

Densitometric evaluation of periprosthetic bone resorption after surgical placement of Accolade I® TMZF® hip stem at 36 months

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Dedicated to the memory of Professor Michele Lisanti (1950-2017)

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Summary

Purpose. The implantation of a hip prosthesis determines changes in the joint biomechanics and it alters distribution of the loads on the surrounding bone. Proximal bone resorption around femoral stems is commonly seen after cementless total hip arthroplasty. The aim of this study was to evaluate the effects of a tapered single wedge HA coated Stem on periprosthetic bone density in the seven Gruen areas to define the pattern of bone remodelling associated with this stem's design.

Methods. 25 patients (11 men and 14 women) were selected in this study in accordance with specific inclusion and exclusion criteria. Patients underwent total hip replacement with Accolade I® TMZF® hip stem. They were all preoperative evaluated using the Harris Hip Score and a standard radiology examination. Clinical, radiological and bone density evaluations were performed on each patient within 6 months and at 12, 24 and 36 months after surgery.

Results. The results at 36 months show a statistically significant increase ($p < 0.001$) of the HHS scores, from 64 during preoperative phase to 93 at 36 months. No patients underwent to revision surgery and no peri-implant

radiolucency was found during radiological assessments. The bone mineral density changes in the seven Gruen zones seen with DXA scan showed a decrease of 2.9% only at the level of the calcar region (R7), a moderate increase at the level of R1, R2 and R3 and a statistically significant increase of BMD ($p < 0,05$) at 24 and 36 months after surgery at the level of R4 (+ 6.2%), R5 (+ 7.2%) and R6 (+ 8.15%).

Conclusion. Our study showed that the use of the Accolade I® TMZF® uncemented stem after 36 months of follow-up is associated to a good load transfer to the periprosthetic bone avoiding the stress shielding phenomena. It showed a definitely positive BMD evolution at the level of all Gruen's zones and especially at the level of the medial region (R5, R6). The only exception was at the level of the calcar region where there was a BMD mildly decrease (from 1.03 to 1.00) most likely due to the stem philosophy (metaphyseal fixation) and to the consequent load transfer to the metaphyseal medial regions (R5, R6).

KEY WORDS: periprosthetic bone remodeling; hip arthroplasty; Gruen's zones; bone mineral density; dual energy X-ray absorptiometry.

Introduction

The implantation of a hip prosthesis determines changes in the joint biomechanics and it alters distribution of the loads on the surrounding bone. Proximal bone resorption around femoral stems is commonly seen after cementless total hip arthroplasty. The reasons for this phenomenon include stress shielding (bone remodeling) and an inflammatory reaction to small particles produced by the various wear modes (bone resorption). Remodeling patterns around a femoral stem are affected by several factors. These include patient-related factors, such as gender, age, initial femoral bone stock, patient activity and underlying-disease and prosthesis-related factors, such as the type of fixation, stem length, stiffness, design, the extent of the coating area and the method of femoral bone fixation (1-8). One of the first Authors that studied periprosthetic bone remodeling was Gruen in 1979, he standardized the seven zones around the stem that must be studied to evaluate aseptic loosening (Zone 1: Greater trochanter; Zone 2: Proximal lateral; Zone 3: Distal Lateral; Zone 4: Tip; Zone 5: Distal Medial; Zone 6: Proximal Medial; Zone 7: Calcar) (9). This classification was used on first with cemented implant but it became useful also for the study of cementless implant. Actually the Gruen's classification is used for the study of periprosthetic bone mineral density with the Dual Energy X-ray Absorptiometry (DEXA) scan that is considered the method of choice to *in vivo* quantify the bone loss after a prosthetic implant (10). In literature is well documented as the use of short stem is associated to a better load transfer to the proximal femoral region and on the contrary the use of "standard" stem is often

associated to a relevant stress shielding phenomena (11-14). Aim of this study is to evaluate the bone remodelling around a frequently used standard metaphyseal fixation type of stem with low percentage probability of revision at 1, 3, 5, 7 and 10 years (15).

Materials and methods

We performed a prospective non-randomised clinical study (local ethics committee approval number 2931). The aim of this study was to evaluate the effects of a tapered single wedge HA coated Stem Stryker Accolade I® on periprosthetic bone density in the seven Gruen's areas to define the pattern of bone remodelling associated with this stem's design. This type of stem is made of a beta titanium alloy (TMZF), with a circumferential coating of hydroxyapatite of 50 µm (PureFix™ HA) obtained with Plasma Spray technique.

All patients undergoing surgery for hip replacement prosthesis with the Accolade® stem, in the period between January 2009 and December 2010, were included in the study. The exclusion criteria were: patients unable to understand the study and unable to give a written consent to the study, patients who had reported previous hip surgery or previous hip fractures, patients with bone metabolism diseases, patients taking drugs that can influence the bone metabolism, patients that sustained intraoperative periprosthetic fractures, patients with inflammatory diseases, patients with history of cancer, patients with unintentional movements that could interfere with DEXA analysis, and patients with history of malabsorption (i.e., coeliac disease).

Patients were evaluated by means of a densitometrical, clinical, and radiographic follow-up over a period of 36 months. All patients underwent total hip arthroplasty with the same surgical technique executed by the same surgeon (ML) through the mini posterolateral approach. Bone mineral density (BMD) calculation was performed by means of the Discovery™ DXA system (Hologic, Inc., Bedford, Massachusetts) with a "Metal Remover" system. The densitometric evaluation was conducted in the seven regions of interest (ROI) described by Gruen and were adapted to the stem design: ROI 1 Great Trochanter, ROI 2 Superior Lateral, ROI 3 Inferior Lateral, ROI 4 Stem Apex, ROI 5 Inferior Medial, ROI 6 Superior Medial, and ROI 7 Calcar. The errors related to the limb rotation were avoided using a leg holder provided by the manufacturer of the DEXA scan. Each patient enrolled in the study underwent a clinical, radiographic, and densitometric evaluation according to the following scheme: T0 (before the hospital discharge), T1 (6 months after surgery), T2 (12 months after surgery), T3 (24 months after surgery), T4 (36 months after surgery). For all the seven Gruen's zones we recorded, the BMD variation from the baseline value (T0).

Clinical evaluation was done with a standard examination and with the Harris Hip Score. Anterior to posterior (AP) and false-profile radiographic images of the involved hip were evaluated at each follow-up step. We also recorded if any other disease that could influence bone metabolism appears during the follow-up. All the complications occurred during the follow-up period were recorded. Statistical analysis of data was done using Student's t Test to compare preoperative and postoperative Harris Hip Score (HHS), while Wilcoxon signed-ranks test was used to compare density bone variations measured by DEXA, considering statistically significant a p-value inferior to 0.05.

Results

According to the established inclusion and exclusion criteria we recruited 25 patients (11 males and 14 females) with an average age of 66 years (range 50-76). All the patients were operated on by the same surgeon (ML) using a mini posterolateral approach. After 36 months of follow-up no patient underwent hip revision surgery and we did not record any major complications like dislocation or infection. From the radiographic evaluation, any radiolucency lines or any signs of stem mobilization were noted. There were two cases of heterotopic ossifications that were radiographically visible but not clinically relevant. Clinical and functional results obtained by means of the Harris Hip Score demonstrated a significant improvement. HHS increased from 56 preoperative points to 91 postoperative points after 36 months (p-value < 0.001). None of the Patients reported new diseases that could influence bone mineral metabolism.

The results of the densitometric evaluation after 36 months of implantation showed a BMD decrease in the calcar zone (R7), a mild BMD increase in the lateral metaphyseal regions (R2, R3) and at the level of the greater trochanter (R1) and a BMD increase in the medial metaphyseal regions (R5, R6) and at the apex of the stem (R4). We recorded minimal changes in BMD at the level of the greater trochanter (+1,27%) and at the level of the calcar (-2.9%). BMD increased significantly after three years at the level of the medial distal regions (R5 +7.2% - R6 + 8,15%) and at the level of the apex (R4 + 6,2%) (Figure 1). The BMD changes were statistically significant only in the medial metaphyseal regions (R5, R6) and the level of the apex of the stem after 36 months (Wilcoxon signed ranks test, P<0.05). The results for each region of interest are reported in Table 1.

Discussion

Periprosthetic bone remodelling is one of the main causes of aseptic stem mobilization and although it could depend by several factors related to the type of implant, to the surgical technique and to the patient (intrinsic patient's factors). Implant design and fixation are reported from most of the Authors as the main factors that influence the preprosthetic bone remodelling (1-5). The use of straight stem (Type 3 of the Khanjua classification) (16) is associated with high level of bone resorption in the proximal femoral regions. Korovesis et al. and Brodner et al. studied the tapered rectangular titanium cementless Alloclassic® Zweymüller® Stem which after 4 years in longitudinal studies showed 7% and 14% bone loss in zone 7 (Calcar) respectively (6, 17). Albanese et al. in a comparative study between 6 different stem designs confirmed the presence of bone loss in zone 7 (calcar) in the Alloclassic® group (13). The Alloclassic® stem is also associated to a significative increase of BMD value in zone 4 under the tip of the stem according to the distal fixation philosophy of this stem design (13).

On these basis started an intensive research for stems with characteristics (design, materials and coating) that can minimize stress shielding phenomena. Stems with a metaphyseal or a meta-diaphyseal fixation seem to reduce this phenomenon compared to conventional long stems (12-14). The best way to *in vivo* study the effects of the stem design on periprosthetic bone remodelling is to use a prospective densitometric evaluation. DEXA analysis of Gruen's areas is

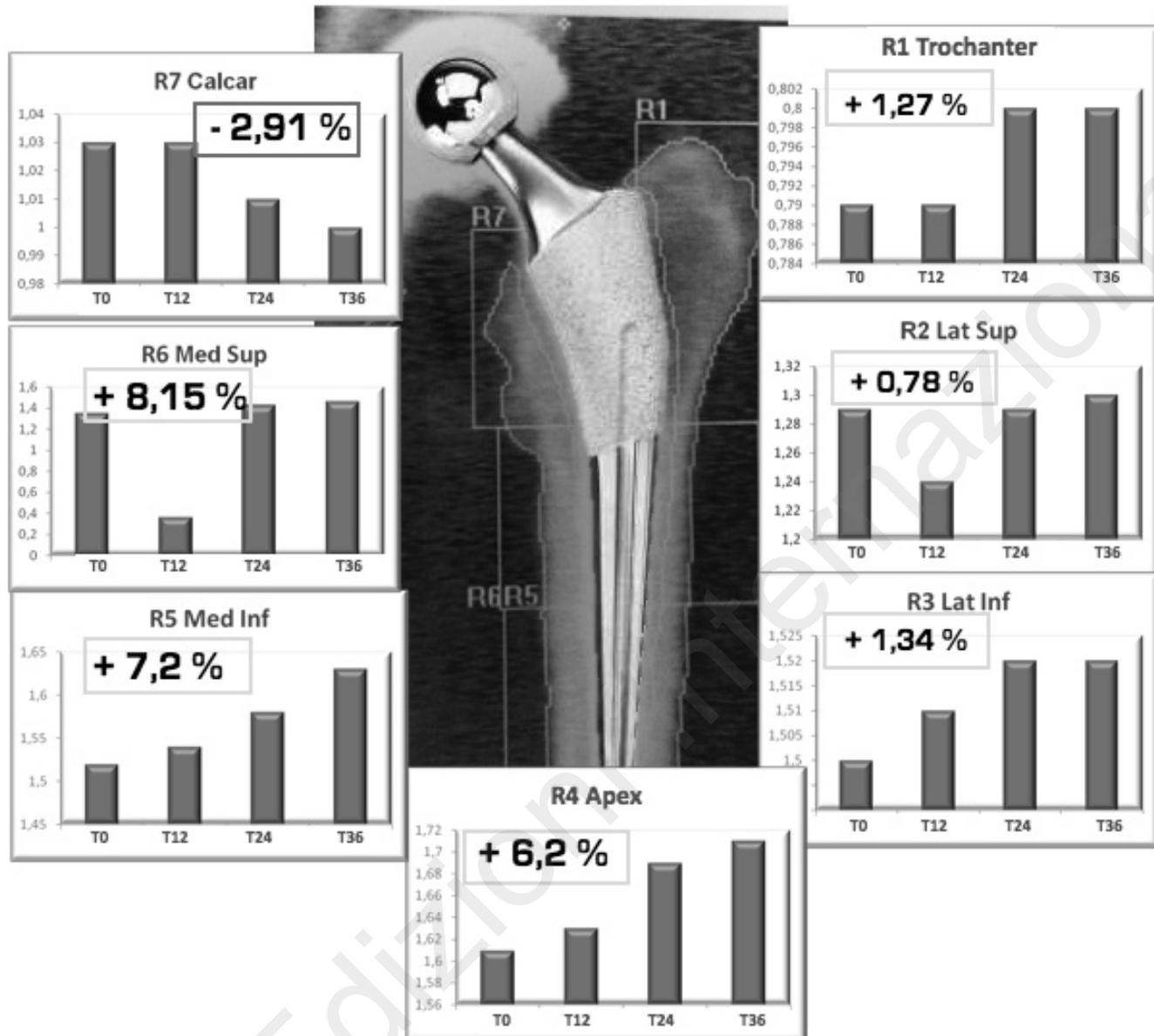


Figure 1 - Graphic representation of the BMD changes in the seven Gruen's zones after 36 months of follow-up.

described as the most used protocol in the evaluation of periprosthetic bone reabsorption after implantation of conventional and new generation stems (13, 18).

The Stryker Accolade I® Stem is a tapered single wedge design and it could be classified as a Type I Stem type according to Khanjua et al. (16). Type 1 stems are designed to engage metaphyseal cortical bone in one plane: medial to lateral. They are flat and thin in the anterior-posterior plane. The component narrows proximally, primarily in the medial lateral plane, and tapers distally. The coating is typically on the proximal one-third to five-eighths of the implant. Initial stability is obtained by wedge fixation in the medial-lateral plane or three-point fixation along the stem length.

In literature various densitometric studies on the tapered CLS Spotorno® collarless titanium alloy single wedge design have been published. Using this stem Roth et al. reported a bone loss in the calcar region of 19% after 1 year and Sabo et al. reported a bone loss of 12% after 2 years (19, 20). Gibbons et al. published a comparison study between the CLS®

stem and the AML® (DePuy Synthes) stem reporting respectively a 20% (CLS®) and a 38% (AML®) decrease in zone 7 after a mean of 4 years (21). Bone remodeling around the CLS® stem was also evaluated at 12 and 17 years postoperatively reporting the lowest relative BMD values in the calcar region (zone 7) (22).

Partially in contrast with these data the results of our study showed that the use of the Accolade I® TMZF non-cemented tapered stem design is associated with a positive BMD variation trend in all Gruen areas; we recorded only a mild decrease of BMD (from 1.03 to 1.00) in the calcar zone (R7), probably due to a shift of loads towards inferior regions (R5, R6) compared to physiological condition. The data obtained from the densitometric evaluation and the absence of a cortical reaction in the lateral diaphyseal region of the femur (R2, R3) suggest that this kind of stem has no distal shift of loads in this region. This phenomenon is frequently observed with longer straight stems (Type 3) and it is related to proximal bone reabsorption and appearance of leg pain (6, 13, 17, 19, 21, 22).

Table 1 - Summary of the BMD variations in the seven Gruen's zones.

Region	T0	T1	T2	T3	Overall BMD variations
	(postop)	(12 months)	(24 months)	(36 months)	
	gr/cm ²	gr/cm ²	gr/cm ²	gr/cm ²	
R1 Trochanter	0,79	0,79	0,8	0,8	+ 1,27%
R2 Lat Sup	1,29	1,24	1,29	1,3	+ 0,78%
R3 Lat Inf	1,5	1,51	1,52	1,52	+ 1,32
R4 Apex	1,61	1,63	1,69	1,71	+ 6,2%
R5 Med Inf	1,52	1,54	1,58	1,63	+ 7,2%
R6 Med Sup	1,35	1,37	1,43	1,46	+ 8,15%
R7 Calcar	1,03	1,03	1,01	1	- 2,91%

Our data are compatible with results from the study of Albanese who has evidenced that a short stem can distribute forces in a more physiologic way, producing a better pattern of periprosthetic bone reabsorption in the metaphyseal region and an increase of BMD in medial cortical region (13). The data obtained after a 3 years evaluation are very similar to the data that we have obtained using a short stem (Metha stem) and they demonstrate that the use of the Accolade® stem is associate to a physiological load transfer on the surrounding bone (14). While for the Metha stem (neck preserving stem) the pattern of bone remodelling seem to be related to the level of the neck osteotomy and consequently to the final stem position (varus-valgus) for the Accolade® stem the stem final position is more reproducible (standard stem) and we did not found any correlation between BMD variations and different stem orientation in varus and valgus (14).

Conclusions

Our study revealed that the use of the Accolade I® TMZF® uncemented stem after 36 months of follow-up is associated to a good load transfer to the preriprosthetic bone avoiding the stress shielding phenomena. It shows a definitely positive BMD evolution at the level of all Gruen zones and especially at the level of the medial region (R5, R6). The only exception where BMD results mildly decreased (from 1.03 to 1.00) is at the level of the calcar region most likely due to the stem philosophy (metaphyseal fixation) and to the consequent load transfer to the metaphyseal medial regions (R5, R6). In the future it will be interesting to study the changes that the new design of this stem (Accolade II) will determine in the periprosthetic bone remodeling. The main limitations of our study were the small number of patients and the relative short follow-up of the study.

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