A comparison study of the outcomes of ceramic on ceramic total hip arthroplasty in young versus older patients. A minimum 10-year follow-up prospective matched study.

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A COMPARISON STUDY OF THE OUTCOMES OF CERAMIC ON CERAMIC TOTAL HIP ARTHROPLASTY IN YOUNG VERSUS OLDER PATIENTS. A MINIMUM 10-YEAR FOLLOW-UP PROSPECTIVE MATCHED STUDY

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ABSTRACT

Background: The purpose was to analyze the outcome and prosthesis survival in patients aged between 20 and 40 years who received a cementless total hip arthroplasty (THA) with a minimum follow-up of 10 years as compared with older patients.

Methods: Prospective matched comparative study between 94 young patients with mean age of 37.2 (range, 22-40) years and 90 older patients with mean age of 64.7 (range, 60-70) years treated with ceramic on ceramic THA. Clinical outcomes were assessed by the Harris Hip Score, Reduced Western Ontario and MacMaster University and Short-Form-12 questionnaires. Radiological evaluation was also performed. The primary outcome was the THA survival rate.

Results: Mean follow-up of 13.6 (range, 10-15) years. At the final follow-up, there was no significant difference between groups in HSS score (p= 0.356), WOMAC-pain (p= 0.461), SF12-physical (p= 0.305) or SF12-mental (p= 0.511), but younger group had significantly higher WOMAC-function score (p= 0.013). There were 7 revisions in the younger group and 4 in the older group (p= 0.197). The 14-year prosthesis survival for any reason was 93.2% (95% CI, 86.7–99.7 %) in the younger group and 98.3 % (95% CI, 95.1-100 %) in the older group (p= 0.189). For aseptic reason, the 14-year survival was 94.7% (95% CI, 88.9–100 %) in the younger group and 98.3 % (95% CI, 95.1-100 %) in the older group (p= 0.332).

Conclusions: At minimum follow-up of 10 years, THA with cementless stem and ceramic-on-ceramic bearing provides successful survival and functional outcomes in young patients between 20 and 40 years old.
Keywords: Young patients; Total hip arthroplasty; Cementless; Ceramic-on ceramic; Survival
INTRODUCTION

Total hip arthroplasty (THA) has proven to be an effective procedure for restoring function and mobility for end-stage osteoarthritis with predictable and reproducible results at long-term in the elderly [1]. The successful outcomes in elderly patients, in concert with improvements in surgical techniques, component designs and biomaterials, have resulted in extended indication to younger and more active patients [2].

Traditionally, surgeons have been reluctant to perform THA in young patients because they are more active and with a long life expectancy which may influence the survival of the THA. Thus, THA in young and active patients has been shown to be associated with higher rate of mechanical failure than those in older patients [3], mainly because of polyethylene wear, osteolysis and aseptic loosening [4,5]. These failures have been attributed to the early use of all cemented components, screw-in acetabular designs, polyethylene bearing surfaces, and the higher activity level of the patients. In recent decades, the survival of the THA has improved thanks to technological advances such as cementless components and alternative bearing surfaces. Ceramic-on-ceramic bearing surfaces provide several benefits, making it a reasonable bearing surface in these patients [6,7]. The wear debris from ceramic bearing surfaces is usually well tolerated, and alumina particles are relatively bioinert compared with metal and polyethylene debris [8].

Numerous studies on THA in young patients have been reported although the concept of young is critical. Previous studies have either focused on young patients under the age of 60 [9-11] or very young patients less than 20 years old [5,12]. However, the activity levels and expectations of these population groups are usually different. Some studies have long-term analyzed THA in patients aged between 20 and 40 years [13-18]. However, all of them were retrospective studies, focused on either femoral or acetabular component survival, and comparison with older patients was not performed. In addition, most of those studies reported
on mixed prosthetic designs, and prospective long-term studies on modern bearings in young patients are limited. To our knowledge, only one study has prospectively compared young and older patients [6], but the mean follow-up was 5.6 years. On the other hand, outcomes after THA in young patients are controversial in the recent literature. Some authors have reported excellent long-term survival of cementless THA [11,16,19-21]. However, other studies have reported high rate of acetabular [15,22] or femoral loosening at medium-term [9,14]. Thus, THA is still controversial in young and active patients despite advancements in implant technology, and there is a paucity of prospective literature on implant survival and long-term patient-reported outcomes after primary THA in young patients. The purpose of this study was to analyze the long-term outcomes and prosthesis survival in patients aged between 20 and 40 years who received a cementless THA as compared with patients older than 60 years.

MATERIAL AND METHODS

A prospective matched cohort study was designed to assess outcomes and survival after primary THA in young patients. Initially, a minimum follow-up of 5 years was required for evaluation but later this follow-up was extended to 10 years. All patients gave informed consent to participate in the study which was approved by our institutional review board. Patients underwent primary THA between 2002 and 2007 were eligible for study. Inclusion criterion was age between 20 and 40 years. The indication for THA in young patients was severe hip osteoarthritis with severe pain and disability (Harris hip score –HHS- less than 60) [23]. The exclusion criterion was neurological disease (2 patients). Patients aged between 60 and 70 years who underwent primary THA during the same time were selected as a control group (older group). This age range was chosen to ensure a minimum level of activity in the control patients for the purpose of comparison with younger
patients. The cohorts were matched for gender, body mass index (within 3 Kg/m2), and preoperative hip function (within 5 points) according to the HSS.

Surgical procedure

All procedures were performed by the same two senior surgeons. All surgeries were performed in a standardized way under spinal anesthesia in an operating room with laminar flow. A Hardinge [24] lateral approach was used. The Duofit cementless modular hip system (Samo, Bologna, Italy) was used in all patients. The femoral component was a modular collarless design composed of a titanium alloy with proximal porous coating. The stem was inserted by press-fit technique after reaming of the femoral canal. The acetabular component (Sparkup, Samo, Italy) was a modular hemispheric metal-backed design with titanium porous coating. All THA were done with ceramic-on-ceramic bearing (Biolox delta alumina, Samo, Italy). The choice of this bearing was based on age (less than 70 years old). The cup was inserted using a reaming technique and with press-fit. Even though the stability of the cup was satisfactory, adjunctive two screws were usually used. Autografts using the femoral head were used 4 young patients with acetabular dysplasia or protrusion. Ceramic femoral head size varied between 32 mm (for 44-46 mm cups), 36 mm (48-50 mm cups) and 40 mm (52-70 mm cups). The median cup size used was 50 mm in both groups.

According to a standard protocol, all patients had antibiotic prophylaxis for 24 hours (started one hour prior to the skin incision), and thromboembolic prophylaxis with low-molecular-weight heparin for 30 days. All patients were allowed to stand on the second postoperative day, and were instructed to weight-bearing as tolerated with the use of an assistive device as needed. They were advised to use a pair of crutches for six weeks.

Follow-up evaluation
Clinical and radiographic evaluation was performed preoperatively and postoperatively at 3, 6, and 12 months, and then biannually until at least 5 years. For this study, those patients with a follow-up less than 10 years were invited to return for re-evaluation.

The last clinical and radiological evaluations were carried out by two independent surgeons who had not participated in the surgeries. The primary outcome was the THA survival rate, which was defined as the proportion of arthroplasties surviving without revision (removal or exchange of any component) during the follow-up time.

Clinical evaluation was performed by the Harris hip score [23]. Reduced Western Ontario and MacMaster University (WOMAC) [25] and Short-Form 12 (SF-12) [26] questionnaires, both validated for our country, were also administered. Thigh pain was also rated as none, slight, moderate or severe. All patients were asked specifically about any noise in the hip in the last visit. All patients were surveyed regarding their ability to return to their occupational activities and perform recreational activities.

The radiological evaluation was done by standardized weight bearing anteroposterior and lateral radiographs. The latest available radiographs were compared with the initial postoperative radiographs. Cup position was assessed according to the acetabular abduction angle. The cup was assessed on the basis of DeLee and Charnley zones [27]. Loosening of the cup was defined when there was a change in the position greater than 5 degrees on anteroposterior radiographs, progressive discontinuous radiolucent lines wider than 2 mm in at least 2 zones, or a continuous radiolucent line. On the femoral side, the zones described by Gruen et al. [28] were used. Loosening of the stem was defined when there was a progressive subsidence greater than 5 mm, a progressive change of position of 3 degrees or more, or a continuous radiolucent line wider than 2 mm.

Statistical analysis
The sample size was calculated a priori on the primary outcome variable (THA survival). We considered a relevant difference between groups of 10% in the prosthesis survival. In order to detect that difference, with a standard deviation of 10, alpha of 5% and power of 90%, 78 patients were needed in each group. Assuming a drop-out rate of 10%, at least 86 patients per group were required.

Statistical analysis was performed using SPSS software v. 19 (SPSS Inc., Chicago, USA). Normal distribution was assessed by the Shapiro-Wilk test. Analyses between groups were performed with the chi-square test, Fisher exact test or Mantel-Haenszel test for categorical variables, and Student t-test or non-parametric Mann-Whitney U-test for continuous variables. For comparison between pre- and post-operative data, the paired t-test or Wilcoxon signed-rank test were used.

Multivariate logistic regression was used to identify independent variables associated to THA revision, and the results were shown as odds ratio (OR) with 95% confidence interval (CI). Prosthesis survival was assessed by the Kaplan-Meier method with revision for any reason as end-point, and comparison between groups by the log-rank test. Statistical significance was considered for p values less than 0.05 in all tests.

RESULTS

A total of 101 patients in each group were enrolled. Of them, 7 patients in the young group were lost to follow-up. In the older group, 5 patients were lost to follow-up and 6 other died for causes unrelated to the arthroplasty before 10 postoperative years. All those patients were excluded. Preoperative data of the remaining patients are shown in Table 1. Mean follow-up from THA to the last visit was 13.6 (range 10-15, SD 3.7) years in both groups.

Main outcome
There were 7 revisions in the younger group and 4 in the older group (p= 0.197). Revisions in the younger group included one early wound deep infection, and 5 aseptic cup loosening (in 3 rheumatoid arthritis patients and in 2 with avascular head necrosis, between 8 and 11 postoperative years). Moreover, radiographs in one young patient showed asymmetry in the centering of the femoral head at 10 postoperative years, which was treated with only insert exchange. In the older group, there was one early wound deep infection, one periprosthetic femoral fracture at 6 postoperative years, and 2 aseptic cup loosening at 5 and 7 postoperative years, respectively. No other major complications, such as peroneal palsy, dislocation, or ceramic fracture, occurred in either group.

The cumulative survival of the THA at 14-year for any reason (Fig. 1) was 93.2% (95% CI, 86.7–99.7 %) in the younger group and 98.3 % (95% CI, 95.1-100 %) in the older group, and this difference was not significant (log rank, p= 0.189).

Considering only aseptic revisions, the cumulative survival at 14-year was 94.7% (95% CI, 88.9–100 %) in the younger group and 98.3 % (95% CI, 95.1-100 %) in the older group, and this difference was not significant (log rank, p= 0.332).

Secondary outcomes

All clinical scores significantly improved from preoperative to the last follow-up in both groups (p= 0.001) (Table 2). At the last follow-up, there was no significant difference between groups in HSS score (p= 0.356). Likewise, there were no significant differences in WOMAC-pain (p= 0.461), SF12-physical (p= 0.305) or SF12-mental (p= 0.511), but there was significant difference in WOMAC-function (p= 0.013). In the younger group, 5 (5.3%) patients had slight or occasional thigh pain, while this was in 3 (3.3%) patients in the older group (p= 0.384). None patients had moderate or severe pain in either group. One patient in the younger group complained of occasional squeaking in some hip position although this was
not detected in the clinical examination, the hip functioned well and no radiological findings were observed. Another patient in the older group experienced transient painless noise during the 2 first postoperative years which resolved spontaneously.

Sixty-nine young patients (73.4%) were married during follow-up and all of them have normal lives. In the younger group, 88 patients were able to walk without any support, and 6 with a cane. All of them returned to their preoperative occupational activities and were participating in routine recreational activities at last follow-up. Six patients in this younger group participated in some sports activity. All patients in the older group were retired at the last visit, and 14 of them used a cane to walk.

Radiologically in the unrevised hips at the last follow-up, 5 (5.7%) young patients and 2 (2.3%) older patient presented asymptomatic incomplete radiolucent lines less than 1 mm in at least one zone around the acetabular component (Gruen zones 1 or 2). No radiolucent lines around the femoral component or osteolysis around either component were found in either group. There was no femoral subsidence greater than 5 mm in any hip.

**DISCUSSION**

The main finding of the present study was that using contemporary cementless implants with ceramic-on-ceramic bearing surface, patients aged 20-40 years had a long-term THA survival no significantly different than those older patients. In this study, the survival of cementless ceramic-on-ceramic implants for aseptic reasons in young patients with a median age of 37.2 years was encouraging, averaging 94.7% at 14 years. This was lower than survival in patients aged 60-70 years (98.3%), but the difference was not significant. Likewise, there was no significant difference between groups according to HSS score.

The number of THA is expected to increase among young patients, and this procedure in the young population is still a challenging problem. In earlier studies, high rates of failure were
observed in cemented THA in young patients under the age of 55 years [3], and excessive wear of the polyethylene liner resulted in numerous revisions of modular cementless cups [2].

The cementless stem was not a concern in the present study. The estimated survival rates of the contemporary cementless titanium stems in young patients at medium- and long-term seem to be encouraging [15,29]. However, when polyethylene bearing surfaces are used the polyethylene debris can lead to a high rate of osteolysis in the proximal femur. Earlier reports of conventional metal-on-polyethylene bearings have shown relatively poor results and high rates of loosening in patients younger than 30 years, with some failure rates as much as 45% to 54% at 9-to-15 years follow-up [3,30]. Wangen et al. [15], in a review of patients younger than 30 years treated with a cementless THA and mean follow-up of 13 years, reported excellent survival of the stems. However, the authors also reported high rates of polyethylene wear and proximal femoral bone loss with 49 % of cup revisions due to mechanical failures.

Pakos et al. [31], in 45 THA in young patients under 30 years with a mean follow-up of 9 years, reported 22% cup revisions due to polyethylene wear and aseptic loosening. McAuley et al. [32], in a large series of cementless titanium porous-coated THA in patients 50 years and younger, found a THA survival of 89% at 10-years and 60% at 15-years with worse outcomes in patients that were 40 years and younger.

The reasons for failure in the young patients of the present study were aseptic loosening of the acetabular component (2 patients, 3.2%) and ceramic liner wear (1 patient, 1.6%). These data were consistent with those in other studies of contemporary ceramic-on-ceramic bearings [1,6,7,33,34]. In the study by Byun et al. [16] of 41 patients younger than 30 years who received cementless third-generation ceramic-on-ceramic implants for osteonecrosis of the femoral head, the authors reported no loosening of the femoral stem or acetabular cup at a mean follow-up of 8 years. Swarup et al. [17] reported that ceramic-on-ceramic bearing was shown to have better cup survival compared to metal-on-plastic implant in young patients.
In the present study, a failure of bone incorporation at the implant interface was intraoperatively observed in the two cases of aseptic cup loosening. Similar findings were found in other studies with ceramic-on-ceramic bearings [5]. Osteolysis has infrequently been reported in association with ceramic-on-ceramic bearing THA, and the few reported cases were associated with earlier generations of ceramic [33]. In the present study, osteolysis was not found on radiographs in any patient at final follow-up. According to a 10-year follow-up study by Kim et al. [34] using cementless THA with ceramic-on-ceramic bearing, no osteolysis was observed in 93 hips of patients operated on when the patients were younger than 45 years. These authors did not detect acetabular or femoral osteolysis by means of radiographs and CT scans. The limited occurrence of osteolysis observed with ceramic-on-ceramic bearing surfaces is thought to be attributable to a lower concentration of wear particles in the periprosthetic tissue around the bearing [35].

Other complication reported for ceramic-on-ceramic bearings is the transient noise [36]. The frequency of noise was low in the present study.

Our study showed that young patients underwent THA had improved function after surgery. Other studies with cementless THA in young patients have shown a significant improvement in HSS and patient-reported outcomes scores in most patients younger than 45 years [5,15,34,36].

There are several strengths in the present study. This study was the second reported with a prospective design [6], but our follow-up was longer. All surgeries were performed by two senior surgeons who used the same surgical technique. The same THA was used in all patients. The postoperative follow-up was sufficiently long to assess clinical outcomes and to determine the prevalence of complications. In addition, this study included comparative outcomes with an older cohort.
However, the present study had also several limitations. An important limitation concerns diagnostic heterogeneity of the sample of patients, which could influence the outcomes. As in the majority of the published studies, we did not stratify our analysis for the index diagnosis due to the small number of patients in each subgroup which limited our ability to generate conclusions. However, we do believe that our patient population was representative of the typical young population presenting for THA. Although significant predictors of failure of THA in the young group were not found, the results should be interpreted with caution due to the small number of failed THA. We evaluated osteolysis only on radiographs, although CT scans would be more sensitive for osteolysis detection. However, CT is costly and associated with a risk of radiation exposure. More large prospective studies are necessary.

CONCLUSION

In conclusion, THA with cementless stem and ceramic-on-ceramic bearing provides successful survival and functional outcomes in young patients between 20 and 40 years old for at least 10 years of follow-up. We believe that these findings justify the use of cementless THA in that young population suffering of degenerative hip disease.

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LEGEND OF FIGURES

Fig. 1. Kaplan-Meier cumulative survival of the prostheses for any reason (p= 0.189).

Fig. 2. Kaplan-Meier cumulative survival of the prostheses for aseptic reasons (p= 0.332).
**Table 1.** Baseline data in both groups

<table>
<thead>
<tr>
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<th>Younger group</th>
<th>Older group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n</strong></td>
<td>94</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>37.2 (3.6)</td>
<td>64.7 (5.7)</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Gender (M/F)</strong></td>
<td>56/38</td>
<td>51/39</td>
<td>0.855</td>
</tr>
<tr>
<td><strong>BMI (g/m²)</strong></td>
<td>27.3 (3.4)</td>
<td>28.5 (4.8)</td>
<td>0.054</td>
</tr>
<tr>
<td><strong>Diagnoses</strong></td>
<td></td>
<td></td>
<td>NA</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>66</td>
<td>82</td>
<td></td>
</tr>
<tr>
<td>FHAN</td>
<td>12 (5)</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Sequela Perthes</td>
<td>4 (1)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Posttraumatic arthritis</td>
<td>3 (3)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Slipped femoral epiphysis</td>
<td>2 (2)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>DDH</td>
<td>1 (1)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Sequela septic arthritis</td>
<td>1 (1)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Continuous variables: mean (standard deviation). FHAN: femoral head avascular necrosis.

DDH: developmental dysplasia of the hip. Diagnoses: in parentheses prior hip surgeries. NA: not applicable.
### Table 2. Data of the clinical outcomes

<table>
<thead>
<tr>
<th></th>
<th>Younger group</th>
<th>Older group</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td>HSS pre</td>
<td>46.1 (7.9)</td>
<td>48.0 (8.7)</td>
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</tr>
<tr>
<td>HSS post</td>
<td>88.4 (11.3)</td>
<td>86.6 (10.2)</td>
<td>0.356</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>WOMAC-function pre</td>
<td>48.3 (9.2)</td>
<td>46.7 (11.4)</td>
<td>0.392</td>
</tr>
<tr>
<td>WOMAC-function post</td>
<td>84.7 (10.1)</td>
<td>80.2 (9.8)</td>
<td>0.013</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>WOMAC-pain pre</td>
<td>38.3 (7.1)</td>
<td>36.3 (6.2)</td>
<td>0.099</td>
</tr>
<tr>
<td>WOMAC-pain post</td>
<td>87.1 (6.2)</td>
<td>88.0 (7.3)</td>
<td>0.461</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>SF12-physical pre</td>
<td>35.6 (12.2)</td>
<td>33.2 (11.7)</td>
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</tr>
<tr>
<td>SF12-physical post</td>
<td>79.3 (10.4)</td>
<td>77.1 (13.2)</td>
<td>0.305</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>SF12-mental pre</td>
<td>42.7 (11.6)</td>
<td>45.4 (12.3)</td>
<td>0.212</td>
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<tr>
<td>SF12-mental post</td>
<td>77.8 (10.4)</td>
<td>79.2 (13.1)</td>
<td>0.511</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
<td>0.001</td>
<td></td>
</tr>
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Data as mean (standard deviation). Pre: preoperative. Post: at last follow-up.