Evaluation of accuracy and precision of bone markers for the measurement of migration of hip prostheses

A COMPARISON OF CONVENTIONAL MEASUREMENTS

R. Biedermann, B. Stöckl, M. Krismer, P. Mayrhofer, E. Ornstein, H. Franzén

From the University of Innsbruck, Austria

Our aim was to determine whether tantalum markers improved the accuracy and/or precision of methods for the measurement of migration in total hip replacement based on conventional measurements without mathematical correction of the data, and with Ein Bild Roentgen Analyse – Femoral Component Analysis (EBRA-FCA) which allows a computerised correction. Three observers independently analysed 13 series of roentgen-stereophotogrammetric-analysis (RSA)-compatible radiographs (88). Data were obtained from conventional measurements, EBRA-FCA and the RSA method and all the results were compared with the RSA data. Radiological evaluation was also used to quantify in how many radiographs the intraosseous position of the bone markers had been simulated. The results showed that tantalum markers improve reliability whereas they do not affect accuracy for conventional measurements and for EBRA-FCA. Because of the danger of third-body wear their implantation should be avoided unless they are an integral part of the method.

J Bone Joint Surg [Br] 2001;83-B:767-71.

Received 14 September 1999; Accepted after revision 15 June 2000

The measurement of migration in total hip replacement (THR) is of increasing importance in the quality control of new designs of implant, since early migration can predict

late aseptic failure of the prosthesis.¹⁻⁵ Several methods have been developed for the detection of the migration of femoral and acetabular components.^{3,6-9} In assessing these, it is very important to differentiate between accuracy and precision. Accuracy is defined as the difference between measured and true values whereas precision expresses the reliability (reproducibility) of a method. The most accurate method developed so far, roentgen stereophotogrammetric analysis (RSA), has an accuracy of about 0.2 mm and is based on the use of bone markers.¹⁰ It requires prospective planning and a stereoradiological technique. Other methods are easier to perform and are based on measurements on conventional radiographs, but they have inferior accuracy.^{3,6,7,9,11-13} Attempts at improvement in accuracy concern the correction of magnification and the choice of the reference line; the shorter the reference distance, the greater the accuracy.^{3,6,13} It has been suggested that placing a tantalum marker close to the shoulder of the prosthesis would improve accuracy¹⁴ and a number of systems for the implantation of metal markers in bone have been presented.¹⁵ Malchau et al¹⁶ have shown that bone markers improve the accuracy of conventional measurements, but even with a reference line between a marker implanted in the shoulder of the prosthesis and that in the lesser trochanter, the accuracy was found to be only 3.9 mm.

There have been no studies to evaluate whether implanted markers led to better accuracy or precision in the Ein Bild Roentgen Analyse-Femoral Component Analysis (EBRA-FCA) method⁶ or in those of Walker et al,³ Hardinge et al,⁹ and Braud and Freeman.¹³

Our aim was to determine whether tantalum markers improved the accuracy and/or precision of methods based on conventional measurements in digitised radiographs which do not have mathematical correction of data, as compared with EBRA-FCA which has a computerised correction strategy.

Materials and Methods

Three observers independently analysed 13 series of RSA-compatible radiographs (88) which had been taken at 6 weeks and 3, 6, 12, 18 and 24 months after operation. In two series those taken after 24 months and in one series those after six months were missing. In each series, a mean

R. Biedermann, MD, Registrar
B. Stöckl, MD, Senior Registrar
M. Krismer, MD, Associate Professor
Department of Orthopaedics, University of Innsbruck, Anichstrasse 35, A-6020 Innsbruck, Austria.

P. Mayrhofer, PhD, Assistant Professor
Department of Geometry, Institute of Mathematics and Geometry, University of Innsbruck, Technikerstrasse 113, A-6020 Innsbruck, Austria.

E. Ornstein, MD, PhD, Chief Orthopaedic Surgeon
Department of Orthopaedics, Håssleholm-Kristianstad Hospitals, S-281 25 Håssleholm, Sweden.

H. Franzén, MD, PhD, Senior Orthopaedic Surgeon
Department of Orthopaedics, University of Hospital of Lund, S-221 85 Lund, Sweden.

Correspondence should be sent to Dr M. Krismer.

©2001 British Editorial Society of Bone and Joint Surgery
0301-620X/01/510575 \$2.00

Fig. 1

One series of radiographs. All seven images are zoomed on to the greater trochanter (EBRA-FCA software) to identify the clearest structure of this bony reference point.

number of 9.8 tantalum balls (5 to 13) had been inserted.

Measurements were made from scanned radiographs using a reference line, parallel to the axis of the shaft of the prosthesis, between the shoulder of the prosthesis and either the contour of the greater trochanter or an implanted tantalum marker, as well as between the shoulder and tantalum balls inserted into the lesser trochanter.

Before setting the reference lines, all the radiographs of a series were compared with each other to make sure that the same contour of the greater trochanter could be identified. With EBRA-FCA software, it is possible to zoom all the images of a series on to the greater trochanter to identify the clearest structure (Fig. 1).

Measurements were made by one observer between the shoulder of the stem and the greater trochanter as well as between the stem and all tantalum markers which were within the bone and showed no sign of loosening (109). Two other observers measured migration in the same way between the stem of the shoulder and the greater trochanter, and between the stem and two tantalum markers, one positioned in the greater trochanter and the other in the lesser trochanter (2×39).

Data were obtained from conventional measurements on digitised radiographs without correction of data, with the EBRA-FCA program which calculates migration between

comparable radiographs of a series,⁶ and with the RSA method,⁸ data for which were obtained in another centre. The comparability limit for the EBRA-FCA program was set at 3 mm.

The findings of all three observers were used to evaluate the accuracy and precision of the measurements made with tantalum balls and by bony landmarks. All the results were compared with the RSA data, and the differences between measured migration and RSA results were calculated for the entire period of observation.

In some radiographs we found bone markers positioned in the soft tissue which seemed to be within the bone in other films of the same series. This effect is caused by the different projections of markers in relation to the bone and the prosthesis as a result of the three-dimensional movements of the femur. If these radiographs had been missing, identification of the false position of the bone markers would not have been possible. We therefore tried to determine the number of radiographs in which the intraosseous position of the bone markers had been simulated.

Statistical analysis. We attempted to determine whether the choice of a certain reference point (bone-greater trochanter, tantalum markers in the lesser and greater trochanter) could influence the accuracy of the measurement of migration. Differences of variance (0-hypothesis $\sigma_1^2 = \sigma_2^2$)

Fig. 2a

Fig. 2b

Differences in migration a) for conventional measurements and RSA and b) for EBRA-FCA and RSA. The results are presented for measurements between the greater trochanter and the shoulder of the stem (dark bars) and between tantalum balls and the shoulder (lighter grey bars). The difference between EBRA-FCA and conventional measurements is highly significant ($p = 0.0001$).

were calculated by Levene's test using the general linear model procedure (GLM) of SAS software (SAS Institute, North Carolina). Interobserver reliability was computed by Cronbach's alpha.

Results

Accuracy. Conventional measurements between the greater trochanter and the shoulder of the stem in comparison with RSA data (at 24 months, median -1.7 ; interquartile range -4.5 to 0.7) were not significantly different from those between a marker and the shoulder of the prosthesis (median -1.1 ; interquartile range -2.5 to 0.9 ; Fig. 2a). A similar result was seen in a comparison of EBRA-FCA measurements between the greater trochanter and the shoulder of the stem (at 24 months, median -0.3 ; interquartile range -0.7 to 0.1) and tantalum markers (median -0.4 ; interquartile range -1.2 to 0.6 ; Fig. 2b).

The distribution of the results was significantly wider for conventional measurements than for EBRA-FCA, indicat-

ing that only the choice of the method, but not the choice of the landmark, could improve accuracy (Fig. 2).

Precision. Reliability at 24 months for the conventional measurements between the bone markers and the shoulders of the prosthesis was $\sigma = 0.99$ (Cronbach's coefficient alpha for standardised variables). The precision of measurements between the greater trochanter and the shoulder of the prosthesis was slightly worse ($\sigma = 0.93$). Measurements with tantalum markers and with the greater trochanter were less precise using the correction system of the migration curve with EBRA-FCA software (for both $\sigma = 0.89$).

Radiological evaluation of marker position. The mean percentage of markers per radiographic series located in the soft tissue was 10.6 (0 to 30.8). In 3 of 13 series (23.1%), one marker was projected on the bone in more than three radiographs of a series and therefore simulated a position within the bone. In one series, the extraosseous position of such a marker could only be detected in one radiograph. In six of the series (46.1%), one or more tantalum markers was hidden behind the prosthesis (Fig. 3).

Fig. 3a

Fig. 3b

Figure 3a shows a tantalum marker (a) projected onto the femur although implanted in the soft tissue, and a second marker (b) hidden behind the prosthesis. The real position of bone markers can only be detected if they are projected as in figure 3b.

Fig. 4

The migration curves of one patient, measured by RSA (solid, dark-line), by EBRA-FCA between the greater trochanter and the shoulder of the stem (thin, continuous, dark lines), and by conventional measurements between tantalum markers and the shoulder (dotted, grey lines). The variation between the conventional measurements and EBRA is comparable, but the difference is higher for the grey lines. These migration curves explain why the accuracy of a method is more important than its precision.

Discussion

Bone markers. Malchau et al.¹⁶ pointed out that the accuracy of measurement of migration of the stem on conventional radiographs varies between 4 mm and up to more than 1 cm depending on the choice of landmarks. They had better results using bone markers and therefore suggested that these be used for measurements on conventional radiographs. Another recent study¹⁴ claimed that subsidence can be determined accurately on a radiograph, if tantalum markers are placed in the greater trochanter near the shoulder of the prosthesis. Histological studies have demonstrated the inertness of tantalum markers.^{10,17} Nevertheless, RSA measurement in the same study showed some markers to be initially unstable.¹⁷ Aronson, Jonsson and Alberius¹⁸ stated that the position of markers relative to the bone can change with time because of the constant process of bone remodelling, especially with bone rarefaction such as osteoporosis.

They mentioned that care is essential when implanting markers to avoid such complications as instability or unfavourable tissue reactions. Eldridge et al.¹⁹ found that in 40% of cases the tantalum balls were located outside the proximal femur on the postoperative radiograph, although all were considered to be within the bone at operation. They pointed out the danger of third-body wear and suggested that markers be used only for research in small series of patients. In our series, a mean of 10.6% of all markers was within the soft tissue (in 69% of all series). In

23% of all series, one marker simulated an intraosseous position in several radiographs of a series and would have led to false results for migration.

In our study, bone markers in the greater or in the lesser trochanter did not give better accuracy of the measurement of migration than the bony landmark and were equal to conventional measurements and EBRA-FCA.

Our findings demonstrate that if a clear contour of the greater trochanter can be identified a fiducial reference point does not contribute as much to accuracy as mathematical correction of the differences in projection, produced by movements of the femur. The latter have more influence on reference lines than the choice of the reference point (Fig. 1).

The only comparable study so far has been carried out by Malchau et al.¹⁶ They reported better results with tantalum markers in the greater and lesser trochanter, but differences were only seen for manual measurements on plain radiographs. For the lesser trochanter to the shoulder of the prosthesis, the mean is 5.3 mm for the bony landmark against 3.9 mm for a tantalum marker. The results for digitised radiographs were the same for the bony landmark and the tantalum marker; 4.1 mm for both. In Malchau's study, there were greater differences for manual measurements on plain radiographs and only small discrepancies in measurements on digitised radiographs for other reference lines (lesser trochanter to the centre of the femoral head, greater trochanter to the centre of the femoral head), although measurements on plain and digitised radiographs

are reported to show no significant difference. In contrast to our own findings, they reported better results for the tantalum marker in comparison with the bony landmark (manual, 6.9 v 9.1 mm; digital 6.3 v 8.4 mm) for the reference line between the greater trochanter and the shoulder of the stem.

Their interobserver error using this landmark was 10 to 15 times greater than that of Braud and Freeman.¹³ Heterotopic ossification may have been the reason for the poorer results for this reference line. The prerequisite for a good result is a clear contour of the greater trochanter. Our experience has shown that the more radiographs which are available within the first postoperative months, the better can a clear contour be identified. The reason for this are bone appositions on the greater trochanter despite the use of indomethacin postoperatively. In the study of Malchau et al¹⁶ in 33 cases, only two radiographs were taken, one postoperatively and the other after two years. In 18 cases, a third one was taken after five years.

Accuracy and precision. The evaluation of the accuracy of a method for the measurement of migration is very difficult because true migration is not known. The accuracy of RSA was tested by measurement in a three-dimensional glass model with implanted tantalum markers and known co-ordinates.⁸ EBRA-FCA was compared with RSA.⁶ Walker et al³ evaluated accuracy mathematically in a theoretical analysis. In a second experimental analysis, they evaluated the variation in the measurements of vertical stem-to-femur positions for different reference points and orientations of the femur which defined their reproducibility. Braud and Freeman¹³ evaluated reproducibility by testing the variance producing errors in centering of the x-ray beam proximally and distally.

For the MAXIMA hip technique⁹ and the methods of Sutherland et al²⁰ and Müller, Matuschek and Thümler,²¹ the amount of accuracy and reproducibility is mentioned, but not their method of evaluation. Accuracy is more important than precision as can be seen from Figure 4. In our study the best precision was achieved with conventional measurements between markers and the shoulder of the prosthesis. Measurements between a bony landmark and the shoulder were only slightly less reliable, but those corrected by the EBRA-FCA software showed the worst reproducibility independently of the landmark in spite of better accuracy. This may be explained by the clear contour of two metal reference points which can easily be identified, the relatively short distance to measure and the lack of mathematical correction of the distance in conventional measurements.

We conclude that tantalum markers improve reliability whereas they do not affect accuracy in conventional measurements and EBRA-FCA. Because of the danger of third-body wear, such methods should avoid depending on the implantation of bone markers unless they are necessary for the method as in RSA or MIRA.²²

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References

1. **Krismer M, Biedermann R, Stöckl B, et al.** The prediction of failure of the stem in THR by measurement of early migration using EBRA-FCA. *J Bone Joint Surg [Br]* 1999;81-B:273-80.
2. **Freeman MAR, Plante-Bordeneuve P.** Early migration and late aseptic failure of proximal femoral prostheses. *J Bone Joint Surg [Br]* 1994;76-B:432-8.
3. **Walker PS, Mai SE, Cobb AG, Bentley G, Hua J.** Prediction of clinical outcome of THR from migration measurements on standard radiographs: a study of cemented Charnley and Stanmore femoral stems. *J Bone Joint Surg [Br]* 1995;77-B:705-14.
4. **Kobayashi A, Donnelly WJ, Scott G, Freeman MAR.** Early radiological observations may predict the long-term survival of femoral hip prostheses. *J Bone Joint Surg [Br]* 1997;79-B:583-9.
5. **Ilchmann T, Markovic L, Joshi A, et al.** Migration and wear of long-term successful Charnley total hip replacements. *J Bone Joint Surg [Br]* 1998;80-B:377-81.
6. **Biedermann R, Krismer M, Stöckl B, et al.** Accuracy of EBRA-FCA in the measurement of migration of femoral components of total hip replacement. *J Bone Joint Surg [Br]* 1999;81-B:266-72.
7. **Krismer M, Bauer R, Tschupik J, Mayrhofer P.** EBRA: a method to measure migration of acetabular components. *J Biomech* 1995;28:1225-36.
8. **Selvik G.** Roentgen stereophotogrammetry: a method for the study of the kinematics of the skeletal system. *Acta Orthop Scand* 1989;232Suppl:1-51.
9. **Hardinge K, Porter ML, Jones PR, Hukins DWL, Taylor CJ.** Measurement of total hip prostheses using image analysis: the MAX-IMA hip technique. *J Bone Joint Surg [Br]* 1991;73-B:724-8.
10. **Kärrholm J, Herberts P, Hultmark P, et al.** Radiostereometry of hip prostheses: review of methodology and clinical results. *Clin Orthop* 1997;344:94-110.
11. **Ilchmann T, Franzen H, Mjöberg B, Wingstrand H.** Measurement accuracy in acetabular cup migration: a comparison of four radiologic methods versus roentgen stereophotogrammetric analysis. *J Arthroplasty* 1992;7:121-7.
12. **Nunn D, Freeman MAR, Hill PF, Evans SJW.** The measurement of migration of the acetabular component of hip prostheses. *J Bone Joint Surg [Br]* 1989;71-B:629-31.
13. **Braud P, Freeman MAR.** The effect of retention of the femoral neck and of cement upon the stability of a proximal femoral prosthesis. *J Arthroplasty* 1990;5:s5-10.
14. **Lüem M.** Early clinical results using the FCA-method on tantalum marked femora. *Hip Int* 1999;109.
15. **Ilchmann T, Winter E.** Migration, subsidence and wear after hip replacement. *Hip Int* 1999;9:104-11.
16. **Malchau H, Kärrholm J, Wang YX, Herberts P.** Accuracy of migration analysis in hip arthroplasty: digitized and conventional radiography, compared to radiostereometry in 51 patients. *Acta Orthop Scand* 1995;66:418-24.
17. **Alberius P.** Bone reactions to tantalum markers: a scanning electron microscopic study. *Acta Anat (Basel)* 1983;115:310-8.
18. **Aronson AS, Jonsson N, Alberius P.** Tantalum markers in radiography: an assessment of tissue reactions. *Skeletal Radiol* 1985;14:207-11.
19. **Eldridge DJ, Avramidis K, Lee M, Learmonth ID.** Tantalum ball position after total hip arthroplasty. *J Bone Joint Surg [Br]* 1998;80-B:414-6.
20. **Sutherland CJ, Wilde AH, Borden LS, Marks KE.** A ten-year follow-up of one hundred consecutive Müller curved-stem total hip replacement arthroplasties. *J Bone Joint Surg [Am]* 1982;64-A:970-82.
21. **Müller R, Matuschek T, Thümler P.** Digitale Röntgenbildbearbeitung zur Messung von Schaftwanderungen in der Hüftendoprothetik. *Orthop Praxis* 1996;32:177-9.
22. **Carlsson LV, Albrektsson BE, Freeman MA, et al.** A new radiographic method for detection of tibial component migration in total knee arthroplasty. *J Arthroplasty* 1993;8:117-23.