# Section III: Quality Issues

# Pelvic Periprosthetic Bone Mineral Density Measurement Around Cemented vs Cementless Acetabular Prostheses

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## Abstract

We compared the short-term precision of pelvic periprosthetic bone mineral density (BMD) measurement around a cementless acetabular prosthesis (n = 29) vs a cemented all-polyethylene acetabular prosthesis (n = 19) in patients after total hip arthroplasty. Two dual-energy x-ray absorptiometry scans of the pelvis were made on the same day in each subject with subject repositioning between scans and analyzed independently with a 4-region of interest model. Precision was expressed as coefficient of variation (CV%). The measured BMD around the cemented prostheses was greater than the cementless prostheses p < 0.004, all analyses). The net CV for pelvic BMD measurements around the cementless prosthesis was 1.9% vs 3.6% around the cemented prosthesis (*F*-test p < 0.001). The CVs of individual regions of interest was between 2.8% and 4.8% for the cementless prosthesis vs 4.4% to 8.4% for the cemented prosthesis (*F*-test; p < 0.05, all comparisons). Prospective studies would require 57 subjects to detect a 10% change in net pelvic BMD around a cementless prosthesis and 122 to detect a similar change around a cemented prosthesis with 90% power and with an alpha error of 0.05. In conclusion, the precision of pelvic BMD measurements made around cementless prostheses are better vs those for cemented prostheses. Dual-energy x-ray absorptiometry studies of cemented prosthesis require approximately double the number of subjects vs cementless prostheses to achieve a similar level of power.

Key Words: BMD; DXA; pelvis; precision; total hip arthroplasty.

### Introduction

Dual-energy x-ray absorptiometry (DXA) is the tool of choice for measuring longitudinal change in bone mineral density (BMD) around femoral prosthetic components after total hip arthroplasty (THA) (1-3). Although DXA is an important tool to evaluate strain-adaptive remodeling changes around femoral prosthetic designs (4,5), limited data exist regarding the measurement of postoperative change in BMD around pelvic prosthetic components (6).

Instrument precision is an important characteristic in serial measurements as it informs sample size estimates in longitudinal studies and affects the ability of the measurement tool to detect change both between groups in randomized control

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studies and within individuals as a postoperative assessment tool. We have previously described and validated a 4-region of interest (ROI) model that uses DXA to measure pelvic periprosthetic BMD around cementless prostheses. However, the precision of DXA measurements is affected by the method of implant fixation that may involve the use of radio-opaque poly-methyl-methacrylate bone cement. At the proximal femur bone, cement increases artificially the measured BMD by 20%-30% and may mask true longitudinal changes in BMD (1,7). Manual exclusion of cement from analysis ROIs adversely affects measurement precision (8) and thus also impacts on sample size estimates for prospective study. Although these effects have been characterized previously at the femoral site, little is known about the impact of cement at the pelvic site on estimates of precision and its impact on measured BMD and sample size estimates for prospective study.

The aim of this study was to examine the effect of bone cement on mean pelvic BMD measurements and the global precision of pelvic periprosthetic BMD measurements after insertion of a cementless, acetabular metal shell vs a cemented all-polyethylene acetabular prosthesis. Using these data, we constructed approximate sample size models for prospective comparative studies.

#### Methods

The datasets used in this study comprised serial DXA scans of the pelvis taken on the same day after a period of repositioning, as previously detailed (6,8). In brief, subjects with uncomplicated primary or secondary osteoarthritis affecting the hip undergoing unilateral THA with a cemented femoral component were recruited. Subjects with a history of metabolic bone disease, inflammatory arthritis, and patients who had taken pharmacological doses of oral steroids, hormonereplacement therapy, tamoxifen, calcium, or vitamin D during the previous year or had ever received bisphosphonate therapy were excluded. The subject recruitment for these studies predated the clinical use of strontium ranelate or parathyroid hormone for the treatment of osteoporosis. All subjects provided informed written consent before participation in the studies, which were approved by a local research ethics committee.

The cementless pelvic component group comprised 29 subjects (17 men and 12 women, Table 1) who had previously undergone hybrid THA using a cementless, hemispherical, press-fit, titanium acetabular prosthesis with a conventional polyethylene liner (Plasmacup, BBraun Ltd, Sheffield, UK) and a cemented femoral prosthesis (Exeter prosthesis, Stryker Ltd, Staines, UK; or TPS prosthesis, DePuy Synthes, Leeds, UK). The cemented pelvic component group consisted of 19 (3 men and 16 women) subjects who had previously undergone fully cemented THA with an all-polyethylene Charnley LPW (DePuy Synthes) acetabular prosthesis and a cemented femoral prosthesis (Exeter or TPS).

#### Scan Acquisition

Scans were acquired with the same Hologic QDR 4500 A fan bean densitometer (Hologic, Waltham, MA) via the Hologic "metal removal hip" scanning mode that has a point resolution of 0.06 mm and line spacing of 0.11 mm. Subjects were examined in the supine position with the legs extended and the foot on the affected side held in a neutral position by a Hologic foot-positioning device. Pelvic scans were acquired beginning 2 cm below the lower border of the inferior pubic ramus using a field width of 15 cm and continued proximally to 2 cm above the lower limit of the sacroiliac joint. The scans were centered such that the acetabular prosthesis lay in the center of the field (8). Serial scans were acquired following subject mobilization and repositioning.

#### Scan Analysis

All scans were analyzed independently by the same investigator (RLJ) using Hologic QDR metal removal software (version 8) using a 4-region of interest (ROI) model previously described (Fig. 1) (8).

#### Statistical Analysis

Any measured changes in BMD between serial scans were assumed to have arisen through measurement error, as both scans for each subject were acquired on the same day. Precision was calculated for each periprosthetic region of interest and for the "net" region that represented a global measure for the combined regions and was expressed as coefficient of variation (CV%) and as least significant change (LSC%) via the use of standard formulae: CV% was calculated as follows, where  $\delta$  = standard deviation of the paired measurements and  $\mu$  = mean of all the measurements:

$$\mathrm{CV}\% = 100 \times \frac{\left(\delta/\sqrt{2}\right)}{\mu}$$

Least significant change (LSC%) is the minimum magnitude of measured percentage change that is not caused by measurement errors, and calculated as follows:

#### $LSC\% = CV\% \times 2.8$

The illustrative power calculations based on these CV measurements were made as follows: Where precision was

Table 1   Characteristics of Study Subjects			
Characteristic	Cementless pelvic prosthesis $(n = 29)$	Cemented pelvic prosthesis ( $n = 19$ )	<i>p</i> Value between groups
Age at surgery, yr <sup>a</sup>	51.3 (9.8)	71.6 (6.0)	0.037
Months postoperative <sup><i>a</i></sup>	6.3 (3.0)	24.6 (1.4)	0.001
Sex, female/male ratio <sup>b</sup>	12:17	16:3	0.006
THA side, right:left <sup>b</sup>	15:14	9:10	1.000
Height, m <sup>a</sup>	1.73 (0.08)	1.63 (0.10)	0.821
Weight, kg <sup>a</sup>	85.4 (15.7)	76.0 (16.3)	0.799
BMI, kg/m <sup>2a</sup>	28.4 (4.8)	28.7 (5.5)	0.820

Note: Data are mean (SD).

Abbr: BMI, body mass index; THA, total hip arthroplasty.

<sup>*a*</sup>Analysis is cementless vs cemented prosthesis groups by *t*-test.

<sup>b</sup>Analysis is cementless vs cemented prosthesis groups by  $\chi^2$  test.

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