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Bone mineral density as a marker of hip implant longevity: a prospective assessment of a cementless stem with dual-energy X-ray absorptiometry at twenty years

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Abstract

Purpose Bone remodeling around the femoral component after total hip arthroplasty (THA) is considered to be an important factor in long-term stability and seems to be strictly related to the stem design, coating, and fixation. Stress shielding, micro-movement, and high intra-articular fluid pressure might activate macrophages and osteoclasts, causing progressive bone density decreases. Here we analyze the bone mineral density (BMD) around a cementless femoral stem during a 20-year period to better understand the adaptive bone changes around such implants during long-term follow-up.

Methods In this retrospective study, 14 patients treated by THA were reviewed from a cohort of 84. Clinical evaluation with Harris Hip Score and radiographic assessment were performed throughout a 20-year follow-up. To evaluate the bone remodeling around the stem, we monitored the femoral BMD in four regions of interest with a dual-energy X-ray absorptiometry (DEXA) post-operatively and at one, two, three, five and 20 years of follow-up.

Results The main BMD changes between the post-operative examination and the 20-year follow-up varied between + 11.19% and + 24.30%. Patients with signs of loosening, low Harris Hip Scores, and pain showed decreasing BMD values.

Conclusions The correlation between the clinical result and BMD values could suggest DEXA results as a predictor of implant loosening or longevity.

Keywords Total hip arthroplasty · DEXA · Cementless stem · Prosthetic loosening · Periprosthetic BMD

Introduction

The worldwide incidence of performed total hip arthroplasties is approximately 1,000,000 per year [1]. Revisions and the risk of total hip replacement increases with decreasing patient-age of the first implant [2]. Patients younger than 50 years at the time of surgery have a greater chance of requiring a revision; patients around 58 years old have a 50% possibility of a revision; patients over 77 years old have a smaller chance of revision. Aseptic loosening incidence increases with the development of new, shorter implants with cementless proximal fixation and proximal load transfer to achieve a physiological loading pattern [3].

Bone mineral density (BMD) changes in the proximal femur after total hip arthroplasties depend on patient- and implant-related factors. The patient-related factors include diabetes, osteoporosis, kidney failure, rheumatoid arthritis, therapy with alendronate and calcitonin in osteoporotic patients, and therapy with Warfarin, Ciclosporin A, Fans, and heparin [4, 5]. The implant-related factors include biocompatibility, which significantly influences the bone integration process. Titanium is widely used because of its high biocompatibility, high resistance to corrosion, and low inflammatory response [6, 7].

A porosity of about 80 μm provides excellent integration [8]. Implant characteristics influence load transmission. Appropriate load forces induce new bone formation and osteointegration. Biomechanical aspects that influence a correct load distribution are a range of motion, implant fixation, tissue damage during

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implantation, tissue tension after THA, component orientation (stem, cup), and bearing material. Mechanical stress is associated with implant failure [9].

In the proximal femur, the load is transmitted from the femoral head, through the cortical and cancellous bone of the femoral neck, to the femoral diaphysis. However, the insertion of a metallic implant changes this load force distribution and could modify the periprosthetic BMD [10]. X-ray, computed tomography (CT), and magnetic resonance imaging (MRI) provide only qualitative data on bone density. Technical improvements in dual-energy X-ray absorptiometry (DEXA) provide an accurate quantitative measure of bone around the metallic implant [11]. Several studies have evaluated the changes in periprosthetic BMD [10–13].

Bone remodeling around the femoral component after THA is considered to be an important factor in long-term stability and seems to be strictly related to the stem design, coating, and fixation [5, 14].

This study analyzes the BMD around a cementless femoral stem over a 20-year period, thereby gaining a better understanding of the adaptive, long-term bone changes around such implants.

Materials and methods

In this retrospective study, 14 patients who had undergone to periodic hip radiographs (AP, axial views) and densitometric controls (Bone Density Scan DXA) after total hip arthroplasty (THA) with Correcta Stem (Zimmer) were reviewed from a cohort of 84 patients treated between 1994 and 1998. This study was approved by the local ethics committee, and all of the procedures followed the principles of the Helsinki declaration.

From the initial cohort of 84 patients, 70 patients were excluded from the study: eight (9.5%) patients died over the study period, 42 (50%) patients were excluded because of a lack of densitometric and radiographic assessment, six (7.1%) had a traumatic periprosthetic fracture, ten (11.9%) were treated with bisphosphonates, and four (4.7%) had a treatment with steroidal drugs for at least six months of the study period. Therefore, the study group included 14 patients for a total of 18 hips, eight (57.1%) at the left side and six (52.9%) at the right. Six (39.3%) patients were male and eight (60.7%) female. The mean age at the time of surgery was 75.6 ± 5.05 years (range, 66.2–82.3 years).

All of the patients in the study group underwent THA for severe osteoarthritis of the hip. All THAs were performed at our institute by two experienced orthopaedic surgeons (G.S; L.C.), through a standard anterolateral approach. In all cases, the Allocor (Zimmer) press-fit cup with Ultra High Molecular Weight PolyEtylene (UHMWPE) insert was used. The Correcta (Zimmer) biological stem was used. A ceramic (Biolox Delta) head was used. In our study, we examined only

the stem and not the cup. The Correcta (Zimmer) Stem was designed in 1992 by the homonymous Italian group. It was implanted in the 1990s and progressively abandoned for the newest prosthetic designs. It is an anatomical stem in a Titanium(Ti)-Aluminum(Al)-(Niobium)Nb alloy with a neck-shaft-angle (NSA) of 135°, an antiversion of 6°, and an antitorsion of 4°. Proximally, it ends with a 12/14 cone, including a trapezoidal section that ends distally with four splines, thus avoiding cortical hypertrophy.

Clinical evaluation

Clinical evaluation was performed pre-operatively, post-operatively, and at one, three, five and 20 years after surgery, using the Harris hip score (HHS) [15]. The score has a maximum of 100 points. A total score of 70 is considered a poor outcome, 70–80 is considered fair, 80–90 is good, and 90–100 is an excellent outcome [16].

Radiographic assessment

Radiographic assessment was performed using the criteria introduced by Vresilovic et al. [17].

Anteroposterior and axial view X-ray was performed at one and six months, and one, five and 20 years. Stem correct fitting, osteolysis area, and radiolucent lines around the stem, cortical hypertrophy, calcar resorption, and presence of heterotopic ossification were assessed.

Stem alignment was evaluated by measuring the angle formed between the long axis of the prosthesis and the axis of the femur. A post-operative alignment was considered valgus if more than 3° and varus if less than 3°. Changing of stem alignment was evaluated.

The presence of radiolucent lines, osteolysis, and calcar resorption as signs of periprosthetic resorption were highlighted.

DEXA assessment

DEXA images were performed at three months, and one, three, five and 20 years with Lunar DPX® (8 KV; 0.75 mA; with a voltage between 38 and 70 KeV) and the data analyzed with "slow scan mode" software.

Starting from the Gruen zones, we obtained four regions of interest (ROI) for the stem evaluation: the calcar region (ROI 1) corresponding to Gruen zone 7; the trochanter region (ROI 4) corresponding to Gruen zone 1; and the medial (ROI 2) and the lateral (ROI 3) area near the stem corresponding to Gruen zones 5–6 and 2–3 respectively.

Statistical analysis

Post hoc analysis was performed using Ministat® and MedCalc® software. The intraindividual difference at

follow-up was tested by the Tukey-Kramer method. All tests were two-tailed and a p value less than 0.05 was considered statistically significant.

Results

At 20-years follow-up, the mean HHS was 82.07 ± 8.25 (range, 65 to 92). Only two patients (14%, patients 13 and 14) had a HHS less than 70. Only one patient (7%) referred to pain during daily activities.

At 20 years, the radiological assessment showed a condition of stability of the prosthetic implant and the absence of osteolysis in 13 of 14 patients (98%). One patient (2%) showed a loosening of the cup (patient 14). Heterotopic calcification was observed in three patients (21.4%). Calcar resorption was observed in patient 14. Radiolucent lines were observed in patient 13 and 14.

DEXA assessment showed an increase of BMD in all ROIs analyzed. The percentage of increase in BMD between post-operative and at 20-years post-surgery is shown in Table 1.

The main BMD changes between the post-operative examination and the 20-year follow-up varied between $+11.19\%$ in ROI 1 and $+24.30\%$ in ROI 3 (Table 2). This increase of the mean BMD (g/cm^2) between the post-operative and 20-year examination was significant in all regions ($p < 0.05$).

In region 1, values increased slightly. We noticed an increase of $+9.09\%$ at one year, $+13.64\%$ at two years, $+12.73\%$ at three years, $+10\%$ at five years, up to an increase of 11.19% at 20 years. A progressive BMD increase was also reported in ROI 2 with a one year increase of $+9.45\%$, $+4.48\%$ at two years, $+10.95\%$ at three years, and $+14.43\%$ at five years, and ending with an increase of $+22.14\%$ at the last follow-up.

In ROI 3, the BMD increases $+2.78\%$ in the first year; $+1.11\%$ in the second year; $+11.12\%$ in the third year; $+13.33\%$ at five years, and $+24.30$ at 20 years. We observed progressive BMD loss in ROI 4 until the third year, -2.22% at one year, -7.78% at two years, -20.05% at three years, $-$

Table 2 Mean BMD increase between post-operative and after 20-years follow-up

R.O.I.	Gain %	p value
1	+ 11.19%	< 0.05
2	+ 22.14%	< 0.05
3	+ 24.30%	< 0.05
4	+ 22.67%	< 0.05

15.56% at five years, with a final gain of 22.67 at 20 years (Fig. 1).

Discussion

This study evaluated bone remodeling around a cementless stem and any correlation with BMD changes. At the 20-year follow-up, we observed an increase of BMD in all analyzed regions. BMD changes at the 20-year follow-up are suggestive of proximal femoral diaphysis load transfer with osteointegration.

BMD periprosthetic has a multifactorial aetiology. Age, sex, osteoporosis, focal osteolysis, and stress shielding are the most important factors of a BMD decrease. Stress shielding is a reduction of bone density due to load decreases after prosthesis implantation. This phenomenon is due to the absence of an adequate mechanical stimulus. The extent of stress shielding depends on the size, design, and elastic module of an implant [18].

According to Venesmaa et al. [19], the post-operative BMD value is the baseline-value to use to estimate the periprosthetic bone changes. This is because bone loss occurs during surgery, with a BMD reduction of 13–19% in the calcar region. A study of Lerch et al. [20] reported as blood-flow disorders following femoral preparation affect almost all regions, causing a BMD decrease during the first three to six months after surgery. For this reason, we decided to perform the first DEXA after three months of the surgery, to allow blood flow reestablishment.

Table 1 BMD increase in ROI for each patient (pcs) between post-operative and at 20-years post-surgery

| Gain%	pcs1	pcs2	pcs3	pcs4	pcs5	pcs6	pcs7	pcs8(left)	pcs8(right)
ROI 1	5.21%	3.55%	204.72%	− 57.81%	9.54%	26.91%	8.57%	− 18.33%	35.18%
ROI 2	30.72%	100.00%	70.19%	64.47%	10.36%	37.48%	23.79%	− 6.63%	− 3.04%
ROI 3	15.48%	15.74%	77.32%	58.16%	13.02%	40.06%	47.59%	− 27.17%	55.74%
ROI 4	5.4%	− 14.41%	− 6.88%	18.2%	− 8.67%	− 13.5%	− 8.00%	− 8.00%	n.v
Gain%	pcs9	pcs10(left)	pcs10(right)	pcs11(left)	pcs11(right)	pcs12(left)	pcs12(right)	pcs13	pcs14
ROI 1	− 14.31%	17.15%	n.v	10.1%	55.54%	− 12.79%	− 1.8%	− 64.92%	− 16.22%
ROI 2	36.6%	− 22.7%	53.41%	15.01%	− 0.15%	52.74%	46.44%	− 48.33%	− 20.59%
ROI 3	18.72%	− 20.44%	− 5.66%	25.81%	19.52%	57.76%	92.6%	− 30.6%	− 16.31%
ROI 4	6.48%	187.45%	n.v	− 8.52%	− 8.03%	52.41%	32.99%	64.56%	71.29%

n.v no value
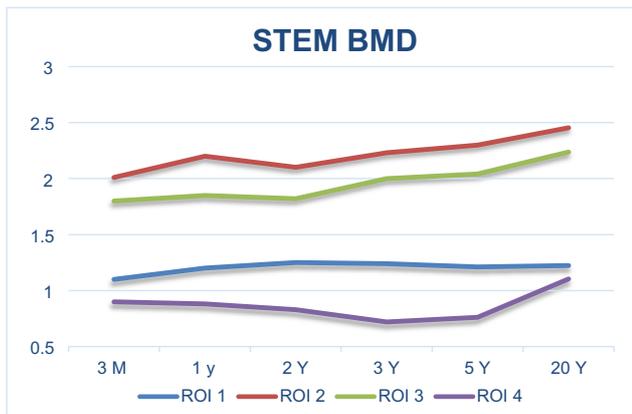
Fig. 1 BMD increase during follow-up

A difference in the pattern of BMD changes between various stem types has already been reported, as well as the differences in BMD changes among the different types of implants, both of which are due to variations in stress transmission [21–23].

In the stem that we analyzed, the asymmetric profiles of the proximal stem zone provide, on the medial side, the load on the arch of Adams and, on the lateral side, provide the good contact and filling. These factors could explain the BMD gains in ROI 1 and 4. In the metaphysis, the two curves are almost symmetrical, producing a characteristic funnel shape, favouring a good contact and a medial-lateral stress distribution, even on cancellous and cortical medial and lateral. The distal area is characterized by medial and lateral profiles, straight and symmetrical, and angled at 4.5°, which provides the distribution of the vertical loads on the shaft. The quadrangular section better determines the filling and load distribution. This particular distribution of loads on the medial and lateral cortical would explain the BMD gains registered in ROIs 2 and 3. Good clinical and radiographic results could relate to the BMD gains.

These data contrast with the data in the literature, where the controls densitometric at three, five and 15 years, which show a generalized loss of BMD in all regions analyzed.

Pitto et al. [18] showed how taper-design stems aim to achieve metaphyseal fixation with a proximal load transfer to limit stress shielding. However, a loss of BMD in stem and cup at five years of follow-up was reported in a patient with the press-fit cup and uncemented stem ceramic-ceramic paring implants.

Brodner et al. [24] found that BMD increased significantly in Gruen ROIs 2, 4, and 5 by 11%, 3%, and 11% respectively, and decreased significantly in Gruen ROIs 1, 6, and 7 by 3%, 6%, and 14% respectively, over a five year period in patients with Ti6Al7Nb tapered rectangular stem.

Lerch et al. [20] report BMD decreases in the greater trochanter and a poor increase in the calcar region.

In our study, good clinical and radiographic outcome after 20 years of implantation were related to densitometric data. Early radiographic signs of loosening were found only in patients that had a BMD decrease. Only two patients with a sign of loosening had an HHS below 70, and one of these had pain. In both patients, we noticed decreasing BMD values.

Aseptic loosening depends on several factors. Nixon et al. [25] demonstrated how osteoclast activation by particulate wear debris could cause bone resorption. Stress shielding, micro-movement, the ingress of particulate debris through the prosthesis-bone interface, and high intraarticular fluid pressure might activate macrophages and damage the bone. A progressive bone density decreasing is showed, and patients with the loosening of the femoral component had a lower periprosthetic BMD.

The correlation between the clinical result and BMD values could suggest DEXA results as a predictor of implant loosening or longevity. Load force transmission depends on the implant type and correct fill. These factors influence periprosthetic bone remodeling, causing the phenomena responsible for loosening, such as stress shield and osteolysis, which can be detected by densitometric exam.

DEXA is an easy exam with low cost and low radiation exposure and is well-suited to following bone modification around a prosthetic implant. DEXA is considered the most accurate exam to find small alterations in periprosthetic BMD [26]; it allows the examiner to quantify the periprosthetic bone loss and, in case of osteolysis, is useful for evaluating its evolution and the response to conservative treatment [27].

Cavalli et al. [26] reported how the use of bisphosphonates in animal models and human clinical trials reduced radiographic periprosthetic radiolucency by inhibiting debris-induced osteolysis, as well as by stimulating the osteoblastic proliferation, which allows the periprosthetic BMD to increase. Zhang et al. [28] showed how the statin use would prevent the bone loss around the stem implant after THA activating osteoblasts and controlling bone resorption caused by the inhibited osteoclasts.

An assessment of the periprosthetic BMD values could be useful not only to predict loosening phenomena but, above all, to start therapeutic strategies that can improve the longevity of the implant.

Limits of the study were retrospective study, lack of control group, and low number of subjects to detect significant BMD differences between the sexes or between different stem sizes.

Conclusion

This study confirms how a prosthesis, which ensures optimum distribution of the load forces, associated to an appropriate technique for surgical implantation, appears essential to ensure a good bone remodeling associated at a BMD gain in periprosthetic areas.

Low radiation exposure and low costs make the densitometric exam well-suited to evaluating periprosthetic osseointegration

and implant longevity and can be started early, thereby allowing properly therapy aimed at preventing loosening.

Compliance with ethical standards

Conflict of interest   The authors declare that they have no conflict of interest.

Ethical approval   All procedures were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent   Informed consent was obtained from all individual participants included in the study.

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