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Title of the paper:

Adaptive bone remodeling with new design of the ABG stem. Densitometric study

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There are no conflicts of interest

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ABSTRACT

Introduction: In order to establish the pattern of bone remodelling caused by a cementless, anatomic implant, we intend to evaluate the changes in bone mineral density observed after surgery in the Gruen zones.

Material & methods: A controlled, prospective study was carried out, in which a group of 37 patients suffering from primary coxarthrosis were densitrometrically analyzed over the one year period following the implant of an ANATO® stem (Stryker®). The patient's healthy hip was taken as the control. Any differences in the remodelling pattern were compared according to age, body mass index and implant size.

Results: Decreases in bone mineral density were observed after 3 months in all of the zones studied. However, this bone mineral density loss was recovered in all zones by the end of the study, except in zone 7 where a decrease of 7.2% in bone mass was observed. In zones 2 and 6, where more loads are transmitted, bone mass preservation, in accordance with Wolff's law, can be seen. No differences were found in the remodelling pattern in relation to age and body mass index. Neither were there any differences related to stem size except in zones 1 and 7.

Conclusion: the ANATO® stem achieves an efficient transmission of loads between the stem and the proximal femur, providing enough mechanical loads for bone preservation. It is only in zone 7 where significant bone atrophy can be observed, attributable to the damage that this area suffers during the surgical process and the subsequent stress-shielding caused by the implant design.

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KEY WORDS: Hip, total arthroplasty, bone densitometry, periprosthetic bone remodelling

INTRODUCTION:

Bone remodelling after a hip arthroplasty can be observed with all models of cemented and cementless femoral stems. Following the implantation of a femoral stem, the biomechanics of the hip change and the bone reacts to the new situation in accordance with Wolff's law, in a process of adaptive remodelling (1). These remodelling changes are attributable to both the mechanical and biological factors which react to the new biomechanical situation. Among these factors are those which are influenced by the implant itself, such as implant size, rigidity, extension of porous coating (2), design (3) or alloy; and factors dependent on the patient, such as age, weight, gender or most importantly the preoperative bone mass (BM) (4,5).

Considering that a BM loss of 30-40% is required in order to observe the results in a plain radiograph (6), the prospective studies which use Dual Energy X-ray Absorptiometry (DEXA) are considered to be the ideal method to assess the changes in bone mass caused by different stems over the years (7,8,9)

Densitometric studies with different implants have made it possible to quantify the influence of these factors in bone remodelling and provide information for the redesign of implants in use or for the design of new implants. Additionally, this method has proven to be reliable and precise and is considered ideal for repeated examinations in follow-ups due to its accuracy and low radiation (9).

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Several studies have been published about the ABG I® prothesis (Stryker®) over the last two decades, with good clinical and radiological results (10,11,12), but the femoral stem caused notable stress-shielding, leading to 30% decreases in bone mass in Gruen zones 1 and 7 (13)

The redesign of this implant (ABG-II®), matched the clinical and radiological results in addition to improving the bone modeling results (14). The decreases in bone mass dropped to 15% in the greater trochanter and calcar at 5 years, decreases which are noticeable 6 months after implantation (15).

At the beginning of 2015 the development of the ABG II® implant (ANATO®) emerged. The modifications in the design of its components and its composition aim to maintain the good clinical and radiological results of its predecessors whilst attaining a decrease in stress-shielding to achieve greater preservation of bone density in the long term.

The ANATO® stem is a "refinement" of an efficient, previous design. It allows for the choice of a neutral or anteverted neck, adapted to the anatomy of each patient. The alloy has been modified, changing from $TM_{12}Z_6F_2$ in the ABG-II® to Ti_6AlV_4 in the ANATO® stem. In addition it has a biological coating of hydroxyapatite with greater porosity. Finally, the shorter stem length in the large sizes conserves more distal bone and improves the transmission of forces at a proximal level, which is expected to favour a decrease in proximal femur atrophy.

The purpose of this study is to evaluate the variation in BM caused by the periprosthetic remodelling of this new implant (ANATO®) in a group of patients over

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the first 12 months post operative period, taking the contralateral, healthy hip as control.

MATERIAL AND METHODS:

In order to know the periprosthetic remodelling caused by the ANATO® stem, a prospective study was designed using the healthy hip as control. We included those patients operated on between the months of March and September 2015. Data collection was carried out through the use of clinical records and anamnesis. The study was approved by the Ethics Committee.

Densitometric evaluation:

The variation in BM was taken as evaluation criterion using 30 by 30 pixel squares for each one of the 7 Gruen zones for both the healthy and unhealthy hip. Bone mass determinations were carried out with the LUNAR DPX enCORE densitometer (General Electrics Healthcare, Madison) using a software with metal exclusion. The measurements were done on both hips in the pre-op and one year after the operation, while measurements of the operated hip were also taken in the immediate postoperative period and at 3 and 6 months after the operation. In addition, the influence of other variables in bone remodelling, such as age and BMI, were evaluated at the one year stage.

Changes in hip rotation during a densitometric examination are known to have an influence on the reliability of the measurements obtained (16). Therefore, a patient positioning protocol was designed in order to ensure the reliability of these

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examinations. Quality controls were done every morning for the DXA equipment to verify system stability, as specified by manufacturer's guidelines

Study population

The study inclusion criteria were for patients to be diagnosed for treatment with this type of implant due to primary coxarthrosis, not to have any radiological signs of osteoporosis, to have a healthy contralateral hip and to accept to participate in the study.

The study group consisted of 37 patients in the ANATO® group (31 men and 6 women), with an average BMI of 29.2 kg/m^2 (18-32; D.S. 4.50). The average age was 57.3 years (36-75; D.S.8.47**)**. All patients completed the one-year follow-up.

Anatomic stem

The implant used was the ANATO® stem (Stryker®, USA), with a cementless cup (TRIDENT®) and ceramic on polyethylene wearing couple (the latter two not being object of this study). It is a cementless, anatomical stem, with press-fit metaphyseal fixation and a Ti_6AlV_4 alloy (Figure.1). It offers a neutral or 7º anteverted neck, making it possible to choose one or the other depending on the patient's anatomy and intraoperative stability. At the metaphyseal level the implant has a scale design on the front and rear surfaces, which help to transform the axial forces into transversal ones thus improving the stability of the implant, in addition to a Hydroxyapatite PureFix® coating.

From size 4 onwards, the total length of larger implants does not increase. However,

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the metaphyseal part of the implant does, in order to adapt to the femoral morphology of the patients. The implant tail, which is thinner and more polished, retains the sole purpose of aligning the implant within the femoral canal to avoid varus or valgus malalignment.

In summary, the fundamental differences with respect to the previous model (ABG II®) are:

- Anteverted and neutral neck options.
- Change in the alloy: Ti_6AlV_4 (ANATO®); $TM_{12}Z_6F_2$ (ABG II®)
- Shorter length and distal diameter in the large sizes of the ANATO® model (Figure 2)
- Plasma Spray and biological hydroxyapatite coating with greater porosity.

Surgical technique:

All patients were operated on in the lateral decubitus position, with a posterolateral approach performed by the same group of 7 surgeons. Antibiotic prophylaxis was implemented using Cefazolin, or Teicoplanin in case of allergy, for 24 hours and antithrombotic treatment was carried out using low molecular weight heparins over a period of 30 days.

The patients rested in bed for the first 24 hours, after which the drainage was removed from the wound. From this moment the patients began to assume the sitting position on the edge of the bed or in a high chair. Later, isometric exercises of

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the lower limbs were allowed before walking with crutches or walking frames in partial weight bearing, depending on tolerance.

The patients continued walking with partial support for 6 weeks, at which time the crutch of the operated hip was withdrawn and full weight bearing was allowed. At 3 months the last crutch was removed from the health hip and free movement was authorized.

Returning to work was allowed after 6 weeks for sedentary jobs and after 3 months for light physical work. Heavy physical work was not allowed.

Statistical analysis

The statistical study was carried out using SPSS software, version 20.0. The Chi square test was used for the comparison of percentages, the Student's t-test was used for the median with homogeneous parameters; and the Kruskall-Wallis test was used for the median with non-homogeneous parameters.

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RESULTS:

The evolution of bone mass in both hips of these patients is presented in Table 1. The table shows the pre-operative and one-year post-op results of both hips, and the 3 and 6 month scans of the affected hip. Postoperative values were taken as reference for monitoring bone mineral density in the operated hip.

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3 months after the operation there is a generalized bone loss, visible in all of the areas. This is probably due to surgical rasping, which compromises the endosteal blood supply, and the moderate inactivity in postoperative period.

However, a recovery of bone mineral density (BMD) can be seen in zones 1, 2, 3, 4, 5 and 6 within six months of the operation, which can be attributed to the effect of full weight bearing. This increase in BMD was maintained a year after the operation in those indicated zones.

However, in zone 7 a different pattern was observed. There was a temporary recovery of BMD in this zone at six months, but with a subsequent loss of mineral density at the one year follow-up. The BMD showed a decrease of -9.9% at 3 months, -5.3% at 6 months and -7.2% at one year, this decrease was statistically significant (p:0.01)

When the BMD differences between age groups (Table 2) were compared at the end of the follow-up, the median of the sample, 57 years, was taken as the cut-off point. A variation of -7.8% to + 3.8% of BMD was observed in the group younger than 57, and there was a variation of -6.7% to + 2.5% in the group aged over 58. There were no statistically significant differences between the groups in any of the zones.

To evaluate the BMD differences at the end of the follow-up according to body mass index (BMI) (Table II), the sample was divided into two groups (GROUP 1: BMI<30 and GROUP 2: BMI>30). The cut-off point was set at 30 as it was the median of the sample and it divided the sample into two homogeneous groups. We found that in

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the BMI < 30 group there were variations in BMD ranging from -11.2% to +0.7% while in the BMI>30 group the variations ranged between -4.4% and +5.4%. These differences were statistically significant in zones 1, 2 and 3 in the total comparison of both groups.

With respect to BM evolution in the healthy hip (Table 3), which was taken as control, a bone mass variation of -3.2% to +0.6% was observed. These values ranged between -100 and + 23.4 mgr/cm2 at the end of the 12 months in the operated hip in contrast to the healthy hip which ranged between -30.4 and +47.4 mgr/cm2 , with this difference being statistically significant in zone 7.

Finally, when comparing the evolution of BMD between stem sizes (Table 4), some differences were observed. The larger, more rigid stems transmit the loads to the bone from the central areas of the implant to the proximal femoral isthmus, where denser bone is found. As a consequence, there is greater stress-shielding and atrophy of the proximal zones, which is significant in zone 1, and relevant, although not statistically significant, in zone 7. There is a significant difference between sizes in zone 4, but it is not clinically relevant. It is probably due the bone loss caused by intramedullary over reaming so as to avoid the contact of the implant tail with the diaphyseal bone.

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DISCUSSION:

The implantation of a femoral stem produces the so-called adaptive remodelling, which has a multifactorial origin (17, 18, 19).

In order to accurately quantify the changes in bone density which occur in the femur due to this process, it is essential to use DEXA in long term follow-up (20).

Previous studies using densitometry to evaluate the variation in BMD of the proximal femur after the implantation of a cementless femoral stem show that at 3 and 6 months after surgery, BM decreases can occur. These decreases can range from 4 to 50 % of the initial bone mass, depending on the implant, the surgical technique and the methodology used for its measurement. Among the main causes of these losses we can mention the partial weight bearing during the first weeks after the operation and the immediate decrease of bone stock after femoral preparation with reaming and rasping, the latter being able to jeopardize up to 10 % of the initial bone stock (21,22).

Furthermore, we must take into account that the surgical technique has an important influence on the changes which occur in the early period. The preparation of the metaphysis and the press-fit system of the implant can cause micro-fractures in the cancellous bone that can be reabsorbed in the following weeks, producing new decreases of bone mass which can be detected in the first 3 months after the operation.

It is accepted that most remodelling stabilizes at the end of the first year post-operation, when bone mineral density appears to reach a plateau in all the areas around the stem, from which point the changes reflect the biomechanical response

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of the bone in accordance with Wolff's Law (23,24).

Studies carried out on previous models of this stem (ABG-I® and ABG-II®), show a slight loss of bone in zones 2 to 6 12 months after implantation. However, these losses were already present at 3 and 6 months post-op and were more significant in the ABG-I® implant. In both stems, the most pronounced losses were observed in Gruen zones 1 and 7. The redesign of the stem (ABG II®) by widening the antero-posterior metaphyseal diameter in addition to the ABG-II® implant's shorter tail with reduced diameter, explains the decrease in bone loss in proximal zones (15), since this improved the transmission of loads.

In our study, we also observed decreases in BMD at 3 months in all the zones studied, probably due to the damage suffered during surgery and the partial weight bearing of the operated limb. However, recovery was observed in all of the zones over the following months, except in zone 7, which becomes partially bypassed as it does not receive enough mechanical loads to favour bone recovery. In zones 2 and 6, where more loads are transmitted, bone mass preservation is observed in accordance with Wolff's law.

Other authors (25) have confirmed that age affects the density of trabecular and cortical bone. In our study, the younger patients with, in principle, better bone quality and more rigid femurs, were observed to have no significant remodelling differences when compared to the group of patients aged over 57. Hence, it is concluded that with this stem, age does not determine a different pattern of remodelling if the initial BM is conserved.

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Some studies have determined the negative influence being overweight can have on the functional recovery of patients, pain management and incidence of infections (26). When studying the influence of BMI on remodelling, some variations in the pattern of remodelling between groups were observed, but only significant differences were found in some areas. In the BMI < 30 group, a slight loss of bone was observed in zones 1 to 5, bone preservation was noted in zone 6, but with the greatest loss being in zone 7. In the BMI > 30 group, slight changes were observed in bone mass in zones 1 to 6, but the general tendency in these areas was to preserve bone, with slight atrophy in zone 7. The differences between these two groups, although statistically significant, are not clinically relevant, and can be attributed to the higher level of physical activity that is usually observed in patients with BMI <30. With these results it would seem that the body mass index does not bring about large differences in femoral periprosthetic remodelling after implantation of the ANATO® stem in the first postoperative year.

When evaluating bone mass variations between the operated and healthy hip at the end of the post-operative year, significant differences were only found in zone 7. Therefore, we could conclude that in the middle and distal zones of the operated hip, BMD evolution is no different to the involutional changes observed in the healthy hip. We can also conclude that more follow-up time is needed to find any differences, with some studies recommending up to three years more (27). This suggests that the ANATO® stem, recreates a fairly physiological load pattern, which allows the preservation of bone mass in all areas except zone 7.

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With regard to the variation of BMD in relation to stem size, we could see that the difference in the total length of the implant, according to the size of the stem, does not determine any other differences, to those mentioned in zones 1 and 7. This is because the extension of the biological layer, where the fixation and integration of the implant is achieved, increases proportionally to the size of the implant, seeking at all times to adapt to the proximal femoral morphology. The tail of the implant is for the sole purpose of aligning the stem, being polished and thin to avoid bone fixation at that level.

A similar result to this was observed in a recent study, which compared bone remodelling between a standard length cementless stem and a shorter cementless stem in all seven Gruen zones at two years. At the end of the follow up, they did not find any statistically significant differences in periprosthetic bone loss between the two stems (28).

It is known that differences in the angle of anteversion of the femoral neck can modify bone remodelling in zones 1 and 7 (29). In our case, as we used the 7º anteverted neck model in all the cases, we were not able to draw conclusions in this respect, being a point to study in future evaluations.

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<u>Limitations of the study</u>:

- Firstly, the low number of patients, especially female, may be insufficient. Consequently a larger number would contribute more statistical power to our sample.

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- Secondly, the follow-up time of one year prevents us from evaluating long-term bone remodelling changes, although it is accepted that remodelling changes occur in the first postoperative year.

In conclusion, the ANATO® stem allows an efficient transmission of loads from the stem to the proximal femur, providing enough mechanical loads for bone preservation. Only in zone 7 is any significant bone atrophy observed, attributable initially to the denervation and devascularization which this area suffers during the surgical technique. This causes a bone atrophy which is already visible at three months. The bone losses in this area were not recovered by the end of the study as area 7 does not receive a physiological stimulus from the stem for bone recovery.

Disclosures:

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Figure 1: Image of the two implants used. The ANATO stem (left) and the ABG-II stem (right)

Figure 2: Image of two cases, not included in this study, to show the difference in length between the ABG II stem and the ANATO stem according to stem size. In the image on the left, a size 4 ABG II stem in the right hip and a size 4 ANATO stem in the left hip, showing that both implants are the same length. In the image on the right, a size 6 ABG II stem in the right hip and a size 6 ANATO stem in the left hip, showing the difference in length between one and the other despite being the same size.

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<u>TABLE I.</u> Evolution of bone mass in both hips over one year

Gruen Zones	Pre-op	Post-op Reference	3 months	6 months	1 year	Healthy-Preop Control	Healthy 1 year
Area 1	917	918	884	922	901	964	933
Variation			-3,7%	0,40%	-1,80%		-3,20%
P			0,879	0,488	0,211		0,023
Area 2	1599	1823	1778	1844	1846	1684	1671
Variation			-2,4%	1,10%	1,20%		-0,70%
P			0,54	0,474	0,237		0,706
Area 3	1970	2132	2042	2148	2155	2044	2022
Variation			-4,2%	0,70%	1,10%		-1,70%
P			0,628	0,423	0,418		0,184
Area 4	2108	2067	2012	2029	2043	2127	2076
Variation			-3%	-1,80%	-1,10%		-2,30%
P			0,47	0,671	0,332		0,001
Area 5	2039	2118	2010	2076	2090	2085	2054
Variation			-5%	-1,90%	-1,30%		-1,40%
P			0,046	0,177	0,448		0,02
Area 6	1647	1695	1622	1694	1730	1715	1672
Variation			-4,3%	-0,10%	2,0%		-2,50%
P			0,063	0,977	0,337		0,06
Area 7	1224	1375	1250	1301	1275	1231	1239
Max-Min			-9,9%	-5,30%	-7,2%		0,60%
p			0,001	0,041	0,01		0,669

Changes in bone density, in both the operated and healthy hip for the ANATO stem, during 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.

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TABLE 2: Differences at the end of the follow-up according to age and body mass index

	BMI up to 30 (n=19)		BMI over 30 (n= 18)			Up to 57 years old (n = 18)		Over 57 years old (n= 19)		
Gruen Zones	BMD postop	BMD 12 m	BMD postop	BMD 12 m	p-value	BMD postop	BMD 12 m	BMD postop	BMD 12 m	p-value
Área 1 % variation P value	922	881 -4.4% 0.296	911	941 +3.2% 0.312	0.034	909	906 -0.3% 0.910	926	895 -3.3% 0.474	0.357
Área 2 % variation P value	1836	1800 -1.9% 0.432	1802	1901 +5.4% 0.029	0.028	1849	1888 +2.1% 0.300	1798	1807 +0.5% 0.877	0.852
Área 3 % variation P value	2114	2089 -1.2% 0.499	2118	2233 +5.4% 0.003	0.039	2138	2220 +3.8% 0.114	2126	2094 -1.5% 0.497	0.788
Área 4 % variation P value	2052	1995 -2.7% 0.102	2078	2096 +0.8% 0.624	0.174	2068	2067 -0.1% 0.997	2067	2021 -2.2% 0.265	0.904
Área 5 % variation P value	2085	2024 -2.9% 0.159	2149	2160 +0.5% 0.874	0.434	2112	2098 -0.6% 0.814	2125	2083 -1.9% 0.378	0.483
Área 6 % variation P value	1673	1686 +0.7% 0.833	1686	1752 +3.9% 0.188	0.274	1653	1679 +1.5% 0.554	1734	1778 +2.5% 0.463	0.387
Área 7 % variation P value	1362	1209 - 11.2% 0.002	1388	1327 -4.4% 0.358	0.185	1381	1273 -7.8% 0.050	1370	1278 -6.7% 0.102	0.612

Comparision of bone remodelling determined by the stem according to BMI and age. Bone density is expressed in mg of hydroxyapatite per cm2. The percentage of variation is related to the post-operative scan, considered as the basel

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TABLE III. Bone mineral evolution in the healthy hip

Difference BMD At 1 year n=37	CASES	Control (healthy)	p
F1	-17,3	28,6	0,696
F2	23,4	4,5	0,593
F3	23,2	10,2	0,307
F4	-23,7	47,4	0,339
F5	-28	-30,4	0,951
F6	35,3	42,4	0,105
F7	-100,1	-18,1	0,010

Bone density changes in the contralateral, healthy hip throughout the follow-up. Bone density is expressed in mg of hydroxyapatite

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TABLE IV. Comparation the evolution of bone mineral density between stem sizes

Gruen Zones	(size <= 4) 15 days	3 m	6m	12 m	(size >5) 15 days	3 m	6 m	12 m	p
Area 1	900	886 -1.5%	931 +3.4%	920 +2.2%	940	852 -9.3%	892 -5.1%	869 -7.5%	0,034
Area 2	1799	1771 -1.5%	1839 +2.2%	1821 +1.2%	1858	1780 -4.1%	1848 -0.5%	1899 +2.2%	0,951
Area 3	2082	2015 -3.2%	2124 +2.0%	2133 +2.4%	2211	2073 -6.2%	2177 -1.5%	2195 -0.7%	0,265
Area 4	2008	1971 -1.8%	1995 -0.6%	2036 +1.3%	2143	2052 -4.2%	2065 -3.6%	2042 -4.7%	0,012
Area 5	2053	1942 -5.4%	2033 -0.9%	2048 -0.2%	2189	2081 -4.9%	2119 -3.1%	2133 -2.5%	0,543
Area 6	1666	1592 -4.4%	1644 -1.3%	1687 +1.2%	1710	1655 -3.2%	1748 +2.2%	1800 +5.2%	0,442
Area 7	1352	1251 -7.4%	1329 -1.7%	1309 -3.1%	1386	1238 -10.6%	1234 -10.9%	1206 -12.9%	0,121

Comparison of bone remodelling between stem sizes. 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.

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image1-37-2.JPG

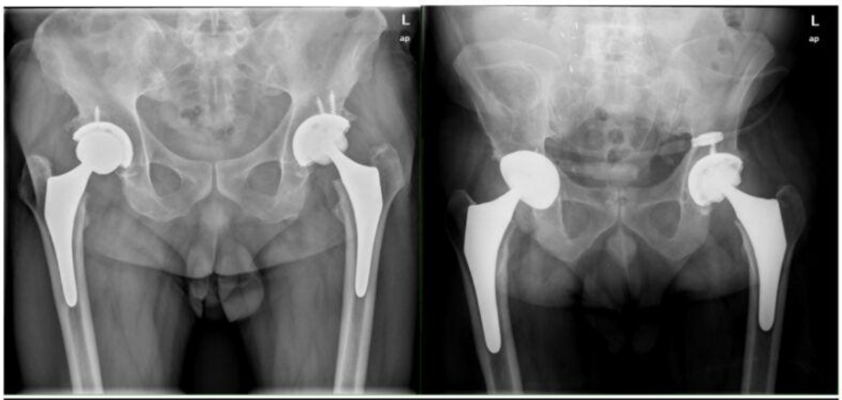

image2-10-2.JPG