Fixation of the tibial component using CMW-1 or Palacos bone cement with gentamicin

Similar outcome in a randomized radiostereometric study of 51 total knee arthroplasties

Gunnar Adalberth[1], Kjell G Nilsson[2], Johan Kärrholm[3] and Helen Hassander[4]

Departments of Orthopaedics, [1]University of Uppsala, SE-751 85 Uppsala, [2]Umeå, and [3]Göteborg, and [4]Chemical Engineering, University of Lund, Sweden. gunnar. adalberth@ortopedi.uu.se
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ABSTRACT – We studied CMW-1 bone cement with gentamicin in the laboratory and in a randomized clinical study. Palacos bone cement containing gentamicin was used as the control. In the preclinical evaluation, the CMW cement had slightly less mechanical strength. In the clinical study, 51 patients (51 knees) operated on with total knee arthroplasty were studied for 2 years. We used radiostereometric analysis to measure migration of the tibial components, randomized to fixation with either of the two types of cement. The extent and pattern of migration were similar in both groups, and we found no differences in the number, size and extent of radiolucent lines or clinical outcome. No complications occurred. Our findings suggest a need for more studies of CMW-1 bone cement containing gentamicin in a larger cohort of patients.

Acrylic bone cement has become the standard in the fixation of orthopedic implants to bone despite numerous studies of various types of uncemented fixation. Several bone cements with different chemical, mechanical and handling characteristics have appeared on the Scandinavian markets. The ranking of the performance of these cements in the Norwegian and Swedish National Hip Arthroplasty Registers (Havelin et al. 1995, Malchau et al. 2000) has stimulated the selection of brands with the best performance, but has also made the market more uniform. High viscosity cements have replaced low viscosity ones and antibiotic-containing cements are preferred because of their slightly better performance. The data in hip arthroplasty registers have gradually led many surgeons to change to bone cement containing antibiotics also in total knee arthroplasty (TKA). For many years only one bone cement that contained an antibiotic was approved for use on the Swedish market, i.e., Palacos cum gentamicin (Schering-Plough, Labo, Belgium). In 1996, CMW-1 with gentamicin (DePuy, Warsaw, Indiana, USA) became available.

Numerous failures, not least the fast dissemination of Boneloc cement, have underlined the importance of waiting for the results of prospective randomized clinical trials before accepting new products and technologies (Linder 1995, Thanner et al. 1995, Nilsson and Dalén 1998).

Our aims were to study the in vitro mechanical, chemical and thermal properties of CMW-1 bone cement with gentamicin and its clinical performance in a randomized trial. In the clinical study, we evaluated the efficacy of this cement in fixing the tibial component in total knee arthroplasty with radiostereometric analysis. Palacos with gentamicin was used as the control.

Material and methods

Laboratory tests

Both cements were mixed using the Optivac vacuum mixing system, according to the recommendations of the manufacturers. Palacos was prechilled to 4 °C, but CMW was mixed at room temperature as in clinical work. Their tensile

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strength, elastic modulus, fracture strain, curing temperature, glass transition temperature, and amount of monomer remaining after curing were studied. Details about the methodology have been reported elsewhere (Thanner et al. 1995).

The glass transition temperature was analyzed using differential scanning calorimetry in a Mettler TA 3000 system. Samples of cement were heated to 250 °C, cooled to –150 °C, and heated again to 250 °C. The maximum curing temperature was measured using a thermocouple placed in the middle of samples molded according to ASTM F451.

Release of soluble substances was evaluated by placing pieces of cured cement in phosphorous buffer (PBS, pH 7.2). The weight of the samples was recorded before placement in 50 mL PBS for 24 hours and 21 days at 37 °C. The samples were then dried at 60 °C for 1 week, before determining their relative change in weight.

In the mechanical testing, waisted test bars (4 × 5 × 35 mm^3) were molded under pressure. They were kept at room temperature for 24–48 hours before testing. Their tensile strength was studied at a traction speed of 10 mm/min in a tensile testing machine (Schenk25) with a 25 kN load cell.

Patient study

Between October 1996 and June 1997, 51 consecutive patients (51 knees) with primary gonarthrosis were operated on with a metal-backed AMK (Anatomic Modular Knee, DePuy, Warsaw, Indiana) TKA in the Orthopaedic Department, Uppsala University Hospital. Inclusion criteria were gonarthrosis grades III–V (Ahlbäck 1968), age over 60 years, body weight below 100 kg and no previous ipsilateral knee surgery. Patients fulfilling the inclusion criteria entered the study after giving their informed consent. The study was approved by the Ethics Committee of the University of Uppsala.

The two bone cements were randomized by opening a sealed envelope during the operation. 26 knees received CMW-1 with gentamicin (CMW), and 25 knees Palacos with gentamicin (Palacos). 8 men and 17 women received Palacos, and 7 men and 19 women received CMW. Their median age was 71 (58–82) years (Palacos) and 72 (58–85) years (CMW). All patients attended every follow-up examination.

The prosthesis

We used a standard AMK 4 mm cobalt-chrome tibial base plate. The undersurface had transverse grooves (Grid-Lock), a central fixed stem and two posteriorly placed pegs. A slightly dished polyethylene insert ("standard") with a minimum thickness of 8 mm articulated against the femoral component. The polyethylene insert is machined from extruded bar (GUR 1050 resin), and sterilized in gas plasma. The mean total thickness of the tibial component was 12 (12–18) mm, with no difference between the groups. No patellar prosthesis was used.

The operation

After applying a tourniquet, the knee was approached through a straight midline skin incision and a medial parapatellar arthrotomy. An extramedullary tibial guide was used. The posterior cruciate ligament was retained in all knees, but was partially recessed to balance the knee, when necessary. The size of the tibial component was chosen to give maximum coverage of the cut tibial surface. This surface was thoroughly irrigated and dried. After mixing, the cement was applied to the undersurface of the implant only, no cement was placed in the stem hole. The tibial component was then hammered against the bone and kept under pressure while the cement was setting.

7–9 tantalum spheres (RSA Biomedical Innovations, Umeå, Sweden) with a diameter of 0.5 or 0.8 mm were spread out into the proximal tibial metaphysis, and another 6 spheres were inserted into the polyethylene of the tibial component for the subsequent radiostereometric analyses.

Early mobilization with physiotherapy and immediate full weight bearing using crutches, as tolerated, was implemented in all cases.

The bone cements

Both cements, of high viscosity (Kühn 2000), differed mainly concerning their content of antibiotics, type and content of contrast medium, and the way in which the powder was sterilized (Table 1). They were mixed in a vacuum using the Optivac system (Scandimed, Sjöbo, Sweden).

Radiostereometric analysis (RSA)

The initial radiostereometric examination (refer-

Table 1. Characteristics of the two bone cements[a]

	Palacos (% w/w)		CMW (% w/w)	
Liquid				
Monomer	methylmethacrylate	97.98	methylmethacrylate	98.25
Accelerator	N,N-dimethyl-p-toluidine	2.02	N,N-dimethyl-p-toluidine	0.81
Stabilizer	hydroquinone	60 ppm	hydroquinone	25 ppm
			ascorbic acid[b]	0.02
Plasticizer	–		ethanol[b]	0.92
Color	chlorophyllin	0.002	–	
Powder				
Polymer	poly (methylacrylate, methylmethacrylate)	82.15	poly (methyl-methacrylate)	84.73
Opacifier	zirconium dioxide	15.00	barium sulfate	9.00
Initiator	bensoyl peroxide	0.78	bensoyl peroxide	2.05
Color	chlorophyllin	0.002	–	
Antibiotics	gentamicin sulfate	2.06	gentamicin sulfate	4.23
Sterilization	ethylene oxide		γ-sterilization	

[a] Kühn K-D. Bone cements. Up-to-date comparison of physical and chemical properties of commercial materials. Springer-Verlag, 2000
[b] ascorbic acid and ethanol were excluded from the liquid in batches made after August 1997

ence examination) was done 3–10 days after the operation, and the subsequent ones at 4, 12, and 24 months. The patients were examined supine with the knee of interest inside a calibration cage. On the initial examination, the knee was placed with the anatomical axes of the knee parallel to the axes of the calibration cage.

The radiostereometric evaluation was done with UmRSA software (RSA Biomedical Innovations, Umeå, Sweden). The method we used has been described elsewhere (Selvik 1989, Nilsson and Kärrholm 1993, Nilsson et al. 1995). Since the tantalum markers in the tibial components were not inserted in exactly the same place in all patients, standardized positions for measurements of prosthetic translations were reconstructed on the tibial tray (Nilsson et al. 1995). These positions were located at the edge (medially, laterally, anteriorly, posteromedially, posterolaterally) and at the center of the tibial tray.

The relative movements of the tibial components were recorded using the tantalum markers in the tibia as the fixed reference segment. The rotations were expressed as rotations about the transverse (x-axis, anterior-posterior rotation), longitudinal (y-axis, internal-external rotation), and sagittal (z-axis, varus-valgus rotation) axes of the knee. Maximum lift-off and subsidence were defined as the maximum proximal and distal translations of the tibial component, respectively. Maximum migration (MTPM) was used as defined by Ryd (1986).

The precision of the measurements was determined as described elsewhere (Kärrholm and Snorrason 1992, Adalberth et al. 1999, Nilsson et al. 1999, Adalberth et al. 2000) with double examinations of all patients on one or two occasions during the follow-up. Significant rotations at the 99% level were > 0.15° (transverse axis), > 0.20° (longitudinal axis), and > 0.10° (sagittal axis). The corresponding values for subsidence and lift-off were > 0.10 mm.

According to Ryd et al. (1995) aseptic loosening can be predicted by dividing the tibial components into nonmigrating ("stable") or continuously migrating ("unstable") based on the amount of the maximum migration during the second postoperative year. Because of the inferior quality of the stereoradiographs, 2 knees fixed with Palacos bone cement could not be adequately analyzed with RSA: 1 knee at 12 months, and 1 at 24 months.

Measurements on conventional radiographs

The alignment of the tibial component in relation to the long axis of tibia was measured with Nilsson et al.'s method (1991). We used standard anterior-

Table 2. Results of laboratory testing of the cements (median, range)

	Palacos		CMW		
	n		n		P-value[a]
Tensile strength at break (MPa)	17	39.6 (24–48	7	37.3 (19–41)	0.09
E-modulus (MPa)	17	657 (468–741)	7	730 (616–798)	0.04
Fracture strain (%)	17	7.7 (5.2–11.1)	7	6.1 (4.0–8.0)	0.001
Curing temperature (°C)					
Sample 1	1	49.6 at 13 min.	1	60.6 at 7 min.	
Sample 2	1	52.2 at 16 min.	1	60.0 at 7 min.	
Glass transition temperature (°C)	2	107 and 109	2	108 and 110	
Weight loss 1 day in PBS[b] (%)	2	0.4 and 0.5	2	0.7 and 0.8	
Weight loss 21 days in PBS[b] (%)	2	0.4 and 0.4	2	0.7 and 0.8	

[a] Mann-Whitney U-test, statistical comparison was done only if > 3 sample sizes
[b] PBS phosphorous buffer, pH 7.2

posterior and lateral radiographs with the beam tangential to the tibial component to determine the presence and size of radiolucent lines at the tibial component interface, as described by the Knee Society (Ewald 1989).

Clinical evaluation

Clinical evaluation was done preoperatively, and at 4, 12, and 24 months using the Knee Society scoring system (Insall et al. 1989).

Statistics

We used the Mann-Whitney U-test to compare the RSA results at 2 years, and the Mann-Whitney U-test and Fisher's exact test to compare the clinical variables and the Knee Society score. Median values and ranges for the parameters are given. The RSA data of both cements were skewed, with most results clustered together but with occasional outliers and extreme values, which tended to affect the means. Therefore, the median and range as well as the mean and 95% confidence limits of the mean at 2 years are given. To show changes in migration over time, two boxplot graphs are also presented. P-values < 0.05 were considered significant. On the basis of the results of the previous study on Boneloc bone cement (Nilsson and Dalén 1998), we wished to detect differences larger than 0.35 mm and 0.5°. Our study design with 80% probability could detect a difference in maximum subsidence, MTPM, and rotations of 0.3 mm, and 0.25°–0.4°, respectively.

Results

Laboratory testing

The CMW samples had a higher E-modulus and lower fracture strain than the Palacos ones (p = 0.04 and 0.001) (Table 2). This cement also tended to have lower tensile strength at break (p = 0.09). We found no obvious differences in glass transition temperature or weight loss.

Radiostereometry

At 2 years, the absolute rotations of the tibial plateau reached 0.21°–0.34° (range 0°–2.05°) in the Palacos group. In the CMW group, the corresponding rotations were 0.22°– 0.31° (range 0.01°–2.68°) with no differences between the groups (Palacos vs CMW; p = 0.3–1.0) (Table 3). Posterior tilt was somewhat commoner than anterior tilt in both groups (CMW; 16 of 26, Palacos; 19 of 24), but varus-valgus and internal-external rotation were more evenly distributed. The results for maximum subsidence (Figure 1), MTPM (Figure 2), and lift-off did not differ significantly between the groups (Palacos vs CMW; p = 0.5–0.8) (Table 3). In 9 Palacos knees and 7 CMW knees, the tibial component showed continuous migration between 12 and 24 months, but 19 CMW knees and 14 Palacos knees were classified as stable (p = 0.5).

Measurements on conventional radiographs

The alignment of the tibial component in relation to the tibia did not differ significantly between the groups. In both groups, the mean alignment in the

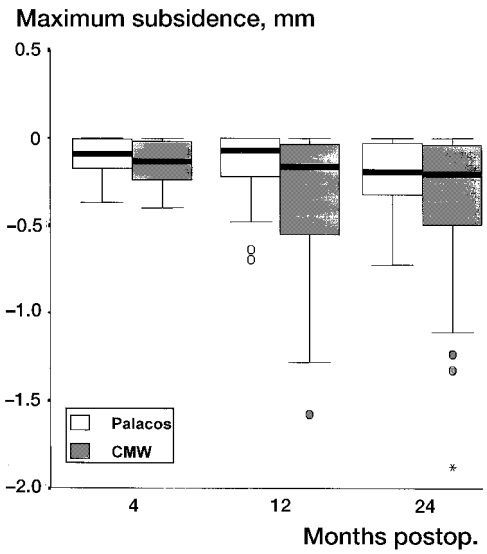

Figure 1. Boxplot showing maximum subsidence of the tibial components fixed with Palacos or CMW 1 bone cement containing gentamicin. The thick line in the box corresponds to the median, and the box the interquartile range. Outliers (●) are values > 1.5–3 times the interquartile range, and extreme values (✱) are those > 3 times the interquartile range.

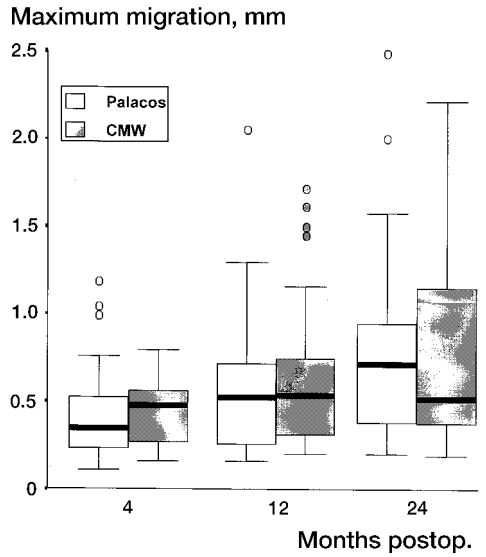

Figure 2. Boxplot showing maximum migration of the tibial components fixed with Palacos or CMW 1 bone cement containing gentamicin.
For legend, see 1.

frontal plane was 90° (86–93), and in the sagittal plane 86° (83–90) (p = 0.2–0.8).

Radiolucent lines (RL) between cement and bone were seen in 17 knees with CMW and 14 with Palacos. In all knees, these lines were first detected at 3 months, being no more than 1 mm thick, and located at the most medial and/or lateral 10 mm of the implant. Occasionally, similar lines were also seen at the most anterior and/or posterior part of the implant. In most cases, these lines did not progress (CMW 14/17, Palacos: 11/14). The amount of migration was similar in knees with or without RL in both groups (p = 0.5–0.9). In 3 CMW knees and 3 Palacos knees, the RL increased in size, being 1–2 mm thick under the entire implant at 24 months. However, the migration was similar in knees with no RL and those with progressive RL in both groups (p = 0.4–0.9).

Table 3. Results of migration of the tibial component in the two groups at 2 years

	Mean		95%CL [a]		Median		Minimum		Maximum	
	Palacos	CMW	Palacos	CMW	Palacos	CMW	Palacos	CMW	Palacos	CMW
Absolute rotations (°)										
Anterior/posterior tilt	0.39	0.56	0.25–0.53	0.31–0.81	0.34	0.31	0.02	0.05	1.40	2.68
Internal/external rotation	0.32	0.30	0.19–0.45	0.19–0.41	0.21	0.22	0.04	0.01	1.03	1.12
Varus/valgus tilt	0.39	0.44	0.18–0.61	0.25–0.63	0.21	0.27	0	0.04	2.05	2.08
Maximum lift-off (mm)	0.42	0.40	0.24–0.61	0.28–0.52	0.23	0.31	0	0.03	1.92	1.01
Maximum total point motion (mm)	0.80	0.78	0.55–1.05	0.56–1.01	0.71	0.51	0.19	0.19	2.48	2.21
Maximum subsidence (mm)	-0.22	-0.38	-0.31– -0.14	-0.58 – -0.18	-0.19	-0.21	-0.73	-1.88	0	0

[a] 95% confidence limit of the mean

Table 4. Knee Society knee and function scores and range of motion in the 2 groups, median (range)

	Palacos	P-value[a]	CMW
Knee score			
preoperative	39 (11–69)	ns	40 (24–63)
4 months	84 (65–96)	ns	88 (80–96)
12 months	87 (39–96)	ns	90 (81–97)
24 months	91 (80–96v	ns	92 (85–98)
Function score			
preoperative	45 (30–70v	ns	45 (5–60)
4 months	70 (40–100)	ns	70 (55–90)
12 v	90 (15–100)	ns	90 (55–100)
24 v	90 (15–110)	ns	90 (55–100)
Range of motion			
preoperative	100 (55–120)	ns	105 (75–115)
24 months	110 (85–125)	ns	115 (90–120)

[a] Mann-Whitney U-test

Clinical outcome

We found no statistically significant differences between the groups at any time (Table 4).

Complications

3 complications occurred in the Palacos group and 1 in the CMW group. In the former, 1 woman developed a postoperative deep venous thrombosis; 1 womanunderwent mobilization under anesthesia 6 weeks postoperatively to increase knee flexion, and 1 womanhad a displaced patellar fracture after a fall 4 months postoperatively. Despite two attempts at operative intervention, pseudarthrosis developed, which resulted in low knee and function scores. The amounts of migration of the tibial component in this patient were about the same as the median of the Palacos group as a whole. In the CMW group, 1 man had a stroke 4 months after surgery and therefore had difficulty in walking and a low function score.

Discussion

CMW-1 bone cement without gentamicin has a comparatively good long-term clinical record in total hips (Havelin et al. 1995, Malchau et al. 2000), but its clinical performance when it contains gentamicin has been poorly documented, not least in total knees. The addition of any substances to bone cement (for instance, antibiotics) can change its mechanical properties (Kühn 2000). Preclinical and clinical studies of such cements are therefore necessary before they are used routinely (Malchau 1995).

The troulbe with Boneloc (Linder 1995) could have been avoided if the surgeons had waited for the results of the prospective randomized trials (Thanner et al. 1995, Nilsson and Dalén 1998). These studies predicted a higher risk of clinical failure with use of Boneloc cement—i.e., within 6 weeks (total hips) and 6 months (total knees).

In the present study, we found no differences between the two cements in fixation of the tibial component. Moreover, the proportions of "stable" and "continuously migrating" implants were also similar. Previous laboratory tests have shown somewhat lower values for CMW than Palacos, as regards various aspects of mechanical strength (Kühn 2000), a finding partly confirmed by our study. However, this did not affect the fixation results, as measured by RSA. One explanation could be that the experimental differences are not important clinically, at least in the short term. Longer follow-up is necessary until the clinical implications of our findings can be definitely established. We would advise against the extrapolation of our data to total hip arthroplasty. The mechanical forces acting at the interface of a knee prosthesis differ from those observed in total hips, especially as regards the femoral component. At this location, not only the interface between the bone and the cement should be considered, but also the interface between the stem and the cement where debonding and micromotions may be of fundamental importance for clinical survival (Nivbrant et al. 2001).

Damage to the bone at the bone-cement interface has been said to be caused by leakage of monomer (methylmethacrylate) (Kindt-Larsen et al. 1995) and release of heat (Mjöberg 1986, Stürup et al. 1994) before and during curing of the cement. CMW bone cement has a slightly higher setting temperature, contains a higher proportion of monomer (Table 2) and therefore may be theoretically more harmful to the interface. The distribution and size of radiolucent lines at the cement-bone interface were similar with both cements, as also were the proportions of lines that did and did not prog-

ress in the two groups. Moreover, the exact etiology of radiolucent lines is not yet clear, and analysis of the size and extent of radiolucent lines is a rather unreliable method (Freeman 1999). In our study, fluoroscopically-guided radiographs were not available, instead stereoradiographs were used. Although they were exposed with the central beam as tangential to the metal backing as possible, the undulated bone/cement interface and small deviations from the optimal position may have affected the evaluation. If this is true, such errors should be equally distributed in the groups.

One difference between the two cements of potential importance for the long-term results is the different types of contrast medium used in CMW and Palacos. Zirconium oxide is more abrasive than barium sulfate. Nivbrant et al. (2001) found a slightly higher penetration rate of THR fixed with Palacos bone cement than of Cemex cement with barium sulfate. The difference was small and it is uncertain whether it is of clinical importance. It has also been asserted that they induce different inflammatory responses (Sabokbar et al. 1997, Wimhurst et al. 2001), but this finding is disputed.

The constituents of a bone cement may affect the longevity of an implant in numerous ways. Our study could not evaluate factors such as wear and inflammatory response, which may become important in the long term. Concerning fixation of the tibial component, CMW-1 bone cement with gentamicin performed as well as Palacos R with gentamicin. This finding supports the need for more studies in larger patient populations, but cannot be extrapolated to other locations such as the hip. To prove that CMW with gentamicin is equally able to fixate a total hip replacement would require a separate study.

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