Evaluation of Boneloc®

Chemical and mechanical properties, and a randomized clinical study of 30 total hip arthroplasties

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We evaluated the mechanical, chemical and clinical properties of Boneloc® cement using radiostereometry and a series of laboratory tests. Compared to a standard cement (Palacos®) the new cement displayed reduced tensile strength, elastic modulus, curing and glass transition temperatures. The amount of MMA extracted during 3 weeks in methanol was smaller for the Boneloc®, but the total amount of released monomers was larger. The adhesion to stainless steel and bone did not differ.

Radiostereometric analysis during the first postoperative year in 30 patients randomized to fixation of hip prostheses using either of the 2 cements displayed increased proximal migration of the cup and increased stem subsidence when Boneloc® had been used. Part of the stem subsidence occurred inside the cement mantle. On the basis of these findings, we conclude that the inferior fixation in the Boneloc group is mainly caused by its mechanical properties. Other mechanisms, such as increased release of monomers, may also be important.

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Loosening of cemented joint prostheses has a multifactorial etiology. A number of investigations have focused on the importance of the quality of the bone-cement interface created at the operation (Majkowski et al. 1993, 1994, Jansson 1994, Juliusson et al. 1994, Ritter et al. 1994). Poor penetration of the cement into the trabecular bone caused by insufficient preparation and interposition of blood reduces the strength of the interface and may cause loosening. Heat generation during curing or the release of toxic substances, such as free radicals may damage the bone and cause resorption due to necrosis (Leeson and Lippitt 1993, Stürup et al. 1994). Once cured the cement must have a high resistance to fatigue failure and act as a barrier against joint fluid and wear particles (Howie et al 1988, Gelb et al. 1994).

In 1986, Mjöberg postulated that heat generation was a main reason for the failure of cemented hip prostheses. Later Stürup et al. (1994) questioned the importance of heat alone and concluded that hot toxic chemicals released during curing of the cement were more significant causes of such failure. A new bone cement, Boneloc®, was developed to reduce the leakage of chemicals and the curing temperature. In a canine model, this cement was found to diminish bone necrosis and bone remodeling (Nimb et al. 1993).

The aims of this study were to characterize some of the chemical and mechanical properties of this cement and to evaluate its ability to stabilize a total hip arthroplasty in a clinical series. Conventional polymethyl methacrylate cement was used as the control.

Material, patients, and methods

Laboratory tests

The Boneloc® (B) cement was mixed according to the instructions delivered by the manufacturer and deaereated under reduced pressure. The Palacos (P) cement was handmixed for determination of the curing temperature. In the other experiments, it was mixed under reduced pressure. The composition of the two bone cements is presented in Table 1.

Characterization of the cement

Tensile testing. Waisted test bars (length 120 mm, width at waist 10 mm, at both ends 20 mm, thickness 4 mm) were prepared by introducing the cement into a silicone rubber mold. The dimensions of the bars were checked after removal of the mold. They were tested on a tensile testing machine (JJ Instrument T

Table 1. Composition of the two bone cements

	Palacos®		Boneloc®	
Liquid				
Monomer	methylmethacrylate	97.8%	methylmethacrylate	50%
			decylmethacrylate	30%
			isobornylmethacrylate	20%
Accelerator	N,N-dimethyl-p-toluidine	2.1 %	N,N-dimethyl-p-toluidine	0.5 %
			dihydroxypropyl-p-toluidine	0.9%
Stabilizing agent	hydrokinon	65 ppm	hydrokinin-monomethylether	100 ppm
Color	chlorophyll		–	
Powder				
Polymer	methylmethacrylate-methylacrylate	84.5%	methyl-butyl-methacrylate	90%
Contrast medium	zirconium oxide	15%	zirconium oxide	10%
Initiator	benzoyl peroxide	0.5%	benzoyl peroxide	0.7%
Color	chlorophyll	0.05%	Fd.&Blue No.2 Al.Lake	0.1%
Liquid/powder ratio	31/69		32/68	

30 K), equipped with a 5000 N load cell and at a strain rate of 500 mm/min.

Shear strength metal/cement. Test specimens were prepared by molding cement in polystyrene tubes (Ø 28 mm). Before the cement had cured, 50 × 15 × 1 mm strips of stainless steel were introduced 25 mm into the cement. After 1 week in room temperature, the tube was removed and the shear strength of the metal-cement bonding was tested by pulling the metal strips in a tensile testing machine.

Curing temperature. Bone cements were mixed in ambient temperature and transferred into test tubes of glass (Ø 20 mm, height 25 mm) thermostatted at 37 °C. A thermoelement was immediately placed in the cement and the temperature increase versus time and the maximum temperature were recorded.

Differential Scanning Calorimetry (DSC). The thermal properties of the cured cements were determined with a Mettler TA 3000 System equipped with a low temperature cell. DSC traces were run twice between −150 °C and +300° at a heating rate of 20 °C/min, with cooling between the 2 runs.

Extraction from samples of cement. Samples of cured cement (5 × 5 × 5 mm; approx. 25 g) were extracted in phosphate buffered saline (PBS), pH 7.2, and in methanol, respectively. The samples were weighed and immersed in 50 mL of the liquids for 24 hours and 21 days at 37 °C. After extraction the samples were dried in an oven at 60 °C for 2 weeks and then in a vacuum oven at 60 °C until constant weight was achieved. The extracts were analyzed by HPLC (C18 reversed phase) with water/methanol 50/50 (v/v) as an eluent.

Bone cement interface. Paired specimens of fresh frozen bones from sheep (proximal humerus or femur) were thawed and their most proximal ends were removed using a saw. The center of the medullary cavity was removed and the specimens were rinsed and dried. Vacuum or hand-mixed Palacos® or Boneloc® was injected or finger-packed into the medullary cavity by two of the authors with long experience in hip surgery. After curing, sample disks were mounted on stubs, coated with Au/Pd. The bone/cement interface and the cement morphology were examined with an ISI-100A Scanning Electron Microscope (SEM).

Clinical study

30 patients (30 hips, 8 men, 22 women; mean age 71 (63–76) years, planned for cemented THA were studied. Before the operation the patients were randomly allocated to fixation of the prosthesis, using either Boneloc® (B) (Polymers Rekonstructive A/S) or Palacos® with gentamicin (P) (Schering-Plough). 16 patients received Palacos®and 14 Boneloc® cement. 27 patients (14 P/13B) had primary arthrosis, 2 had femoral head necrosis after cervical neck fracture (P) and 1 arthrosis due to dysplasia (B).

A transgluteal lateral approach was used. After reaming, the bone was prepared using brushes, high-pressure lavage, distal plugging of the femoral canal and tamponades soaked in a solution containing adrenaline. The cement was injected into the femur using a proximal plug applied to the syringe to exert continuous pressure during 1–2 minutes. On the acetabular side a circular plastic pressurizer was utilized. The Palacos® cement was vacuum-mixed (Mitab). The Boneloc® powder and fluid were delivered in a plastic tube. The components were separated by a membrane which was broken before application. An

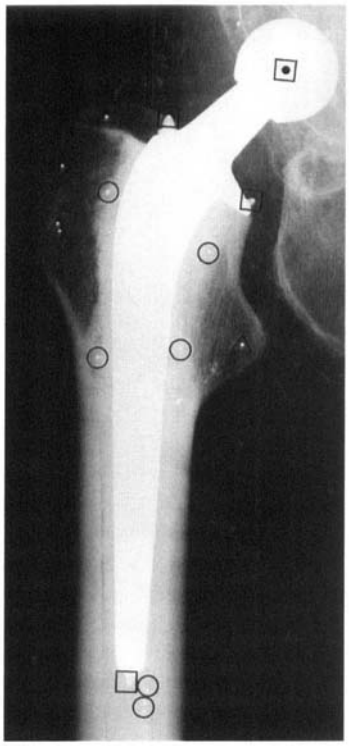

Figure 1. Postoperative radiograph of the Spectron stem (Palacos®). △ bone markers, ○ cement markers, □ prosthetic markers.

all-polyethylene acetabular cup and a chrome-cobalt stem and head were used in all cases (Spectron EF, Smith & Nephew).

Before insertion of the components 0.8 mm tantalum markers were inserted into the bone surrounding the acetabulum and into the proximal femur. Tantalum markers were also inserted into the edges of the cup during surgery. Before the operation, the femoral component had been supplied with 3 titanium plugs, each with one tantalum marker (Figure 1). Spherical tantalum pellets were also inserted into the cement to permit evaluations of micromotions of the femoral component in the cement mantle. These markers had a diameter of 1 mm to facilitate separation between bone and cement markers on the stereoradiographs.

The patients were mobilized 1–2 days after the operation and were encouraged to use crutches for 6-8 weeks.

Radiostereometry

Radiostereographic examinations were done with the patient supine postoperatively, at 6 weeks, 6 and 12 months. A uniplanar technique with the calibration cage positioned under the examination table was employed. The evaluation of the radiographs has been described previously (Kärrholm 1989, Kärrholm et al. 1994b, Önsten 1994). The migration of the cup was measured as rotations about the three cardinal axes and translations of the cup center along the same axes. The migration of the femoral component in relation to the bone markers was evaluated as rotations about the 3 cardinal axes and as subsidence of the center of the prosthesis corresponding to the gravitational center of the segment defined by the 3 stem markers and the center of the femoral head. Migration of the femoral stem in relation to the cement markers was studied only in terms of subsidence. The precision of the measurements was evaluated from double examinations of the stem in 28 of the patients and of the cup in 27 patients. The mean values + 2.8 SD of the differences between 2 subsequent radiostereometric examinations were 0.15 mm (medial–lateral and proximal–distal translations), and 0.26 mm (anterior–posterior translations) as regards the socket and 0.18 mm for stem subsidence (proximal–distal translations). The corresponding values for rotations were 0.81, 0.77, and 0.35, and 0.78, 1.66, and 0.25 degrees for the cup and stem, respectively (rotations about the transverse, longitudinal and sagittal axes).

Conventional radiography

Conventional radiography, including AP, lateral and pelvic views, was done postoperatively and after 1 year. The radiographs were measured on a digitizing tablet (Ortho-Graphics Inc.™, Salt Lake City, UT) connected to a personal computer. On the postoperative radiographs the relative contact between the cement and the cortical bone was measured (Kärrholm et al. 1994b). On postoperative and follow-up radiographs the location of any radiolucent line was classified according to DeLee and Charnley (1976) and Gruen et al. (1979). The extent of these lines in each region was classified into 4 grades: no lucency, < 50%, 50–99% and 100% lucency. In addition, the entire length of the radiolucent lines on the AP view of the femur was related to the femoral stem length or, as regards the socket, to the calculated circumference of the acetabular cement mantle (Kärrholm and Snorrason 1992, Kärrholm et al. 1994b). The increase in radiolucent lines was calculated by subtracting the postoperative from the follow-up values.

Clinical evaluation

The Harris hip score was used. Pain was also graded on a visual analogue scale.

Table 2. Characterization of the cement. Mean, *SD*

	Palacos®			Boneloc®		
	n			n		
Tensile strength at break (MPa)	7	33.4	*2.2* **	5	15.2	*3.0*
Young's modulus (MPa)	7	579	*51* *	5	426	*96*
Shear strength	2	5.8	*0.2*	3	6.0	*2*
Curing temperature °C	2	73	*5*	3	50	*4*
Glass transition temperature °C	1	119		1	74	
Weight loss 21 days in PBS (%)	2	1	*0.3*	2	1	*0.2*
Weight loss 21 days in methanol (%)	2	3.8	*0.1*	2	5.0	*0.1*
MMA in methanol after 24 hours (%)	1	0.01		1	0.01	
MMA in methanol after 21 days (%)	1	0.12		1	0.03	

* $p < 0.05$, ** $p < 0.01$. Mann-Whitney U-test

Table 3. Migration of the cup and stem in relation to the bone during the postoperative year. Mean, *SD*

	Palacos®				Boneloc®			
	Signed value		Absolute value		Signed value		Absolute value	
Cup translations								
medial (+) / lateral (–)	–0.06	*0.136*	0.11	*0.09*	0.07	*0.18*	0.12	*0.14*
proximal (+) / distal (–)	0.14	*0.17*	0.15	*0.16*	0.26	*0.20*	0.24	*0.21*
anterior (+) / posterior (–)	0.10	*0.32*	0.22	*0.25*	–0.02	*0.17*	0.12	*0.11*
Cup rotations								
anterior (+) / posterior (–) tilt	0.18	*0.57*	0.46	*0.36*	0.16	*0.58*	0.44	*0.35*
ante- (+) / retroversion (–)	0.12	*0.39*	0.32	*0.24*	0.02	*0.48*	0.35	*0.28*
more (+) / less (–) inclination	0.26	*0.47*	0.31	*0.44*	–0.10	*0.74*	0.45	*0.55*
Stem translations								
proximal (+) / distal (–)	–0.03	*0.12*	0.10	*0.07*	–0.26	*0.28*	0.27	*0.27*
Stem rotations								
anterior (+) / posterior (–) tilt	0.03	*0.35*	0.23	*0.28*	0.04	*0.19*	0.16	*0.10*
ante- (+) / retroversion (–)	–0.64	*0.69*	0.74	*0.47*	–0.54	*0.68*	0.60	*0.63*
varus (+) / valgus (–) tilt	–0.04	*0.16*	0.11	*0.12*	0.03	*0.16*	0.13	*0.10*

Missing observations

1 patient died of a malignant disease between the 6 and 12 months follow-up (Boneloc® group). In one other patient (Palacos® group) poor marking of the acetabular bone prevented accurate stereoradiographic evaluation of the cup. In 24 hips (14 P, 10 B) the tantalum markers inserted into the cement could be visualized at all the examinations.

Statistics

Evaluation was done only if at least 5 observations were available in one group. Statistical evaluation of the radiostereometric results was done only on signed values (Table 3). To reduce the risk of a spuriously-occurring significance only one test, including all follow-up occasions for each direction of the motions in the radiostereometric evaluation, was used in the comparison between the 2 cements.

Results

Characterization of the cement

Boneloc® displayed reduced tensile strength and elastic modulus (Table 2). The shear strengths of the metal/ cement interface were similar.

The curing and glass transition temperatures of the Boneloc® cement were 23 and 45 °C lower than those recorded for Palacos®.

In aqueous solution, the amounts extracted were similar for the 2 cements. As expected, the amount of MMA extracted during 3 weeks in methanol was smaller for the Boneloc®, but the total amount of monomers extracted from this cement was larger, as reflected by an increased loss of weight.

The SEM micrographs revealed good and similar adhesion between the two types of cement and cancellous bone. Fracture lines, probably caused by the preparation technique, were occasionally observed,

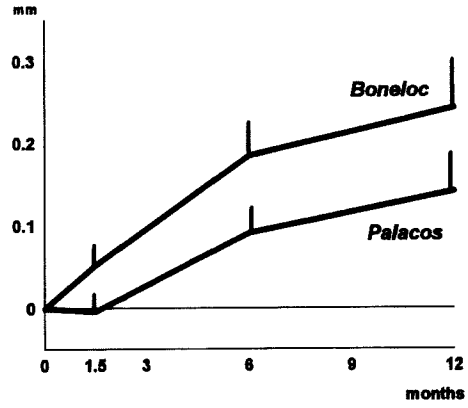

Figure 2. Proximal migration of the cup (mean, SE).

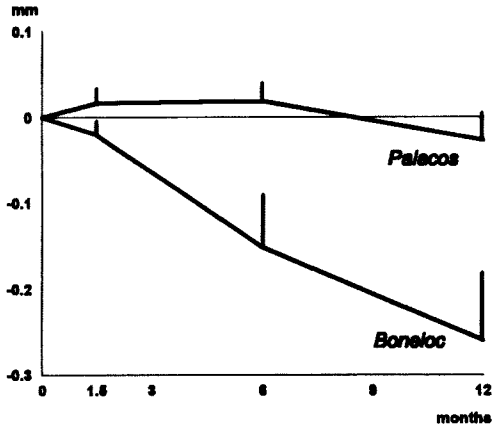

Figure 3. Subsidence of the stem in relation to bone (mean, SE).

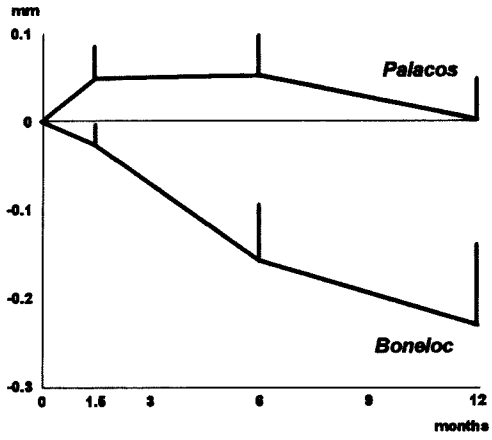

Figure 4. Subsidence of the stem in relation to cement (mean, SE).

but only in the bone. In the cortical region cracks were seen in the bone/cement interface independently of the cement used. As expected, hand-mixed cement of both types was more porous and contained larger voids than the vacuum-mixed samples.

Radiostereometry

Cup. Cups fixated with Palacos® displayed a small lateral migration, whereas the cups fixated with Boneloc® migrated medially (6 weeks, 6 and 12 months: p 0.03, repeated measurements MANOVA). Increased proximal migration was noted in the Boneloc® group (p 0.04, repeated measurements MANOVA, Figure 2). The mean anterior–posterior translations did not differ.

Stem. In the group fixed with standard cement, the mean proximal–distal migration of the stem was close to zero throughout the observation period. 1 year after the operation, 1 of 16 stems fixed with Palacos® had subsided more than 0.18 mm (0.27 mm). In the Boneloc® group an increasing subsidence was recorded and especially after 6 months (6 w vs 6 m: NS [not significant], 6 m vs 12 m: p 0.03, 6 w vs 1 year: p 0.002; Wilcoxon matched-pairs signed-ranks test). 1 year after the operation 6 of 13 stems had subsided 0.22–1.0 mm (P vs B, all observations 6 w–12 m: p 0.005, repeated measurement MANOVA, Figure 3).

The mean stem rotations about the transverse and anterior–posterior axes were close to zero in the two groups. A tendency to rotation into retroversion was observed, regardless of the type of cement used (Table 3).

Increased subsidence of the metallic stem inside the cement mantle was noted in the Boneloc® group (p 0.02, repeated measurement MANOVA). The proximal-distal displacements of the cement mantle in relation to the bone did not differ (p 0.2; mean (*SD*) at 1 year; P: –0.04 (*0.06*) mm; B: –0.1 (*0.12*) mm). In 5 of 6 femoral components that subsided significantly (> 0.18 mm), 36–89 percent of this motion occurred in the cement mantle (Table 4). In one other subsiding stem (B) the cement markers could not be accurately visualized.

Radiography

Cup. On the follow-up AP radiographs of the acetabulum, newly-developed radiolucent lines corresponding to 11 (0–47) / 30 (0–50) percent (P / B) of the acetabular cup circumference were recorded (p 0.04, Mann-Whitney U-test). Increased

Table 4. Seven femoral stems displaying subsidence exceeding –0.18 mm after 1 year. Percent subsidence of the stem inside the cement mantel is shown

Type of cement	Subsidence		
	bone-stem[a]	cement-stem[b]	percent
P	–0.27	–0.16	59
B	–1.00	–0.89	89
B	–0.50	–0.18	36
B	–0.40	–0.18	45
B	–0.37	–0.28	76
B	–0.36	–0.25	69
B	–0.22	–[c]	–[c]

[a]Subsidence of the metallic stem in relation to the bone
[b]Subsidence of the metallic stem in relation to the cement
[c]Missing observation

Table 5. Clinical results. Median and range

	Palacos®		Boneloc®	
Harris hip score				
preoperatively	51	*24–70*	45	*22–61*
1 year	90	*56–97*	93	*65–99*
Harris pain score				
preoperatively	20	*10–30*	20	*10–20*
1 year	40	*20–44*	40	*30–44*
Visual analogue scale (pain, mm)				
preoperatively	67	*50–99*	66	*25–100*
1 year	6	*0–50*	3	*0–37*

frequency and extension of these lines were found laterally (p 0.009) and centrally (p 0.01) on the AP view (Mann-Whitney U-test).

Stem. On the postoperative AP radiographs increased relative cement-cortical bone contact was noted in the femoral prostheses fixated with Boneloc® cement (median, range, P: 41, 9–59 percent; B: 50, 33–63 percent, p 0.03, Mann-Whitney U-test). On the follow-up AP radiographs of the stem, a slight increase of these lines was noted in both groups (P: 8 percent 0–18: B: 3, 0–23 percent).

Clinical results

The preoperative scores and visual analogue ratings improved during the postoperative year (p 0.0004–0.002, Wilcoxon matched-pairs signed-ranks test), and did not differ between the two groups of patients (Table 5).

Discussion

In strain-controlled fatigue tests of the second generation of Boneloc® (new delivery system) and Simplex P® cements, the former proved to be superior. In stress-controlled tests (±5–±25 MPa) it was inferior (Kindt-Larsen et al. 1995). The interpretation of this finding was uncertain, especially in the light of the methodological difficulties encountered in these types of tests (Carter et al. 1982, Rimnac et al. 1986). In our mechanical test, however, Boneloc® was found to be a softer material than Palacos®. Previously, Weightman et al. (1987) investigated another cement formula also containing butyl methacrylate with a low modulus of elasticity. When tested on femoral components inserted into cadaveric bone an increase in creep was recorded. We noted stem migration inside the cement mantle, regardless of the type of cement used. In the Boneloc® group this motion was more pronounced, perhaps because of an effect of increased elasticity and inferior in vivo fatigue properties. The rigid body corresponding to the cement markers, placed peripherally in the cement mantle, did not show greater deformation (= mean error of rigid body fitting) than the rigid body in the femoral bone, suggesting that no fracture or total disintegration of the mantle occurred. This is consistent with a central deformation and a maintained external structure. However, in 2 cases the mantle also slid more than 0.18 mm in relation to the bone.

Mjöberg (1986) studied the efficacy of a cold-curing cement, using radiostereometry. This cement was made of the same mono- and polymers as conventional cement, but had a different particle size degradation, allowing for a smaller amount of the monomer needed to wet the powder. 4 months after the operation, this concept proved to be superior to conventional cement, but no long-term follow-up has been presented. Toksvig-Larsen et al. (1991) measured the heat generated during cementation of hip arthroplasties, using Palacos® with gentamicin, and concluded that, due to temperature elevation during curing, significant bone necrosis could be expected in slightly more than 10 percent of the cases. As regards the Boneloc® cement, the potential benefit of its lower curing temperature seems to be outweighed by some drawbacks.

Steen Jensen et al. (1991) compared monomer leakage from cement pellets made of conventional polymethyl methacrylate and a new formula corresponding to Boneloc® and found the MMA leakage to be 13–19 times higher from the conventional cement. In our study we found no difference after 24 hours. After 3 weeks and as an effect of the smaller

proportion of MMA in the Boneloc® cement, the release of this monomer was also smaller. If all types of monomers extracted were considered, the release from Boneloc® was larger.

The monomers used in Boneloc® are readily dissolved in organic media, such as lipids corresponding to the environment in the medullary cavity or the porosities in the cancellous bone. Because of the low glass transition temperature of Boneloc®, the molecular mobility at 37 °C should allow migration of residual monomers. Whether this phenomenon has any clinical relevance is not known, but it could be of importance especially as regards the increased amount of radiolucent lines and the inferior fixation noted in the acetabulum and the femoral components with a subsiding femoral cement mantle.

In the canine tibia, higher percentage of osteoid formation, less dead bone and less formation of fibrous tissue have been found after injection of MMA/ DMA/IBMA cement into the medullary cavity (Nimb et al. 1993). In our study significant subsidence of the femoral cement mantle was only observed in the Boneloc® group (2 cases, Table 4) questioning the clinical relevance of this finding. Subsequently, Morberg et al. (personal communication) could not reproduce the beneficial effect on the bone morphology of the cold-curing cement when studied in the rabbit.

At an early stage, it was shown that femoral component loosening could be initiated at the interface between the cement and the metallic prosthesis (Fornasier and Cameron 1976). In 1983, Linder and Hansson noted a close contact between bone and cement surrounding a retrieved femoral component. Later, Maloney et al. (1989) and Jasty et al. (1990) made the same observation and suggested that metal-cement debonding and subsequent fracture of the cement caused femoral loosening. According to Kärrholm et al. (1994a) early subsidence of the femoral component should not exceed 0.3–0.4 mm during the first 6 months to avoid revision within 5–8 years after the operation. This amount of migration was noted in only 3 hips all operated with the cold-curing cement. Motions at the prosthesis-cement interface were demonstrated in almost all subsiding implants, indicating that this is a significant failure mechanism. However, early micromotions of the mantle also occurred, showing that the initiation of fixation failure is more complicated than previously suggested (Harris 1994).

Acetabular components fixated with the second (Kärrholm et al. 1995) or third (Önsten et al. 1994) generation of cementing techniques seem to display a small, but over time slightly increasing migration. This was also noted in our patients from the 6 months follow-up, regardless of the type of bone cement used. Contrary to the femoral component, this migration probably represents rather the motion at the bone-cement interface as suggested by the radiolucent lines. Increased migration and length of radiolucent lines after the use of the cold-curing cement suggest that the cement/bone interface is more susceptible to penetration by the joint fluid and progressive biologic degradation, ending in clinical loosening.

Increased early migration of the cup must be interpreted as an increased risk of future clinical failures, even if this remains to be definitely established. However, previous radiostereometric studies of the cementless screw ring have indicated that pronounced early migration of the socket is an ominous sign (Snorrason and Kärrholm 1990). In a study of 20 threaded cups displaying extensive early migration, 4 were revised within 5 years after the index operation because of continuing migration and pain (unpublished observation).

In conclusion, the cold-curing cement provided an inferior fixation of both the acetabular and femoral components compared to standard cement. In the femur this was due to both mechanical failure of the cement and failure at the prosthesis/bone interface, as evidenced by radiostereometry and supported by some of the laboratory findings. The initiation of acetabular failure is not precisely known, but may have occurred more frequently at the cement/bone interface, as verified by the early radiolucenccies. Because early micromotions indicate increased risk of later clinical loosening, we cannot recommend use of the cold-curing Boneloc® cement.

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