Total Hip Prosthetic Osteointegration: an Absorptiometric Study*

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Purpose. To assess the degree of osteointegration of a hip prosthesis model, quantifying periprosthetic changes by means of x-ray absortiometry.
Materials and methods. Seventy-three patients were selected, who had been operated on over a 5-year period. An ABG II hip prosthesis was implanted in all patients. Periprosthetic bone modifications were quantified by means of x-ray absortiometry.
Results. On analyzing the measurements of the different femoral areas, it can be observed that generally there is more bone stock in the lower periprosthetic regions (mean bone mineral density [BMD] is 1.678 g/cm^2 in Gruen's zone 4) as compared with the higher metaphyseal regions (Mean BMD is 0.680 g/cm^2 in Gruen's zone 1). When one looks at periacetabular bone areas, all of them show a decrease in BMD from the fifth year onwards. In DeLee's zone 1, BMD increases until the third year, after which it gradually decreases until the last year.
Conclusions. This is due to the use of additional screws in the above mentioned area, which give rise to an increased initial fixation and unleash osteogenic processes between the first and the third year. Nevertheless, from the third year the screws start becoming incompetent, fixation becomes insufficient and a series of osteolytic processes ensue, which are responsible for the BMD decrease in DeLee's zone 1. In zone 2, BMD remains constant.

Key words: *hip prosthesis, osteointegration, bone densitometry.*

Estudio mediante absorciometría de la integración de una prótesis total de cadera*

Objetivos. Se ha valorado la osteointegración de un modelo de prótesis de cadera, cuantificando los cambios periprotésicos mediante densitometría de absorción de rayos X.
Material y método. Se seleccionaron 73 pacientes intervenidos durante 5 años. En todos los pacientes se implantó un modelo protésico tipo ABG II. Se cuantificaron los cambios óseos periprotésicos mediante densitometría de absorción de rayos X.
Resultados. Cuando se observan los datos de medición en las diferentes áreas del fémur, se aprecia que en general hay una mayor masa ósea en las zonas inferiores periprotésicas, densidad mineral ósea (DMO) media de 1,678 g/cm^2 en el área 4 de Gruen, cuando se compara con las metafisarias superiores, DMO media de 0,680 g/cm^2 en el área 1. Al analizar las zonas óseas periacetabulares, se aprecia un descenso de la DMO en todas ellas a partir del quinto año. En el área 1 de DeLee, la DMO asciende hasta el tercer año, momento en el que se produce un descenso progresivo hasta el último año.
Conclusiones. Esto se debe al anclaje adicional de los tornillos, los cuales se introducen en dicha zona, dando lugar a un aumento de la fijación inicial y a una activación de los procesos osteogénicos entre el primer y tercer año. Sin embargo, a partir del tercer año se produciría un anclaje insuficiente por ineficacia de los tornillos, activándose entonces los fenómenos osteolíticos, siendo responsables del descenso de la DMO en el área 1 de DeLee. En el área 2, la DMO se mantiene constante.

Palabras clave: *prótesis de cadera, osteointegración, densitometría ósea.*

Prosthetic replacement has been one of the most significant advances made in orthopedics in the last four decades and has overridden older surgical approaches used to address hip pathology like arthrodesis or resection arthroplasty[1-4].

*SECOT Foundation Award for Clinical Research into Orthopedic and Trauma Surgery 2005.

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Received: March 2006.
Accepted: June 2006.

The promising results obtained with cemented prostheses in the 70s resulted in their use in patients with hip osteoarthritis[5]. However, with the passing of time problems related to the cementation technique became apparent: high failure rate in patients over 50 (according to some authors close to 50% in the first 10 years[6-8]), inflammatory reaction caused by polymethylmethacrylate that produced osteolytic areas around the prosthesis (the so-called «cement disease»[9-11], and technical problems provoked by cement removal during revision surgery[12]. These problems led to the development of other prosthetic fixation techniques s an alternative to cementation. The basic purpose was achieving direct implant fixation through bone ingrowth in order to achieve the active osteointegration of the prosthesis to the host bone[13-15].

With this idea in mind, a large amount of hip implants were introduced during the 80s aimed at improving stability and bone apposition, thereby promoting bone ingrowth into the implant, i.e. biological fixation. However, in spite of the excellent results obtained with uncemented prostheses, several problems have been observed with the passage of time such as the detachment of the porous coating, periprosthetic lysis, distal femoral stem migration and bone atrophy in the proximal area, all of which significantly compromise the stability of these implants[4,16,17].

Postoperative assessment of periprosthetic bone remodeling, in particular of the bone atrophy and the status of the bone-prosthesis interface, can be challenging. Imaging studies, which are the most frequently used way to follow up these patients, have not shown themselves capable of providing an early and objective quantification of these phenomena[15]. Conventional x-rays are not sensitive enough since you must have bone loss of at least 30% to detect anything. In addition, this is not a very system technique since it depends largely on the radiological technique and type of film used, the distance to the lens and femoral exposure[16,18,19].

Periprosthetic osteolysis appears radiologically as a diffuse thinning of the femoral cortex or as a local cystic lesion which, if too extensive, could lead to large lytic areas (fig. 1)[17,20,21]. Osteolysis incidence varies as a function of the type of uncemented prosthesis in place and of the shape, size, makeup and type of the surface finish.

Femoral component migration is another phenomenon that can be observed in imaging studies. Displacement that is non-progressive and lower than 3 mm does not count as prosthetic loosening. Rather, they are seen as a result of the seating of the femoral stem in the femoral canal after a variable post-surgical period, whose duration will depend on the type of prosthetic design used[17,22,23]. Displacement higher than 3 mm could give rise to an initial instability of the femoral component and could jeopardize incorporation to the host bone.

Technetium 99 scintigraphy possesses high sensitivity for the detection and follow-up of any pathological process; however its specificity is very low and periprosthetic enhancement is not synonymous with implant loosening[18,24,25]. Isotope studies carried out to analyze the results of hip replacement have shown that the increased enhancement of the above mentioned radionuclide tends to ebb away 6 months post-op at the level of the cup, one year post-op around the metaphyseal cortex and after 5 years post-op at the calcar and the tip of the femoral stem, which means that isotope enhancement during those periods can be considered normal[19,26,27]. Other methods like computed axial tomography (CAT) or nuclear magnetic resonance (NMRi) dos not permit an accurate quantitative measurement of the bone mass around the prosthetic implant. This is due to the fact that the metal in the prosthesis is a major source of error in the analysis of adjacent bone. Moreover, attempts to show the value of applying the recently-developed SPECT technique (single photon emission computed tomography), which can be applied to the assessment of bone turnover, to predicting or detecting prosthetic failure have ended in failure[20,28,29].

In the last few decades, the development of absorptiometric techniques has made it possible to accurately quantify the involutional bone loss that sets in after the

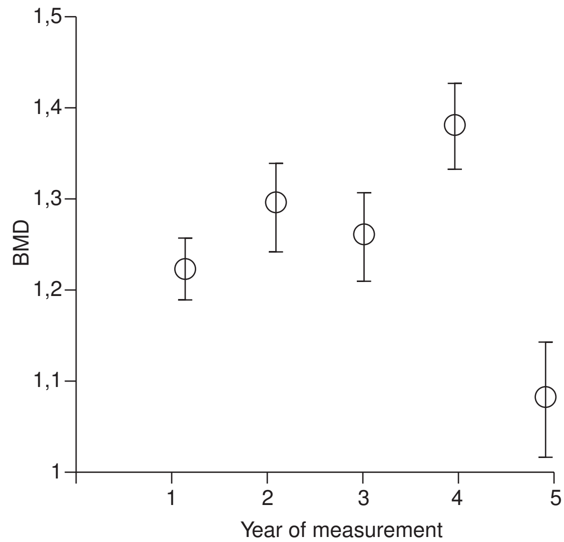

Figure 1. 95% Bonferroni confidence interval, depending on year of measurement. BMD: Bone Mineral Density.

fourth decade of life. These techniques have been used for the diagnosis and follow-up of osteoporosis, especially in post-menopausal women. Recently, thanks to the advent of densitometric studies, which can quantitatively assess bone mass, this technique is being used to determine the degree of bone turnover that has taken place around a foreign body such as a hip prosthesis[21-23,30,31].

The present study sets out to assess osteointegration of an anatomical hip prosthesis, quantifying periprosthetic bone remodeling through dual x-ray absorptiometry densitometry, and to establish the influence of preoperative bone quality on periprosthetic remodeling (age, gender, weight, height).

MATERIALS AND METHODS

The same prosthetic design was implanted in all patients (ABG II, Stryker©, Michigan, USA) with an anatomical femoral component and a hemispherical cup. Fixation was restricted to the metaphyseal area, where the stem featured a scale-shaped design on its anterior, posterior and medial aspects, which imparted the assembly with greater stability. Secondary fixation of the prosthesis was achieved by a 60-micron layer of hydroxyapatite on the stem's proximal area[24,32,33]. The device used in the study was a Hologic QDR 4500, a third-generation densitometer.

The adaptation of the ABG II prosthesis was assessed by controlling bone mineral density postoperatively, both in the implanted and the healthy hips, as well as by considering the patient's age, gender and body mass index (BMI). The procedure followed consisted in comparing a hip with a prosthesis with a hip without one. The areas measured were the three DeLee zones for the cup and the 7 Gruen zones for the femur. The years elapsed between surgery and the densitometric study was also measured (Table 1).

All patients had to provide their informed consent. They were given information on the diagnostic test they would be subjected to and on the reasons why such a test would be conducted.

The patients analyzed were all patients that had undergone primary hip replacement surgery with an ABG II system between January 1998 and December 2003; the total was 73 patients.

As regards computer software, we used Systat 10.0 for setting up the data base and Statgraphics plus 3.0 for the statistical analysis. Regardless of the response analyzed (BMD at the femur or at the acetabulum), the design of the covariance model included four factors and two covariables (age and BMI, which cannot be controlled).

The experimental unit for this study consists of each patient and the observation of BMD in a certain area of bone, under the pre-established conditions (gender, procedure analyzed, measurement area and year of bone evaluation). Use was made of the Kolmogorov-Smirnov hypothesis test, since the simples were small and the random variable was continuous. Using the multi-comparison method we were able to relate two variables with each other and find out what influence they exert on the response. The method chosen was Bonferroni's multiple interval mapping, which uses the same level of significance for all comparisons and operates independently of the features of the different designs.

RESULTS

As regards the year when the densitometric study was conducted postoperatively, it was shown that BMD increased after the first year post-op and then leveled off until the fourth year. Subsequently, a sharp drop ensued (Table 1 & Figure 1).

After a general study on the bone bass of both femurs, an analysis was performed of the interactions between the different main effects. An examination of the variations of BMD depending on the patient's gender, comparing the operated hips with the control group, it

Table 1. Bone Mineral Density expressed in g/cm^2 of bone present at different times post-op

Mean	Standard deviation	Confidence interval	Measurement period	
			Lower limit	Upper limit
Year ≤ 1	1.237	0.0111	1.2149	1.2586
1 < year ≤ 2	1.297	0.0166	1.2644	1.3295
2 < year ≤ 3	1.278	0.0156	1.2475	1.3089
3 < year ≤ 4	1.375	0.0165	1.3422	1.4069
Year > 4	1.124	0.0217	1.0826	1.1660

Table 2. Bone Mineral Density (BMD) expressed in g/cm2 of bone comparing patient's gender and time of measurement of BMD in years

Gender	Measurement period	Mean	Standard deviation	Confidence interval	
				Lower limit	Upper limit
Females	Year ≤ 1	1.144	0.0163	1.1121	1.1762
	1 < year ≤ 2	1.253	0.0168	1.2197	1.2858
	2 < year ≤ 3	1.148	0.0246	1.1002	1.1967
	3 < year ≤ 4	1.272	0.0197	1.2331	1.3105
	Year > 4	0.920	0.0316	0.8578	0.9816
Males	Year ≤ 1	1.329	0.0155	1.2989	1.3599
	1 < year ≤ 2	1.341	0.0279	1.2862	1.3960
	2 < year ≤ 3	1.408	0.0195	1.3698	1.4462
	3 < year ≤ 4	1.477	0.0253	1.4275	1.5270
	Year > 4	1.329	0.0291	1.2718	1.3860

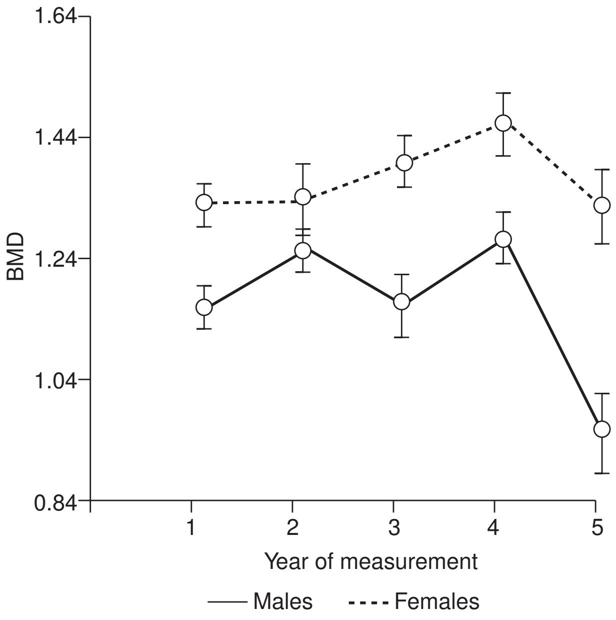

Figure 2. Interaction between the patient's gender and the year of measurement of Bone Mineral Density (BMD).

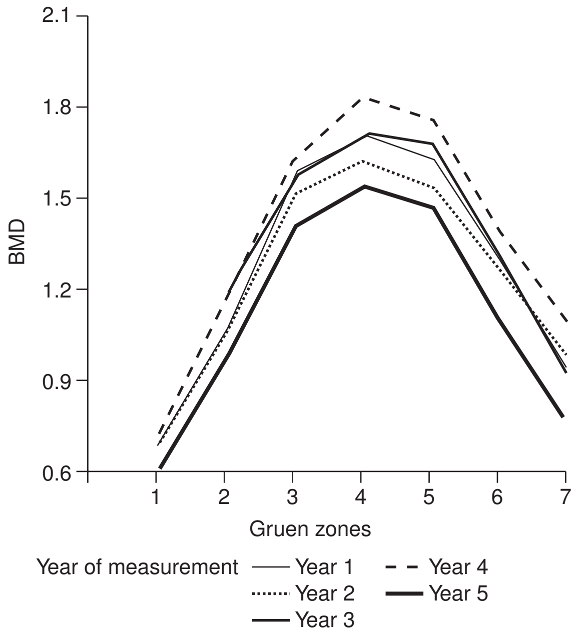

Figure 3. Interaction between Gruen zones in the operated hip and the year of measurement of the Bone Mineral Density (BMD).

was observed that, in females, mean BMD is significantly lower in the two hips analyzed. However, in males a more marked fall in BMD was evident when both hips were compared ($p < 0.05$).

On looking into bone mass remodeling around the implant, for both males and females, it was observed that, for males, bone mass remodeling shows almost no differences over time. There was even an increase in the third and fourth year post-op, followed by a decrease in the fifth year to levels similar to those in the first year. Nonetheless, in the female group, where BMD was lower, a sharper drop in bone mass was identified from the fourth year after prosthetic implantation (Table 1 & Fig. 1).

The graph showing the interaction between year of measurement and gender (Fig. 2) clearly shows the interplay between both effects ($p < 0.05$), since BMI of females presented an irregular trend over time vis à vis the male group. Specifically, if one looks at the third year of measurement, one sees that the hip BMD for males increases while that for females drops.

Emphasis should be laid on the BMD changes that take place over time in the different Gruen zones of the operated hip. It was observed that after the first year post-op BMD increased in all areas, values staying virtually unchanged until the fifth year (fig. 3). From then onwards, there was a generalized decrease of BMD in all Gruen, zones, particularly in zones 1 and 7. In addition,

Table 3. Bone Mineral Density expressed in g/cm2 according to cup and time of measurement (years)

Hip	Measurement period	Mean	Standard deviation	Confidence interval	
				Lower limit	Upper limit
Without a prosthesis	Year ≤ 1	1.251	0.0376	1.1773	1.3250
	1 < year ≤ 2	1.268	0.0554	1.1586	1.3765
	2 < year ≤ 3	1.264	0.0531	1.1598	1.3687
	3 < year ≤ 4	1.152	0.0546	1.0449	1.2595
	Year > 4	1.083	0.0717	0.9419	1.2239
With a prosthesis	Year ≤ 1	1.170	0.0376	1.0960	1.2437
	1 < year ≤ 2	1.145	0.0554	1.0365	1.2544
	2 < year ≤ 3	1.053	0.0531	0.9481	1.1571
	3 < year ≤ 4	1.065	0.0545	0.9575	1.1720
	Year > 4	0.929	0.0717	0.7884	1.0704

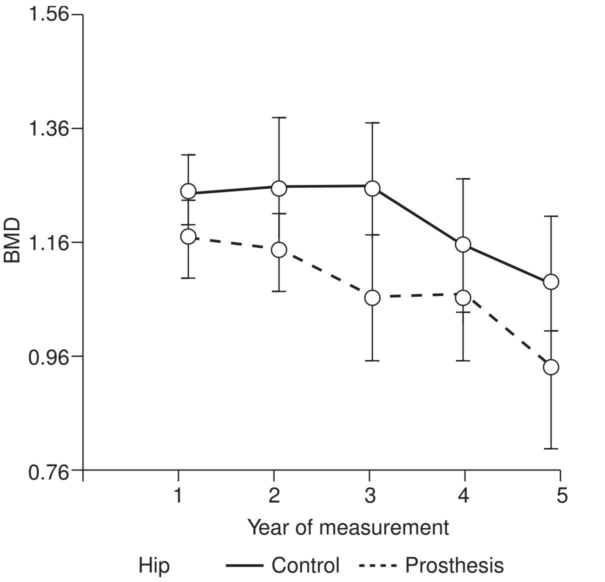

Figure 4. Interaction between year of measurement and cup analyzed. BMD: Bone Mineral Density.

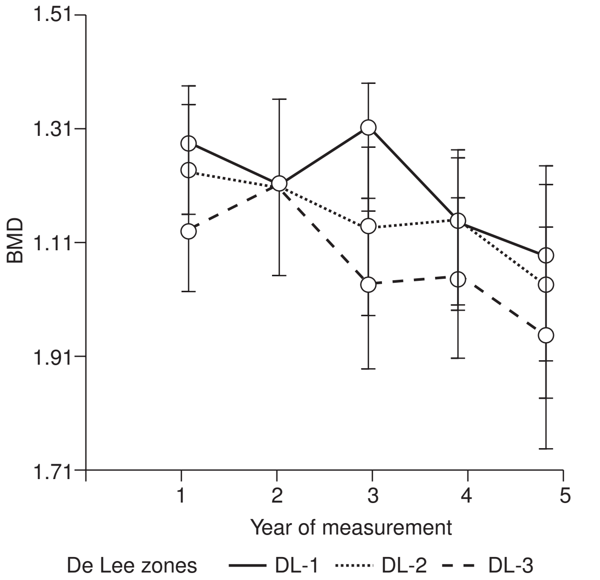

Figure 5. Interaction between year of measurement and DeLee zones, analyzed in hips with a prosthesis. BMD: Bone Mineral Density.

it was shown that in zone 7 there is an increased scatter of results by comparison with the same proximal area, but on the lateral side (Gruen zone 1).

The analysis of both hips in connection with the time of measurement, taken from surgery to the performance of the densitometry, shows a gradual decrease of bone mass in the hip with a prosthesis, which becomes more marked during the third year post-op. Bone mass decrease in the control acetabulum is progressive, although it becomes more noticeable during the third year post-op (Table 3).

Therefore one could infer that there is interaction between both effects. Nevertheless, according to the results of the variance analysis, this interaction is not significant enough to assume that it may affect the response (BMD) (Fig. 4).

An analysis of the changes taking place in the different DeLee zones of the operated hip, with respect to the period of densitometric measurement, shows a drop in BMD in all of them. DeLee zone 3 was characterized by the greatest bone loss from the third year since cup placement. In zone 1 BMD was seen to increase until the third year and then went on to go down steadily until the fifth year. This is the zone that shows a steeper falling from the third year post-implantation (Table 4 & Fig. 5).

Also, there is homogeneity in the time elapsed between implant placement and the performance of the densitometry test. For most patients in the series (34.25%) the period between surgery and densitometry was less than one year and for the rest it was between two and five years, the number of patients subjected to the test each year ranking from 5 to 20%. From these da-

Table 4. Bone Mineral Density (BMD) en g/cm2 in the different DeLee zones for the operated hip; measurement time expressed in years.

Measurement area	Measurement period	Mean	Standard deviation	Confidence interval	
				Lower limit	Upper limit
L1	Year ≤ 1	1.218	0.0664	1.0868	1.3486
	1 < year ≤ 2	1.074	0.0975	0.8818	1.2666
	2 < year ≤ 3	1.236	0.0941	1.0503	1.4215
	3 < year ≤ 4	1.071	0.0958	0.8821	1.2599
	Year > 4	0.967	0.1267	0.7169	1.2166
L2	Year À ≤ 1	1.204	0.0664	1.0731	1.3349
	1 < year ≤ 2	1.116	0.0975	0.9238	1.3086
	2 < year ≤ 3	1.007	0.0941	0.8211	1.1923
	3 < year ≤ 4	1.060	0.0958	0.8707	1.2486
	Year > 4	0.901	0.1267	0.6514	1.1512
L3	Year À ≤ 1	1.105	0.0664	0.9741	1.2359
	1 < year ≤ 2	1.235	0.0975	1.0427	1.4275
	2 < year ≤ 3	0.914	0.0941	0.7282	1.0994
	3 < year ≤ 4	1.024	0.0958	0.8351	1.2129
	Year > 4	0.949	0.0958	0.6994	1.1992

ta one can infer that about 10% of patients were horizontally assessed until the fifth year, which is understandable in an initial prospective study. One could predict that, were this study to progress, in 5 years' time about 35% of patients would have a comparative horizontal study every year until the end of the 5-year period.

The percentage of women receiving an anatomic prosthesis was 53.42%. This group has a mean BMD index at the femoral level of 1.147 g/cm^2, substantially lower than that of the male group (1.377 g/cm^2) (Fig. 2); at the acetabular level mean BMD is 0.967 g/cm^2 for the female group and 1.308 g/cm^2 for males (Fig. 3). Mean BMD is 1.678 g/cm^2 in zone 4, when compared with the upper metaphyseal areas; mean BMD is 0.680 g/cm^2 in zone 1 (Fig. 2).

All of this means that when analyzing the different Gruen zones in both hips a BMD decrease is observed in the operated hip, as compared with the healthy one. Both hips show statistically significant differences ($p < 0.05$) in terms of the bone response in each of the Gruen zones. For that reason, one might expect that there will be differences in the bone response between the implanted and the contralateral hips. This will lead to an overall decrease in bone mass, which will be more marked in certain areas. However, funnily enough, BMD variations from proximal to distal are the same in both hips. This phenomenon is reflected in several densitometric studies[34,35].

In the infero-medial metaphyseal area (zone 6) a BMD increase of over 5% is observed. This corresponds to the area where the stem is anchored. This phenomenon is often detected in imaging studies by densifications of the cancellous tissue, which result from changes in stress patterns and the osteogenic stimulation of the periprosthetic bone[35,36]. Conversely, in the supero-lateral cortex (zone 2) there is a 5%-7% reduction in BMD. This finding runs contrary to the results of an earlier study[37], which found increases in zone 2. This finding could be related to a less stable support of the stem along the lateral metaphysis than along the internal metaphyseal area, resulting in micromotions in Gruen zone 2, which lead to the above mentioned losses in bone mass.

DISCUSSION

Bone remodeling in the vicinity of a hip prosthesis has been a topic of interest in orthopedics since the beginning of arthroplasty. Aseptic prosthetic loosening and periprosthetic bone loss have been widely studied processes given the dreadful consequences they entail[25].

An added problem is the lack of accurate diagnostic tools that can identify prosthetic loosening early enough[26-28,34,38]. Imaging techniques are widely used nowadays but can only detect BMD variations above 30%[27,29,35,37]. Most studies on hip replacement surgery are based on an analysis of clinical data and of plain films[28,30]. CAT and NMRi only provide qualitative data about periprosthetic bone loss.

Densitometry is the technique used to diagnose reductions in BMD around hip prostheses of around 5%[29,31,36,39], which corresponds to changes in BMD of approximately 0.16 g/cm^2. For that reason, DEXA scans are considered a reproducible method, capable of qualitatively analyzing BMD around a metal implant[30,32,40].

In the present study, one same hip prosthesis model is analyzed. Patients were grouped according to gender, measurement site and time elapsed from implantation until the densitometry was carried out.

Correct patient placement is fundamental for a densitometric study; it proved to be the most highly variable factor in this study. This means that persons in charge of performing the test should be appropriately trained. The patient should be placed in the supine position, with the limb to be explored stabilized in neutral rotation.

The initial stability of the prosthesis is not the only factor that influences bone remodeling, other factors are the extent of the porous coating and the firmness of the femoral component, which is a function of both the cross-sectional diameter of the stem and the metal alloy it is made of. So the more rigid stems, greater in diameter and length, will make distal filling more difficult and, as a result, will promote less BMD at the tip, as compared with more flexible stems.

The analysis of BMD variations in the operated femur carried out in this study indicated that age, weight and height determined significant differences across subgroups. Nevertheless, gender was the patient-inherent variable that most influenced bone remodeling.

The presence of the age and BMD covariables in the statistical analysis are fundamental. These variables have significant values (for age, $p = 0.0415$; for BMD, $p = 0,0103$), which means that both contribute to reducing experimental error and therefore facilitate the task of detecting true BMD-related differences between the studied hips.

As regards BMD differences between males and females in the presence of an anatomic hip prosthesis, they can be justified by the variations in bone mineral content found in the first year of the study. The measurements of the different areas in the femur show that there is more bone stock in the lower periprosthetic areas in both male and female patients.

It has been observed, that for the anatomic ABG II stem, load transfer between bone and implant occurs in the upper region of Gruen zone 2 and in Gruen zone 6, where a balance is struck between the stiffness of the bone and the rigidity of the stem[36,39,40]. The idea is to shift this load transfer area to a more proximal region of the femur, preserving the physiological stimulus in order to assure greater bone conservation below that area[39,40]. This phenomenon is reflected in the current paper, where BMD is higher in the metaphyseal area than in the greater trochanter and the calcar.

A separate investigation of the more proximal areas of the operated femur reveals that with the passing of time there is a more significant drop in BMD values than for the greater trochanter. Although it is still zone 1 that has the lowest BMD values in all the different years studied, it is in the calcar area that the most significant decrease in BMD occurs from the fourth year post-implantation ($p < 0,05$).

Another interesting area in the operated hip, as regards the changes taking place over time, is the area around the tip of the stem (Guen zone 4). This area shows a gradual BMD increase from the first to the fourth year post-implantation. Subsequently, the BMD shows a marked decrease.

Initial osteogenic events are related with adaptive phenomena between the implant and the host bone, whereas lytic processes occurring from the fourth year are due to micromotion in the distal area of a stem that is anchored predominantly to the femoral metaphysis. Such distal osteopenia means that there will be no eventual pedestal formation in this type of stem.

When one analyzes acetabular BMD in the different time periods, one is struck by the fact that BMD decreases in both hips almost simultaneously, although there is always less bone density on the operated side. It could be said that the progression of both acetabulums is the same over time. This phenomenon can be explained away by the high frequency of bilaterality in basic hip arthropathy, which makes contralateral non-operated hips more painful than operated hips over time. As a result, patients progressively offload their osteoarthritic hip, living rise to a generalized BMD decrease over time[40].

A study of the changes occurring in the different periacetabular bone areas in the different follow-up periods (Fig.4) shows a BMD reduction in all these areas from the fifth year post-implantation. The behavior of DeLee zone 1 is noteworthy, since BMD went up until the third year and subsequently gradually decreased until the last year of the study. This is due to the additional fixation provided by the screws used in that area[40], giving rise to an increased initial fixation and an activation of osteogenic processes between the first and third year. Nevertheless, from the third year screws start to fail, fixation becomes deficient and all of this triggers a series of osteolytic phenomena that cause a depletion of BMD in DeLee zone 1. In zone 2, BMD stays constant throughout the follow-up period.

A comparison of both acetabulums shows that fluctuations of BMD in the healthy socket are more erratic in the different DeLee zones, although at the end of the follow-up period the BMD rate is practically the same in all three zones. The loss of bone mass in the control acetabulum from the fifth year postimplantation is related with the offload of the non-operated limb, which gradually becomes symptomatic, and with the involutional bone loss that occurs over time[40].

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Conflict of interests: We, the authors, have not received any economic support to carry out this study. Nor have we signed any agreement with any commercial firm to receive benefits or fees. On the other hand, no commercial firm has provided nor will provide economic support to non-profit foundations, educational institutions or any of the other non-profit organizations that we are members of.