Low- vs high-viscosity cement in hip arthroplasty

No radiographic difference in 226 arthrosis cases followed for 5 years

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In 1984 and 1985, 352 hips were randomly assigned to total hip arthroplasty with either low- or high-viscosity cement at 5 Swedish orthopedic departments. Of the 267 hips finally included in the study, 226 were examined clinically and radiographically after 54–77 months.

Radiographically, 21 definite stem loosenings and 1 probable stem loosening were observed (10 percent) and 4 additional stems had been exchanged before the 5-year examination. In the survivorship analysis, 261 stem prostheses were included and using this method, 7 percent were radiographically loose after 5 years. There were 4 definitely loose and 8 probably loose acetabular cups. No difference was found between cement of high and low viscosity with regard to prosthetic fixation.

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There is now overwhelming evidence that the technical quality of the surgery, notably cementation, is important for the long-term stability of the stem prosthesis (Beckenbaugh and Ilstrup 1978, Carlsson and Gentz 1980, Harris and McGann 1986, Paterson et al. 1986, Russotti et al. 1988). How often and why the cemented acetabular prostheses loosen is less clear, but friction, bone stock quality and wear seem to play major roles (Gold and Walker 1974, Charnley 1979, Ma et al. 1983, Carlsson et al. 1986, Havelin et al. 1986, Murray and Rushton 1990, Ohlin 1990, Ohlin et al. 1990). The properties of the bone cement itself, notably the chemical composition, the temperature developed during curing (Mjöberg 1986) and the viscosity (Miller et al. 1979), the two latter being influenced by storage and handling, are probably also of importance for prosthetic fixation.

We investigated the clinical performance and radiographic stability in a prospective, multicenter, randomized study, comparing total hip replacement performed with a new low-viscosity bone cement and an already established bone cement of high viscosity.

Patients and methods

352 consecutive hips scheduled for primary total hip replacement were randomly assigned on the day of surgery to be operated on with either the low- or high-viscosity bone cement. Separate randomizations were performed for each of the 5 centers taking part in the study. The cements were both available with and without gentamicin. Those centers which routinely used gentamicin cement for infection prophylaxis continued to do so, while those which only used systemic prophylaxis used bone cement without gentamicin. Follow-up examinations were performed after 3–6, 12, 24, and 60 months. The study was approved by the Ethics Committee and the Medical Product Agency.

17 of the randomized hips were classified as drop-outs peroperatively (Table 1). 8 patients with the same number of hips died before the 5-year follow-up and were then classified as postoperative drop-outs, whereas 46 hips were classified as missing because the patients did not attend the final examination. On request and, according to the policy of Acta Orthopaedica Scandinavica, we excluded another 37 hips with diagnoses other than osteoarthrosis after the study had been concluded. 18 of the 37 hips had been performed for rheumatoid arthritis, 9 for complications after femoral neck fracture, and 10 for various other reasons. Thus, 226 hips (86 percent) of 264 possible hips were examined 5 years postoperatively. 35 of the missing hips, and thus a total of 261 hips, were included in a radiographic survivorship analysis.

Age, sex and weight did not differ between groups in the patients whose hips had been followed for 5 years (Table 2).

Table 1. Peroperative drop-outs from the study

	No of hips
Wrong bone cement	4
Uncemented prosthesis	1
Technical problems	3
The patient died before any postop examination	2
Randomized but never operated on (3), previously operated on with total hip replacement (2)	5
Did not attend any postoperative examination	2
Total	17

Table 2. Age, weight and sex (n 226)

	Low-viscosity		High-viscosity	
	Men	Women	Men	Women
n	44	68	53	61
Age				
Mean, *SD*	68 *7*	69 *10*	66 *10*	69 *10*
Range	52–85	37–85	43–86	37–83
Weight				
Mean, *SD*	82 *11*	71 *13*	82 *12*	69 *11*
Range	62–116	47–119	56–106	45–93

Bone cements

2 high-viscosity bone cements, Palacos R and Refobacin Palacos, were compared with 2 bone cements of lower viscosity, EMD 42521 and EMD 42522, all produced by E. Merck, Darmstadt, Germany. In the 2 cement types with lower viscosity- the more quickly-polymerizing of the 2 polymer components had been omitted. Refobacin Palacos and EMD 42522 contained 0.5 g and 1.0 g gentamicin base, respectively, per 40 g polymer powder. The various types of bone cement were always mixed in vacuum for the acetabulum in a bowl and for the femur in a syringe. In Lund and Kristianstad chilled high-viscosity bone cement (+4 °C) was used whereas the other 3 centers used high-viscosity bone cement stored at room temperature.

The mechanical characteristics—including fatigue properties of the 4 cement types in the present study—have been investigated. In all tests the low-viscosity cements had equal or superior values (FHI Institut für Werkstoffkunde, Freiburg, Germany 1986).

Surgery

The surgical approach and type of prosthesis used before the start of this study differed in the participating centers and were not changed because of this study (Table 3). However, agreement was reached on insertion of a bone or a plastic plug in the femoral canal and, thereafter, cleaning the canal thoroughly by using a pulsating lavage. The vacuum mixed cement was applied through a cement gun (Mitab, Sjöbo, Sweden) in a retrograde fashion and the top of the femur sealed off with a silicone plug, while the surgeon exerted the final pressure with the gun. Each center was provided with the same equipment for application of the cement. The stem prosthesis was inserted within 3–4 minutes after cement mixing had started. On the acetabular side, the bone was thoroughly cleaned after reaming, the vacuum-mixed cement inserted as soon as possible after mixing and pressurized for 3–4 minutes, using a special device (Exeter, Shiley Howmedica).

Table 3. Number and type of prostheses

	Low-viscosity	High-viscosity	Total
Charnley	33	31	64
Lubinus	14	23	37
HD2	11	7	18
Exeter	35	36	71
Scan hip	19	17	36
Total	112	114	226

Clinical evaluation

The patients and hips were scored according to Merle d'Aubigné and Postel (1954), as modified by Charnley (1979), which also included grouping of patients into categories A, B and C.

Radiographic evaluation

Serial radiographs of each hip, from those taken immediately postoperatively to those obtained after 5 years, were thoroughly analyzed according to a separate protocol, by one of the investigators, who did not know whether low-viscosity or high-viscosity cement had been used. The criteria for radiographic stem and socket loosening are presented in Table 4. The separation of criteria into definite, probable or possible stem loosening was essentially according to Harris et al. (1982). The criteria for definite or probable socket loosening were those recommended by Carlsson and Gentz (1984).

Table 4. Radiographic definitions of stem and socket loosenings

Definite stem loosening
Migration with or within the cement, e.g., any new cement-metal separation
and/or cement fracture
and/or localized endosteal bone resorption
and/or bone cement lucencies surrounding the whole prosthesis in the AP and lateral views. Progressing after 1 year and eventually > 2 mm in width.

Probable stem loosening
Bone-cement lucency progressing after 1 year, the width equal to or exceeding 2 mm in more than 2 of the 7 zones.

Possible stem loosening
Bone lucencies but only progressing after 1 year in 1 or 2 of the 7 zones and eventually less than 2 mm.

Definite socket loosening
Grade III, according to Carlsson and Gentz (1984), i.e., migration or other change of position of the socket.

Probable socket loosening
Grade II, according to Carlsson and Gentz (1984), i.e., unchanged position but a radiolucency equal to or exceeding 2 mm in the 2 upper quadrants.

Statistics

Chi-square analysis was used for tests of frequencies. If the assumptions for this test were not fulfilled, Fischer's exact test was used. In order to test the differences between means, Student's *t*-test was applied. Survivorship analyses were performed, according to the method described by Kaplan and Meier (1958), and a log-rank test was utilized in comparing groups.

Results

There were 21 definite stem loosenings and 1 probable stem loosening. No "possible" loosening was observed. Only 4 definite and 8 probable loose sockets were observed. 2 of the definite and 2 of the probable socket loosenings were combined with definite stem loosening (Tables 5 and 6). Definite and probable (1 case) loosenings of the stem prosthesis were thus observed in 22 cases (10 percent) with 9/112 cases operated with low-viscosity cement and 13/114 cases with high-viscosity cement.

Table 5. Radiographic findings and pain score in definite and probable (1 case) stem loosenings (n 272)

Hip No.	Center[c]	Prosthesis	Type of cement	Subsidence mm	Endosteal bone resorptions	Progressive lucencies	Cement fracture	Pain score	Socket loosening
1	I	Exeter	low	6	+	+	–	5	–
6[a]	I	"	low	2	+	+	–	–	–
22[a]	I	"	low	2	+	+	–	–	–
24	I	"	high	1	–	+	–	5	probable
30	I	"	high	1	–	–	–	6	–
32	I	"	low	2	–	–	+	6	–
33	I	"	low	–	+	+	–	6	–
35	I	"	high	–	–	+	–	6	–
43	I	"	high	1	–	–	–	6	–
–	II								
421	III	Lubinus	high	–	–	+	–	4	probable
439	III	"	high	–	–	+	–	6	–
455	III	Exeter	high	10	–	+	+	6	–
458	III	Lubinus	low	1	+	+	–	6	–
461	III	"	low	–	+	+	+	6	–
475	III	"	high	1	–	–	–	6	–
485	III	"	low	6	+	+	+	5	–
608	IV	Scan hip	low	–	–	+	–	3	–
648	IV	"	low	1	–	–	–	3	–
649	IV	"	high	–	+	+	–	6	definite
656	IV	"	high	–	+	–	–	6	–
666[b]	IV	"	high	–	–	+	–	6	–
672	IV	"	high	–	+	+	–	6	–
803	V	Charnley	high	3	+	–	+	6	–
816[a]	V	"	high	–	+	–	–	–	–
825[a]	V	"	low	1	–	–	–	–	–
830	V	"	low	1	–	–	–	6	–
854	V	"	low	–	+	+	–	6	–
893	V	"	high	–	+	–	–	3	definite

[a] not included in the 5-year follow-up due to revision
[b] probable loosening of the stem
[c] I Gävle, II Huddinge, III Kristianstad, IV Lund, V Malmö

Table 6. The definte and probable socket loosenings

Hip No.	Center[a]	Socket loosening	Prosthetic design	Type of cement	Loose stem
24	I	probable	Exeter	high	+
44	I	probable	Exeter	high	–
411	III	probable	Exeter	high	–
416	III	probable	Exeter	low	–
421	III	probable	Lubinus	high	+
468	III	definite	Exeter	low	–
492	III	probable	Exeter	low	–
649	IV	definite	Scan hip	high	+
657	IV	definite	Scan hip	high	–
667	IV	probable	Scan hip	low	–
673	IV	probable	Scan hip	high	–
893	V	definite	Charnley	high	+

[a] I Gävle, II Huddinge, III Kristianstad, IV Lund, V Malmö

Loosening of the stem, including the only probable loosening, were correlated to sex, age, diagnosis, patient category, approach and prosthetic design. No differences were found with respect to sex and diagnosis. However, patients with definitely loose stem were on average 5 years younger at the time of the operation than patients with an intact stem (P 0.03).

Loosenings occurred more often in hips implanted through a posterior approach (P 0.02).

8 of the 12 definitely or probably loose sockets were inserted with the use of high-viscosity bone cement and 4 with low-viscosity cement (P 0.4, Table 6).

Radiographic survivorship analysis

Radiographic survivorship analysis with definite stem loosening as the end-point revealed that 7 percent of the stems were loose after 5 years; the cumulative survivals were in both groups 0.9. No differences were observed in survival for hips fixed with low- or high-viscosity cements. Nor did survival differ for cements with or without gentamicin, irrespective of viscosity.

Survivorship analysis of the sockets was not meaningful since there were few failures.

Function

There was no difference with respect to function between hips operated on with low- or high- viscosity bone cement (Table 7).

Technical quality of the surgery

Perforations with penetration of bone cement into the pelvis occurred equally often or in about 10 percent, irrespective of cement viscosity. Unwanted distribution of bone cement around the socket occurred in 25 percent with low-viscosity cement and in 18 percent with high-viscosity cement (P 0.2).

Special difficulties during surgery were reported in 27/226 cases followed for 5 years or in 32/261 cases of those included. The majority of the difficulties were more or less "normal", e.g., obesitas, dysplasia of the acetabulum or a narrow femoral canal. However, in 9 cases there were difficulties concerning handling and pressurization of the cement in the acetabulum (EMD 42522, 7 cases and Refobacin Palacos, 2 cases). 6 of these cases involved timing and cement viscosity in the femur (EMD 42522, 4 cases, Refobacin Palacos, 1 and Palacos R, 1). For these reasons, 3 components implanted using low-viscosity and 4 using high-viscosity bone cement had to be exchanged at the index operation.

Discussion

The improved technique for cementation of the femoral component introduced at the end of the 1970s, i.e., thorough preparation of the femoral canal, introduction of a plug, and retrograde filling of the canal with bone cement has resulted in a reduction in radiographic loosening (Harris and McGann 1986, Paterson

Table 7. Function score according to Merle d'Aubigné and Postel (1954), as modified by Charnley (1979) (n 226)

Patient category	Viscosity	n	Pain			Walking ability			Range of motion		
			Preop	2 yr	5 yr	Preop	2 yr	5 yr	Preop	2 yr	5 yr
A	high	47	2.4	5.7	5.7	2.7	5.3	5.1	3.5	4.7	5.1
	low	29	2.5	5.4	5.6	2.7	5.0	4.9	3.5	4.8	5.0
B	high	50	2.7	5.5	5.9	2.5	5.0	5.1	3.2	4.5	4.9
	low	52	2.5	5.8	5.6	2.3	4.9	4.7	3.1	4.5	4.9
C	high	15	2.7	5.8	5.8	2.2	4.5	4.5	3.7	4.9	4.9
	low	28	1.9	4.7	5.9	2.0	3.6	3.9	3.3	3.6	4.7

et al. 1986, Russotti et al. 1988). To what extent the enhanced fatigue characteristics resulting from centrifugation or mixing in vacuum contributes to prosthetic stability has not yet been established.

Our study was initiated by reports by Miller et al. (1979) and Noble and Swarts (1983) demonstrating an increased area of contact between bone and low-viscosity cement which led to expectations of a better long-term fixation of joint prostheses. However, in our study, the use of low- or high-viscosity cement implied an almost identical risk of stem loosening after 5 years.

Our rate of definite stem loosening (10 percent after 5 years) was 4–5 times higher than the rates reported by Harris and McGann (1986), Paterson et al. (1986), Russotti et al. (1988) and Mulroy and Harris (1990), but only one fourth of the rate of radiographic stem loosening in Charnley prostheses inserted in Malmö, Sweden, during 1968–1972 (Carlsson and Gentz 1980). However, Mulroy and Harris (1990) did not include the 7 percent rate of localized osteolysis in their figures, in spite of the fact that such lesions can enlarge very rapidly and necessitate exchange, whether the stem prosthesis is loose or not (Tallroth et al. 1989). The multicenter nature of our study, involving not less than 52 surgeons, could have had a negative influence. Furthermore, the use of 2 cement viscosities was a drawback compared with the above-mentioned studies.

Handling of bone cements with a very low viscosity, like LVC, has proved to be difficult, and the 5–8 year results of a series of 198 Charnley hips performed with the use of the LVC-cement at a Swedish department were alarming (Granhed et al. 1991). 13 percent of the stems had been revised after 5 years and 20 percent after 8 years. Including radiographic loosenings, the rates were 26 percent and 38 percent, respectively. The inferior fatigue characteristics of the LVC cements, as pointed out by Davies et al. (1989), may also have contributed to these poor results. The loosening rate in our series was much less and there was no difference between cement of low- and of high-viscosity.

Definitions of radiographic stem loosening are crucial, but it has been generally agreed that migration of a component implies that it is loose. Subsidence as an isolated phenomenon occurred in 7/25 definite stem loosenings, and in 8/25 cases it was combined with either progressive bone cement lucencies and/or localized endosteal osteolysis. This last-mentioned phenomenon has been reported on extensively during the last few years both in cemented and cementless designs, both in "stable" and "loose" hips (Carlsson et al. 1983, Huddleston 1988, Anthony et al. 1990, Maloney et al. 1990, Willert et al. 1990, Borssén et al. 1991). Localized endosteal osteolysis was observed in our series in 11/27 of the definite loosenings—in 3 cases as the only radiographic sign of loosening; 2 of these 3 cases have been revised. It is striking that 15 of the 22 non-revised hips with stem loosening were painless; only 4 had marked pain. However, it is well recognized that radiographic findings most often precede pain in cases with a loosening stem.

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