

THE EFFECT OF FEMORAL STEM SIZE ON FAILURE RATES IN TOTAL HIP REPLACEMENT CEMENTED WITH BONELOC

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We report the clinical and radiological outcome of 111 primary Taperloc® hip arthroplasties implanted with Boneloc® bone cement and the effect of stem size on survival. The mean follow-up was 5.3 years (range 3.2-6.6 years). The average age of the patients at operation was 73.4 years. Twenty-seven were male and 84 female. We defined clinical failures as those who had revision for aseptic loosening, or those symptomatic with pain and subsequent confirmation of radiographic loosening. The overall failure rate noted for this type of stem was 20.7%. Failure occurred on average at 3.3 years (0.3-6.3 years). However, when the data is broken down to different sizes of stem, the patients who had smaller Taperloc® stems (7.5 mm or 10 mm) had a 27% failure rate whereas stems equal to, or greater than, 12.5 mm had a 12% failure rate over the same period ($p < 0.05$). As compared to other types of femoral stems used with Boneloc cement, the Taperloc® stems survive better. Furthermore, larger stems survive even better. We suggest that these larger stems behave more like uncemented femoral stems. The finish on the stem is not a major contributor as has been suggested in the past.

Keywords : Boneloc ; acrylic cement ; hip arthroplasty.
Mots-clés : Boneloc ; ciment acrylique ; prothèse totale de hanche.

INTRODUCTION

Boneloc® cement (Biomet, Bridgend, South Wales, UK) (methyl methacrylate-n-decyl methacrylate-isoboryl methacrylate [mma-dma-ibma]) was marketed in the UK in the early 90s as a new substitute for existing cement.

It proved popular at the time because it possessed the following properties : based on animal and clinical studies it was thought to be less toxic (6, 7, 10, 12), it had a lower temperature of polymerization than other existing cement types (16), it caused reduced leakage of monomer into the air, cement mixing was simplified by the use of an integrated single mixing system (2) and it was cheaper.

Unfortunately, along with these benefits there were problems. Early loosening was noted after primary total hip replacements using Boneloc cement (5, 11, 13). This resulted in the product being finally withdrawn from the market in April 1995.

It is now well established that Boneloc leads to early failures of the femoral stem. This paper aims to review the results of total hip replacements cemented with Boneloc cement using Taperloc® (Biomet, South Wales, UK) stems and to study the possible effect of stem size.

PATIENTS AND METHODS

At Princess Royal Hospital, between March 1993 and April 1995, there were a total of 217 patients who had Boneloc® cement used for their total hip replacements. Of these, 133 hips had Taperloc® femoral stems implanted with Boneloc cement as a primary procedure.

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This was the main prosthesis used in total hip replacement during the period of Boneloc use.

We reviewed the clinical notes of these 133 patients and attempted to contact them during the last 18 months. We reviewed their progress through telephone questionnaires, clinic attendance and radiographic review. Seventeen of these patients had died and 5 more were not contactable. These patients had no hip problems at their last follow-up. The present study is based upon the findings in 111 patients who were reviewed.

We defined clinical failure as those who had revision for aseptic loosening, or those symptomatic with pain (1) and subsequent confirmation of radiographic loosening (> 5 mm migration of the stem, or fracture of cement, or a radiolucent zone of > 2 mm around the prosthesis, or osteolysis sufficient to result in endosteal erosion in >50% of at least 1 Gruen zone) (15).

RESULTS

The average age of the patients at operation was 73.4 years (range 46.2 to 89.9).

Of the 111 primary hips reviewed, 27 were in male and 84 in female patients.

These operations were carried out for osteoarthritis in 109 patients and rheumatoid arthritis in 2 patients. Consultants carried out 57 of these operations while specialist registrars under supervision performed the remaining 54.

The Taperloc femoral stem sizes used in the 111 hips were as follows :

7.5 mm ----- 13 patients
 10 mm ----- 50 patients
 12.5 mm ----- 34 patients
 15 mm ----- 13 patients
 17.5 mm ----- 1 patient

The overall failure rate in the above group was 23/111 (= 20.7%) ; failures were noted on average at 3.3 years. (0.3-6.3 years). Seven failures were in males and sixteen in females. Specialist registrars had performed 13 of these operations. There was no significant difference between the registrars' and consultants' failure rates. The average follow-up for the remainder of the patients without failure was 5.3 years (range 3.2 - 6.6 years). The failure rate for the various stems were :

7.5 mm ----- 5 patients ----- 5/13 = 33.3%
 10 mm ----- 12 patients ----- 12/49 = 20.6%
 12.5 mm ----- 4 patients ----- 4/34 = 8.9%
 15 mm ----- 2 patients ----- 2/14 = 15.4%
 17.5 mm ----- 0 patients ----- 0/1 = 0%

The patients who had smaller Taperloc stems (7.5 mm or 10 mm) (17/62) had a 27% failure rate whereas stems equal to or greater than 12.5 mm had a (6/49) 12% failure rate ($p < 0.05$).

DISCUSSION

The Taperloc stems used with Boneloc cement had a 20.7% failure rate at 5 years. This is far lower than a series of Charnley hip replacements, where it was shown that 55% of Charnley total hip replacements have failed over a similar length of time with this cement (15). This variation in different stems is further illustrated by Furnes *et al.* (3) who found that Boneloc cemented Charnley components had a 14 times higher risk of revision when compared with other cement ; the Exeter had a 7 fold increased risk of revision (14). The study by Furnes *et al.* has suggested the much poorer outcome of the Charnley prostheses with this cement, as compared with the Exeter, was due to the smooth surface of the Exeter in comparison with the Charnley. If the finish on the stem was the main factor in the outcome in these stems, we would have expected the Taperloc stem with an Interloc® finish to have as bad or worse a failure rate as the Charnley stems.

Gebuhr *et al.* (4), have also reported previously in this journal on Taperloc stems cemented with Boneloc. They noted in their sample of 42 patients the failure rate at 9 years was 57%. As expected, this rate is much higher than our results, as their follow-up is almost twice as long and these figures just about reach the failure rates reported for Charnley prostheses with Boneloc cement at less than 5 years (15), which further reinforces our data.

Our study has also found that the size of the Taperloc stem appears to have an inverse relationship with the risk of revision i.e. the smaller stems (≤ 10 mm) had almost double the revision rate of the larger stems (≥ 12 mm) : 27% versus 12%.

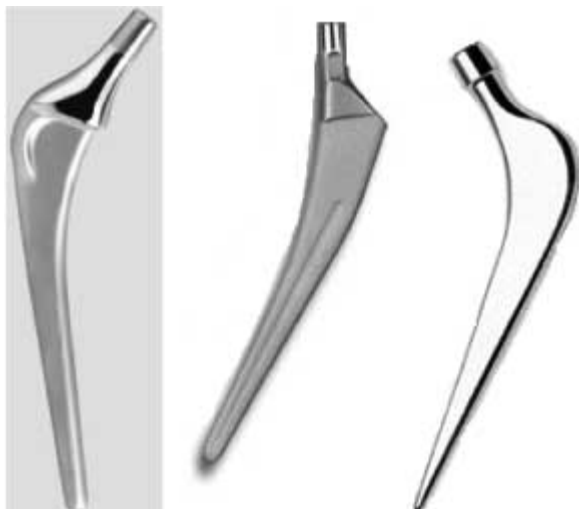


Fig. 1. — *a.* Charnley matt finish. *b.* Biomet Interloc® finish. *c.* Polished Exeter (courtesy of DePuy International and Biomet).

Thanner *et al.* (14) explained prosthetic failure by evaluating the chemical and mechanical properties of the cement. They found that Boneloc had reduced tensile strength and reduced elastic modulus compared to other cements. One suggestion for the better survival of the Taperloc stem is that the cement was more pressurized at insertion with better cement interdigitation at these higher pressures.

The osteolytic process that has been noted very soon after signs of loosening by us and others (9), implies that a constituent within Boneloc (presumably exposed monomers) causes a local inflammatory reaction that leads to rapid failure and bone destruction. With larger stems there is less cement (8), less exposed monomer and thus a reduced inflammatory response, allowing better survival.

In addition, bigger stems may be less reliant on the cement mantle for 3-point fixation acting more like fit and fill uncemented stems.

In conclusion, failure of total hip replacements using Boneloc cement is less when Taperloc femoral stems are used than with Charnley or Exeter stems. The risk of failure is further reduced when using larger stem sizes. The bigger stems act more like uncemented stems. The differences in survival of the different stems are more likely due to the size and shape of the stems rather than to the surface finish of these cemented stems.

REFERENCES

1. Britton A. R., Murray D. W., Bulstrode C. J., McPherson K., Denham R. A. Pain levels after total hip replacements. *J. Bone Joint Surg.*, 1997,79-B, 93-98.
2. Darre E., Jorgensen L. G., Vedel P., Jensen S. J. Breathing zone concentrations of methylmethacrylate monomer during joint replacement operations. *Pharmacology & Toxicology*, 1992, 71, 198-200.
3. Furnes O., Lie S. A., Havelin L. I., Vollset S. E., Engesaeter L. B. Exeter and Charnley arthroplasties with Boneloc or high viscosity cement. *Acta Orthop. Scand.*, 1997, 68, 515-520.
4. Gebuhr P., Stentzer K., Thomsen F., Levi N. Failure of total hip arthroplasty with Boneloc bone cement. *Acta Orthop. Belg.*, 2000, 66, 473-476.
5. Havelin L. I., Espehaug B. E., Vollset S. E., Engesaeter L.B. The effect of the type of cement upon the early revision of Charnley total hip prostheses. *J. Bone Joint Surg.*, 1995, 77-A, 1543-1550.
6. Jensen J. S., Sylvest A., Trap B., Jensen J. C. Genotoxicity of acrylic bone cements. *Pharmacology & toxicology*, 1991, 69, 386-389.
7. Jensen J. S., Trap B., Skydsgaard K. Delayed contact hypersensitivity and surgical glove penetration with acrylic bone cements. *Acta Orthop. Scand.*, 1991, 62, 24-28.
8. Mellors S., FRCS MPhil. Thesis " Femoral reamers and cement mantle thickness", University of Sussex, 1999.
9. Nilsen A.R., Wiig M. Total hip arthroplasty with Boneloc. *Acta Orthop. Scand.*, 1996, 67, 57-59.
10. Nimb L., Sturup J., Jensen J. S. Improved cortical histology after cementation with a new MMA-DMA-IBMA bone cement: an animal study. *J. Biomed. Mat. Res.*, 1993, 27, 565-574.
11. Riegels-Nielsen P., Sorensen L., Andersen H. M., Lindequist S. Boneloc cemented total hip prostheses. Loosening in 28/43 cases after 3-38 months. *Acta Orthop. Scand.*, 1995, 66, 215-217.
12. Sturup J., Nimb L., Jensen J. S. Blood Perfusion and remodelling activity in canine tibial diaphysis after filing with a new bone cement. *Biomaterials*, 1995, 16, 845-848.
13. Suominen S. Early failures with Boneloc bone cement. *Acta Orthop. Scand.*, 1995, 66, 13.
14. Thanner J., Freij-Larsson C., Karrholm J., *et al.* Evaluation of Boneloc - chemical and mechanical properties and randomised clinical study of 30 total hip arthroplasties. *Acta Orthop. Scand.*, 1995, 66, 207-214.
15. Walczak J. P., D'Arcy J. C., Ross K.R., James S. E., Bonnici A. V., Koka S. R., Morris R. W. Low-friction arthroplasty with Boneloc bone-cement. *J. Arthroplasty*, 2000, 15, 205-209.
16. Wykman A. G., Sandersjoo G. A. Low polymerisation temperature with Boneloc. *Acta Orthop. Scand.*, 1995, 66, 218-219.

SAMENVATTING

*Y. KALAIRAJAH, S. MOLLOY, M. PATTERSON.
Het effect van de stammaat op faling van totale heupprothesen gecementeerd met Boneloc.*

Deze studie rapporteert de klinische en radiografische resultaten van 111 Biomet Taperloc totale heupprothesen gecementeerd met Boneloc en gaat het effect na van de stamafmeting op de overlevingscijfers. De gemiddelde opvolgingstijd voor de geslaagde heupen was 5.3 jaar. De gemiddelde leeftijd van de patiënten bij operatie was 73.4 jaar. Er waren 27 mannen en 84 vrouwen. Een klinische faling was voor ons revisie voor aseptische loslating, of pijn met radiografische bevestiging van loslating. 20.7% faalden na gemiddeld 3.3 jaar (0.3-6.3 jaar). Patiënten met een kleinere Biomet Taperloc stammaat (7.5-10 mm) hadden een hogere falingskans (27%), dan deze met een stam van 12.5 mm of dikker (12%) en dit over een gelijke opvolg periode ($p < 0.045$). In vergelijking met de Charnley en Exeter prothesisstam tevens gecementeerd met Boneloc had de Biomet Taperloc een groter kans op slagen. Breder stems hebben beter kansen. We denken dat met een bredere maat van stam de prothesis langer overleeft omdat de stam zich meer gedraagt als bij een ongecementeerde prothesis en dat de oppervlakte afwerking van de stam min bijdraagt dan is vooropgesteld in het verleden.

RÉSUMÉ

*Y. KALAIRAJAH, S. MOLLOY, M. PATTERSON.
Influence de la taille des tiges fémorales sur le taux d'échec après arthroplastie prothétique de la hanche fixée au ciment Boneloc.*

Les auteurs présentent les résultats cliniques et radiologiques de 111 arthroplasties par prothèse totale de hanche au cours desquelles des tiges Taperloc® ont été fixées au ciment Boneloc® ; ils ont étudié l'influence de la taille de la tige sur la survie. Le suivi moyen était de 5,3 ans (extrêmes : 3,2-6,6 ans). L'âge moyen à l'opération était de 73,4 ans ; il y avait 27 hommes et 84 femmes. L'échec clinique a été défini par la survenue d'une reprise chirurgicale pour descellement aseptique ou par la présence de douleurs chez des patients qui présentaient un descellement radiologique. Le taux d'échec global avec cette tige a été de 20,7%. Les échecs sont survenus en moyenne après 3,3 ans (0,3-6,3 ans). Cependant, lorsqu'on analyse les échecs en fonction de la taille prothétique, on constate un taux d'échec de 27% chez les patients qui étaient porteurs d'une tige Taperloc® de petite taille (7,5 mm ou 10 mm), contre 12% chez ceux qui étaient porteurs d'une tige de diamètre égal ou supérieur à 12,5 mm ($p < 0,05$). La survie des tiges Taperloc® fixées au ciment Boneloc® apparaît meilleure que celle d'autres types de tiges. De plus, les tiges volumineuses ont une survie encore meilleure. Ceci suggère que ces grosses tiges se comportent davantage comme des tiges fémorales sans ciment. L'état de surface de la tige ne semble pas être un facteur capital, comme certains l'ont suggéré.