Changes in periprosthetic bone remodelling after redesigning an anatomic cementless stem

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Received: 21 August 2007 / Revised: 19 October 2007 / Accepted: 26 November 2007 / Published online: 11 January 2008
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Abstract The aim of this prospective cohort study was to determine the densitometric relevance of minor design modifications of a cementless stem designed to improve proximal load transfer. We used a prospective cohort study with densitometric analysis over a five-year period of two groups of patients with primary osteoarthritis. The first group, 56 hips, received the first version of the ABG stem (ABG-I); the second group, 54 hips, had the ABG-II stem. The results obtained with the ABG-I stem showed a decrease of bone density in proximal areas that ranged from 13% to 37%. However, the new design had a decrease of the same areas that ranged from 9% to 23%. These differences were noted at the end of the first post-operative year and remained stable, except in zone 7, where they were progressive. There is little evidence that the modified stem reduces femoral bone density loss.

Résumé Nous avons revu de façon rétrospective 68 hanches chez 62 patients présentant une dysplasie acétabulaire et ayant bénéficié d'une ostéotomie péri-acétabulaire. Parmi ces 68 hanches, 33 avaient en préopératoire une rétroversion acétabulaire (groupe rétroversion) et 35 une antéversion (groupe contrôle). Toutes les hanches ont été évaluées selon le score de Harris. L'évaluation radiographique de la

rétroversion acétabulaire et du mur postérieur déficient ont été basées sur le signe du croisement et le signe du mur extérieur. Les scores cliniques des deux groupes au suivi final était semblable. Dans le groupe rétroversion, 12 hanches avaient antéversé leur acétabulum en post-opératoire le signe du mur postérieur disparaissant, mais celui-ci restant présent dans 21 hanches avec un acétabulum en rétroversion post-opératoire. Parmi les 21 hanches avec acétabulum rétroversé une coxarthrose postérieure s'est développée à 5 ans post-opératoire. Lorsque l'on réalise une correction par ostéotomie pour une hanche dysplasique avec un acétabulum rétroversé, il est important de corriger cette rétroversion de façon à prévenir une coxarthrose secondaire due à la déficience du mur postérieur.

Introduction

Periprosthetic bone remodelling following the insertion of a cementless femoral stem can be attributed to mechanical [7, 14] and biological factors [6, 23] in response to the new biomechanical situation created by the prostheses. In the last 20 years, dual-energy X-ray absorptiometry (DEXA) has been used to quantify the changes of bone mineral density (BMD) attributed to periprosthetic remodelling, and it is thought to be ideal for long-term follow-up studies [1, 11, 21].

Given the amount of variables influencing bone remodelling, it is exceptional to study some of them separately in vivo. There are few studies that analyse the influence in BMD that small changes in stem design can cause by using two homogeneous groups of patients. With the redesign of the ABG stem, an anatomical cementless stem, we carried out a prospective study which included two groups of patients who received one of the two versions of the stem and who

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completed a five-year clinical, radiographic and densitometric follow-up. The aim was to quantify the effect that a thinner, shorter and polished diaphyseal part of the stem had on promoting better metaphyseal load transfer by analysing the BMD changes in the proximal femur.

Methods

To study the possible differences of bone remodelling determined by the two ABG stem designs (ABG-I and ABG-II), we designed a prospective cohort study that quantified the BMD changes around the implant in a five-year follow-up period. The size of the sample was calculated by considering the average loss of BMD reported in previous studies in the seven zones of Gruen [6, 8, 10, 18, 20, 21, 23]. So, a minimum of 60 patients were considered necessary to be included in the study group. The inclusion criteria were as follows: firstly, the ABG stem should be indicated by the patients' condition according to the shape of the femur and their bone quality; secondly, involvement should be unilateral, since the healthy opposite hip was used to compare the physiological BMD changes; and lastly, patients had to sign a document granting their informed consent to participate in the study. The local Research Ethics Committee authorised the study. So, all of the patients suffering from unilateral osteoarthritis who were seen in the Adult Hip Unit and who met the inclusion criteria were included in the ABG-I or ABG-II groups according to the day of their first consultation (odd day: ABG-I; even: ABG-II). Sixty patients were included in each group between February and October 1999, when the manufacturer introduced the new design and ancillary, which co-existed in our hospital with the old one. However, only 56 patients of the first group and 54 of the second completed the five-year follow-up. All of the data from the lost patients were excluded from the study. The demographics and pre-operative Merle d'Aubigné scores included in Table 1 correspond to those patients who completed the follow-up.

Table 1 Demographics and Merle d'Aubigné (MDA) score of both groups

	ABG-I group (<i>n</i> =56)	ABG-II group (<i>n</i> =54)
Age	60.1 (39–85)	59.2 (38–83)
Gender	27 M; 29 F	26 M; 28 F
Height	160.9 m	166.5 m
Weight	72.1 kg (52–98)	74.4 kg (49–107)
Pain	2.54 (min: 1; max: 4)	2.46 (min: 2; max: 3)
Range of movement	3.81 (min: 2; max: 5)	2.99 (min: 2; max: 4)
Ability to walk	3.44 (min: 2; max: 5)	3.38 (min: 2; max: 5)
MDA score	9.81	8.93

The implants used (Fig. 1) were the two versions, I and II, of the ABG stem (Stryker Howmedica, Mahway, New Jersey), which is a cementless, anatomical, titanium press-fit stem with metaphyseal anchorage. The cups were the ABG-I type for the first group and the ABG-II type for the second; in both cases, a press-fit cementless cup, with almost identical design (the only differences were in the polyethylene locking system that made it impossible to use the old liners in the new cups) but different polyethylene composition. The cup was not part of the study. The anterior and posterior design at the metaphyseal level is scale-like to enhance the stability of the implant; and is coated with hydroxyapatite (HA). The tip of the implant is thin and short, avoiding endo-medullary contact with the diaphysis. The differences introduced in the ABG-II are as follows: slight antero-posterior metaphyseal flare, shorter (on average 1 cm, depending on the size of the implant), highly polished tip with smaller diameter (on average 2 mm) to avoid bony anchoring at this level and endo-medullary contact; the aim is to achieve proximal load transfer and avoid bone atrophy due to stress-shielding.

All of the patients were operated upon using a standard posterior approach by the same pair of surgeons in each group. The femoral canal was prepared with diaphyseal reaming (1 mm more than the tip diameter calculated pre-operatively) and progressive broaching, leaving 2–3 mm of metaphyseal cancellous bone around the stem. The bearing surface was metal-on-polyethylene in all cases. Post-operatively, all of the patients received low-molecular-weight heparin for prophylaxis against deep venous thrombosis, and antibiotic prophylaxis for the first 48 h. Partial weight-bearing with two crutches was allowed during the first six weeks and walking with a cane was recommended for another six weeks.

Clinical evaluation was done using the Merle d'Aubigné score pre-operatively and every year after the operation. Radiographs were obtained annually to determine changes in cup or stem position and any other radiographic findings according to the criteria of Engh et al. [5].

The evolution criteria used were the BMD variations in a series of small frames of 30×30 pixels of each one of the seven Gruen zones, both in the operated and in the healthy hip. To ensure the precise placement of the boxes throughout the study, we used the scan comparison software included in the densitometer. BMD measurements were made with an Hologic QDR 1000 densitometer (Hologic Inc., Waltham, Massachusetts), using the Hologic metal exclusion software. Five scans were performed on the operated hip: pre-operative, at the 15th post-operative day, six months, one and five post-operative years. And only two scans were performed on the contralateral hip: pre-operative and at five post-operative years. Nevertheless, for the operated hip, we took the BMD determined in the

Fig. 1 **a** ABG-I stem. **b** Post-operative radiograph of the ABG-I stem. **c** Radiographic features of the ABG-I stem five years post-operatively. Bone mass in the middle and distal areas seems preserved, but were decreased in the proximal femur

post-operative scan as the baseline value for all of the comparisons.

Patient positioning was considered to be of utmost importance to guarantee the reliability of the measurements [4, 15]. So, a positioning protocol was designed to place the patients in the supine position on the scanner table. The technical features of the densitometer were: precision error in the femur of 1.5–2% and error due to inter-observer variability between 1.6–2%.

For the statistical analyses, an analysis of variance (ANOVA) test for each stem with a significance level of 0.05 was used to analyse significant changes of the BMD in every femoral area between the post-operative scan, 6 months, one and five years post-operatively. When those differences existed, a Student's *t*-test with a significance level of 0.025 was performed to analyse the results between the post-operative time and six post-operative months, post-operative and one year post-operative results, and between the first and fifth year post-operatively. Later, a Student's independent groups *t*-test with a significance level of 0.05 was performed to compare the results of BMD between the groups at the post-operative time, six post-operative months, one and five post-operative years. Finally, a Student's *t*-test for the related data was performed to compare the BMD between the operated and the control hip at five years follow-up.

Results

The comparison of the measurements obtained throughout the follow-up showed some differences in the patterns of remodelling caused by the two stems (Table 2). Post-operative values were taken as baseline for the BMD follow-up in the operated hip. Between the pre- and post-operative values, we found a decrease that ranged from

2.6% to 8.8% in the ABG-I group and from 0.2% to 6.5% in the ABG-II group; these decreases were attributed to the effect of the surgical reaming and rasping, without statistical differences between groups. Six months after the surgery, an additional decrease of BMD was observed in most of the zones around both stems, which was considered to be the result of the rest period and partial weight bearing during the three post-operative months, and the later effects of the surgery. However, there were slight differences attributable to the early effect of the different biomechanical patterns. The ABG-II stem showed some bone mass recovery in areas 2 and 6, with a reduced bone loss in area 7. The period between six and 12 post-operative months reflects the bone response to the new biomechanical environment produced by the hip replacement. In that time, some differences between stems appear. In the ABG-I group, there is a slight additional loss of BMD in zone 1, and some bone recovery in the middle and distal areas around the implant. The ABG-II group shows a similar pattern of remodelling without additional bone loss in the proximal femur. Finally, the patterns of remodelling of these implants showed certain differences in the period from the end of the first to the end of the fifth year. The ABG-I group had minor changes of BMD in zones 1 to 6, but a late decrease in zone 7 that reached up to 37.4%. On the contrary, the ABG-II group had a slow but progressive recovery of BMD in zones 2 and 6, no changes in zones 3, 4 and 5, with a late decrease in zones 1 and 7 that reached 9.0% and 23.8%, respectively. Between implants, at five years follow-up, the differences were statistically significant only in areas 6 and 7.

Clinical evolution was considered good in all of the patients in both groups who completed the densitometric study (Merle d'Aubigné score 16.90 for ABG-I and 16.71 for ABG-II) without significant complications. The radiological evolution at the end of the fifth year follow-up

Table 2 Bone density changes in the operated hip for ABG-I and ABG-II stems throughout the follow-up. Bone density is expressed in mg of hydroxyapatite per cm². The percentage of variation is related to the post-operative scan, considered as the baseline values

Femur	ABG-I					ABG-II				
	Pre-operative	Post-operative (baseline)	6 months	1 year	5 years	Pre-operative	Post-operative (baseline)	6 months	1 year	5 years
Zone 1										
BMD	746	680	622	596	587	788	760	709	703	691
S.D.	169.5	145.4	228.5	182.3	203.1	176.5	197.3	191.3	199.7	224.9
% change			-8.52	-12.3	-13.67			-6.71	-7.5	-9.07
<i>p</i>			0.047	0.001*	0.001*			0.064	0.041	0.009*
Zone 2										
BMD	1,166	1,125	1,072	1,095	1,187	1,183	1,166	1,173	1,142	1,315
S.D.	265.6	209.0	291.5	276.7	409.1	257.8	249.7	297.3	281.4	327.3
% change			-4.71	-2.66	+5.51			+0.60	-2.05	+12.78
<i>p</i>			0.104	0.239	0.061			0.443	0.453	0.001*
Zone 3										
BMD	1,488	1,411	1,299	1,374	1,418	1,479	1,436	1,380	1,390	1,406
S.D.	282.8	181.6	263.8	260.3	305.5	265.7	262.7	271.3	246.3	248.9
% change			-7.93	-2.62	+0.49			-3.89	-3.20	-2.08
<i>p</i>			0.006*	0.069	0.403			0.085	0.395	0.209
Zone 4										
BMD	1,582	1,482	1,485	1,497	1,467	1,632	1,604	1,514	1,572	1,602
S.D.	273.5	211.9	263.0	231.4	289.7	281.2	284.5	290.4	290.3	286.5
% change			+0.20	+1.01	-1.01			-5.61	-1.99	-0.12
<i>p</i>			0.684	0.776	0.718			0.065	0.485	0.525
Zone 5										
BMD	1,545	1,462	1,440	1,446	1,482	1,596	1,582	1,510	1,565	1,683
S.D.	360.0	301.0	284.3	273.5	356.9	341.2	313.9	288.2	290.3	293.9
% change			-1.50	-1.09	+1.36			-4.55	-1.07	+6.38
<i>p</i>			0.140	0.074	0.122			0.082	0.347	0.052
Zone 6										
BMD	1,353	1,317	1,188	1,197	1,331	1,365	1,361	1,390	1,407	1,531
S.D.	383.7	315.1	315.2	310.8	471.1	365.6	322.2	334.9	313.5	328.1
% change			-9.79	-9.11	+1.06			+2.01	+3.37	+12.16
<i>p</i>			0.002*	0.005*	0.560			0.329	0.074	0.002*
Zone 7										
BMD	1,285	1,172	846	852	733	1,277	1,193	1,037	1,002	908
S.D.	304.2	305.6	321.9	310.3	282.1	299.6	290.4	310.9	300.2	274.8
% change			-27.8	-27.3	-37.45			-13.0	-16.1	-23.88
<i>p</i>			0.001*	0.001*	0.001*			0.001*	0.001*	0.001*

*Statistically significant change of bone mass

period proved that all stems were stable; there was no significant cortical hypertrophy nor were there radiolucent or reactive lines. However, in the ABG-I group, we noted cancellous condensation in zones 2, 3, 5 and 6 in more than 80% of the patients and bone resorption in 32% of the patients in zone 1 and 68% in zone 7. In the ABG-II group, we noted cancellous condensation in zones 2, 3, 5 and 6 in more than 46% of the patients and bone resorption in 32.5% of the patients in zone 1 and 38.8% in zone 7 (Fig. 2).

No differences were found pre-operatively between the healthy and the affected hip. The BMD evolution in the contralateral, healthy hip showed slight differences in this period in both groups (Table 3). At the end of the study,

there was a decrease that ranged from 3.2% to 8.6%, which was more evident in the proximal part of the femur and more cancellous bone, reflecting the regressive changes of aging. When compared with the operated hip, the BMD in the middle and distal areas were similar in both hips. Only in zone 7 were there significantly reduced values on the operated hip.

Discussion

Bone remodelling after a hip replacement has a multi-factorial aetiology [2, 22, 23]. In the early post-operative

Fig. 2 **a** ABG-II stem. **b** Post-operative radiograph of the ABG-II stem. **c** At five years follow-up, this stem seem to have cause a reduced loss of bone density in proximal areas, with similar changes in the middle and distal parts around the stem

period, rapid bone loss can be detected as a consequence of post-operative rest, partial weight bearing and surgical technique [10, 11]. In order to quantify and reduce the amount of this loss, which ranged between 0.2% to 8.8%, we took the post-operative scan as the baseline value to calculate later changes due to the biomechanical response to the implant.

Nevertheless, the surgical technique still has an influence on the changes that occur in the first six months. The final rasping and press-fit setting of the stem can cause additional micro-fractures in the surrounding cancellous bone that will suffer resorption in the following weeks and a new decrease of BMD. Later, the effect of the loads and the stress-shielding can increase the amount of loss in areas with reduced load transfer and promote bone recovery in those with an adequate load transmission. The addition of biological and mechanical factors can explain the decrease of BMD in this zone, which reached 27% at six post-operative months in the ABG-I group but only 13% in the ABG-II group.

Most of the remodelling is established at the end of the first post-operative year, when the BMD seems to reach a plateau in all of the areas around the stem [6, 9, 17, 22, 24]. The results of our study suggest that this stability appears between the sixth and twelfth months, reflecting the biomechanical response of the bone according to Wolff's law. After that period, the hip reaches a balance that is maintained with minor changes over the next five years. However, in area 7, was there some late and additional decrease caused by bone resorption secondary to stress-shielding, which was more intense in the ABG-I stem. On the contrary, there was BMD recovery in those areas that efficiently transmit the loads from the stem to the bone. The differences of BMD between stems in areas 2 and 6 at five years suggest two slightly different biomechanical patterns, more efficient in the case of ABG-II, to preserve proximal femoral bone.

Table 3 Bone density changes in the contralateral, healthy hip throughout the follow-up in both groups. Bone density is expressed in mg of hydroxyapatite per cm²

Femur	ABG-I		ABG-II	
	Pre-operative	5 years	Pre-operative	5 years
Zone 1				
BMD	822	771	834	788
S.D.	147.8	174.7	175.1	148.2
% change		-6.0%		-5.5%
<i>p</i>		0.231		0.246
Zone 2				
BMD	1,251	1,222	1,230	1,170
S.D.	204.9	212.9	208.8	216.4
% change		-2.3%		-4.7%
<i>p</i>		0.737		0.704
Zone 3				
BMD	1,539	1,521	1,552	1,518
S.D.	235.7	242.9	247.5	240.2
% change		-0.6%		-4.7%
<i>p</i>		0.362		0.385
Zone 4				
BMD	1,727	1,706	1,684	1,622
S.D.	251.1	260.4	301.8	259.6
% change		-1.2%		-3.6%
<i>p</i>		0.791		0.570
Zone 5				
BMD	1,690	1,664	1,708	1,627
S.D.	296.2	254.6	265.3	255.9
% change		-1.5%		-4.7%
<i>p</i>		0.248		0.251
Zone 6				
BMD	1,413	1,341	1,379	1,306
S.D.	264.0	280.6	285.7	255.9
% change		-5.0%		-4.7%
<i>p</i>		0.355		0.374
Zone 7				
BMD	1,297	1,215	1,284	1,179
S.D.	228.0	241.1	243.5	230.2
% change		-6.3%		-8.2%
<i>p</i>		0.695		0.789

In previous DEXA studies, first-generation cementless stems (usually straight, collared, extensively coated) showed proximal bone loss that reached up to 45% BMD at 24 post-operative months [14, 22, 23]. Second-generation cementless stems (anatomic design, metaphyseal press-fit, proximal coating) made of titanium still had a decrease of BMD at the end of the second year that ranged from 20% to 25% [9, 17]. Tapered femoral components had a proximal loss between 10% to 30% [1, 6, 19]. Custom-made implants reported the best results regarding the proximal loss of BMD, but with a fall of between 10% to 15% at the end of the third year [12, 13]. Recently, femoral stems with reduced stiffness showed a 15% reduction of BMD in the calcar at the end of the second year [7, 9, 16]. The patterns of remodelling produced by these anatomic, cementless stems were similar to those shown by other second-generation cementless stems [6, 9, 17].

Long-term remodelling can be influenced by various different factors, such as age-related changes. Several studies have proven that aging affects both trabecular and cortical bone [22, 23]. Nonetheless, the amount of these changes in our study at the five-year follow-up was reduced, ranging from 3.8% to 8.0%. This small decrease of BMD in the healthy hip suggests that the changes of the activity level due to the surgery were not intensive enough to significantly affect the BMD of these patients, and their post-operative activity level was similar to normal subjects. These changes coincided with those observed in the Spanish population, which had an average decrease of 3.7% between groups aged 50–59 vs. 60–69 years old [3]. Thus, the differences of BMD observed between the operated and healthy hip were significant only in zone 7 in both groups. These facts allow us to propose that the age-related effects in people who are 60 years old at the time of the surgery have a minimal influence in their BMD five years after a hip replacement.

We acknowledge some limitations of the study. First, we used a non-randomised comparative clinical trial, which supplies reduced clinical evidence, especially with the minor differences observed in this study. And second, the size of the implant was decided in order to obtain a solid metaphyseal fixation and a minimum of 2 or 3 mm of cancellous bone around the implant. However, in some patients with more dense cancellous bone, we used smaller implants that left more metaphyseal bone, which can cause some changes in the pattern of load transfer.

In conclusion, these anatomical cementless stems provide a pattern of load transfer that helps to preserve similar rates of bone density in the middle and distal zones of the femur when compared with the contralateral, healthy hip. However, the new design of this stem seems to be associated with a modest reduction of BMD loss in the proximal femur.

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