Inferior performance of Boneloc® bone cement in total knee arthroplasty

A prospective randomized study comparing Boneloc® with Palacos® using radiostereometry (RSA) in 19 patients

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We compared Boneloc® bone cement with conventional cement (Palacos®) in fixating the tibial component during 2–5 years in 19 patients with gonarthrosis undergoing total knee arthroplasty in a prospective randomized study. Boneloc displayed significantly larger migration, subsidence and lift-off than Palacos. The difference was identifiable already within 3 months postoperatively, but became significant at 12 months. In the Boneloc group, all components showed subsidence of the posterior part and lift-off of the anterior part of the tibial component, whereas in the Palacos group, the locations of subsidence and lift-off were evenly distributed about the edge of the implant. At 5 years, both Boneloc knees so far investigated were clinical failures with high migration rates. We conclude that, even in total knee arthroplasty, there is a substantial risk that Boneloc leads to inferior clinical results, but later than in hip replacements.

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Boneloc® bone cement was developed in an attempt to improve conventional bone cement by reducing the leakage of toxic chemicals and to lower the curing temperature (Nimb et al. 1993). The present study was initially designed to investigate whether these changes offered better fixation of the tibial component in total knee arthroplasty than conventional bone cement in a prospective randomized manner, using radiostereometry (RSA). However, Boneloc soon turned out to be a failure in total hip arthroplasty. In a RSA study, total hips fixed with Boneloc migrated more than those with conventional bone cement within only a few months postoperatively (Thanner et al. 1995). Several clinical reports on high revision rates of total hip arthroplasty during 1995 led to its withdrawal from the market during the summer of 1995 (Havelin et al. 1995, Linder 1995, Riegels-Nielsen et al. 1995, Suominen 1995). The unfavorable results in hip arthroplasty indicated serious deficiencies in the new bone cement. Therefore, in March 1995, we decided to stop the present study prematurely, before the scheduled number of patients had been operated on.

Boneloc has probably also been used in total knee arthroplasty, but very few results have been published. Gebuhr et al. (1996) reported 5 revisions due to loosening in a series of 99 total knees, within 2–5 years postoperatively. Since we have now encountered 2 clinical failures in the 2 initial knees operated on with Boneloc followed for 5 years so far, and since the pattern of migration up to 2 years is very alarming, we now present the results after 2–5 years in our interrupted study comparing Boneloc with conventional bone cement.

Patients and methods

23 patients (23 knees, 12 women; mean age 71 (61–90) years), with gonarthrosis stage III to V according to Ahlbäck (1968) were operated on between 1993 and March 1995. At the operation, the patients were randomly assigned to fixation of the tibial component with Boneloc (Polymers Reconstructive A/S) or Palacos® cum Gentamicin (Schering-Plough). During the study, the manufacturer of Boneloc changed the package and the way the bone cement was mixed. This resulted in 11 knees being operated on with Palacos, 8 knees with Boneloc I, and 4 knees with Boneloc II. Soon after the operation on one of the patients operated, with Boneloc II sustained an ipsilateral supracondylar femoral fracture that was treated in another country with open reduction and internal fixation. Because of complications (pseudarthrosis and septic arthritis of the knee) related to the treat-

Table 1. Preoperative data (mean and range) in the groups after randomization

	Palacos			Boneloc	
Patients (women) [a]	11 (6)				8 (4)
Age	73	61–81	ns [b]	72	61–90
Weight, kg	77	62–100	ns [b]	78	59–95
Tibial component thickness, mm	11.8	11–15	ns [b]	11.8	11–13

[a] 1 man with Palacos fixation died 3 months postoperatively
[b] Mann-Whitney U-test

ment of the fracture, this patient had to be excluded from the follow-up. Since the remaining 3 knees with Boneloc II were too few to draw meaningful conclusions from, and in order to keep the material as homogeneous as possible and, finally, since the independent mechanical testing was performed on Boneloc I (Thanner et al. 1995), this article presents only the results of the knees operated on with Boneloc I. Thus, 19 knees (11 with Palacos and 8 with Boneloc I) were included in the study. The two groups were similar as regards age, weight, range of motion, preoperative knee alignment, and Knee Society Knee and Function scores (Tables 1 and 2). Most knees were varus-maligned.

Before entering the study, all patients were fully informed about the purpose of the study and agreed to participate. The study was not assessed by the local ethics committee because at the time it was planned (1992), contrary to nowadays, this was not the routine in the department. However, the study design has been assessed in retrospect by the ethics committee, with no objections.

The operation was performed with a tourniquet, using a straight anterior approach. The cut surface of the proximal tibia was cleaned with high-pressure lavage. The cement was injected onto the tibial surface, using a special delivery nozzle. Cement was also applied on the undersurface of the tibial component. The component was hammered onto the tibia and then pressed by the trial femoral component with the straight leg raised, while the cement was curing. The Palacos cement was vacuum-mixed in the cooled state in a special mixing device (Mitab/Scandimed). The Boneloc cement was mixed in vacuum in the large syringe in which the powder and fluid were delivered. A Miller Galante II (MGII) tibial component (Zimmer) with porous titan fiber-mesh undersurface was used in all knees. The precoated MGII tibial component was not used, due to concern about cement incompatibility between the polymethylmethacrylate of the precoating and the butylmethacrylate of the Boneloc cement. All femoral components were fixated with Palacos cement.

Table 2. Clinical and radiographic results, median and range

	Palacos			Boneloc	
Knee Society Knee Score					
preoperatively	20	0–60	ns [b]	13	4–34
24 months	93	83–97	ns [b]	97	76–100
	0.005 [a]			0.012 [a]	
Knee Society Pain Score					
preoperatively	0	0–30	ns [b]	0	0
24 months	50	40–50	ns [b]	50	40–50
	0.003 [a]			0.007 [a]	
Knee Society Function Score					
preoperatively	50	40–70	ns [b]	45	25–60
24 months	90	60–100	ns [b]	92	45–100
	0.007 [a]			0.012 [a]	
Hip–Knee–Ankle angle					
preoperatively	175	168–196	ns [b]	169	165–202
postoperatively	180	176–184	nsb	180	178–183
	ns [a]			ns [a]	
Range of motion					
preoperatively	100	55–130	ns [b]	106	70–130
24 months	110	90–130	ns [b]	117	100–125
	ns [a]			ns [a]	

[a] Wilcoxon signed rank test, comparing preoperative with postoperative or 24 months' results
[b] Mann–Whitney U-test, comparing the two groups

At the operation, 0.5 and 0.8 mm tantalum spheres were inserted into the proximal tibial metaphysis and the polyethylene of the tibial component, to allow for the radiostereometric evaluation.

The patients were mobilized on the first postoperative day and were encouraged to bear weight on the operated knee as much as tolerated, using crutches in the initial 6 weeks. Active and passive knee motion were commenced on the first postoperative day.

Radiostereometry (RSA)

Radiostereometric examinations were performed with the patient in the supine position and scheduled to be done within one week postoperatively, and thereafter at 6 weeks, 3, 6, 12, 24 months and 5 years. Our modified technique of using RSA in knee arthroplasty has been presented previously (Nilsson and Kärrholm 1993, Nilsson et al. 1995). The migration of the tibial component was measured as rotations about the three cardinal axes of the knee and translations at 6 standardized positions on the tibial component (Nilsson and Kärrholm 1993).

The tibial components were classified into nonmigrating ("stable") or continuously migrating ("unstable"), based on the magnitude of the maximum migration during the second postoperative year, as suggested by Ryd et al. (1995). The criterion for being classified "stable" was a change of less than 0.2 mm between 12 and 24 months in maximum *migration*.

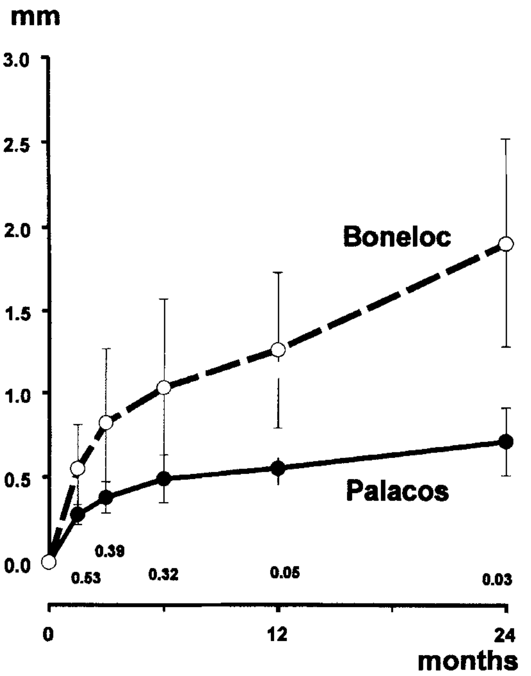

Figure 1. Maximum migration of the tibial components (mean, SE) (Mann-Whitney U-test).

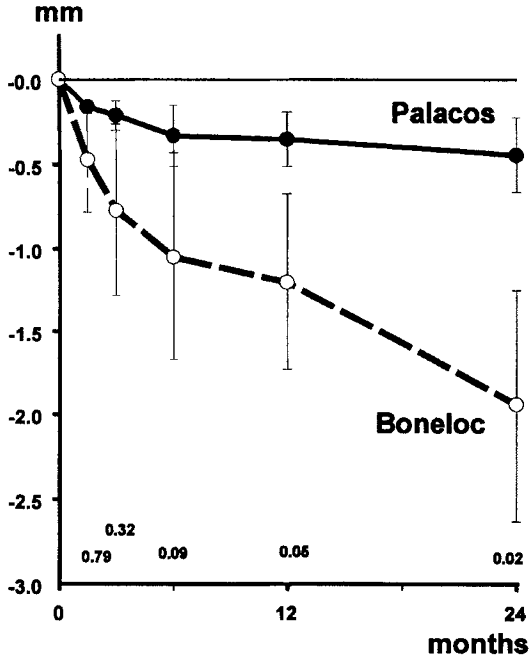

Figure 2. Maximum subsidence of the tibial components (mean, SE), (Mann-Whitney U-test).

The accuracy of the measurements was determined from double examinations of all patients. The absolute mean value of all the recorded differences between two double examinations with a standard deviation of 2.58 represented the total error of the determinations at the 99% level of significance, based on a normal distribution of each type of rotation and translation (Kärrholm and Snorrason 1992). The critical value for subsidence and lift-off was 0.10 mm, and for rotations 0.3°.

Radiolucent lines

The presence and size of radiolucencies at the cement-bone interface was determined as described by the Knee Society (Ewald 1989).

Clinical evaluation

The Knee Society Knee and Function Scores were used (Insall et al. 1989).

Missing observations

One patient (Palacos group) died of unrelated causes 3 months postoperatively

Statistics

The statistical analysis was performed using the computer software SPSS for Windows (SPSS for Windows, 6.1.3, SPSS Inc. Chicago, IL, USA) on a personal computer. The statistical method used is indicated for each calculation.

Results

Radiostereometry

The tibial components fixated with Boneloc migrated more than those fixated with Palacos. The difference was noticeable even at 3 months and became statistically significant from 12 months and onwards (Figure 1). The migration seemed to increase continuously in the Boneloc group, whereas there was a tendency for the migration to level off in the Palacos group. The same pattern was seen as regards the rotation (Table 3). Only 2 of the remaining 10 tibial components fixated with Palacos displayed continuously increasing migration between 12 and 24 months according to Ryd et al. (1995), compared to 6 of the 8 tibial components fixated with Boneloc ($p = 0.05$, Fisher's exact test).

The largest difference between Palacos and Boneloc was found in maximum subsidence, where the Boneloc fixated components subsided more than 4 times as much as the Palacos fixated implants at 2 years (1.9 ± 1.8 mm vs 0.4 ± 0.7 mm, $p = 0.02$, Mann-Whitney U-test) (Figure 2). In the Palacos group, the subsidence tended to level off whereas in the Boneloc

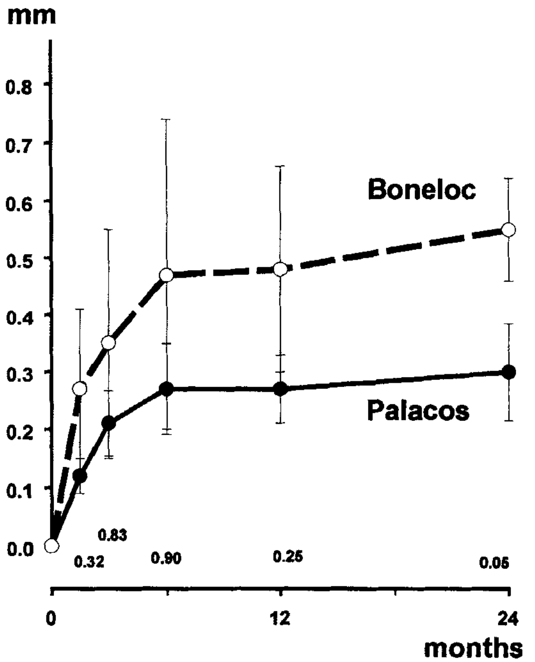

Figure 3. Maximum lift-off of the tibial components (mean, SE), (Mann-Whitney U-test).

group, the magnitude of subsidence increased during the entire follow-up period. Maximum lift-off of the implants was about 2 times higher in the Boneloc group (Figure 3), and tended to stabilize after 6 months in both groups. In the Boneloc group, all components subsided at the posterior part and displayed lift-off at the anterior part, whereas in the Palacos group, the location of maximum subsidence and lift-off was evenly distributed about the edge of the implant.

At 5 years, 4 knees (2 Palacos and 2 Boneloc) have been investigated so far. Both knees fixated with Boneloc displayed subsidence of the posterior part 6–12 mm, corresponding to a posterior rotation of the component about the transverse axis of 8–12 degrees. The 2 knees operated on with Palacos, on the other hand, displayed only slightly more migration than after 24 months.

Radiolucent lines

There were no radiolucencies at the bone-cement interface in the Palacos group. In the Boneloc group, all tibial components displayed a radiolucent line at zone 1 (medial part of the component) with a width of 1–3 mm. These radiolucencies were usually first observed at the 6 months investigation and thereafter they progressed in width up to 24 months. In 2 knees, the radiolucency was evident as early as at 6 weeks and 3 months, respectively. In 2 knees, there was also a 1 mm line at the anterior part of the bone-cement interface (zone 1, lateral view).

Table 3. Absolute rotations of the tibial component about the transverse, longitudinal, and sagittal axes of the knee. Mean (SD)

Rotation	Palacos			Boneloc	
Anterior/posterior					
6 w	0.21	0.16		0.40	0.58
3 mo	0.33	0.29		0.69	1.07
6 mo	0.40	0.68		0.82	1.19
12 mo	0.38	0.60		1.18	1.18
24 mo	0.57	0.90	a	2.01	1.68
Internal/external					
6 w	0.12	0.14		0.25	0.15
3 mo	0.21	0.14		0.20	0.12
6 mo	0.20	0.12		0.15	0.10
12 mo	0.23	0.16		0.29	0.19
24 mo	0.25	0.18		0.40	0.32
Varus/valgus					
6 w	0.09	0.11		0.41	0.99
3 mo	0.13	0.24	a	0.75	1.64
6 mo	0.21	0.22		0.92	1.89
12 mo	0.24	0.21		0.97	1.68
24 mo	0.32	0.28		1.03	1.50

[a] $p < 0.05$, Mann-Whitney U-test

Clinical results

There were no complications or failures in the two groups during the first 2 years. The preoperative Knee Society knee, pain and function scores improved ($p = 0.003$–0.012, Wilcoxon signed rank test) and did not differ between the 2 groups (Table 2). At 5 years, however, both patients operated on with Boneloc complained of pain in the knee, which had started during the fourth postoperative year. Both patients have been recommended reoperation, but in one patient the general medical condition precludes revision.

Discussion

Our results are similar to those of Thanner et al. (1995) in total hip replacements, the difference being that statistical significance was obtained earlier in the total hips. Thanner et al. (1995) showed that Boneloc had reduced tensile strength and increased elasticity compared to Palacos. We believe that the large initial migration of the tibial components in our study was caused by insufficient strength or increased deformation of the cement. Thanner et al. (1995) also found that, due to its lower glass transition temperature, Boneloc released larger amounts of monomers to the interface. This could lead to increased bone resorption at the interface, causing progressive radiolucency and accelerating subsidence.

Kinematic analysis during weight bearing of patients with replaced knees has shown that the femoral contact area on the tibia is always located posteriorly in the extended and semi-extended knee and, with increasing knee flexion, the contact area moves anteriorly (Stiehl et al. 1995, Banks et al. 1997, Nilsson et al. 1997). This implies that the largest loads on the tibial component will be located posteriorly during the main part of the gait cycle. It could explain the pattern of migration in the Boneloc group. Palacos, being stronger and less elastic, probably can resist these forces better.

The femoral component of a hip arthroplasty is subjected to large torsional forces and this can explain why the inferior properties of the Boneloc cement became significant as early as 6 weeks postoperatively in the study by Thanner et al. (1995). The tibial component and the cement are subjected mainly to compressive and distractive forces, and this as well as a thinner cement mantle can explain why the difference was observed later in the knees.

In hip replacements, where RSA revealed significantly increased migration after only 6 weeks (Thanner et al. 1995), many of the clinical failures were encountered within 2 years (Riegels-Nielsen et al. 1995, Suominen 1995). In knees where the migration is slower, it seems that the clinical failures appear some years later. In contrast to Gebuhr et al. (1996), who concluded that Boneloc apparently gave no disastrous results within 3–5 years in total knees, we think that there is a substantial risk of a high complication rate in the future. We therefore recommend that all knees with Boneloc be followed, in order to detect clinical failures early.

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