Porous Titanium Plasma-Sprayed Acetabular Cup with Hydroxyapatite-Coating in Primary Total Hip Arthroplasty: Clinical and Radiographic Results

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Abstract

Purpose: Porous-coated cups have reported long-term excellent bone fixation and excellent clinical results in total hip arthroplasty (THA). However there is no clinical evidence of the benefit of an additional plasma-sprayed hydroxyapatite (HA) coating over a porous plasma-sprayed titanium coating in cementless press-fit acetabular shell used in THA.

The aim of this study was to investigate implant survival and clinical and radiographic results with particular interest in bone fixation of a cementless porous titanium (Ti) and Hydroxyapatite (HA) plasma-sprayed press-fit modular acetabular cup with a polar flattened design in primary THA.

Materials and methods: A consecutive series of 77 patients (79 hips) underwent primary THA receiving a cementless press-fit acetabular component with a porous plasma-sprayed Ti and HA double coating. At an average follow-up of 71 months (range from 60 to 93 months) 66 patients (68 hips) were available for complete clinical and radiological evaluation.

Results: Harris hip score improved significantly from 50.0 to 96.0. All acetabular cups showed excellent stability and radiographic signs of osseointegration with no radiolucent lines or osteolysis. No implant failure with revision or reintervention was recorded. Implant survival was 100% for revision for any reason as the end point.

Conclusion: This study reported mid-term excellent results of primary fixation and osseointegration of a porous plasma-sprayed Ti and HA press-fit acetabular cup in primary THA.

Keywords: Titanium; THA; Acetabular; Hydroxyapatite

Introduction

One of the most performed and successful procedure in orthopaedic surgery is total hip arthroplasty (THA): it satisfies the increasing functional requests in patients suffering from hip degenerative osteoarthritis that, nowadays, are older and more active than in the past [1].

For this reason, prosthetic implants were developed and designed in a constant improvement process to be more safe, effective and durable. New cementless press-fit acetabular cups with enhanced fixation ability were introduced and studied over the last decades in order to prevent implants’ aseptic loosening, which is considered as the most common reason of failure for the acetabular component in primary THA [2].

The clinical success and durability of cementless press-fit acetabular cups highly relies on the initial mechanical stability of the implant and on the rate and the amount of subsequent biological fixation [3].

Intrinsic factors, such as acetabular bone quality and bone remodelling and extrinsic factors, such as implant design, material properties and implant positioning, are involved in this biological process. Whereas the initial mechanical stability of the cup can be improved by a polar flattened design of the cup which leads to an increased equatorial contact pressure, the biological fixation depends on the material properties and topography of the implant surface [5].

During the last years hydroxyapatite (HA) has been advocated to improve bone osseointegration. However, the major limitation of HA coatings, when used to coat smooth metallic shell for uncemented press-fit acetabular components, was the high delamination risk of the HA layer from the prosthetic substrate which caused the mobilization and failure of the shells [6,7].

Different porous titanium (Ti) coatings, as sintered Ti fiber mesh, sintered Ti beads and plasma-sprayed Ti powders, were used to allow biological implant fixation of uncemented press-fit acetabular components. Several hemispheric porous-coated cups demonstrated long-term excellent bone fixation and clinical results in THA [8-10].
The combination of porous Ti surface together with the osseoconductivity property of HA coating has been shown in vivo to promote increased new bone apposition into the pore space and increased bone-to-implant direct contact in comparison to porous Ti without HA coating [11]. Moreover, precoating the prosthetic surface with a plasma-sprayed porous Ti layer before plasma spraying the HA layer was thought to be a solution to provide a strong bond between HA and the prosthesis therefore to solve HA coating delamination [12]. Thus, the addition of an osteoconductive HA layer might lead to faster bone ingrowth and ongrowth into the porous Ti coating and earlier achievement of secondary stability.

The aim of the present study was to investigate the bone fixation of a cementless porous Ti and HA plasma-sprayed press-fit modular acetabular cup with a polar flattened design in primary THA by assessing the implant survival and its clinical and radiographic results.

Materials and Methods

Between February 2010 and December 2012, a consecutive series of 77 patients (79 hips) underwent primary THA, receiving the same cementless press-fit acetabular component. All surgical procedures were performed by the two senior surgeons.

All 77 patients were eligible to be enrolled in this single-center retrospective study. All patients gave their informed consent before surgery. The study was authorized by the local Ethics Committee and was performed in accordance to the Ethical Standard of the Declaration of Helsinki.

Acetabular implant characteristics and distribution

The acetabular component used in all hips was the Jump System® Cup, a cementless press-fit modular acetabular shell by Permedica S.p.A., Merate, Italy (Figure 1). The shell was made of Ti6Al4V alloy (ISO 5832/3) and double-coated by commercially pure Ti (ISO 5832/2) and HA, Ca$_{10}$(PO$_4$)$_6$(OH)$_2$ (ISO 13779/2). This coating was plasma sprayed in air onto the cup surface in two steps: a first porous Ti coating with a 500 µm-thickness, 30% porosity and non-interconnected pores with a mean pore size of 250 µm and a second external HA coating with a 40 µm-thickness. The mean surface roughness (Ra) of the coating was 24 µm (Rt, 160 µm). Thus, the rationale of this double coating was firstly to enhance the primary implant stability through an elevated surface roughness which ensure high friction against bone, secondly to promote new bone formation and fast bone ingrowth and osseointegration through HA and, last but not least, to guarantee a long-term biomechanical fixation through porous Ti (Figure 2). The cup design was characterized by a hemispherical design with a polar flattening. The outer profile of the shell was determined by two radii in transverse section. The first radius defined the hemispherical profile of the cup, while the second radius, greater than the first one, defined the flattened polar zone. The peripheral uncoated edge of the shell was rounded, smooth and exceeded the coated hemispheric profile of the cup. The acetabular cup allowed to use up to 3 screws for additional screw fixation in case of poor bone quality or unsatisfying primary stability. The cup sizes used ranged from 46 mm to 60 mm diameters. All hips received a modular ultra-high molecular weight polyethylene (UHMWPE) liner against a ceramic ball head. Two different UHMWPE liners were used: a conventional UHMWPE (GUR 1020) E-beam sterilized in 22 hips (32%) and a moderately cross-linked (60 kGy) UHMWPE blended with 0.1% wt vitamin-E (GUR1020E) and Eto sterilized (VITAL-XEµ) in the remaining 46 hips (68%).

A 36 mm-diameter Biolox Delta® ceramic articular head was used in 58 hips, 40 in 17 cases, 32 in 3 patients, and only one 28. For the femoral side, different designs of cementless femoral stems were implanted, except in 2 hips where it was used a cemented stem.

Surgical technique

Posterolateral surgical approach with lateral decubitus position was used in all cases. The planned orientation of the cup considered an inclination angle of 45° ± 5° and anteversion angle of 20° ± 5°.

Intravenous antibiotics were administered preoperatively and antitromboembolic prophylaxis was performed until complete gait recovery. Oral nonsteroidal anti-inflammatory drug (diclofenac, 100 mg per day) for the first 10 days was administered as heterotopic ossification prophylaxis.13 Patient
mobilization started from the first postoperative day. Patient started to walk with two crutches in second day.

Data collection

Any intraoperative complications were recorded: The clinical assessment was performed preoperatively and at the last follow-up using the Harris hip score (HHS) [14]. At the final follow-up patients were asked for any adverse event or complication arisen after the operation, related or unrelated to the implant.

Radiographs were taken at 3, 6 and 12 months after surgery, and then every 2 years, with an AP view of the pelvis and an AP and lateral view of the affected hip. The radiographic assessment was performed by comparing the last radiographs with the immediate post operatively radiographs and included the assessment of cup migration, inclination angle of the cup, presence of heterotopic periarticular ossifications according to Brooker classification [15], presence of a residual polar gap, osseointegration, radiolucent lines and osteolysis, according to the zones described by DeLee and Charnley [16]. The acetabular component was considered radiographically loose if there was ≥ 3 mm of migration from either the interteardrop or vertical lines, or a change of ≥ 4 in the abduction angle [17] Inclination of the cup was measured as the angle between the interteardrop line and a line drawn across the cranial and the caudal edges of the cup [18]. Osseointegration of the acetabular cup was evaluated according to the radiographic signs described by Moore et al [19].

Statistical analysis

Cumulative implant survival was calculated according to Kaplan-Meier method [20] considering as the end point implant failure with revision for any reason and for aseptic loosening.

Statistical analysis was performed by a statistic software SPSS v.16. Significant differences of continuous variables were tested with Student t-test.

Results

Eleven patients did not attend the last follow-up evaluation: out of these 11 patients 3 patients died before the beginning of the study for reasons unrelated to the surgical procedure, 5 were lost to follow-up and 3 were contacted but refused to undergo the clinical and radiographic follow-up.

All 66 patients were invited to return to the clinic to undergo the study follow-up. Thus, 66 patients (68 hips, 2 female patients had a bilateral THA) were available for a complete clinical and radiographic evaluation of the operated hip. The study population included 36 women (53%) and 32 men (47%), with a mean age of 66.3 years, ranging from 35 to 93 years, at the time of surgery.

The most common diagnosis was primary osteoarthritis in 57 cases (83.8%), followed by hip dysplasia in 5 (7.4%), femoral head osteonecrosis in 3 (4.4%), rheumatoid arthritis in 2 (2.9%) and femoral neck fracture in 1 case (1.5%). Average follow-up was 71 months (ranging from 60 to 93 months).

Clinical Results

Mean HHS improved significantly from 50.0 (28.5 to 83.1) before surgery to 96.0 (78.3 to 100) at the last follow-up (p < 0.01). Satisfactory clinical results were observed in all cases, with a substantial improvement in terms of functional recovery and pain relief (Table 1). All patients regained a normal lifestyle, with good mobility, joint functionality and no limitations in daily activities. Five patients with severe heterotopic ossifications had slight limp and could perform daily activities with little discomfort, sometimes taking painkillers as needed but without the use of aids at home, only a stick or crutch outside to feel more psychologically safe.

Radiographic Results

The radiographic assessment involved all the 68 hips. Average acetabular inclination angle was 42° (31° to 55°). Fixation screws were used in 3 hips (3.8%) to improve primary cup stability (2 hips each one with 2 screws and 1 hip with 1 screw).

In all cases, acetabular cups showed excellent stability, without any signs of migration or loosening.

All cups showed evident signs of excellent osseointegration, as the presence of radial trabeculae adjacent to the cup, with no periprosthetic radiolucent lines, no signs of bone remodelling caused by stress-shielding or wear debris-related osteolysis (Figure 3) Only 1 hip showed a focal area of bone resorption around a fixation screw probably caused by backside wear of the polyethylene insert. Polar gap behind the acetabular cup was not visible in any radiographs taken at the latest follow-up. Severe heterotopic ossifications (Brooker III) were seen in 5 hips (7.3%).

Table 1: Harris Hip Score domains showing significant improvement from preoperative evaluation to the last follow-up (average ± SD).

<table>
<thead>
<tr>
<th>Harris Hip Score Domain</th>
<th>Preoperative</th>
<th>St. Dev.</th>
<th>Postoperative</th>
<th>St. Dev.</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>16.9</td>
<td>±8.5</td>
<td>43.7</td>
<td>±8.5</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Function</td>
<td>30.1</td>
<td>±3.7</td>
<td>44.6</td>
<td>±1.8</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Absence of dermity</td>
<td>1.1</td>
<td>±0.1</td>
<td>3.2</td>
<td>±0.9</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>ROM Flexion</td>
<td>85.6</td>
<td>±15.2</td>
<td>102</td>
<td>±12.0</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Abduction</td>
<td>21.1</td>
<td>±8.7</td>
<td>37.1</td>
<td>±5.4</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Adduction</td>
<td>9.6</td>
<td>±7.4</td>
<td>18.7</td>
<td>±3.9</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>External rotation</td>
<td>15.9</td>
<td>±12.1</td>
<td>28.1</td>
<td>±6.9</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Internal rotation</td>
<td>4.3</td>
<td>±3.0</td>
<td>13.1</td>
<td>±4.6</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
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No implant failure was recorded. No implant infection was found. One intraoperative fissuration of the femur occurred during insertion of a press-fit stem that needed no cerclage; the femoral fracture healed spontaneously. No patient underwent neither revision nor reoperation surgery; hence, the survivorship of the implant was 100% for revision for any reason as the end point.

Discussion

The primary stability of a prosthetic implant is one of the most important factors to establish an adequate osseointegration with the host bone [21]. Thus, a necessary requirement for a cementless prosthetic acetabular component in THA is to immediately achieve an adequate anchorage in the acetabular cavity to allow long-term stability and to ensure implant survival.

The secondary fixation is provided by the material and surface texture properties of the implant to create a direct biological bond. The advantage of porous prosthetic surfaces is represented by the better biological anchorage of the implant to the surrounding bone tissue because of increased bone-to-implant contact area which enables bone ingrowth into the pore space and increased bone ongrowth [22]. Several coatings have been studied and developed to meet this another important requirement.

Plasma-sprayed HA coating was employed to enhance new bone formation and to lead to a faster osseointegration. Many studies have demonstrated in vivo and from retrievals analysis that Ti implants coated by plasma-sprayed HA achieve greater direct bone apposition and higher interfacial strength during the early implantation period compared to the uncoated Ti implants [23-26]. However, HA coating over an insufficient roughened acetabular shell was found to be improper to promote adequate and durable cup stability. Unacceptable failure rates were found in multiple studies associated with HA-coated smooth acetabular shells in cementless THA [6,7]. These failures were caused by aseptic loosening of the cup due to insufficient adhesion between the HA coating and the prosthetic substrate [27-28]. Plasma-sprayed HA thin coating over precoated plasma-sprayed porous Ti was introduced to increase the adhesion strength between HA layer and the prosthetic substrate and to increase surface roughness and porosity to promote bone ingrowth and biomechanical anchorage of the implant [11,12]. Plasma-sprayed porous Ti press-fit modular acetabular cups showed excellent results in primary THA in the midterm [29-31]. Also additional plasma-sprayed HA upon plasma-sprayed porous Ti coatings have been successfully employed with press-fit acetabular shells as demonstrated by the excellent results reported in primary THA up to 11 year-follow-up [31,32].

However up today there is no clear evidence about the real clinical benefit of an additional plasma-sprayed HA over a porous Ti coating. Regarding primary stability, additional HA coating seems to have no advantages in comparison to HA-uncoated porous acetabular shell, as shown by a randomized radiostereometric study [33]. A randomized clinical trial investigating the bone mineral density changing determined by DEXA scanning around calcium phosphate plasma-sprayed coated porous Ti cup revealed no significant differences at three years after surgery in comparison to the uncoated porous Ti same acetabular component [34], as also reported by Massari et al [35].

Gottliebsen et al., reported a significantly increased revision rate for aseptic loosening with a HA-uncoated press-fit porous cup than the HA-coated cup with same bearings at 11-year follow-up [31]. Again, Gottliebsen et al., in the same study reported a significantly increase in the amount of osteolysis around HA-uncoated press-fit porous cup compared with the HA-coated cup, consistently with the aseptic loosening failures [31]. HA coating may protect acetabular cups against loosening and osteolysis through a sealing effect at the bone-implant interface and thus, be more resistant to wear-particles migration than non-HA coated modern metal shells [36].

The mid-term results found in the present study were comparable to those found by Berend et al. [37], who recently reported a 99.5% survival rate at a minimum of 3-year follow-up with a porous plasma-sprayed acetabular shell with highly cross-linked vitamin E-infused UHMWPE.

In the present study significant radiographic results of stability and osseointegration of the acetabular cup were found in all hips, independently from diagnosis and patient. The complete absence of radioluencies around the acetabular cups was consistent with a physiological bone remodelling with good periprosthetic bone loading without stress-shielding phenomena. All patients had the clinical improvement that one can expect from THA at short term. Nevertheless the results are consistent in suggesting the safeness and the reliability of the studied implant. Similarly, no clinical and radiographic differences between the two groups of different polyethylenes have been detected in this study. The use of the vitamin-E added polyethylene liner has been adopted after its introduction in the market due to the superior wear and mechanical resistance compared to the conventional one [38].

Figure 3 AP radiographs taken at the last follow-up (male, 77 years at surgery, right side, and follow up 70 months) of the operated hip showing an excellent osseointegration of the acetabular cup.
Longer follow-up will clarify the effective performances of the two different materials.

Limitations of our study were the small sample size of the population, the relative short follow-up and the lack of a control group with the same acetabular cup without additional HA coating.

Conclusion

The present study showed mid-term excellent primary fixation and osseointegration of a plasma-sprayed HA and porous Ti press-fit acetabular cup in primary THA. The reported clinical and radiographic results support the use of a plasma-sprayed HA and Ti coating in a cementless press-fit acetabular cup. Longer follow-up is required to assess long-term survivorship of this acetabular cup.

References


