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Cancellous and cortical bone mineral density around an elastic press-fit socket in total hip arthroplasty

A prospective 2-year follow-up study using quantitative CT BMD measurements in 25 patients

Dean F M PAKVIS [1], Petra J C HEESTERBEEK [2], Marianne SEVERENS [2], and Maarten SPRUIT [1]

[1] Department of Orthopaedic surgery, Sint Maartenskliniek; [2] Sint Maartenskliniek Research, Nijmegen, the Netherlands.
Correspondence: d.pakvis@ocon.nl

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Background and purpose — The acetabular component has remained the weakest link in hip arthroplasty for achievement of long-term survival. One of the possible explanatory factors for acetabular failure has been acetabular stress shielding. For this, we investigated the effects of a cementless elastic socket on acetabular bone mineral density (BMD).

Patients and methods — During 2008–2009, we performed a single-center prospective cohort trial on 25 patients (mean age 64 (SD 4), 18 females) in whom we implanted a cementless elastic press-fit socket. Using quantitative BMD measurements on CT, we determined the change in BMD surrounding the acetabular component over a 2-year follow-up period.

Results — We found a statistically significant decrease in cancellous BMD (–14% to –35%) and a stable level of cortical BMD (5% to –5%) surrounding the elastic press-fit cup during the follow-up period. The main decrease was seen during the first 6 months after implantation. During the second year, cancellous BMD showed a further decrease in the medial and lower acetabular regions.

Interpretation — We found no evidence that an elastic press-fit socket would prevent acetabular stress shielding during a 2-year follow-up.

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Sufficient bone stock is essential for reconstructive hip surgeons when performing revision hip surgery. On the femoral side of hip arthroplasty, several authors have described a decline in bone stock due to femoral bone remodeling following the implantation of a femoral stem (Engh et al. 1993, 2003). Femoral stress shielding has been accepted as a potential failure mechanism, so engineers have adapted the femoral stem design to prevent this phenomenon.

Although the acetabular component is deemed to be the weakest link in total hip arthroplasty, only a few authors have described, discussed, and supported the idea of changes in bone morphology after the implantation of an acetabular component (Schmidt et al. 2002, Mueller et al. 2007a, 2007b, Pitto et al. 2008, Meneghini et al. 2010). In a native hip joint, the stress transfer passes through the supero-medial acetabular bone, but finite-element models have shown different load patterns after the implantation of cemented or cementless sockets (Huiskes 1987, Levenston et al. 1993).

Especially in cementless press-fit sockets, the main load transfer is at the peripheral rim of the acetabulum. This results in unloading of the medial and supero-medial acetabular bone and a decline in bone density according to Wolf's law. The unloading of bone and decline in bone density poses a risk of aseptic loosening (Huo et al. 2008). As a solution to this problem, Levenston et al. (1993) advocated the development of sockets with more circumferential load transfer onto the acetabular bone. Meneghini et al. (2010) showed that when using an implant with an elastic modulus closer to human bone, there is better load transfer onto the surrounding bone, resulting in less stress shielding and acetabular bone of higher quality.

Polyethylene is a material with an elastic modulus close to that of human bone. This feature of polyethylene and the theory of optimal transfer of stress onto the surrounding bone formed the basis of the development of the Robert Mathys (RM) cementless polyethylene titanium coated socket.

We evaluated the effect of press-fit cementless sockets with low elastic modulus on the changes in acetabular bone mineral density using quantitative CT BMD measurements. We hypothesized that the elastic modulus of this cementless press-fit socket would lead to a physiological stress transfer that reduces the effect of stress shielding.

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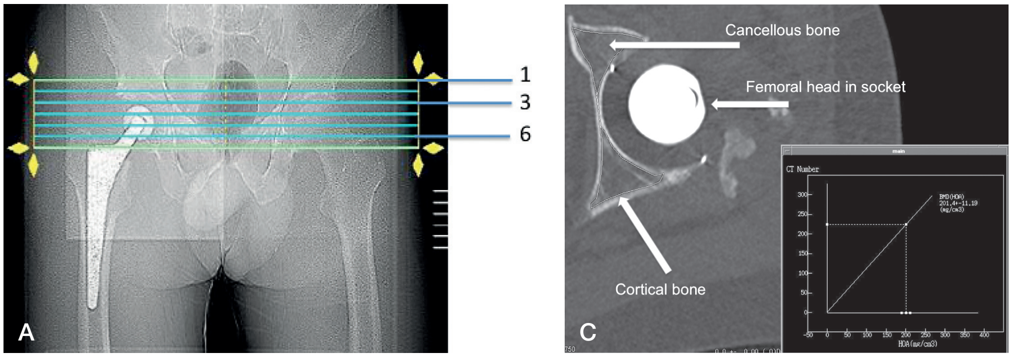
Figure 1. RM cementless press-fit socket (Mathys AG, Bettlach, Switzerland).



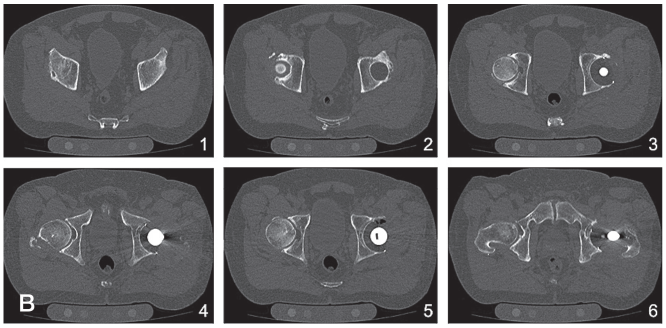


Figure 2. A. Scanogram. B. Sequential CT slices surrounding the acetabular component. C. measurement of cancellous BMD. In total, 6 axial scans were performed starting 10 mm above the socket, parallel to the horizontal teardrop line.

Patients and methods

The inclusion for this single-center, prospective cohort study was conducted between 2008 and 2009 at Sint Maartenskliniek, Nijmegen, the Netherlands. The inclusion criteria were having unilateral primary osteoarthritis, being on the waiting list for total hip replacement, BMI < 36, age between 18 and 70 years, and having given written informed consent. Patients with secondary osteoarthritis, previous acetabular surgery, pregnancy, disorders of bone metabolism, and anti-osteoporotic medications were excluded from the study.

Surgical technique

2 senior orthopedic surgeons performed all the operations. Prophylactic third-generation cephalosporins were given to all patients. All arthroplasties were performed using a posterolateral approach in a clean-air operating theater with laminar flow. Reaming of the acetabulum was undersized by 1.6 mm to achieve adequate press-fit. The RM press-fit socket (Mathys AG, Bettlach, Switzerland) is an all-polyethylene socket with a titanium-particle coating. The socket has a hemispherical monoblock design with a flatted pole and is made from nitrogen-radiation sterilized UHMW (ISO 5834-1+2) polyethylene (Figure 1). A cementless, grit-blasted, titanium alloy (Ti6Al4V ISO 5832-3) CLS Spotorno femoral stem (Zimmer, Warsaw, IN) was used in all cases. In all patients, a 32-mm ceramic (Al_2O3) head was used.

All patients were mobilized on the first postoperative day, and immediate full weight bearing was allowed using crutches during the early postoperative rehabilitation period, supervised by a physiotherapist. All patients received nadoparine for 6 weeks as thrombosis profylaxis. The patients were followed for 2 years.

Measurement of bone mineral density

During the first postoperative week, a baseline computed tomography (CT) scan was carried out. Follow-up CT images were taken during the outpatient clinic visits at 6 and 24 months. We used a conventional CT scanner (Toshiba RXL Aquilion 32) with a standardized scanning protocol (135 kV, 200 mA, 1–2 mSv) using 1-mm slices at 10-mm intervals (Figure 2). In total, 6 axial scans were performed starting 10 mm above the socket. The contralateral side was used as a control. One author (DP) determined the region of interest separately for cancellous and cortical bone at each level, and performed BMD measurements using specialized BMD software (Toshiba BMD software) (Figure 2). A phantom containing 5 defined calcium hydroxyapatite markers, positioned below the patient, was used to calibrate and measure the cortical and cancellous BMD values (mg/cm^3).

The BMD was determined in all 6 slices on the prosthetic side for all tomography scans (baseline scan, 6 months, and 24 months), and in 3 slices (1, 3, and 6) on the control side for the baseline scan and 24-month follow-up.

Clinical outcome

The Harris hip score (HHS) and the Oxford hip score (OHS) were determined preoperatively and at each clinical follow-up (2 months, 6 months, 12 months, and 24 months). Pain scores were measured using a visual analog scale (VAS). All adverse events and complications were recorded and analyzed, to monitor the safety of the technique used.

Statistics

Normality of BMD was checked with a Shapiro-Wilk test and visually inspected with Q-Q plots. To test for changes in BMD in the different slices over time, repeated-measures ANOVAs with the factors SLICE x TIME were performed on

Table 1. Study demographics

No. of patients	25
Sex distribution, M/F	7/18
Age, mean (SD) (range)	64 (4) (56–71)
BMI, mean (SD) (range)	27 (3.1) (23–36)

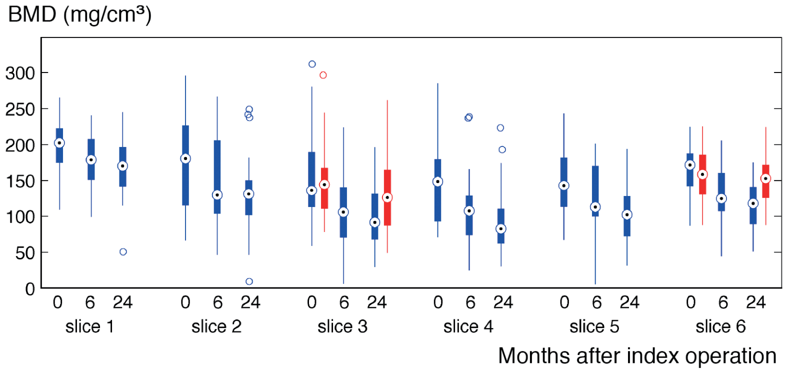


Figure 3. Box plots of the cancellous bone mineral density in the 6 slices for the baseline, 6-month, and 24-month follow-up measurements. Blue bars indicate the BMD in the prosthetic hip; red bars indicate the BMD in the contralateral hip. The median is indicated by the central circle, thick lines are interquartile range, and the thin lines are total range excluding outliers, which are indicated by circles.

Table 2. Changes in BMD (%) relative to immediately postoperatively

	6 months postoperatively	24 months postoperatively	
	Prosthetic side	Prosthetic side	Control side
Cancellous bone			
1	−9.6	−14	
2	−17	−26	
3	−29	−35	−12
4	−23	−32	
5	−16	−31	
6	−20	−31	−5
Cortical bone			
1	−1	−3	
2	−4	−5	
3	−3	−4	5
4	−1	0	
5	0	5	
6	−5	−1	0

the absolute BMD data for both cancellous bone and cortical bone on the side with the prosthesis. To evaluate differences in BMD changes between the prosthetic side and the control side, separate ANOVAs with the factors SIDE x SLICE x TIME were performed on the BMD values of both cancellous and cortical bone on the slices that were available on the control side. If appropriate, post hoc analyses on significant main and interaction effects were performed with Bonferroni correction for multiple comparisons.

Changes in clinical measures (OHS, HHS, and VAS pain score) over time were evaluated with a non-parametric Friedman test, and post hoc analyses were performed with a Wilcoxon signed-rank test with Bonferroni correction.

The limits of agreement of the BMD measurement (bias and precision) were calculated using Bland and Altman's statistical method in 10 random samples, and these were 57 mg/cm^3 and 81mg/cm^3, respectively, for cancellous and cortical bone. Statistical analyses were performed using SPSS (version 19.0.0) and MATLAB R2010b, with $p < 0.05$ being considered statistically significant.

Ethics

This study was performed in compliance with the Declaration of Helsinki for medical research involving human subjects. The study was approved by the local ethical committee for Arnhem-Nijmegen (reg. no 2007294 24-01-2008).

Results

25 patients were enrolled in the study (Table 1). Due to difficulties in proper CT scan alignment in 1 patient, the slices were not comparable during analysis. This patient was therefore excluded from further analysis.

Because patients were aligned based on the prosthetic side, slice alignment for the control side was not always perfect. Due to this imperfect alignment, we excluded the baseline or 24-month follow-up measurement of the most cranial slice (slice no. 1, 10 mm above the socket) on the control side in 10 patients during analysis.

Cancellous bone

A decrease in BMD over time was seen in the cancellous bone in all 6 slices on the prosthetic side (Figure 3). At 6-month follow-up, the decrease was between −9.6% and −29% relative to the baseline BMD values (Table 2). At 24-month follow-up, BMD decreased even further to levels between −14% and −35%. These effects were supported by a statistically significant main effect of time ($p < 0.001$); post hoc tests showed that BMD at 6- and 24-month follow-up was lower than at baseline. Furthermore, BMD at the 24-month follow-up was lower than at the 6-month follow-up.

BMD was different between slices at all time points (baseline, 6 months, and 24 months) ($p < 0.001$). The BMD in the most cranial slice (Figure 2) was higher than in the other slices. BMD in slice 2 was higher than in slices 3, 4, and 5.

For the comparison of BMD in the prosthetic side and in the control side, slices 3 and 6 were used. In the baseline measurement, there was no difference between BMD on the prosthetic side and control side, whereas in the 24-month follow-up measurement, the control BMD was higher than the BMD

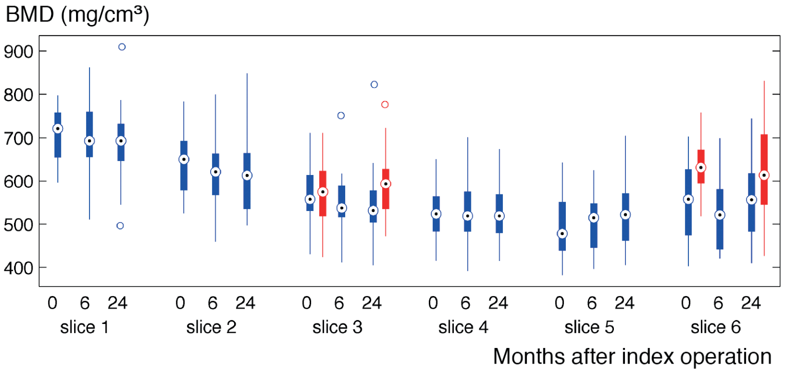


Figure 4. Box plots of the cortical bone mineral density in the 6 slices for the baseline, 6-month, and 24-month follow-up measurements. Blue bars indicate the BMD on the prosthetic side and red bars indicate the BMD on the control side.

on the prosthetic side (p < 0.001). This could be explained by an interaction between side and time (p < 0.001). On both the prosthetic side and the control side, the BMD decreased over time (p < 0.001 and p = 0.01, respectively).

Cortical bone

In the cortical bone on the prosthetic side, changes over time were between 0.2% and –5.4% at 6-month follow-up and between 4.8% and –4.9% at 24-month follow-up (Figure 4 and Table 2). The 6 slices showed different patterns of changes in BMD over time, indicated by an interaction between slice and time (p = 0.03).

However, in all slices BMD was not statistically significantly different at the 3 times of measurement. In the comparison of BMD in the prosthetic and control slices, there were interactions between slice, side, and time (p = 0.04). Therefore, changes were evaluated per slice: in slice 3, in the baseline BMD the prosthetic and control BMD values were similar. In contrast, in the 24-month follow-up measurement, BMD on the control side was higher than on the prosthetic side (p = 0.004). In slice 6, the control side showed a higher BMD value than the prosthetic side at baseline and also after 24 months (p < 0.001).

Clinical results

Hip function improved over time, as assessed by both the OHS and the HHS. Post hoc analysis indicated that hip function improved after surgery and during recovery (Table 3). After 6 months, hip function stabilized. Furthermore, VAS pain scores decreased over time. Post hoc test revealed a decrease in pain after surgery (Table 3). There were missing values for HHS in 2 patients, for OHS in 4 patients, and for VAS in 3 patients.

Discussion

In this prospective cohort study, we found a decrease in cancellous BMD and a stable level of cortical BMD surrounding the elastic press-fit cup during the follow-up period. The main decrease was seen during the first 6 months after implantation. Because the mean acetabular BMD showed a decrease in the peri-acetabular bone during follow-up, our study hypothesis could not be confirmed.

The main reason for acetabular revision surgery is aseptic loosening, which can be viewed as the endpoint of several pathways leading to failure. Inadequate primary fixation, reaction to wear debris, increased joint fluid reaction (Fahlgren et al. 2010), immunological reactions, (Huber et al. 2009) and acetabular stress shielding are possible mechanisms resulting in aseptic loosening of the socket.

Although there are contradictory views on the relevance of acetabular stress shielding (Moore et al. 2006, Stepniewski et al. 2008, Huo et al. 2008, Meneghini et al. 2010, Kress et al. 2011), the most challenging issue for hip revision surgeons is adequate management of substantial acetabular bone loss. In patients with high demands and long-term expectations especially, stress shielding may be of clinical relevance (Sporer et al. 2005, Digas et al. 2006) and result in peri-acetabular bone adaptation.

Quantitative CT measurements are capable of differentiating between cancellous and cortical bone (Schmidt et al. 2000, Pitto et al. 2007). Because of the expense and the radiation, it has only been used in a few studies to quantify cortical and cancellous bone adaptation in acetabular bone (Meneghini et al. 2009, Mueller et al. 2009, Kress et al. 2011).

In 2 studies (Meneghini et al. 2009, Mueller et al. 2009), a reduction in BMD was found after implantation of different

Table 3. Clinical scores. Values are median (range)

	Preoperative	2 months postoperative	p-value [a]	6 months postoperative	p-value [a]	12 months postoperative	p-value [a]	24 months postoperative	p-value [a]
OHS	24 (15–34)	34 (14–47)	0.04	45 (11–48)	< 0.001	47 (22–48)	< 0.001	45 (19–48)	< 0.001
HHS	61 (39–81)	77 (47–100)	0.03	95 (32–100)	< 0.001	98 (65–100)	< 0.001	96 (57–100)	< 0.001
VAS	50 (6–87)	13 (0–50)	0.001	0 (0–80)	< 0.001	0 (0–70)	< 0.001	0 (0–70)	< 0.001

[a] p-values are derived from the comparison with preoperative values, with the Wilcoxon signed-rank test.

types of acetabular components. In both studies, the more flexible implant showed a smaller reduction in BMD during the follow-up period. The press-fit socket used in our study has an elasticity modulus comparable to that of bone. The properties of this construct permit transmission of physiological stress onto the acetabular bone behind the socket, thus reducing the possible effect of stress shielding. With this flexible socket, we found the largest decrease in cancellous BMD in the region medial to the socket (35%).

We observed the smallest decrease at the acetabular roof (14%), cranial to the socket and in line with the stress vector crossing the acetabulum, indicating stress transfer along the physiological stress lines. The increased caudal and decreased cranial cortical reaction was similar to the results found by Mueller et al. (2007a) and Kress et al. (2011). The basis of this reaction can be explained by the press-fit implantation of the socket with—in accordance with performed finite-element analysis—the loading of the acetabular cortical rim (Huiskes 1987).

Bone adaptation leading to stress shielding could be a long-term process. The longest follow-up of acetabular stress shielding was published by Kress et al. (2011). A fiber-mesh press-fit socket was implanted and evaluated with BMD measurements over a 10-year follow-up period. The authors anticipated that the loss in BMD would be a continuous process. However, in contrast to the stress-shielding hypothesis, cancellous bone density showed a steady state during the last 7 years of follow-up.

Our data showed a lower decrease in BMD at the end of the 2-year follow-up period. This could possibly indicate a stabilization in acetabular cancellous BMD, especially in the cranial zones surrounding the socket. The cortical BMD appeared to have stabilized at the 2-year follow-up.

On the contralateral side, we also found a decrease in cancellous BMD. Although they were equal preoperatively, after 2 years of follow-up the BMD on the control side was higher than the BMD on the prosthetic side. The explanation for this could be that during recovery, weight bearing is not normal and therefore the implanted socket will change the force distribution—and as a result influence bone density.

We were not able to validate our hypotheses. One possible explanation for the absence of the expected prevention of stress shielding might be that stress transfer onto the surrounding acetabular bone is a multifactorial process which not only depends on the socket elasticity, but may also be influenced by other factors such as socket geometry, hip mechanics, socket position, fixation method, articulation, and patient characteristics.

This study had some limitations. We have reported short-term results on a phenomenon that could be a long-term process. However, as with the bone healing process after fractures (de Jong et al. 2014), short-term quantitative CT measurements are able to provide relevant data on the bone remodeling process.

Due to slice alignment on the prosthetic side, the cranial slice on the control side was missing in some cases. We feel that this limitation was of no consequence for the outcome of the study, because our main focus was the change in acetabular BMD surrounding the socket. In all patients, the slices acquired surrounded the socket and its contralateral counterpart.

Concerns about multiplicity issues and about precision and bias can be raised when using software measuring BMD around acetabular components at a number of levels. ANOVA techniques with a conservative post hoc analysis were chosen to address multiplicity issues as best we could. To reduce error and increase the repeatability factor, 1 investigator performed all BMD measurements.

We assessed the limits of agreement to quantify this bias and precision. In cortical bone, the limit of agreement was larger than the differences found, and in cancellous bone it was around these difference levels. Thus, we cannot exclude that the changes in BMD were actually caused by measurement precision.

However, as mentioned before, the results are in agreement with those of previous studies (Wright et al. 2001, Wilkinson et al. 2001, Field et al. 2006, Mueller et al. 2006, 2007a, 2007b, 2009, Pitto et al. 2008, Meneghini et al. 2010, Kress et al. 2011) and they may represent a true effect.

In summary, we observed a moderate reduction in cancellous BMD and a steady state in cortical BMD 6–24 months after implantation of an elastic cementless monobloc press-fit socket with mechanical properties in line with the elastic modulus of bone. We found no support for the hypothesis that an elastic press-fit socket can prevent acetabular stress shielding. Further follow-up will be necessary to determine the long-term effect of the elastic properties on stress shielding, osteolysis, and socket survival.

The study protocol and further information concerning the study is available through the corresponding author.

DP: main investigator, study design, data analysis, manuscript preparation. PH: statistical analysis, data interpretation, manuscript preparation. MSS: statistical analysis, data analysis, manuscript preparation. MS: study design, senior surgeon, manuscript preparation.

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No competing interests declared.

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