Cemented versus uncemented socket in hip arthroplasty

A radiostereometric study of 60 randomized hips followed for 2 years

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60 patients with arthrosis who received a Charnley total hip replacement were randomly assigned to either an uncemented porous Harris-Galante type I socket or a cemented all-polyethylene Charnley socket. Socket migration and rotation were studied by radiostereometry (RSA) for 2 years. After 2 years, all sockets were still in situ. There was no difference in migration or rotation between the 2 socket designs, nor was there any difference in pain or function.

We conclude that the initial fixation of the Harris-Galante socket resembles that of the Charnley socket.

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Good clinical and radiographical short- and medium-term results of the uncemented, porous-coated Harris-Galante socket have been published (Lachiewicz et al. 1992, Schmalzried and Harris 1992). This socket design was developed to obtain optimum stability, enabling bony ingrowth (Harris et al. 1983). However, with the exception of a study published by ourselves (Önsten et al. 1994), no controlled or randomized study has been presented where the clinical and radiographic performances of this socket have been compared to those of cemented sockets. In the light of the potential long-term problems of increased wear and osteolysis associated with metal-backed, modular acetabular components (Owen et al. 1994, Bono et al. 1994, Hernandez et al. 1994), we think it is vital to assess whether the asserted benefit of uncemented sockets with respect to early stability is valid or not. In such a comparison, the cemented, all-polyethylene Charnley socket, with its well-documented long-time performance (Garcia-Cimbrelo and Munuera 1992, Neumann et al. 1994), can be regarded as a "gold standard".

We compared in a series of 60 randomized hip replacements the micromotions during 2 years postoperatively of the uncemented Harris-Galante type I socket and the cemented Charnley socket, by the use of radiostereometry (roentgen stereophotogrammetric analysis).

Patients and methods

This study includes 60 patients aged 40–70 years who between December 1988 and May 1991 underwent unilateral total hip replacement for primary arthrosis (Table 1). By the use of a computer program, and with the patients' informed consent, a random assignation to either a cemented, all polyethylene Charnley socket (n 30) or an uncemented, porous Harris-Galante type I socket (n 30) was made on the day before surgery. The study was approved by the Ethics Committee of Lund University.

The patients were operated on in the supine position, using a transtrochanteric incision and epidural anesthesia. A Charnley femoral component (head 22 mm) was cemented in all cases after reaming, brushing and high-pressure lavage of the femoral canal. The femoral canal was plugged distally and the

Table 1. Demographic data. Number of patients or mean *SD*, respectively

	Charnley	Harris-Galante
Men	16	17
Women	14	13
Side		
Right	13	16
Left	17	14
Age	63 *6*	62 *6*
Weight	78 *17*	78 *16*

Table 2. Number of markers, configuration number and mean error of rigid body fitting at the latest examination for the two groups. Mean, median (range)

	HG			P-value	CH		
Number of markers in the pelvis	6.3	6	(3–9)	n.s	6.7	7	(3–9)
Configuration number of markers in the pelvis	37.2	31.5	(17–107)	n.s	41.0	29.5	(18–184)
ME of markers in the pelvis	0.21	0.23	(0.08–0.29)	n.s	0.22	0.22	(0.11–0.30)
Number of markers in the socket	5.9	6	(2–9)	0.005	7.3	8	(4–9)
Configuration number of markers in the socket	49.6	48	(35–78)	n.s	50.1	41	(28–162)
ME of markers in the socket	0.17	0.18	(0.03–0.30)	0.04	0.14	0.13	(0.03–0.30)

cement was injected in a retrograde manner using a cement gun. Vacuum-mixed, high-viscosity cement (Palacos®, Essex) was used for all implants placed with cement.

The Charnley sockets (CH) were of the flanged ogee type (Shelley and Wroblewski 1988), and were implanted after reaming the acetabulum to bleeding bone centrally, preserving the subchondral bone superiorly. High-pressure lavage was used and about five 6-mm anchorage holes were drilled.

The Harris-Galante type I socket (HG) has a polyethylene insert and a titanium alloy shell (Tivanium®, Zimmer), coated with a pure titanium mesh with a fiber diameter of 0.25 mm and a pore size of 0.4 mm. The HG sockets were inserted after reaming the acetabulum to the same size as the selected prosthesis, and to the extent that bleeding bone appeared centrally and that the reamer was stable and fully contained. Stability was determined with the aid of a shell positioner. 2–4 cancellous titanium screws, with a diameter of 5.1 mm and directed proximally-medially or proximally-posteriorly, were used for additional fixation. A firm grip at the last turn of the screw driver was required for at least 2 screws. Apparently unstable screws were removed. In 17 cases, 2 screws were used and in 11 and 2 cases, 3 and 4 screws, respectively.

All patients were mobilized on the second postoperative day with partial weight bearing, and they used 2 crutches for 6 weeks. Thereafter full weight bearing was allowed.

At operation 5–10 tantalum markers 0.8 mm were inserted into both the pelvis and the sockets. The marker wire was removed in the CH sockets, and the tantalum markers were embedded about 1.5 mm in the polyethylene at the medial and lateral edges as well as on the convex, outer side, using a 0.9 mm drill-bit. Prior to assembly, the polyethylene liners of the HG sockets were marked in the same way.

Postoperative radiostereometric examination was performed within 1 week, with the patient in the supine position and using the uniplanar technique (Selvik 1974, 1989). By using high-resolution radiographic technique, most tantalum markers on the convex side of the polyethylene liners in the HG sockets could be visualized. The quality of the examination is dependent on the number, spacing and stability of the markers (Kärrholm 1989). The degree of marker instability is expressed in mm as the mean error of rigid body fitting (Selvik 1974, 1989)—in this study, only values below 0.3 were accepted. The spacing of the markers is expressed as a condition number, showing how far from a straight line the markers are distributed (Nyström 1990, Söderkvist 1990). A high condition number indicates a poor scattering of the markers. These variables were compared in the 2 patient groups by a Mann-Whitney test (Table 2).

Movements of the sockets were calculated as displacements relative to the pelvis along and around the 3 axes in the laboratory coordinate system. The accuracy of the radiostereometry in this study was evaluated in 50 patients—25 with CH and 25 with HG sockets (Table 3). One double examination from each patient was used to calculate 99 percent confidence intervals for the smallest significant movements (Mjöberg 1986).

Repeated examinations were performed at 3 months (50 cases), 12 months (58 cases) and 24 months (57 cases). 2 CH cases had to be omitted from the study (Cases 3 and 8) due to insufficient number of tantalum markers and failure to obtain proper radiographs, respectively. 1 CH patient (Case 12) could not return for the 24-month examination

Table 3. 99 percent confidence intervals for the smallest significant movements

	Migration, mm	Rotation, degrees
Transverse axis	0.2	0.7
Longitudinal axis	0.2	0.7
Sagittal axis	0.3	0.3

Table 4. Number of sockets examined and radiostereometric results at the 3 time points. Results are given in absolute values, i.e., independent of direction, of migration and rotation in mm and degrees, respectively. Mean, median (range)

	3 months		12 months		24 months	
Axis	CH	HG	CH	HG	CH	HG
Migration	n 24	n 26	n 28	n 30	n 27	n 30
Transverse	0.18 0.09 (0.01–1.00)	0.19 0.16 (0.01–1.22)	0.14 0.06 (0–0.66)	0.21 0.12 (0–1.22)	0.23 0.12 (0–1.42)	0.24 0.18 (0–1.09)
Longitudinal	0.15 0.09 (0–0.78)	0.14 0.08 (0.01–0.50)	0.28 0.12 (0.01–2.20)	0.15 0.11 (0–0.58)	0.32 0.13 (0–2.76)	0.18 0.14 (0–0.64)
Sagittal	0.15 0.10 (0–0.61)	0.18 0.12 (0.01–0.81)	0.12 0.06 (0–0.76)	0.22 0.16 (0.03–0.65)	0.19 0.10 (0.01–1.23)	0.23 0.20 (0.02–0.64)
Rotation	n 24	n 26	n 28	n 29	n 27	n 29
Transverse	0.43 0.24 (0.02–4.65)	0.36 0.33 (0.02–0.86)	0.46 0.31 (0.02–3.73)	0.43 0.35 (0.01–1.48)	0.44 0.22 (0.01–3.65)	0.78 0.43 (0.02–9.97)
Longitudinal	0.40 0.26 (0.02–2.72)	0.39 0.39 (0–1.06)	0.53 0.31 (0.03–2.71)	0.55 0.45 (0.02–1.85)	0.60 0.31 (0.01–2.88)	1.01 0.47 (0.01–15.56)
Sagittal	0.42 0.24 (0–3.02)	0.48 0.44 (0.02–1.69)	0.52 0.31 (0–2.48)	0.60 0.50 (0.03–1.88)	0.54 0.23 (0.02–3.22)	0.61 0.46 (0.03–1.85)

due to a distant transfer in residence. Rotation could not be evaluated in 1 HG case (Case 2) due to instability of all but 2 markers. But since these markers were situated at the medial and lateral edges, the means of their migrations represent the migration of this particular socket. Thus, at 2 years, migration could be evaluated in 27 CH and 30 HG and rotation in 27 CH and 29 HG (Table 4).

The positions of the sockets in terms of inclination (abduction angle) and version were evaluated from standard postoperative radiographs, including one anteroposterior view of the pelvis centered on the symphysis and one anteroposterior view of the hip centered on the joint. The degree of inclination was assessed using the teardrop line as a reference. The version, i.e., the angle of opening of the socket in the frontal plane, was calculated from the two diameters of its elipsoid projection on the films. Anteversion and retroversion were determined by comparing the anteroposterior pelvic and hip views (Pettersson et al. 1982).

Pain and function were assessed by the Harris (1969) hip score.

The Mann-Whitney test was used to compare the radiostereometric results, the Harris hip scores and the positions of the sockets. The chi-square test was used to compare the number of unstable sockets with reference to the limits for significant migration. Further, simple correlation and regression analyses were performed. When taking movements along and around each of the 3 axes into consideration simultaneously, the Mahalanobis distances (BMDP®) were calculated. This is an euclidic, multivariate analysis for detecting outliers, and was used to count the distance in each case to the origin of coordinates, taking the standard deviations for each variable into consideration. The data generated by the 6 degrees of freedom in the kinematic analysis were thus reduced to 2: migration and rotation.

Results

No hip in either series has so far been revised. The mean Harris pain score at 2 years was for both groups 42 of a possible 44. The mean Harris hip score at 2 years was 93 for the HG and 91 for the CH group.

When comparing the absolute values of migration and rotation in the 3 cardinal axes, there were no differences between the 2 groups at 3 months or at 2 years (Table 4). However, at 12 months the HG sockets had migrated more along the transverse axis (P 0.03) and the sagittal axis (P 0.0002).

No difference was found between the 2 groups when comparing the Mahalanobis distances at 2 years. At 1 year, the HG group had migrated more (P 0.01), but there was no difference in rotation.

At 2 years, 2 CH (Cases 1 and 52) and 3 HG (Cases 22, 48, and 60) were significant outliers ($P < 0.05$) with respect to the Mahalanobis distances for migration. For rotation, 2 CH (Cases 1 and 27) and 1 HG (Case 60) were significant outliers.

When comparing the number of sockets in the 2 groups that displayed significant movements in any of the 6 parameters (Table 3), 15/27 CH and 28/30 HG had significant movements at 2 years (P 0.001). Correspondingly, at 1 year 18/28 CH and 27/30 HG had significant movements (*P* 0.008). There was no difference between the 2 groups at 3 months with respect to the number of migrating sockets.

The HG socket in Case 60 had rotated more than any other socket. This rotation took place between 1 and 2 years and amounted to 18 degrees. The instant (helical) axis of rotation ran through the center of the opening of the socket in an orthogonal mode and further through the apex of the socket, indicating that the polyethylene liner in this case had rotated within the metallic shell. In the further analyses this case was excluded.

There was no correlation between pain and functional scores at 2 years and the outcome in the radiostereometry. Nor was there any correlation between weight, age or sex and the radiostereometric results.

The mean inclinations of the HG and CH sockets were 41 and 40 degrees, respectively. 2 CH sockets were placed in retroversion (7 degrees both cases), while the remainder were placed in a mean of 9 degrees of anteversion, as compared to the mean of 12 degrees of anteversion in the HG group (*P* 0.02). There was no correlation between the outcome in the radiostereometry and the positions of the sockets in either group.

HG sockets with 2 screws did not differ from those with 3 screws with respect to the radiostereometric results.

Discussion

The validity of early implant micromotion, as measured by radiostereometry with respect to the long-time retention in both knee and hip replacements, has now been established. Thus, Ryd et al. (1994) in a long-term study of tibial components in knee replacement, found all implants that were later to be revised to have a distinct, abnormal postoperative migratory pattern. Kärrholm et al. (1994) reached the same conclusion regarding the femoral component in hip replacement. Mjöberg et al. (1985) found prosthetic migration to correlate with clinical signs of loosening. Thus, with respect to skeletal fixation, radiostereometry can identify adverse prosthetic designs and techniques at an early stage.

In this study, the tantalum markers were inserted during the operation into non-articulating parts of the sockets, and the insertion took place well outside the patient. Thus, no polyethylene debris was liberated into the wound, and we do not believe that the markers per se will have any future adverse effects on the implants.

Regarding the quality variables of the radiostereometry in the 2 groups, only minor differences were found, reflecting that the error of the method was about the same in both prosthetic groups. Since the error of the method is not uniformly distributed in the 3 cardinal axes, we used the Mahalanobis distances, rather than the Pythagorean theorem, to identify the sockets that had migrated or rotated most, i.e., the outlying sockets. This multivariate test has the advantage of taking into consideration both the variations and the dependency between the variables.

We found no difference between the socket designs at 3 months or 2 years when comparing the absolute values of migration and rotation. The same was found regarding the Mahalanobis distances. At 1 year, however, the HG sockets had larger motions. It is possible that this finding reflects bone ingrowth and thereby stabilization of the HG sockets between 1 and 2 years.

With respect to the limits for significant motions, there were more unstable sockets in the HG group at 2 years. However, some caution is warranted in the interpretation of the rate of unstable implants, since the limits for significant motions vary with the technical accuracy of the radiostereometry. Thus, given an optimal number and scattering of the markers, almost all implants could theoretically be found to be unstable. Hence, we believe that the validity of the method lies in comparing micromotions between groups.

The motions in the HG sockets could theoretically be explained by small displacements of the polyethylene liners within the metallic shells. In 1 of the cases this was apparent—the liner had rotated 18 degrees. It might be argued, however, that such displacements of the polyethylene liners could be even more deleterious, with respect to debris production and possible osteolysis, than displacements of the metallic shell (Cooper et al. 1992).

In conclusion, we did not find that the HG socket had a better fixation than the CH socket in this prospective and randomized series of 60 total hip replacements. With its potential for wear and corrosion, the use of the HG socket should still be considered experimental surgery.

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