Boneloc® cemented total hip prostheses

Loosening in 28/43 cases after 3–38 months

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We report our early results with 43 total hip prostheses (25 Charnley and 18 LMT) inserted during 1991 with Boneloc® cement. The indication was primary arthrosis (38) and rheumatoid arthritis (5). After 18 (3–38) months, 28 stems were loose and 18 hips have been revised 1–4 years after primary surgery.

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The Boneloc® bone cement system is marketed as being less toxic (Jensen et al. 1991, Sylvest et al. 1992), easier to handle, and having reduced polymer leakage into the air because of an integrated mixing and application cartridge system (Darre et al. 1993), and lower polymerization temperature than conventional bone cement (Nimb et al. 1993).

In 1991 we used Boneloc® cement in 43 hip arthroplasties. Several patients complained of severe postoperative thigh pain. In 2 cases this was an indication for exploration of the hip after only 1 year, although there were no radiological signs of loosening. In both cases, the stem was loose and the cement was fragmented. Because of this observation we have followed all Boneloc® hips regularly and we now report our early disastrous experience with this cement.

Patients and methods

From January to August 1991 we used Boneloc® bone cement (Polymers Reconstructive A/S, Denmark) for 43 total hip replacements in 43 patients (26 women and 17 men) aged 69 (50–86) years. The diagnoses were primary arthrosis in 38 cases and rheumatoid arthritis in 5 cases. There were 25 Charnley prostheses, inserted through an anterolateral approach with trochanter osteotomy, and 18 LMT prostheses, inserted through a posterior approach, according to the surgeons' choices. In all patients, a polyethylene acetabular component without metal backing was used.

The Boneloc® cement was stored in a refrigerator at 4–6 °C. We used a polyethylene femoral plug and the cement was inserted with a cement gun and then pressurized. Femoral cement filling was evaluated as sufficient in all cases with a cement mantle of not less than 2 mm. Neutral position of the femoral stem was considered as less than 5° of varus. 2 stems were inserted in the varus position.

Peroperatively there were 3 fractures of the major trochanter during insertion of the stem, which in 1 case required a longer stem than originally planned.

The patients were allowed full weight-bearing on the second postoperative day. Routine radiographs were taken after 2 weeks, 3 and 12 months in all cases. After the observation of early loosening in 2 cases, we followed all patients with radiographs annually or until revision. Loosening was classified according to Gruen et al. (1979).

Results

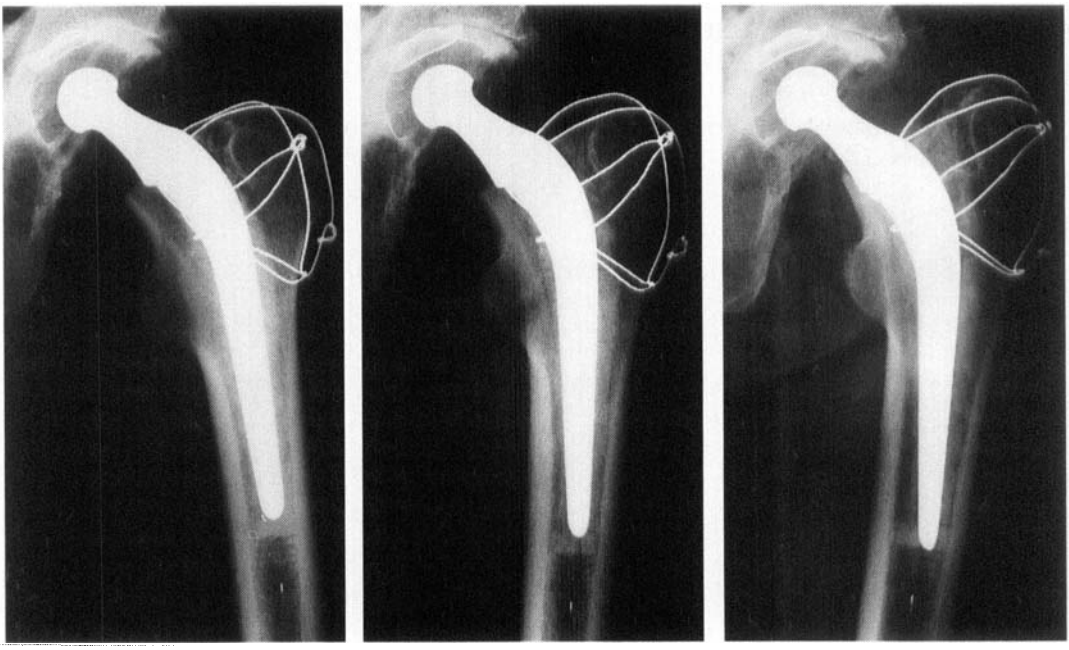
4 patients died during the follow-up period without known prosthetic loosening.

Thigh pain occurred in 21 patients and 2 patients had disabling pain after only 1 month. The time for appearance of pain was a mean of 8 (1–35) months and in all cases the stems proved to be loose.

Radiographic loosening of the stem was observed in 28 patients after 18 (3–38) months, which in 9 cases was preceded by a cement fracture, visible in zone 3 or 4 (Figure 1). Radiographically, 2 acetabular components were probably loose, with a progressing radiolucent line in zones 2 and 3.

18 hips have so far been revised for aseptic loosening and severe pain after 2 (1–4) years (Table 1). At

Figure 1. 56-year-old man with a Charnley hip replacement for primary arthrosis.



Postoperative radiograph.

3 months postop. A vertical cement fracture is visible below the tip of the prosthesis.

1 year postop. The prosthesis has subsided 1 cm and a horizontal cement fracture is now evident in zone 3.

reoperation, the cement was fragmented and not adherent to the femoral component. The cement was obviously weaker and more brittle than other cement types and thus rather easy to remove from the bone. In 8 cases, the cups were loose, including the 2 that were probably loose radiographically. Furthermore, 10 loose stems are not yet revised. 8 of these have little, if any, pain and 2 patients have not been revised because of poor health.

1 patient had a cerebral hemorrhage just after revision and died 5 weeks later.

Table 1. Clinical findings at reoperation for loose Boneloc®-cemented hip prostheses

Prosthesis	No.	Loose stem	Loose stem and cup
Charnley	15	9	6
LMT	3	1	2
Total	18	10	8

Discussion

Boneloc® cement was introduced as less toxic and with lower exothermic temperature than conventional cements. This should reduce the risk of aseptic loosening, as the cytotoxic effect and heat-induced cortical necrosis are reduced (Jensen et al. 1991, Nimb et al. 1993, Stürup et al. 1994). In spite of these theoretical advantages, we observed a catastrophically high loosening rate. A possible reason may be that Boneloc® is weaker than other cement types. Cement fractures are often seen in areas with stress concentration and may be related to weak cement (Chao et al. 1992). This probability is supported by the course shown in Figure 1 and we observed the phenomenon very early in 9 cases. During revision, the cement was fragmented and easy to disintegrate and remove from the bone, indicating both weakness and insufficient bone-cement interlock. This confirms the observation by Suominen (1995). The inferior mechanical properties observed by Kindt-Larsen et al. (1995) during stress-controlled fatigue-testing may be more important than realized by the authors themselves. In consequence, we now change both components, even though only one of them may be found loose during revision.

Another possible reason for early loosening may be an unsuitable cementing technique (Mjöberg 1994) and varus position of the femoral component (Gruen et al. 1979, Hierton et al. 1983). However, all the participating surgeons were experienced hip surgeons. During the same period they inserted another 45 THR with conventional bone cement and only one of these presented radiographic but asymptomatic loosening. The cement filling was adequate in all cases and only 2 stems were in the varus position. Furthermore, the frequency of loosening was evenly distributed throughout the period when the Boneloc® cement was used, and independently of the surgeon's experience with the cement.

We also observed an unpredictable behavior of the cement, in spite of storage at constant temperature. In the first period after mixing, the cement was very liquid, followed by a doughy phase which, shortly after, resulted in a high viscosity which made insertion of the components difficult. This caused 3 fractures in the trochanteric region. In the beginning of the period this unpredictable polymerization was claimed to be caused by insufficient membranes in the combined mixing and application chamber, but cement behavior was unchanged, although a new production series was used. The new vacuum package of Boneloc® may have solved this problem (Kindt-Larsen et al. 1995)

During revision, we found 8 loose acetabular components, although only 2 were probably loose radiographically. In no case was the cup the only loose component. The acetabular loosening rate corresponds to that in other series (Mulroy and Harris 1990) and stresses the difficulty of diagnosing cup loosening with conventional radiography.

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