Quantitative CT-assisted osteodensitometry of femoral adaptive bone remodelling after uncemented total hip arthroplasty

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Abstract The aim of this prospective study was to measure bone density changes and to assess adaptive bone remodelling after uncemented total hip arthroplasty with a taper-design femoral component using quantitative computer-tomography-assisted osteodensitometry. This method is able to differentiate cortical and cancellous bone structures. Twenty-seven consecutive patients (29 hips) with degenerative joint disease were enrolled in the study. Serial clinical, radiological and CT-osteodensitometry assessments were performed after the index operation. At the 2-year follow-up, the clinical outcome was rated satisfactory in all hips. The radiological assessment showed signs of osteointegration and stable fixation of all cups and stems. We observed a -17% decrease of cortical bone density and -22% decrease of cancellous bone density in the greater trochanter and femoral neck region. Cortical and cancellous bone density decrease at the level of the lesser

trochanter was -9% and respectively -4% . We observed small changes of cortical bone density in the diaphyseal regions; in contrast, cancellous bone density increased (range 6% to 27%) in the diaphyseal regions. Overall, a trend of bone density recovery was observed throughout the follow-up period. Periprosthetic bone density changes at the 2-year follow-up are suggestive of stable osteointegration with proximal femoral diaphysis load transfer and moderate metaphyseal stress-shielding.

Résumé Le but de cette étude prospective est de mesurer par scanner et ostéodensitométrie la densité osseuse et le remodelage osseux après prothèse non cimentée. Cette méthode permet de différencier les structures osseuses corticales et spongieuses. 27 patients consécutifs (29 hanches) présentant une coxarthrose ont été inclus dans cette étude qui a comporté une analyse radiologique, scanographique et ostéodensitométrie. Pour toutes les hanches à deux ans de suivi post-opératoire, le devenir clinique de ces patients était satisfaisant. La radiologie montrait des signes d'ostéointégration et de fixation stables dans toutes les cupules et pour toutes les pièces fémorales. Nous avons observé une diminution de 17% de la densité corticale et de 22% de la densité de l'os spongieux au niveau du grand trochanter et au niveau du calcar. Il existe également une diminution de la densité osseuse au niveau du petit trochanter tant sur le plan cortical 9% qu'au niveau de l'os spongieux 4% . Nous avons également observé de petites modifications de la densité osseuse corticale au niveau de la région diaphysaire, a contrario nous avons également mis en évidence une augmentation de la densité osseuse de l'os spongieux à ce niveau (de 6 à 27%). Ces différentes modifications osseuses nous permettent, à deux ans de suivi post-opératoire, de penser que l'ostéointégration proximale des éléments prothétiques entraîne un transfert de charge et un stress-shielding métaphysaire modéré.

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Bone loss around the implant can compromise long-term outcomes of total hip arthroplasty (THA) [13]. Bone loss might contribute to the risk of aseptic loosening and may predispose to periprosthetic fractures and to difficulties to obtain stable reconstruction in revision arthroplasty [4]. The degree of bone mineralisation is a decisive parameter of bone quality and correlates to implant and bone stability [7]. Thus, the use of osteodensitometry for the assessment of bone quality can be clinically relevant for patients with osteoporosis and other metabolic bone disorders. Osteodensitometry is particularly important for quantitative monitoring of patients managed with THA using new prostheses with short-term clinical records [8, 9, 13].

Bone density (BD) assessment using dual energy X-ray absorptiometry (DXA) has been used to monitor bone remodelling changes after THA [10, 24, 25]. The major disadvantage of DXA is the inability to differentiate between cortical and cancellous bone.

In previous studies, we presented an innovative in-vivo method of quantitative computer-tomography (qCT)-assisted osteodensitometry that accurately differentiates cortical and cancellous BD changes around the femoral component after THA [12, 16]. The objective of this prospective one-cohort study was to assess femoral bone adaptive remodelling around an uncemented femoral component with a taper design and hydroxyapatite (HA) coating.

Materials and methods

Twenty-nine consecutive patients (32 hips) with degenerative joint disease and without deformity of the proximal femur were enrolled in this study. The criteria for exclusion were age less than 18 years and more than 80 years, refusal to consent, pregnancy, metabolic bone disease, and previous failed THA. All hips were operated on by one surgeon in one institution. The average age of the patients at the index operation was 58 years (range, 30–80 years). There were 16 men and 13 women. The patients received an uncemented THA with a taper-design femoral component coated with HA (Summit; DePuy International, Leeds, UK) and a press-fit titanium cup (Duraloc; DePuy) with alumina-alumina pairing (BioloX, CeramTec, Plochingen, Germany). The Summit stem has a medially rounded, laterally flared proximal cross-sectional geometry with a 3° frontal-plane taper configuration. Its neck-shaft-angle is 130°. The stem is manufactured from a high-strength, low-stiffness forged titanium alloy with metaphyseal HA coating. The diaphyseal portion of the stem is grit-blasted; the surface of its distal end is polished. Postoperatively, patients commenced touch weight bearing for 4–6 weeks and full-weight bearing thereafter. The clinical outcome was assessed using the Harris Hip Score and the Oxford

Hip Score. Serial anterior-posterior and lateral-view radiographs were taken post-operatively, 6 months, 12 months and 24 months after the index operation. Pre-operative radiological bone quality according to the classification of Dorr et al. [2] was rated A in all hips.

Computed tomography scans were carried out on all patients post-operatively, 1 year and 2 years after the index operation. We used a conventional CT scanner (Siemens SomatomPlus; Munich, Germany) and a standardised scanning protocol with 2-mm slice thickness. Serial axial scans were acquired at 10-mm intervals in the diaphyseal region and 5-mm intervals in the metaphyseal region. We analysed five regions of interest (ROI) along the length of the proximal femur (Fig. 1). The scan axis was always adjusted vertical to the axis of the prosthesis determined by the angle of the lateral topogram. An extended CT scale was used for the reconstruction of the images. A synthetic phantom containing a circular sample with defined HA concentration was scanned during every examination for conversion of Hounsfield units (HU) into hydroxyapatite (mgCaHA/ml) equivalents. This operation was required to convert radiological bone density to true bone mineral density.

The CT scans were downloaded onto a dedicated software (CAPPA postOP, CAS Innovations AG, Erlangen, Germany). The scans were automatically evaluated on the basis of an adaptive automatic tracer algorithm that outlined the contour of the outer and inner cortical bone as well as the prostheses. Limited manual interaction was required for the correction of inaccurate segmentation especially due to metal artefacts. Cortical and cancellous BD was separately analysed for both the operated and the non-operated side.

The statistical analysis was carried out using the “R” software package (Version 2.1.1, Vienna, Austria). For all analyses we did one-way ANOVA, using the Levene test to check for equal variance, and the Shapiro-Wilks test to check for normality. Of primary interest was the determination of the average difference between the postoperative, 1-year and 2-year follow-up BD changes for both the cancellous and cortical bone. With this in mind, we averaged the bone slice readings

Fig. 1 The five regions of interest for the CT-assisted osteodensitometry. Region 1 = greater trochanter and neck of femur; region 2 = lesser trochanter; region 3 = 5 cm above the tip of the stem; region 4 = tip of the stem; region 5 = 2 cm below the tip of the stem

for each patient and carried out a paired *t*-test analysis (on the difference in BD) for cortical and cancellous bone.

Results

Twenty-seven patients (29 hips) were clinically and radiologically assessed at the 1-year and 2-year follow-up. One patient moved overseas and one patient with bilateral THA who inadvertently commenced bisphosphonate therapy were excluded from the study. There were no severe complications requiring revision surgery. The mean preoperative Harris Hip Score was rated 38 points (range, 22–70 points) and was rated 96 points (range, 87–100 points) at the 2-year follow-up. The mean preoperative Oxford Hip Score was rated 42 points (range, 35–58 points) and was rated 19 points (range, 12–22 points) at the 2-year follow-up. All patients were able to walk without limping at follow-up. No patient reported thigh pain requiring analgesics, and no patient reported squeaking or any other noise from the ceramic hip joint. The radiological assessment showed stable fixation of cups and stems with good osteointegration in all the hips. There was no evidence of any radiolucent lines, osteolytic lesions or postoperative subsidence.

Results of qCT osteodensitometry analysis are depicted in Tables 1 and 2 and Figs. 2 and 3. The analysis of the surface area of each scan slice showed no statistical difference between postoperative, 1-year and 2-year scans, confirming adequate precision for evaluation of the same bone area.

Cortical bone

There was strong evidence that the BD was higher immediately after the operation than after 1 year ($p=0.004$). We estimate that the mean density was between 19.83 mgCaHA/ml and 123.28 mgCaHA/ml higher immediately after surgery than 1 year after the index operation (95% CI) or that the median density was 2% to 12% higher. However, at the 2-year follow-up we observed a partial reconstitution of BD. This

Table 1 Postoperative baseline cortical BD values (mean $\pm$ standard deviation) and follow-up BD values in the five regions of interest (ROI) (1= greater trochanter region; 5=2 cm below the tip of the stem)

ROI	Post-operative		1 year		2 years	
	Mean	Std dev	Mean	Std dev	Mean	Std dev
1	847.9	115.9	667.3	131.0	702.8	136.4
2	993.4	113.1	912.9	147.6	903.2	258.9
3	1,270.6	45.8	1,215.1	55.5	1,259.5	42.4
4	1,292.1	49.8	1,266.7	53.4	1,298.6	45.0
5	1,291.2	55.0	1,275.3	53.4	1,304.9	45.1

Table 2 Postoperative baseline cancellous BD values (mean $\pm$ standard deviation) and follow-up BD values in the five regions of interest (ROI) (1= greater trochanter region; 5=2 cm below the tip of the stem)

ROI	Post-operative		1 year		2 years	
	Mean	Std dev	Mean	Std dev	Mean	Std dev
1	203.3	72.7	130.1	90.6	158.6	69.5
2	331.2	52.8	278.2	72.7	317.6	86.6
3	506.6	113.3	420.4	99.0	547.8	114.0
4	253.7	62.2	225	60.5	321.3	80.4
5	189	43.3	156.2	39.2	200.5	49.5

phenomenon was particularly evident in the diaphyseal regions. There was no evidence of a difference in BD immediately after surgery and after 2 years ($p=0.1$).

Cancellous bone

There was strong evidence that the density was higher immediately after the operation than after 1 year ($p=0.001$). We estimate that the mean density was between 54.79 mgCaHA/ml and 90.38 mgCaHA/ml higher immediately after surgery than 1 year after the index operation (95% CI) or that the median density is 8.861% to 39.920% higher. At the 2-year follow-up, we observed partial BD reconstitution in the two proximal regions and BD increase in the diaphyseal regions. There was no evidence of a difference in density immediately after surgery and after 2 years ($p=0.7$). There was very strong evidence of a difference between 1 and 2 years ($p=0.0001$). We estimate that the mean BD was between 67.19 mgCaHA/ml and 102.78 mgCaHA/ml lower 1 year after surgery than 2 years after the index operation (95% CI) or that the median density was 11.671% to 31.285% lower.

Comparing BD changes in the ROI 1 with changes occurring in the ROI 2 to 5

We compared the percentage change in BD for region 1 to the average percentage change in density for the other four regions, at the 1-year and the 2-year follow-up, for cancellous and cortical bone. We did this by subtracting the BD at year 1 and year 2 from the postoperative BD baseline values and then dividing this by the postoperative bone density (to convert the change to a percentage). Thus a positive percentage represents a decrease in bone density. For cortical bone, at year 1 we have very strong evidence of a difference ($p=0.009$); we estimate that the percentage decrease in BD is between 14.5% and 24.4% greater for the greater trochanter region than for the average across the other four regions. At year 2, we have very strong evidence of a difference ($p=0.006$); we estimate that the percentage decrease in BD is between 11.8% and 23.1% greater for

Fig. 2 Cortical BD changes in the five regions of interest at the 1-year and 2-year follow-up

region 1 than for the average across the other four regions (Fig. 4). For cancellous bone, at year 1 we have strong evidence of a difference ($p=0.008$); we estimate that the percentage decrease in BD is between 8% and 51.1% greater for region 1 than for the average across the other

four regions. At year 2 we have very strong evidence of a difference ($p=0.0001$); we estimate that the percentage decrease in BD is between 25.1% and 71.8% greater for region 1 than for the average across the other four regions (Fig. 5).

Fig. 3 Cancellous BD changes in the five regions of interest at the 1-year and 2-year follow-up

Fig. 4 BD changes observed in the greater trochanter and femoral neck region (level 1) versus BD changes observed in the regions below the lesser trochanter (rest) for cortical bone at the 1-year and 2-year follow-up

Analysis for high BD baseline versus BD changes at follow-up

We separated the patients into two groups based on whether they were above or below the midpoint between the maximum and minimum BD baseline values (averaged across the five ROIs). We looked at loss of BD after 1 year and 2 years for cortical and cancellous bone. In all four cases there were no significant differences. For cortical bone, at the 1-year follow-up the p-value was 0.3; at the

Fig. 5 BD changes observed in the greater trochanter and femoral neck region (level 1) versus BD changes observed in the regions below the lesser trochanter (rest) for cancellous bone at the 1-year and 2-year follow-up

2-year follow-up the p-value was 0.3. For cancellous bone, at the 1-year follow-up the p-value was 0.4; at the 2-year follow-up the p-value was 0.5.

Changes of femoral cortical and cancellous BD of the non-operated site were unremarkable.

Discussion

The aim of this prospective study was to measure BD changes and assess adaptive remodelling around a recently released femoral component with taper design and HA coating. At the 2-year follow-up, we observed a -17% decrease of cortical BD and -22% decrease of cancellous BD in the greater trochanter and femoral neck region. Cortical and cancellous BD decrease at the level of the lesser trochanter was -9% and respectively -4% . We observed small changes of cortical BD in the diaphyseal regions; in contrast, cancellous BD increased (range 6% to 27%) in the diaphyseal regions. Overall, a trend of BD recovery was observed throughout the follow-up period. Changes of BD at the 2-year follow-up are suggestive of proximal femur diaphysis load transfer with osteointegration and moderate metaphyseal stress-shielding.

Bone density changes adjacent to an implant have a multifactorial aetiology. While age-related changes occur, focal osteolysis and stress shielding are the most important causal factors of periprosthetic bone loss [3]. Stress shielding is a phenomenon that describes the tendency of bone to atrophy in the absence of an adequate mechanical stimulus based on the principles known as Wolff's law [23]. The extent of stress-shielding depends on the size, design and elastic module of an implant and its biomechanical interactions with cortical and cancellous bone structures [6, 13, 22].

Taper-design stems aim to achieve metaphyseal fixation with proximal load transfer to limit stress shielding. Finite-element analyses showed that the extent of stress shielding is directly correlated to stem stiffness, with lower E-modulus materials like titanium-reducing proximal stress shielding [6, 21]. HA-coated implants show a good clinical and radiological outcome with moderate BD loss and improved implant fixation when compared with porous-coated implants [10, 18, 20]. Histological analyses in cadaveric specimens have shown sound proximal and distal HA stem-bone osteointegrations in a relatively short period after THA [1]. Such findings may reduce proximal stress shielding and provide a circumferential barrier to wear debris that induces osteolysis [1, 14]. DXA studies have reported proximal bone resorption around uncemented stems, which can range from 20 to 50% [5, 14, 20, 24]. Structural differences of cortical and cancellous bone are not taken into consideration when measuring BD after THA with DXA [24, 25]. Using sectional CT imaging, a separate analysis of cortical and cancellous bone structures can be achieved [17, 18]. The CT-assisted

osteodensitometry technology used in this study is accurate and reproducible [16, 19]. We found BD loss ranging from -17% to -0.9% in the cortical bone and ranging from -22% to -4% in the cancellous bone. Interestingly, in some regions of the diaphyseal portion we observed an increase of cancellous BD ranging from $+6\%$ to $+27\%$. This phenomenon is probably related to osteointegration processes and new bone apposition around the implant. The reported figures compare favourably with other osteodensitometry studies on uncemented femoral components [18]. However, direct comparison of DXA studies and qCT-assisted studies is difficult; first, the former is mono-dimensional, whereas qCT is volumetric; second, DXA can assess only overall loss of BD, whereas qCT separates cortical and cancellous bone structures. Therefore, the use of frontal-plane regions of interests like the Gruen zones is not suitable for qCT. Several studies have reported the highest levels of BD resorption in Gruen zones 1 or 7, which corresponds with our most proximal scan around the greater trochanter and femoral neck, where we also found the highest levels of cancellous and cortical BD loss (ROI 1 and 2) [5, 10]. Other studies have reported a BD loss of greater than 50% in the calcar region [14, 25]. In the present study, changes of BD in the most proximal region including the greater trochanter and the neck of the femur showed a decrease between 11.8% and 23.1% greater than the average across the other four ROIs. Similarly, the decrease in cancellous BD was between 25.1% and 71.8% greater for the trochanter and neck region than for the average across the other four regions.

Studies on uncemented stems have shown partial BD recovery after an initial postoperative bone loss [11, 17]. Similarly, a study carried out on HA-coated tapered stems reported a BD decrease in the 1st postoperative year with a recovery at the 3-year follow-up [15]. The present study confirms partial restoration of the postoperative cortical and cancellous BD values in the trochanter and neck region and complete cortical BD restoration in the diaphyseal region. Interestingly, we observed an increase of cancellous BD in the diaphyseal region.

In summary, the taper-design stem assessed in this study has shown satisfactory clinical and radiological results. Quantitative CT-assisted osteodensitometry showed moderate proximal femur BD loss. Changes of BD observed 2 years after THA with the Summit stem compare favourably with BD changes reported in other studies using anatomical-design and taper-design stems. In conjunction with finite-elements analysis, qCT is able to generate accurate patient-specific meshes on which to model implants and their effect on bone remodelling [21]. This technology can be useful in predicting bone remodelling and the quality of implant fixation using prostheses with different design and/or biomaterials [13]. In the future, this tool could be used for pre-clinical validation of new

implants before their widespread introduction in the clinical practice.

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