Hydroxyapatite in total hip arthroplasty. Our experience with a plasma spray porous titanium alloy/hydroxyapatite double-coated cementless stem

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Summary

Purpose. Total hip arthroplasty could fail due to many factors and one of the most common is the aseptic loosening. In order to achieve an effective osseointegration and reduce risk of loosening, the use of cemented implant, contact porous bearing surface and organic coating were developed. Aim of this study was to evaluate clinical and radiological mid-term outcomes of a porous titanium alloy/hydroxyapatite double coating manufactured cementless femoral stem applied with “plasma spray” technique and to demonstrate the possibility to use this stem in different types of femoral canals.

Methods. Between January 2008 and December 2012, 240 consecutive primary total hip arthroplasties (THAs) were performed using a porous titanium alloy/hydroxyapatite double coating manufactured cementless femoral stem. 182 patients were examined: 136 were females (74.7%) and 46 males (25.2%); average age was 72 years old (ranging from 26 to 92 years old).

For each patient, Harris Hip Scores (HHS) and Womac Scores were collected. All X-ray images were analyzed in order to demonstrate stem survival rate and subsidence.

Results. Harris Hip Score was good or excellent in 85% of the cases (average 90%) and mean WOMAC score was 97.5 (ranging from 73.4 to 100). No cases of early/late infection or periprosthetic fracture were noticed, with an excellent implant survival rate (100%) in a mean period of 40 months (ranging from 24 and 84 months). 5 cases presented acute implant dislocation, 2 due to wrong cup positioning in a dysplastic acetabulum and 3 after ground level fall. Dorr classification of femoral geometry was used and the results were: 51 type A bone, 53 type B bone and 78 type C bone. Stem subsidence over 2 mm was considered as a risk factor of future implant loosening and was evidenced in 3 female patients with type C of Dorr classification.

No radiolucencies signs around the proximally coated portion of stem or proximal reabsorption were visible during the radiographic follow-up.

Conclusions. Concerning the use of porous titanium alloy/hydroxyapatite double coating, this study reported an excellent implant survival rate in a mid-term period with a rate of 1,64% of subsidence in patients with type C of femoral canal but with an optimal HHS and Womac Score results.

Regarding this stem, primary stability is guaranteed by trapezoid shape of proximal region and tapering in frontal plane through press-fit technique. Radiological absence of pedestal has been accepted as sign of no excessive stress transmission to distal cortex due to its tapered diaphyseal region.

Thanks to the reported data, Authors can consider this double coating a valid choice with an excellent medium-term survival and encouraging subsidence results.

Further studies are needed to ensure these results can be replicated.

KEY WORDS: total hip arthroplasty; hydroxyapatite; osteoporosis; osseointegration.

Introduction

Over the last few decade, total hip arthroplasty (THA) has become a common procedure and every year one million of worldwide surgical procedure are performed (1). Several of international literature reports focused on THA results and complications. Implant loosening/lysis shows a linear increase and after the third year it exceeds the dislocation and it become the most common complication. The 2013 Annual Australian Report documented femoral component revision rate of 26.4% (2). Actually only few alternative approaches are currently available to manage the aseptic implant loosening and this risk is definitely increased in patients with osteoporosis (3).

Many fixation systems were studied over the time in order to prevent aseptic implant loosening. Use of cement, porous bearing surface and organic coating were developed in order to achieve an effective osseointegration with a vital bone-implant contact (4).

In this context, use of coating surfaces is aimed to decrease this feared complications. Hydroxyapatite (HA) has been used for long time to achieve permanent implant mechanical fixation within in the bone and to involve osseointegration, i.e. the creation of a biological and mechanical bond between implant and bone (5-9).

As stressed by Hahn and Palich, plasma sprayed, combined titanium alloy/HA coating that consists of a first layer of porous ti-
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Titanium and a second layer of HA, designed to provide a strong adherent bond to the hydroxyapatite and therefore to prevent coating delamination (10). The combination with porous surface together with the osseointductivity and osseoconductivity of hydroxyapatite coating can promote bone ingrowth into the pore space (11).

In literature early stem migration in the distal direction is reported as a predictive factor for implant loosening (12) and failure of osseointegration of the femoral component. Failure of osseointegration is defined as a progressive circumferential radiolucency around the proximal porous coating on both anteroposterior (AP) and false-profile radiographic images of the hip, with absence of spot weld or other radiographic evidence of bony ingrowth (13). Aim of this report was to evaluate the efficacy of a plasma spray porous titanium alloy/HA double coating to promote bony ingrowth and mechanical stabilization of a single wedge tapered straight cementless femoral stems (14).

Materials and methods

This single-center retrospective study was approved by our local ethical committee, and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All patients gave written consent.

Eligible subjects included those who had undergone THA performed by two experienced orthopaedic hip surgeons (ML and EB). The inclusion criteria were: 1) patients undergoing elective primary THA due to for osteoarthritis, osteonecrosis, dysplasia, post traumatic arthritis or acute femoral neck fracture; 2) femoral fixation with a porous titanium alloy/hydroxyapatite double coating manufactured cementless femoral stem and 3) patients over 18 years old. Exclusion criteria: 1) revision THA; 2) patients affected by bone mineral disease; 3) THA for femoral metastasis or infection; 4) and the presence of other kind of femoral implant.

From January 2008 to December 2012, we performed a total of 991 THA, of this 240 meet the inclusion/exclusion criteria and they were enrolled in the study. All surgeries were performed using a posterolateral approach with patient placed in lateral position. When the follow-up visit was performed, 8 patients had passed away, 40 were impossible to reach due to wrong phone number and 10 moved on other countries and we were able to review a total of 182 patients, 136 females (74.7%) and 46 males (25.2%); the mean age was 72 years old (ranging from 26 to 92 years old) (Table 1). The right side was involved in 112 cases, whereas left side in 66 cases, while 4 patients underwent to bilateral implant. Implant surgery was performed after an acute femoral neck fracture in 10 cases (5.4%).

Mean follow-up time was 40 months (ranging from 24 to 84 months) (Figure 1).

Implant design. In all the patients a porous titanium alloy/hydroxyapatite double coating manufactured cementless femoral stem was implanted (Exacta press-fit femoral stem; Permedica manufacturing; Merate, LC; Italia). According to Khanuja et al., this stem is considered as type 1, single wedge tapered straight cementless femoral stem (14). The stem was foreseen in a standard version characterized by a 135° CCD and in a high off-set version (HX-Pore Lateral), characterized by a 127° CCD angle with a higher offset at neck level (+ 6 mm offset for each size) without modifying the stem body length. Stem surface is entirely coated with a double coating of 300 μm pure titanium + 50 μm hydroxyapa-
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Table 1 - Demographic data, surgical indications and characteristics of the implants.

<table>
<thead>
<tr>
<th>Patients Details</th>
<th>Number</th>
<th>Male/female</th>
<th>Age at time of surgery (y/o)</th>
<th>Causes of surgery</th>
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<tr>
<td></td>
<td>182</td>
<td>46/136</td>
<td>72 y/o (26 - 92 y/o)</td>
<td>Osteoarthritis</td>
</tr>
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<td></td>
<td>Avascular necrosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Congenital Hip Dysplasia</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Neck femoral fracture</td>
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<table>
<thead>
<tr>
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<tr>
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<table>
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<th>5</th>
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<td>4</td>
<td>21</td>
<td>49</td>
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<td>18</td>
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<table>
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<th>Head diameter</th>
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<th>32</th>
<th>36</th>
<th>40</th>
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<tr>
<td></td>
<td>7</td>
<td>7</td>
<td>152</td>
<td>16</td>
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<table>
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<tr>
<th>Cup model</th>
<th>Press-fit</th>
<th>Truncated cone</th>
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<td></td>
<td>155</td>
<td>27</td>
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</table>

<table>
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<tr>
<th>Bearing surface (head/liner)</th>
<th>Ceramic/Polyethylene</th>
<th>Metal/Polyethylene</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>121</td>
<td>61</td>
</tr>
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</table>

Clinical evaluation
Routine clinical and radiographic examinations were performed preoperatively; the postoperative follow-up was made at 1, 3, and 6 months and yearly thereafter. Patients were scored as routinely in our practice preoperatively with the Harris Hip Score (HHS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (15, 16); the same scores were used during the follow-up. The Harris hip score (HHS), a disease-specific health status scale used to measure the outcome of total hip arthroplasty. The domains covered are pain, function, absence of deformity, and range of motion. The pain domain measures pain severity and its effect on activities and need for pain medication. The function domain consists of daily activities (stair use, using public transportation, sitting, and managing shoes and socks) and gait (limp, support needed, and walking distance). Deformity takes into account hip flexion, adduction, internal rotation, and extremity length discrepancy. Range of motion measures hip flexion, abduction, external and internal rotation, and adduction.

The WOMAC is used to assess pain, stiffness, and physical function in patients with hip and/or knee osteoarthritis. It consists of 24 items divided into 3 subscales: Pain (5 items): during walking, using stairs, in bed, sitting or lying, and standing, Stiffness (2 items): after first waking and later in the day and Physical Function (17 items): stair use, rising from sitting, standing, bending, walking, getting in/out of a car, shopping, putting on/taking off socks, rising from bed, lying in bed, getting in/out of bath, sitting, getting on/off toilet, heavy household duties, light household duties.

Radiographic Evaluation
Antero-posterior (AP) and false-profile radiographic images of affected hip were evaluated and compared with the previous radiographic images performed at 1, 6 and 12 months and annually as internal follow-up, in order to evaluate stem subsidence. If necessary additional clinical and radiographic images examinations were performed based on patient’s symptoms. Stem subsidence was evaluated as the distance between the great trochanter tip and a line drawn between two radiological references.
of the stem, (see Figure 2 for more details). These measurements were done independently by two experience surgeons (E.B, M.L) and in case of disagreement it was discussed together. To minimize operator-mistakes, all X-rays were calibrated using the known head diameter of al implants using OrthoView™ digital planning software (OrthoView LLC, Jacksonville, Florida).

Two-years subsidence rates over 2 mm was considered as predictive factor for early loosening and considered as a risk factor for future aseptic implant loosening (17) (Figure 3).

All preoperative X-rays were categorized according to femoral canal shape using the Dorr cortical bone classification (18). Type A bone was defined as having thick cortical walls with a narrow and funnel shape of the proximal femoral canal (champagne flute canal). Type B bone showed thin medial and posterior cortices, frequently with irregular endosteal surfaces. Type C bone had dramatically thin medial and posterior cortices with a more cylindrical shape to the femoral canal (stove-piper canal).

All X-rays were scanned by the Authors in order to analyze the osseointegration failure, which was defined as a progressive circumferential radiolucency around the proximal porous coating on both AP and false-profile radiographs of the hip, with absence of spot welds or other radiographic evidence of bony ingrowth as defined by other Authors (19). The cortical thickening and bridging sclerosis at prosthesis tip (called pedestal) was considered as sign of distally stress loading.

Radiolucencies with respect to the stem were classified according to the system of Gruen et al. on anteroposterior and lateral radiographs and they were recorded as less than one millimeter, between one and three millimeters or more than three millimeters in width (20).

Results

Clinical outcome. Harris Hip Score was good or excellent in 85% of the cases (average 90%) and mean WOMAC score was 97.5 (ranging from 73.4 to 100). No cases of early/late infection were reported.

5 cases presented acute implant dislocation, 2 due to wrong cup positioning in a dysplastic acetabulum and 3 after ground level falls in the first post-operative time. All 5 dislocations were promptly reduced in the operating room and stem revision surgery was not necessary. At time of evaluation, all patients presented an average HHS of 85 points.

3 patients (1.6%) reported thigh pain after 12 months of implant but until now this sporadic pain did not need revision surgery. 2 cases of superficial skin infection were observed and no surgical revision was needed.

Radiological evaluation. No cases of periprosthetic fracture were noticed, with an excellent implant survival rate (100%) in a mean period of 40 months (ranging from 24 and 84 months). The Dorr classification of femoral geometry was assessed by examination of the AP and lateral hip films. Using this classification method, it was found a number of 51 type A bone canal, 53 type B bone and 78 type C bone and all data was expressed in Table 2.

Stem subsidence over 2 mm was considered as a risk factor of future implant loosening and was evidenced in 3 female patients with type C of Dorr classification.

The first case with a subsidence of 3 mm was a 56 years old female with HHS of 93, Womac Score of 97.5 and follow up of 40 months. The second case with a subsidence of 2.5 mm was a 79 years old female with HHS of 85, Womac Score of 96 and follow-up of 76 months. The third case with a subsidence of 2 mm was a 63 years old female with HHS of 90, Womac Score of 93 and follow-up of 24 months.

Analyzing X-rays at 6 weeks from surgery, any periprosthetic radiolucencies and osteolysis signs were noticed. At the last examination no case of pedestal sign was evidenced.

Radiological results at the last examination showed radiolucencies of under one millimeter in 150 cases (82,4%), between one and three millimeters in 32 (17,5%) and none over three millimeters in width.

In the anteroposterior view, 80% and in the lateral view, 79% of radiolucencies were seen in the proximal part of the hip stem (Gruen zones 1, 7, 8, 14).

Osteolysis in term of a sharp demarcated radiolucent space with a rounded or scalloped appearance extending away from the implant was not detected around any stem.

Discussion

Currently, implant loosening is one of the most dangerous risks for
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In order to prevent implant loosening, many fixation systems were studied over the years. In this context the surface coatings could contribute to reduce this feared complications. Hydroxyapatite has been used for long time in order to achieve the permanent mechanical fixation of an implant in the bone bed to involve the process of osseointegration, i.e. the creation of a biological and mechanical bond between the implant and the bone (5-9). This study has shown a medium-term clinical and radiological outcomes after the use of femoral hip stems with porous titanium alloy/HA type coating.

Focusing on stem design, primary stability is guaranteed by trapezoid shape of proximal region and tapering in frontal plane through press-fit technique. The intraoperative insertion and extraction was easy and the surgeon can adjust stem anteversion during implantation through an introducer connecting system.

Radiological absence of pedestal has been accepted as sign of no excessive stress transmission to distal cortex thanks to its tapered diaphyseal region and this can allow the prosthesis wedging into endomedullary canal without producing elevated stress on the distal cortical bone. In Literature is underlined the effect of groove geometry on cementless femoral stem component in THA (21) and this system is characterized by rounded profile, without hard angles and with grooves to increase the bone/prostheses contact area favoring osseointegration and eliminating risk of stress concentrations on the distal cortical bone.

The low reported rate of subsidence was suggested to be linked to design of proximal and distal grooves. Infact proximal horizontal grooves increase axial stability while distal vertical grooves increase rotational stability. Data showed no subsidence in Type A and B

Table 2 - Dorr classification of femoral geometry.

<table>
<thead>
<tr>
<th>Dorr Classification</th>
<th>Number (percentage)</th>
<th>Mean Age (years)</th>
<th>Female vs Male (percentage)</th>
<th>Stem Subsidence (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Type</td>
<td>51 (28%)</td>
<td>72 y.</td>
<td>35 vs 16 (68% - 32%)</td>
<td>0.86 (0.04 - 1.73)</td>
</tr>
<tr>
<td>B Type</td>
<td>53 (29%)</td>
<td>71 y.</td>
<td>39 vs 14 (73% - 27%)</td>
<td>0.61 (0.1 - 1.8)</td>
</tr>
<tr>
<td>C Type</td>
<td>78 (43%)</td>
<td>74 y.</td>
<td>62 vs 16 (79% - 21%)</td>
<td>1.03 (0.1 - 3)</td>
</tr>
</tbody>
</table>

Figure 3 - Post op and 40 months follow-up showing a subsidence of 3 mm of the stem in a 56-year-old female with HHS of 93, Womac Score of 97.5.
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and 3.8% in type C respectively. Scanning these data, it was debated the relationship between subsidence and type of femoral canal shape. In patient with Type C bone, with thin medial and posterior cortices and a more cylindrical shape of the femoral canal, orthopaedic surgeons should search and find intraoperatively a very good primary stability otherwise subsidence risk could occur in the next future.

In the 3 cases with subsidence, a mean HHS result of 89.3 and a mean WOMAC Score result of 95.5 with a mean follow-up of 46.6 months were found. This complication was noticed only in women, with a mean age of 66 years old and was not statistically significant.

In Literature, major Authors reported their experience with HA coated femoral stem with long-term outcomes (5, 24, 25) and they reported an excellent results with this kind of stem. As stressed by Claus et al. (19), the survival rates of fully HA-coated stems have proven to be outstanding and in Norwegian Arthroplasty Register 1987-2004, the 15-year survival rate (95.1%) was comparable to the best of the cemented stems examined (13).

A recent meta-analysis showed that HA is better than porous coating. HA coating had higher HHS, less incidence of thigh pain, superior proximal femoral osteointegration and better preservation of peri-prosthetic bone quality (26).

Conversely, a recent analysis of 116,069 THAs in the Nordic Arthroplasty Register Association (NARA) database stressed that uncemented HA-coated stems had similar result to those of uncemented stem with porous coating or rough sand-blasted stems. This analysis underlined that the use of HA coating on stems available both with and without this surface treatment had no clinically relevant effect on their outcome (27). Regarding thigh pain, from our data, 1.6% of patients reported thigh pain after 12 months of follow up but until now this sporadic pain did not need revision surgery. In Literature it is expressed how the thickness and purity of HA and implant design could be related to incidence of thigh pain. Brown et al. support that incidence of thigh pain decreased abruptly after the first postoperative year (28).

Conclusion

In our study there are some key strength and limitations. All implants were performed by two same experienced orthopaedic hip surgeon and in Literature is expressed how surgeon experience and skills had a large impact on the treatment outcome and furthermore, it is known that single-surgeon series produce superior results compared to multi-surgeon series (24). The main limitations to this study were the medium term follow-up, the absence of a control group and large inclusion criteria.

As showed by the clinical and radiological evaluation, the porous titanium alloy/hydroxyapatite double coating (HX-Pore surface coating) could be considered usable and safe for all patients regardless of femoral shapes. The HX-Pore surface coating contributes to the primary stem stability, thanks to elevated roughness and elevated bone friction and to the secondary stem stability promoting the primary stem stability, thanks to elevated roughness and elevated surface eliminated pointed contact and stress concentration on the distal cortical, reducing the risk of thigh pain and stress-shielding.

The external HA coating layer promoting osteointegration around the stem could also have a sealing effect prevent polyethylene wear debris migration from joint space towards distal area of the femoral canal. The large inclusion criteria of the study, a limitation of this study as said above, could also be also key strength, proving the versatility of this kind of stem. Further studies are needed in order to ensure these results can be replicated.

Disclosure

All the Authors do not have any conflict of interest: Conflict of Interest: Nil.

The experiment comply with the current laws of Italy. All human and animal studies have been approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1984 Declaration of Helsinki and its later amendments.

Informed consent was obtained from all individual participants included in the study.

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