Exeter and Charnley arthroplasties with Boneloc or high viscosity cement

Comparison of 1,127 arthroplasties followed for 5 years in the Norwegian Arthroplasty Register

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During the years 1991–1994, the Norwegian Arthroplasty Register recorded 1,324 primary hip arthroplasties implanted with the Boneloc cement. We have compared the survival until revision due to aseptic loosening for Charnley (n 955) and Exeter (n 172) prostheses. The Boneloc cemented hips were also compared with high viscosity cemented hips implanted during the same period.

In the Boneloc cemented group, the estimated probability of survival at 4.5 years of a Charnley femoral component was 74% and for an Exeter femoral component 97% ($p < 0.0001$). Using a Cox regression model with adjustment for age, gender, type of cement, systemic antibiotic and stratified for diagnosis, an 8 times higher risk of revision was found in Boneloc cemented Charnley femoral components than in Exeter femoral components ($p < 0.0001$). For the acetabular components, the difference between the Charnley and Exeter components with Boneloc cement was not statistically significant.

In both the Charnley and the Exeter prostheses, the high viscosity cemented components had significantly better survival than the Boneloc cemented components. The Cox regression model showed that a Boneloc cemented Charnley femoral component had a 14 times higher risk of revision than a high viscosity cemented component ($p < 0.0001$), and for Exeter femoral components a 7 times higher revision risk was found in the Boneloc cemented components ($p = 0.003$).

Our results confirm the previously reported inferior results of Charnley prostheses implanted with Boneloc cement and inferior results of Boneloc cemented Exeter prostheses as well, but less pronounced than for Charnley prostheses.

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The Norwegian Arthroplasty Register has reported that Charnley femoral components implanted with Boneloc cement had a 2-year survival rate of 96% compared to a 5.5-year survival rate of 98% for high viscosity cemented components ($p < 0.0001$) (Havelin et al. 1995). Other authors have found similar short-term results using the Charnley prosthesis cemented with Boneloc (Linder 1995, Riegels-Nielsen et al. 1995, Nilsen and Wiig 1996). In two reports (Jensen et al. 1995, Klyver et al. 1996), the short-term results (2–4 years) of Boneloc cemented Bimetric, Taperloc and Exeter prostheses were considered acceptable by the authors.

We report the revision rate of prostheses implanted with Boneloc cement after 5 years of follow-up, and investigate if the inferior results are restricted to the Charnley prosthesis or if the cement is also inferior to that of other prostheses.

Patients and methods

During 1991–1994, the Norwegian Arthroplasty Register recorded 1,324 primary arthroplasties implanted with Boneloc cement. The Boneloc cement (Polymers Reconstructive A/S, Farum, Denmark) was introduced in Norway 1991 and used until 1994. Only Boneloc I (first generation) was used in Norway (personal communication, Biomet, Norway 1996). The collection of data in the register has been reported previously (Havelin et al. 1993). Analyses in the present study were restricted to primary arthroplasties with the same prosthesis brand in the acetabulum and femur and the same cement in the femur and acetabulum. Patients with missing data were excluded. All diagnoses at the primary operation were included in the analyses. The Charnley prosthesis (DePuy, Leeds, England) was used in 955 hips, with a median follow-

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up of 3.4 (0–5) years, while the Exeter prosthesis (polished) (Howmedica International, Herouville, France) was used in 172 hips with a median follow-up of 3.8 (0–5) years. As no other prosthesis brand was used with Boneloc cement in more than 40 hips, and the remaining group consisted of 9 types of prostheses used in 69 hips, this group was excluded from further analyses. Such restrictions left 1,127 primary arthroplasties for analyses.

The Boneloc cemented hips were compared with high viscosity cemented hips implanted during the same period, since the latter type of cement gives good results (Havelin et al. 1995). The high viscosity cements were Palacos with or without gentamicin (Schering-Plough International Inc., Kenilworth, New Jersey, USA), Simplex (Howmedica International, London, UK) and CMW I (CMW Laboratories Dentsply, Exeter, UK).

Survival, defined as the time to revision due to aseptic loosening, was studied by the Kaplan-Meier method and differences in survival between groups were tested with the log-rank test. As a visual presentation, 95% linear confidence limits, using Greenwood's formula (Altman 1991) are given with the Kaplan-Meier curves. Overlapping 95% confidence limits for survival curves do not exclude a significant log-rank test. The follow-up in this study was 0–5 years, but the survival percentages are given at 4.5 years to have a sufficient number of hips at risk. The survival analyses were performed separately for femoral and acetabular components. The median follow-up was calculated by the reverse Kaplan-Meier method (Schemper and Smith 1996). The survival of components revised for reasons other than aseptic loosening and of those in patients who had died or had emigrated from Norway were censored on the day of revision, death or emigration. Patients who died or had emigrated were identified from files provided by the Central Bureau of Statistics in Oslo. The follow-up was until 31st January 1996. Separate analyses were also done for all causes of revision, including aseptic loosening, fracture, pain, dislocation and deep infection. The Cox proportional hazards model was used to assess and adjust for the influence of age (< 65, 65–75, > 75), gender, type of cement, diagnosis and systemic antibiotic on the survival of the prostheses. The analyses were done with the SPSS (1993) statistical package.

Results

Only small differences related to age, gender and diagnostic categories were found between the 4 groups (Table 1). There were 22% men in the Boneloc cemented Exeter group, compared to 28% in the Boneloc cemented Charnley group. There were more patients with sequelae after hip fracture in the group with high viscosity cemented Charnley prostheses than in the other groups.

Table 1. Characteristics of Boneloc cemented Charnley and Exeter prostheses, and for high viscosity cemented Charnley and Exeter prostheses. The Norwegian Arthroplasty Register 1991–1994

	Boneloc cemented		High viscosity cemented	
	Charnley	Exeter	Charnley	Exeter
Total number of hips	955	172	6,621	1,645
Gender (%men)	28	22	27	30
Median duration of follow-up (years) [a]	3.4	3.8	2.6	2.9
Mean age (years)	72	72	72	71
Diagnosis (%)				
Primary coxarthrosis	82	69	70	75
Rheumatoid arthritis	2.3	9.9	3.5	3.6
Sequelae after hip fracture	5.2	11	18	9.0
Sequelae after hip dislocation and dysplasia	7.2	7.0	5.1	7.6
Others	2.1	2.9	3.2	3.4
Missing information	1	0	0.5	1.2

[a] The median follow-up for the femoral components are given. The difference in median follow-up for the acetabular and femoral components are small.

The Charnley prosthesis was implanted with Boneloc cement in 19 hospitals and the Exeter prosthesis with Boneloc in 2 hospitals. The Charnley prosthesis was implanted with high viscosity cement in 44 hospitals and the Exeter prosthesis in 9 hospitals.

In the Boneloc group, the estimated probability of survival of a Charnley femoral component was 74% at 4.5 years (95% confidence interval (CI) 69–79) and for an Exeter femoral component the survival was 97% (CI 94–100), log rank test $p < 0.0001$. For the acetabular components implanted with Boneloc cement, the estimated probability of survival of a Charnley acetabular component was 92% (95% CI 90–94) and for an Exeter acetabular component the survival was 97 (95% CI 94–100) ($p = 0.1$).

The high viscosity cemented Charnley components showed better results than the Boneloc cemented components, both for the acetabulum ($p < 0.0001$) and the femur ($p < 0.0001$).

There was also a difference between the Exeter components, implanted with high viscosity cement, and Boneloc cement, but less pronounced, $p = 0.002$ for femoral components and $p = 0.006$ for acetabular components (Figure).

Table 2. Kaplan-Meier 4.5-year survival estimates and Cox regression failure rate ratios (FRR). The Cox regression model included age, gender, systemic antibiotic, type of cement, type of prosthesis and it was stratified for diagnosis. The Norwegian Arthroplasty Register 1991–1994

Prosthesis and cement combination	No. of hips	No. of revisions	No. at risk at 4.5 years	Survival percent at 4.5 years (95% CI)	FRR (95% CI)	p-value
Aseptic loosening: femoral components						
Charnley/High viscosity	6,621	65	713	98.2 (97.7–98.7)	1	
Charnley/Boneloc	955	162	57	74.1 (69.2–78.9)	14 (11–19)	< 0.0001
Exeter/High viscosity	1,645	5	192	99.6 (99.3–99.9)	0.24 (0.10–0.61)	0.002
Exeter/Boneloc	172	4	31	97.0 (94.1–100)	1.8 (0.64–4.9)	0.3
Aseptic loosening: acetabular components						
Charnley/High viscosity	6,621	21	713	99.4 (99.2–99.7)	1	
Charnley/Boneloc	955	51	57	92.1 (89.8–94.4)	14 (8–23)	< 0.0001
Exeter/High viscosity	1,645	11	192	99.2 (98.7–99.7)	1.8 (0.85–3.7)	0.1
Exeter/Boneloc	172	5	31	96.8 (94.1–99.6)	7.2 (2.7–19)	0.0001
Acetabular and femoral components combined and revision due to all causes						
Charnley/High viscosity	6,621	124	713	96.7 (96.1–97.3)	1	
Charnley/Boneloc	955	182	57	71.7 (66.8–76.7)	8.8 (6.7–11)	< 0.0001
Exeter/High viscosity	1,645	27	192	97.8 (96.8–98.7)	0.76 (0.49–1.2)	0.2
Exeter/Boneloc	172	13	31	90.8 (85.9–95.7)	3.2 (1.8–5.7)	0.0001

Survival analyses of Charnley and Exeter prostheses (acetabulum and femur together), with revision due to all causes as endpoint, showed the same pattern as analyses, with revision due to aseptic loosening as endpoint (Table 2), but the difference between the two prostheses was less pronounced because of more revisions due to causes other than aseptic loosening, such as pain and dislocation in the Boneloc cemented Exeter group.

Cox regression

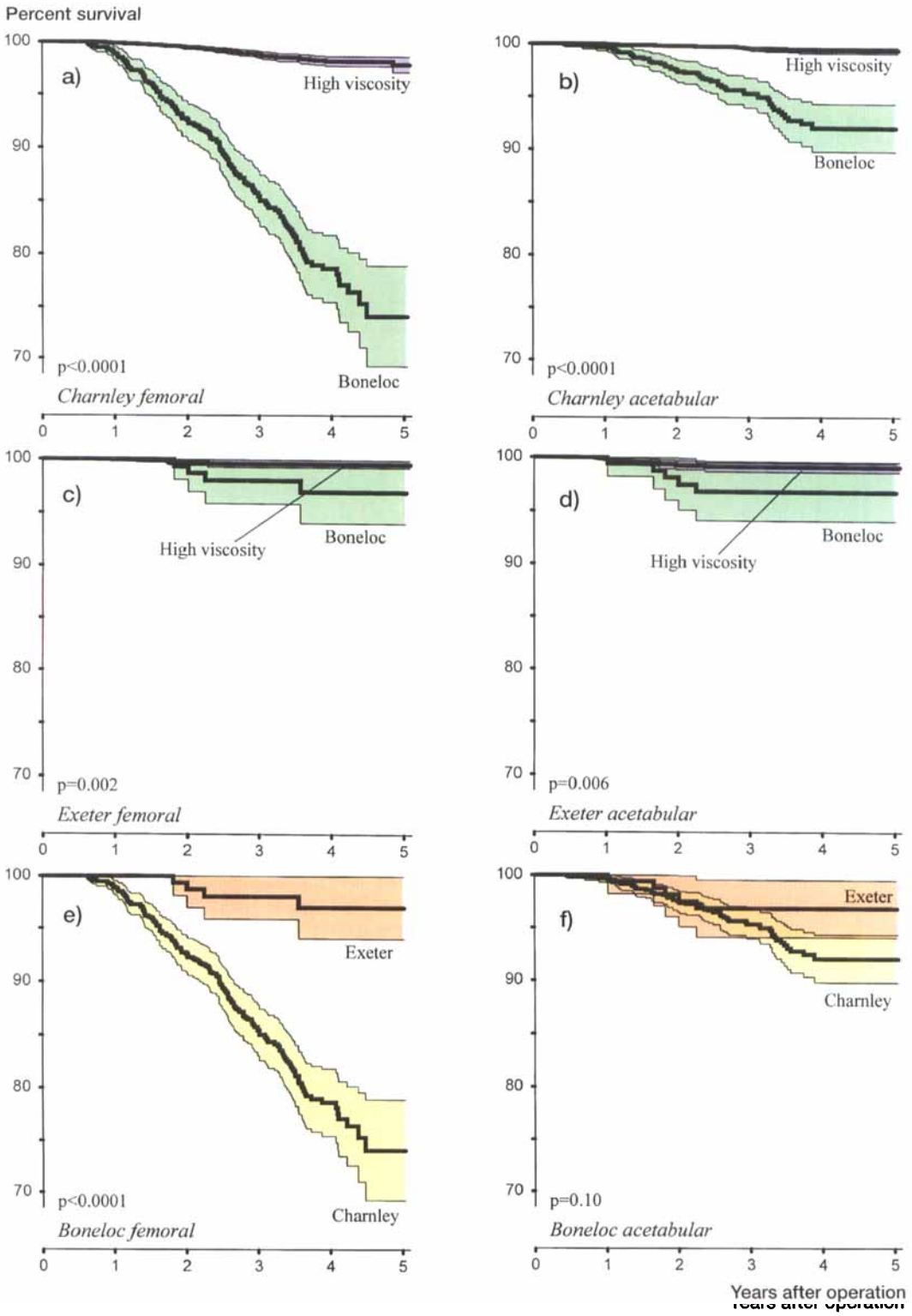
Cox proportional hazards regression analysis, with adjustment for age, gender, type of cement, systemic antibiotic and stratified for diagnosis, shows that a Boneloc cemented Charnley femoral component had an adjusted failure rate 8 times higher than that for a Boneloc cemented Exeter femoral component (Table 2). A Boneloc cemented Charnley femoral component ran a 14 times higher risk of revision than a high viscosity cemented Charnley femoral component, and for an acetabular component the risk was 14 times higher. A Boneloc cemented Exeter femoral component had a 7 times higher risk of revision than a high viscosity cemented Exeter femoral component, and for an acetabular component the risk was 4 times higher. Analyses including revision due to all causes, as endpoint and acetabulum and femur combined, showed that Boneloc cemented Charnley prostheses had a 3 times higher risk of revision than Boneloc cemented Exeter prostheses.

Discussion

Our survival analyses demonstrate that Boneloc cement gives inferior results compared with high viscosity cement both for Charnley prostheses and Exeter prostheses.

The 4.5-year results of our study confirm the previously reported inferior 2-year survival results of Charnley hip prostheses implanted with Boneloc cement (Havelin et al. 1995). With a survival rate of 74% at 4.5 years, the results are even worse than those of the Christiansen prostheses (Sudmann et al. 1983, Ahnfelt et al. 1990, Furnes et al. 1996). Our results also agreed with those in a report from a Norwegian hospital where radiographic loosening was found in 102 of 157 cases after only 0.5–3 years of observation (Nilsen and Wiig 1996).

Boneloc cement was introduced in Norway in 1991, and became popular because of its asserted lower toxicity, low temperature rise during setting and its closed system for application (Jensen et al. 1991, Nimb et al. 1993, Kindt-Larsen et al. 1995). It had 14% of the market for bone cement in Norway in 1992 (Annual Report 1996, The Norwegian Arthroplasty Register, Norway). The Boneloc cement had a new formula and a shorter working time than conventional cements (Jensen et al. 1991, Kindt-Larsen et al. 1995, Thanner et al. 1995). Problems associated with learning to use the new equipment and the shorter working time of the cement may have adversely affected the results. However, in a report from the Norwegian Arthroplasty Register, where the first 25 hips at each hospital were excluded from the analyses, similarly poor results for the Boneloc cement were



Kaplan-Meier analyses of revision due to aseptic loosening. The area within the 95% confidence limits is colored. The p-values refer to a log-rank test of differences in survivorship between the curves. In curves a)–d) one group is implanted with high viscosity cement and one group is implanted with Boneloc cement. In curves a) and f) the Boneloc cemented Charnley and Exeter components are compared. The Norwegian Arthroplasty Register 1991–1994.

found (Havelin et al. 1995). Thus, the learning curve and shorter handling time cannot fully explain the inferior results.

Boneloc's formula (50 % methylmethacrylate, 30% n-decyl-methacrylate and 20 % isobornyl methacrylate (Jensen et al. 1991, Thanner et al. 1995) was tested by the manufacturer (Kindt-Larsen et al. 1995) and by an independent group (Thanner et al. 1995). The results of their studies were conflicting. Thanner et al. concluded that the new cold-curing cement provided a poorer fixation of both the acetabulum and femoral components than standard high viscosity cement. In the femur this was attributed to both mechanical failure of the cement and failure at the prosthesis/bone interface, as demonstrated by radiostereometry (RSA) and supported by laboratory findings.

Generally, if the polymerization (curing) temperature is lowered in polymethylmethacrylate (PMMA) bone cement, the mechanical performance of the cement is reduced (Charnley 1972, Haas et al. 1975, Seymor and Carraher 1981, Dogan et al. 1995). The Boneloc cement has a glass transition temperature 45 °C lower than that of the conventional Palacos cement. Correspondingly, the curing temperature is 23 °C lower for Boneloc (Thanner et al. 1995). The potential benefits of a lower curing temperature (Mjöberg 1986) could be outweighed by poorer mechanical performance, such as less stiffness (elastic modulus) and tensile strength, and increased rate of creep when loaded.

In May 1994, all orthopedic surgeons in Norway were informed by a letter from the Norwegian Arthroplasty Register about the alarming 3-year survival results. This might have increased the rate of revision surgery after this date, but not before.

We found a difference between the survival rates of Charnley and Exeter femoral components implanted with Boneloc cement, which can probably be explained by the difference in prosthesis design. The Exeter femoral component has a double tapering section and a polished surface (Fowler et al. 1988). The double tapering section leads to distal movement of the stem in the mantle of cement, without disruption of the cement-bone interface, so-called distal movement by creep (Fowler et al. 1988). This design may tolerate better a bone cement with poorer mechanical performance than the design of the Charnley prosthesis. Our results for the Exeter implant are in accordance with other results for the Exeter prosthesis and with results of prostheses having a double tapering design (Jensen et al. 1995, Riegels-Nielsen et al. 1995, Klyver et al. 1996).

It must be emphasized that our material concerning the Exeter prosthesis implanted with Boneloc cement is limited. Only two hospitals used this combination of implant and cement, which therefore is not representative of the whole country. There can be a surgeon bias on the view of early revision, and the experience and technique of each surgeon will influence the results to a great extent. Some surgeons may also have great faith in their prosthesis and thus be inclined to delay revision, even if the prosthesis obviously is radiographically loose.

Our results show that the Exeter femoral components perform marginally better than the Charnley femoral components implanted with high viscosity cement but, by using all causes of revision as endpoint and acetabulum and femur combined in the analyses, we find no difference between the two prostheses. This is partly attributed to more revisions in Exeter acetabular components than Charnley acetabular components. One therefore cannot conclude that the Exeter prosthesis is better than the Charnley prosthesis on the basis of the results of this study. In another study from the Norwegian Arthroplasty Register (Espehaug et al. 1995), there was no statistically significant difference in the 5-year results between the probability of survival of a Charnley and Exeter prosthesis (femoral and acetabulum combined), when implanted with high viscosity cement.

We found no statistically significant difference between the Exeter and Charnley acetabular components implanted with Boneloc cement. This is to be expected, since the Charnley and Exeter acetabular components are both polyethylene cups of similar design. The small tendency towards more revisions in Charnley acetabular components can be explained by a probable tendency to revise the acetabulum at the same time as one revises the femoral component.

Boneloc cement has been used in 33 countries and in approximately 14,000–21,000 hips, depending on whether 2 or 3 portions of cement have been used in each hip (Polymers Reconstructive AS, personal communication 1996). The annual extra revision cost of using this cement in Norway (1,324 hips in a 4-year period) is estimated at 0.9 million USD (Engesæter et al. 1996). Boneloc cement was introduced on the Norwegian market and the international market, with only laboratory tests as documentation. There were no clinical or randomized studies to support the laboratory tests. We agree that new prosthesis designs and new cements should have documentation, including laboratory tests and randomized clinical studies with RSA techniques, before they are introduced on the market (Malchau 1995, Murray et al. 1995, Nilsson and Kärrholm 1996).

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