Outcome of hybrid stem fixation in osteoporotic female patients. A minimum five-year follow-up study

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Received: 16 June 2008 / Revised: 9 July 2008 / Accepted: 9 July 2008 / Published online: 20 August 2008
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Abstract In osteoporotic patients cemented stems are usually used to achieve a good primary stability. However, when patients are obese or active the long-term survival of cemented prostheses is questioned. In these patients, a partially-cemented stem with a hybrid fixation could be advantageous. A hybrid stem was retrospectively evaluated at a minimum follow-up of 60 months (mean, 75 months) in 58 osteoporotic women: seventeen with a body mass index (BMI) >30 (obese), 41 with a BMI between 25 and 29.9 (overweight), and an UCLA score for activity level >6. At the latest follow up, the Harris hip score improved from 33.5 points preoperatively to 81.6 points, and the WOMAC score improved significantly. Three stems (4.9%) had an asymptomatic subsidence of less than 2.5 mm; no stem was revised. These results support the use of partially-cemented stems in heavy or active osteoporotic women.

Résumé Chez les patients présentant une ostéoporose une pièce fémorale cimentée est habituellement utilisée de façon à avoir une bonne stabilité. Cependant chez certains patients obèses et très actifs la courbe de survie peut, dans ce cas, être altérée. Ces patients ont eu la possibilité d'être opérés avec une prothèse partiellement cimentée, cette fixation hybride pouvant être avantageuse. Matériel et méthode: cette prothèse fémorale hybride a été évaluée de façon rétrospective avec un minimum de suivi de 60 mois (en moyenne 75 mois) chez 58 patients ostéoporotiques, 17

femmes présentant un BMI > 30 (obèses), 41 avec un BMI entre 25 et 29,9 (surpoids) et un score UCLA supérieur à 6. Résultats: au dernier suivi le score de Harris a montré une amélioration de 33,5 points en préopératoire à 81,6 points, le score de Womac s'est également amélioré de façon significative. Trois pièces fémorales ont présenté une migration (4,9%) de moins de 2,5 millimètres, aucune révision fémorale n'a été réalisée. En conclusion, ces résultats permettent de penser qu'une prothèse partiellement cimentée hybride est indiquée chez ces patients obèses actifs et présentant une ostéoporose notamment chez la femme.

Introduction

Primary stability is a paramount factor for the long-term success of cemented and cementless hip stems. In young patients, with good bone quality, primary stability is easily achieved, and cementless stems are usually employed [10]. In cases of elderly osteoporotic patients, the cemented technique is considered to be the gold standard [7]. The long-term problem with cemented stems is cement fatigue, due to the application of repeated loads [13]. Patient activity and high loads influence the long term survival of cemented stems. In active or heavy osteoporotic patients, the ideal fixation could be a hybrid fixation with the best features from both fixation techniques already in use. A partially-cemented hip stem (Anca DualFit, Wright, Arlington, TN, USA) was derived from a successful anatomical cementless design already in use in clinical practice (AncaFit, Wright) and was then validated extensively preclinically [2, 5, 20, 23]. Primary stability is achieved by press-fitting the stem into the femoral canal as for a standard cementless stem, and pressurising bone cement

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into two pockets in the metaphyseal region of the stem. Secondary fixation is then achieved by the bone on-growth on to the remaining porous and hydroxyapatite-coated surface of the stem (Fig. 1).

Other reports on partially-cemented stems have been published, sometimes with concerning outcomes [1, 15, 16, 24], but these stems are derived from a cemented stem, where the cement mantle surrounds the proximal half. To our knowledge there is only one published paper on a cementless partially-cemented stem. This stem (Mathys Option3000, Z-stem, Option 3000, Mathys Orthopaedics, Bettlach, Switzerland) features a proximal matte cementless contact, with a cement pocket surrounding the metaphyseal part of the stem, whereas the distal half of the stem is cementless and polished. This stem has shown promising preclinical and intermediate follow-up results [8]. The Anca DualFit is different from this stem, as it does not feature a cement mantle wrapping part of the stem's length, but hosts two separate cement pockets on the anterior and posterior sides. This difference is important, in the first case the cement mantle is subjected to the typical hoop tensile stresses that are responsible for cement failure in cemented

hip stems [22]; in the second case, conversely, the two cement pockets of cement are mainly subjected to compressive stress [23].

The aim of this study was to present, at a minimum five-year follow-up, the clinical results of a cementless partially cemented stem implanted in heavy or active osteoporotic patients.

Materials and methods

A retrospective clinical study was carried out on 91 consecutive primary total hip arthroplasties implanted in 87 women in postmenopausal age between March 1997 and January 2002. In all cases an Anca DualFit (Wright, Arlington, TN, USA) femoral component and an Anca Fit (Wright, Arlington, TN, USA) acetabular component with a ceramic-on-ceramic coupling (Bilox Forte, Ceramtec, Stuttgart) were implanted through an anterolateral approach. Twelve patients (13 hips) were lost in the clinical and radiological follow-up, two patients (two hips) died, and three (three hips) became disabled some years postoperatively for reasons unrelated to the operation. The remaining 70 patients (73 hips) were evaluated before surgery by dual energy X-ray absorptiometry (DEXA), and 63 of them (66 hips) were osteoporotic.

To be included in the study these osteoporotic patients had to be obese (body mass index >30) or had to be overweight and had a high level of activity [25] (UCLA activity rate >6). Of the 63 osteoporotic patients, 17 were obese (18 hips) and 46 (48 hips) were overweight (body mass index 25–29.9). Each overweight patient was rated using the 10-point UCLA activity level scoring system; 41 of them (43 hips) were found to have a high activity level (UCLA >6), while five patients (five hips) did not meet the inclusion criteria.

In conclusion, all the 58 eligible patients (61 hips) were followed-up for at least five years (average, six years and three months). The average age at surgery was 69.9 years (range, 53.5–82.6 years); preoperative diagnosis is described in Table 1.

Fig. 1 A partially cemented stem after laboratory test in a composite femur (model 3103; Pacific Research Labs, Vashon Island, WA, USA). The arrows show a metaphyseal cement pocket in a longitudinal dissection of the composite femur

Table 1 Preoperative diagnosis

Diagnosis	Hips	Patients	%
Primary arthritis	47	44	77.1
Femoral neck fracture	5	5	8.2
Developmental dysplasia of the hip	4	4	6.6
Rheumatoid arthritis	2	2	3.3
Septic hip infection	1	1	1.6
Avascular necrosis	1	1	1.6
Post traumatic necrosis	1	1	1.6
Total	61	58	100

The Anca DualFit stem is made of Ti6Al14V alloy (Fig. 1), has the same shape of the original AncaFit cementless stem (Wright, Arlington, TN, USA), and presents a sandblasted, hydroxapatite-coated surface in the distal part to achieve secondary stability by bone on-growth. Only the anterior and posterior pockets for the cement have a polished finish so as to avoid formation of wear debris in case of fretting. The surgical technique for this prosthesis involves broaching the femoral canal as for an anatomic cementless stem. Then, the stem is press-fitted in the femoral canal by hammering. When the stem has achieved suboptimal primary stability, especially in the longitudinal axis, the bone cement is pressurised in the two metaphyseal pockets by a dedicated device. The cement gives the stem the final primary stability.

The rehabilitation program began the day after surgery and consisted of four weeks of toe-touching weight bearing with crutches or walker, partial weight bearing with one crutch for the next two weeks, and then full weight bearing.

Clinical assessments, using the Harris hip score [11] and WOMAC score [3], were collected preoperatively and at last follow-up.

A nonbiased radiologist made all radiographic examinations. Stem stability, bone on-growth, stress shielding, and stress concentration were assessed by Engh's method's [9].

For the hemispheric press-fit cup, more than 2 mm progressive widening of a radiolucent line, and migration of more than 5 mm or 5° was defined as loosening. Ectopic bone formation was classified according to the Brooker classification [4].

Moreover, the varus–valgus positioning of the stems were estimated—between 5° of varus and 5° of valgus were considered correctly positioned.

A two-tailed paired *t*-test was used for comparison of preoperative and postoperative WOMAC values.

Results

All patients gained significant clinical improvement after surgery. No stem or cup was revised due to aseptic loosening at the latest follow-up (average six years and three months).

Clinical results

Clinical results were evaluated from a subjective and an objective point of view. The Harris hip score, investigating patients' abilities and range of motions in an objective way, improved from a mean of 33.55 (poor) preoperatively to a mean of 81.65 (good) at the last follow-up. Furthermore, the WOMAC score measured the extent of pain, function, and stiffness perceived by patients; at five years all parameters had significant improvements (Table 2).

Table 2 WOMAC score

WOMAC	Before surgery	Min–Max	After surgery	Min–Max	<i>p</i>
Pain	15.4	(8–20)	0.5	(0–15)	0.001
Function	56.7	(45–65)	6.5	(0–46)	0.001
Stiffness	5.4	(3–7)	0.3	(0–1)	0.001

Radiological results

No stems were revised for aseptic loosening or demonstrated radiographic evidence of loosening at minimum five years from the surgery (Fig. 2).

Of 61 stems, 58 (95.1%) were implanted in a neutral position. Only three stems (4.9%) subsided (less than 2.5 mm), but these stems appeared stabilised and patients were asymptomatic. Osseous on-growth was found in 57 hips (93.4%), and fibrous on-growth in four hips (6.5%). One hip (1.6%) showed stress shielding in zone 7, and stress concentration was present in nine hips (14.8%) (seven cases in zone 5, two cases in zone 3).

All cups appeared to be stable without progressive widening of the radiolucent line or more than 5 mm or 5° migration at the last follow-up.

At five years, radiographs showed 32 hips (52.5%) with ectopic bone formation (17 hips grade 1, nine hips grade 2, six hips grade 3).

Discussion

This study reports the mid-term clinical and radiographic results of a hip stem with a hybrid fixation. This innovative method might be useful in heavy or active osteoporotic patients where the fixation commonly in use (cemented and cementless) shows some limits [7, 6, 17, 21].

The co-existence of osteoporosis and osteoarthritis remains obscure [18], but it is clear that particularly in developed countries, the obese and osteoporotic populations are increasing in a parallel way [12]; in fact, overweight and obesity contribute to oestrogen hormonal changes and probably contribute to osteoporosis. Furthermore, overweight and obesity promote the early development of osteoarthritis, leading to joint replacement in most patients.

Commonly, cemented hip replacements provide an excellent primary fixation by giving an initial “custom fit” and resistance to axial and torsional stresses, thus allowing early pain-free function. The disadvantages, however, may be considerable in active people; indeed long-term cement fatigue, due to the application of repeated loads during daily activity [13], can drive the stem to failure. Furthermore, in case of failure, the cement may be difficult to

Fig. 2 A partially cemented total hip arthroplasty in an osteoporotic femur. The preoperative anteroposterior view of the pelvis (**a**) and lateral view of the left hip (**b**) demonstrate the poor bone quality of the femur (stove pipe femur). **c** Postoperative anteroposterior view of the pelvis at seven-year follow up demonstrates the good osteointegration of the stem without signs of stress shielding or stress concentration. **d** Postoperative lateral view of the hip at seven-year follow-up; the *black arrow* shows the cemented fixation in the metaphyseal region, the *white arrow* shows the osteointegration of the cementless part of the stem in the diaphyseal region of the femur

remove [14]. Otherwise, cementless stems have good outcomes in long-term follow-up thanks to their stable secondary fixation, but they could produce problems in osteoporotic [7] and heavy patients [6]. Furthermore, the poor bone quality in addition to severe and continuous loads can lead to early stress shielding [21] and a higher incidence of thigh pain, as well as a decrease in function [17].

The “cementless partially cemented Anca DualFit” stem provides a primary stability in osteoporotic femora not only by the cement mantle but also by the cementless design. Furthermore, a secondary stability is assured by the bone on-growth onto the porous and hydroxyapatite-coated surface of the distal part of stem (70%), which supports patient activity and high loads, and theoretically, ensures a long-term survival.

The behaviour of the Anca DualFit stem has been extensively tested preclinically [2, 5, 20, 23]; load transfer, primary stem stability, and long-term performance (including fatigue damage of the cement) under severe loading, have been investigated in vitro and very good results were found (micromotions never exceeded 80 microns). The mid-term clinical results seem to confirm the in vitro findings.

Other reports on partially cemented stems, derived from a cemented stem, where the cement mantle was limited to the proximal half, have been published, but not with encouraging outcomes [15, 24]. In particular, Vora and Kudrna [24] investigated prospectively a consecutive series of 22 young people with proximally implanted cemented stems (Bridge Hip System, Wright Medical Technology, Arlington, TN); the authors found a 23% rate of aseptic mechanical loosening at an average of 46.2 months after surgery. The reason for this high loosening rate was attributed to the excessive removal of proximal cancellous bone during surgery and the resulting poor bone–cement interface. Jones and Willie [15] retrieved and analysed 16 proximally cemented femoral stems (Bridge Hip System, Wright Medical Technology, Arlington, TN) and they suggested the reason for that implant failure was due to the insufficient proximal cement–bone interface and the poor distal bone–implant interface.

In both reports the authors used a stem with a “cemented design” that appeared inadequate in the hybrid fixation for various reasons. First of all, the Bridge Hip stem is surrounded by a cement mantle as a standard cement

prostheses; thus, the cement is mainly subjected to tensile hoop stresses, which are most critical for brittle material [22], such as PMMA. On the other hand the Bridge Hip does not assure sufficient bone on-growth onto the polished distal part of the stem; in contrast, the Anca DualFit stem is also able to synthesise the value of a cementless stem guaranteeing a secondary fixation with a good bone on-growth thanks to its “cementless design”.

Einsiedel et al. reported good results [8] in a prospective clinical trial on 133 consecutive hips replacements using a cementless design in a partially cemented stem. At the mid-term follow-up (5.08 years) clinical and radiological results seemed to be encouraging, with an average Harris hip score of 89.3 (good), but with nine cases retrieved (7%). This report is different from ours because osteoporosis is considered a contraindication for surgery and osteoporotic patients were discarded from the study; besides, the cement pocket of the stem is circumferential, resembling more the Bridge stem than the Anca DualFit stem, with all the possible consequences described above.

The shortcoming of our study is the mid-term follow-up (average six years and three months). Otherwise, the theoretical advantage of a hybrid fixation with respect to a cementless fixation is the increased primary stability; the failure of primary stability leads to an early subsidence of the stem, usually within the first 12 months after surgery [19]. Thus, at six-year follow-up it would be sufficient to evaluate the efficacy of the primary stability in this new fixation technique.

In this study we evaluated 61 hip replacements in 58 heavy and active osteoporotic women in postmenopausal age.

The number of heavy and active osteoporotic patients undergoing total hip arthroplasty (THA) is increasing. The surgeon must always evaluate the daily activity and bone quality of patients undergoing THA. In cases of heavy and active osteoporotic patients, it might be difficult to choose a cemented or a cementless implant. The “cementless partially cemented” Anca DualFit stem, with cement confined in two small pockets in the metaphyseal region, seems to act properly at a minimum follow-up of five years.

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