralized as described above. To determine the thickness of the PE, the smallest distance between the metal femoral condyle and the tibial tray (h) was measured. Magnification was corrected for by dividing the measured width of the tibial tray (w) by the original width (see Figure 5.4).

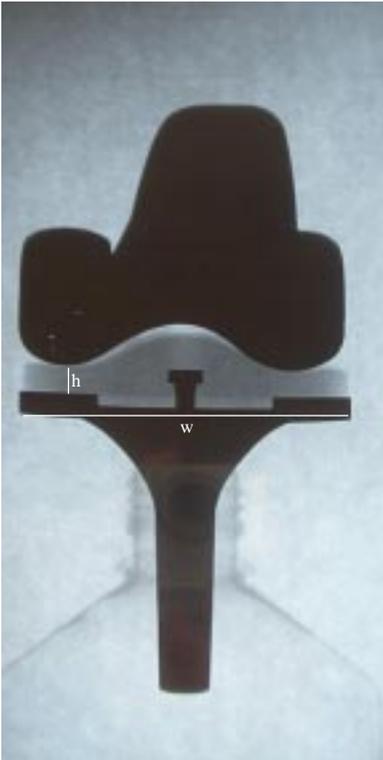


Figure 5.4. The thickness of the PE insert radiographically was calculated by the formula: $h/(w/\text{original width of the tibial tray})$.

At radiographic examination of different unused PE inserts, we found a thickness of 2.0 ± 0.00 mm for size 7, a thickness of 4.0 ± 0.04 mm for size 9, a thickness of 6.0 ± 0.08 mm for size 11 and a thickness of 8.0 ± 0.15 mm for size 13 (see Table 5.2).

Table 5.2. Projected thicknesses of different unused PE inserts as measured on radiographs.

| Size | Thickness measured radiographically mean \pm sd | n |
|------|--|----|
| 7 | 2.0 ± 0.00 | 2 |
| 9 | 4.0 ± 0.04 | 25 |
| 11 | 6.0 ± 0.08 | 6 |
| 13 | 8.0 ± 0.15 | 8 |

5.3.3 Determination of the intraclass correlation coefficient

Reliability of the radiographic measurements compared to the original thickness was determined with an intraclass correlation coefficient¹⁸⁵. With an analysis of variance, no significant difference was found between measurements with a Vernier calliper and those on a radiograph ($p=0.971$). Because no difference was found between these methods of measurement, an intraclass correlation coefficient could be determined in a one-way model for the average score. The intraclass correlation coefficient for measurement of the PE thickness with a Vernier calliper and on a radiograph was 0.999.

5.3.4 Discussion

Bartel et al.⁷¹ found an increase in stresses on the polyethylene with decreasing thickness. They recommended a polyethylene thickness of at least eight to ten millimeters. The original thickness of the load-bearing area of the PE insert of the SKI prosthesis we found was only 2.0 and 4.0 mm for the sizes 7 and 9, which were used mostly (see Appendix 1). This is far less than the recommended thickness.

There is little information about in vivo wear measurement, because of practical issues related to the patient's positioning and reproduction of the X-ray beam projection⁹⁷. Because of the raised border on the tibial plateau of the SKI prosthesis it can be centralized fluoroscopically. The PE thickness of the SKI prosthesis could be measured accurately on a fluoroscopically centralized X-ray (intraclass correlation coefficient = 0.999). When manufacturers of knee prostheses add a marker to the PE insert in future designs, it is possible to centralize the knee prosthesis radiographically to be able to determine the amount of wear in vivo.

5.3.5 Conclusions

The PE thickness of the SKI prosthesis is far less than the recommended eight to ten millimeters for the sizes 7, 9 and 11.

The PE thickness of the SKI prosthesis can be measured accurately on a fluoroscopically centralized X-ray, with an intraclass correlation coefficient of 0.999.

5.4 SHORT OR FULL-LENGTH LEG RADIOGRAPHS?

Alignment of the leg can be determined on full-length leg and short radiographs by measuring the femoro-tibial angle (FTA). It represents the varus or valgus angle of the lower extremity. In some studies no

significant difference was found between measurements of the FTA on long and short radiographs³, but in other studies significant differences were found^{173;188;189}. In this study the differences between measurements on a long and a short radiograph were determined.

With an intramedullary guidance instrument a knee prosthesis is aligned through the knee center. We also determined the differences between measuring the FTA through the true anatomical axes of the femur and tibia and through the knee center.

The FTA is the angle on the lateral side between the femoral anatomical axis and the tibial anatomical axis. The anatomical axis of the shaft can be drawn in two different ways:

1. through four points representing the shaft centers of the femur and tibia. The point of intersection of these lines may be beyond the knee center (see Figure 5.5a and 5.5c).
2. through two points representing the shaft centers of the femur and tibia, and the knee center. The knee center can be defined as the intersection of the line through the center of the stem of the tibial component and the line touching both femoral condyles (see Figure 5.5b and 5.5d).

We analyzed the difference between the FTAs measured in four different ways:

- **FTA I:** the anatomical axis was drawn through the femoral and tibial shaft centers on a full-length leg radiograph (see Figure 5.5a).
- **FTA II:** the anatomical axis was drawn through the femoral and tibial shaft centers and the knee center and on a full-length leg radiograph (see Figure 5.5b).
- **FTA III:** the anatomical axis was drawn through the femoral and tibial shaft centers on a short radiograph (see Figure 5.5c).
- **FTA IV:** the anatomical axis was drawn through the femoral and tibial shaft centers and the knee center on a short radiograph (see Figure 5.5d).

FTA I represents the true anatomical axis. To determine the position of the knee prosthesis intraoperatively with an intramedullary guidance instrument, the knee is aligned through the lines representing FTA II.

To determine the difference between the FTA measured on a full-length leg radiograph and the FTA measured on a short radiograph (FTA I versus III and FTA II versus IV), a paired samples t-test was used. The difference between the true anatomical axis (FTA I) and the axis used to determine the alignment of the prosthesis with an intramedullary

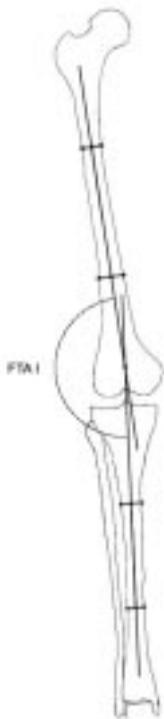


Fig. 5.5a

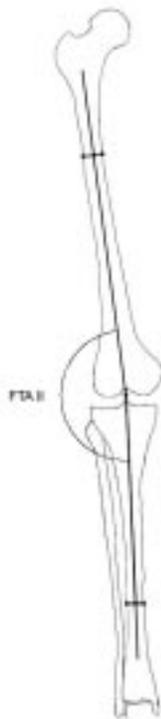


Fig. 5.5b

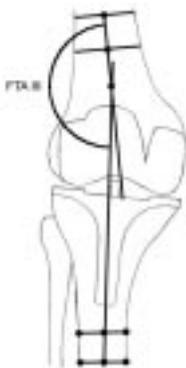


Fig. 5.5c



Fig. 5.5d

Figure 5.5a-d.

- 5.5a: FTA I: the anatomical axis is drawn through the femoral and tibial shaft centers on a full-length leg radiograph.
- 5.5b: FTA II: the anatomical axis is drawn through the femoral and tibial shaft centers and the knee center and on a full-length leg radiograph.
- 5.5c: FTA III: the anatomical axis is drawn through the femoral and tibial shaft centers on a short radiograph.
- 5.5d: FTA IV: the anatomical axis is drawn through the femoral and tibial shaft centers and the knee center on a short radiograph.

guidance instrument (FTA II) was determined with a paired samples t-test. A difference was considered significant if the p-value was <0.05.

To know how much FTA I and III, II and IV, and I and II differed, a Bland Altman ¹⁸⁶ plot was drawn. In this plot, the differences between two measurements are plotted against their mean. The mean difference and the standard deviation of the differences estimate the bias. In 68 knees of the patients seen in the second follow-up study, the set of X-

Table 5.3. Mean values of FTA I, II, III and IV measured in 68 knees. Comparing the FTA measured on a full-length leg radiograph with the FTA measured on a short radiograph (FTA I with III and FTA II with IV) shows a significant difference. Measuring the FTA through the true anatomical axis of the femur and tibia (FTA I) shows a significant difference with the FTA measured through the center of the knee (FTA II).

| | femoro-tibial angle (FTA) mean ± sd (min-max) | FTA II | FTA III |
|---------|--|---------------|----------------|
| FTA I | 172.1 ± 6.1 (153-184) | * | * |
| FTA II | 174.1 ± 5.1 (160-187) | | |
| FTA III | 175.1 ± 5.4 (159-190) | | |
| FTA IV | 177.3 ± 4.1 (167-190) | * | |

* *p-value <0.001, paired samples t-test*

rays was complete, to measure all four different FTA angles.

5.4.1 Results

The mean values of FTA I, II, III and IV are listed in Table 5.3. The FTA measured on a full-length leg radiograph (FTA I and II) was smaller on average, compared with the FTA measured on a short radiograph (FTA III and IV). The difference between the FTA measured on a full-length leg radiograph and the FTA measured on a short radiograph (FTA I versus III and FTA II versus IV) was significant ($p < 0.001$).

The difference between the FTA measured through the true anatomical axis of the femur and tibia (FTA I) and the axis measured through the center of the knee, used to align a knee prosthesis with an intramedullary guidance instrument (FTA II), was significant too ($p < 0.001$).

The mean difference between FTA I and FTA III was $3.0^\circ \pm 3.1$. This means that the measurements of the FTA on a short radiograph through the true anatomical axis of the femur and tibia may be 9.2° above or 3.3° below the measurements of the FTA on a full-length leg radiograph (see Figure 5.6).

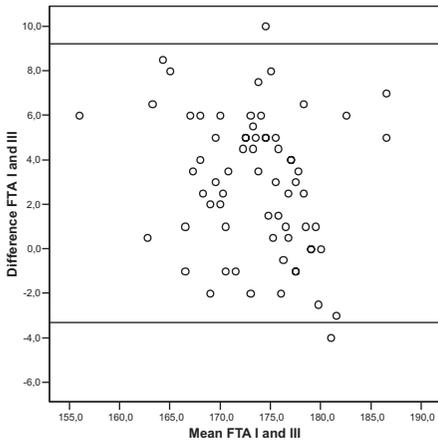


Figure 5.6. Bland Altman plot of FTA I and III. Measurements of the FTA on a short radiograph through the true anatomical axis of the femur and tibia may be 9.2° above or 3.3° below the measurements of the FTA on a full-length leg radiograph, with a mean difference of 3.0° .

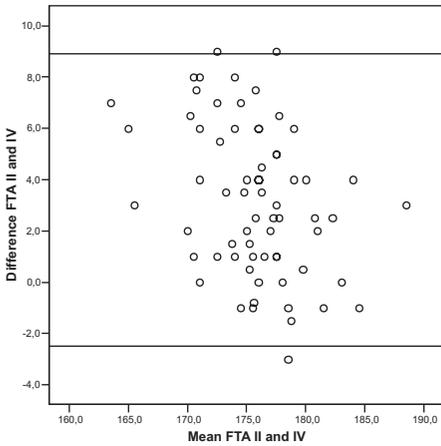


Figure 5.7. Bland Altman plot of FTA II and IV. Measurements of the FTA on a short radiograph through the knee center may be 8.8° above or 2.5° below the measurements of the FTA on a full-length leg radiograph, with a mean difference of 3.2° .

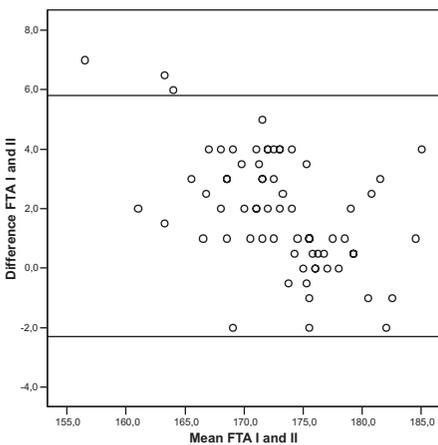


Figure 5.8. Bland Altman plot of FTA I and II. Measurements of the FTA measured through the knee center may be 5.8° above or 2.3° below the FTA on a full-length leg radiograph through the true anatomical axis of the femur and tibia, with a mean difference of 1.8° .

The mean difference between FTA II and FTA IV was $3.2^\circ \pm 2.8$. This means that measurements of the FTA on a short radiograph through the knee center may be 8.8° above or 2.5° below the measurements of the FTA on a full-length leg radiograph (see Figure 5.7).

The mean difference between FTA I and II was $1.8^\circ \pm 2.0$. This means that the measurements of the FTA measured through the knee center may be 5.8° above or 2.3° below the FTA on a full-length leg radiograph through the true anatomical axis of the femur and tibia (see Figure 5.8)

5.4.2 Discussion

To determine the varus or valgus angle of the lower extremity, FTA I is probably the most reliable measurement, because it is measured through the true anatomical axes of the femur and tibia on a full-length leg radiograph. Measuring the FTA on a short radiograph may underestimate or overestimate the femoro-tibial angle by bowing of the tibia or femur, previous tibial osteotomies or flexion contractures^{173;173;187;188}. Some authors³ found no significant difference between measurements on long and short radiographs, but others^{173;188;189} found significant differences. In our study, a difference of $3.0^\circ \pm 3.1$ was found between measurements of the FTA on long and short radiographs if the FTA was measured through the true anatomical axes of the femur and the tibia, and a difference of $3.2^\circ \pm 2.8$ if the FTA was measured through the knee center. Clinically this is a large difference.

Moreland et al.⁹⁰ stated that the anatomical axis of the femur did not pass through the center of the knee. To position a knee prosthesis, the intramedullary guidance instruments are entered into the knee center of the femur and tibia. Comparison of the measurements of the FTA through the true anatomical axis (FTA I) and the axis guided by an intramedullary rod through the knee center (FTA II) shows a significant difference, with a mean of $1.8^\circ \pm 2.0$.

5.4.3 Conclusions

In our study, the FTA cannot be measured on a short radiograph. With an intramedullary guidance instrument, a knee prosthesis is not aligned through the real anatomical axis of the femur and tibia. The mean FTA determined with an intramedullary guidance instrument through the knee center is $1.8^\circ \pm 2.0$ higher compared to the FTA through the true anatomical axis of the femur and tibia.

5.5 WEAR AND WEAR RATE

With the reliable radiographic measurement of wear in vivo as described in section 5.3, we were able to analyze the factors that might have an influence on the presence of wear and on the wear rate.

5.5.1 Materials and methods

5.5.1.1 Patient characteristics

All patients seen in the second follow-up study were included in the radiographic study. At Tc, 79 patients (97 knees) were available for follow-up. Eleven patients (12 knees) were seen at home without radiographic examination, leaving 68 patients (85 knees) available for radiographic examination of the SKI prosthesis. Of all the knees available for radiographic examination, the wear could not be determined in 14 knees because of flexion contractures or because they were not properly centralized, incomplete or taken in a non-weight bearing position. This left 58 patients (71 knees) available for determination of wear and wear rate. All details of the patients included in the radiographic study are described in Appendix 2.

The mean time of follow-up of the patients included in the radiographic study was 14.0 ± 2.5 years (range 10.0-19.1). Of all the knees included in the radiographic study, 18 knees (21.2%) had had an exchange of the PE insert prior to radiographic examination. In 12 of these knees the wear rate could also be determined on fluoroscopically centralized X-rays in the first follow-up study, before PE exchange.

5.5.1.2 Determining the amount of wear and wear rate

To determine the thickness of the PE insert at follow-up, the smallest distance between the metal femoral condyle and the tibial tray on the fluoroscopically centralized AP radiograph was measured. This was done for the medial and for the lateral side. Magnification was corrected by dividing the measured width of the tibial tray by the known width (see Figure 5.4). To determine the amount of wear, the distance measured on the radiograph was subtracted from the original thickness of the PE insert (see section 5.3), giving the wear in millimeters.

Table 5.4. Number of knees with and without wear.

| | Wear | No wear |
|--------------|--|------------|
| | Exchange of the PE insert (n=17) ≥ 2mm loss in height radiographically (n=14) | n=40 |
| Total | 31 (43.7%) | 40 (56.3%) |

By measuring both the medial and lateral side of the PE insert, we occasionally found that the measured thickness was more than the original thickness. This is probably due to lift-off of the femoral component, which is already seen at very small eccentric loads and can be caused by implant design and soft-tissue laxity¹⁹⁰⁻¹⁹³. Therefore, to determine the amount of wear of each prosthesis we only used the amount of wear measured on the loaded side.

Knees with wear were determined as knees that had had a PE exchange or knees with a loss in height of the PE insert ≥ 2 mm radiographically. The limit was set at 2 mm, because this means a loss of the total height of the thinnest available insert. A loss in height of less than 2 mm could also be caused by creep or surface deformation and may not be caused by wear^{101;102}. The annual wear rate was determined by dividing the total amount of wear by the number of years the prosthesis was in situ. If there had been a PE exchange, the total amount of wear was divided by the number of years after a PE exchange.

5.5.2 Statistical analysis

We analyzed and considered the factors that may influence and contribute to the presence of wear and the wear rate (see section 3.2.3):

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

To analyze the factors that might contribute to the presence of wear, a univariate logistic regression analysis at knee level was performed for each factor separately. To correct for all factors that might influence the presence of wear, a multivariate logistic regression analysis was performed. The regression coefficients (B), standard error (se) and p-value will be presented in Table 5.5. The odds ratio can be calculated by the formula e^B . A factor was considered significant if the p-value was <0.05 .

* 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).

Table 5.5. Multivariate logistic regression analysis with the Logistic regression coefficient (B), standard error (se) and p-value of the relation between the presence of wear and the factors that may influence the presence of wear in 71 knees. The only significant factor that contributed to the presence of wear was screw loosening.

| | n | Wear n (%) | No wear n (%) | B | se | p-value |
|---|----|-------------------------|------------------------|--------|-------|--------------|
| Diagnosis | | | | | | |
| Degenerative arthritis | 26 | 15 (57.7%) | 11 (42.3%) | | | |
| Rheumatoid arthritis | 35 | 12 (34.3%) | 23 (65.7%) | -0.594 | 0.879 | 0.499 |
| Other | 10 | 4 (40.0%) | 6 (60.0%) | -0.949 | 0.973 | 0.330 |
| Sex | | | | | | |
| Male | 14 | 9 (62.3%) | 5 (35.7%) | | | |
| Female | 57 | 22 (38.6%) | 35 (61.4%) | 0.655 | 0.876 | 0.455 |
| Body weight (mean ± sd (min-max)) | | | | | | |
| | 71 | 76.0 ± 14.2 (46-102) | 68.0 ± 10.5 (52-90) | 0.034 | 0.030 | 0.256 |
| Age at the time of surgery (mean ± sd (min-max)) | | | | | | |
| | 71 | 54.8 ± 14.6 (28-84) | 57.9 ± 14.9 (24-83) | -0.022 | 0.027 | 0.424 |
| Function Score (mean ± sd (min-max)) | | | | | | |
| | 71 | 51.7 ± 25.7 (0-100) | 41.2 ± 29.1 (0-90) | 0.016 | 0.012 | 0.181 |
| PE thickness | | | | | | |
| 7 | 71 | 31 (54.4%) | 26 (45.6%) | -0.018 | 0.197 | 0.929 |
| 9 | | 7 (70.0%) | 3 (30.0%) | | | |
| 11 | | 1 (50.0%) | 1 (50.0%) | | | |
| 13 | | 1 (50.0%) | 1 (50.0%) | | | |
| Time of follow-up (mean ± sd (min-max)) | | | | | | |
| | 71 | 13.7 ± 2.6 (10-19) | 14.3 ± 2.5 (10-19) | -0.037 | 0.122 | 0.760 |
| Screw loosening | | | | | | |
| Yes | 13 | 11 (84.6%) | 2 (15.4%) | | | |
| No | 58 | 20 (34.5%) | 38 (65.5%) | -2.194 | 0.884 | 0.013 |

Table 5.6. Wear rate in all knees available for radiographic examination of wear (n=71). The wear rate was determined in knees with wear (n=31) and without wear (n=40). No significant difference in wear rates was found before and after a PE exchange (n=12).

| | n | Mean wear rate (mm/year) ± sd (min-max) |
|---|----|---|
| All knees | 71 | 0.14 ± 0.25 (0.00-1.50) |
| Prostheses with wear: | | |
| No PE exchange ² | 31 | 0.29 ± 0.33 (0.04-1.50) |
| After PE exchange (at Tc) | 14 | 0.24 ± 0.21 (0.08-0.89) |
| | 17 | 0.27 ± 0.43 (0.00-1.50) ¹ |
| Before PE exchange | 12 | 0.16 ± 0.11 (0.04-0.45) ¹ |
| Prostheses with no wear or slight wear ³ | 40 | 0.05 ± 0.04 (0.00-0.17) |

¹ Paired samples t-test, p=0.219

² ≥ 2 mm loss in height of the PE insert at radiographic examination

³ < 2 mm loss in height of the PE insert at radiographic examination

To analyze the factors that might influence the wear rate, 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 Table 5.7. A factor was considered significant if the p-value was <0.05.

5.5.3 Results

5.5.3.1 Presence of wear

Of all knees available for the analysis of wear, 31 knees (43.7%) had wear and 40 knees (56.3%) had no wear or slight wear. The group of knees with wear consisted of 17 knees that had had an exchange of the PE insert and 14 knees that had a loss in height of the PE insert ≥ 2 mm at radiographic examination (see Table 5.4).

In the group of patients included in the radiographic analysis, in patients with degenerative arthritis more wear was seen compared to patients with rheumatoid arthritis and other diagnoses, more wear was seen in male patients compared to female patients and patients with wear were younger on average, but the differences were not significant. The PE thickness had no influence on the presence of wear.

In a logistic regression analysis, patients with increased body weight had significantly more wear ($p=0.009$), patients with a higher activity level had significantly more wear ($p=0.027$), and knees with screw loosening had significantly more wear ($p=0.004$). Corrected for all factors, the only significant factor contributing to the presence of wear was loosening of the screw. Wear was seen in 84.6% of the knees with screw loosening, while 34.5% of the knees with a fixed screw had wear (see Table 5.5).

5.5.3.2 Wear rate

The mean annual wear rate of all prostheses included in the radiographic analysis was 0.14 ± 0.25 mm. The mean annual wear rate of all prostheses with wear was 0.29 ± 0.33 mm ($n=31$). For prostheses with wear with the original PE insert in situ, the annual wear rate was 0.24 ± 0.21 mm ($n=14$). For prostheses with wear that had an exchange of the PE insert this was 0.27 ± 0.43 mm ($n=17$) after the exchange. In 12 of the knees that had a PE exchange, in which the wear rate could also be determined before exchange, we found an annual wear rate of 0.16 ± 0.11 mm. Although the mean wear rate seemed to increase after PE exchange, a paired t-test showed no significant difference between the wear rates before and after exchange of the PE insert ($p=0.219$). The mean annual wear rate of prostheses with no wear or slight wear was 0.05 ± 0.04 mm ($n=40$) (see Table 5.6).

Patients with degenerative arthritis had a higher annual wear rate compared to patients with rheumatoid arthritis and other diagnoses, but the difference was not significant. Sex, body weight, age at the time of surgery, activity level, PE thickness and time of follow-up had no significant influence on the wear rate.

The only factor that had a significant influence on the wear rate was screw loosening. Knees with screw loosening had an annual wear rate that was more than four times higher compared to knees with a fixed screw (0.39 ± 0.45 mm versus 0.09 ± 0.13 mm) (see Table 5.7).

Table 5.7. Univariate analysis of variance with the test statistic F-value and p-value of the factors that might influence the wear rate, corrected for all factors (n=71).

| Factors that may have an influence on the wear rate | n | Annual wear rate (mm) mean \pm sd (min-max) | F-value | p-value |
|---|----|---|---------|------------------|
| Diagnosis | | | 0.514 | 0.601 |
| Degenerative arthritis | 26 | 0.17 ± 0.19 (0.00-0.89) | | |
| Rheumatoid arthritis | 35 | 0.14 ± 0.31 (0.00-1.50) | | |
| Other | 10 | 0.07 ± 0.08 (0.00-0.22) | | |
| Sex | | | | |
| Male | 14 | 0.15 ± 0.13 (0.01-0.50) | | |
| Female | 57 | 0.14 ± 0.27 (0.00-1.50) | 0.077 | 0.783 |
| Body weight | 71 | | 0.011 | 0.919 |
| Age at the time of surgery | 71 | | 1.545 | 0.219 |
| Function Score | 71 | | 0.019 | 0.892 |
| PE thickness | | | 0.490 | 0.486 |
| 7 | 56 | 0.13 ± 0.26 (0.00-1.50) | | |
| 9 | 10 | 0.12 ± 0.12 (0.00-0.31) | | |
| 11 | 2 | 0.46 ± 0.61 (0.03-0.89) | | |
| 13 | 2 | 0.17 ± 0.12 (0.09-0.25) | | |
| Time of follow-up | 71 | | 0.498 | 0.483 |
| Screw loosening | | | | |
| Yes | 13 | 0.39 ± 0.45 (0.04-1.50) | | |
| No | 58 | 0.09 ± 0.13 (0.00-0.89) | 15.474 | <0.001 |

5.5.4 Discussion

In Chapter 3 we found that patients with wear had a significantly higher activity level, were younger at the time of surgery and had significantly more screw loosening. In the group of patients available for radiographic examination, patients with wear had a higher activity level, were slightly younger at the time of surgery, had more body weight, and had more

screw loosening. Corrected for all factors, the only factor that had significant influence on the presence of wear and the wear rate was screw loosening. The group of patients included in the radiographic study is a selection of patients with the longest follow-up time. Therefore, activity level and age at the time of surgery may not be significant anymore in this selected group of patients. Knees with loosening of the screw had a wear rate that was more than four times higher compared to knees with a fixed screw. Knees with screw loosening had a mean annual wear rate of 0.39 mm. This means a full thickness wear of the thinnest PE insert in five years. The wear rate in knees with screw loosening may even be higher, because some of the screws were tightened again or locked.

Most studies about polyethylene wear in total knee replacement are retrieval analyses. Benjamin et al.¹⁹⁴ found an average annual wear rate of 0.35 mm in 33 retrieved polyethylene inserts from three different posterior cruciate-retaining knee systems. Few reports have been published about in vivo polyethylene wear in total knee replacement. Hoshino et al.⁹⁷ used a computer-vision technique and found an annual wear rate of 0.23 mm. Matsuda et al.¹⁹⁵ found an annual wear rate of 0.13 mm in 20 posterior cruciate-retaining knee prostheses on a standard AP radiograph after a mean follow-up of 7 years. Sanzen et al.¹⁹⁶ described the amount of wear in 158 PCA knees with fluoroscopically guided X-ray measurement. After a mean follow-up of 7 years, they found an average wear of 1.4 mm at the medial compartment and an average wear of 0.7 mm at the lateral component in patients with degenerative arthritis. In patients with rheumatoid arthritis they found an average wear of 0.7 mm at the medial compartment and an average wear of 0.4 mm at the lateral component. The annual wear rate is not described, but it is similar to our results from a rough calculation. In our study we found a mean annual wear rate of 0.14 ± 0.25 mm for all prostheses that were available for radiographic analysis. Prostheses with wear had a mean annual wear rate of 0.29 ± 0.33 mm. After a PE exchange there seemed to be an increase in the wear rate, but this was not significant.

To determine the wear rate, we assumed a linear wear rate in time. However, the wear rate may be non-linear, with an increase if wear is already present. The amount of wear can only be determined accurately on fluoroscopically centralized X-rays. Because most of radiographs that were made on earlier outpatient visits were not centralized fluoroscopically, we were not able to determine the course of the wear rate in time.

5.5.5 Conclusions

The annual wear rate of all knees included in the radiographic analysis was 0.14 mm. The annual wear rate for prostheses with wear was 0.29 mm. No significant change in wear rate was seen after a PE exchange.

In the group of patients included in the radiographic analysis, loosening of the screw was the only factor that contributed significantly to the presence of wear and the wear rate. Knees with loosening of the screw had a wear rate that was more than four times higher compared to knees with a fixed screw. We were not able to determine the course of the wear rate in time.

5.6 WEAR AND ALIGNMENT OF THE PROSTHESIS

In the next section, the relation between the wear rate and the alignment of the femoral and tibial components on the AP and lateral fluoroscopically centralized radiographs will be described.

5.6.1 Material and Methods

5.6.1.1 Patient characteristics

To analyze the most homogeneous group of knees to determine the influence of alignment of the prosthesis on the wear rate, the analysis was performed in knees that had had no PE exchange (54 knees, 47 patients). The patient characteristics are described in Appendix 2. The mean time of follow-up of these patients was 14.0 years \pm 2.6 (range 10.0-19.1).

5.6.1.2 Alignment of the prosthesis

The position of the prosthesis was determined on the short, fluoroscopically centralized AP and lateral radiographs, as recommended by the Knee Society¹⁹⁷ (see Figure 5.9).

The anatomical axes of the femur and tibia were drawn through two points representing the shaft centers of the distal femur and the proximal tibia. On the AP radiograph, the position of the femoral component was determined by the angle on the medial side between the anatomical axis of the femur and the line touching both condyles (angle α). The position of the tibial component was determined by the angle on the medial side between the anatomical axis of the tibia and the line parallel to the tibial tray (angle β).

On the lateral radiograph the position of the femoral component was determined by angle γ , that of the tibial component by angle σ .

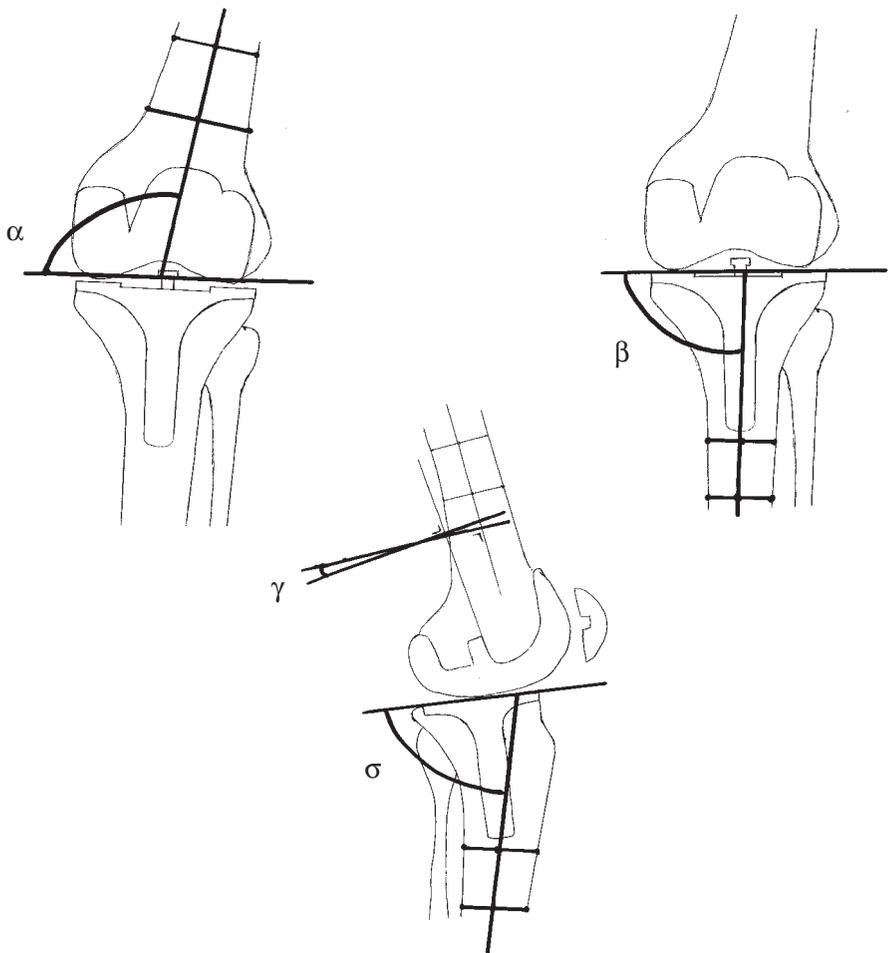


Figure 5.9. Angles α , β , γ and σ :

- Angle α represents the position of the femoral component in the AP view: the angle on the medial side between the anatomical axis of the femur and the line touching both condyles.
- Angle β represents the position of tibial component in the AP view: the angle on the medial side between the anatomical axis of the tibia and the line parallel to the tibial tray.
- Angle γ represents the position of the femoral component in the lateral view: the angle between the anatomical axis of the femur and the stem of the femoral component.
- Angle σ represents the slope of the tibial component in the lateral view: the angle between the anatomical axis of the tibia and the line parallel to the tibial tray.

Angle γ is the angle between the anatomical axis of the femur and the stem of the femoral component. The angle has a negative value for extension of the femoral component and a positive value if the femoral component is placed in flexion. Angle σ is the angle between the

anatomical axis of the tibia and the line parallel to the tibial tray. It represents the slope of the tibial component.

The femoral component should be within 4° to 11° of valgus (angle α 94° - 101°)^{87;188;198;199}. On the lateral view, the alignment of the femoral component should be parallel or nearly parallel to the long axis of the femur (angle γ $0^\circ \pm 5^\circ$)^{87;198}. The alignment of the tibial component should be perpendicular to the tibial shaft or in slight valgus position on the AP view (angle β 84° - 90°). On the lateral view, the tibial component should be horizontal or should slope downwards posteriorly no more than 10° (angle σ 80° - 90°)^{87;198-200}.

5.6.2 Statistical analysis

We assumed finding a low wear rate at an optimal alignment of the prosthesis and an increase in wear rate in a more valgus or varus position, or if the prosthesis was placed in more flexion or extension. A non-linear regression analysis was performed for angles α , β , γ and σ in order to study a quadratic relation (see Appendix 5).

5.6.3 Results

5.6.3.1 Angle α

The mean angle α of the knees that had had no PE exchange in the second follow-up study was $99.0^\circ \pm 3.7$ (range 86-104). There were 42 knees (77.7%) with a correct alignment of the femoral component (angle α between 94° and 101°), four knees (7.4%) with an extreme varus position (angle $\alpha < 94^\circ$) and seven knees (13.0%) with an extreme valgus position (angle $\alpha > 101^\circ$). In one knee, angle α could not be determined because only a small part of the distal femur was seen on the radiograph. Non-linear regression analysis showed no significant relation between angle α and the wear rate ($p=0.563$).

5.6.3.2 Angle β

The mean angle β was $85.7^\circ \pm 3.3$ (range 76-93). Of all tibial components, 39 (72.2%) had a correct alignment (angle β between 84° and 90°), 12 (22.2%) had an extreme varus position (angle $\beta < 84^\circ$) and three (5.5%) had a valgus position (angle $\beta > 90^\circ$). No significant relation was found between the position of the tibial component in AP direction and the wear rate ($p=0.305$) (see Figure 5.10).

5.6.3.3 Angle γ

The mean angle γ was $-5.7^\circ \pm 5.3$ (range -17-9). Of all femoral components, 22 (40.7%) had a correct alignment in the sagittal plane (angle γ between



Figure 5.10. AP radiograph of a SKI prosthesis in an 86-year old female patient, 16 years after implantation, with malalignment of both components (angle $\alpha = 102^\circ$, angle $\beta = 79^\circ$). The annual wear rate in this knee was only 0.06 mm.

-5° and 5°), 28 (51.9%) had a position in extension (angle $\gamma < -5^\circ$) and two (3.7%) had a position in flexion (angle $\gamma > 5^\circ$). In two knees, angle γ could not be determined because only a small part of the distal femur was seen on the radiograph.

Prostheses with the femoral component placed in more flexion and especially in more extension seemed to have a higher wear rate, but non-linear regression analysis showed no significant influence of angle γ on the wear rate ($p=0.092$) (see Figure 5.11).

5.6.3.4 Angle σ

The mean angle σ was $86.5^\circ \pm 3.7$ (78-96). Of all tibial components, 42 (77.7%) had a correct alignment in the saggital plane (angle σ between 80° and 90°), one knee (1.9%) had a backslope of more than 10° and

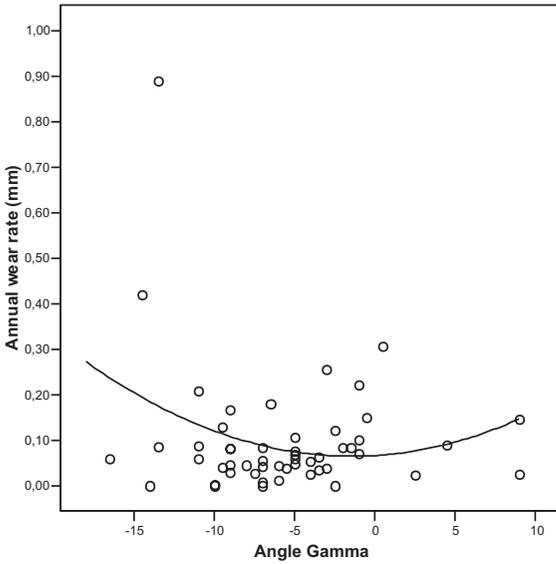


Figure 5.11. Angle γ and wear rate. Knees with a femoral component in flexion (Angle $\gamma > 0^\circ$) and especially in extension (Angle $\gamma < 0^\circ$) seemed to have a higher wear rate, but the relation was not significant (non-linear regression analysis, $p=0.092$)

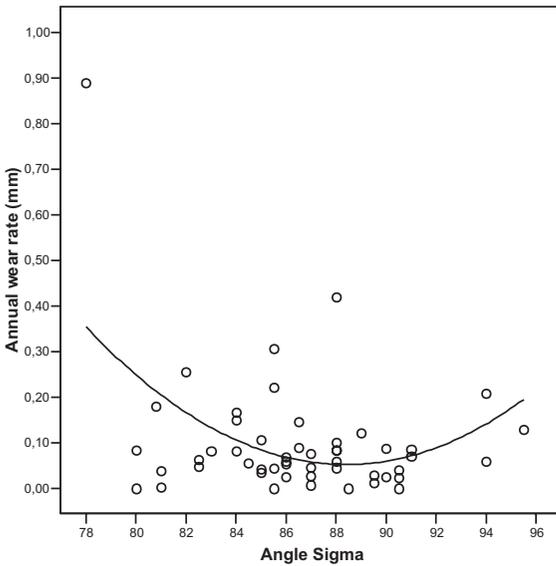


Figure 5.12. Angle σ and wear rate. Knees with more backslope or an upslope seemed to have a higher wear rate, but the relation was not significant ($p=0.113$).

eight knees (14.8%) had an upslope (angle $\sigma > 90^\circ$). In three knees, angle σ could not be determined because only a small part of the proximal tibia was seen. Knees with more backslope or an upslope seemed to have a higher wear rate, but this relation was not significant ($p=0.113$) (see Figure 5.12).

5.6.4 Discussion

Prosthetic alignment is assumed to be crucial for the success of total knee arthroplasty¹⁹⁸.

In this study the analysis of the influence of the prosthesis alignment on the wear rate was performed after a mean follow-up of 14.0 years. The group of patients studied was a selection of all patients with a SKI prosthesis. The knees with malalignment may have been revised before the start of this radiographic study. In the knees included in the analysis, the alignment of the prosthesis may have been changed in time. Because radiographs on earlier outpatient visits were not centralized properly, we were not able to determine if there had been a change in position of the prosthesis. As the knees included in this study had no clinical or radiographic signs of loosening, we assume there had been no change in position of the prosthesis in the course of time.

In the group of patients available for radiographic examination, 20.4% of the knees had malalignment of the femoral component in the AP view and 55.6% in the lateral view. In 27.7% of the knees, malalignment of the tibial component was seen in the AP view, and in 16.7% in the lateral view. Although the position of the prosthesis may have changed in time, and the study was performed in a selected group of patients, it seems that the external guidance instruments used in the SKI prosthesis did not accurately align the components.

In this group of patients, prostheses with the femoral component placed in flexion and especially in extension seemed to have higher wear rates, but a significant relation could not be demonstrated. The polyethylene insert in the SKI prosthesis is relatively flat. The posterior side of the femoral component is sharply curved. Positioning of the femoral component in flexion and especially in extension may cause a higher point loading and may induce a higher wear rate (see Figure 5.13). An increased backslope or an upslope also seemed to cause more wear, but the relation was not significant either.

No significant relation was found between the wear rate and the position of the femoral or tibial components. Considering three degrees of freedom for each component (varus/valgus, flexion/extension and internal/external rotation) with three major possibilities for each degree



Figure 5.13. Lateral radiograph of a SKI prosthesis with the femoral component placed in extreme extension (angle $\gamma = -17^\circ$). The sharply curved posterior side of the femoral component may cause a higher wear rate due to a higher point loading.

of freedom (varus-neutral-valgus, flexion-neutral-extension and internal-neutral-external rotation), there are 9 (3x3) possibilities of prosthetic placement for each component. For placement of both components there are 81 (9x9) possibilities. Because of this large number of possibilities and the small number of patients, it is not surprising to find no relation between the wear rate and the position of the femoral or tibial component separately. It is more likely that the alignment of the limb, especially the mechanical axis, may influence the wear rate. In addition to the alignment of the prosthesis or limb, there are probably other factors in this small number of patients that may influence the wear rate, such as body weight, activity level and screw loosening (see Chapter 3 and section 5.5).

5.6.5 Conclusions

The external guidance instruments used in the SKI prosthesis did not accurately align the components. In particular, malalignment of the femoral component in the lateral view was seen in the majority of the knees available for radiographic examination.

The position of the femoral or the tibial component of the SKI prosthesis had no significant influence on the wear rate. Placement of the femoral component of the SKI prosthesis in flexion and especially in extension, or the tibial component with an increased backslope or an upslope, seemed to cause a higher wear rate, but a significant relation could not be demonstrated.

5.7 WEAR AND ALIGNMENT OF THE LIMB

The wear rate may be influenced by the loading axis of the lower extremity, resulting from the position of the components separately. In the next section the relation between the wear rate and the alignment of the lower extremity, measured on full-length leg radiographs, will be described.

5.7.1 *Materials and methods*

5.7.1.1 *Patient characteristics*

To analyze the most homogeneous group of knees to determine the influence of the alignment of the limb on the wear rate, the analysis was performed only for knees that had had no PE exchange (54 knees, 47 patients). All details of the patients are described in Appendix 2.

5.7.1.2 *Alignment of the limb*

In section 5.4 we showed that short radiographs in our study could not be used to determine the femoro-tibial angle. In this study we used the FTA measured on a full-length leg radiograph through the anatomical axes of the femur and the tibia, as represented by FTA I (see Figure 5.14a). The correct postoperative alignment has been defined by Kettelkamp et al.²⁰¹ as a femoro-tibial angle of 173°. Others considered a femoro-tibial angle of 173°-177° acceptable²⁰².

The mechanical axis of the lower limb is determined by drawing a line from the center of the hip to the center of the talus. The Weight Bearing Ratio (WBR), as used by Matsuda et al.¹⁹⁵, is calculated by dividing the distance from this line to the medial side of the tibial plateau, through the entire width of the tibial plateau (see Figure 5.14b). In the ideal situation, when the mechanical axis crosses the center of the knee, the WBR is 50%. If the mechanical axis crosses the medial side of the knee, as is seen in a varus alignment, the WBR is <50%. If the mechanical axis crosses the lateral side of the knee, as is seen in a valgus alignment, the WBR is >50%.

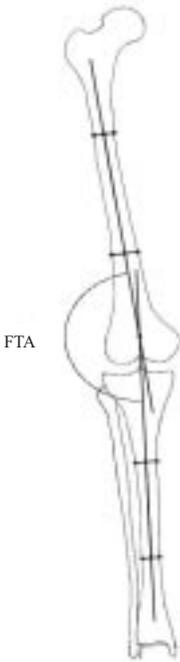


Fig. 5.14a

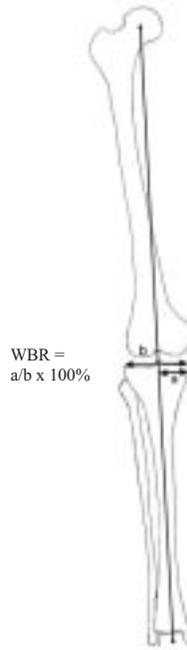


Fig. 5.14b

Figure 5.14 a and b. Femoro-tibial angle (FTA) (Figure 5.14a) and Weight Bearing Ratio (WBR) (Figure 5.14b) on a full-length leg radiograph. For measurement of the FTA, the anatomical axes of the femur and tibia are drawn through four points representing the shaft centers. The WBR is calculated by dividing the distance from the medial side of the plateau to the mechanical axis (a) through the entire width of the plateau (b), the mechanical axis being the line that connects the center of the femoral head with the center of the talus.

5.7.2 Statistical analysis

We assumed finding a low wear rate at an optimal alignment of the limb and an increase in wear rate either in a more valgus or a varus position of the leg. For both the FTA and WBR, a non-linear regression analysis was performed in order to study a quadratic relation (see Appendix 5).

5.7.3 Results

5.7.3.1 Femoro-tibial angle

The mean femoro-tibial angle of all knees included in the analysis was $172.0^\circ \pm 5.9$ (range 160-184). Correct alignment of the leg (FTA 173° - 177°) was seen in 14 knees (25.9%). Extreme valgus of the leg (FTA $< 173^\circ$)

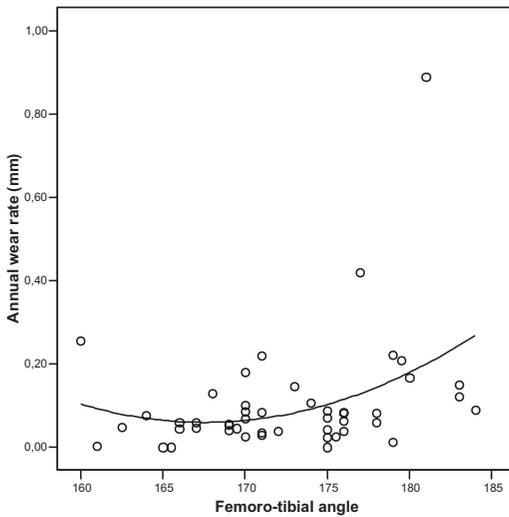


Figure 5.15. Femoro-tibial angle and wear rate in the prostheses that had had no PE exchange at the second follow-up study. Legs with an increasing valgus and especially legs with an increasing varus alignment seemed to have a higher wear rate, but non-linear regression analysis showed no significant influence of the FTA on the wear rate ($p=0.647$).

was seen in 30 knees (55.6%) and a varus position of the leg (FTA > 177°) was seen in 10 knees (18.5%).

Legs with an increasing valgus and especially legs with an increasing varus alignment seemed to have a higher wear rate, but non-linear regression analysis showed no significant influence of the FTA on the wear rate ($p=0.647$) (see Figure 5.15).

5.7.3.2 Weight Bearing Ratio

The mean Weight Bearing Ratio in all knees included in the analysis was $48.1\% \pm 25.6$ (range 0-110). There were 28 knees (51.9%) with a mechanical axis through the medial side of the prosthesis, 25 knees (46.2%) with a mechanical axis through the lateral side of the knee, and in one knee (1.9%) the mechanical axis went exactly through the center of the prosthesis.

Knees with a mechanical axis through the medial side of the knee (WBR < 50%) and to a lesser extent through the lateral side of the knee (WBR > 50%) seemed to have a higher wear rate if the mechanical axis was further from the center of the knee. However, non-linear regression analysis showed no significant influence of the WBR on the wear rate ($p=0.841$) (see Figure 5.16).

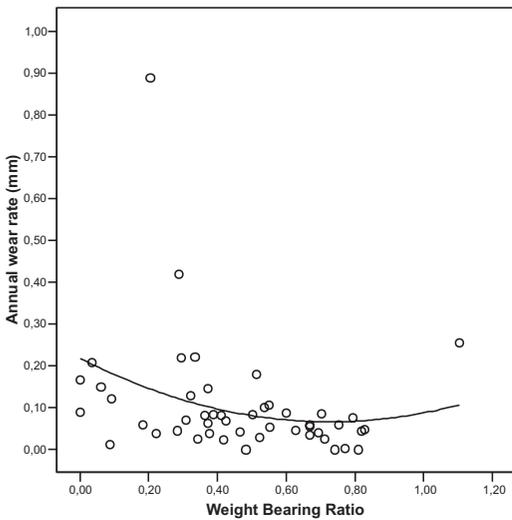


Figure 5.16. Weight Bearing Ratio and wear rate in the prostheses that had had no PE exchange at the second follow-up study. Knees with a mechanical axis through the medial side of the knee (WBR < 50%) and to a lesser extent through the lateral side of the knee (WBR > 50%) seemed to have a higher wear rate if the mechanical axis was further from the center of the knee, but non-linear regression analysis showed no significant influence of the WBR on the wear rate ($p=0.841$).

5.7.4 Discussion

Correct alignment of the limb is important to reduce the amount of wear. Malalignment of the limb may lead to higher wear rates, and this may contribute to failure and early loosening of the prosthetic components^{195,203,204}. Walker²⁰⁵ described a simple relationship between the tibiofemoral angle and total load on the knee joint, in which a 9° varus shift from normal alignment will cause a 50% increase in total load on the knee. Volz²⁰⁶ related that the joint reactive force will approximately double for every 5° of increased angular deformity. Johnson et al.²⁰⁷ also described a trend of increasing total load in the knee with increasing malalignment in a gait analysis study. Ritter et al.²⁰⁴ found a significantly higher revision rate in knees with a varus alignment. Jeffery et al.²⁰³ reported that an error in alignment of more than 3° from the mechanical axis significantly increased the incidence of loosening.

To determine the influence of the alignment of the leg on the wear rate in this study, radiographs were used after a mean follow-up period of 14.0 years. Because the study was retrospective and no full-length leg radiographs had been made shortly after implantation of the prosthesis, we were not able to analyze the influence of the initial

alignment of the leg on the wear rate. The alignment of the leg may have changed in the course of time, due to increasing ligament laxity of the knee or polyethylene wear. The mean amount of wear in the knees included in the study was 1.1 ± 1.0 mm. Therefore, we assume the influence of changes in limb alignment due to wear to be small. However, we cannot deny that there may be an influence on the limb alignment by wear and/or ligament laxity.

In the group of knees available for radiographic examination, 74.1% of the knees had malalignment of the leg. A valgus malalignment was seen in the majority of the knees (FTA $< 173^\circ$). The malalignment may be due to incorrect placement of the prosthesis, because of the inaccurate external guidance instrument or because of increasing ligament laxity in time.

No significant relation was found between alignment of the limb and the wear rate, but in varus alignment of the limb and to a lesser extent in valgus alignment knees seemed to have a higher wear rate. The analysis was performed in a selection of all patients with a SKI prosthesis. Knees with malalignment may have been revised before the start of the radiographic study. Because wear is a multifactorial process^{63,85,86,208}, an analysis in a larger group of patients with documentation of the initial alignment should be performed.

5.7.5 Conclusions

Malalignment of the leg, especially valgus malalignment, was seen in the majority of knees available for radiographic analysis. In varus alignment of the limb and to a lesser extent in valgus alignment, the SKI prosthesis seemed to have a higher wear rate, but the relation was not significant.

