The Journal of Arthroplasty Vol. 20 No. 6 2005

Fluoride-Containing Acrylic Bone Cement in Total Hip Arthroplasty. Randomized Evaluation of 97 Stems Using Radiostereometry and Dual-Energy X-ray Absorptiometry

Georgios Digas, MD,PhD, Jonas Thanner, PhD,
Christian Anderberg, MD, and Johan Kärrholm, MD, PhD

Abstract: Ninety patients (97 hips) scheduled for total hip arthroplasty were stratified to fixation of the femoral component using fluoride-containing cement or Palacos with gentamicin. Whole polyethylene Reflection and press-fit Trilogy cups were used. All patients received Spectron EF stem. The micromotions of the stem were measured with radiostereometric analysis and the periprosthetic bone mineral density with automatic and manual dual-energy x-ray absorptiometry (DEXA) analysis. At 2 years, the choice of cement did not influence the subsidence or rotations of the stem. The DEXA analysis revealed more loss of periprosthetic bone mineral density in fluoride cement group. We speculate that forming of fluorapatite crystals, toxic effects of the fluoride, or lower radiopacity of the fluoride cement might explain this finding. According to our study with 2-year of follow-up, there is no obvious advantage of addition of fluoride to acrylic bone cement when used to fixate the femoral component in total hip arthroplasty. **Key words:** total hip arthroplasty, fluoride cement, stem fixation, radiostereometric analysis, periprosthetic BMD.

Addition of growth hormone, bioglass, and fluoride to acrylic bone cement has been done to improve the interface and reduce the risk of prosthetic loosening. So far, these so-called bioactive cements have mainly been studied in the laboratory. One of these cements containing fluoride is commercially available and has performed well in preclinical evaluations [1,2]. Sodium fluoride has a double action on the bony tissue. First, a biochemical effect is achieved by bonding to the hydroxyapatite in the bone mineral structure forming fluorapatite [3,4]. Compared with hydroxyapatite, this substance is more stable because of increased resistance to osteoclastic resorptions [5,6]. Second, a biologic effect is achieved by a direct activity on the osteoblasts, whose differentiation and proliferation are stimulated [7,8], resulting in increased volume of the bony trabeculae [9-11].

Histological studies in the rabbit comparing low-temperature curing cement with and without addition of fluoride have shown activation of osteoblasts and increased volume of bone matrix [2]. If these experimental results are reproducible in the clinical situation, addition of sodium

From the Department of Orthopaedics, Sahlgrenska University Hospital, Göteborg, Sweden.
Submitted June 12, 2003; accepted December 16, 2004.
No benefits or funds were received in support of the study.
Reprint request: Georgios Digas, MD, Department of Orthopaedics, Institute of Surgical Science, Sahlgrenska University Hospital, Göteborg University, S-41345 Göteborg, Sweden.

0883-5403/05/1906-0004$30.00/0
doi:10.1016/j.arth.2004.12.056

Table 1. Patient Data and Harris Hip and Pain Scores

	Cemex-F	PALACOS
Men/women	9/35	10/36
Age	69 (41-79)	71 (31-86)
Primary/ secondary arthrosis	23/24	25/25
Weight (kg)	72 (45-107)	67 (38-108)
Harris hip score		
Total		
Preoperative	35 (9-78)	37 (7-78)
2 y	93 (48-100)	95 (54-100)
Difference 0-2 y	49 (−11 to 73)	48 (19-78)
Pain		
Preoperative	10 (0-30)	10 (0-30)
2 y	44 (10-44)	44 (30-44)
Difference 0-2 y	30 (−10 to 44)	30 (10-44)

Median (range). There were no significant differences between the groups ($P > .10$, Mann-Whitney U test).

fluoride to bone cement may speed up the early formation of bone at the interface and thereby improve the fixation and to a certain extent decrease the loss of bone mineral in the proximal femur after total hip arthroplasty (THA). Thus, addition of fluoride to acrylic bone cement would be one way to improve the quality of the bone-cement interface. We designed a randomized study to compare a fluoride-containing cement (Cemex-F) with a standard bone cement (Palacos with gentamicin).

Patients and Methods

Ninety patients (97 hips) with median age 70 (31-81) years and weight 69 (38-108) kg on our waiting list for THA accepted to participate (Table 1). All types of preoperative diagnoses were included. The choice of fixation was stratified based on age (≤55/>55 years), sex, diagnosis (primary arthrosis, inflammatory arthritis/long-term cortisone treatment, sequela after femoral neck fracture), and bone quality according to preoperative dual-energy x-ray absorptiometry (DEXA) measurements (less or equal vs higher bone mineral density [BMD] than age-matched controls). The last variable was excluded from the stratification protocol in patients with remaining osteosynthesis in their hip. A software was used for stratification and randomization [12]. The stratification was designed to as far as possible create 3 main groups of approximately equal size (2 cemented groups and 1 hybrid group). In the stratification procedure, the patients randomly received either 1 of 2 all-cemented alternatives. These 2 alternatives were fluoride cement (Cemex-F, Tecres SpA, Italy) or Palacos R with gentamicin cement (Schering Plough, Heraeus Kulzer, Wehrheim, Germany) using the same types of cement for both components (Table 2). If the patients were randomized to the hybrid group, the fixation of the femoral component was again randomized to either of 2 cements.

Reflection all-polyethylene cups (Smith & Nephew, USA) were used for cemented and porous press-fit Trilogy cups (Zimmer, Inc, Warsaw, Ind, USA) with tricalcium/hydroxyapatite coating for uncemented fixation. All patients received Spectron stems (Smith & Nephew). This straight stem is made of cobalt chromium alloy. Its proximal third is grit-blasted (Ra: 2.8 μm). The distal part is smoother (Ra: 0.7 μm), and a centralizer is attached to the tip of the stem. Twenty-eight–millimeter femoral heads made of cobalt chromium were used in all but 3 hips, which received heads made of zirconium. None of the bilaterally operated patients received the same cement on both sides. The local ethical committee approved the study. Eleven surgeons were involved working in 1 joint arthroplasty unit and all with great experience in hip arthroplasty.

Table 2. Composition of the Bone Cements

	Cemex Fluoride		Palacos Gentamicin	
Liquid				
Monomer	Methylmethacrylate	98.2%	Methylmethacrylate	98%
Accelerator	*N,N*-dimetyl-*p*-toluidine	1.8%	*N,N*-dimetyl-*p*-toluidine	2.0%
Stabilizing agent	Hydroquinone	75 ppm	Hydroquinone	60 ppm
Color	–		Chlorophyllin	0.4 mg
Powder				
Polymer	Polymetylmethacrylate	85.0%	Poly(methylacrylate/methyl methacrylate)	85.2%
Contrast medium	Barium sulfate	6.0%	Zirconium oxide	11.8%
Initiator	Benzoyl peroxide	3.0%	Benzoyl peroxide	1.0%
Antibiotics	Sodium fluoride	6.0%	Gentamicin sulfate (0.55-g base)	2.0%
Liquid/powder ratio		27/73		30/70

ppm: Parts per million.