Aseptic loosening of Boneloc^R cemented hip prostheses

N. Wedderkopp¹, F. Andersen-Ranberg¹, M. B. Andersen², N. B. Termansen¹

¹ Orthopaedic Department, Svendborg Hospital, Sevenborg, Sweden

² Department of Surgery, Svendborg Hospital, Sevenborg, Sweden

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Summary. *We present a systematic clinical and radiographic study of 147 patients who had total hip replacements from February 1992 to May 1993. Boneloc^R cement was used in 108, and Palacos^R cement with gentamicin in 39 patients who had an increased risk of infection. At follow-up after 24 to 39 months, 26 cases with Boneloc^R cement had failed; there were no clinical failures in the Palacos^R group.*

Résumé. *Nous présentons ici les résultats d'un suivi systématique post-opératoire sur deux ans, à la fois clinique et radiologique, réalisé sur un groupe de 147 patients qui ont eu entre février 1992 et mai 1993 une prothèse totale de la hanche. Pour 108 prothèses ordinaires on a utilisé le ciment Boneloc® et pour 39 qui présentaient un risque accru d'infection on a utilisé le ciment Palacos® avec Gentamicine. A la fin de la période d'observation (de 24 à 39 mois) on a constaté 26 cas d'échec dans les prothèses réalisées avec Boneloc®, aucun dans celles réalisées avec Palacos® avec Gentamicine.*

Introduction

The clinical performance of new implants, which are marketed with insufficient documentation, is

often unsatisfactory. Boneloc^R cement was marketed without any clinical documentation. We began using it for routine total hip replacements (THR) in February 1992 because there was promise of it being less toxic [6, 12, 15], it would be easier to handle, polymer leakage into the air was reduced because of an integrated mixing system [2, 7, 12], and it had a lower polymerisation temperature than our usual cement (Palacos^R) [12].

After one year, the frequency of loosening was so high that we discontinued Boneloc^R and began using Palacos^R again.

This paper presents the results of a clinical and radiographic follow up at 2 years of all the patients who had a THR in this period and to report our experience with Boneloc^R cement after observation from 24 to 39 months.

Patients and methods

Between February 1992 and April 1993, 147 THRs were performed in the Orthopaedic Department of Svendborg Hospital. Charnley components were used in every case with either a lateral (Charnley), anterolateral (Hardinge) or posterior (Moore) approach. The femoral canal was blocked with a polyethylene plug. The cement was inserted with a cement gun and then pressurised.

The Boneloc^R cement (Polymers Reconstructive A/S, Farum, Denmark – distributed by Biomet Denmark A/S) was used for uncomplicated cases. Palacos^R with gentamicin (Shering-Plough Inc, Farum, Denmark) was used for cases where there was an increased risk of infection such as failed primary arthroplasties, previous operations on the hip, rheumatoid arthritis and patients treated with steroids.

Both types of cement were mixed according to the manufacturer's instructions and the composition of each is shown in Table 1.

The number of patients, their diagnosis, age and sex are shown in Tables 2 and 3.

Reprint requests to: N. Wedderkopp, Department of Physical Education, Odense University, DK-5230 Odense, Denmark

Table 1. Composition of Boneloc^R and Palacos^R cement

Cement	Palacos ®		Boneloc ®	
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 32/68	0.1%
Liquid:				
Monomer	Methylmethacrylate	97.8%	Methylmethacrylate	50%
			Decylmethacrylate	30%
			Isobornylmethacrylate	18.6%
Accelerator	N,N-dimethyl-p-toludine	2.1%	N,N-dimethyl-p-toludine	0.5%
			Dihydroxypropyl-p-toludine	0.9%
Stabilizing agent	hydrokinon	65 ppm	Hydrokinone-monomethylether	100 ppm
Liquid/powder ratio	31/69		32/68	

Table 2. Preoperative diagnoses in 147 THR's

Diagnosis	Osteoarthritis	Fracture seq.	Childhood diseases	Rheumatoid arthritis	Failure of primary arthroplasty
Boneloc ^R	100	2	6	0	0
Palacos ^R	13	8	8	4	6

Table 3. Age and sex distribution in 147 THR's

	Total	Female	Male	Age
Boneloc ^R	108	60	48	67 (25–85)
Palacos ^R	39	23	16	66 (33–85)

The preoperative function was evaluated using Merle d'Aubigne and Postel's method [3]. This was repeated at the 2 year follow up. Radiographs were taken after 2 weeks, 3 months, 6 months and 2 years.

The distribution of cement around the femoral stem was analysed in the radiographs by Gruen et al's modification [5] of Kristiansen and Jensen's method [8]. DeLee and Charnley's method was used for the acetabular socket [4]. The femoral stem was divided into 5 and the socket into 3 zones. The packing of the cement was defined as adequate if the thickness of the cement mantle was at least 2 mm in more than half of the zones (Fig. 1).

Radiographs at the 2 year follow up were evaluated, and the stability of the implants was classified into 3 categories: (1) definitely loose radiographically: there was migration of 2 mm or more, a radiolucent zone of more than 2 mm in 3 of 5 zones around the stem and in 2 of 3 zones around the socket, or if there were any cement fractures; (2) not loose: there was no migration and no radiolucent area of more than 2 mm in 2 of 5 zones around the stem and in one of 3 zones around the socket. (3) possibly loose: anything in between (1) and (2) [8, 9].

Results

Eight patients died during the follow up without known prosthetic loosening, 7 with Boneloc^R and

Fig. 1. Radiographic zones into which the socket and stem are divided in relation to the distribution of cement

Table 4. Number of loose prostheses at the 2 year follow-up

		Not loose	Possibly loose	Radio-graphic loosening
Boneloc ^R	Acetabulum	85	5	2
	Femur	64	5	22
Palacos ^R with Gentamycin	Acetabulum	38	0	0
	Femur	37	0	1

one with Palacos^R. One patient with Boneloc^R was lost to follow up because of chronic heart disease.

The number of loose prostheses is shown in Table 4. Radiographic cement fractures were found in 8 of the loose prostheses.

During follow up (0 to 24 months), 9 patients had their prostheses revised, with the stem only involved. Clinical failure was defined as radiographic loosening and pain leading to revision. At the end of the period of observation (24 to 39 months), clinical failure had occurred in 26 patients in the Boneloc^R group. Nineteen were revised; further operation was contraindicated because of medical conditions in 2; one had died; one was waiting for revision, and 3 had not yet accepted reoperation. Prosthesis survival in the Boneloc^R group is shown by a Kaplan-Meier plot (Fig. 2). There were no clinical failures in the Palacos^R group.

The distribution of the cement was analysed according to Kristansen and Jensen [8] and found to be good in all the implants, except for one in the Boneloc^R group, but this patient had no signs of loosening.

In the Boneloc^R group, 2 femoral stems were positioned in 5° to 10° of varus. In the Palacos^R group, 4 femoral stems were in 5° to 10° of varus; none were in greater varus than this and none were in valgus. The malpositioned prostheses showed no signs of loosening.

The preoperative function index was 9.1 (range 4 to 15) in the Palacos^R group and 9.8 (range 6 to 15) in the Boneloc^R. At 2 years, the index was 15.4 in both groups (Palacos^R 10 to 18; Boneloc^R 7 to 18). Eighteen patients in the Boneloc^R group regularly experienced pain, and 12 used paracetamol or nonsteroidal anti-inflammatory drugs. In the Palacos^R group, 2 had pain regularly and also used weak analgesics.

Thirteen patients in the Boneloc^R group were dissatisfied with their results at follow-up. They reported that their symptoms had become worse since their last routine examination 6 months after

Fig. 2. Kaplan-Meier survival curve for Charnley prostheses cemented with Boneloc^R

the operation. Two in the Palacos^R group were dissatisfied, but their symptoms had not become worse since their last examination.

There was no difference in the frequency of loosening when the different operative techniques were compared.

Discussion

Boneloc^R cement was introduced because of several theoretical and practical advantages. It was less toxic [6, 15], easier to handle with less polymer leakage into air because of the integrated mixing and application system [2]. The polymerisation temperature was lower and there was a lower concentration of methylmethacrylate in venous blood. Residual amines in the cement had been reduced [6].

In spite of these theoretical advantages, earlier studies had shown unacceptably high rates of loosening [11, 13, 14] which were confirmed in our study. Loosening might follow poor cementing technique, with inadequate filling of cavities or malposition of the femoral stem, but we have shown that this was not the explanation in our cases.

Thanner et al compared Palacos^R and Boneloc^R and confirmed the finding of a lower concentration of methylmethacrylate in venous blood, but if all types of monomers were considered the release from Boneloc^R was greater than from Palacos^R [16]. They also showed that tensile strength and elastic modulus were less in Boneloc^R compared to Palacos^R, and that it provided less good fixation of both acetabular and femoral components [16].

In our cases, the stem tended to loosen, and at revision we found fragmentation of the cement and poor fixation to bone. The reason could be the low glass transition temperature of Boneloc^R allowing migration of residual monomers at 37 °C which possibly create increased radiolucent lines and less good fixation [16].

We also noticed unpredictable behaviour of Boneloc^R, often with a very short setting time which made it difficult to insert the components. Nevertheless, Riegels-Nielsen et al did not find cement fractures in the trochanteric region [13].

Thanner et al. also described stem migration inside the cement mantle, especially with Boneloc^R, and suggested this might be due to increased elasticity and inferior in vitro fatigue properties [16] which could explain the cement fractures in our study.

More than half of our cases cemented with Palacos^R with gentamicin were done for the primary treatment of fractures of the femoral neck, for the sequelae of childhood diseases and the failure of primary THRs (Table 2), and a higher rate of loosening might have been expected. On the contrary, the risk of loosening in the Boneloc^R group was 8 times greater than with Palacos^R.

Table 4 shows that the number of possible loose prostheses in the Boneloc^R group suggesting that revision will be needed in the future.

We recommend that Boneloc^R cement should not be used. Patients who have a THR with this type of cement should be told about the risk of loosening and offered further follow-up.

References

1. Ahnfelt L, Herberts P, Malchau H, Anderson GB (1990) Prognosis of total hip replacement. *Acta Orthop Scand* [Suppl 238]: 61
2. Darre E, Hölmich P, Jensen JS (1993) The use and handling of acrylic bone cement in Danish orthopaedic departments. *Pharmacol Toxicol* 72: 332–335
3. D'Aubigne M, Postel M (1954) Functional results of hip arthroplasty with acrylic prosthesis. *J Bone Joint Surg [Am]* 36: 451–475
4. DeLee JD, Charnley J (1976) Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop* 121: 20–32
5. Gruen TA, McNeice GM, Amstutz HC (1979) "Modes of failure" of cemented stem-type femoral component. *Clin Orthop* 141: 17–27
6. Jensen JS, Sylvest A, Trap B, Jensen JC (1991) Genotoxicity of acrylic bone cements. *Pharmacol Toxicol* 69: 386–389
7. Kindt-Larsen T, Smith DB, Jensen JS (1995) Innovations in acrylic bone cement and application equipment. *J Appl Biomater* 6: 75–83
8. Kristiansen B, Jensen JS (1985) Biomechanical factors in loosening of the Stanmore hip. *Acta Orthop Scand* 56: 21–24
9. Laursen JO, Wedderkopp N, Pedersen BK & Mossing NB (1994) Cementeret hoftealloplastik. 11–13 års efterundersøgelse af Richards serie 2 hofteprotese. *Ugeskr Læg* 156: 5505–5509
10. Mjöberg B (1994) Theories of wear and loosening in hip prostheses. Wear-induced loosening vs. loosening induced wear—a review. *Acta Orthop Scand* 65: 361–371
11. Nielsen AR, Wiig M (1996) Total hip arthroplasty with Boneloc. Loosening in 102/157 cases after 0.5–3 years. *Acta Orthop Scand* 67: 57–59
12. Nimb L, Styru J, Jensen JS (1993) Improved cortical histology after cementation with a new MMA-DMA-IBMA bone cement: an animal study. *J Biomed Mater Res* 127: 565–574
13. Riegels-Nielsen P, Sørensen L, Andersen HM, Lindquist S (1995) Boneloc cemented total hip prosthesis. *Acta Orthop Scand* 66: 215–217
14. Suominen S (1995) Early failure Boneloc bone cement. 4/8 femoral stems loose within 3 years. *Acta Orthop Scand* 66: 13
15. Sylvest A, Kramhøft M, Jensen JS, Thomsen LD, Jensen JC (1992) Monomer in central venous blood during polymerization of bone cements and toxicity of a new monomer. *Eur J Exp Musculoskel Res* 1: 47–50
16. Thanner J, Freij-Larsson, Kärrholm J, Malchau H, Wesslén B (1995) Evaluation of Boneloc. *Acta Orthop Scand* 66: 207–214