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The Effects of Technique Changes on Aseptic Loosening of the Femoral Component in Hip Resurfacing. Results of 600 Conserve® Plus With a 3 to 9 Year Follow-up

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Running title: Technique and femoral Loosening

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ABSTRACT

The purpose of the present study was to determine the effectiveness of modifications in the surgical technique on loosening of the femoral component in the first 600 consecutive Conserve® Plus metal-on metal hybrid resurfacings. These modifications were gradually introduced over time but all the changes were implemented after the first 300 hips. Average age of the patients was 48.9 years and 74% were male. Average follow-up was 70.5 months for the first 300 hips and 42.4 months for the second 300 and there was a significant improvement (p=0.016) of the second 300 hips over the first 300 in a time-dependant analysis using as an end point the time to appearance of a radiolucency suggesting potential femoral component loosening. None of the components with cemented stems showed femoral radiolucencies or were revised for aseptic loosening. Adding fixation holes in the dome and chamfered areas and cleansing and drying using a suction tip in the dome hole were significantly related to the improvement of the results. Positioning the femoral component in a more valgus position did not show any effect as an independent variable.

INTRODUCTION

Surface arthroplasty of the hip using metal-on-metal (MOM) bearings was introduced in the 1990's [1-4]. The first detailed analysis of the MOM hybrid surface arthroplasty with Conserve® Plus (Wright Medical Technologies, TN, USA) implantations identified loosening of the femoral component as the main mode of failure[5] just as had been the case with the first generation of metal-on-polyethylene resurfacings[6,7]. Unlike polyethylene resurfacings, however, osteolysis secondary to debris was not identified as a risk factor for the development of radiolucencies (insecure femoral fixation) and loosening, presumably because the wear has been only a few microns per year and the debris has a lower inflammatory response[8]. Unlike metal-on-polyethylene bearings, the increased diameter of the femoral ball does not adversely affect the wear of metal-on-metal components [9,10].

Our initial risk analysis for loosening highlighted the association of clinical failures and radiographic signs of loosening with a small area of fixation, the presence of femoral head cysts greater than 1 cm in size, and a varus positioning of the femoral component[5,11,12]. The quality of bone preparation was not specifically addressed in that analysis. However, the review of the intra-operative photographs taken after preparation of the femoral head lead to subsequent changes in bone cleaning, drying, and an increase in the contact area between bone and cement with additional drill holes. The purpose of this review was to compare the occurrence of loosening and radiographic signs of loosening of the femoral component between the first and second 300 hips of a consecutive series of over 900 metal-on metal hybrid surface arthroplasties and relate the results to technique changes instituted.

METHODS AND MATERIALS

Between November 1996 and March 2003, 600 hips in 519 patients were implanted with Conserve® Plus resurfacing components (Wright Medical Technologies, TN, USA) after hospital institutional review board approval, and as part of a Food and Drug Administration clinical trial. The details of the patient demographics, including the distribution of etiologies and diagnoses, are presented in Table 1.

The initial surgical technique has been described in detail elsewhere [5,13,14]. Briefly, the femoral head is prepared by cylindrical reaming, removing the femoral dome bone with an oscillating saw and chamfering the head. Cystic material and necrotic bone were removed with curettes and a high-speed burr. The system was designed to provide a one mm cement mantle. Photographs of the prepared femoral head were made prior to cementation. Since the initiation of the series, several modifications have been made to the surgical technique as a consequence of our previous radiographic and loosening analysis. Not all the changes took place at the same time and some proceeded from a gradual process. However by case 300 all these changes had been initiated, and we will refer to the first 300 cases as 1st generation femoral fixation technique (group 1) and the next 300 hips the 2nd generation femoral fixation technique (Group 2). The changes pertaining to the two generations of femoral fixation techniques are summarized in Table 2.

Surgical changes

Initially the head was cemented after chamfer reaming without further preparation or just drilling a few three-millimeter fixation holes to a depth of three to five millimeters in the dome area. The addition of drilled holes into the femoral head affects the bone-cement contact area in a very effective manner as shown in Table 3. We increased the number of holes drilled and the area in which these holes are drilled, adding the chamfered region of the prepared femoral head. Table 4 shows the evolution of the number and position of the drill holes throughout the series.

A suction tip was placed in the central hole to dry the femoral head after jet lavage and during cement pressurization of the cylindrically reamed head. This improvement was made after the first 100 cases.

The review of the retrieval and intra-operative photographs of the early failure cases suggested that an incomplete removal of all cystic material could be related to loosening. A more meticulous preparation of the bone surface was implemented to remove all debris utilizing a high-speed burr, and better clean and dry the bone prior to cementation. An example of these technical changes is shown in figure 1.

The orientation of the femoral component in the frontal plane also evolved throughout the series as the target stem shaft angle shifted from anatomic (stem aligned with the neck axis) to a greater valgus of 140 degrees. This modification was effective after the first 100 cases. Table 5 shows the evolution of the stem shaft angle by series of 100 consecutive hips.

The metaphyseal stem, originally designed to be left uncemented and ensure proper component alignment, was cemented in 161 hips. In nine of the first 300 hips the stem was cemented because of severe neck osteopenia or especially large defects such as those resulting from previous coring or hemisurface arthroplasty. In the next 300 hips, 152 were cemented-in to better evaluate the effects of cementation as an improvement of initial fixation, and to evaluate any possible negative consequences such as femoral neck stress shielding. This included series of 100 hips in which 92 stems were cemented in irrespective of bone quality and cyst formation. The remaining eight were not cemented because of an oversight (4 cases) or the decision to match the technique with that of the previously operated contralateral hip in 4 bilateral patients.

Outcome Evaluation

For this study the UCLA 10 point pain, walking, function and activity scores were calculated[15]pre-operatively and at last follow-up along with SF-12 physical and mental scores as an evaluation of quality of life[16]. Harris hip scores[17] were computed post-operatively as an element of comparison with other studies.

Radiographic analysis

All of the patients had antero-posterior, modified table-down lateral, and Johnson cross-table lateral radiographs of the pelvis taken preoperatively and, where possible, during each follow-up. The radiographic analysis system previously described was utilized to analyze femoral fixation by critically scrutinizing the presence or absence of radiolucencies in three zones around the short metaphyseal stem[5]. The metaphyseal stem/femoral shaft angle was measured from the post-operative antero-posterior radiographs as an assessment of femoral component positioning.

Radiographs have been evaluated preoperatively and postoperatively at three to four months, one year and at yearly intervals. Three patients (four hips) died at twenty-one, twenty-three and seventy months postoperatively of causes unrelated to the surgery. Three patients (0.5%) were lost to clinical follow-up. Eighteen hips (3.8%) failed to provide 2-year minimum radiographs and the radiographic analysis was based on 582 cases.

Statistics

The comparisons between the two groups were made using survivorship techniques (log rank test for comparing Kaplan-Meier survivorship curves) to account for the differences in follow-up time. The time to first appearance of substantial stem radiolucencies was used as end point. The Cox multivariate proportional hazards model was used to evaluate the effects of the various technical changes and adjust comparisons for previously identified pre-operative risk factors[5], in particular the surface arthroplasty risk index (SARI)[11]. Student's t-test was used in the comparison of clinical outcome results.

RESULTS

Clinical results

The average duration of follow-up was 82 months (range, 69 to 109) for group 1 and 54 months (range, 33 to 69) for group 2. The outcome study results (UCLA hip score, Harris Hip score and SF-12 scores) are summarized in Table 6. The post-operative UCLA function score and HHS showed a significant ($p<0.05$) improvement from group 2 over group 1.

Radiographic Results

At this time there are substantial femoral metaphyseal stem radiolucencies in 13 hips (2.2%) that have not been revised. Only one patient was symptomatic at the time of last follow-up before being lost to follow-up. Combining hips converted to THR for femoral loosening and asymptomatic hips with a radiolucency, the average time of first appearance of these radiolucencies was 25.4 months (range, 9 to 50) and 93.5% (19 out of 31) were evident by 3 years, the minimum follow-up period of Group 2.

The average pain and activity scores of the group with radiolucencies at the time they were identified were not statistically different from the rest of the cohort.

Group 1 and group 2 were compared using the time to first appearance of a metaphyseal stem radiolucency as the end point. For this analysis, we excluded the components in which the stem had been cemented because most of the cemented stems are part of group 2 and the cementing of the stem was not a permanent technical change (the indication for cementing the stem varied throughout the series as mentioned in the Methods section). Group 1 was at greater risk ($p=0.016$) of developing a radiolucency than group 2 (Figure 2).

The following analysis was designed to determine the contribution of each surgical change to this overall improvement in the survivorship results. Here again the end point chosen was either time to radiolucency or revision when the hip was converted to THR and did not show a radiolucency. Table 7 shows the proportional hazard ratios and levels of significance of the surgical changes taken one at a time. We have not identified any radiolucency in any of the components in which the short metaphyseal stem was cemented. An example of the value of stem cementation is shown in figure 3.

Finally, the stem/femoral shaft angle measured from the low antero-posterior pelvis radiographs was 2.4° greater for group 2 (average 137.8°) compared to group 1 (average 135.4°, $p=0.0002$).

Conversions to total hip replacement

There were 18 revisions in 17 patients for definite femoral loosening including one, which was loose and revised at a different institution but we did not receive the specimen for analysis. In addition, one patient was radiologically loose and symptomatic but was lost to follow-up. All but one of these femoral component loosenings (hip #340) happened in the first group. There were 10 male and 7 female patients. The average age was 43.8 years (range, 15 to 66). The average component size was 44.4mm (range, 36 to 52). There were ten patients with osteoarthritis (one post-traumatic), two with osteonecrosis, three with hip dysplasia, one with Legg-Calvé-Perthes disease, and one with ankylosing spondylitis. The average time of the first observed radiolucency was 26.5 months (range, 12 to 50) and the average time to first symptoms was 32.2 months (range, 14 to 61). The degree and progression of symptoms was variable but none had acute pain and none required urgent or emergent surgery in contrast to earlier versions of hip resurfacing without the metaphyseal stem. In fact, 4 hips, which loosened and migrated into varus tended to stabilize so that the symptoms lessened prior to revision. The average time to revision was 50.8 months (range, 23 to 100). All but one of the femoral failures were converted to total hip replacements using a unipolar ball of a size matched for the well-fixed socket and all now have well-functioning replacements without complication.

The last hip in the series revised for femoral loosening was hip #340 (surgery date 6/8/00) and the last hip in the series showing a metaphyseal stem radiolucency was hip #

464 (surgery date 9/13/01). Table 8 summarizes the number of femoral component loosening and radiolucencies for each group.

The activity levels were high in eleven patients (Activity rating was eight in two patients and nine or ten in nine patients). Seven of the failed hips (38.8%) were resurfaced in the earliest development stage of 100 hips, before the femoral suction tip was developed and any fixation holes drilled into the chamfered area. Since our prior report[5], 11 hips loosened and have been converted to THR, 9 of which demonstrated substantial radiolucencies prior to becoming symptomatic.

Using the conversion to THR as end point, we also performed a Kaplan-Maier survivorship analysis on the hips that had no femoral cysts or cysts smaller than 1cm at surgery to evaluate what the overall performance of the device could be with a strict patient screening for bone quality. At 3 years, the survivorship was 99.3% (95%CI: 97.3 to 99.8).

DISCUSSION

The most important result from the present study is the greater resistance to the development of metaphyseal stem radiolucencies and femoral loosening of the hips from the second generation femoral fixation technique, compared to the first generation. With similar patient demographics, risk factors, and the same post-operative protocol, the only possible explanation for this result is an improvement of the surgical technique. The main limitation of this study relies in the fact that all of the changes in technique were not made at the same time but represent an evolution as we evaluated more failed cases and were able to relate the intra-operative photographs of the femoral head to the histological retrieval analysis. However this does not offset the substantial improvement in results and the demonstrated efficacy of the surgical changes made. Fortunately, most of these changes were made prior to initiation of the multi-center IDE trial and our instructions to the participating surgeons. From the present study which has been greatly aided by a careful review of the intra-operative photographs of the femoral heads prior to cementation, we can infer that adequate initial fixation (ensured by meticulous cleaning of the bone cysts with curettes and sebatome (high-speed burr), proper drying of the head before cementation and maximization of the interface area between bone and cement) are the main factors leading to a reduction of early femoral component loosening. It is not possible to measure the very qualitative improvement in removal of cystic material but the difference that the high speed burr made in preparation was quite evident when all of the intra-operative photographs were serially reviewed as illustrated in figure 1.The need for an increased number and an expanded location (chamfered area) of fixation holes was suggested by comparing the intra-op photos of several patients who loosened to the retrieved femoral component with the retained acrylic, as illustrated in Figure 4. The sectioned head showed a qualitative difference in the depth of penetration and distribution of acrylic fixation of the various areas of the head. The superior surface of the head was sclerotic and dense which is typical in osteoarthritis and there was no or minimal penetration of acrylic into the bone superiorly compared to the more inferior surface which was cancellous and contained acrylic projections into the trabeculae to a depth of 2-3 mm.

Cementation of the Metaphyseal Stem

There were no loosenings or radiolucencies in the 161 hips where the stem was cemented in despite large cystic defects and this observation suggested that this adjunct to fixation might be important. Even though we have demonstrated that efforts to improve fixation by bone preparation techniques alone are very effective in eliminating problematic hips we recommend cementing in the femoral stem in the higher risk group (cysts >one cm, small component size <46mm, etc.) in addition to using additional drill holes in the prepared femoral head to increase fixation area. To this date there does not appear to be any adverse stress shielding on the femoral neck due to the cementation as previously observed in a canine model when the stem was porous coated[18]. However, our concern is the possibility that a cemented stem combined with repetitive impact cycles might introduce a small degree of micromotion between materials of a different elastic modulus (acrylic, bone and metallic stem), leading to loosening. This is the rationale behind our current recommendation for patients with risk factors and cemented stems to avoid impact activities, at least until we have long term data.

The early failure of several femoral components implanted among the first 100 hips with a stem shaft angle inferior to 130° triggered our decision to place the femoral component in more valgus. Later on, Beaulé et al. highlighted the theoretical advantage of valgus over varus positioning which has been shown to be detrimental to the longevity of the prosthesis[12] as it generates stresses of a greater magnitude in the femoral neck. The average difference of 2.4° in femoral stem-shaft angle between the 2 groups certainly does not justify by itself the observed difference in occurrence of a radiolucency but shows a deliberate intention to avoid a varus placement. In the present study, the effect of a varus angle on the appearance of a radiolucency could not be demonstrated even though 47% of the hips revised for femoral loosening in this series had an angle of less than 130°. The detrimental effect of varus placement might in fact be limited to the hips already showing signs of micro-motion at the bone-cement interface, by accelerating the loosening process.

Femoral loosening has not been reported to any degree in three recent literature reports in which the patients operated upon had essentially a diagnosis of primary ostearthritis with good bone quality[19-21]. These data are comparable with our results in patients with good bone quality. Etiologic groups other than primary osteoarthritis often include younger patients, of smaller body size with frequently larger femoral head cysts. These cases are the most challenging and if the surgeon plans a resurfacing, the surgical technique needs to be optimized.

Loosening can be due to inadequate initial fixation or failure of fixation from other causes. It is probable that many who are still functioning have deficiencies in fixation but the area and distribution of fixation have been sufficient and commensurate with the activity level of the patient.

Additional data on high activity levels, especially high impact and durability are needed, However since the mechanism of wear debris-induced osteolysis and loosening has not been observed in the present study unlike with the earlier metal on polyethylene resurfacing, low-impact activities such as unlimited cycling may apparently be safely performed.

SUMMARY

Initial fixation technique is critical to minimize the membrane formation in order to prevent micro-motion, which can lead to loosening. Younger patients with several risk factors for femoral radiolucency and loosening remain a challenge: they need to have the very best bone preparation and circumferential fixation including stem cementation and they should avoid impact activities. Older patients with compromised bone and small fixation surface area have the option of a total hip replacement, which, with modern designs, bearing materials and techniques, should have very good durability.

The institution of the described changes in technique has dramatically reduced the incidence of radiolucencies in the short term and it is conceivable that mid-term and long-term loosening failures can be eliminated. For surgeons who may consider performing the surface arthroplasty, it is important to study the technique and to start with patients who have sufficient area for fixation (i.e. large component size), and good bone quality to facilitate adequate and durable fixation.

Table 1. Patient demographics by group.

	Groupe 1	Group 2	p
Age at surgery (years)	48.5 (15 - 71)	49.3 (15 - 78)	0.3451
Weight (Kg)	84.9 (45 - 164)	81.8 (42 - 135)	0.0274
Height (cm)	174.9 (152 - 198)	175.6 (140 - 198)	0.3483
BMI	27.6 (18 - 46)	26.3 (17 - 41)	0.0004
Femoral Component size	46.8	46.5	0.438
SARI	2.7	2.5	0.289
Male Patients	76%	74%	
Female Patients	24%	26%	
Charnley class A	45%	57%	
Charnley class B	47%	39%	
Charnley class C	8%	5%	

Etiologies	Group 1	Group 2
Osteoarthritis	67.6%	65.7%
Osteonecrosis	8.7%	7.3%
Developmental dysplasia	10.7%	11.3%
Post-traumatic arthritis	6.7%	8.0%
Legg Calve Perthes	1.7%	3.3%
Slipped capital femoral epiphysis	1.7%	2.0%
Ankylosing spondylitis	1.0%	0.3%
Juvenile rheumatoid arthritis	0.7%	0.3%
Rheumatoid arthritis	1.0%	1.3%
Melorheostosis	0.3%	0.0%
Pigmented Villonodular Synovitis	0.0%	0.3%

Previous surgeries	Group1	Group 2
Previous osteotomy	6	5
Previous coring	9	3
Previous hemisurface arthroplasty	2	0
Previous pinning	6	7
Previous Judet graft	1	0
Previous acetabular reconstruction	1	1
Previous ORIF	0	3

Table 2. Summary of the technical changes pertaining to the 2 generations of femoral fixation.

	First Generation	Second Generation
Suction	No suction (1st 100 hips)	Dome suction
Drilled holes	A few dome holes (0 if good bone quality) - None in the chamfered area	Increased number – Chamfer holes added
Stem cementation	Stem not cemented (only in rare cases with bad bone quality)	Stem cemented in 152 regardless of cyst size
Target stem-shaft angle	Anatomic (1st 100 hips)	140 degrees
Removal of cystic debris	Incomplete - Curette only	Complete – High-speed burr

Table 3. Contact area between bone and cement

Head Size	**Resected bone/cement contact area (mm2)**	**With 13 drilled holes (mm2)**
36	2204.6	3130.6
38	2574.3	3500.3
40	3178.3	4104.2
42	3531.2	4457.2
44	3885.4	4811.4
46	4267.4	5193.3
48	4654.5	5580.5
50	5160.3	6086.3
52	5485.5	6411.5
54	5485.5	6411.5

Table 4. Average number (range) of drill holes made in the dome and the chamfered area of the reamed femoral head before cementation. Comparison between groups and breakdown by series of 100 hips.

	Dome	Chamfer	Total
Group 1	6.6 (0-15)	2.7 (0-13)	9.2 (0-23)
Group 2	7.0 (0-15)	5.8 (0-17)	12.8 (3-28)
p	0.0666	0.0001	0.0001
1st100	6	1	7
2nd100	7	3	9
3rd100	7	4	11
4th100	8	5	13
5th100	7	6	13
6th100	6	7	13

Table 5. Evolution of femoral component orientation in the frontal plane, measured by the stem shaft angle (SSA).

	Average (range)	p	% hips with SSA > 140
1st100	131.1 (110 to 150)	<0.0001	78%
2nd100	137.6 (111 to 163)	NS	59%
3rd100	137.7 (124 to 155)	NS	53%
4th100	138.1 (127 to 156)	NS	59%
5th100	137.8 (125 to 160)	NS	62%
6th100	137.6 (122 to 159)	NS	60%

Note: in the first 300 hips 63% had a SSA less than 140º and in the second 300 hips 60% had a SSA inferior to 140º

Table 6. Summary of the clinical results from UCLA hip scores, SF-12, and Harris hip scores (HHS) for both groups.

		Groupe 1 Pre-op	Group 2 Pre-op	p	Groupe 1 Post-op	Group 2 Post-op	p
UCLA	**Pain**	3.6	3.3	0.0019	9.4	9.5	0.0693
	Walking	6.0	6.2	0.1038	9.6	9.7	0.0756
	Function	5.8	5.6	0.0722	9.3	9.6	0.0150
	Activity	4.7	4.5	0.1520	7.5	7.6	0.2442
SF-12	**Physical**	31.4	32.2	0.2051	50.1	51.0	0.2600
	Mental	47.0	47.9	0.4174	52.0	53.5	0.0707
HHS		N/A	N/A	N/A	91.5	93.8	0.0036

Table 7: Cox proportional hazard ratios and levels of significance of the various surgical changes instituted throughout the series.

	Cox proportional hazard ratio	p
Cementation of the stem	0.1683208	0.014
*** Number of drilled holes (Increment of 5 holes)**	0.6693800	0.048
*** Stem shaft angle (increment of 3 degrees)**	0.9573400	0.455
*** First 100 vs. rest**	0.5253303	0.052
*** 1st vs. 2nd generation**	0.3281483	0.036

* Analysis performed for non-cemented metaphyseal stems after adjustment for SARI

Table 8: summary of the number of femoral component loosening and radiolucencies for each group (n=300 in each group).

	Femoral Loosening	Femoral Radiolucencies	Total	Average Follow-up (months)
Group 1	17 (5.7%)	11(3.7%)	28	82
Group 2	1 (0.3%)	2 (0.7%)	3	54

FIGURES

Figure 1A — Intra-operative photograph of the femoral head after preparation in a 43 year-old female with developmental dysplasia of the hip (hip number 174 in the series). Note the absence of drilled holes in the sclerotic bone of the chamfered area and the incomplete removal of cystic material in the defects (arrows). The femoral component loosened and the hip was converted to a THR 39 months after resurfacing.

Figure 1B — Intra-operative photograph of the femoral head after preparation in a 54 year-old male with primary osteoarthritis (hip number 546 in the series). The drilled holes cover the entire dome and chamfered areas and there is no residual cystic material visible in the defect.

Figure 2 — Kaplan-Maier survivorship curves of group 1 (the first 300 hips) vs. group 2 (the next 300 hips) using the time of appearance of a femoral radiolucency as end point. The hips with a cemented metaphyseal stem were removed from this comparison to assess the effects of the other surgical changes implemented throughout the series.

Figure 3A — Preoperative AP view of a 31 year-old female (hips number 306 and 307 in the series) with severe systemic lupus erythematosus, osteonecrosis and with several risk factors for loosening: small component size and severe cystic degeneration (multiple cysts 1 to 2 cm on both sides).

Figure 3B The stem was cemented on the right side and remains well fixed while the left, with the uncemented stem, although still asymptomatic, is radiographically loose. Note the bone formation around the stem tip, which presumably represents an attempt from the bone to stabilize the component.

Figure 4A Preoperative AP view of a 39 year-old male with inflammatory type osteoarthritis. Insert shows the femoral head after preparation. Note the absence of fixation holes into the sclerotic bone inferiorly (the superior surface of the head from this posterior approach)

Figure 4B 39 months after surgery, the femoral component loosened as shown by the wide radiolucency around the metaphyseal stem. The insert shows the retrieved component and the smooth acrylic surface adjacent to the femoral head sclerotic bone, which did not have sufficient bone-cement bonding.

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Figure 1A
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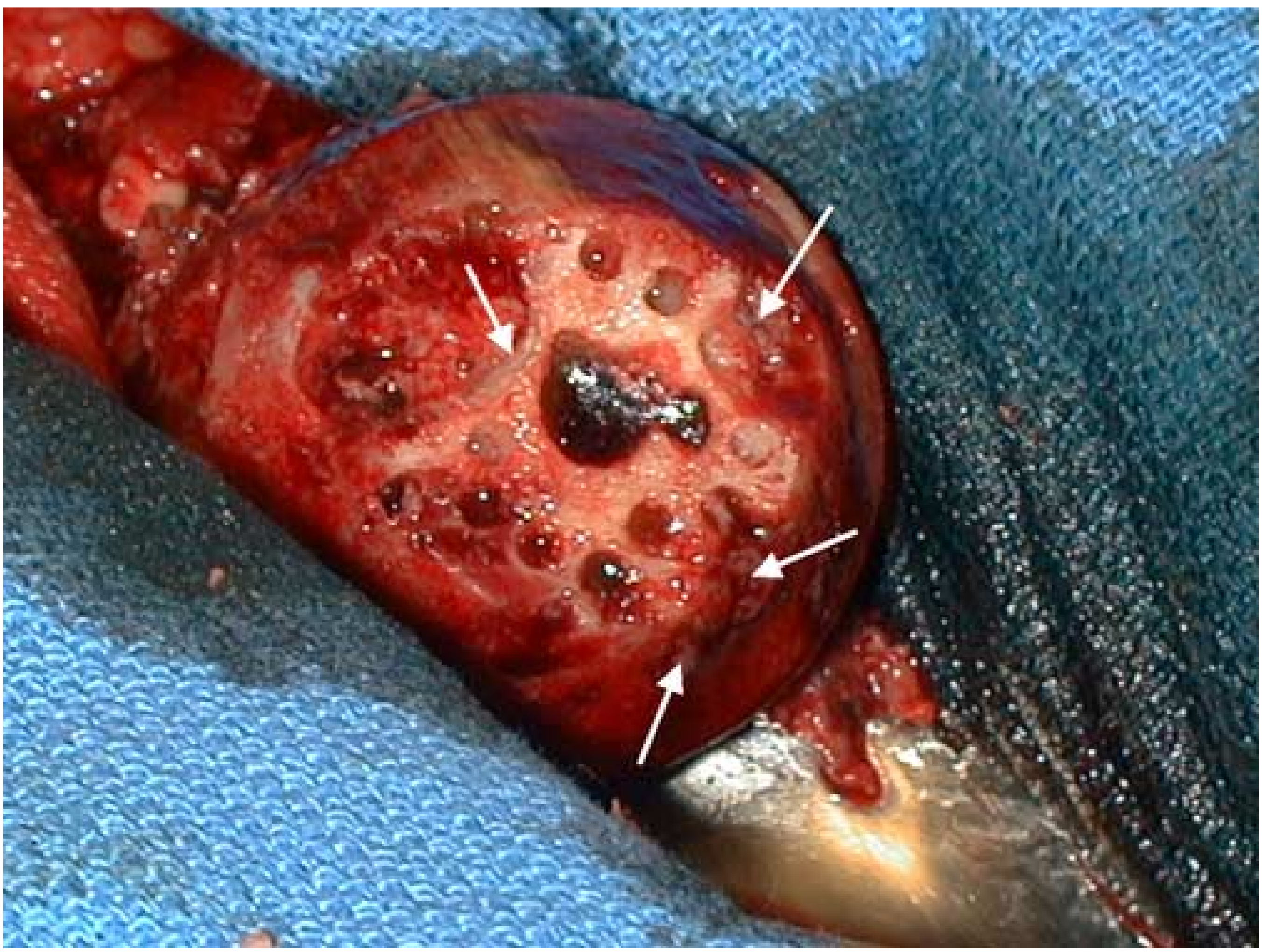

Figure 1B
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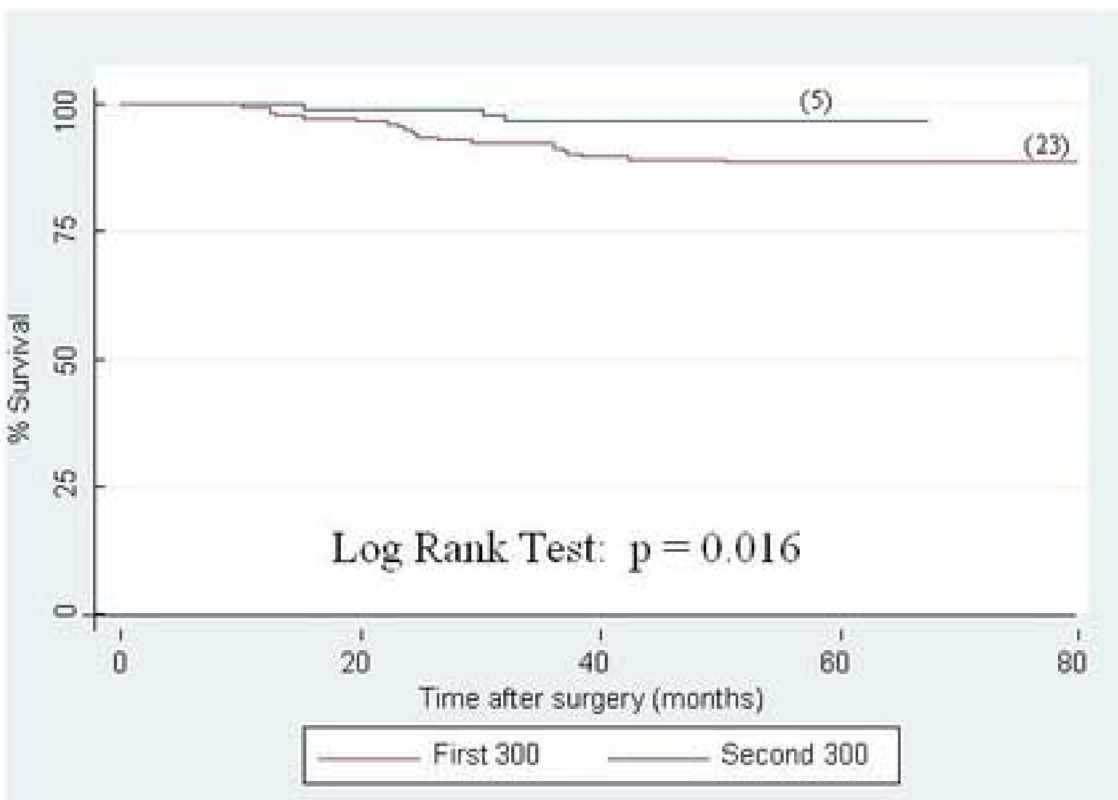

Figure 3A
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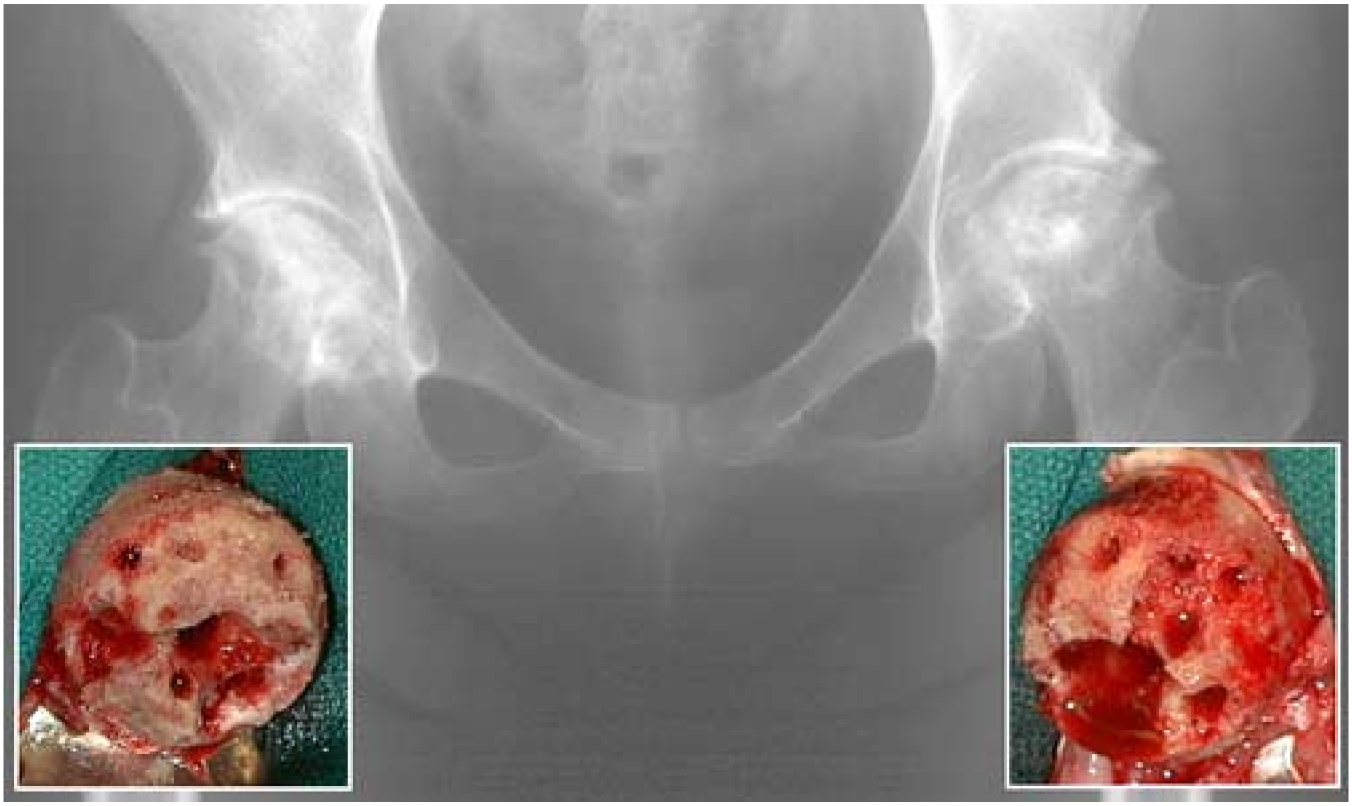

Figure 3B
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Figure 4A
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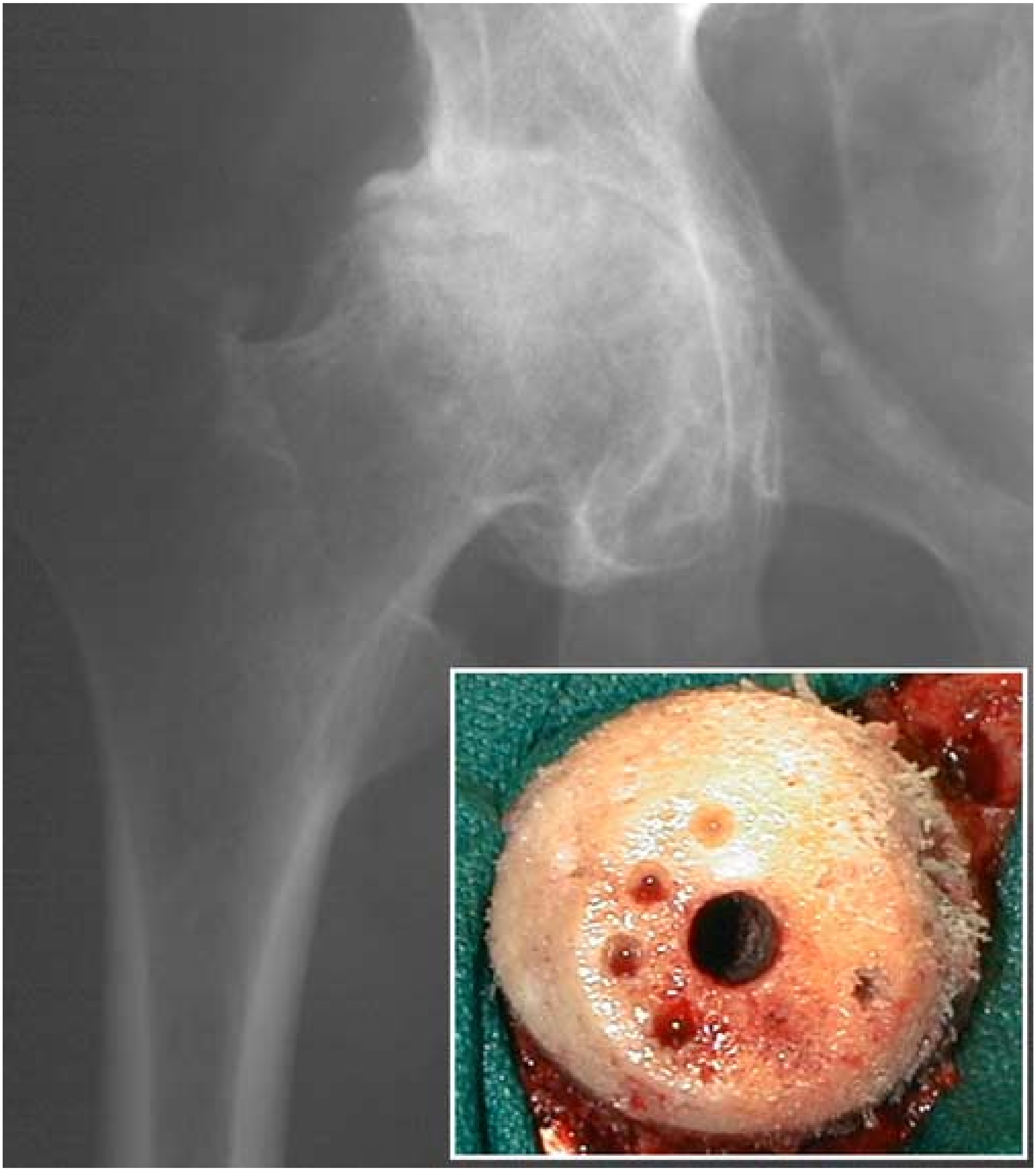

Figure 4B
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