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ORIGINAL STUDY

Uncemented femoral stem design influences the occurrence rate of postoperative fractures after primary hip arthroplasty : A comparison of the Image® and Profile® stems

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Two consecutive series of hip arthroplasties with closely similar anatomic uncemented femoral implants [207 Profile® (DePuy) and 171 Image® (Smith&Nephew) stems] were compared with regard to postoperative femoral fractures. All arthroplasties were performed by senior staff surgeons, mainly on patients below 65 years of age. In the Image® group the occurrence rate of postoperative periprosthetic femoral fractures was higher (9.36%) compared to the Profile® group (2.99%) and fractures occurred earlier (1.69 y vs. 8.84 y). The bulkier proximal part, the thinner cylindrical distal two thirds and the larger offset probably resulted in less rotational stability and increased proximal torsional load transfer during activities of daily living. This resulted in femoral fractures after minor trauma, without osteolysis. This study emphasizes the need for close follow-up when introducing new implants, even if they rely on known principles and feature only minor changes from proven concepts.

Keywords : total hip arthroplasty ; uncemented femoral stem ; periprosthetic fracture.

INTRODUCTION

Periprosthetic femoral fractures present a challenging problem. Estimates of their occurrence rate range from 0.11% to 18% (*2-4,6-8,12-13,16-21,23*). The largest series, from the Mayo Clinic Joint Registry, reports a fracture rate of 1.1% (262/23,980) after primary hip arthroplasties (*2*). The Swedish Hip Arthroplasty Register found a 21 year cumulative incidence of periprosthetic fractures of 0.4% (688 cases) after primary arthroplasty and 2.1% (361 cases) after revision (*14*). This is probably an underestimation of the real problem because only periprosthetic fractures treated by revision arthroplasty were taken into account in that register.

Various factors can explain the large variation in occurrence rate reported in literature. Firstly, study populations are often inhomogeneous and diverse (*2-4,6-8,12-13,16-21,23*). Most series mix cemented and uncemented implants. They also include both, fractures after primary and revision arthroplasty, as well as intra-operative and postoperative fractures. Secondly, major osteolysis is often an important contributing factor which can lead to

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spontaneous fractures. In the Swedish Hip Register, four out of five periprosthetic fractures occurred after minor trauma (*13*). A typical mechanism is the step to keep from falling when stumbling (*10*). Such minor "trauma" increases the load on the hip joint to above 2.5 times bodyweight and can cause periprosthetic fractures when the bone is weakened.

Although fracture around a femoral stem is a rare complication, it is problematic for both the individual patient and the orthopaedic community. For the individual patient it results in considerable dysfunction, morbidity and mortality (*3*). In patients older than 65 years, the functional outcome after revision for femoral fracture is worse than after elective revision surgery (*24*). Moreover, the six-month mortality rate is higher for revisions due to a fracture (7.3%) compared to elective revisions (0.9%) (*24*). The one-year mortality rate for patients who sustained a periprosthetic fracture is 11%. This is similar to the one-year mortality after hip fractures in the absence of an implant (16.5%) and significantly higher than that after primary total hip or knee replacement (2.9%) (*3*).

For the orthopaedic community it is a problem on the rise. Periprosthetic fractures are the third most frequent cause for revision, after aseptic loosening and recurrent dislocation (*18*). Although the annual incidence (0.045%-0.13%) has only a slight tendency to increase over time (*12*), the actual overall number of periprosthetic femoral fractures will increase more dramatically (*11*). This can be explained by the broadening of indications for hip arthroplasty in both, the young active patients and the elderly. As young patients continue their active lifestyle they are more susceptible to high-energy trauma. In the elderly and less fit patients there is an obvious risk for recurrent falls. Moreover, as life expectancy is increasing, more and older patients with poor bone quality will have indwelling femoral prostheses with osteolysis. Finally, fractures are more common after revision procedures, which will become more frequent as well.

It is clear that the number of periprosthetic fractures is rising and will pose a challenge in the near future. Implant related risk factors are poorly understood and minor changes in stem design may have an impact on the postoperative fracture rate. Design and type of prosthesis do play an important role in fracture mechanisms. Fractures around the mid portion of the stem typically occur in patients with uncemented implants, not with cemented designs. Loose cemented prostheses nearly always fracture at the stem tip. Fractures distal to the stem tip are most common in patients with fixed cemented implants (*1*).

In this study, we compared the occurrence rate of periprosthetic femoral fractures following hip arthroplasty with a new anatomic proximal loading stem (Image®, Smith & Nephew, Memphis, Tennessee, USA) to historical data gained using a stem with a comparable design (Profile®, DePuy Orthopaedics, Warsaw, Indiana, USA). In a similar population, we recorded an increased fracture rate after the introduction of the new device and analysed possible causes.

MATERIALS AND METHODS

Patient population

All consecutive patients undergoing an elective, total or bipolar uncemented primary hip arthroplasty in our institution between 1989 and 2005 were included. Hip arthroplasties for fractures were excluded. All procedures were performed by senior staff orthopaedic surgeons, mainly on patients below the age of 65. The main reasons for hip replacement were primary osteoarthritis and osteonecrosis of the femoral head (table I). Between 1989 and 2000 we performed 207 procedures with Profile® stems in 173 patients, and 171 Image® stems were implanted in 149 patients between 1998 and 2005. In the overlapping period the choice of implant was according to the surgeon's preference.

Implants and implantation technique

The titanium alloy Profile® stem (fig 1) was hydroxyapatite coated in its proximal third. The proximal stem geometry was designed to fit-and-fill the metaphyseal region of the proximal femur. The anterior and medial surfaces were "anatomic", meaning that they were designed to follow the internal cortical contour of the medullary canal (fig 2). The posterior and lateral surfaces were slightly curved in order to prevent the natural tendency to varus and anterior tilt induced by abutment against the greater trochanter when a straight stem is

Table I. — Primary diagnosis

Diagnosis	Profile® (207 stems)	Image® (171 stems)
Primary osteoarthritis	131	114
Osteonecrosis	66	51
Posttraumatic osteoarthritis	1	3
Rheumatoid arthritis	5	2
Developmental dysplasia of the hip	4	1

inserted. The distal two thirds of the stem was grit blasted and almost straight with a round cross-section. The distal part of the stem was bulky compared to the metaphyseal region. The Profile® stem had a neck-shaft angle of 140° and only one offset per stem size, varying from 24 mm (stem size 000, neck length +1.5) to 45 mm without a skirted 28 mm head (stem size 6, neck length +8.5) and to 50 mm with a skirted 28 mm head (stem size 6, neck length +15.5).

The Image® stem (fig 1) was developed in collaboration with three university hospitals [Saarland University Hospital, Homburg-Saar (Germany), Hôpitaux Universitaires de Strasbourg, Strasbourg (France) and Universitair Ziekenhuis Brussel, Brussels (Belgium)]. The goal was to produce an anatomic stem that addressed the problems of mid thigh pain and insufficient offset encountered with several other uncemented implants, including the Profile® stem. Similar to the Profile® stem, the titanium alloy Image® stem was hydroxyapatite coated in its proximal third. The "anatomic" proximal stem shape was based on computed tomography (CT) analysis of 30 femora and intended to fit-and-fill the metaphyseal region. The medial and anterior surfaces of the implant were designed to follow the inner cortex of the medial and anterior metaphysis (fig 2). The posterior and lateral surfaces were straight to facilitate stem insertion along the trajectory of the straight reamers and to enhance the contact with the cancellous bone of the greater trochanter. The distal two thirds of the stem was grit blasted and cylindrical. The stem tip was round and

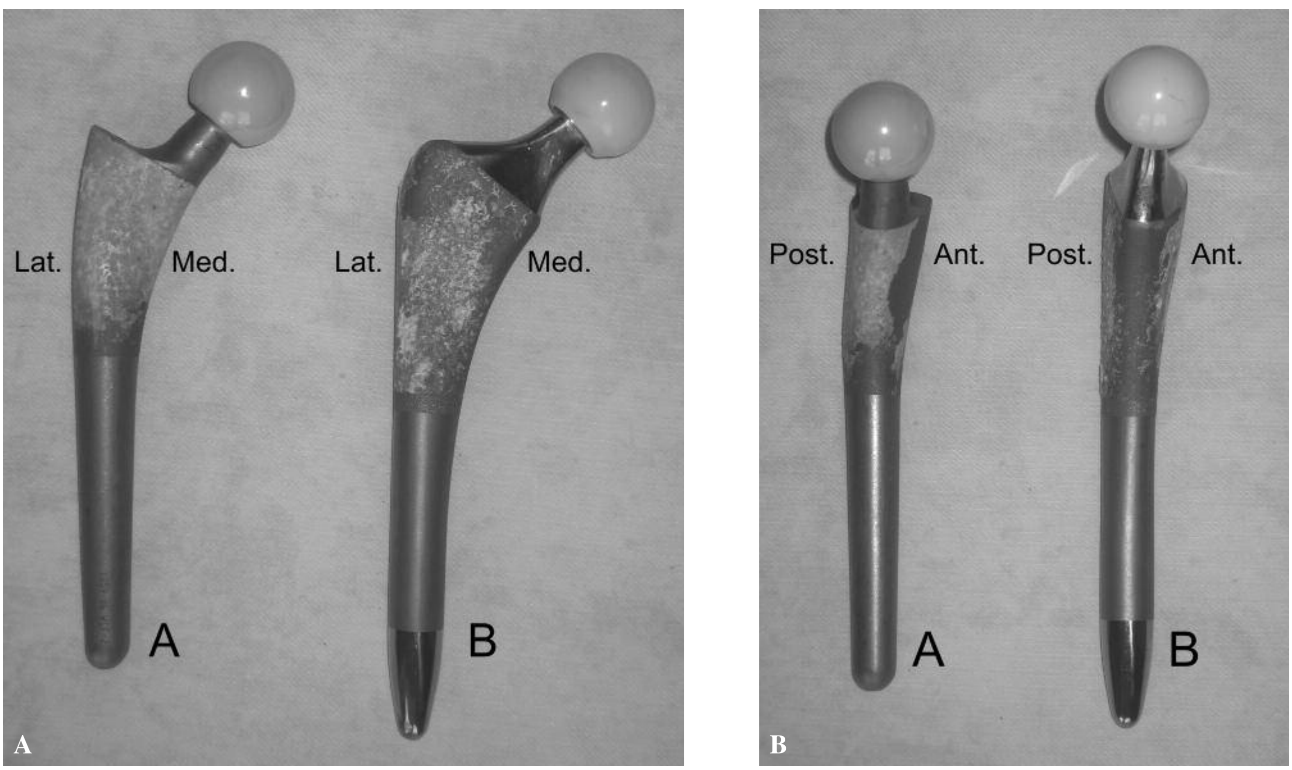

Fig. 1. — Profile® (DePuy Orthopaedics, Warsaw, USA) (A) and Image® (Smith & Nephew, Memphis, USA) (B) uncemented stem. Ant. = Anterior, Post. = Posterior, Lat. = Lateral, Med. = Medial. Both implants were retrieved during revision surgery and have different sizes.

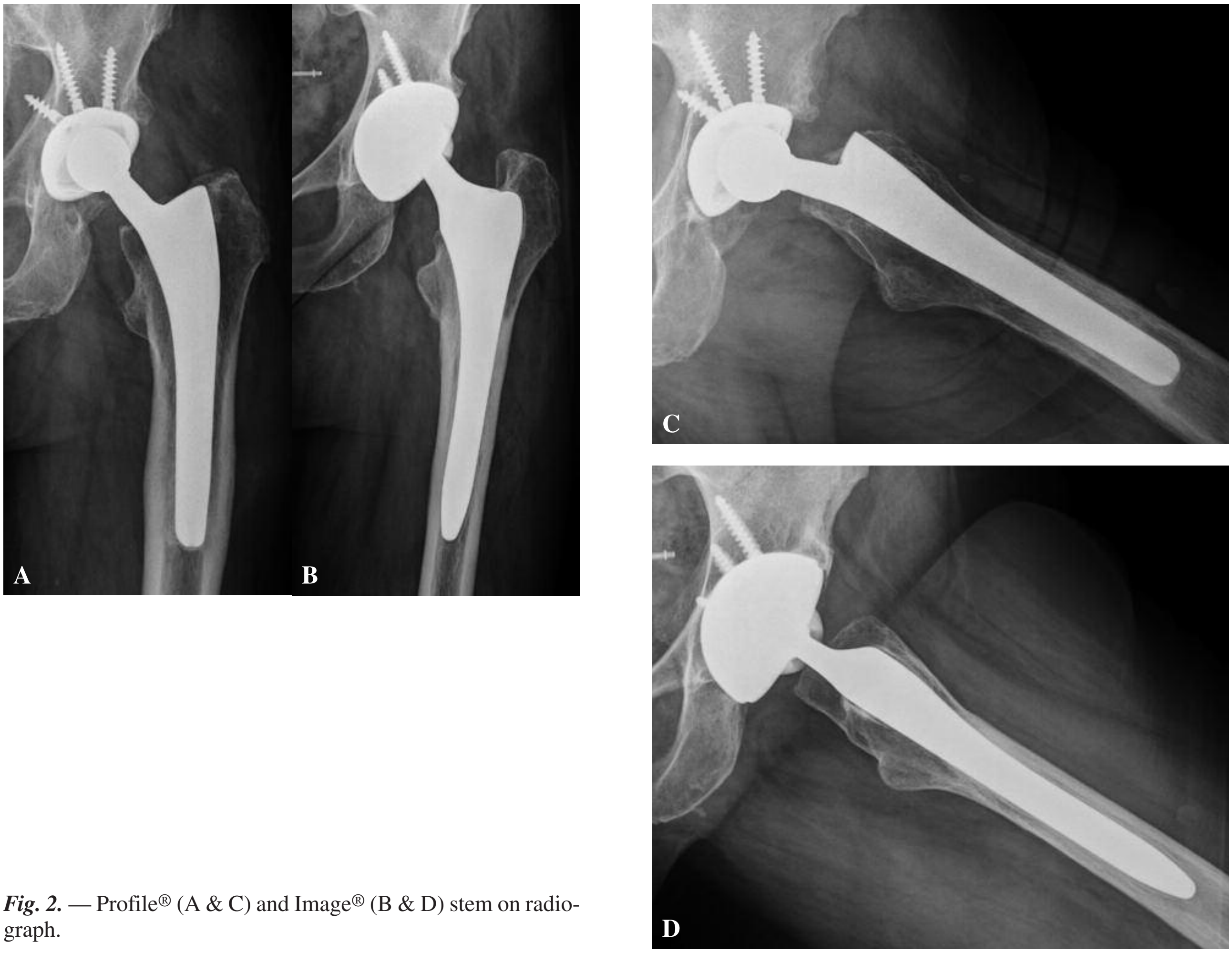

Fig. 2. — Profile® (A & C) and Image® (B & D) stem on radiograph.

polished to avoid ingrowth and mid thigh pain. Compared to the Profile® stem, the Image® stem was thinner distally, bulkier proximally and had a less steep medial curvature (fig 3). The Image® stem had a neck-shaft angle of 134° and only one offset per stem size varying from 33.8 mm (stem size 9, neck length -3 mm) to 53.8 mm without a skirted 28 mm head (stem size 16, neck length +8) and to 59.5 mm with a skirted 28 mm head (stem size 16, neck length +16). Overall, the offset of the Image® stem was larger than that of the Profile® stem.

The implantation technique of both stems was similar. First, straight cylindrical reamers of increasing size were used until distal cortical contact was achieved. Then, consecutive broaches were introduced to shape the proximal femur until the broach size matched the size of the last reamer.

Outcome measures and follow-up

All patients described above were included prospectively in a database (OrthoWave 5.8.4, Aria Software, Bruay Labuissière, France) and were asked to attend the clinic every two years for a radiological and standardized clinical follow-up with assessment of Harris Hip (9) and Merle d'Aubigné Score (5). The closing date for follow-up was June 30th, 2009.

All femoral fractures occurring after the index arthroplasty, in patients whose initial postoperative radiographs were normal, were considered as postoperative fractures. Fractures recognised during surgery were excluded. The fractures were classified according to the Vancouver Classification (6) and the treatment was standardized. Undisplaced fractures with a stable implant

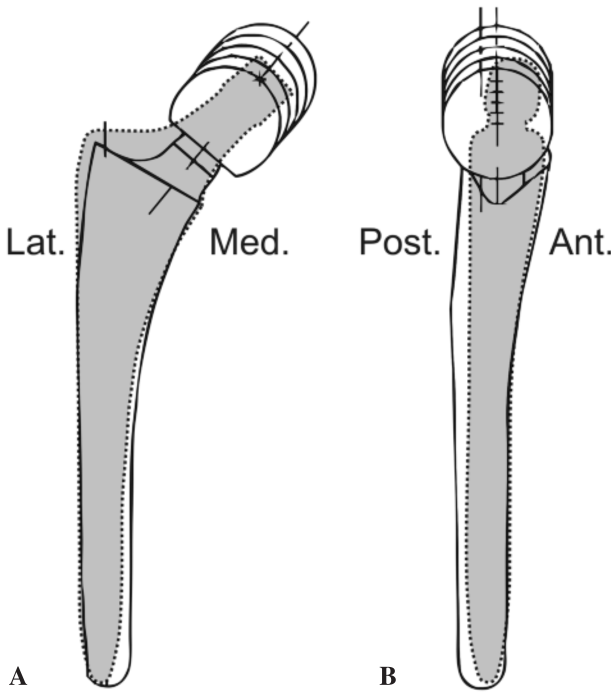

Fig. 3. — Superposition of the templates of a Profile® stem size 11 (white, —) and an Image® stem size 2 (gray, ····). Both stems have similar dimensions. In the AP view (A), the Image® stem is bulkier in the proximal 1/3, but not in the lateral view (B). In both views, the Image® stem is thinner distally. Ant. = Anterior, Post. = Posterior, Lat. = Lateral, Med. = Medial.

were treated conservatively with protected weight bearing. Mildly displaced fractures with an implant that appeared stable were managed with open reduction and internal fixation. Fracture fixation was performed with cerclage wires or a plate with cables and screws. Fractures associated with a loose implant were treated by revision with a long (un)cemented stem and cerclage wiring of the fracture.

Statistical analysis

Statistical analysis was performed with Excel 2003 (Microsoft, Redmond, Washington, USA). Nominal data and frequencies were compared with a Chi-square test. Numeric ratio variables were compared with a Student t-test. The homogeneity of variance between groups was assessed with a Levene F-test and t-ratios were adjusted when needed. Statistical significance was set at a p-value < 0.05.

RESULTS

In total, 378 stems (Profile®/Image® : 207/171) were implanted in 322 patients (Profile®/Image® : 173/149) ; 318 stems had a follow-up of at least two years. Two hundred and seven stems were evaluated within two years before the closing date. Five patients (six stems) in the Profile® group and none in the Image® group were excluded because of missing follow-up data (table II). Both groups were similar in terms of sex ratio and affected side. At primary arthroplasty, Image® patients were about four years older than Profile® patients. In the Image® group the occurrence rate of postoperative periprosthetic femoral fractures was higher (9.36%) compared to the Profile® group (2.99%) and fractures occurred earlier (1.69 years vs. 8.84 years) (table III).

Six fractures were noted in the Profile® group and 16 in the Image® group (table IV). Most of the periprosthetic fractures (Profile® 6/6, Image® 11/16) were spiral and none were related to osteolysis or to radiologic signs of implant loosening prior to the fracture. Typically, periprosthetic fractures initiated at the anterior border of the calcar cut, extended medially below the calcar region into the medial cortex around the middle or distal third of the stem and ended posteriorly halfway the femoral neck cut i.e., medial to the greater trochanter. The fracture pattern often corresponded to the avulsion of a large medial fragment including the calcar and the lesser trochanter and extending to the middle third of the stem, but preserving the greater trochanter and the lateral cortex (fig 4 & 5).

Table II. — Follow-up

	Profile®	®Image
Implanted stems	207 (100%)	171 (100%)
Any follow-up	201 (97%)	171 (100%)
Follow-up ≥ 2 years	174 (84%)	144 (84%)
Follow-up ≥ 5 years	152 (73%)	79 (46%)
Follow-up within 2 years of closing date	87 (42%)	120 (70%)
Deceased (stems - patients)	16-12 (8%-7%)	8-8 (5%-5%)

Table III. — Comparison of the Profile® and Image® stems included in the series

	Profile® (201 stems)	Image® (171 stems)	p-value	Statistical test
Left / Right	98 / 103	94 / 77	0.2320	Chi²
Male / Female	117 / 84	94 / 77	0.5299	Chi²
Average age (SD ; range)	53.16 y (10.62 ; 15.74-69.65)	57.01 y (8.59 ; 27.24-74.74)	0.0001 *	t-test
Average follow-up (SD ; range)	9.04 y (5.03 ; 0.12-19.8)	4.92 y (2.65 ; 0.05-10.57)	< 0.0001 *	t-test
Fracture occurrence rate	6/201-2.99%	16/171-9.36%	0.0094 *	Chi²
Average time to fracture (SD ; range)	8.84 y (5.73 ; 0.14-15.06)	1.69 y (1.67 ; 0.03-5.69)	0.0299 *	t-test

SD = Standard Deviation
* = Statistical significance $p < 0.05$.

One patient was hit by a car as a pedestrian, the other patients sustained their fractures after a minor trauma i.e., a fall from their own height. All six fractures in the Profile® group were displaced and the stem appeared to be loose (Vancouver B_2). These fractures were treated with cerclage wiring and all stems were revised : five with a long uncemented stem and one with a cemented stem. In the Image® group, the three greater trochanter fractures (Vancouver A_G) were minimally displaced and were treated conservatively with protected weight bearing. Seven fractures were diaphyseal and associated with a stable implant (Vancouver B_1). Two of them were undisplaced and were treated conservatively. The remaining five fractures were displaced and were treated with open reduction and internal fixation. One was fixed with cerclage wiring (fig 4), one with cerclage wiring supplemented with a trochanteric plate and the remaining three with plate osteosynthesis (Cable Ready, Zimmer, Warsaw, Indiana, USA). Two of the latter implants subsided and one of them was revised with a long uncemented stem. All six displaced diaphyseal fractures combined with a loose implant (Vancouver B_2) were revised with a long uncemented stem and cerclage wiring (fig 5). Clinical outcome (Harris Hip Score and Merle d'Aubigné Score) did not markedly change when comparing the values before fracture and at the final visit. There was also no statistical difference in clinical scores between the different treatment options after fracture (table IV).

DISCUSSION

In similar patient populations, the occurrence rate and the timing of postoperative periprosthetic femoral fractures after uncemented hip arthroplasty were significantly influenced by stem design. In the Image® group, we noted more fractures and these fractures occurred earlier than in the Profile® group. All fractures occurred in the absence of osteolysis or radiographic signs of implant loosening, and most fractures were long and spiral. This pattern suggests a torsional overloading mechanism, and such fractures about the mid part of the stem are typical for uncemented stems (*1,15*). It is unlikely that these fractures were unrecognised intra-operatively, although small unnoticed initiating calcar cracks cannot be excluded with certainty. Moreover, none of the initial postoperative radiographs showed a fracture, and their spiral nature is atypical for unrecognised intra-operative fractures. Even though fractures in the Image® group occurred earlier, the majority (17/22) did not present in the immediate postoperative period but later (> 3 months) during rehabilitation, when more strenuous activities were performed.

The difference in occurrence rate and timing of periprosthetic femoral fractures is difficult to explain. However, we suggest several hypotheses. Firstly, the proximal metaphyseal part of the Image® stem was bulkier and the cylindrical distal two thirds was thinner compared to the Profile®

Table IV. — Overview of postoperative periprosthetic fractures : characteristics, treatment and outcome.

Stem	Sex	Neck length	Trauma	Time to fracture (y)	Vancouver	Fracture treatment	Secondary surgery	HHS before fracture	HHS at final visit
Profile® 1	M	+8.5	Minor	6.85	B_2	Revision	No	-	67
Profile® 2	F	+8.5	Minor	5.51	B_2	Revision	No	-	91
Profile® 3	F	+5	RTA	0.14	B_2	Revision	No	-	77
Profile® 4	F	+8.5	Minor	14.24	B_2	Revision	No	100	70
Profile® 5	M	+8.5	Minor	15.06	B_2	Revision	No	96	78
Profile® 6	F	+8.5	Minor	11.23	B_2	Revision	Re-revision	57	54
Image® 1	F	+8	Minor	0.06	A_G	Conservative	No	-	-
Image® 2	F	+4	Minor	0.05	A_G	Conservative	No	-	97
Image® 3	M	+8	Minor	0.12	A_G	Conservative	No	-	-
Image® 4	M	+4	Minor	1.47	B_1	Conservative	No	96	84
Image® 5	M	+4	Minor	1.30	B_1	Conservative	No	93	90
Image® 6	F	0	Minor	5.69	B_1	Cerclage	No	98	94
Image® 7	F	+4	Minor	0.42	B_1	Plate	No	39	84
Image® 8	F	0	Minor	2.47	B_1	Plate	No	76	90
Image® 9	F	+4	Minor	1.80	B_1	Plate	No	76	79
Image® 10	M	+8	Minor	0.30	B_1	Plate	Revision	91	97
Image® 11	M	+12	Minor	0.03	B_2	Revision	No	-	86
Image® 12	M	+8	Minor	1.23	B_2	Revision	No	93	93
Image® 13	M	+4	Minor	2.05	B_2	Revision	No	96	100
Image® 14	M	0	Minor	3.99	B_2	Revision	No	100	97
Image® 15	M	+4	Minor	2.19	B_2	Revision	No	77	84
Image® 16	M	+8	Minor	3.89	B_2	Revision	No	74	45

F = Female ; M = Male ; RTA = Road Traffic Accident ; HHS = Harris Hip Score.

stem. The increased proximal to distal filling ratio was intended to favour proximal femoral loading and to reduce the occurrence of mid thigh pain and stress shielding. However, this also resulted in more aggressive proximal broaching and weakening or cracking of the anterior cortex and the greater trochanter. Such weakening or unnoticed intra-operative cracks could favour late periprosthetic fractures. Secondly, the reduced cylindrical cross-section of the distal third of the Image® stem did not provide much rotational stability. This might have favoured excessive rotational load transfer to the weakened proximal femur. However, it remains uncertain if the larger cross-section of the distal third of the Profile® stem made a big difference. Thirdly, the larger offset of the Image® stem resulted in larger torque loads compared to the Profile® stem. The combination of these features might explain the higher risk of spiral fractures around the stem in the absence of osteolysis. Finally, the quality of the bone ingrowth could be questioned in both groups. All six Profile® stems and 8/13 Image® stems that were associated with a diaphyseal fracture, were found to be loose at surgery or after fracture fixation. However, there were no radiographic signs of loosening or major osteolysis prior to fracture.

Our fracture treatment algorithm was based on the Vancouver classification proposed by Duncan and Masri (*6*), a classification which has been extensively investigated and widely used (*7,16-18,20,23*). Treatment depended on the fracture site and displacement, on the implant stability and on the quality of the surrounding bone stock. In our series, two diaphyseal fractures with a stable implant (B_1) were treated conservatively. This conservative approach has been advocated by some (*23,18*) but not by others (*7,16,17,20*) who recommend operative treatment of B_1 fractures. We believe we were successful because both fractures were spiral and undisplaced and because of the absence of osteolysis. This

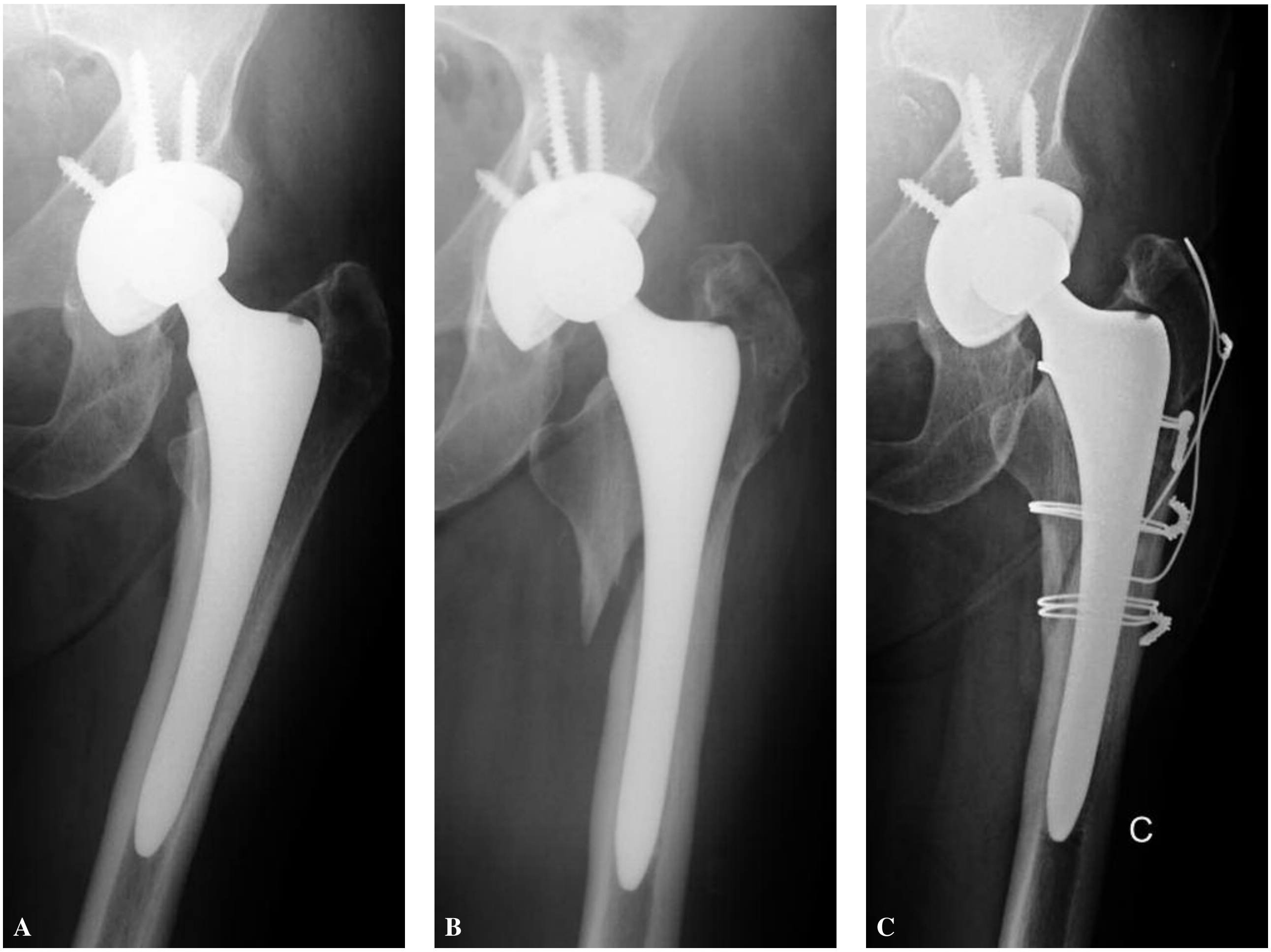

Fig. 4. — Image® stem : Before fracture (A) – Fracture (B) – After fracture treatment : open reduction and internal fixation (C).

allowed the implant to remain stable or to stabilize with minimal subsidence. Five diaphyseal fractures in the presence of a stable implant (B_1) but with displacement, were treated with cerclage wires and/or plate osteosynthesis. Some authors recommend strut allograft augmentation – with or without plating – for B_1 fractures (*22*). We did not opt for this treatment because, in our cases, we considered fracture stability to be the main issue rather than bone stock. Two stems with B_1 fractures subsided significantly after osteosynthesis and one of them needed revision. Both implants were probably loose after the fracture, although this was not recognised on the pre-operative radiographs or during surgery. This emphasizes the need for thorough pre-operative and intra-operative assessment of the implant fixation. In every case, the surgeon needs to be prepared to change the treatment strategy during the intervention and should have all necessary implants available in theatre. Diaphyseal fractures with a loose implant (B_2) should benefit from a revision arthroplasty with a long, usually uncemented stem. The stem should bypass the fracture by at least two femoral diameters.

This investigation has a few shortcomings. It is a retrospective comparative study of two groups which were treated consecutively. The two consecutive series however included comparable patients, operated by the same surgical team with a similar operative technique. A second limitation is the

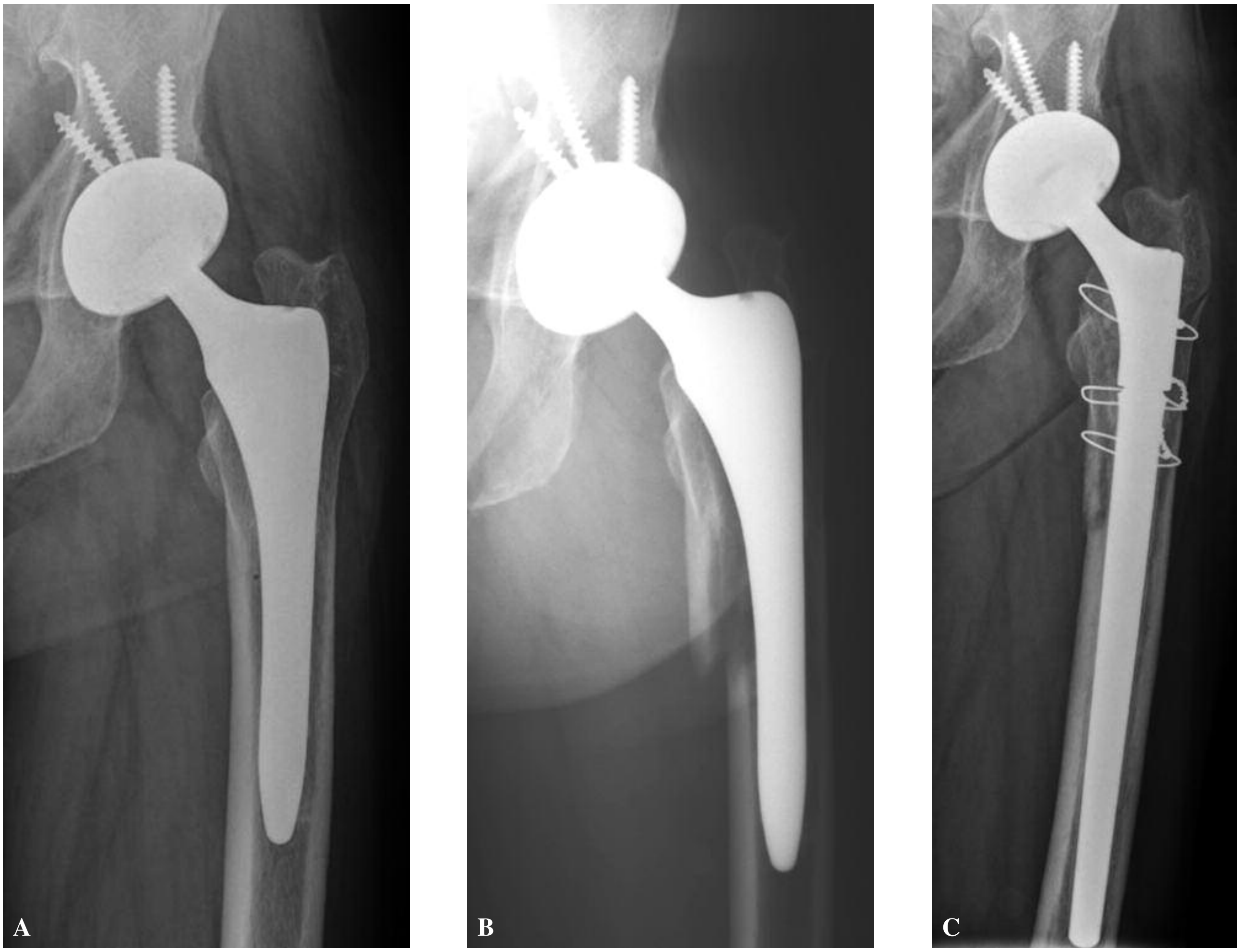

Fig. 5. — Image® stem : Before fracture (A) – Fracture (B) – After fracture treatment : uncemented stem revision with cerclage wires (C).

unequal follow-up period of both groups. However, the Image® stem, which had the shortest follow-up, also had the highest fracture rate. The higher occurrence rate of postoperative periprosthetic fractures noted in the Image® group is therefore probably an underestimation of the real problem. Finally, our series include a relatively small number of patients. This allowed the detection of a statistically significant difference in fracture rate and timing but the small number of fractures puts some restrictions to the conclusions about treatment strategy and outcome.

CONCLUSION

This study emphasizes the need for close follow-up when introducing new implants, even if they rely on known principles and show only minor differences with proven concepts. Small changes may have important consequences, such as the three-fold increase in periprosthetic femoral fracture rate reported in this study. Anatomic devices with a bulky metaphyseal part, intended to load the proximal femur but with limited distal rotational stability, could be at risk.

Fracture treatment should be based on fracture pattern and implant stability. Minor, undisplaced proximal fractures without implant loosening and osteolysis (undisplaced Vancouver A and B_1), can be treated conservatively with protected weight bearing. Displaced fractures with a stable implant (displaced Vancouver A and B_1), are best addressed with open reduction and internal fixation. The stability of the implant should be assessed intra-operatively, to avoid later subsidence or loosening. The surgeon should always be prepared to revise the stem, even if the pre-operative assessment suggests a stable implant. The use of strut allograft can only be omitted if bone quality is good and osteolysis is not an issue, as in our study. Unstable implants (Vancouver B_2) have to be revised, preferably with an uncemented stem providing distal rotational stability and bypassing the fracture by at least two femoral diameters.

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