

FAILURE OF TOTAL HIP ARTHROPLASTY WITH BONELOC BONE CEMENT

P. GEBUHR¹, K. STENTZER¹, F. THOMSEN², N. LEVI¹

Early failure of Boneloc cemented total hip arthroplasty is well documented. However, information regarding the long term prognosis is scanty. The aim of this study was therefore to assess the long term failure rate of total hip replacement with Boneloc bone cement.

Between January 1991 and March 1992, Boneloc bone cement (Polymers Reconstructive A/S, Farum, Denmark) was used in 42 consecutive total hip replacements in 42 patients. The average age of the patients was 75 years. There were 25 women and 17 men. The diagnosis at operation was osteoarthritis in all cases. A cemented Muller Taperloc femoral stem was used with a cemented Muller acetabular cup (Biomet, Warsaw, USA). The follow-up time was 9 years. All patients underwent radiographic control the first postoperative year and annually after 1995. To date 21 patients have been revised for aseptic loosening at a mean of 5 years (range : one year to 8 years). Three other patients have definite radiographic evidence of loosening. The overall failure rate is therefore $24/42 = 57\%$. Our results confirm the previously reported poor results of Boneloc bone cement for hip arthroplasty and support the recommendation of indefinite follow-up for surviving prostheses. New prosthesis designs and new cements should have documentation, including laboratory tests and randomized clinical studies with radiostereometric evaluation. However, the ethical responsibility rests heavily on the shoulders of the clinician to make a correct analysis of the need for a new product before he begins to use it.

Key words : hip ; arthroplasty ; cement ; Boneloc.

Mots-cles : hanche ; arthroplastie ; ciment ; Boneloc.

INTRODUCTION

Early failure of Boneloc cemented total hip arthroplasty is well documented and the product was withdrawn worldwide in 1995 (3, 4, 5, 7, 9, 12, 14, 15). However, information regarding the long term prognosis is scanty. The aim of this study was therefore to assess the long term failure rate of total hip replacement with Boneloc bone cement.

MATERIAL AND METHODS

Between January 1991 and March 1992, Boneloc bone cement (Polymers Reconstructive A/S, Farum, Denmark) was used in 42 consecutive total hip replacements in 42 patients. The average age of the patients was 75 years (range : 60-85 years). There were 25 women and 17 men. The diagnosis at operation was osteoarthritis in all cases. A Muller Taperloc femoral stem was used with a Muller acetabular cup (Biomet, Warsaw, USA). A posterior approach was used in all cases. A polyethylene femoral plug was used. The Boneloc cement was inserted with a cement gun and then pressurized. Routine perioperative antibiotic prophylaxis was 2 gram Dicloxacillin intravenously (patients allergic to penicillin were given 3 gram Cefuroxim). Horizontal laminar air flow through the operating room was used. Standard

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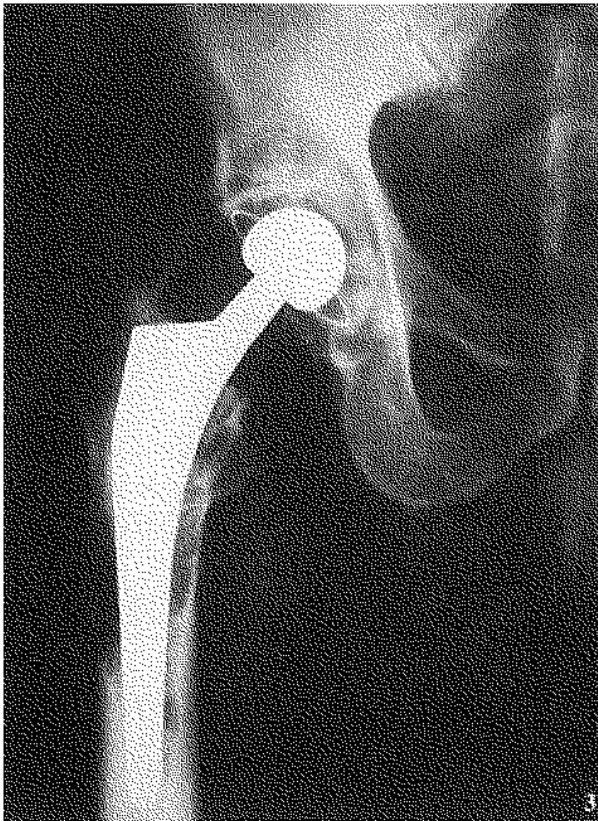
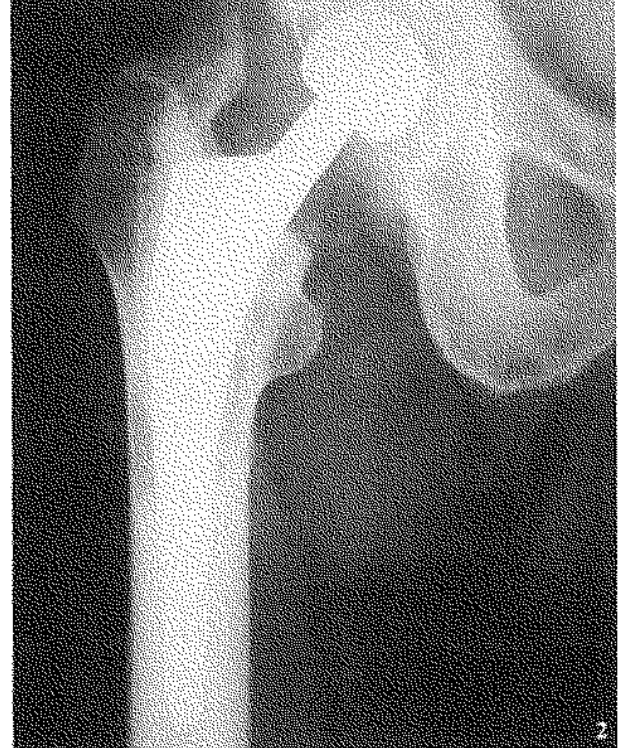


Fig. 1, 2 and 3. — Hip arthroplasty with Boneloc cement post-operatively and after 2 and 4 years with typical loosening of the femoral stem.

prophylactic anticoagulation was with Fragmin (Dalteparin) 2500 IU per day and graduated pressure elastic stockings (TED). Physical therapy began the day after the operation and the patients were mobilized fully weight-bearing the day after the operation. The follow-up time was 9 years. All patients were offered radiographs the first postoperative year and annually after 1995.

RESULTS

Postoperatively one patient dislocated his hip twice. There were no cases of deep infection. To date 21 patients have been revised for aseptic loosening at a mean of 5 years (range: one year to 8 years). Further 3 patients have definite radiographic evidence of loosening.

Failures concerned the femoral stem in all cases and the cup in 9 cases. The overall failure rate is therefore $24/42 = 57\%$. During the follow-up period, 10 patients died at a mean of 5 years without known prosthetic loosening leading to revision surgery, and 4 patients were lost to follow-up.

DISCUSSION

Boneloc bone cement was introduced in 1991 and marketed as a cold-curing and less toxic bone cement, which reduced thermal necrosis to host bone and methylmethacrylate monomer toxicity to host and user (1, 2, 7, 8, 10, 11, 13, 15). It became popular because of its asserted lower toxicity, low temperature rise during setting and its closed system for application preventing air inclusion and giving a homogenous mixture without environmental pollution (1, 3). Boneloc was used in 33 countries and in approximately 14000-21000 hips depending on whether 2 or 3 portions of cement were used in each hip (3). However, Boneloc cement was introduced with only laboratory test as documentation (3). There were no clinical, radiostereometry digitized radiographic or randomized studies to support the laboratory test (3). An aseptic loosening rate of 3-5% is to be expected after 10 years with conventional bone cement (7). In contrast, a catastrophic high early loosening rate was observed with Boneloc. In a personal series, Suominen (1995) observed component loosening and fragmented cement in 4 of 8 total hip replacements after 32 months (12). Two patients were reoperated. Also, Riegel-Nielsen *et al.* (1995), reported loosening in 28 out of 43 total hip prostheses after 18 months (9). A total of 18 hips were revised. Similarly, Nilsen *et al.* (1996) found loosening in 102 out of 157 cases after a mean follow-up time of 2 years and 24 hips had been revised (7). In a review of the Norwegian Arthroplasty register, Furnes *et al.* (1997) reported that the probability of survival at 4.5 years for Boneloc cemented Charnley femoral component was 75% (n = 955 primary hip arthroplasties) compared with 98.2% (n = 6621 primary hip arthroplasties) with conventional high viscosity cement (3). Furthermore, in a randomized radiostereometric analysis of

30 patients, Thanner *et al.* (1995) found inferior fixation in the Boneloc group during the first post-operative year, mainly caused by its inferior mechanical properties (14). Acrylic bone cements are two-component polymer systems consisting of liquid acrylate monomer and a powder of copolymer (10). The liquid of conventional bone cement (Palacos R) contains 97.8% methylmethacrylate monomer with about 2.1% N,N-dimethyl-p-toluidine as an accelerator and small amounts of stabilizer. The Palacos R powder contains 84.5% methylmethacrylate-methylacrylate polymer and 15% zirconium oxide as contrast medium (10, 14). The liquid of the Boneloc bone cement contains only 50% methylmethacrylate monomer, the other half is replaced with 30% decylmethacrylate and 20% isobornylmethacrylate. The Boneloc powder contains 90% methyl-butyl-methacrylate-polymer and 10% zirconium oxide as contrast medium (10, 14). The curing and glass transition temperatures of the Boneloc cement are 23° and 45° Celsius lower than the conventional Palacos R cement (14). The tensile strength and Young's elastic modulus of the Palacos R cement are 33.4 and 579. In contrast, the tensile strength and Young's elastic modulus of the Boneloc cement are reduced to 15.2 and 426 (14).

The product was finally withdrawn worldwide in April 1995 (15). This reiterates the lessons that seemingly logical improvement to implant design may hide unforeseen dangers (15). New prosthesis designs and new cements should have documentation, including laboratory tests and randomized clinical studies with radiostereometric radiography (3, 6). It also emphasizes the need to monitor the progress of patients with modified implants and to maintain scrupulous follow-up (6, 15). However, the ethical responsibility rests heavily on the shoulders of the clinician to make a correct analysis of the need for a new product before he begins to use it (5).

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SAMENVATTING

P. GEBUHR, K. STENTZER, F. THOMSEN, N. LEVI.
Mislukkingen na het gebruik van Boneloc cement bij volledige vervangingsartroplastiek van de heup.

Vroegtijdige loslating na volledige vervangingsartroplastiek van de heup met gebruik van Boneloc cement is een welbekend probleem. Over de resultaten op lange termijn bestaat echter weinig informatie ; dit was precies het doel van de voorliggende studie. De auteurs gebruikten Boneloc cement (Polymers Reconstructive A/S, Farum, Denemarken) bij 42 opeenvolgende operaties bij evenveel patiënten, tussen januari 1991 en maart 1992. De patiënten waren gemiddeld 75 jaar oud ; er waren 25 vrouwen en 17 mannen. Coxartrose was steeds de indicatie. Een Müller Taperloc (konisch, zelfblokkerend) femorale component werd gebruikt, samen met een Müller acetabulaire component (Biomet, Warsaw, USA) ; beiden werden ingecementeerd. De follow-up bedroeg 9 jaar. Alle patiënten kregen een röntgencontrole na één jaar, en dan — vanaf 1995 — jaarlijks. Tot op heden werden 21 ingrepen hernomen wegens aseptische loslating, gemiddeld na 5 jaar (uiterste waarden : één jaar en 8 jaar). Drie andere patiënten vertoonden daarenboven radiologisch zekerheidstekens van loslating. Het totale misluktingspercentage was dus 57% (24/42).

Deze resultaten bevestigen dus de vroeger beschreven slechte resultaten met Boneloc bij volledige vervangingsartroplastiek van de heup ; ook sporen ze aan tot een nauwgezette follow-up van de overlevende prothesen, zonder tijdslimiet. Nieuwe prothesen en nieuwe cementtypes zouden moeten uitgetest worden, zowel experimenteel als met behulp van gerandomiseerde klinische studies steunend op radio-stereometrisch onderzoek. De clinicus van zijn kant draagt de ethische verantwoordelijkheid op voorhand na te gaan of het wel verantwoord is een nieuw product te gaan gebruiken.

RÉSUMÉ

P. GEBUHR, K. STENTZER, F. THOMSEN, N. LEVI.
Echec de l'arthroplastie totale de hanche réalisée avec le ciment Boneloc.

Les échecs précoces enregistrés après arthroplastie totale de hanche utilisant le ciment Boneloc sont bien connus, mais on a peu de renseignements sur le pronostic à long terme. Ce travail avait pour but de préciser le taux d'échec à long terme de l'arthroplastie de hanche réalisée avec du ciment Boneloc. Le ciment Boneloc a été utilisé entre janvier 1991 et mars 1992 dans 42 arthroplasties totales de hanche successives chez 42 patients. L'âge moyen était de 75 ans ; il y avait 25 femmes et 17 hommes. L'indication était dans tous

les cas une coxarthrose. Une tige fémorale cimentée autobloquante de Müller a été associée à une cupule acétabulaire de Müller cimentée (Biomet, Warsaw, U.S.A.). Le suivi maximum est de 9 ans. Tous les patients ont subi un contrôle radiologique à un an puis chaque année à partir de 1995.

A ce jour, 21 hanches ont été reprises pour descellement aseptique après un délai moyen de 5 ans (extrêmes : 1 an et 8 ans). En outre, 3 patients ont des signes radiologiques de descellement certain. Le taux d'échec total est ainsi de $24/42 = 57\%$.

Nos constatations confirment les médiocres résultats déjà rapportés pour l'arthroplastie de hanche utilisant le ciment Boneloc ; elles justifient un suivi attentif des prothèses survivantes, sans limitation de temps. En matière d'arthroplastie prothétique, la commercialisation de nouveaux implants et de nouveaux ciments devrait être précédée de tests en laboratoire et d'études cliniques randomisées avec évaluation radiostéréométrique. Sur le plan éthique, le clinicien a le devoir d'évaluer correctement la nécessité d'un nouveau produit avant de commencer à l'utiliser.