

Paper II

Palamed G compared with Palacos R with gentamicin in Charnley total hip replacement

A RANDOMISED, RADIOSTEREOMETRIC STUDY OF 60 HIPs

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We performed a randomised, radiostereometric study comparing two different bone cements, one of which has been sparsely clinically documented. Randomisation of 60 total hip replacements (57 patients) into two groups of 30 was undertaken. All the patients were operated on using a cemented Charnley total hip replacement, the only difference between groups being the bone cement used to secure the femoral component. The two cements used were Palamed G and Palacos R with gentamicin. The patients were followed up with repeated clinical and radiostereometric examinations for two years to assess the micromovement of the femoral component and the clinical outcome.

The mean subsidence was 0.18 mm and 0.21 mm, and the mean internal rotation was 1.7° and 2.0° at two years for the Palamed G and Palacos R with gentamicin bone cements, respectively. We found no statistically significant differences between the groups. Micromovement occurred between the femoral component and the cement, while the cement mantle was stable inside the bone. The Harris hip score improved from a mean of 38 points (14 to 54) and 36 (10 to 57) pre-operatively to a mean of 92 (77 to 100) and 91 (63 to 100) at two years in the Palamed G and Palacos R groups, respectively. No differences were found between the groups.

Both bone cements provided good initial fixation of the femoral component and good clinical results at two years.

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The long-term performance of cemented total hip replacement (THR) is dependent on many factors, including the characteristics of the patient, the surgical technique, the choice of prosthesis, the cementing technique and the properties of the bone cement used. The impact of modern cementing technique on the survival of cemented THRs has been documented.^{1,2} Although all bone cements used in current clinical practice are based on methylmethacrylate, their performance differs physically and clinically. Poor results with some low-viscosity cements^{1,3} and particularly with Boneloc cement (Biomet, Warsaw, Indiana)^{4,5} have demonstrated the importance of the selection of the correct cement for clinical practice. Several high-viscosity antibiotic-loaded bone cements have given good long-term results in the Scandinavian arthroplasty registers.^{1,3,6}

One of the well-documented high-viscosity bone cements is Palacos R with gentamicin (Schering Plough, Labo nv Belgium), hereafter referred to as Palacos R. Palamed G (Biomet Merck, Darmstadt, Germany) is a high-viscosity antibiotic-loaded bone cement based on Refobacin-Palacos R from the same com-

pany.^{3,6} Since the conduct of this study the distribution of the two bone cements has changed (September 1995). This is commented on at the end of the article. Palacos R has an initially reduced viscosity which allows mixing without pre-chilling, yielding a homogeneous cement with reduced porosity.^{7,8} It has been mechanically tested, reaching standards superior to the ISO 5833 (International Standards 5833/1-2) concerning compressive strength, Young's modulus and bending strength. The maximum temperature, the penetration of the cement and the elution of gentamicin are also found to be comparable or superior to other Palacos-based bone cements.^{9,10} Based on *in vitro* evidence of good physical and chemical properties, we wished to evaluate the clinical performance of Palamed G bone cement.

The relationship between early migration and late aseptic loosening has been documented using conventional radiography^{11,12} and radiostereometric analysis (RSA).¹³⁻¹⁵ The latter is a highly accurate method for the evaluation of prosthetic migration allowing the assessment of new implants, cements or surgical technique using only small numbers of

Table I. Details of the hips in both groups

	Palamed G	Palacos R
Mean age in yrs (range)	74 (62 to 82)	74 (63 to 84)
Gender		
M:F	5:23	7:23
Mean body weight in kg (range)	67 (48 to 95)	69 (55 to 100)
Charnley class (A:B:C)*	19:9:0	12:13:5
Diagnosis†		
Osteoarthritis	18	19
Post-traumatic	7	5
Rheumatoid arthritis	2	7
Acute fracture	2	1

* A, unilateral hip disease with no other disability; B, bilateral hip disease with no other disability; C, unilateral or bilateral hip disease with generalised systemic factors affecting function

† more than one diagnosis was recorded in some of the patients

patients.¹⁶ The degree of micromovement during the first one or two years has been shown to correlate with the medium- or long-term performance of cemented joint prostheses and can thus be used as a predictor in early clinical evaluation.^{13,15,17}

Our aim was to evaluate the early migration of a cemented femoral component using Palamed G bone cement, using Palacos R as a reference. The null hypothesis was that the stability of the stem was equal in the two study groups. Furthermore, we wished to determine whether the micromovement occurred at the cement-stem interface or between the cement mantle and the bone. The study was approved by the Regional Ethical Committee.

Patients and Methods

A total of 60 hips in 57 patients was randomised to receive either Palamed G or Palacos R for fixation of a Charnley femoral component (DePuy International Ltd, Leeds, United Kingdom). The three bilaterally operated patients, as an effect of randomisation, received the same cement in both hips. Two of these were in the Palacos R group and one in the Palamed G group. Two patients (two hips) were excluded; one because of post-operative dislocation and infection, and the other died before the three-month examination. Both patients were in the Palamed G group, leaving 28 hips in this group and 58 overall.

The diagnosis and details of the patients are given in Table I.

Operative technique. Four surgeons (LIH, AS, OF, GH) operated on all the patients, and randomisation was arranged so that each operated on an equal number of patients in the two groups. This was done to avoid the influence of the surgeon on the results. A stainless-steel, monoblock 22 mm head Charnley flanged 40 femoral component was used in all patients. It was supplied with tantalum markers on its tip and shoulder from the manufacturer. The centre of the femoral head was used as a third point for the three-dimensional assessment of the stem in calculations of movement. The acetabular component used was a Charnley Ogee cup

with an outer diameter of 40 mm or 43 mm (DePuy International Ltd) inserted with Palacos R with gentamicin cement in all patients. The procedure was standardised using a modified direct lateral approach¹⁸ with the patient in the lateral decubitus position. We used a third-generation cementing technique (high-pressure lavage, femoral cement restrictor, retrograde cement injection with cement gun and cement pressurisation). An envelope with the type of cement to be used in the femur was opened after preparing the femur and performing trial reduction, leg-length measurement and testing of stability.

Palamed G cement was stored at a constant temperature of 20°C in a temperature storage cabin and Palacos R cement at 8°C in a refrigerator. The cements were taken out immediately before use, and mixing was done using the Optivac system (Biomet). This is a closed vacuum-mixing system producing homogeneous cement with low porosity (macroporosity below 0.5%, microporosity below 1 pore per 100 mm³).⁸ Insertion of the femoral stem was performed at 4.5 minutes after mixing for Palamed G, and at six minutes for Palacos R, according to the manufacturers' recommendations. The temperature of the operating room was between 20°C and 21°C.

All patients received systemic prophylactic antibiotics (four doses of cefuroxime 2 g, or two doses of clindamycin 0.6 g in the presence of penicillin allergy). For thromboprophylaxis, 2500 units of Dalteparin was given intra-operatively after spinal anaesthesia and was continued for ten days at a daily dose rate of 5000 units. The patients were allowed to mobilise, partially weight-bearing with crutches, from the first post-operative day.

Radiostereometry. Seven or eight tantalum markers (RSA Biomedical Innovations, Umeå, Sweden) with a diameter of 1.0 mm were inserted into the proximal femur. Additional tantalum markers 0.8 mm in diameter were inserted into the cement restrictor (two) and into the cement mantle (approximately six) during cementing and insertion of the stem.

The initial RSA examination was performed three and five days (mean 4.3) after operation with repeat examinations at 3, 6, 12 and 24 months. The patient was supine and the uniplanar technique (cage 43, RSA Biomedical) was used with the calibration cage under the examination table. Simultaneous exposures were obtained with one gantry-mounted and one portable x-ray tube. Using the UmRSA Digital measure version 5.0 software (RSA Biomedical) the three-dimensional position of the markers and the translations and rotations of the gravitational centre of the segment of the stem were computed. The upper limit for the mean error of rigid-body fitting was set at 0.35 mm and that for the condition number at 150.¹⁹ These limits ensured that there was proper stability and distribution of the tantalum markers. A condition number higher than 150 implies poor distribution of the tantalum markers in bone and/or cement. This adversely affects the accuracy of migration measurements. Validation of the precision of our

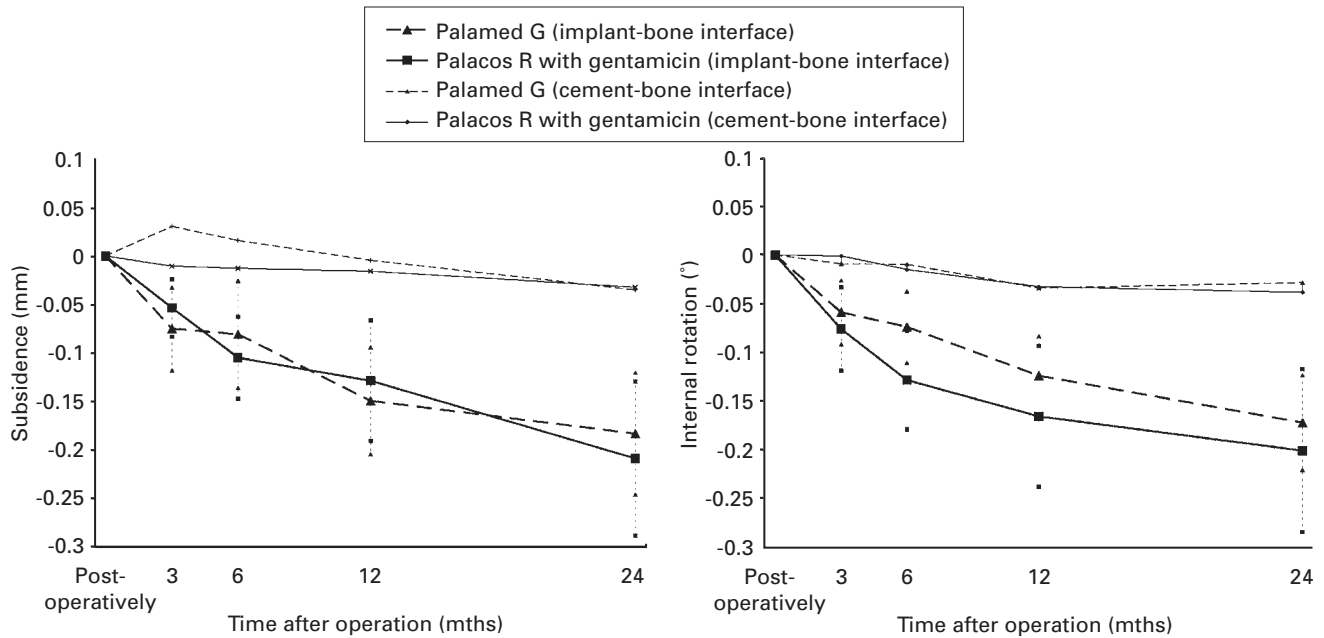


Fig. 1a

Fig. 1b

Observed mean values of a) subsidence and b) internal rotation of the femoral components with the two cements at the cement-bone interfaces (with standard error of means).

RSA technique was done by double examinations of 27 patients at the 12-month examination.²⁰

Clinical follow-up. Clinical evaluation using the Harris hip score (HHS)²¹ was performed pre-operatively, at 3, 12 and 24 months post-operatively, and will in due course take place at five and ten years in conjunction with conventional radiological examinations.

Statistical analysis. Limits for significant translations and rotations were calculated as the 99% confidence interval (CI) of the absolute mean values from analyses of the double examinations. The effects of the cement (Palamed G, Palacos R) and the time (3, 6, 12 and 24 months) on the RSA migration data and on the clinical outcome data were investigated in a mixed-effects model.²² Assumptions for the mixed-effects analyses were assessed based on residual plots and normal probability plots of the residuals and of the estimated random effects. Analyses were performed using the statistical package S-Plus (Insightful Inc., Seattle, Washington). Differences were regarded as being statistically significant if the p value was less than 0.05. The data presented in the Tables and Figures are observed data, whereas the p values are based on estimates from the mixed-effects model.

Results

Radiostereometric analysis. Femoral components in both groups subsided and rotated into internal rotation. Subsidence (negative translation along the y-axis; distal migration) at two years was 0.18 mm and 0.21 mm, and internal rotation (negative rotation around the y-axis; retroversion) was

1.7° and 2.0° for the Palamed G and Palacos R groups, respectively (Fig. 1). Micromovements in the other directions were all of minor magnitude. The mixed-effects analyses showed no consistent differences between the cements with time, and at one and two years follow-up we observed no statistically significant differences ($p = 0.2$ to $p = 0.9$). Table II gives the micromovement observed in translations and rotations relative to three axes (x, y and z) at two years for the three interfaces. Most micromovement occurred at the cement-stem interface. In the Palacos R group, the cement mantle rotated -0.2° around the x-axis (extension) relative to the femur. Movement of the cement mantle in all other directions was within the precision of the RSA measurements. We therefore concluded that the cement mantle was stable relative to the femur. We investigated the patients with internal rotation exceeding 3° (3.4° to 7.9°) and/or subsidence of more than 0.35 mm (0.38 to 0.93) separately. None of these patients had clinical evidence of loosening or radiological signs of loosening on conventional radiographs at follow-up at two years (Table III). The number of examinations suitable for the calculation of micromovement of all three segments (femoral component, cement and bone) at the different time intervals, are given in Table IV. At two years, 22 and 21 sets of examinations were included in each group. In measurements of the stem-bone segment, however, another six hips were included, thereby increasing the numbers available to 26 and 23 in the Palamed G and Palacos R groups, respectively. The reasons for the exclusion of patients and missing two-year RSA data are given in Table V.

Table II. Observed mean values for micromovement at the three interfaces at radiostereometric analysis (RSA) follow-up at two years. Rotation around the x-axis is flexion-extension, about the y-axis external-internal rotation and about the z-axis abduction-adduction. Translation at the x-axis is medial to lateral, in the y-axis distal to proximal and in the z-axis posterior to anterior. We defined positive values for the right limb

	Rotation (°)			Translation (mm)		
	x	y	z	x	y	z
Cement-stem						
Palamed G	-0.103	-1.635	0.165	0.048	-0.144	-0.244
Palacos R	-0.009	-1.820	0.184	0.078	-0.136	-0.201
Precision*	0.09	0.48	0.13	0.114	0.061	0.114
p value†	0.3	0.9	0.8	0.3	0.8	0.7
Stem-bone						
Palamed G	-0.136	-1.722	0.229	-0.010	-0.183	-0.259
Palacos R	-0.238	-2.008	0.324	0.027	-0.208	-0.273
Precision*	0.15	0.38	0.09	0.064	0.051	0.116
p value†	0.5	0.9	0.7	0.5	0.8	0.8
Cement-bone						
Palamed G	-0.050	-0.285	0.105	-0.029	-0.035	0.052
Palacos R	-0.210	-0.386	0.150	0.052	-0.032	0.108
Precision*	0.12	0.40	0.11	0.081	0.045	0.144
p value†	0.2	0.7	0.5	0.3	0.9	0.6

* calculation of precision is based on 27 double examinations

† mixed-effects model including all RSA examinations

Table III. Results for those hips when the femoral component rotated more than 3° and/or subsided more than 0.35 mm

Case	Cement	Subsidence (mm)	Rotation (°)	Harris hip score
4	Palacos R	0.38	-	96
13	Palacos R	0.93	7.82	100
18	Palamed G	-	4.83	98
20	Palamed G	0.39	-	100
25	Palamed G	0.58	-	91
30	Palacos R	-	3.86	100
49	Palacos R	-	7.91	96
52	Palacos R	0.39	3.41	100
54	Palamed G	0.50	4.75	98
57	Palamed G	0.46	3.38	93

Clinical results. In the Palamed G group the mean HHS increased from 38 points (14 to 54) pre-operatively to 88 (51 to 100) at one year and 92 (77 to 100) at two years. The corresponding scores for the Palacos R group were 36 (10 to 57), 87 (67 to 100) and 91 (63 to 100), respectively. There were therefore no statistically significant dif-

ferences between the groups (mixed-effects model, $p = 0.2$ to 0.9).

Discussion

During the two first years, the two bone cements performed equally well in fixation of the femoral component. A subsid-

Table IV. Number of examinations available for complete calculation of micromovement at the different time intervals. Numbers in brackets represent examinations available for the calculations of micromovement between the femoral component and bone

Months	Palamed G	Palacos R
Post-operatively	27	29
3	21 (24)	21 (25)
6	20 (24)	20 (25)
12	22 (27)	23 (23)
24	22 (26)	21 (23)

Table V. Radiostereometric analysis (RSA) examinations missing at two years, and exclusions

Number of patients	Palamed G/ Palacos R	Reason for missing RSA examination
9	4/5	Condition number > 150*
4	2/2	Death of patient†
2	1/1	Missing or inadequate index RSA examination
1	1/0	Post-operative dislocation. Excluded
1	0/1	Stem markers obscured at RSA at two years

* calculation of movement of the stem relative to the bone included in 7 of 9

† one patient died before three months after operation and was excluded

ence of 0.2 mm is considered by some authors to be safe with respect to long-term performance.^{13,14} The migration into internal rotation found in our study, however, is slightly larger than that in other studies. Grant et al²³ found internal rotation of 1.1° at two years with the Charnley Elite Plus (DePuy) using Palacos R with gentamicin bone cement. Alfaro-Adrián, Gill and Murray²⁴ found internal rotation of 1.3° at two years using the Charnley Elite stem and CMW bone cement (DePuy). Onsten et al²⁵ found 1.25 mm posterior migration of the centre of the femoral head using the Charnley stem and Palacos R bone cement. If it is supposed that there is an offset of 40 mm and rotation around the centre of the diaphyseal portion of the femoral stem; this corresponds with 1.8° ($\tan n \text{ degrees} = 1.25/40$).

Gill et al²⁶ proposed that there was a correlation between decreasing femoral component anteversion and posterior migration of the head. In our study we did not measure anteversion of the femoral components post-operatively and therefore do not know whether the degree of anteversion affected the degree of internal rotation at follow-up. Intra-operatively, we aimed at anatomical anteversion of the femoral component according to the cut femoral neck. On average, this would be approximately 10° of anteversion. In our study, the initial RSA examination was performed at three to five days after the operation and before vigorous mobilisation of the patient. The latter influences the initial micromovement,¹⁹ and an early initial examination may detect micromovement not seen when the initial examinations are delayed. The post-operative RSA examinations in the studies compared above were undertaken within seven days,²³ unspecified post-operatively²⁵ or between one and two weeks after operation.²⁵ The slightly higher internal rotation in our patients may be explained by their relatively early initial RSA examinations. The two-year RSA examinations in our study were actually performed in all patients more than two years after the operation, the mean delay being 61 days (10 to 190). The 24-month RSA follow-up was therefore actually a 26-month follow-up. Calculated values of translation and rotation would be expected to be slightly lower at 24 months. With a precision of 0.4° for internal rotation, and taking the previously mentioned aspects into account we believe that the internal rotation found in our study matches published results reasonably well.²³⁻²⁵

The rate of movement in our series was, as expected, highest initially. Between one and two years, the mean rate of internal rotation was 0.45°/year (0° to 2.1°) as compared with 1.44°/year (0° to 3.7°) in the first year. The mean rate of subsidence was 0.03 mm/year (0 to 0.45) in the second year but 0.14 mm/year (0 to 0.56) in the first year. We plan to re-examine our patients at five and ten years in order to further evaluate migration of the femoral component and clinical outcomes.

Knowing the technical difficulties in obtaining high-quality RSA examinations, our study was planned to allow for exclusions. The most frequent cause of excluded RSA

examinations was a high condition number. Poor distribution and visibility of cement markers caused the high condition number in most cases (6 of 9). The stem and bone markers, however, were properly placed and readily identified. In these six hips, high-precision measurements of movement at the stem-bone interface were undertaken while measurements at the cement-bone and stem-cement interfaces were excluded. Accurate placement of cement markers is difficult as the femoral stem easily obscures the markers in one or both projections. The precision in our study, also in the calculation of relative movement of the cement mantle (Table II), is still good, and is comparable with that found in other studies using similar RSA techniques.^{20,23,27}

In our study, the cement mantle was shown to be stable while the stem internally rotated and subsided inside the cement. Micromovement of the cement mantle has not been widely studied and, of the published studies, most have found the cement to be stable although the femoral component moves inside the cement.^{24,27,28} This corresponds with our findings.

The proportion of Charnley class-B and class-C hips was higher in the Palacos R group than in the Palamed G group (Table I) mainly because of a larger proportion of patients with rheumatoid arthritis in the former group. This should not influence migration of the Charnley stem, since migration in patients with rheumatoid arthritis has been found not to differ from that in those with primary osteoarthritis.²⁵ It might have been expected, however, that the clinical scores differed according to the somewhat skewed material, but this was not found to be the case.

Different designs of the femoral component may have different tolerance to the qualities of the bone cement. The Boneloc cement was better tolerated by the double-tapered, polished Exeter femoral component than by the Charnley femoral component although still yielding inferior results than high-viscosity cements.⁴ It cannot be assumed that the results of our study can be applied to all designs of cemented stem. New bone cements should, as new implants, be introduced in a stepwise manner, as proposed by Malchau.²⁹ Several bone cements (Boneloc (Biomet), CMW I and II (DePuy), Sulfix (Stryker Corp., Kalamazoo, Michigan)) which have fulfilled *in vitro* tests according to the ISO standard,³⁰ have proved to be clinically inferior to the best well-documented cements on the market.^{3,4,6} *In vitro* evidence of physical and chemical properties should not be considered to be evidence of good clinical results. Therefore, documentation of clinical performance is vital before considering widespread use. The only clinical investigation of the Palamed G bone cement which we have identified involved the fixation of tibial components in a series of 35 total knee replacements (TKR). This was not a randomised study and the published RSA follow-up was limited to one year. The authors concluded that migration with the Palamed G cement was comparable with results reported in other RSA studies in cemented TKR.³¹ In our

RSA study, micromovement of the Charnley stem using the Palamed G cement proved to be equal to that with Palacos R cement, the latter having documented good long-term clinical results.^{1,3,6} It is therefore anticipated that Palamed G cement should give similar long-term results given the supposed predictive nature of RSA studies. However, the performance of larger randomised trials with long-term follow-up, and ultimately prospective follow-up in national registries is advisable to ensure safe practice.

At the time of patient inclusion, the bone cements Palamed®G and Palacos®R with Gentamicin were distributed by Biomet and Schering Plough, respectively. The two bone cements are now both produced and traded by Heraeus Kulzer GmbH/Heraeus Medical. According to Heraeus Kulzer, their current bone cements, called Palamed® G and Palacos® R + G, have the same properties as the corresponding cements used in the study.

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