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Original Article

Preparation of the Femoral Bone Cavity for Cementless Stems: Broaching vs Compaction. A Five-Year Randomized Radiostereometric Analysis and Dual Energy X-Ray Absorption Study

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ABSTRACT

Background: Short-term experimental and animal studies have confirmed superior fixation of cementless implants inserted with compaction compared to broaching of the cancellous bone.
Methods: Forty-four hips in 42 patients (19 men) were randomly operated using cementless hydroxyapatite-coated Bi-Metric stems. Patients were followed with radiostereometric analysis at baseline, 6 and 12 weeks, 1, 2, and 5 years, and measurements of periprosthetic bone mineral density at baseline, 1, 2, and 5 years. Complications during the study period and clinical outcome measures of Harris Hip Score were recorded at mean 7 years (5-8.8) after surgery.
Results: Absolute migrations of medio/lateral translations between the broaching group and the compaction group of mean 0.14 mm (standard deviation [SD] 0.10) vs mean 0.30 mm (SD 0.27) ($P = .01$) at 1 year, and of mean 0.13 mm (SD 0.10) vs 0.34 mm (0.31) ($P = .01$) at 5 years were different. Absolute valgus/varus rotations of mean 0.12° (SD 0.13°) in the broaching group were less than mean 0.35° (0.45°) in the compaction group ($P < .01$) at 1 year, but at 5 years no difference was observed ($P = .19$). Subsidence and retroversion were similar between groups at all follow-ups ($P > .13$). The compaction group had significantly less bone loss than the broaching group in Gruen zone 3 (distal-lateral to the stem) at 1 and 5 years. No further differences in bone mineral density changes were found between groups up to 5 years after surgery. Complications throughout the period and clinical outcome measures of Harris Hip Score were similar at 7 years (5-8.8) after surgery.
Conclusion: We found increased migration when preparing the bone with compaction compared with broaching in cementless femoral stems.

Survival rates in cementless femoral stems of modern design have shown promising long-term results [1-5]. In Denmark, approximately 121.000 primary total hip arthroplasties were performed from 1995 to 2012, and of the implants used in 2012, more than 2 out of 3 were cementless [6]. Factors which may affect the long-term results and favor periprosthetic bone remodeling involves the following: immediate primary fixation achieved at the time of implantation; initial and ongoing bone ingrowth into the implant surface; implant designs; materials; and coatings [7,8]. When primary fixation do not provide a sufficient stability, the implant will migrate inside the bone and a fibrous membrane will form between the bone and the implant surface [9]. Femoral bone cavity preparation can be done with conventional broaching technique where the cancellous bone is partly removed by the toothed broaches during preparation of the femoral bone cavity. In contrast, an alternative bone preparation technique, compaction, sequentially compresses the existing cancellous bone using increasing sizes of smooth tamps [10]. The compaction technique has proven some advantages in a canine study using cylindrical implants; it

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gives a more dense bone-shell around the implant and results in a "spring-back effect" of the compacted bone, which may increase implant fixation by a mechanical bone-implant interlock mechanism, and by biological mechanisms providing a better bony scaffold for the essential bone ingrowth into the implant surface [11]. Furthermore, the compaction technique has demonstrated enhanced primary fixation and increased periprosthetic bone mineral density (BMD) in short-term experimental *in vitro* and *in vivo* animal studies [10,12-16]. However, some potential disadvantages have also been described; human cadaver studies showed that bone preparation using smooth tamps involved a greater risk of femoral fractures than using sharp rasps [17,18]. Also, compression of cancellous bone could lead to microfracturing and breakage of trabeculae, which could result in nonvital periprosthetic bone and hence to a loss of implant fixation [16,19].

No human *in vivo* studies have investigated the potential advantages and disadvantages of the compaction technique in comparison to the broaching technique. The purpose of this 5-year prospective randomized clinical trial was to compare femoral stems implanted by the 2 bone preparation techniques: broaching vs compaction of the cancellous bone. We tested 3 hypotheses: (1) compaction of the cancellous bone provide superior stem fixation than broaching; (2) compaction of the cancellous bone increase the periprosthetic BMD more than broaching; and (3) compaction of the cancellous bone does not increase the risk of intraoperative femoral fractures.

Materials and Methods

Design and Patients

Between October 2001 and November 2005, 44 hips in 42 patients (19 men) received cementless hydroxyapatite (HA)-coated Bi-Metric stems (Biomet, Inc). Patients were randomized to bone preparation of the femoral cavity by broaching ($n = 22$) or compaction technique ($n = 22$) (Fig. 1, Table 1).

Randomization was performed by a computer software, and consisted of block randomization using sealed envelopes in blocks of 10 patients. The patients were positioned at the operation table before the envelope was drawn. All patients were blinded for the used operation technique. The technicians who performed the radiostereometric analyses (RSAs) and the dual energy x-ray absorption (DXA) analyses were also blinded.

Inclusion criteria were symptomatic and radiographically verified osteoarthritis of the hip, age between 18 and 70 years, and sufficient bone quality to allow insertion of a cementless femoral stem (assessed by preoperative radiographs and by intraoperative evaluation). Exclusion criteria were severe bone deformities unsuitable for the use of the Bi-Metric stem, metabolic and inflammatory bone disorders (including rheumatoid arthritis), neuromuscular or vascular diseases of the legs, regular systemic glucocorticoid treatment, active cancer or chemotherapy treatment, women planning pregnancy, chronic infectious diseases, and diagnosed osteoporosis.

Operations were performed at either Aarhus University Hospital ($n = 36$) or Farsoe Hospital ($n = 8$), but all follow-up examinations were performed at Aarhus University Hospital.

Patients were followed with RSA at baseline (within 1 week after surgery), 6 and 12 weeks, 1, 2, and 5 years after surgery to examine migration of the femoral stem. Furthermore, DXA scans were performed postoperatively and at 1, 2, and 5 years after surgery for measurements of periprosthetic BMD. Supplementary clinical outcome measures of Harris Hip Score (HHS) [20] and complications throughout the observation period were obtained 7 years (range 5-8.8) after surgery.

All examinations were designed and carried out in compliance with the Helsinki II declaration, laws on personal data protection, and laws on patient's rights. All patients gave informed consent before entering the study. The study was approved by the Central Denmark Region Committee on Biomedical Research (Journal no. 2000065; issue date January 4, 2000) and by the Data Protection Agency (Protocol no. 1-16-02-62-09). The project was registered with www.clinicaltrials.gov (Unilateral project sub-study NCT00318396).

Surgery and Prosthesis

Five experienced orthopedic hip surgeons undertook the operations using a posterolateral approach. Intraoperatively, the hip surgeon first ensured that the bone quality was satisfactory for a cementless procedure and next randomized the patient to either broaching or compaction femoral bone preparation using consecutively numbered envelopes. All patients received cementless Bi-Metric proximal HA-coated femoral stems (Biomet, Inc, Warsaw, IN). Patients operated at Aarhus University Hospital received cementless Mallery Head HA-coated shells (Biomet, Inc) with an Acrom Ringlock ultra-high-molecular-weight polyethylene liner. Patients operated at Farsoe Hospital received cementless Trilogy fiber-mesh shells (Zimmer, Inc, Warsaw, IN) with a longevity ultra-high-molecular-weight polyethylene liner. A chrome-cobalt 28-mm femoral head was inserted in all patients. All patients were instructed to walk with 40 kg weight bearing for the first 6 weeks after surgery and thereafter free loading and activity were allowed.

Instruments and Femoral Bone Preparation Technique

Instruments for a cementless primary hip arthroplasty were used (Bi-Metric hip; Biomet, Inc). The proximal half of the toothed broaches had a diamond-shaped surface, and the remaining distal part had a smooth surface. The tamps only had a smooth surface. The corresponding broach and tamp sizes had the same base volume as the broaches, but without the teeth (Fig. 2).

Radiostereometric Analysis

For RSA measurements, 8-10 tantalum markers (1 mm) were inserted into the greater and lesser trochanteric region during surgery. Furthermore, all stems were modified with 3 small 1-mm marker towers (tantalum beads; Wennbergs Finmek, Gunnilse, Sweden) distributed with 1 marker tower distally on the tip of the stem, 1 marker tower proximal-medial (calcar region), and 1 marker tower proximal-lateral (shoulder of the stem). RSA stereoradiographs were obtained using a uniplanar Aarhus setup with the patient in standard position: supine, body parallel with the examination table, and the big toes pointing straight up and the calibration box placed under the examination table. Two fixed radiographic tubes with a 40° angle between them were positioned above the patient. Model-based RSA version 3.2 (RSAcore, Leiden, The Netherlands) was used to calculate the implant migration. Implant migration was assessed on all follow-up stereoradiographs using the postoperative stereoradiograph as the reference. Stereoradiographs were analyzed using elementary geometrical shapes: large-marker hip model. However, stereoradiograph series of 4 patients (2 broaching and 2 compaction) were analyzed using an elementary geometrical shape hip stem model due to technical issues with missing stem markers [21]. All RSA analyses of implant migrations were performed by 2 experienced RSA technicians. Translations (implant movement along the axes) were expressed as x-translations (medial/lateral direction), y-translations (proximal/distal direction), and z-translations