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Radiographic assessment of cup migration and wear after hip replacement

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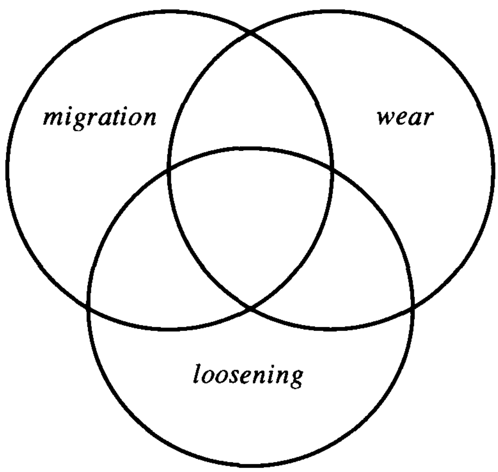

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List of papers

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1. Ilchmann T, Franzén 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 (2): 121-7.
2. Ilchmann T, Freeman MAR, Mjöberg B. Accuracy of the Nunn method in measuring acetabular cup migration. Upsala J Med Sci 1992; 97: 67-8.
3. Ilchmann T, Mjöberg B, Wingstrand H. Measurement accuracy in acetabular cup wear. Three retrospective methods compared with roentgen stereophotogrammetry. J Arthroplasty 1995; 10 (5): 636-42.
4. Ilchmann T, Kesteris U, Wingstrand H. Effect of pelvic tilt on migration and wear measurements after total hip arthroplasty. Unpublished.
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6. Ilchmann T, Markovic C, Joshi AO, Hardinge K, Murphy J, Wingstrand H. Migration and wear of long-term successful Charnley total hip replacement. Unpublished.

Contents

Introduction

More than 800,000 total hip replacements (THR) are done worldwide each year, and the number of primary operations is still increasing (Malchau et al. 1993). The main obstacle to long-term functioning of these implants is component-loosening, and revision surgery has become an important socioeconomic problem. However, the definition of clinical and radiographic loosening is controversial and no objective criteria are available for describing the results with an implant (Galante 1985). Since the mechanism of loosening is only partly understood, it is hard to improve implants and surgical techniques (Huiskes 1993, Linder 1994, Mjöberg 1991).

Recent studies have shown that particle debris may be a major cause of osteolysis, contributing to implant loosening (Goodman 1994, Huk et al. 1994, Murray and Rushton 1990). The increasing number of hips implanted in younger and more active patients makes problems of the bearing surfaces and wear more apparent. In most of the commonly used orthopedic implants, the polyethylene of the articular surface is the main source of debris and there is general agreement that polyethylene wear should be minimized (Buchhorn et al. 1984, Garcia-Cimbelo and Munuera 1992, Isaac et al. 1992).

Murray et al. (1995) stated that most of the implants used in Britain had little, if any, follow-up and documentation. Furnes et al. (1996) pointed out that more than 200 combinations of implants were used in Norway (4.5 million inhabitants), which raises the question whether there is a need for such a variety of implants (Bulstrode et al. 1993).

Follow-up is required to obtain more knowledge of joint replacement surgery. The number of patients subjected to risk should be minimal. In a consensus conference, a standardized clinical follow-up was proposed (Johnston et al. 1990). Walking distance, hip flexion and pain were considered the main clinical parameters, since they show good correlation with other common clinical findings (Bryant et al. 1993). Records of health profiles and questionnaires to patients are useful tools in the clinical follow-up (Franzén et al. 1997, Wiklund and Romanus 1991).

Radiographic follow-up should be performed to detect possible changes at an early stage. This is the most objective way of comparing different implants. Charnley introduced serial standardized radiographic follow-up as a routine in his hospital as early as in the 1960's. DeLee and Charnley (1976) defined radiolucent zones around the acetabular cup and Gruen et al. (1979) around the femoral stem and new or increasing radiolucencies were found to have prognostic value (Pacheco et al. 1988, Hodgkinson et al. 1988, Strömberg et al. 1996). However, there is considerable disagreement in interindividual observations of radiolucencies of the acetabular cup (Brand et al. 1985) and Jacobs et al. (1989) thought plain radiographs were inadequate for evaluation of the cement-bone interface of femoral stems. Engh et al. (1993) stated that the numbers of radiolucencies and gaps are underestimated, compared with the real situation at implant removal. Therefore, component migration and wear should be measured with standardized methods, which are more reliable and have proven prognostic value (Freeman and Plante-Bordeneuve 1994, Krismer et al. 1996, Stocks et al. 1995, Mjöberg 1991).

Review of literature

Methods for evaluating migration

The simplest way to assess migration of the acetabular cup is to make direct measurements on radiographs with a slide-caliper. Differences in the focus, positioning of the patient, focus-film distance and positioning of the central beam cause different projections of the hip or pelvis on the film-plane and are sources of error. Radiographs of the pelvis are commonly used in migration studies, but even standardized projections can only partly overcome those problems. Various reference lines have been considered to increase the accuracy of measurements, but their reliability is uncertain (Middha and Singhal 1992).

Sutherland et al. (1982) used the teardrop line and Köhler's line as reference lines. Thorén and Sahlstedt (1990) proposed the use of only one line: a tangent to the apertura pelvis. Nunn et al. (1989) suggested the teardrop line and a perpendicular line through the teardrop. Wetherell et al. (1989) proposed the "obturator brim line" and the "sacroiliac–symphysis line" as reference lines.

With more sophisticated methods, the pelvis, prosthesis and bony or artificial landmarks are digitized and the position of the implant is analyzed with a personal computer. A research group in the Sulzer Company (Winterthur, Switzerland) tried to define prominent bony pelvic landmarks and digitize their position. The specially designed software analyzes the position of the markers and should correct for any tilt of the pelvis causing translation and rotation of these reference points. The position of the digitized implant is then calculated in relation to such a system of reference points (Ilchmann et al. 1992).

Liossis et al. (personal communication) implanted tantalum markers in the periacetabular bone for measuring migration of the cup. A personal computer, a digitizing table and markers with an implantation instrument were needed. According to their estimates the implantation of markers improved the accuracy of measurement. This method, not yet published, can be used only for prospective studies.

Malchau et al. (1995) compared simple manual measurements with measurements on digitized images, where the computed distances were based on landmarks defined by the examiner. They found no significant improvement by simply using the computer, without taking into account effects of projection differences and pelvic tilt.

Hardinge et al. (1991) introduced automatic image analysis, the MAXIMA method. A personal computer equipped with a frame grabber card, high resolution video camera, copy stand and a light box were utilized. The radiograph was digitized with the camera. With this method, the intensity, contrast and consistency could be increased and points and lines were generated automatically. Furthermore, reference lines could be drawn interactively. The software could even analyze stem-bending, subsidence, bone remodeling and also reconstruct the Shenton line. High reproducibility was shown, but there were no clinical studies and no data on measurement accuracy.

The "Ein Bild Röntgen Analyse," EBRA method (Krismer et al. 1995, Russe 1988), employs a grid of transverse and longitudinal tangents on prominent landmarks of the pelvis contour. The data are processed in specially designed software. Pelvic tilt can be evaluated by calculating the distance between corresponding grid-lines. Horizontal and vertical migration, cup inclination and anteversion, as well as prosthetic wear, can be obtained. This method is already being used in clinical research (Dihlmann et al. 1994, Krismer et al. 1994, 1996, Lemaire and Rodriguez 1996).

With radiostereometric analysis, RSA (Selvik 1989), tantalum balls must be implanted peroperatively as landmarks in the skeletal structures. For postoperative follow-up, the patient is placed in a calibration cage and two stereometric radiographs are taken simultaneously. Any movement of the markers and of the implant can be calculated in 3 dimensions. This method is very accurate and well documented.

Methods for evaluating wear

It has been questioned whether polyethylene wear can be measured on plain radiographs (Clarke et al. 1976). Charnley and Cupic (1973) proposed that the distance from the prosthetic head to both edges of the contrast wire on the latest follow-up radiograph gives a measure of penetration of the femoral head into the cup. This uniradiographic technique was quick and it was thought unnecessary to take magnification into consideration. This technique assumed that wear would occur mainly in the vertical direction. Since it was not possible to detect wear in the craniomedial direction, it was inevitably underestimated (Charnley and Halley 1975). To solve this problem, the duoradiographic method was introduced (Charnley and Halley 1975, Griffith et al. 1978). On an early postoperative and on the latest follow-up radiographs, the distance from the femoral head contour to the contrast wire of the Charnley cup was measured in the vertical and horizontal directions. The difference was interpreted as radiographic wear, after correcting for magnification.

Livermore et al. (1990) determined the thinnest part of the polyethylene layer on the latest follow-up radiograph, correcting for radiographic magnification by measuring the size of the femoral head. On the first postoperative radiograph, the thickness of the layer was measured in the same area and the difference between the two radiographs was considered as linear wear. Scheier and Sandel (1976) described a method to measure wear on acetabular cups with the contrast wire in the equatorial plane. The distances between the edges of the femoral head and the contrast-wire and between the head-center and the axis of the contrast wire were thus measured.

Metal-backed cups, especially in combination with ceramic heads, may require other routines for measuring wear, since the contours are difficult to define.

Wear can be measured by computerized methods. No clinical data are available on use of the MAXIMA method (Hardinge et al. 1991). Analysis of wear with the EBRA method has recently been incorporated with the method and described during the present study (Ilchmann et al. 1995).

Devane et al. (1995) reported a new computerized method for three-dimensional wear measurements in metal-backed acetabular cups and calculation of the volumetric wear using custom-made software. By measuring head and cup migration separately, three-dimensional prosthetic wear studies can be done using RSA (Baldursson et al. 1979, Franzén and Mjöberg 1990, Kärrholm 1989).

It is generally accepted that there is a strong correlation between radiographic measurements and direct measurements on retrieved cups (Bankston et al. 1994, Livermore et al. 1990, Sychterz et al. 1996, Wroblewski 1986), although measurements of radiographic linear wear may underestimate the real wear (Hall et al. 1995, Kabo et al. 1993). Various techniques are proposed for measurements on retrieved cups. Using the shadow radiographic technique, negative prints of the inner surface of the cup are made. Tangential light provides a two-dimensional projection of the inner surface of the cup, allowing measurements of the linear wear. For volumetric wear, the volume of the inner surface of the cup can be measured and the original volume subtracted (Hashimoto et al. 1995, Isaac et al. 1992, Wroblewski 1985).

The true volumetric wear, in most cases, is overestimated by merely calculating the volume of a penetration cylinder based on the diameter of the head and the penetration depth. Kabo et al. (1993) therefore proposed a more correct formula for calculation of the wear volume.

Linear wear and/or volumetric wear may also be overestimated because of plastic deformation of the polyethylene (Rose et al. 1980) and the volume of particles released in the joint may be lower than calculated. This deformation, which occurs especially in thin polyethylene cups, may cause aseptic loosening (Berry et al. 1994). Lee and Pienkowsky (1996) developed a method which can quantify the compressive creep under physiological load. This might allow estimation of the true in vivo wear by subtracting the calculated plastic deformation.

Migration and loosening

There is no consensus concerning the definition of implant "loosening". Distinctions are made between clinical and radiographic loosening. Implants that cause pain on walking, demonstrating a resorption of more than one millimeter around the whole cement-bone interface and migration, are definitely loose. However, most cases present only some of these signs and are therefore regarded as probably loose. Even during revision surgery, it is difficult to assess how well fixed the implant is (Hodgkinson et al. 1988). Furthermore, it is difficult to determine when the loosening process started.

Studies using RSA indicate that about 50 % of the acetabular cups, whether cemented or not, move or "migrate" in relation to the pelvis shortly after implantation (Mjöberg 1986, Önsten et al. 1993). This is an even commoner phenomenon in cases of revision surgery (Franzén et al. 1993). Early migration of knee replacement components increases the likelihood of late clinical failure and revision (Ryd et al. 1995). This was also demonstrated for the subsidence of femoral stems (Freeman and Plante-Bordeneuve 1994, Kärrholm et al. 1994), and recently, it was shown to be true also for acetabular cups (Stocks et al. 1995, Krismer et al. 1996). Furthermore, Nilsson et al. (1994) demonstrated, that early radiographic loosening impairs quality of life in the long-run.

However, initial early migration of implants may stop in some implants, because of increased osteointegration. Other implants continue to migrate and eventually result in clinical failure and revision.

Mjöberg (1991) consequently proposed the use of absence of migration as a determinant of implant survival. The prerequisite for this is that migration can be measured with high accuracy.

Wear and loosening

There is general agreement that debris from an implant damages the periprosthetic tissue (Bullough 1994, Harris 1994, Schmalzried et al. 1992, Willert and Semlitsch 1977). Debris is produced in areas of friction along the prosthetic articular surface, at the junction of modular systems or at sites of fixation, like the prosthesis-bone interface, cement-bone and the cement-prosthesis interface (Barbour et al. 1995, Huk et al. 1994, Wroblewski et al. 1987). Third-body wear may occur when particles become trapped between the head and the cup surface (Amstutz et al. 1992, Jasty et al. 1994, Morrey and Ilstrup 1989, Zichner and Willert 1992).

Polyethylene is the material most frequently used on the acetabular cup surface. Polyethylene particles are harmful to the prosthetic-bone interface and the bone-stock (Goodman 1994, Huk et al. 1994, Murray and Rushton 1990). This finding has aroused interest in polyethylene research (Amis 1996, Li and Burstein 1994)

The deleterious biologic effects may be related to size, shape and number of the particles (Hirakawa et al. 1996). Microparticles may be recognized by macrophages and phagocytosis will occur as a nonspecific immune response. Since the macrophages cannot digest the polyethylene particles, cytokines, growth-factors and other liberated enzymes may stimulate osteoclasts and bone resorption (Amstutz et al. 1992, Harris et al. 1976, Ohlin et al. 1990). Larger fragments of polyethylene may cause foreign body reactions by giant cells, but probably induce less bone resorption (Goodman et al. 1988b). Thus, even in case of similar linear wear rates in different implants, the quality of the debris must be taken into account when discussing its harmfulness (Campbell 1995). Schmalzried et al. (1992) suggested the hypothesis of the "effective joint space" as the periprosthetic region that is accessible to joint fluid. According to that theory, the joint fluid, and therefore the particles, follow the path of least resistance, depending on how close the contact is between the bone and the prosthesis. A disruption in the interface may progress from the periphery to the dome, with subsequent loosening due to macrophage-induced bone resorption.

McKellop et al. (1995) claimed that hundreds of thousands of particles may be liberated from the entire bearing-surface with each step during walking. Since standard histological examination of the debris cannot detect small particles, Campbell et al. (1995) propose more sensitive methods to assess the total amount of particles on a submicron level.

Histologic studies are often made of retrieved specimens and cellular reactions are difficult to interpret when failure has preceded the surgical revision. However, the cause/effect relationship cannot be determined (Mjöberg 1994). Wear occurs to some degree in all joint replacements, but most of these are doing well clinically (Sychterz et al. 1996). Aspenberg and Herbertsson (1996) found experimentally that the response of an interface to particles may be more benign than the response to micromovements, but the main problem with in vitro studies is the clinical relevance of the results. Moreover, in vivo animal models often use limited cyclic or one-time particle load which differs from the clinical situation with its continuous particle liberation (Wright and Goodman 1996).

Most of the wear particles remain locally in the periprosthetic tissue, but they have been found even in regional lymph nodes and in almost all organs (Bauer et al. 1994, Case et al. 1994). There is very little evidence of local or systemic hypersensitivity due to wear debris (Carlsson et al. 1980, Goldring et al. 1983, Lalor et al. 1991, Santavirta et al. 1991). No implant-related malignancies have been found (Goodfellow 1992) and there seems to be no increased risk of tumors developing after joint replacement (Lewold et al. 1996, Mathiesen et al. 1995).

Little is known about parameters affecting the in vivo wear-rate of polyethylene. There is a correlation between wear and activity of the patient, but activity is difficult to measure. Schmalzried et al. (1997) suggested, that assessment of activity might be more important than the time of implantation and they used an electronic podometer to count gait cycles, which showed considerable individual differences. Cates at al. (1993) found positive correlations between cup migration, metal backing, male gender and linear polyethylene wear. Shih et al. (1997) reported a positive correlation between linear wear, age and osteolysis. Other clinical parameters, like body weight and diagnosis, showed no correlation with wear, especially on well-fixed acetabular cups (Sychterz et al. 1996). There may be an interrelationship between these variables that produces relatively low levels of significance (Isaac et al. 1992). The influence of position and orientation of the cup, the antetorsion and the offset of the femoral component and the post-operative discrepancy in leg-length may also affect the biomechanics of the hip, the stresses on the head-cup area and finally, the direction and amount of linear wear (Sarmiento et al. 1990, Pagnano et al. 1996).

Implant-related factors, like the size and the material of the femoral head, may affect linear wear (Kesteris et al. 1996, Livermore et al. 1990, Ritter et al. 1983, Wroblewski et al. 1992). The surface quality of the femoral head is important. Scratches of 1 µm may increase the wear-rate 20- to 70-fold (McNie et al. 1997).

The fabrication of raw polyethylene is not standardized and changes may occur in quality that are not acknowledged, or even anticipated, by the implant manufacturer. Furthermore, the quality may change as a result of the various production processes of the implant itself. Milling implants from a polyethylene-stock has been considered to reduce fusion defects of polyethylene powder particles (Li et al. 1995). The process of sterilizing has come into the focus of interest and gamma radiation was found to increase the process of oxidation and thus the wear (Fisher et al. 1995), which was further affected by the various methods used to store the implant (Blunn and Bell 1996, McKellop 1995, Rimnac et al. 1994). New sterilization processes, e.g., with ethylene oxide, have been introduced, which may change the mechanical properties of the material (Plester 1970). Nevertheless, it is questionable whether there really is an alternative to polyethylene as a prosthetic bearing-surface (Amis 1996).

It is debated whether polyethylene wear is the cause or a consequence of prosthetic loosening (Mjöberg 1994). In already loose implants, micromovements may lead to an eccentric load on the cup and thus to increased wear. Furthermore, micromovements and cyclic pressure phenomena during gait may affect the distribution of the particles and further damage the bone stock (Anthony et al. 1990, Robertsson et al. 1997). Debris may be produced in the damaged interface itself, causing more injury to the local tissues and in the artificial joint space (Hirakawa et al. 1996, Huk et al. 1994). However, it is questionable whether a well-fixed implant can fail only because of the local tissue damage caused by particle debris (Engh et al. 1993). It is not known whether the particles can penetrate an intact bone-implant interface and initiate the destructive process and loosening.

In addition to the harmful biological response to polyethylene wear, there are some mechanical reasons for late failure due to linear wear. A well-fixed implant may simply wear out (Berry et al. 1994). Increasing frictional torques may then contribute to the process of loosening (Charnley 1979, Ma et al. 1983). The penetration of the head may also result in a gradual impingement of the femoral neck, with increased stress on the interface, and may even lever the cup out of its anchorage (Murray 1992).

It has been shown that linear wear of polyethylene correlates to prosthetic loosening (Buchhorn et al. 1984, Garcia-Cimbelo and Munuera 1992, Isaac et al. 1992, Weightman et al. 1991). Although that correlation is not sufficiently understood, there is a wide agreement that the liberation of debris particles and linear wear of polyethylene should be minimized.

Author's studies

Methods are needed for accurately measuring acetabular cup migration and wear after hip replacement.

The EBRA (Ein Bild Röntgen Analyse) method was recently introduced as a computerized method for radiographic assessment of acetabular cup migration. The EBRA method and three other commonly used methods were evaluated and compared to radiostereometry, RSA (Paper 1). The Nunn method (Nunn et al. 1989) for migration measurement was also compared to radiostereometry (Paper 2).

A subroutine for wear measurement was added to the EBRA method. The new EBRA software and two standard methods of wear measurement were evaluated and compared to RSA (Paper 3).

Pelvic tilt was regarded as the main source of errors of measurement in migration and wear assessment. Experimentally, the effect of pelvic tilt on such measurements with standard methods was evaluated and compared to the EBRA method, which was thought to detect and exclude tilted radiographs (Paper 4).

The EBRA method had proved promising in the previous studies, but more information should be gained about the measurement accuracy. The precision of the input procedure, repeated radiographic examinations and the intra- and interobserver errors were assessed with EBRA and compared to standard methods (Paper 5).

Normative data about acetabular cup migration and wear should be gained from long-term surviving hip replacements. The reliability, practical use and clinical applications of the different measurement methods were compared in 25 clinically successful Charnley total hip arthroplasties, without radiographic signs of loosening (Paper 6).

Methods of measurement

Radiostereometry (RSA) (Selvik 1989)

The acetabular cups are prepared preoperatively with tantalum balls embedded in the plastic. Peroperatively, 4 to 8 tantalum balls are implanted in the pelvic bone close to the acetabulum. Roentgen stereophotogrammetric exposures from 2 positions, with an approximately 40° angle between the x-ray sources, are obtained simultaneously with a reference tantalum ball-marked frame in the background, behind the patient. The positions of the tantalum balls and the reference frame on the radiographs are digitized on a high-precision digitizing table and the position in 3 dimensions of each tantalum ball, and thus of the component, is computed. The tantalum ball configuration in the pelvis represents a coordinate system fixed to it and in the subsequent examinations the pelvis is mathematically re-oriented to its position in the original examination. The migration of the acetabular component and of the femoral head (wear) in relation to this coordinate system is then calculated.

EBRA (Russe 1988, Krismer et al. 1995)

The EBRA method (Ein Bild Röntgen Analyse) requires a pencil, a ruler and a digitizing table connected to a personal computer with specially developed software.

A system of parallel and rectangular tangents on prominent pelvic structures defines the position of the pelvis (Figure 1). A simulated sphere, based on the grid-lines, should improve the accuracy of measurements. The positions of the tangents and the shape of the implants are digitized. A comparability algorithm divides the series of radiographs into comparable series, analyzing the distance between grid-lines. At least 4 radiographs are required, but additional radiographs may improve the accuracy of this method. A control procedure shows the degree of comparability (limit of comparability "L"); extreme projections are excluded by the software. Migration-time and wear-time diagrams are constructed in the horizontal and vertical directions (Figure 2). Anteversion and inclination of the cup are also analyzed.

Standard methods

For measuring distances, a slide-caliper with a 0.1-mm scale was used. Unless stated otherwise, all measurements of migration and wear were corrected for radiographic magnification (f). It was calculated from the measured femoral head size (f = measured head size/real head size).

When measuring migration with the method described by *Sutherland et al.* (1982), the sacroiliac line, the Köhler line and the teardrop line are drawn on the radiograph. The distances between the midpoint of the widest diameter of the metal ring of the acetabular cup, the teardrop line and the Köhler line are measured to show the position of the implant.

For migration measurements with the *Wetherell*

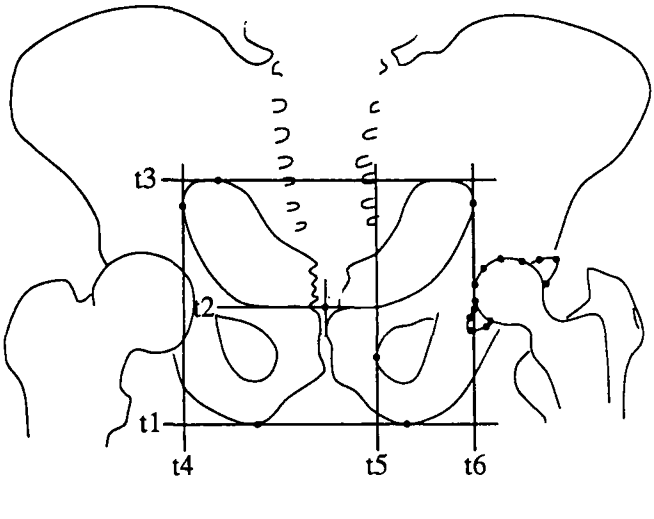

Figure 1. Construction of the reference lines with EBRA. T1–t3 are parallels. T1 is placed on the distal border of the tuber ischiadicum (alternatively on the distal border of the foramen obturatum) on the side of the hip replacement, t2 on the cranial border of the symphysis, t3 on the cranial border of the pelvic aperture (alternatively on the best visible foramen in the sacrum). T4–t6 are perpendicular to t1–t3. T4 and t6 mark the inner border of the large pelvic aperture, t5 the medial border of the foramen obturatum.

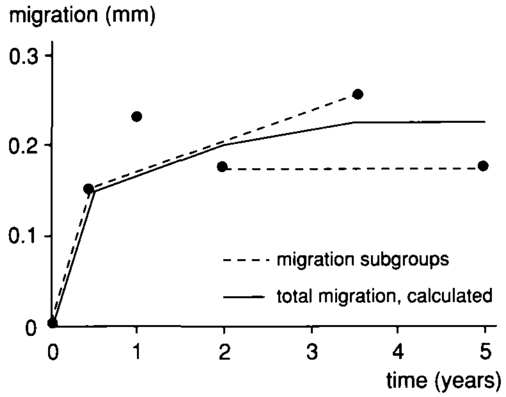

Figure 2. Imaginary construction of a mean migration curve based on 6 radiographs. Two subgroups with similar projections, consisting of 2 and 3 radiographs, were found by the software. For the radiograph at one year, no radiograph with a corresponding projection could be found, and therefore it was excluded from analysis. In the interval from 2–3.5 years, there was an overlap of two subgroups. The mean trend of both curves was calculated, representing the gradient in the total migration curve for that period.

method (Wetherell et al. 1989), the sacroiliac-symphysis line (parallel to a line through the sacroiliac joints) and the obturator brim line (a tangent to the apertura pelvis, passing through the center of the obturator foramen) are used as reference lines.

Using the *Nunn* method (Nunn et al. 1989), the inter-teardrop line and a perpendicular line through the center of the teardrop are drawn. In the vertical direction, this is identical with the reference line described by Sutherland (Figure 3).

When measuring wear with the *Scheier-Sandel* method (Scheier and Sandel 1976), a pencil, ruler, transparent template with concentric circles and a slide-caliper are needed. The center of the femoral head is located, using the template. The changes in position of the center, in relation to the contrast wire, are measured in the equatorial and central directions. Total wear is calculated by vectorial addition.

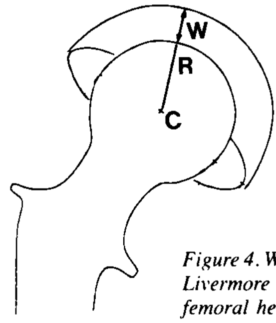

Figure 4. Wear measurements with the Livermore method. The center of the femoral head (C) is identified with a template. A radial line (R) is drawn from C, passing through the thinnest part of the polyethylene. The distance W indicates the thickness of the polyethylene layer in the film plane.

With the *Livermore* method (Livermore et al. 1989), a pair of compasses is needed. Measurements are made on the prosthesis/cement interface. The center of the femoral head is marked with the template, the thinnest part of the plastic is estimated with the compasses by placing them in the center of the femoral head. A radial line is drawn through the center and the thinnest point of the cup. The prosthesis/cement interface is marked on this line. The distance between the border of the femoral head and the prosthesis/cement interface is measured with the slide caliper. The distance on the postoperative radiograph, subtracted from the current radiograph, is regarded as wear (Figure 4).

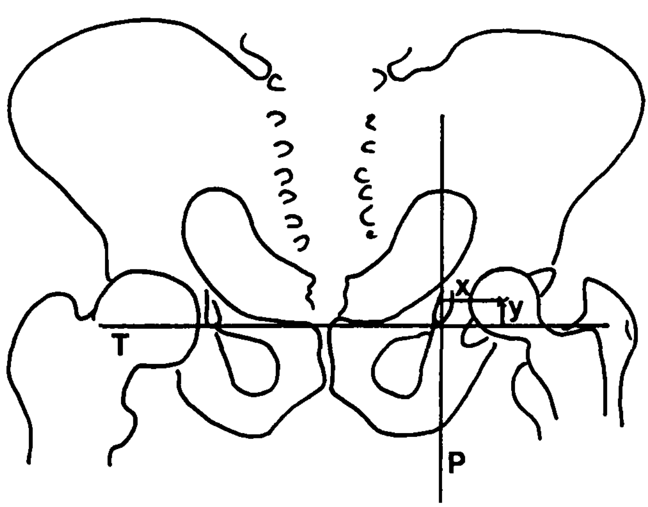

Figure 3. Migration measurement with the Nunn method in the medial (x) and cranial (y) direction. The inter-teardrop line (T) passes through the distal edges of both teardrops. P is perpendicular to T, passing through the center of the teardrop on the side of the hip replacement.

Methods of evaluation

Unless stated otherwise, all measurements, except those with RSA, were made by the author. All lines were drawn with a sharpened soft pencil, special care being taken not to damage the radiographs. In case of repeated measurements, all lines were erased with alcohol.

Comparison with RSA

Fourteen patients underwent total hip arthroplasty for primary coxarthrosis (Franzén and Mjöberg 1990). The implant was a cemented Scanhip® (MitAB, Sweden) arthroplasty with a 32 mm femoral head and a cemented high-density polyethylene cup with an equatorial, circular contrast wire. The acetabular components had been prepared with tantalum ball markers, preoperatively embedded in the polyethylene. Tantalum ball markers were also implanted peroperatively, close to the acetabulum in the pelvic bone. RSA was performed at 1 week, 4 and 6 months, as well as 1 and 3 years postoperatively. One patient was excluded from this study because of lost radiographs. Each of the remaining 13 patients had between 3 and 7 standard anteroposterior (AP) radiographs of the pelvis taken during these 3 years, without special care regarding positioning of the patient on the table. Single measurements were made on a total of 56 pelvis radiographs with the EBRA, Sutherland and Wetherell methods. Measurements were also made on 34 radiographs from 9 patients using the Nunn method; they were performed by the co-workers of Nunn. At the time of analyses, the results of the RSA were not known.

We found a discrepancy between head and cup migration when using the EBRA method in the migration study. This discrepancy was interpreted as wear of the implant. As a consequence, based on a proposal by the author, the EBRA software was modified and a subroutine for wear analysis in the software was added. All radiographs were re-measured with this new software. Wear was also measured by the Scheier-Sandel and the Livermore methods.

The results of measurements were corrected by subtraction of the "true" values, which were considered to be the corresponding RSA values at that time. These AP radiographs, not obtained on the exact same date as the RSA examinations, were corrected by a value linearly interpolated from 2 RSA examinations just before and after that date. The means and the standard deviations of the differences between the values obtained with the compared methods and the corresponding RSA values were calculated.

Tilt study

A polyethylene cup with a spherical, equatorial contrast wire (Scanhip®, MitAB, Sjöbo, Sweden) was cemented in the right acetabulum of a human skeleton pelvis. A femoral component, head diameter 22 mm, was fixed in the cup. The pelvis was fixed on a radiolucent plate in moderate inclination, which was estimated to be the spontaneous neutral position of a patient. A standard AP radiograph of the pelvis was taken in this position with a focus-film distance of 1100 mm and the center of the central beam on the symphysis. The pelvis was tilted consecutively around a horizontal axis in 2° steps from 2°–16° in lordosis and from 2°–16° in kyphosis. It was also rotated around a vertical axis from 2°–10° to the left and to the right, respectively. In each position, the angle of tilt was measured with a goniometer and a radiograph was taken.

Migration of the cup was measured with the Nunn and EBRA methods, wear was measured with the Livermore, Scheier-Sandel and EBRA methods. In addition, migration measurements in the horizontal direction were made using the Köhler line. In the experimental set-up, no real migration or wear could occur; differences from the radiograph in neutral position were calculated and interpreted as errors of measurement. We calculated the maximal error, the measurement error (standard deviation) and the 95% confidence interval of the measurement error for all corresponding measurements. Statistical significance corresponds to non-overlapping of the confidence intervals of the measurement error.

A clinical situation consisting of 5 tilted radiographs was simulated. We selected the radiographs randomly from the group of moderately tilted projections (maximum 6° of tilt). More extreme projections were added randomly, with a probability of 1/14. Five groups of 5 radiographs each were formed. The results were compared as mentioned above.

Evaluation of EBRA method

Migration was measured with the Nunn method, wear was measured with the Livermore method on all radiographs, disregarding possible exclusions by the EBRA method. For the EBRA measurements, a L=3 mm (limit of comparability) was selected in all examinations. For the input of the prosthesis, a maximal radial error of 0.25 mm, as calculated by the software, was accepted.

Reliability of input procedure

The same clinical radiograph was digitized 5 times with EBRA, using the same reference lines. The radiograph was not moved on the digitizer between the examinations. Nunn and Livermore measurements were made 5 times on the same radiographs, using the same reference lines. With EBRA, the first radiograph is set as zero automatically. Thus, in a similar way, the first measurement with the standard methods was taken as zero, the differences from the first radiograph were considered as errors of input. Five radiographs from 5 different patients were analyzed. The maximal error, the measurement error (standard deviation) and the 95% confidence interval of the measurement error were calculated for all corresponding measurements. Statistical significance corresponds to non-overlapping of the confidence intervals of the measurement error.

Reliability of repeated radiographic examinations

This study was approved by the local Swedish committee on ethics. Five radiographs of the pelvis were taken of the same patient on the same day. The 10 patients included were mobilized with full weight bearing after THA had been performed. They were asked to walk between each radiographic examination. No special care was taken to position the patients, no changes were made in the settings of radiographic equipment between the examinations. No migration or wear should have occurred between the repeated examinations.

The implant position was measured with the EBRA and the Nunn methods. The thickness of the plastic was measured with the EBRA and the Livermore methods. Differences, as compared to the first radiographic examination, were considered as errors of repeated examination and measurement. The results were compared as mentioned above.

Intraobserver variation

Ten patients were operated on with THA (Scanhip®, MitAB, Sjöbo, Sweden), as reported in a previous study (Mjöberg 1986). A series of 5 (4–8) radiographs of the pelvis was taken at regular intervals over a period of 56 (48–68) months, no special care was taken to position the patients. With EBRA, all of the total of 60 radiographs were analyzed, the early postoperative radiographs were considered to be detected by the program in case of possible tilt. With the standard methods, the early postoperative radiographs were excluded to avoid errors of measurement, 48 radiographs were left. All measurements were made twice by the same person, using all methods in question. The measurements were made on different occasions, all lines being thoroughly erased between the examinations. The results were compared as mentioned above.

Interobserver variation

The same radiographs from the study of the intraobserver variation were re-analyzed with all methods by another person, after erasing all lines thoroughly. The results were compared to the corresponding values from the first measurement of the intraobserver difference. The results were compared as mentioned above.

Evaluation of successful hip replacement

Patients were selected from the early cases of Charnley low friction arthroplasties in Wrightington Hospital, Wigan, England. They were operated on in the standardized way described by Charnley (1979). The study was confined to physically active patients with long-lasting total hip replacements. For inclusion in the study, the patient should have had a good clinical result (Grades 5–6, modified D'Aubigné and Postel hip assessment, Charnley 1972). At the latest follow-up, they should still be walking without crutches. A full series of postoperative radiographs and D'Aubigné and Postel assessments were required. The selected patients had not undergone a revision of the acetabular cup on the analyzed side. There should be no radiographic evidence of loosening. The cups had been gamma-sterilized in air, the head diameter was 22.25 mm. They had a marker wire in the coronal plane.

From about 9400 primary total hip replacements in the period from 1963 to 1974, 25 hips (21 patients) fulfilled these criteria. The mean clinical and radiographic follow-up was 22 (17–25) years. A total of 368 radiographs, on average 12 (9–20) radiographs per patient, were studied. All measurements began at the 3-month postoperative examination.

Migration was measured with the Nunn method, wear was measured with the Livermore method.

Twenty hips (307 radiographs) were analyzed with the EBRA method. The remaining 5 had to be excluded, since the contrast wires were obviously not spherical. In 2 Charnley Off-Set Bore cups, the thickness of the plastic was measured in the horizontal and vertical directions. The total wear was calculated by vectorial addition of measured wear in both directions.

In all cups with detectable wear of at least 0.5 mm, the direction of wear was measured on the last radiograph in relation to the teardrop line, 0° directed medially and 180° directed laterally.

Wear-rates for each time-interval between the repeated radiographic examinations were calculated for each patient and method. A regression analysis was made for the wear-rates and time. The mean of the corresponding regression gradients of all patients was calculated. A positive mean gradient would indicate increasing wear-rates with time.

Results

Measurements with the standard methods took about 5 to 10 minutes per radiograph. In some radiographs, the teardrop was difficult to identify, with consequent uncertainty in defining the teardrop line. With the Livermore method, identification of the prosthesis/cement interface was difficult in some cases. With the EBRA method, the analysis took 10 to 15 minutes per radiograph. In some cases, repeated input of the implant was needed for the software because of inaccurate digitization, and this was time-consuming. In some radiographs, it was difficult to identify the prominent pelvic structures that had to be used for drawing the tangents.

Comparison with RSA

None of the patients had clinical symptoms or definite radiographic signs of loosening. With RSA, migration ranged from 0 to 0.9 mm horizontally and 0 to 0.5 mm vertically. All radiographs were analyzed by all methods, but 7 were excluded by the EBRA software. EBRA measurements differed less from the RSA results than did those done by standard methods (Figures 5, 6). When setting a 3 mm limit of comparability, as proposed by Russe (1988), 5 more radiographs were excluded from analysis by the software, but the standard deviation of the mean difference from RSA was further reduced.

With EBRA, we found vertical migration of some femoral heads, but not of the acetabular cups. This difference between head and cup migration increased with time after surgery and was thought to be caused by linear wear of the implant (Figure 6).

RSA revealed significant cranial wear in 11 of the 13 acetabular components. The mean wear was 0.38 mm (SD 0.07; range 0–0.79) after 3 years—i. e., the mean rate of wear was 0.13 mm per year. Only 2 acetabular components showed significant horizontal wear (both 0.21 mm). Negative wear in the caudal direction was found in 3 cases shortly after surgery and in one case even 3 years postoperatively. In these patients, the displacement was 0.4–0.5 mm laterally and 0.3–0.8 mm distally.

With the Scheier-Sandel method, the time-wear diagrams were not linear, which indicated poor accuracy. The average values were greater than RSA values, even when excluding the early postoperative radiographs (Figure 7). With the Livermore method, the time-wear diagrams were almost linear. Using all radiographs, the average exceeded those with RSA. If the early radiographs, up to 3 months postoperatively, were excluded, the average difference was almost zero (Figure 7).

With the modified EBRA software, all radiographs could be analyzed, but 3 measurements in the horizontal and 5 in the vertical directions were excluded by the software because of extreme projection differ-

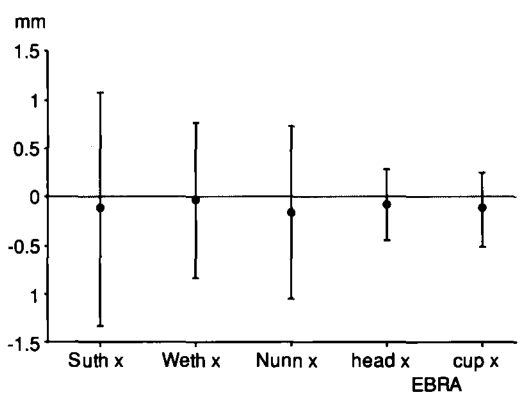

Figure 5. Mean differences and standard deviations of all migration measurements in the horizontal (x) direction, as compared to RSA. Measurements with the Sutherland (Suth x), Wetherell (Weth x) and Nunn methods (Nunn x) and with the EBRA method for the head and cup (head x, cup x).

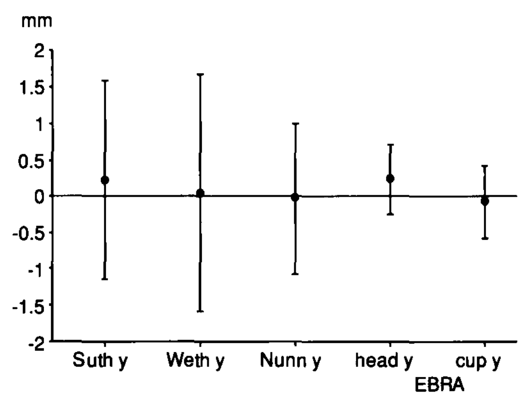

Figure 6. Mean differences and standard deviations of all migration measurements in the vertical (y) direction as compared to RSA (as in Figure 5).

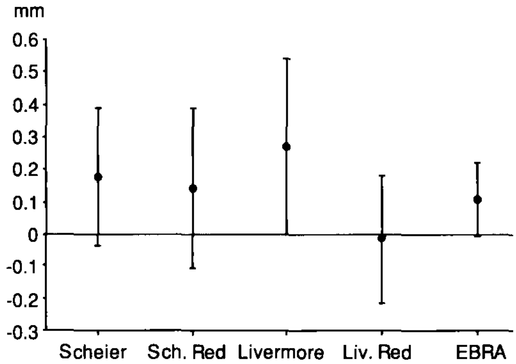

Figure 7. Mean differences and standard deviations of all wear measurements, as compared to RSA. Wear measurements with the Scheier-Sandel (Scheier), Livermore and EBRA methods. Wear measurements after exclusion of the early postoperative radiographs with the Scheier-Sandel (Sch. Red) and Livermore (Liv. Red) methods. Positive mean values indicate errors of measurements that may be caused by joint laxity or interposition by soft tissue in the early postoperative period.

ences. The measured wear increased linearly with time and almost parallel to the RSA measurements. Exclusion of the early postoperative radiographs was not possible, since too few radiographs would have been left to perform the EBRA analysis.

Livermore measurements were better than Scheier-Sandel measurements when excluding the early postoperative radiographs. EBRA measurements were the most accurate.

Comments

The teardrop line, as described by Nunn, should be recommended for rough analysis of prosthetic migration and planning of prosthetic positioning. If the teardrop is difficult to detect, the lines proposed by Wetherell et al. (1989) can be used instead.

For measurements in the horizontal direction, acetabular protrusion may affect the Wetherell and Köhler lines. In these cases the results should be interpreted with caution (Ranawat et al. 1980). The accuracy in assessing prosthetic migration was better with EBRA. Radiographs of poor quality could be detected with EBRA and excluded from the analysis.

The negative wear, as detected with RSA, might be caused by joint laxity or interposition of soft tissue in the early postoperative period. Wear measurements on plain radiographs should not be made earlier than 3 months after surgery to avoid errors of measurement caused by occasional displacements. Taking this into account, measurements with the Livermore method are accurate and reliable. EBRA improves the accuracy of the wear assessment slightly and it provides data on cup migration in the same examination.

Tilt study

The teardrop changed form, size and position, being difficult to identify on the more tilted radiographs. On 3 radiographs, the cup-cement interface could not be identified, therefore wear could not be measured with the Livermore method. Using the EBRA method, the choice of more stringent limits of comparability ($L < 3$ mm) resulted in an increasing number of radiographs that could not be used.

The results of migration measurements, using the Köhler line, and of the Scheier-Sandel wear measurements were similar to those obtained with the Nunn and Livermore methods.

The observed femoral head diameter increased almost linearly with the degree of pelvic tilt, with the minimal size in the neutral position. The maximum difference between the measured head diameters was 0.9 mm.

Tilt around the vertical axis

With the Nunn method, we found a random scatter for measurements in the horizontal direction. The maximal difference between 2 measurements was 3.1 mm. It was 1.1 mm when the radiograph with the most extreme tilt to the right side was excluded. For measurements in the vertical direction, we found a step in the migration measurement around the neutral position. (Figure 8, Table 1). With EBRA, 2 radiographs were excluded from analysis by the software in the horizontal, but no radiographs in the vertical direction. To assess the maximal possible error with EBRA, we ar-

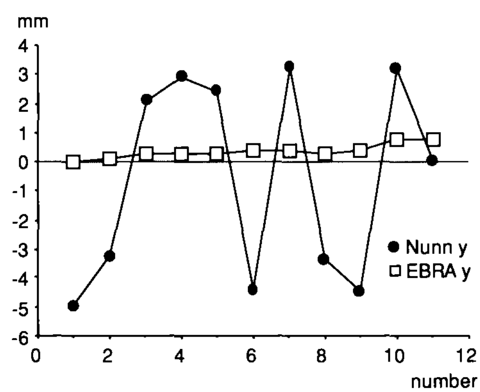

Figure 8. Migration measurements in the vertical (y) direction in 11 radiographs, set in random order, with different degrees of tilt around the vertical axis. Positive values mean cranial migration, as compared to the neutral position. The EBRA measurements were almost straight and indicated no migration. The Nunn measurements showed considerable scatter.

Table 1. Tilt around the vertical axis. Measurements of cup migration with the EBRA and Nunn methods in the horizontal (x) and vertical (y) directions. Wear measurements with the EBRA (EBRA wear) and Livermore methods

Method	n	Maximal error (mm)	Measurement error (mm)	95%CI
EBRA x	9	0.5	0.16	0.11–0.31
EBRA cons x	9	2.2	1.13	0.76–2.16
Nunn x	11	3.1	0.85	0.59–1.49
EBRA y	11	0.3	0.16	0.11–0.28
EBRA cons y	11	2.0	1.10	0.77–1.93
Nunn y	11	5.0	3.48	2.43–6.11
EBRA wear	9	0.1	0.05	0.03–0.10
EBRA w. cons	9	0.4	0.14	0.09–0.27
Livermore	11	0.4	0.14	0.10–0.25

In case of consecutive tilt, there was a systematic error for migration (EBRA cons x, y) and wear (EBRA w. cons) measurements with EBRA. The measurement error is the standard deviation of the corresponding measurements. Non-overlapping of the 95% confidence intervals (95%CI) of the measurement error indicates a significant difference between the methods to compare.

ranged the radiographs in consecutive order, with increasing tilt from the left to the right side. Then, with EBRA, there was increasing migration in the lateral and the caudal directions (Figure 9, Table 1).

The EBRA measurements were significantly better than the Nunn measurements. In case of consecutive tilt, migration measurements with EBRA in the horizontal direction did not differ significantly from those with Nunn (Table 1).

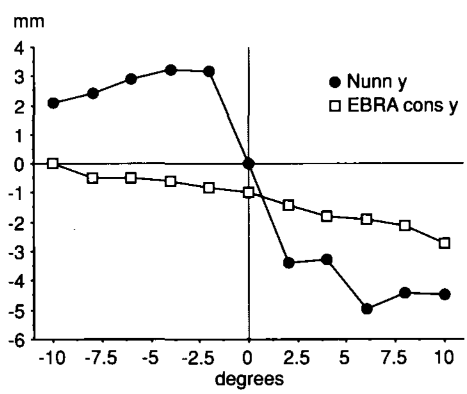

Figure 9. Consecutive tilt around the vertical axis from left to right. Measurements of migration in the vertical (y) direction. The projection differences due to pelvic tilt were too small to be recognized by the EBRA software. Small errors of measurement due to the consecutive pelvic tilt are added gradually, leading to a systematic error of measurement. With the Nunn method, it was difficult to identify the teardrop when passing the neutral (0) position.

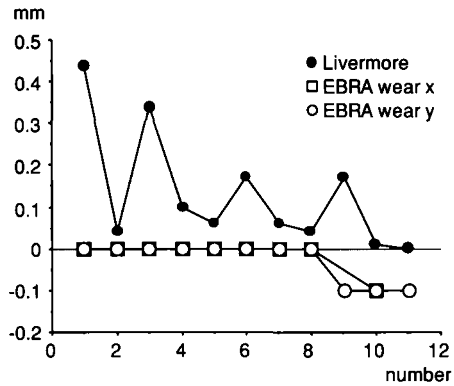

Figure 10. Tilt around the vertical axis. With EBRA, hardly any wear was measured in the horizontal (x) and vertical (y) directions.

With the Livermore method, the maximum difference between all measurements was 0.4 mm for the wear. If the pelvis was tilted less than 6 degrees, the Livermore measurements differed by a maximum of 0.2 mm. As for the migration measurements, hardly any wear was detected with EBRA, arranging the radiographs in a random order. Again, we found a systematic error of measurement when arranging the radiographs in consecutive order (Figure 10, Table 1).

Wear measurements with EBRA were significantly better than with the Livermore method. In case of consecutive tilt, there was no significant difference (Table 1).

Tilt around the horizontal axis

Using the Nunn method, we obtained a random scatter for migration measurements in the horizontal (x) direction. In the vertical (y) direction, the values decreased with increasing kyphosis (Figure 11, Table 2). With EBRA, no radiograph was excluded from measurements in the horizontal (x) direction. For measurements in the vertical (y) direction, 13 of 15 radiographs were excluded from analysis by the software. To assess the maximal possible error with EBRA, the radiographs were arranged in consecutive order, with increasing tilt from lordosis to kyphosis. No effect on the EBRA measurements was found (Figure 11, Table 2).

The EBRA measurements in the horizontal direction were significantly better than the Nunn measurements, even in case of consecutive tilt (Table 2).

With the Livermore method, the maximal error was 0.5 mm for the wear. The maximum error was 0.3 mm if the pelvis was tilted less than 6 degrees. In wear measurements with EBRA, only 2 radiographs were comparable. A change in the order of the radiographs had no effect on results (Table 2).

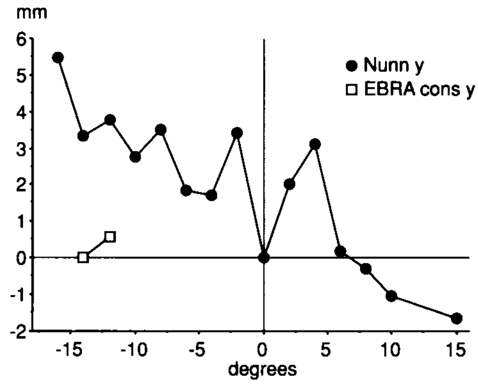

Figure 11. Consecutive tilt around the horizontal axis from lordosis to kyphosis. Measurements of migration in the vertical (y) direction. With EBRA, the projection differences were recognized by the software. Most radiographs were excluded from analysis. With Nunn, there was a tendency towards decreasing values with increasing tilt; the scatter may be caused by other errors of measurement.

Table 2. Tilt around the horizontal axis. For EBRA measurements in the vertical (y) direction, most of the radiographs were detected as tilted and excluded from analysis. A considerable error of measurement was found for the Nunn migration measurements in the vertical direction (as in Table 1)

Method	n	Maximal error (mm)	Measurement error (mm)	95%CI
EBRA x	15	0.2	0.12	0.09–0.19
EBRA cons x	15	0.6	0.15	0.11–0.24
Nunn x	15	1.0	0.37	0.27–0.58
EBRA y	2			
EBRA cons y	2			
Nunn y	15	5.5	2.04	1.49–3.22
EBRA wear	2			
EBRA w. cons	2			
Livermore	15	0.4	0.17	0.12–0.27

Series of 5 randomly combined radiographs

Of the 5 series of 5 random combinations of radiographs, the EBRA software excluded 7 radiographs from measurement in the horizontal and 12 in the vertical directions. The EBRA measurements were significantly better than the Nunn measurements (Table 3). For the wear, 16 out of 25 radiographs were excluded by the EBRA software. The EBRA measurements seemed better than the Livermore measurements, the difference was not significant (Table 3).

Comments

Measurements of the femoral head size proved to be very reliable and can be used to calculate radiographic magnification.

Table 3. Series of a random combination of 5 tilted radiographs. The main improvement was found for migration measurements in the vertical (y) direction (as in Table 1)

Method	n	Maximal error (mm)	Measurement error (mm)	95%CI
EBRA x	18	0.4	0.16	0.12–0.24
Nunn x	25	1.1	0.63	0.49–0.88
EBRA y	13	0.9	0.43	0.31–0.71
Nunn y	25	8.2	3.64	2.84–5.06
EBRA wear	9	0.2	0.09	0.06–0.17
Livermore	25	0.4	0.19	0.15–0.26

The acetabular teardrop line changes with increasing pelvic tilt (Goodman et al. 1988a, Massin et al. 1989), causing errors of migration measurements with the Nunn method. Tilt around the vertical axis may be detected and excluded by an experienced investigator because of a gradual increase in pelvic asymmetry. However, tilt around the horizontal axis, caused by pain or flexion contractions in the hip, may be commoner. This is difficult to detect and may lead to considerable errors of measurement, up to 5.5 mm with the Nunn method.

The EBRA software detected and excluded extreme projections. We found a systematic error in case of consecutive tilt in one direction. However, even in the worst case, EBRA was better than the standard methods, especially for measurements in the vertical direction. Using a stricter limit of comparability, "L", this error may disappear.

For wear measurements, the Livermore method was reasonably accurate and only slightly affected by moderate pelvic tilt. It is recommended for studies focusing on wear alone.

Evaluation of EBRA method

Reliability of the input procedure

The measurements could be made on all radiographs and none of the repeated inputs was excluded by the EBRA software because of projection differences. The input seemed to be more precise for the head than for the cup (Table 4).

The measurement error was significantly lower with the Nunn and Livermore methods than with EBRA. Direct measurements of well-defined structures or lines on single radiographs using the slide caliper were more precise than repeated digitization using EBRA (Table 4).

Reliability of repeated radiographic examinations

The EBRA software excluded some radiographs from

Table 4. Repeated input procedures of the same radiograph. Migration measurements in the horizontal (x) and vertical (y) directions with the EBRA (EBRA head, cup) and Nunn methods. Wear measurements with the EBRA (EBRA wear) and Livermore methods (as in Table 1)

Method	n	Maximal error (mm)	Measurement error (mm)	95%CI
EBRA head x	25	0.2	0.13	0.10–0.18
EBRA cup x	25	0.5	0.25	0.20–0.35
Nunn x	25	0.2	0.11	0.09–0.15
EBRA head y	25	0.4	0.19	0.15–0.26
EBRA cup y	25	0.9	0.31	0.24–0.43
Nunn y	25	0.3	0.11	0.09–0.15
EBRA wear	25	0.4	0.19	0.15–0.26
Livermore	25	0.1	0.06	0.05–0.08

Table 5. Repeated radiographic examinations on the same day. Some radiographs were excluded by the EBRA software (as in Table 1).

Method	n	Maximal error (mm)	Measurement error (mm)	95%CI
EBRA head x	50	0.6	0.25	0.21–0.31
EBRA cup x	50	0.8	0.35	0.29–0.44
Nunn x	50	1.1	0.35	0.29–0.44
EBRA head y	46	0.6	0.20	0.17–0.25
EBRA cup y	47	1.3	0.38	0.32–0.48
Nunn y	50	1.8	0.75	0.63–0.93
EBRA wear	46	0.7	0.17	0.14–0.21
Livermore	50	0.4	0.13	0.11–0.16

Table 6. Assessment of the intraobserver variation. Several radiographs were excluded by the EBRA software, especially for analysis in the cranial (y) direction and for wear measurement (as in Table 1)

Method	n	Maximal error (mm)	Measurement error (mm)	95%CI
EBRA head x	44	2.4	0.55	0.45–0.70
EBRA cup x	39	2.0	0.51	0.42–0.66
Nunn x	48	2.0	0.82	0.68–1.03
EBRA head y	20	1.3	0.64	0.49–0.93
EBRA cup y	18	1.7	0.57	0.43–0.85
Nunn y	48	3.5	1.02	0.85–1.28
EBRA wear	16	0.4	0.15	0.11–0.23
Livermore	48	0.9	0.29	0.24–0.36

Table 7. Assessment of the interobserver variation. Several radiographs were excluded by the EBRA software, especially for analysis in the cranial (y) direction and for wear measurement (as in Table 1)

Method	n	Maximal error (mm)	Measurement error (mm)	95%CI
EBRA head x	50	2.2	0.70	0.58–0.87
EBRA cup x	41	2.5	0.79	0.65–1.01
Nunn x	48	4.5	0.91	0.76–1.14
EBRA head y	23	1.3	0.43	0.33–0.61
EBRA cup y	20	2.6	0.75	0.57–1.10
Nunn y	48	3.5	1.05	0.87–1.32
EBRA wear	17	0.4	0.18	0.13–0.27
Livermore	48	0.9	0.40	0.33–0.50

measurements in the vertical direction (number of measurements, Table 5). With the standard methods, measurements could be made on all radiographs. The measurements of the cup seemed to be less accurate than the measurements of the head (Table 5). With the Nunn method, measurements in the horizontal direction were significantly better than in the vertical direction. In the vertical direction, EBRA measurements were significantly better than Nunn measurements. For the wear measurements, we found no significant difference between EBRA and Livermore (Table 5).

Intraobserver variation

The EBRA software excluded some radiographs for measurement in the horizontal and several in the vertical directions. All radiographs were measured with the standard methods. Migration measurements with EBRA (EBRA cup) were significantly better than with Nunn. Wear measurements with EBRA were significantly better than with Livermore (Table 6).

Interobserver variation

The results were similar to the intraobserver variation. For migration measurements in the horizontal direction, we found no significant difference between EBRA and Nunn. In the vertical direction, EBRA head measurements were significantly better than Nunn measurements. Wear measurements with EBRA were significantly better than with Livermore (Table 7).

Comments

Repeated measurements of well-defined structures can be made very accurately by hand with the slide caliper. The digital input of the EBRA method was less precise. Automatic image analysis, as provided by the MAXIMA method (Hardinge et al. 1991) and by a new version of the EBRA software, may overcome this problem.

In the more clinical situation, assessing the reliability of repeated radiographic examinations and evaluating the intra- and interobserver errors, the EBRA method was better than the standard methods. The tangents on prominent pelvic structures were easily drawn, improving the reproducibility, but some radiographs were excluded by the software from analysis and thus lost to follow-up.

Wear measurements with the Livermore method were almost as reliable as those with EBRA. Sometimes it was difficult to see the prosthesis-cement interface, which may increase the interobserver error. When focusing only on wear, the Livermore method can be recommended.

The main improvement with the EBRA method was found for component migration in the vertical direction. This is the main direction in patients with prosthetic migration and it is of major clinical interest (Stocks et al. 1995). Additional radiographs in the course of follow-up (Russe 1988) and the peroperative implantation of markers in pelvic bone (Malchau et al. 1995) may further improve this method.

Evaluation of successful hip replacement

Nine of 368 radiographs could not be measured with the Livermore method because of difficulties in defining the prosthesis-cement interface. All radiographs were marked and digitized with the EBRA method, but 140 were excluded from analysis by the software.

With the Nunn method, the mean measured migration was 0.6 mm (SD 0.9, range –1.2 to 2.6, 95% confidence interval (95%CI) 0.19 to 0.98) in the horizontal and 0.2 mm (SD 0.7, range –1.7 to 1.4, 95%CI –0.11 to 0.54) in the vertical directions. The measurements were not linear. During follow-up, migration exceeding 3 mm (3.2 mm) was seen on only one radiograph.

As measured with EBRA, the mean migration was 0.2 mm (SD 1.6, range –3.5 to 3.1, 95%CI –0.52 to 1.00) in the horizontal and –1.5 mm (SD 1.5, range –3.8 to 1.2, 95%CI –2.23 to –0.82) in the vertical directions. Eighteen of 20 cups showed negative values for migration in the vertical direction, suggesting caudal migration. No patient had a migration of one or more millimeters in the first 5 postoperative years.

The mean direction of wear was 80° (SD 17°). The most medial direction of wear (55°) was measured in a patient with a shortening of 2 cm on the ipsilateral leg. The most lateral direction of wear (110°) was measured in a patient with an arthrodesis and definite shortening of the contralateral hip.

No wear was detected in 6 hips with the Livermore method, assuming a minimum of 0.5 mm as significant. With EBRA, all measured 20 hips had detectable wear, 3 of them below 0.5 mm. The maximum wear was 3.7 mm after 24 years (0.15 mm per year), as measured with the Livermore method.

With the Livermore method, the mean wear was 1.1 mm (SD 1.0, range 0 to 3.7, 95%CI 0.72 to 1.58), the mean wear-rate was 0.05 mm per year (SD 0.05, range 0 to 0.15, 95%CI 0.03 to 0.07). With EBRA only 20 hips were analyzed. The mean wear was 1.6 mm (SD 0.89, range 0.1 to 3.3, 95%CI 1.13 to 1.97), and the mean wear-rate 0.08 (SD 0.043, range 0.01 to 0.17, 95%CI 0.06 to 0.10).

The mean gradient for the regression of the wear-rates and time was 0.003 (SD 0.02, range –0.03 to 0.04, 95%CI –0.004 to 0.01) with the Livermore method. With EBRA, the mean gradient was –0.001 (SD 0.01, range –0.01 to 0.03, 95%CI –0.007 to 0.005). We found no significant trend towards increasing or decreasing wear-rates with time.

Comments

The selected patients may not be representative of the present spectrum of patients operated on with THR. The criteria for inclusion were very strict; there was neither a clinical nor a radiographic suspicion of cup loosening in any of these patients, all patients were still active, walking without crutches at the latest follow-up.

Migration has predictive value for aseptic loosening (Krismer et al. 1996, Snorrason and Kärrholm 1990, Stocks et al. 1995). Our results confirm that cups without signs of loosening do not migrate, either in the early postoperative period or later. For standard measurements, an accuracy of ± 3 mm, as proposed by Nunn et al. (1989), is realistic.

The caudal migration, as found with EBRA in most of the cups, may be explained by plastic deformation of the cup, with a gradual opening of the contrast wire in the coronal plane. This deformation increases the diameter of the contrast wire and, in case of rigid fixation, it simulates caudal migration of the cup.

With EBRA, we found a higher wear-rate than with the other methods. Wear measurements with EBRA, as well as the migration measurements, are made in relation to the contrast wire. Besides simulating caudal migration, plastic deformation will also simulate an increased linear wear-rate.

Most of our cups showed some wear. "No wear" is thus a matter of definition and probably means no wear detected with the method in use.

We found no changes in the wear-rate with time. Wear seems to be linear with time. There was neither evidence for decreasing wear due to hardening under load (Weightman et al. 1991) nor for increasing wear due to oxidation (Li and Burstein 1994) of the polyethylene. The findings of errors of wear measurement in the early postoperative period, even with RSA, might partly explain such observations (Ilchmann et al. 1995).

The mean wear found in this study is one of the lowest reported. Since there is a correlation between loosening and wear, the strict selection of well-fixed cups in this study may be an explanation; other studies may have included probably or definitely loose implants (Sychterz et al. 1996). Cups with higher wear-rates may have failed already at an earlier stage.

Discussion

Careful follow-up is required for progress in hip replacement surgery. The clinical follow-up should be standardized (Galante 1985, Johnston et al. 1990). A few parameters might be sufficient to describe the clinical outcome (Bryant et al 1993). Health profiles and questionnaires can reduce the number of controls in the out-patient departments, but multicultural comparisons might be difficult (Dawson et al. 1996, Hunt and McEwen 1980, Johanson et al. 1992).

Serial radiographs are the most objective means for comparing different designs of hip replacements. In this way pending failure might be detected before the development of clinical symptoms. Standardized radiographs of the pelvis centered on the symphysis should be taken routinely. The analysis of possible zones of loosening (DeLee and Charnley 1976) is well established. Severe osteolysis will be recognized and revision can be performed in time. However, reproducibility is limited (Brand et al. 1985) and zone analysis is not suitable for multicentre studies.

Measurements on plain radiographs produce more objective and reproducible data. Early and continuous migration of the acetabular cup and high linear wear rates correlate to late aseptic loosening. With standard methods, there are considerable errors in migration and wear measurements and the reliability of the data and the probability of detecting possible failure at an early stage depend on the accuracy of the methods used.

It is difficult to assess the accuracy of methods of migration and wear measurement. Data on methodological precision can be obtained by repeated measurements and calculations of the standard deviation. If accuracy is to be assessed, the deviation from zero should be found but the "real" in vivo migration and wear are not known. Comparison with highly accurate methods like RSA provide such data, but they disregard the error of measurement in the reference method. Comparison with the literature is difficult as different tests were performed to assess accuracy, if it was tested at all. For RSA, Önsten (1994) performed double migration measurements of 50 cups and found levels of significant migration below 0.3 mm at 99% confidence limits in any direction. Mjöberg (1986) performed 30 double measurements with a standard deviation of 0.10 in the transverse (x), 0.06 in the longitudinal (y) and 0.23 mm in the sagittal (z) directions (0.28, 0.15 and 0.62 mm respectively using the Student's t-distribution ($p<0.01$)). In the presented work, all methods in question were tested by the same means to solve such problems.

For simple migration measurements, Nunn's method is recommended. Highly standardized radiographs or the use of grid lines (Amstutz et al. 1986) may further improve that method. In the double measurements, we found a measurement error below 1.1 mm and in the analysis of long-term successful cups, only one migration measurement was more than 3 mm. Thus we conclude that migration exceeding 3 mm is highly significant, if carefully measured by an experienced observer; but often the radiographic measurements are made by inexperienced observers and this might increase the error of measurement.

Effects of pelvic tilt cannot be corrected, even using digitized radiographs and with direct measurements on the screen. However, the measuring procedure can probably be speeded up. The Nunn method is a useful instrument in clinical practice; it estimates whether there might be severe loss of bone due to migration. However, early migration cannot be detected and types of failure for individual patients cannot be described.

For the assessment of acetabular cup wear, reliable measurements can be made with the Livermore method. Errors of measurement can be avoided by excluding the early postoperative radiographs from the analysis. We found a measurement error below 0.5 mm when we assessed double measurements. The border of ceramic heads may be difficult to identify, particularly when combined with metal-backed cups. Such material combinations may need other methods of wear measurement. Since the standard methods have a good correlation with direct wear measurements on retrieved cups, the use of more elaborate methods seems unnecessary, when focusing on wear alone.

We showed that the accuracy of migration measurements is greater with the EBRA method than with standard methods. Digitizing the marking points by hand was less precise than standard measurements with the slide-caliper and the new digitized version of the software might be a further improvement. EBRA differed less from RSA measurements, was less affected by pelvic tilt and the range of values was narrower in repeated measurements than with the Nunn method. The maximum error of measurement was smaller when we assessed double measurements. Wear measurements with EBRA were more reliable than with the Livermore method; but a systematic error in case of consecutive tilt in one direction and a discrepancy between direct wear measurements and subtraction of head and cup migration imply some error in the software.

EBRA can be used in retrospective studies. Some patients may be excluded by the software and thus are lost to follow-up. Furthermore, EBRA is time-consuming. The use of the new digitized version requires more technical equipment, but it speeds up analysis and probably improves the accuracy. EBRA may be a good instrument for clinical studies of new implant designs which have passed the preclinical and, preferably, radiostereometric analysis. It can be used in smaller centers as well. When designing a clinical study, one must ask, whether the improvement in measurement accuracy is worthwhile in relation to the cost in equipment and time.

RSA is highly accurate, so far unequaled by any other method and it has an established place in many orthopedic measurements (Kärrholm 1989). Early implant fixation, types of failure or movements under load can be studied. The disadvantages of RSA, however, are obvious: markers must be implanted peroperatively, limiting RSA to smaller, prospective studies. It is time-consuming and the analysis of the radiographs is complicated. Not least, it requires considerable research facilities and the cost in time and equipment must be well planned. Nevertheless, RSA measurements are unsurpassed with regard to accuracy and the method can be recommended for research units with sufficient resources, doing their first clinical follow-up of new implant designs.

Summary

Methods are needed for accurate measurement of acetabular cup migration and wear after hip replacement. The EBRA (Ein Bild Röntgen Analyse) method was recently introduced as computerized method for radiographic assessment of acetabular cup migration.

In this study, various standard methods for measuring migration were evaluated and compared to radiostereometry (RSA), which has proved to be highly accurate. A subroutine for wear measurement was developed and added to the EBRA method.

Of the standard methods, Nunn's method was the best for migration measurement and Livermore's the best for wear measurement. Measurements with EBRA were better than the standard methods.

Pelvic tilt seemed to be the main source of error in measurements. The effect of pelvic tilt was evaluated experimentally. EBRA detected and excluded tilted radiographs, the errors of measurement being smaller with EBRA than with standard methods.

The precision of the input procedure, repeated radiographic examination, the intra- and interobserver errors were assessed. Apart from the digital input of the data, EBRA was better than the standard methods.

Normal values concerning acetabular cup migration and wear should be obtained from long-term surviving hip replacements, without radiographic signs of loosening. No method of measurement detected evidence of changes in the wear-rate and in migration over time. EBRA showed cold-flow in some cups, but did not provide additional information in the long-term.

Nunn's method for migration measurements and Livermore's method for wear are recommended in clinical practice. EBRA is more accurate and should be used for studies of new implant designs that have passed the preclinical and, preferably, radiostereometric analysis. RSA is unsurpassed and is recommended for early clinical follow-up in a limited number of patients.

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