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Loosening of the cemented hip prosthesis

The importance of heat injury

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Introduction

The use of bone cement in hip arthroplasty, introduced by John Charnley, is one of the most important advances in orthopedic surgery in this century. However, the cement did not solve all the problems associated with prosthetic fixation. The previously high rate of infection has almost been eliminated and mechanical loosening is now the major problem. The results have been good to excellent in most patients (1–8); but because of loosening, the results do deteriorate with time (4–6, 8–10).

The diagnostic criteria of loosening in conventional radiography (10–20), contrast and radionuclide arthrography (16, 21–24), bone scintigraphy (16, 24–28) and roentgen stereophotogrammetry (29–37) are controversial, which may partly account for that the reported rates of loosening vary considerably; the reported rate of radiographic loosening varies from less than 1 per cent to 29 per cent for the acetabular component and from less than 1 per cent to 41 per cent for the femoral component (1–10, 38). Confusion also arises because only some hips with obviously loose prosthetic components are painful (1, 4, 7–9, 39, 40). Finally, the revision rate due to loosening varies 10 years after arthroplasty from 1.5 per cent to 19 per cent (1–6).

The cause of loosening is considered to be multifactorial and has been analyzed using several approaches: viz., clinical research on demographic and physiologic variables (5, 9, 38–44), preparation and cementing technique (8, 40, 45–48), prosthetic design, positioning, friction and wear (1, 3, 5, 8, 9, 38–40, 49–62); biological responses studied in human investigations (63–79) and in animal experiments (80–98); biomechanical investigations—experimental studies (51, 61, 99–130) and theoretical analyses (104, 112, 120, 129, 131–139); and studies on properties of materials (108, 125, 140–160).

In clinical research, correlations have been demonstrated between loosening and age, sex, body weight, physical activity, arthritis/arthrosis, protrusio acetabuli, width of the femoral canal, previous hip surgery, surgeon, cortical support, cleaning, packing of the cement, varus/valgus position, neck length, thickness of the stem, metal-backing, and thickness, eccentricity and wear of the acetabular component. The debate on biological responses as possible causes of loosening has been focused on local vascular injury, thermal injury, toxic injury, infection, reaction to wear products, metal sensitivity, micromovements/strains, reaction to the cement, stress-shielding, and stress concentration. Biomechanical investigations have been concentrated on determination of forces across the hip joint, the resulting stress distribution, and the mechanical strength of the interfaces; determination of heat development and heat conduction; determina-

tion of friction and wear. In studies on properties of materials, attention has particularly been paid to dough viscosity, polymerization rate, heat release, shrinkage, porosity, mechanical strength, fatigue, monomer leakage, water adsorption, and creep of various cement compositions.

In this report the results from our recent investigations (161–165) are presented and analyzed further. Several of these investigations were focused on heat injury as a possible cause of loosening. The aims of the investigations were to find a favorable definition of loosening and to investigate the etiology of mechanical loosening of the cemented hip prosthesis.

Definition

There is a need for an objective and accurate method for assessing mechanical loosening after hip arthroplasty (166). Pain evaluation is not satisfactory; many hips with obviously loose prosthetic components are not painful (1, 4, 7–9, 39, 40). Radiographic assessment is also unsatisfactory (10–20); opinions differ as to the degree of radiolucency (location, width, and extension) that indicates loosening. The accuracy of contrast and radionuclide arthrography (16, 21–24) and of bone scintigraphy (16, 24–28) is debated; discrepancies have been attributed to various techniques and different criteria (24, 27). Roentgen stereophotogrammetric analysis (RSA) (167, 168) allows the accurate detection of prosthetic displacement (29); the interpretation of observed instability and migration is, however, controversial (29–37). No reports have compared arthrography and bone scintigraphy with RSA.

Patients and methods

To evaluate the diagnostic criteria in arthrography, scintigraphy, and RSA, 14 symptomatic hip arthroplasties were examined by these methods (161).

Contrast and radionuclide arthrography (16, 21–24) was performed under fluoroscopic control using a mixture of water-soluble iodine contrast and ^{99m}Tc -sulfur colloid. Penetration of contrast medium and/or radionuclides into bone-cement or cement-prosthesis interfaces was regarded as abnormal.

Bone scintigraphy (16, 24–28) was performed after intravenous administration of ^{99m}Tc -MDP (in all cases at least 19 months after arthroplasty). Increased activity around the acetabular component or at the tip of the femoral component was regarded as an indication of loosening (26, 28).

RSA was performed after percutaneous implantation of tantalum balls in the os ilium and in the trochanter major. The term *instability* is used for prosthetic component displacement in relation to bone upon provocation. The term *migration* is used for displacement over a period of time. A description of the method is given in the Appendix (pp 28–29). Instability was tested using distraction and compression, as well as external and internal rotation (34); migration was tested over a period of 8–42 months.

Results

Of the 28 prosthetic components, 15 (five acetabular and 10 femoral) migrated. The acetabular components migrated cranially and the femoral components distally. Of the 15 migrating prosthetic components, four (one acetabular and three femoral) were found to be unstable upon provocation according to RSA, six (two acetabular and four femoral) gave an abnormal arthrogram, and 13 (three acetabular and all 10 femoral) displayed increased scintigraphic activity (Figures 1 and 2). The 13 nonmigrating components (nine acetabular and four femoral) were stable upon provocation according to RSA, yielded a normal arthrogram, and displayed normal scintigraphic activity. In four hips, which were revised after the investigations on clinical grounds, all the migrating components (one acetabular and three femoral) were loose at surgery, i.e., visible movements could be induced. However, RSA had revealed instability in only two of them (Figures 1 and 2).

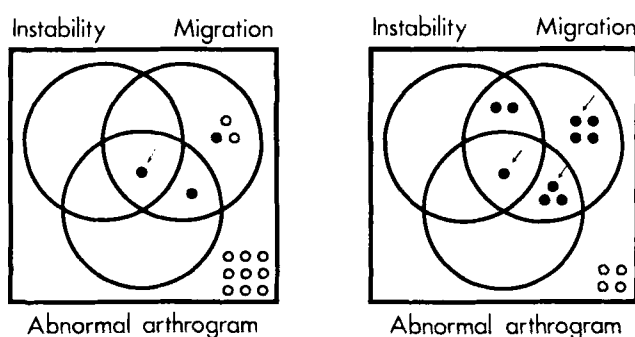


Figure 1 (left). Relation between instability and migration revealed by RSA, arthrography, and bone scintigraphy of the acetabular component in 14 hips. ●=increase in scintigraphic activity. ○=no increase in scintigraphic activity. Arrow indicates revised acetabular component. (Reproduced with permission from *Acta Orthop Scand*.)

Figure 2 (right). Relation between instability and migration revealed by RSA, arthrography, and bone scintigraphy of the femoral component in 14 hips. ●=increase in scintigraphic activity at the tip. ○=no increase in scintigraphic activity. Arrows indicate revised femoral components. (Reproduced with permission from *Acta Orthop Scand*.)

Discussion

To some extent contrast arthrography (16, 21–24), radionuclide arthrography (23), and provocation investigation using RSA (34) complement each other in the detection of instability. In this series none of these methods revealed all the unstable prosthetic components. Two femoral components found to be unstable using RSA and one femoral component found to be loose at revision gave normal arthrograms (Figure 2); fibrous tissue may prevent the arthrographic medium from penetrating the interfaces (16). On the other hand, in four prosthetic components (one acetabular and three femoral) with an abnormal arthrogram—an indirect sign of instability (22)—and in another femoral component found to be loose at revision, RSA did not reveal instability upon provoca-

tion (Figures 1 and 2). Thus, it is not possible to detect all cases of instability using RSA, not even upon rotational provocation (34).

All prosthetic components found to be unstable by RSA or with an abnormal arthrogram or with increased scintigraphic activity or loose at revision were migrating. However, no nonmigrating component demonstrated any of these signs of loosening (Figures 1 and 2). These findings indicate that the best definition of loosening is *migration*.

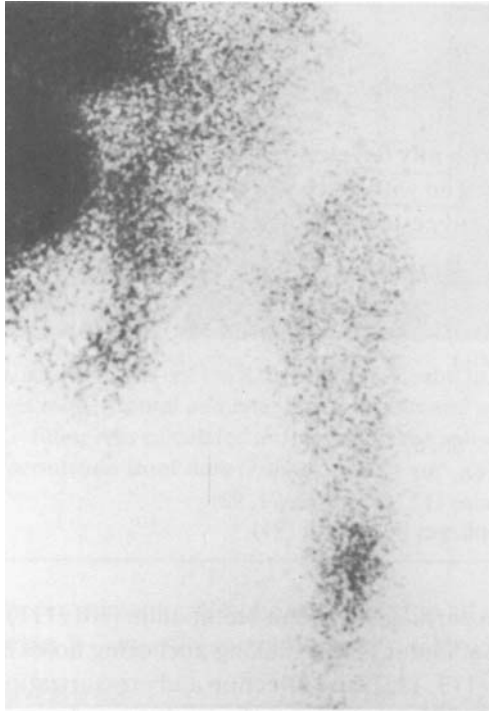


Figure 3. Focal increase in scintigraphic activity at the tip of a migrating femoral component. (Reproduced with permission from *Acta Orthop Scand*.)

Contrast arthrography, radionuclide arthrography, and provocation investigation using RSA displayed low sensitivity in detecting loosening defined as migration. Increased activity at the tip of the femoral component by Tc-MDP-scan (26, 28) was found to be a reliable indicator of migration (Figure 3). Increased activity around the acetabular component was, however, difficult to evaluate because of the deep position of the component and activity caused by the bladder.

The histologic and ultrastructural definition of loosening is disintegration at the bone-implant interface (46, 76). Close contact at this interface is, in cases of loosening, replaced by contact through an intervening connective tissue membrane containing macrophages that resorb bone upon stimulation by micromovements (65, 72, 75). The bone-cement interface is inaccessible for direct examination in situ. However, by searching for migration using RSA, prosthetic fixation can be evaluated in situ.

Etiology

A radiolucent zone frequently develops at the bone-cement interface following arthroplasties and has been linked with mechanical loosening (1, 6, 40). Several explanations for the zone have been suggested (Table 1).

Table 1. Suggested explanations for the radiolucent zone at the bone-cement interface

1. Vascular injury (82, 89, 92, 94)
2. Heat injury (65, 85, 101)
3. Toxic injury (65, 85)
4. Infection (11, 14)
5. Wear products (57, 63, 66, 67, 69, 78)
6. Metal sensitivity (64, 66, 79)
7. Micromovements/strains (12, 17, 65, 72, 77, 92)
8. Stimulation of macrophages by cement (71)

Removal of articular cartilage from the acetabulum (101, 111) and of weak cancellous bone from the proximal femur (113), making anchoring holes in the acetabulum (101, 111), careful cleaning (113, 122), and injection and pressurization of cement into a plugged femoral canal (114, 126) improve mechanical strength in vitro at the bone-cement interface; greatly reduced rates of femoral component loosening have been demonstrated after application of these measures in vivo (1, 8, 48). Biomechanical experiments (113, 122, 125) have indicated that improved interlock is obtained with low-viscosity cement, but this has not been confirmed clinically (54).

The suggested explanations for the radiolucent zone (Table 1) and the proposed advantage of low-viscosity cement were analyzed in three investigations:

1. Bone cement, heat injury, and the radiolucent zone

Material and methods

To study the development of the radiolucent zone in a model in which several of the suggested explanations were not applicable, 6 cases of giant-cell tumor of bone, successfully treated by curettage and cementing were analyzed (162). The mean follow-up time was 4 (2–6) years. During this period, each patient underwent 6–12 conventional

radiographic examinations. All radiographs were reviewed with regard to the volume of the cement fillings (Figure 4). The width of the radiolucent zone was measured at 5-mm intervals around the cement fillings in the frontal and lateral projections.

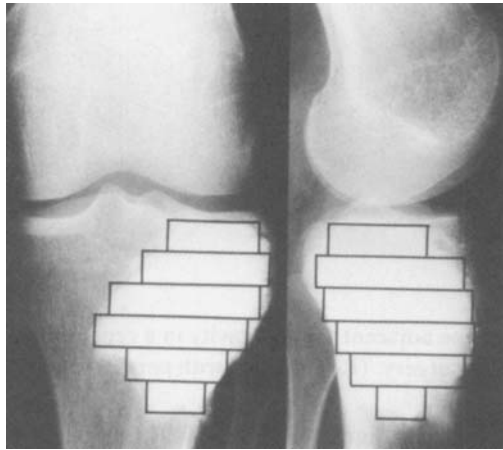


Figure 4. A cement filling divided into 1-cm-thick discs perpendicular to the long axis of the bone. These discs were measured in the frontal and lateral projections and approximated to elliptical cylinders. The volume of a filling was calculated as the sum of the volumes of the corresponding discs. (Reproduced with permission from *Acta Orthop Scand*.)

Results

A radiolucent zone between cement and bone developed in all cases during the first 6 months and became within 3–7 months surrounded by a sclerotic rim (Figure 5). In 2

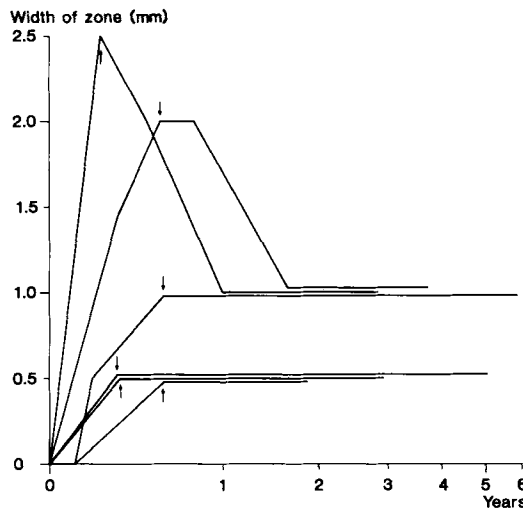


Figure 5. The development of the radiolucent zone (maximal width in 0.5 mm intervals) adjacent to the cancellous bone. Arrows indicate the appearance of the sclerotic rim. (Redrawn with permission from *Acta Orthop Scand*.)

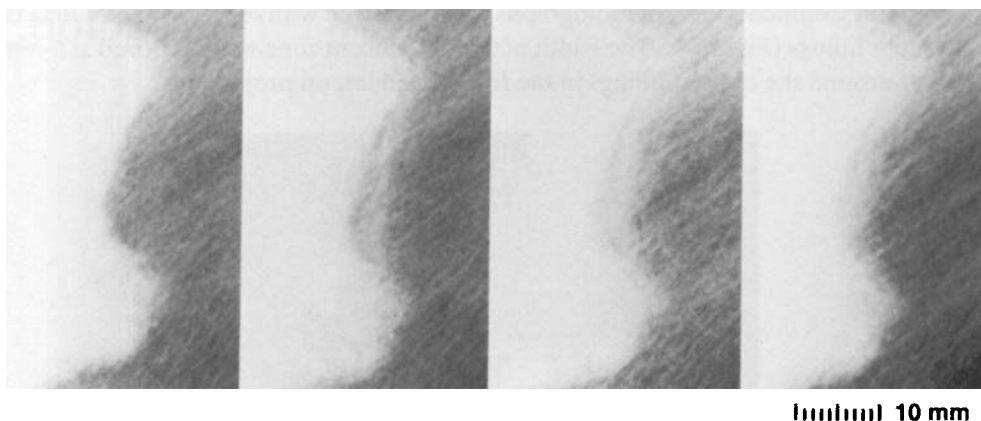


Figure 6. The radiolucent zone adjacent to a concavity in a cement filling 2 weeks, 3 months, 5 months, and 12 months after surgery. (Reproduced with permission from *Acta Orthop Scand*.)

cases the zone then diminished (Figures 5 and 6). In three locations in 2 cases, where the cement filling adjacent to cancellous bone was concave, a considerably wider zone developed (Figure 6). A positive correlation was found between the maximum mean width of the zone adjacent to the cancellous bone and the volume of the cement filling (Figure 7).

Discussion

An increasing radiolucent zone may be caused by resorption of a layer of necrotic bone adjacent to the cement (65). This necrosis has been attributed to peroperative trauma: local vascular injury during reaming (82, 89, 92, 94), heat injury during polymerization (65, 85, 101), and local toxic injury of the methyl methacrylate monomer (65, 85). Surgical trauma may cause vascular disturbance in the diaphysis, but not in the cancellous bone of the metaphysis (89). Furthermore, Feith (85) showed that heat injury during polymerization was more important. The threshold temperature for cell injury is time-dependent; epidermal cell necrosis occurs after 5 seconds at 60°C, after 30 seconds at 55°C and after 5 minutes at 50°C (80). Based on these findings, Huiskes (136) calculated a “necrosis map” for the hip (Figure 8) and concluded that a thicker layer of bone became necrotic in areas adjacent to a concave cement surface. Methyl methacrylate monomer is toxic (85, 86), but the local effect on bone of the leaking monomer is considered to be insignificant (87, 95). In addition, the monomer leakage is proportional to the surface area of the cement, but is independent of its thickness (147).

Several other explanations of the radiolucent zone have been proposed: infection (11, 14), a bone-resorbing granulomatous reaction to wear products (63, 66, 67, 69, 78), metal sensitivity (64, 66, 79), micromovements (12, 17, 65, 77, 92, 99), and bone resorption due to stimulation of macrophages attracted by the cement (71). In the present material, some of these explanations were not applicable; there were no infections and no wear products from polyethylene or metal.

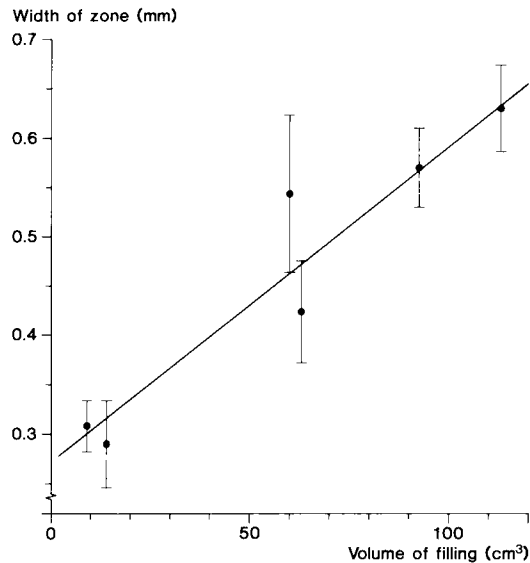


Figure 7. Width (maximum mean) of the radiolucent zones adjacent to the cancellous bone related to the volume of the filling. $r=0.95$, $P=0.004$. Vertical bars indicate the SEM. (Redrawn with permission from *Acta Orthop Scand*.)

The correlation found between the width of the zone adjacent to cancellous bone and the volume of the cement filling (Figure 7) supports the hypothesis that the radiolucent zone is caused by thermal necrosis. Further support derives from the observation that the zone was wider in concave areas and narrower in convex areas (Figure 6). This observation concurs with the prediction of Huiskes (136).

The remaining hypotheses that the zone is caused by local vascular injury at reaming, by micromovements, or by macrophages attracted to the cement can neither explain the correlation between the width of the zone and the volume of the filling nor the wider

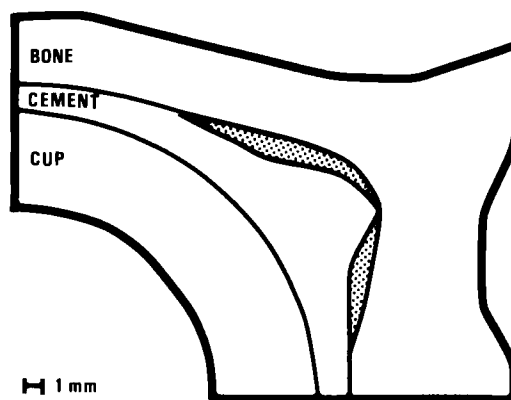


Figure 8. Necrosis map, simplified after Huiskes (136).  = thermal necrosis of bone. (Reproduced with permission from *Acta Orthop Scand*.)

zone in the concavities of the cement. In addition, all tumors were metaphyseal, where vascular injury due to surgical trauma is minimal (89).

Further, the slight linear shrinkage (0.3–0.4 per cent) of a large amount of cement after curing (154), thought by some to initiate loosening (44, 88), cannot account for the development (Figure 5), the shape (Figure 6), or the maximum mean width (Figure 7) of the radiolucent zone.

Recent investigations have demonstrated that bone tissue is even more sensitive to heat than previously believed: The threshold temperature is about 47°C for 1 minute not only for heat injury of bone (93), but also for impaired regeneration of bone (96). A sclerotic rim developed in all the cases as a result of bone regeneration, but in no case was there a complete healing of the radiolucent zone (Figure 5).

In conclusion, the radiolucent zone in this model is probably a consequence of heat injury.

Heat injury can be reduced, and even avoided, by keeping the amount of cement used to a minimum (104, 136, 140). The reduced rate of loosening of femoral components with a thick stem (5, 40, 48, 54) may thus be a consequence of the small amount of cement used, rather than of the higher extrusion pressure of the cement dough (128) or of the increased stiffness of the stem (123, 132). Conversely, the increased rate of loosening in cases with a large femoral canal (3, 5, 40) and following revision arthroplasty (4, 42, 43) may at least partly be due to the larger risk of heat injury.

2. Loosening and the radiolucent zone

Patients and methods

To study the pattern of migration, RSA was performed on 20 cemented (Palacos R cum gentamicin, Merck) Lubinus hip prostheses for arthrosis during the first 2 years after surgery (163). The operative technique included reaming, preservation of most of the subchondral bone in the acetabulum, brushing, lavage, and cement injection into the plugged femoral canal. The cement ingredients were chilled to 4°C prior to mixing in order to prolong the handling time (140, 143). At operation tantalum balls were implanted in the os ilium, in the trochanter major and minor, and in the polyethylene acetabular component. Both RSA and conventional radiography were performed 1 week, 4 months, 1 year, and 2 years postoperatively.

Results

In the 20 hips studied, 11 acetabular and three femoral components were found to have migrated when they were examined 2 years after arthroplasty. In all cases except one (an acetabular component that had migrated 0.2 mm, i.e., at the limit for significance),

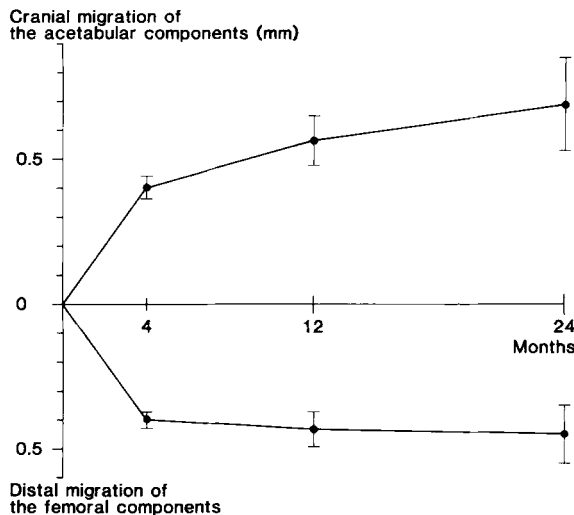


Figure 9. Mean migration along the longitudinal axis of the 11 acetabular and 3 femoral migrating components. Vertical bars indicate the SEM. (Redrawn with permission from *J Bone Joint Surg [Br].*)

migration had been seen at the examination performed 4 months postoperatively. After an initial period of rapid migration, most components migrated slowly (Figure 9). After 2 years, the 11 acetabular components had migrated 0.2–1.8 mm cranially, whereas the three femoral components had migrated 0.3–0.6 mm distally.

A noncontinuous radiolucent zone (maximum width 2 mm) between cement and bone had developed 4 months after surgery in all but two acetabular (one migrating and one nonmigrating) and four femoral (all nonmigrating) components. The width of the zone remained unchanged in all prosthetic components except in the three acetabular components with the most rapid migration (0.7–1.8 mm after 2 years). In these the zone became continuous.

No radiolucency was seen between the cement and the stem of the femoral components, and no fractures of the cement were detected. In all the femoral components (migrating and nonmigrating), a 2–4-mm-wide resorption of the cortical bone beneath the prosthetic collar had developed (Figure 10). Most of this resorption occurred within the first 4 months. No resorption occurred during the second year.

Discussion

The pattern of initial migration of the components may be explained by thermal necrosis of bone; temperatures in the interval 40–70°C at the bone-cement interface have been recorded during the polymerization (100, 102, 109, 140). In cases of heat injury, most of this necrotic bone will be resorbed during the first 4 months (85), allowing a rather rapid migration. Later, in these cases, the cement is separated from the bone by a fibrous tissue membrane containing macrophages (65, 85) that resorb bone upon stimulation by micromovements (65, 72, 75).

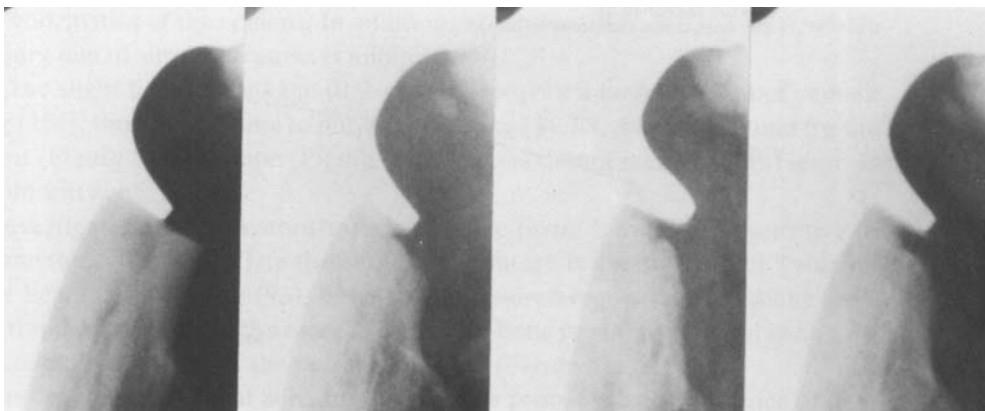


Figure 10. Resorption of bone beneath the collar of a nonmigrating femoral component 1 day, 4 months, 1 year, and 2 years after arthroplasty. (Reproduced with permission from *J Bone Joint Surg [Br].*)

Heat injury can be reduced, apart from keeping the amount of cement used to a minimum, by using metallic implants (102, 109, 136). The less frequent migration of the metallic femoral component, compared with the polyethylene acetabular component ($P = 0.01$, Fisher's exact test), may thus be explained on the basis that the metal acts as a heat sink.

The epidemiology of clinical failures of hip prostheses (1, 4, 5) may also reflect heat injury during the polymerization followed by the induced stresses of normal activities: The femoral component is exposed to greater shear stresses than the acetabular component in hip prosthetic patients during walking and, especially, while climbing stairs, and when rising from a chair (34, 112, 131); loose femoral components can be expected subsequently to develop greater instability and thus result in earlier clinical failure than most loose acetabular components. There were many more migrating acetabular components than migrating femoral components; loose acetabular components can be expected to be proportionally more common in late clinical failures.

The increased rate of failure of long-necked femoral components (50, 52, 56) and of femoral components in the varus position (3, 8, 38, 40, 49, 52, 56) may also be a consequence of greater instability in those femoral components with disintegration at the bone-cement interface which have an increased moment arm from the femoral axis to the head. Similarly, the reported correlation between wear of the acetabular component and the incidence of acetabular-component loosening (55, 58, 61) may be an expression of an earlier clinical failure in loose acetabular components with increased torque due to eccentricity following excessive wear, rather than an expression of a reaction to wear products (63, 66, 67, 69, 78); early clinical failure of eccentric acetabular components as a result of high torque has been demonstrated (51). Finally, a high friction coefficient resulting in high torque transmitted to the acetabular component may contribute to an early clinical failure (61), and Charnley (1) pointed out that the low frictional torque of the small head could explain long-term success, despite migration of the socket.

Thus, in cases of thermal necrosis of the bone, the time lag to clinical failure of different prosthetic components may be explained, apart from by varying degrees of necrosis, by the amount of stress applied, which is unequal for different patients due to body weight (5, 38) and physical activity (38, 54), and which is unequal for different components due to prosthetic design, positioning, friction, and wear.

Radiographic examination was found to be unsatisfactory for assessing mechanical loosening at an early stage (Figure 11). The presence of large resorption lacunae in bone adjacent to cement does not rule out that there are other areas of close contact (1, 74, 76, 90). Conversely, the absence of the radiolucent zone does not rule out early loosening of a prosthetic component; apart from the difficulty of determining the presence and the degree of radiolucency (20), the zone may gradually be obliterated by the migrating component.



Figure 11. Radiograph of a nonmigrating femoral component (left) and of a migrating femoral component (right) 2 years after arthroplasty.

Thus, the increased rate of prosthetic loosening with time after surgery, as detected radiographically (usually defined as lucency of 1–2 mm or more at any portion of the bone-cement interface, lucency at the stem-cement interface, visible cement fracture, or discernible implant migration) (1, 4, 6, 8–10, 13, 39) may be the result of late detection rather than of genuine late loosening.

The nonprogressive resorption of bone beneath the collar of the femoral component, found in all the cases (Figure 10), may be explained by thermal necrosis at cutting-temperatures well above 100°C have been recorded (103, 121)—rather than by local

vascular injury (68), by loosening (92), by stress-shielding (60, 115, 129, 137), by stress concentration (70, 73), or by reaction to wear products (57, 73). Besides, bone resorption due to stress-shielding, also a suggested cause of loosening (60, 115, 129, 137), may be prevented experimentally by four loading cycles during only 8 seconds a day (98), i.e., stress-shielding must be almost perfect to operate.

The biomechanical advantage of a collar is debatable (1, 115–117, 120, 129). The fact that most femoral components without collar-to-bone contact did not migrate indicates, however, that the collar is not essential for prosthetic fixation.

The reduced rate of clinical and/or radiographic loosening of metal-backed acetabular components compared with conventional components (53, 59) may be a result of reduced risk of heat injury during the polymerization rather than of decreased stress in the bone (138, 139). The rapid initial migration of the tibial components seen in most cemented-knee resurfacing arthroplasties (37), metal-backed or not, may, on the other hand, be explained by thermal necrosis induced at cutting. The considerably more pronounced initial migration of uncemented prosthetic components in both hip (36) and knee (37) arthroplasties, however, may be a consequence of prosthetic instability. The importance of initial stability was realized by Charnley (45, 99) when he introduced the use of bone cement.

3. Low- versus high-viscosity bone cement

Patients and methods

Low-viscosity cement was compared with high-viscosity cement in 16 hips examined using RSA during the first postoperative year after Scan total hip arthroplasty for arthrosis (164). Eight prostheses were fixed with low-viscosity (Palacos E-flow cum gentamicin = Osteopal G) and eight with high-viscosity (Palacos R cum gentamicin) cement after randomization. The operative technique included reaming, preservation of most of the subchondral bone in the acetabulum, brushing, high-pressure lavage, pressurization of the cement into the acetabulum, and injection and pressurization of chilled cement into the plugged femoral canal. Tantalum balls were implanted in the pelvis and in the proximal femur at operation. The acetabular components were supplied with tantalum balls by the manufacturer. Two femoral components, both cemented with high-viscosity cement, were excluded because of inadequate bone marking with tantalum balls. RSA was performed 1 week, 4 months, and 1 year postoperatively.

Results

Eight of the 16 acetabular components (4/8 with low-viscosity and 4/8 with high-viscosity cement) and three of the 14 femoral components (3/8 with low-viscosity and 0/6 with

high-viscosity cement) migrated (Figure 12). Migration was rapid during the initial 4 months, then slower (Figures 12 and 13).

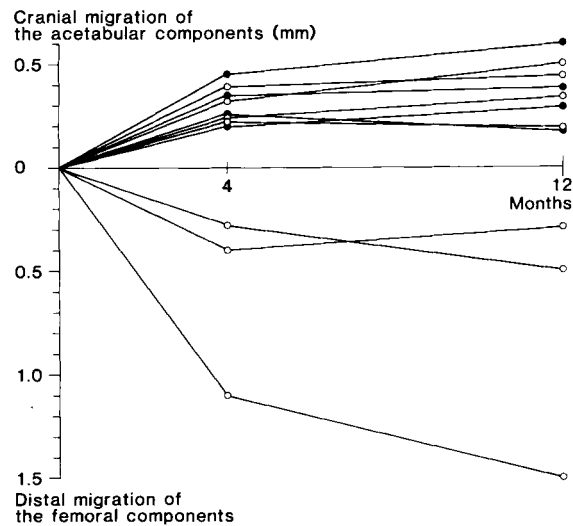


Figure 12. Migration along the longitudinal axis of the migrating 8/16 acetabular and 3/14 femoral components (8/16 acetabular and 11/14 femoral components were nonmigrating). ●=high-viscosity and ○=low-viscosity bone cement. (Reproduced with permission from *Acta Orthop Scand.*)

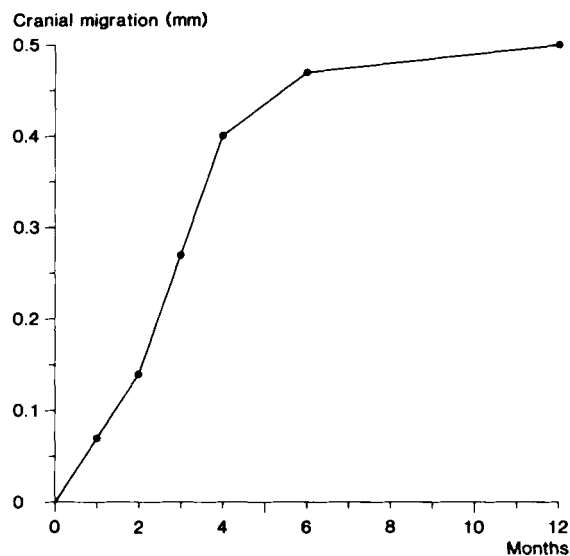


Figure 13. Migration along the longitudinal axis of one acetabular component studied using RSA at close intervals during the first year following arthroplasty.

Discussion

Biomechanical experiments (113, 122, 125) have indicated that the better penetration of low-viscosity cement into cancellous bone improves prosthetic fixation. This was not confirmed by the present investigation; no difference in the pattern of prosthetic migration when using low- and high-viscosity cement was found (Figure 12). The pattern of migration was the same as in a previous series (163) and is probably explained by thermal necrosis rather than by inferior penetration of the cement dough onto or into bone surface irregularities. Thus, low-viscosity cement does not improve prosthetic fixation.

The initial 4 month period after surgery is the optimum period for determination of prosthetic fixation using RSA (Figures 12 and 13); later on, migration may be slow and escape detection for some time if the initial period is not included (161). Once prosthetic fixation has been lost, it probably cannot be reestablished (8, 46, 75) in spite of reactive bone formation, which serves to stabilize the prosthesis (75) but fails because of micromovements. Thus, migration once begun will probably continue and may subsequently result in clinical failure. Most prosthetic components with a slight initial migration will, however, not result in clinical failure for many years (37); prosthetic components with no initial migration should have an even better prognosis.

Prevention

Mechanical loosening of the cemented hip prosthesis may thus be initiated by heat injury of bone. The adverse effect of the heat produced by polymerization was first realized in 1957 by Wiltze et al. (81), and since then several measures have been suggested to reduce it (Table 2). The efficiency of most of these measures have been theoretically evaluated by Huiskes (136). None of the modified cement compositions with greatly reduced heat production has, however, been suitable for use in orthopedic surgery because of unacceptably high dough viscosity, prolonged setting time, or low mechanical strength.

Table 2. Suggested measures to reduce heat injury to bone during polymerization

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1. Reduction of the amount of cement (104, 119, 136)
 2. Use of metal implants (45, 102, 109, 136)
 3. Precooling of the implant (100, 105), the cement (140), or the bone (110)
 4. Increase in the heat capacity of the cement by the addition of heavy metals (83, 153) or by the melting of crystalline monomers (150)
 5. Reduction of the polymerization rate (141, 142)
 6. Reduction of the proportion of monomer by increasing the powder-to-liquid ratio (140, 143), by addition of aqueous gel (85, 91, 148), or by addition of granulate polymer (159).
-

All the commercial cements are prepared by mixing 1 part liquid monomer with about 2 parts powder polymer. The average particle size of the powder is 80 μm (80 per cent by weight within the range 40–120 μm) (149, 151). Specific heat production is directly proportional to the amount of monomer in the dough: 556 joules/gram monomer (146). The amount of liquid mentioned earlier is required to fill out the interspaces between the powder beads and because of absorption of liquid by the powder beads (144). By evacuating entrapped air during mixing, i.e., by vacuum-mixing, a more effective wetting could be achieved (158). However, reduction of the amount of liquid makes the dough more viscous and therefore more difficult to handle (143) and eventually results in incomplete wetting of the dough and thus in reduced mechanical strength of the cured cement. A new cement (Coolfix, Ferring, Malmö, Sweden) has been developed where the amount of liquid needed for complete wetting has been reduced (1 part monomer per 3.5 parts polymer) by better particle size gradation, resulting in closer packing and thus reduced mean interspace while still permitting an acceptable dough viscosity.

Patients and methods

To test the hypothesis that loosening can be prevented by avoidance of heat injury, the initial 4-month migration of the components in 24 Scan total hip prostheses for arthrosis was studied following randomized use of Coolfix and Palacos R cum gentamicin (165).

The two types of cement were used in 12 hips each. The operative technique included reaming, brushing, high-pressure lavage, and injection of cement into the plugged femoral canal. The cement ingredients were chilled to 4°C prior to mixing in order to prolong the handling time. No attempts were made to pressurize the cement onto bone prior to insertion of the prosthetic components. Tantalum balls were implanted in the pelvis and in the proximal femur during the operation. The acetabular components were supplied with tantalum balls by the manufacturer. One acetabular component (with Coolfix) was excluded because of inadequate bone marking with the tantalum balls. RSA was performed 1 week and 4 months postoperatively.

Results

Five of the 12 acetabular components and one of the 12 femoral components with Palacos migrated. The acetabular components migrated 0.2–0.6 mm cranially and the femoral component 0.3 mm distally. Not one of the 11 acetabular and 12 femoral components with Coolfix migrated.

Discussion

The reduced frequency of initial migration after using Coolfix compared with Palacos ($P = 0.01$, Fisher's exact test) may be explained by the reduced risk of heat injury. Pressurization of the cement onto bone prior to insertion of the components is apparently not important for prosthetic fixation; abstaining from pressurization did not bring about inferior results when compared with the earlier investigation (164).

Biomechanical experiments (101, 106, 116) indicate that the initial strength of the bone-cement interface is sufficient for prosthetic fixation. The biocompatibility of cement may be inferior to pure titanium (46, 47, 74, 76, 97), but histologic (1, 90) and ultrastructural (74, 76) investigations have, nevertheless, demonstrated that lasting, close contact between viable bone and cement is possible.

Cement fracture, as a result of fatigue, is thought by some to initiate loosening (88, 124, 135, 156, 157); and increased mechanical strength of the cement has been aimed at (156–160). Fatigue cannot, however, account for the pattern of migration observed at RSA or the epidemiology of clinical and/or radiographic failure (the rate decreasing with time postoperatively for the femoral component while increasing with time for the acetabular component) (1, 4, 5). Further, theoretical analysis indicates that the cement is probably not a weak link if the prosthetic component is well fixed and that fractures only occur with lack of external support (137), e.g., after resorption of a layer of necrotic bone adjacent to the cement. Thus, for several reasons, avoiding heat injury when

using the modern technique for cemented hip arthroplasty should allow permanent prosthetic fixation.

The avoidance of heat injury, however, does not compensate for inadequate preparation and cementing technique: Residual cartilage (101, 111) and tissue debris (113, 122) may prevent sufficient mechanical interlock between the cement and the bone. Weak cancellous bone, especially at the proximal end of the femur, may provide insufficient mechanical support to the cement (1, 8, 9, 40, 49), and inadequately supported cement cannot support an implant (107, 134, 152).

General discussion

Definition

Many studies on loosening have contended with the issue of how to best define loosening so that it provides a predictive value concerning future clinical failure. Loosening defined as significant migration as revealed by RSA (i.e., more than 0.2 mm along the y-axis) may appear to be too broad to some readers; most prosthetic components with a slight initial migration postoperatively will not result in clinical failure, at least not for many years (37). However, prosthetic components with no initial migration should have an even better prognosis. Several authors (1, 74, 76, 90) have demonstrated that lasting close contact between viable bone and cement is possible. The point is that by using RSA probably those prosthetic components that will not result in late clinical failure can be identified 4 months postoperatively. If the definition of loosening is broad, the definition of nonloosening becomes correspondingly restricted. Thus, by turning the issue of definition of loosening to one of nonloosening, the stricter definition allows for rapid evaluation of prosthetic fixation.

Etiology

Inadequate preparation and cementing technique was probably the most important cause of mechanical loosening of the femoral component during the 1960s and early 1970s; greatly reduced rates of femoral component loosening after improved technique have been demonstrated (1, 8, 48). Removal of cartilage in the acetabulum and to some extent the addition of anchoring holes improve mechanical strength in vitro at the bone-cement interface (101, 111), but the clinical importance of this has not been confirmed, probably because of diagnostic difficulties. However, even if adequate preparation and cementing technique is used, loosening may still occur.

The development of the radiolucent zone around cement fillings, a simple model of cemented hip arthroplasty, could be explained by heat injury (see pp. 12–14). This accords with the experimental observations of Feith (85) and Linder (87): Heat injury at polymerization exceeds by far the local vascular injury at reaming (85), and the local injury to bone of the leaking monomer is insignificant (87).

This hypothesis of heat injury applied to cemented hip prostheses is also adequate to explain the pattern of migration observed at RSA: The initial migration may be

explained by resorption of necrotic bone induced by heat injury during the polymerization. The proportionally higher frequency of migration of the polyethylene acetabular component when compared with the metallic femoral component may, as demonstrated by Huiskes (136), be clarified on the basis that the metal acts as a heat sink.

Further, the initial migration and its distribution between the components cannot be accounted for by the many other suggested explanations: Monomer injury cannot explain the higher proportion of acetabular component migration; the bone in the femur should be as susceptible to chemical trauma as the bone in the acetabulum. Products of wear from polyethylene are not expected to have their major influence during the initial 4 postoperative months. Stimulation of macrophages by the cement signifies a general reaction against the cement and cannot account for the proportionally more common migration of the acetabular component. Shrinkage and fatigue of the cement after curing, and stress-shielding of the bone cannot be the reason for the most rapid migration occurring between 1 week and 4 months postoperatively. Micromovements as a result of different degrees of strain between the materials (bone, cement, polyethylene/metal) cannot account for the higher proportion of acetabular component migration, as the major discrepancies in Young's modulus of elasticity are on the femoral side. Inferior penetration of the cement into bone surface irregularities cannot explain the migration of the prosthetic components; contrary to in vitro experiments, pressurization of low-viscosity cement did not improve prosthetic fixation. Finally, local vascular injury associated with reaming cannot explain the reduced frequency of migration after using cement with lower specific heat production.

Heat injury may, however, explain both the results presented in this report and to a great extent the epidemiology of clinical failure (see pp. 14, 16–18). Other explanations are apparently not necessary; the increased rate of clinical and/or radiographic failure with time after arthroplasty may be the result of late detection rather than of genuine late loosening.

Summary and conclusions

The cemented hip arthroplasty is one of the most successful orthopedic operations. However, the results do deteriorate with time because of mechanical loosening. Some hips with obviously loose prosthetic components are not painful. This discrepancy between symptoms and radiographic evidence of loosening has caused uncertainty about the diagnostic criteria that should be applied. This uncertainty has in turn led to confusion about the basic cause of loosening.

The aims of this presentation were to find a favorable definition of loosening and to investigate the etiology of mechanical loosening of the cemented hip prosthesis.

The diagnostic criteria of contrast and radionuclide arthrography, bone scintigraphy, and roentgen stereophotogrammetric analysis (RSA) were evaluated in 14 symptomatic hip arthroplasties examined by these methods. Loosening was found to be best defined as migration; regardless of diagnostic criterion, all loose prosthetic components were migrating, but no nonmigrating component was loose.

The development of the radiolucent zone was analyzed in a simple model consisting of 6 cases of giant-cell tumor of bone successfully treated by curettage and cementing. In locations where the cement filling adjacent to cancellous bone was concave, a considerably wider zone developed. There was a positive correlation between the width of the zone and the volume of cement. The radiolucent zone in this model could be explained by heat injury during the polymerization of bone cement.

The pattern of migration of the components in 20 cemented hip prostheses was studied with RSA and with conventional radiography over a period of 2 years postoperatively. Eleven acetabular and three femoral components migrated. After an initial 4-month period of rapid migration, most components migrated slowly. The initial rapid migration could be accounted for by the resorption of a layer of necrotic bone following heat injury during the polymerization. The less frequent migration of the metallic femoral component as compared with the polyethylene acetabular component could be explained by the metal acting as a heat sink. Radiographic examination was found to be unsatisfactory as a means of detecting mechanical loosening during the first 2 postoperative years. RSA, on the other hand, was capable of revealing migration as early as 4 months postoperatively.

Migration of the components in 16 hip prostheses was studied with RSA for 1 year postoperatively following randomized use of low- and high-viscosity cement. As regards prosthetic migration, no difference was detected between the two types of cement; low-viscosity cement did not improve prosthetic fixation.

The initial 4-month migration of the components in 24 hip prostheses was studied with RSA following randomized use of a conventional cement and a new cement with reduced specific heat production. The new cement resulted in a reduced frequency of migration (not one of these components migrated), indicating that mechanical loosening of the cemented hip prosthesis is initiated by heat injury during the polymerization of the cement.

In conclusion:

1. Mechanical loosening of hip prostheses is best defined as migration, and RSA can reveal migration within 4 months of surgery.
2. Conventional radiography at an early stage, contrast and radionuclide arthrography, and provocation investigation with RSA have low sensitivity in detecting loosening.
3. Bone scintigraphy provides high sensitivity and specificity in the detection of loose femoral components in contrast to acetabular components.
4. Low-viscosity cement does not improve prosthetic fixation.
5. Provided that the preparation and cementing technique is adequate, loosening of the cemented hip prosthesis is initiated by heat injury of bone during the polymerization of the cement.
6. Decreasing the risk of heat injury, e.g., by using cement with reduced heat production, increases the chances of permanent prosthetic fixation.

Appendix: Roentgen stereophotogrammetric analysis (RSA)

Two x-ray tubes with an angle of 40° between the central rays were used to obtain simultaneous exposures. A reference plate with tantalum balls was placed in front of the film plane. Prior to examinations, a glass-plexiglass cage, with tantalum balls in known positions, was used as a calibration device. The examinations were performed without changing the positions of the x-ray tubes or the reference plate.

By measuring the films (Figure 14) using a photogrammetric instrument (Wild Autograph A8) equipped with television magnification and by data processing on a Sperry 1100 computer, the displacements of the acetabular component in relation to the pelvic tantalum balls and the head of the femoral component in relation to the trochanteric tantalum balls were determined. The term *instability* is used for prosthetic component displacement in relation to bone at provocation. The term *migration* is used for displacement with time. A detailed description of the roentgen stereophotogrammetric technique and of the method of making the calculations is given by Selvik (167), Baldursson et al. (29), and Selvik et al. (168).

The technical accuracy of the method was assessed by double examinations in a series (163), where tantalum balls were implanted in the os ilium, in the trochanter major and minor, and in the acetabular component peroperatively. Thirty pelvic and 23 femoral double examinations were performed. The acetabular and femoral component displacements were calculated for these double examinations and the standard deviations of the displacements (errors) from zero (zero is the expected mean difference within pairs) were estimated. The standard deviations for the acetabular component were 0.10, 0.06, and 0.23 mm for the transverse (x), longitudinal (y), and sagittal (z) axis, respectively. The corresponding values for the femoral component were 0.13, 0.06, and 0.25 mm. Using Student's *t* distribution the minimum significant ($P < 0.01$) translations were found to be 0.28, 0.15, and 0.62 mm for the acetabular component and 0.36, 0.17, and 0.70 mm for the femoral component. Measured displacements were not considered significant unless they exceeded 0.4, 0.2, and 0.8 mm for either prosthetic component along these axes. In the earlier investigations of symptomatic hips (33, 34, 161), these confidence intervals were about twice as large due to inferior conditions: There were no tantalum balls in the acetabular component or in the trochanter minor; the position of the acetabular component was assessed using the center of the indicator wire, and the position of the femur was assessed using tantalum balls in the trochanter major only.

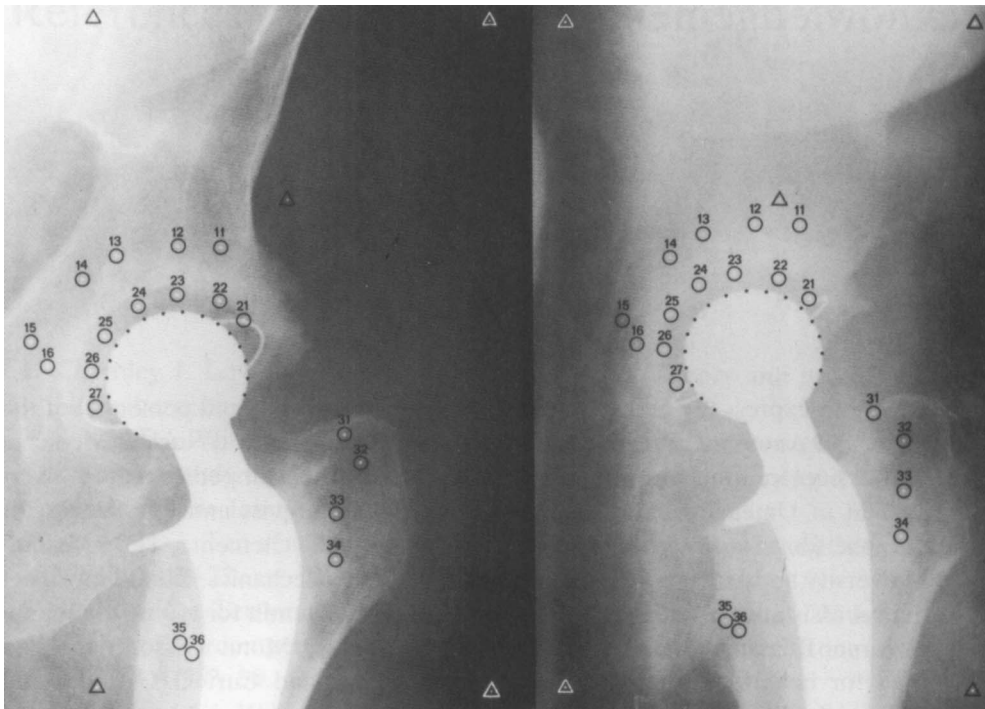


Figure 14. Stereoradiograph of a hip with tantalum balls (○) positioned in the pelvis, in the trochanter major and minor, and in the acetabular component. Reference balls (△) for exact localization of the films. (Reproduced with permission from *Acta Orthop Scand*.)

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