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ORIGINAL STUDY

Accuracy and reproducibility of computer-assisted measurement of polyethylene wear in knee arthroplasty

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When using computer-assisted methods to evaluate polyethylene wear in knee arthroplasty (TKA), variations in the inclination of the X-ray beam and lack of standard calibration may affect accuracy and reproducibility. To address these issues, we evaluated the polyethylene thickness of unimplanted specimens of known dimensions using the Imagika software. Radiographs were taken with small controlled variations in the inclination of the X-ray beam. Reproducibility was studied based on triplicate measurement of 132 fluoroscopic images by three observers. Calibration was tested against a reference based on a spherical metal ball with a known diameter. The mean differences between the measured and true values ranged from 0.6 mm to 0.8 mm. The repeatability coefficient revealed a maximum variation of 0.43 mm for the same observer, and 0.39 mm between observers. There were significant differences between the measurements of polyethylene thickness performed using two different calibration methods. The variance of measurements was lower with digitized images than with fluoroscopic images. Imagika was not efficient to measure wear in TKA.

Keywords : polyethylene wear ; knee arthroplasty ; computer assisted measurements ; reproducibility ; accuracy ; calibration.

INTRODUCTION

Polyethylene wear in total knee arthroplasty (TKA), although less critical than at the hip, is often a matter for concern (*4,11,20*). The consequences can be serious since the polyethylene particles released in the process may induce osteolysis (*5,13,16,17*). *In vitro* studies on a knee simulator or using computerized wear models have concluded to wear rates of 0.16 mm/year (*8,14*). This is in agreement with *in vivo* estimated wear rates, which range from 0.13 mm to 0.20 mm per year (*10,12*). It therefore appears that wear should be measured with an accuracy of 0.1 mm, if early abnormal wear is to be detected *in vivo*, particularly when testing new generation polyethylene.

Wear measurements based on manual, computer-assisted methods are considered to be satisfactory in terms of accuracy (*9*). Indeed, these methods compared well with the more sophisticated techniques used in research laboratories, but which are

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not yet available in current clinical practice (*7,8,10, 12,14,18*). However, their reproducibility remains questionable because it was tested based on coefficients of correlation in small numbers of cases. Furthermore, it is important to identify the acceptable variations in the inclination of the X-ray beam that are compatible with wear detection within the first five years of the component's life. It also remains unclear how measurement accuracy may be affected by such parameters as the type of image (fluoroscopic versus digitized), and the method of calibration used.

To address these questions concerning the accuracy, the reproducibility, and the factors affecting accuracy of wear measurements using a manual, computer-assisted method, we evaluated polyethylene thickness in unimplanted specimens of known dimensions. Radiographs were successively obtained with small, then with more substantial variations in the inclination of the radiographic beam. Accuracy was thus investigated under conditions that were assumed to simulate current clinical situations in which variations in the inclination of the X-ray beam inevitably occur.

Accuracy was tested by comparing the measured values of the insert thickness with the real values that were obtained by direct measurements on the specimens.

Reproducibility was assessed using specific analyses such as calculation of the repeatability coefficient (*3*) and the Bland-Altman method (*1,2*).

The effect of various parameters were studied, such as the type of image used, i.e. digitized radiographs or fluoroscopic images, and also the calibration method. This was tested by comparing a reference method, based on a 28 mm diameter spherical metal ball that was fixed to the stem of the implants, to another method based on the known thickness of the tibial base plate (*19*), which is applicable to most contemporary prosthetic designs.

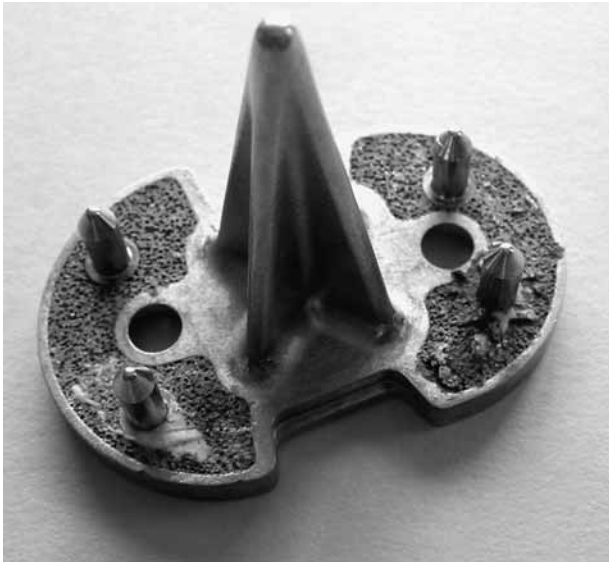

Fig. 1. — This view shows the undersurface of the tibial component with the stem, and the 4 pegs implanted symmetrically below the medial and lateral part of the baseplate.

MATERIALS AND METHODS

The Imagika software (Clinical Measurement Corp., Ridgewood, NJ, USA), designed for radiographic bidimensional measurements in orthopaedics, was adapted to assess the thickness of the polyethylene insert in a total knee prosthesis (Natural Knee, Zimmer, Warsaw, Ind, USA), in radiographs taken with an AP incidence. A triangular stem surrounded by 4 pegs is implanted on the undersurface of the tibial baseplate (fig 1). The pegs allowed controlling the rotation of the baseplate relative to the incident beam, because they appear superimposed on an optimal AP view with no rotation (fig 2). Observers were asked to mark 4 points for guiding the measurement of the minimal width of the radiolucent space separating the femoral component from the tibial baseplate on the lateral and medial side of the implant. The points were to be chosen at the same distance from the midpoint of the tibial base plate, i.e. on a vertical line drawn through the pegs of the tibial base plate. When the pegs were not superimposed, due to some rotation of the prosthesis relative to the incident beam, the vertical lines were drawn through the anterolateral peg on one side and through the anteromedial peg on the opposite side. When the implant was tilted anteriorly, observers were informed that the anterior pegs were the lower ones on the film. When the implant was tilted posteriorly, the anterior pegs were higher than the posterior pegs. When the implant was laterally rotated but not tilted, observers were instructed to select the more lateral pegs. Inversely they were to select the more medial pegs when the implant was internally rotated (fig 3). The system allowed concealing the results from the observer.

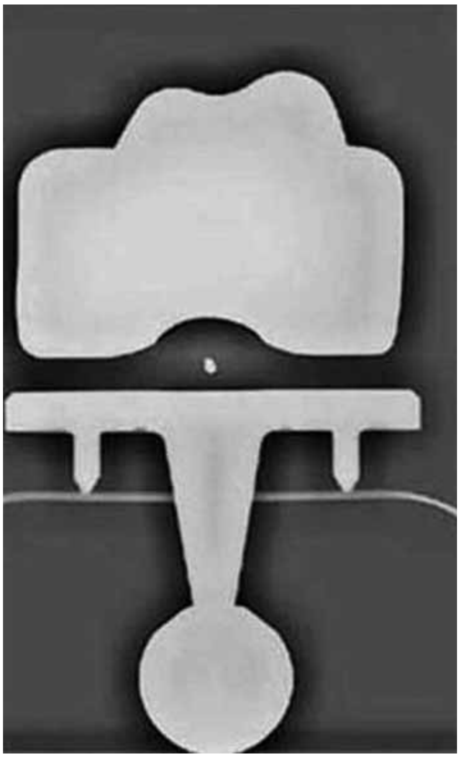

Fig. 2. — The implant in this X-ray image was radiographed with an optimal incidence, in which the pegs at the undersurface of the tibial baseplate appear superimposed. The implant was equipped with a radiographic marker to check the inclination angle. Calibration was done with a metal ball, 28 mm in diameter, affixed to the stem of the tibial base plate. The same specimen was then calibrated by means of the known thickness of the tibial base plate.

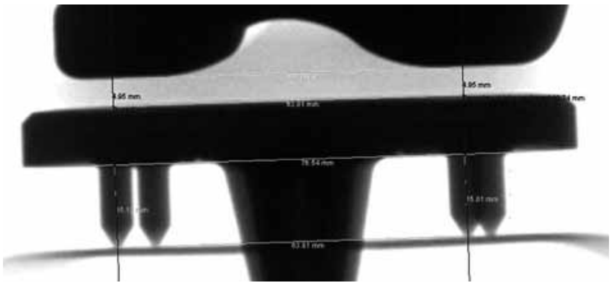

Fig. 3. — The minimal width of the radiolucent space separating the femoral component from the tibial baseplate was determined using a manual, computer-assisted method ; the measurement was made perpendicular to the line joining the tips of the lower medial and lateral pegs.

The inclination of the X-ray beam was controlled as follows : implants were positioned with the tibial stem inserted into a perforated rectangular box until contact was obtained between the lateral pegs located below the tibial baseplate, and the box, thus ensuring that the tibial baseplate was parallel to the surface of the box. The construct was then placed on a flat surface, the horizontality of which was checked with a level gauge.

Inclinations were checked using a plumb-line attached to the image intensifier, showing the angle between the vertical and the position of the arm of the image intensifier. Variations in rotation could be directly read on the graduated arm of the image intensifier (fig 4). The system was formatted by verifying that the horizontality of the image intensifier arm corresponded to a horizontal position of the implant : when the graduations on the image intensifier indicated 0° of tilting and 0° of rotation, the pegs of the implant had to be perfectly superimposed. Then, various inclinations were obtained by changing the rotation and the tilting by 1° increments. Images were digitized automatically at 300 dpi by the image intensifier. Calibration was carried out by means of a 28 mm-diameter metallic head fixed to the stem of the tibial base plate.

One hundred thirty two fluoroscopic radiographs were obtained from 3 prostheses, with tibial components with a nominal thickness of 9, 11, and 13 mm respectively, corresponding to various polyethylene thicknesses. Four sets of images were thus obtained, each set being characterized by the radiographic inclination used. In the first set, containing 30 images, the inclination was considered optimal with rotation less than 5° and tilting less than 3°. In the other three sets, the inclination was suboptimal with some tilting (3-6°, 36 images) or some rotation (5-10°, 36 images), or tilting and rotation combined (36 images).

Accuracy of measurements

It was tested in a first series of 132 measurements done by a single observer. It was studied successively in the four groups with inclination of the X-ray beam, by comparing the measured values to the real values of the tibiofemoral radiolucent space height. The true insert thickness was measured using a calliper graduated to the tenth of a millimetre. It was measured at the deepest point of the inserts after these had been inserted into their respective trays. The thickness of the metal baseplate, which had been initially measured to be 7 mm using the same tool, was then subtracted from the total thickness of the tibial component to determine the thickness of the polyethylene insert. The measured thickness of the polyethylene bearing was 2.9, 4.9, and 6.2 mm

Fig. 4. — The position of the image intensifier with respect to the implant was changed by 1° increments

respectively for the components with a total thickness of 9.9, 11.9, and 13.2 mm. Although inserts were strongly hammered into place, and although they appeared very rigidly fixed to their respective baseplate, a thin space persisted at the rim of the insert attesting their incomplete penetration into their metal tray (fig 5). This is likely to explain that the total thickness of the tibial components was slightly superior to the nominal value stated by the manufacturer. The effect of rotation and tilting was also studied by comparing the lateral side to the medial side in the 4 groups with inclination of the X-ray beam.

Fig. 5. — This photograph shows that the penetration of the polyethylene insert into the metallic tray could not be fully achieved, explaining that the total thickness of the tibial baseplate exceeded the nominal value announced by the manufacturer.

Reproducibility of measurements

The intra- and interobserver reproducibility was calculated from triplicate measurements of the 132 fluoroscopically guided images in randomized order by three observers : a medical resident not specialised in orthopaedic surgery (Observer 1), a senior resident specialised in orthopaedic surgery (Observer 2), and a senior orthopaedic surgeon involved in knee replacement surgery (Observer 3). The observers performed the 132 measurements three times in a blinded fashion at 2-week intervals ; they were not aware either of the result of the measurement or of the precise identification of the picture.

Factors affecting the variance of the measurements

Observer 3 made a series of measurements on a single implant, on films obtained successively with various image qualities (fluoroscopic versus digitized X rays) and using two different methods of calibration.

Table I. — The accuracy of wear measurements with the four types of radiographic incidence (optimal, tilting, rotation, tilting and rotation) : comparison of the true insert thickness and the measured value by a paired t test

Incidence		Number of measurements	Paired t-test (p value)	Mean difference ± standard deviation (mm)
Optimal	Observer 1	30	$p < 0.001$	0.6 ± 0.4
	Observer 2	30	$p < 0.001$	0.8 ± 0.4
	Observer 3	30	$p < 0.001$	0.7 ± 0.4
Rotation	Observer 1	30	$p < 0.001$	0.6 ± 0.4
	Observer 2	30	$p < 0.001$	0.8 ± 0.3
	Observer 3	30	$p < 0.001$	0.7 ± 0.3
Tilting	Observer 1	36	$p < 0.001$	1.7 ± 0.5
	Observer 2	36	$p < 0.001$	1.8 ± 0.6
	Observer 3	36	$p < 0.001$	1.7 ± 0.6
Rotation and Tilting	Observer 1	36	$p < 0.001$	1.7 ± 0.6
	Observer 2	36	$p < 0.001$	1.8 ± 0.6
	Observer 3	36	$p < 0.001$	1.7 ± 0.6

The paired t-test compared differences between the true insert thickness and the measured value.

The effect of image quality was investigated by comparing 2 series of 40 measurements of the height of the radiolucent space separating the femoral component from the tibial baseplate, obtained respectively from the readings of a digitized radiograph and of a fluoroscopic view, both of them taken with an optimal incidence angle (inclination was controlled by the superposition of the pegs) and calibrated using the same method (i.e. based on a circular shape of known diameter). The X-ray images were digitized at 300 dpi (X-ray Film Digitizer, Vidar Systems Corp., Herndon, VA, USA).

The effect of the calibration method was studied by comparing two series of 40 measurements of the height of the radiolucent space separating the femoral component from the tibial baseplate, obtained respectively from the readings of a digitized radiograph taken with optimal incidence. In the first reading, the calibration was done using the same method as in the first part of the study, i.e. by means of a metal ball with a known diameter fixed to the stem of the tibial component. The program incorporated an edge detection algorithm, which was available for circular shapes only. In the second reading, the calibration was done comparing the measured thickness of the tibial base plate to its known thickness (7 mm) (fig 2).

Statistical analysis

It was performed with SPSS software (version 12.0). After checking the normality of the distribution of the series of measurements, the accuracy of measurements was estimated using the paired t test, comparing the measured value to the corresponding true value, in the four groups with different inclinations of the X-ray beam, for each of the three observers. The lateral tibiofemoral radiolucent space height was compared to the medial tibiofemoral radiolucent space height using Pearson's correlation coefficient.

The intra- and interobserver reproducibility was calculated for the set of 132 images as a whole, and separately for each of the four groups with various inclinations of the X-ray beam.

The analysis of variance (one way ANOVA with images as the factor for each reading of one observer) was used to estimate the various components of the variance required for calculations of the intra observer repeatability coefficient (r). The coefficient r, which indicates the maximum difference likely to occur between repeated measurements, was defined as $1.96\times\sqrt{(2s^2)}$, where s^2 was the residual mean square of the ANOVA (within subject standard deviation) (*3*). It was verified that the standard deviation of the differences between measurements done by one observer was unrelated to the magnitude of the measurement (table I). To study the interobserver reproducibility, a two-way repeated measures ANOVA was performed (images as the factor for each observer, 3 repetitions) to estimate the various components of the variance required for calculations of the inter observer repeatability coefficient (r'). The coefficient of repeatability (r') was defined as 2.77×

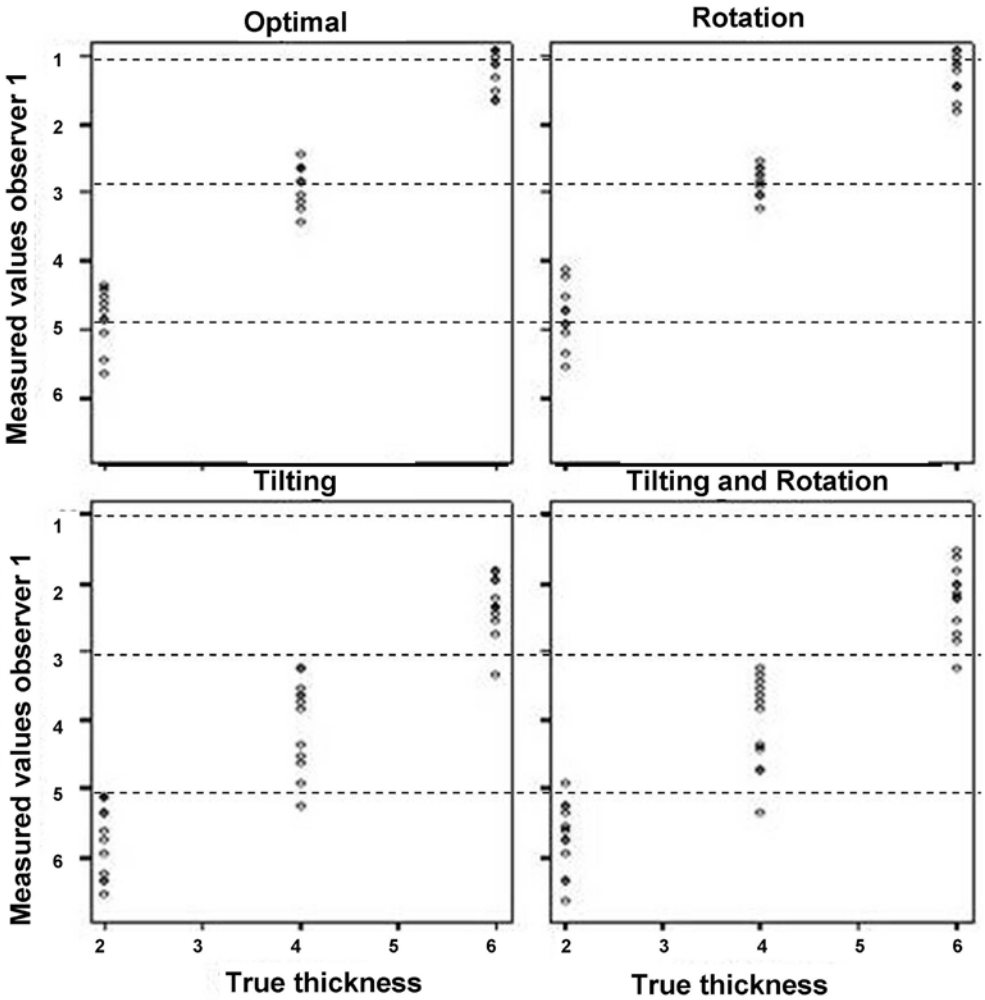

Fig. 6. — The accuracy of wear measurements in total knee arthroplasty is illustrated using four types of inclination (optimal, tilting, rotation, tilting and rotation). The relationship between the true thickness of the insert and the measured value is shown.

$\sqrt{(s^2+so^2+sh^2)}$, where s^2 was the residual mean square of the ANOVA (within subject standard deviation), so^2 was the interobserver mean square and sh^2 represented the interaction (random effect model *(15)*).

The interobserver reproducibility was also estimated by the intraclass correlation coefficients for different observers (ICC). It represents the proportion of the total variation that is due to differences between observers. Finally, the interobserver reproducibility was assessed using the Bland-Altman method *(1,2)* and by performing a matched paired comparison of one observer in turn with each of the other. A paired t test was used, because the distribution of differences between measurements done by two observers was normal. The Pearson coefficient of correlation between the differences of measurements done by two observers and their means was calculated, to verify the absence of funnel effect (i.e. the difference between observers did not depend on the magnitude of the measurements).

Means and variances were calculated in the different series of measurements, which were characterized by their radiographic inclination, the type of image or the method of calibration. Because the differences between measurements were normally distributed, variances were compared on the basis of their quotient F. The level of significance was 0.05.

Table II. — The intraobserver variability of wear measurements for each observer with the four types of radiographic incidence (optimal, tilting, rotation, tilting and rotation) and in the whole series

Incidence		Number of images	Number of measurements	Within subject standard deviation	r (mm)	Pearson correlation coefficient
Optimal	Observer 1	30	90	0.15	0.40	r = 0.17 p > 0.05
	Observer 2	30	90	0.07	0.19	r = 0.14 p > 0.05
	Observer 3	30	90	0.09	0.26	r = 0.96 p > 0.05
Rotation	Observer 1	30	90	0.15	0.43	r = 0.39 p = 0.03
	Observer 2	30	90	0.08	0.23	r = 0.20 p > 0.05
	Observer 3	30	90	0.10	0.27	r = 0.09 p > 0.05
Tilting	Observer 1	36	108	0.15	0.43	r = 0.16 p > 0.05
	Observer 2	36	108	0.65	0.18	r = 0.1 p > 0.05
	Observer 3	36	108	10.0	0.28	r = 0.05 p > 0.05
Rotation and Tilting	Observer 1	36	108	0.14	0.38	r = 0.2 p > 0.05
	Observer 2	36	108	0.09	0.25	r = 0.06 p > 0.05
	Observer 3	36	108	0.11	0.30	r = 0.16 p > 0.05
Whole series	Observer 1	132	396	0.15	0.41	r = 0.13 p > 0.05
	Observer 2	132	396	0.08	0.21	r = 0.03 p > 0.05
	Observer 3	132	396	0.10	0.28	r = 0.04 p > 0.05

r = intraobserver repeatability coefficient

The Pearson correlation was calculated between the standard deviation of the 3 measurements of each observer and their mean to verify that it was unrelated to the magnitude of the measurement.

RESULTS

Accuracy

There was a significant difference between the observed values and the true values on average of the polyethylene thickness (fig 6). The mean differences ranged from 0.6 mm to 0.8 mm when the inclination of the X-ray beam involved no significant tilting (table I). The comparison of successive radiographs of the same implant read by observer 3 showed that a 1° tilting induced an average reduction of 0.36 mm in the apparent thickness of the polyethylene insert. The measurements made on the lateral side were highly correlated to those on the medial side, with a Pearson coefficient of 0.98 or 0.99 depending on the incidence angle, and 0.99 when all incidence angles were considered together.

Reproducibility

The coefficients of repeatability indicated that there could be a variation of as much as 0.4 mm in repeated measurements made on the same X-ray image. This variation was not influenced by the inclination of the X-ray beam (table II). When the inclination was contained within a range of 3° of tilting, the variance of measurements of the same specimen (60 measurements of the 13 mm-thick component by observer 3) was 0.11.

There were also substantial differences between measurements of the same specimen done by the different observers, ranging from 0.36 to 0.39 mm. Although the interclass correlation coefficient indicated good interobserver reproducibility, the Bland-Altman test showed that there was a significant difference between the measurements made by two observers in any of the four types of incidence (table III).

Table III. — Interobserver variability of wear measurements with the four types of radiographic incidence (optimal, tilting, rotation, tilting and rotation) and in the whole series

					Bland-Altman method	
Incidence	Number of measurements	ICC (95% confidence interval)	r' (mm)	Pearson correlation	Paired t-test (mean of difference and standard deviation in mm)	Outliers number/total
Optimal (n = 30)	90	0.98 (0.75-0.99)	0.37	(Obs1 ; Obs2) r = 0.18 p > 0.05 (Obs2 ; Obs3) r = 0.31 p > 0.05 (Obs1 ; Obs3) r = 0.02 p < 0.001	p < 0.001 -0.19 ± 0.14 p < 0.001 0.15 ± 0.15 p > 0.05 -0.04 ± 0.16	1/30 1/30 2/30
Rotation (n = 30)	90	0.98 (0.68-0.99)	0.36	(Obs1 ; Obs2) r = 0.15 p > 0.05 (Obs2 ; Obs3) r = 0.29 p > 0.05 (Obs1 ; Obs3) r = 0.01 p > 0.05	P < 0.001 -0.18 ± 0.12 p > 0.05 0.05 ± 0.16 p < 0.001 0.13 ± 0.14	1/30 1/30 2/30
Tilting (n = 36)	108	0.98 (0.83-0.99)	0.39	(Obs1 ; Obs2) r = 0.38 p = 0.02 (Obs2 ; Obs3) r = -0.11 p > 0.05 (Obs1 ; Obs3) r = 0.44 p < 0.01	p < 0.001 -0.18 ± 0.16 p < 0.001 -0.06 ± 0.17 p < 0.05 0.12±0.16	1/36 2/36 1/36
Rotation and tilting (n = 36)	108	0.99 (0.87-0.99)	0.36	(Obs1 ; Obs2) r = 0.11 p > 0.05 (Obs2 ; Obs3) r = -0.43 p < 0.01 (Obs1 ; Obs3) r = 0.21 p > 0.05	p < 0.001 0.17 ± 0.14 p < 0.001 0.13 ± 0.18 p > 0.05 -0.03 ± 0.18	0/36 2/36 1/36
Whole series (n = 132)	396	0.99 (0.82-0.99)	0.49	(Obs1 ; Obs2) r = 0.19 p < 0.05 (Obs2 ; Obs3) r = -0.23 p < 0.01 (Obs1 ; Obs3) r = 0.13 p > 0.05	p < 0.001 -0.18±0.14 p < 0.001 -0.12 ± 0.17 p < 0.001 -0.07 ± 0.18	1/132 7/132 4/132

ICC = intraclass correlation coefficient
r' = interobserver repeatability coefficient
Pearson's correlation coefficient was calculated between the mean of the two measurements and the difference of the two measurements (observer 1 – observer 2), to show that the difference between the measurements was not correlated to their magnitude.
The paired t-test was used to assess whether the mean of differences differed significantly from zero.
Outliers : number of plot outliers of the interval -1.96 SD ; +1.96 SD of the Bland-Altman plotting.

Factors affecting variance

The comparison between the two types of images (fluoroscopic versus digitized) and between the two methods of calibration showed that the variances were significantly different ($p < 0.001$) (table IV). The lowest variance was obtained with the digitized image, which was calibrated using the circular shape with a known diameter.

DISCUSSION

Measurements of the thickness of the polyethylene insert were significantly different from the real

Table IV. — Variances and mean values of the measurements of the polyethylene thickness of the same insert obtained from the readings of a fluoroscopic view, of a digitized X-ray with 2 different methods of calibration, and with various radiographic inclination

13 mm-thick polyethylene tibial component (emergent part of the polyethylene measured manually as 6.2 mm)	Fluoroscopic Calibration method 1 n = 40	Digitized Calibration method 1 n = 40	Digitized Calibration method 2 n = 40 Fluoroscopic	Various inclination (tilting between -3 and +3°, rotation between -5 and 5°) Calibration method 1 n = 60
Mean (mm)	5.71	6.13	6.09	5.79
Variance	0.004	0.001	0.004	0.11
Standard deviation (mm)	0.06	0.03	0.06	0.34
High//Low (mm)	0.2 (5.6-5.8)	0.07 (6.08-6.15)	0.07 (5.96-6.16)	1.45 (4.98-6.43)

values measured with a calliper, even in the group with a so-called “optimal incidence angle”. This is in agreement with another study, which estimated the mean error at 0.6 mm with a standard deviation of 1 mm, based on calliper measurements on explants retrieved during revision procedures (*6*). This is far below the expected accuracy that was reported in another study (*9*). This can be explained by small variations in the X-ray beam inclination, which were meant to reproduce the conditions under which such measurements are performed in clinical practice. It is also noteworthy that accuracy was more affected by tilting than by rotation in the other groups.

In the present study in which a fixed bearing was tested, measurements on the medial side correlated well with those on the lateral side. This suggests that differences noted in the values measured on the two sides of the same image may be considered of significance. In clinical practice, stress radiographs in valgus and varus are recommended, so as not to underestimate wear in any compartment (*19*). However, the influence of rotation should not be underestimated. Measurements should be made at the deepest part of the insert, which is not at the same distance from the midpoint when rotation is present. In the present study, metal pegs located below the lowest portion of the insert allowed for reproducible placement of the points whatever the rotation. In the absence of some kind of metallic markers, it seems difficult to deal with rotational variations. A similar remark applies to rotating platforms, because it is not possible to control the position of the insert, which is theoretically free to rotate.

The repeatability coefficient showed that measurements made by the same observer were affected by considerable variability. Because this coefficient took into account repeated measurements made on several images at some time interval (to prevent memorization of the position of the points), taken from different implants with different inclinations, it is likely to reflect the real variability of measurements done by a single observer.

The interobserver coefficient of repeatability also showed substantial variations between observers. The Bland-Altman method showed that there were significant differences between the quantitative values obtained by two observers reading the same radiographs.

When performed under optimal conditions, the variance of repeated measurements of the thickness of the polyethylene insert on the same image was better with digitized X-ray images than with fluoroscopic images, and compared favourably with other manual, computer-assisted methods (*9*), or even with fully automatized methods (*7,10,12,18*). However, the interval between the extreme values of the measurements increased to more than 1 mm, if some tilting (less than 3°) occurred, including the error related to intra observer variability. Thus, even in the group in which the variations in the inclination of the X-ray beam were minimal, the within-group variability of inclination angle could be the major reason for the observed variability of the results.

Changing the calibration method significantly influenced the results. First the variance increased when calibration was performed based on the thickness of the tibial baseplate. This is likely to be in relation with the measurements of the thickness of the tibial baseplate itself, which had their own variance. In contrast, using the spherical metal ball with a known diameter, an edge detection algorithm automatically performed the measurements based on those points located at the periphery of the opaque circle, where the contrast was the highest. Subsequently, there was no variance of measurements in relation to calibration. Another limitation of calibration based on the thickness of the tibial baseplate in clinical practice is that one has to rely on a value given by the manufacturer, which may not exactly correspond to the real value. This can be a bias when comparing different implants.

In conclusion, manual computer-assisted methods such as Imagika are not adequate for measuring wear in total knee arthroplasty, because their performance is affected by a poor reproducibility. Thus, any human intervention should be minimized by systematically using edge detection algorithms. In prospective studies, a reference value should be obtained on early postoperative radiographs, and wear should be assessed by comparison with this reference value, while strictly controlling the inclination of the X-ray beam and the calibration throughout the follow-up period. Manufacturers marketing new polyethylene should supply inserts with some kind of metallic markers, so as to allow surgeons to perform a quicker and more precise assessment of polyethylene wear, in comparison with conventional polyethylene (fig 2). Using markers, Duryea *et al* (7) estimated that an irradiation dose of 193 mGy/cm^2, which appears physiologically acceptable, would allow the setting of an optimal inclination for the X-ray beam. We suggest the use of 2 metallic beads embedded in the central part of the polyethylene (which is not submitted to wear), in order to allow fluoroscopic control of the radiographic incidence.

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